Eurosupport 6

Final Evaluation Report

Period: March 1st 2009 - March 1st, 2013

"Developing a training and resource package for improving the sexual and reproductive health of people living with HIV/AIDS"

Institute of Tropical Medicine

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Abbreviations

AP	Associated partner
CAI	Computer-assisted intervention
CBO	Community-based organisation
CISS	Computerised intervention for safer sex
CP	Collaborative partner
ES	Eurosupport
IMM	Intervention Mapping Method
ITM	Institute of Tropical Medicine
MSM	Men having sex with men
NGO	Non-governmental organisation
SRH	Sexual and Reproductive Health
SRHR	Sexual and Reproductive Health and Rights
STI	Sexually transmitted infections
RCT	Randomised controlled trial
TRP	Training and resource package
WP	Work package

Executive Summary

The objective of this final evaluation report was to assess if the project achieved its objectives in a qualitative and timely fashion. We chose to assess this through a self-evaluation report, because of the integrated and robust evaluation approach applied to the project's main outputs.

The project's main objective was to develop evidence-based tools for service providers that enable them to support people living with HIV in their sexual and reproductive health and rights (SRHR). A brief counselling intervention, developed using a systematic health promotion planning tool, was the main project deliverable. The intervention's main goal was to reduce sexual transmission risk and increase condom-use, however, using a comprehensive and rights-based positive prevention framework. The intervention was theory-based and used computer assisted modules to support counsellors.

This intervention, i.e. the CISS ("computerised intervention for safer sex") was embedded in a training and resource package (TRP) for HIV service providers to support people living with HIV in improving their SRH. To achieve the overall project objectives, the project had two major tracks:

(1) *Research and development track* to develop and evaluate counselling interventions including computer-assisted interventions for clinical care and community-based settings

(2) *Capacity building track*, to develop tools for service providers for implementation including training events and the development of online-training tools ('e-learning') for service providers.

In addition, *networking and Dissemination, i.e. the Eurosupport network*, was also an important component of ES 6. The ES network was used to improve capacity building and for dissemination of the TRP. The ES network maintained contacts with more than 420 organisations or individual experts in an integrated field of HIV and SRH. Six biannual newsletters were published informing about the project's progress and disseminating relevant information about to SRHR of people living with HIV and positive prevention. The project website was used for dissemination purposes: http://www.eurosupportstudy.net/eurosupport

This evaluation report looks at process indicators, output indicators, and effect indicators to assess whether the project has reached its objectives. While the overall evaluation focused mainly on process- and output indicators, effect indicators were measured for the CISS intervention. For the latter, a combined approach was applied, using both an experimental prospective design and a cross-sectional study for the process evaluation.

Main problems encountered during the project were related to delays in the development of the computerised tools (due to their comprehensiveness and technical challenges) and in the recruitment of study participants, which necessitated a 12 months no cost extension.

Based on the findings of the combined results of the outcome and the process evaluation as presented in this report, we conclude that:

1) **The Eurosupport 6 project was carried out in an effective and qualitative manner:** the project has produced an evidence-based intervention embedded in a comprehensive training and resource package of high quality and relevance to its users.
2) **The brief counselling intervention working with computer-assisted tools was found to be effective in reducing sexual risk behaviour.** This refers to the three months follow-up after the intervention, and was not fully sustained over the six months follow-up period.

In spite of the multi-faceted barriers encountered during intervention implementation (i.e. on an

individual, provider-related and contextual/structural level), the Eurosupport 6 project produced *good evidence* for the effectiveness of the sexual risk reduction intervention. The complexity of the rigorous intervention design applied in a multi-centre study with nine participating sites raised challenges, but produced good evidence.

When up-scaling the CISS intervention, continuous training using the e-learning tool already developed, as well as face-to-face training events will be crucial to safeguard the theory-based behavioural constructs which are at the base of the intervention. This is crucial if we are to make sure that the CISS will be delivered in a wide range of European HIV care and community-based settings with quality and fidelity to the intervention.

1. Introduction

EUROSUPPORT is a research and networking initiative in the field of HIV/AIDS, which has received support from the European Commission since 1996. Ever since, its overall goal has been to gain scientific insight into newly emerging and quickly changing HIV-related problems by using a flexible and multidisciplinary approach. The Eurosupport network includes HIV-treatment centres, community-based organisations delivering HIV-related services and patient organisations in many European countries, to carry out targeted empirical research on the needs of people living with HIV. Eurosupport 6 is the most recent project in a series of five projects, which all focused on well-being of people living with HIV. Reflecting the changes in the HIV epidemic over the decades, the topics addressed by the various Eurosupport projects ranged from HIV positive people's terminal care needs, their socio-economic challenges, problems with adherence and sexual dysfunctions, the situation of caregivers living with and their HIV-affected families, and more recently sexual and reproductive health (SRH)-related needs and challenges (Eurosupport 5).

The current project Eurosupport 6, co-financed by the European Commission's Public Health Programme 2008, addresses service providers' capacity to improve the SRH of people living with HIV. As such, it is a logic continuation from Eurosupport 5, which assessed evidence on SRH-related needs and factors influencing risk and protection behaviour among people living with HIV. In addition, Eurosupport 5 assessed the needs of service providers to adequately support HIV positive people in SRH and adoption of safer sex practices. Eurosupport 5 concluded with counseling and policy recommendations for an integrated field of HIV and SRH service delivery (→ see the Eurosupport website: www.eurosupportstudy.net). However, counseling guidelines alone are not sufficient to change practices, when service providers lack the capacity, skills and practical tools for implementation. Based on the evidence collected in Eurosupport 5, as well as on the current state-of-the-art literature, Eurosupport 6 aimed at equipping service providers in an integrated HIV and SRH field with such effective, theory-based and easy to use tools to deliver effective counseling. Effective here mean that this tools are able to bring about behavioural change in a specifically defined outcome behaviour, and that subsequently the tools are evidence-based. They must also be able to be integrated in routine service provision, with not too much efforts in additional time or resources in a busy clinical care routine to be used a wide scale.

2. Objectives of this report

Evaluation was a built-in component to this project. It was a cross-cutting activity through all work-packages and project-related activities. However, work-package 3 (for WP structure, see the final implementation report) of the project consisted of all specific actions undertaken to verify if the project's objectives were being reached.

As specified in Annex 1 of the Grant Agreement, the project had two main evaluation components integrated, and two main evaluation questions can be used to demonstrate whether the project was successful:

3) **Has the overall project been carried out in an effective and qualitative manner?** This refers to the documentation of project management processes, such as internal monitoring and quality control through the regular project management. These activities are mainly linked to WP 1 (overall project management and coordination).
4) **Is the brief counselling intervention using computer-assisted tools (i.e. the 'CISS' or *computerised intervention for safer sex*), developed as core piece of the training and resource package (TRP) effective in reducing sexual risk behaviour?** This refers to the scientific evaluation of selected project related outputs, i.e. the scientific evaluation study or the CISS intervention trial.

This evaluation report focuses on the project's progress, using selected process and output indicators relating to the project's performance per specific project objective. We report on the evaluation plan, present the specific evaluation strategy and the tools used. Finally, we will draw some conclusions on the project's achievement.

3. The evaluation strategy employed in Eurosupport 6

The first evaluation question, which we aimed to answer throughout the course of the project by applying different evaluation strategies and tools, is whether the **project's objectives have been reached in a qualitative and timely manner.** For each of the project's specific objectives we have therefore developed specific indicators to be used to verify the specific project objectives. Those indicators were formulated according to SMART[1] criteria for assessing the project's effectiveness, both in relation to the overall project results as well as relating to some of its specific outputs (i.e. three and six months follow up of the intervention, indicators relating to the training modules and the TRP).

However, not *all* these indicators were actually measured throughout the project's lifetime, since some of them are only measurable with a long-term follow-up period. For instance, indicators that measure the project's impact on the level of the target group in a long-term perspective, cannot be measured during the project's running time. It is also not possible to measure impact on the population level. While for instance an indicator such as "how many new onward HIV infection could have been prevented?", would be a beneficial outcome indicator for a positive prevention intervention, at the same time it is an indicator too complex to be measured. We may also assume that improved sexual and reproductive health will positively impact on health-related and overall quality of life. While quality of life should be the ultimate goal of any health promotion intervention, it is methodological very complex to assess such causal pathways and determine that a specific intervention increased quality of life.

The main activity of Eurosupport 6 was to develop and implement theory-based positive prevention interventions for two target groups, i.e. men having sex with men and migrants living with HIV. To develop these intervention a systematic and evidence-based approach was used, i.e. the intervention mapping model (Bartholomew et al. 2006). Evaluation is an integral

[1] SMART stands for:

1. Specific – Objectives should specify what they want to achieve.
2. Measurable – You should be able to measure whether you are meeting the objectives or not.
3. Achievable - Are the objectives you set, achievable and attainable?
4. Realistic – Can you realistically achieve the objectives with the resources you have?
5. Time – When do you want to achieve the set objectives?

part of this model and the final step to improve the intervention. Within the IMM framework, we developed the logic framework for the evaluation, which is explained in more detail under section 3.2 of this report. This lMM logic model guided the evaluation research conducted to assess the intervention's effectiveness.

The project's specific objectives were formulated in a realistic way, indicating that they are achievable within the contextual conditions of the project (e.g. the organsational environments in which the partners worked and implemented the intervention; target group specific conditions, etc.) and the given resources (i.e. the budget available for the evaluation). The specific indicators (see tables below per specific project objectives) serve to verify whether the objectives set have been achieved at the end of the project. We differentiate between process indicators, output indicators, effect- and impact indicators. For each set of indicators we briefly describe the respective achievements. It should be stressed, however, that impact indicators were not measured due to their complexity and the available time frame. The evidence produced within the project and described in this evaluation reported can be differentiated according to process,- output and effect indicators, in accordance with Annex I to the project's Grant Agreement.

3.1 The specific project objectives and their respective indicators

Specific objective 1: To develop evidence-based and theory-guided target group specific interventions to improve the SRH of PLHIV.

Specific objective 1 was achieved through the development of three sets of brief counselling interventions using computer-assisted tools (targeting MSM, migrant women, and migrant men living with HIV) to be delivered by service providers in clinical and community-based HIV care settings.

This specific objective aimed at reducing sexual risk behaviour in the target groups among whom the CISS was implemented (MSM and migrants). The behaviour change achieved was measured through a pre- and post-test experimental design; as described in the study protocol (→ see annex 7 to the final technical implementation report). In addition, and to support the assessment of the effectiveness, an intervention matrix has been developed, which contained the change objectives and the relating specific indicators how to measure them. The

intervention matrix is the main working tool within the IMM framework document, and was also the official deliverable D02 of the project.

Table 1 gives an overview on the indicators developed to measure the achievements relating to the first specific project objective.

Table 1: Process indicators for specific objective 1 (i.e. to develop evidence-based and theory-guided target group specific interventions)

Process indicator	Description
Feasibility to implement the intervention; service providers' fidelity to the intervention	Measured through self-reported assessment tool for counsellors. They self-evaluated the sessions with 82 participants on as scale from 1 to 10 (low-to high). Mean score was 7.83/10. During 91.4% of the set of counselling sessions, CISS facilitated talking about sexual behaviour. In 90.8%, CISS facilitated empathy with the participants' problems related to sexual behaviour. Counsellors reported to use CISS in 93.2% with a client in routine care if they presented with similar indications. An overall of 192 study participants were included in the CISS intervention trial study. This was less than the envisaged sample size of 440 participants.
Implementation of the intervention: integration in routine clinical care (standard care)	The CISS intervention was implemented in the framework of a study, i.e. a randomised trial with intervention and control group. This indicator was assessed in terms of service providers' intention to work with the intervention in the future and how they perceived the degree to which the intervention could potentially be integrated in routine clinical care based on their experiences with the study. This was assessed in a qualitative manner, i.e. through group discussions at the final meeting. Associated partners agreed that the materials are very comprehensive, that they support organisations to look critically at their own SRH services they offer to HIV positive persons, and that they can help to improve current services in a realistic way. Despite this positive feedback, several barriers for enrolment of participant were encountered during the implementation of CISS. These barriers can be clustered into legal, organisational, and individual barriers. Legal issues (criminalisation of HIV), time allocation and support from the team, and personal issues among people living with HIV (fear of being judged, social desirability, financial constraints), were critical to the enrolment of study participants throughout the enrolment phase of the CISS–study. Participants shared the view that the problems experienced during the CISS trial study would be less severe when delivering the

	intervention in regular service provision due to greater flexibility both in promoting the intervention and in delivery format, while respecting its theoretical foundations.
Number of organisations participating in the CISS trial	Nine organisations (main partner and APs) implemented the CISS intervention during the trial study. One associated partner (Slovak Republic) was unable to implement the intervention. The main reason was the legal situation that allowed for prosecution of HIV positive people if they had unsafe sex, which made it difficult for HIV+ patients to address problems with safer sex in service provision. Efforts to improve recruitment were invested to a large extent, but were not successful, because the associated partner was the only HIV treatment centre in the country, and there were no community-based organisations (CBOs) working exclusively for HIV+ people or patient support group to revert to. Most of the associated partners in the participating countries had organised their own local networks of other HIV treatment centres and/or CBOs to improve recruitment. → See table 21, included in section on specific evaluation activities 3.2).

<u>Table 2:</u> Output indicators for specific objective 1 (i.e. to develop evidence-based and theory-guided target group specific interventions)

Output indicator	Description
1 Working document containing the intervention mapping matrix	The IMM framework document was the project's official deliverable D2, and compiled at project month 3. This document was work in progress and continuously updated throughout the first project year to fine-tune the evaluation plan and the study design of the randomised controlled trial study to test the intervention's effectiveness. → see IMM framework document, deliverable D02
3 target-group specific draft interventions to reduce sexual risk behaviour in the context of improved SRH i.e. *'CISS: computer-assisted intervention for safer sex'*	The CISS aims at counsellor-supported self-regulation of sexual risk behaviour and positive prevention for the selected target groups. The three target group interventions (i.e. for MSM, female and male migrants living with HIV) were first made available as draft pilot intervention on a DVD. Implementing partners were concerned about internet connectivity during counselling sessions and thus opted for delivery of the intervention on a DVD rather than an online version of the CISS. The CISS DVDs contained all written prevention material in the partners' languages and all video/audio material sub-titled. The change in strategy from internet-based intervention delivery to using a DVD was reported in the project's mid-term interim report at month 18 and approved by EAHC. The pilot intervention was available at M12, with two months delay

	due to the complexity of the interactive intervention modules and the translation into nine languages of the partners. As the intervention had become much more comprehensive due to the integration of specific underlying intra- inter-and structural determinants driving sexual risk behaviour, the subsequent adaptation to the specific settings (e.g. local resources) and specific languages became also much more complex. The required efforts had been underestimated.
1 set of target-group specific draft intervention manuals	Since mode of delivery as well as underlying theoretical constructs were the same for the distinctive target groups, the originally foreseen target-group specific intervention manuals were combined into one integrated manual for service providers. Part I contained the technical description of the CISS, part II general counselling instructions. The CISS counselling manual was initially made available on the project's e-stream platform and distributed also by e-mail to all project partners in M10. Partners provided feedback. A revised version integrating this feedback was issued after the first training workshop (M12).

Table 3: Effect indicators for specific objective 1 (i.e. to develop evidence-based and theory-guided target group specific interventions)

Effect indicator	Description
Reduced sexual risk behaviour at post-test measurement	This was measured at the end point of the CISS trial: 3 and 6 months after the intervention was completed (the latter time period for follow-up was adapted at the 18 month interim report because of the difficulties in recruitment and the contingent delay). Outcome behaviour was measured in different ways: condom-use at last intercourse and a composite risk index, taking into consideration patient's viral load, partner's serostatus and the overall frequency of unprotected sexual encounters. Because the main characteristics between intervention- and control group participants did not differ at baseline, we can assume that any change in sexual behaviour (assessed after the intervention at three and six months follow-up measurements) can be attributed to the intervention itself. Among the participants from the control group, risk of unprotected intercourse reduced with 0.7% between baseline and 3 months post-intervention. Among participants who were allocated to the CISS-intervention, this risk decreased much more, with 30%. This clear-cut difference in reduction of unprotected sexual intercourse demonstrates the effectiveness of the intervention. When looking at the indicator 'condom use at last intercourse', the

	likelihood that participants of the CISS group would not use a condom was much lower than of the controls (p< 0.04; OR: 0.08 95% CI [0.01;0.90]). A mediation analysis shows that this increase in condom-use can be partially attributed to more positive attitudes towards condom-use (56%) and to improved self-efficacy in safer sex and using condoms. However, the intervention effect was not fully sustained over the longer follow-up period, i.e. after 6 months p-values dropped to 0.07; OR: 1.35 95% CI [0.15; 1.230]).
Reduction of onwards HIV transmission	We may assume that because the intervention has shown to be effective at least for the 3 months follow-up period, some onwards HIV transmission could have been avoided. However, we cannot know to which extent the CISS intervention can contribute to reduction of onwards HIV infection. This would require using biological markers as endpoints in the trial including those of participants' sexual partners, which would raise a number of practical and ethical questions. Measuring this indicator was thus not feasible within the study.

Table 4: Impact indicators for specific objective 1 (i.e. to develop evidence-based and theory-guided target group specific interventions)

Impact indicator	Description
Target group members' improved health-related quality of life	To measure impact on individuals' lives, variables such as overall (health-related) quality (QoL) of life could be assessed. We did not include this indicator as an endpoint into our study, because the relationship between improved SRH and QoL would also be a complex one. While it must be acknowledged that improved QoL matters a lot to people living with HIV, in the framework of this study our main interest was in learning primarily which determinants of sexual risk behaviour can be changed with which type of intervention. However, for future research, it could be relevant to include more global health measures such as health-related quality of life.
Reduced HIV-related societal stigma	Stigma has been shown to also have an impact on sexual risk behaviour of PLHIV (Rojas et al. 2008; Nöstlinger et al. 2010). However, since the intervention does not set out to target stigma in a specific way, such variables were not measured as part of the evaluation.

Overall achievements relating to the specific project objective 1:

The results of the overall evaluation showed that the CISS interventions complied with high quality standards in its design (theory-based, evidence-based) and while it was difficult to enrol sufficient patients, those who participated were quite satisfied with the intervention materials.

Overall, we conclude that the specific objective 1 was achieved: the CISS intervention developed was effective in significantly reducing sexual risk behaviour three months after the last intervention session, when measuring both condom use at last intercourse and using a combined risk score. However, behaviour change was not sustained over a longer follow-up period, i.e. six months post intervention. This outcome evaluation was conducted with less scientific precision that envisaged due to the smaller sample size included in the study, but can still be considered *good* evidence for the effectiveness of interventions, according to the US Centers for Disease Control's (CDC) tier of evidence for behavioural interventions: http://www.cdc.gov/hiv/topics/research/prs/tiers-of-evidence.htm

Specific objective 2: Developing an evidence-based training and resource package (TRP) for service providers

The project's second specific objective consisted of developing the TRP for service providers in clinical care and community-based settings in the HIV/AIDS field working with the two envisaged target groups, i.e. MSM and male and female migrants living with HIV. The work to achieve this second specific objective related mainly to the work carried out in work-package 8 and resulted in the development of the final training and resource package (the TRP).

The development of the TRP was time-wise contingent on the development of the CISS intervention and the results of the evaluation study, thus the delays accumulated and described above, also affected the TRP development. The achievement of this specific objective can be measured by the delivery of the two training events foreseen (month 12 and month 40, after the approval of the no cost extension this event was postponed from month 36 to month 48), and the publication of the final TRP with its four different manuals (i.e. CISS intervention manual; implementation manual including the policy tools; trainer manual; and reference guide on positive prevention).

Table 5: Process indicators for specific objective 2 (i.e. to develop the training and resource package)

Process indicator	Description
Number of overall participants at the training workshops	The first training workshop was held in March 2010 and all APs participated with all the coordinators and some HIV counsellors present. The total number of participants was 21 (administrative staff excluded). The second training workshop was held in February 2013 and in total 33 partners (19 representatives of associated partners and 14 collaborative partners) participated.
Involvement of stakeholders in the development of the TRP	Throughout the development of the TRP stakeholders were invited to participate. This was mainly done through feedback loops that were organised by the respective partners responsible for either intervention development (CNWL) or TRP development (Sensoa). For the development of the CISS, the main AP responsible for this consulted with local networks of community-based organisation and set up a close cooperation with them during the process of the intervention development. These organisations covered all target groups of the CISS (Terence Higgins Trust, Gay men Fighting AIDS; the NAZ project and Positively Women and some faith-based organisations). In addition, HIV patient groups at CNWL/St; Mary's hospital and selected key patients of the health Psychology department were also consulted and their feedback was integrated into the CISS development. Also in France and Belgium, community-based organisations were consulted (Sensoa, AIDES). For the TRP development, collaborative partners were invited to give feedback once the materials were developed to an extent that organisations could give meaningful feedback. After the integration of the study's results into the TRP, an e-survey was conducted among the CPs and their feedback was used to adapt the final TRP. In order to organise a feasible consultancy with these stakeholders, we selected two specific topics, i.e. HIV disclosure and condom-use and presented them as cross-cutting issues across all four manuals included in the TRP. We asked partners to give feedback on these examples. In addition, experts and consultants were involved in developing specific parts of the TRP, such as the reference guide on positive prevention for instance, which was developed with the input of the European AIDS treatment group.

Quality of the trainings delivered (assessed through feedback/evaluation sheet)	*First training workshop:* The quality of the first training was assessed by means of a self-reported survey. An evaluation report was compiled, which has been sent to the EAHC. Overall rate of satisfaction with the workshop was 7.7 on a scale ranging from 1-10 (for more details see below, section on evaluation of the training workshop). *Second training workshop:* The global score of the training was high with an average of 7.6/10. One participant scored the training very low (score 3/10). Unfortunately, this participant did not give any details explaining the low score.

Table 6: Output indicators for specific objective 2 (i.e. to develop the TRP)

Output indicator	Description
1 training and resource package	The final TRP consists of four parts: the CISS intervention manual plus DVDs with the CISS, an implementation manual describing how to integrate the CISS into routine clinical care settings (containing the policy tool), a trainer manual, and a reference guide containing background information on positive prevention and on the integration of HIV and SRH. The manuals were developed in close cooperation between three partners (CNWL, Sensoa and the ITM), since they needed to be fully coherent across the four components and always link back to the CISS intervention. The TRP was produced in 45 hard-copies for the participants of the final training and dissemination workshop, and other interested parties. The TRP is also available as pdf for download on the Eurosupport website.
1 training workshop for associated partners	This training workshop was organised in March 2010 and evaluated (→ see above) A report on the training workshop was produced and disseminated.
1 training workshop for collaborative partners	This training workshop was organised in February 2013 and evaluated (→ see above) A report on the training workshop was produced (→ see report, deliverable D16).
1 e-learning tool	The e-learning tool was produced as part of the computer-assisted tools that were produced in work-package 5. It consists of a of a set of video-clips showing typical counselling situation according to the

	CISS intervention's main modules they follow the set-up of the three counselling sessions ("Who am I?; "Working Through"; and "Today and Tomorrow" developing a personal risk reduction plan. The e-learning tools was produced using the APs' input and they were used for the second training workshop (at the final project meeting); the e-learning tools are available at the CISS website: www.cissweb. com

Table 7: Effect indicators for specific objective 2 (i.e. to develop the TRP)

Effect indicator	Description
Improved capacity and skills of service providers to deliver SRH and positive prevention interventions	The final TRP contains both the intervention and the accompanying training materials, i.e. intervention and implementation manual; trainer manual. The implicit objective of the TRP is to increase the service providers' capacity to deliver meaningful SRH interventions for PLHIV. It had not been suggested to measure this implicit objective within the time framework of this project, thus no related indicators were assessed. According to the proposal submitted we put priority on evaluating the CISS' effectiveness on the level of the service users instead, because people living with HIV are the main beneficiaries of this project. However, for future research, evaluating the effect of the TRP on the service providers could be a useful indicator, in particular with respect to multilevel interventions.

Table 8: Impact indicators for specific objective 2 (i.e. to develop the final TRP)

Impact indicator	Description
Reduction of onwards HIV transmission	Hard biological outcome indictors are seen as the best way to evaluate behavioural interventions using a randomised design. It must be acknowledged that self-reported data on sexual behaviour usually is subject to social desirability and to a certain degree will also depict the way people see themselves as sexual beings, thus not necessarily depicting the sexual behaviour, but partly sexual norms. Compared to self-reported data, biological outcome data could reveal the true effect of a behavioural intervention. For the case of behavioural interventions such as the CISS, the indicator could be onwards HIV infection, but due to practical and ethical issues this indicator would be challenging to measure. Another option could be STI testing among the participants. This could be a relevant outcome indicator for future trials to validate the self-reported data. However, longer follow-up periods must then be considered, to have sufficient power to yield meaningful results.
Target group members' improved health-related quality	To measure impact, variables such as overall health-related quality of life could be assessed. In this project, we did not foresee such a global measure, since we were mainly interested in learning primarily

of life	which determinants of sexual risk behaviour can be changed with which type of intervention. However, for future research, it could be relevant to include more global health measures such as health-related quality of life.
Reduced HIV-related societal stigma	Stigma could be another suggested impact measure. HIV-related stigma has been shown to also have an impact on sexual risk behaviour of PLHIV (Rojas et al. 2008). In the self-assessment of the scientific evaluation of study participants, some variables on HIV related stigma are integrated, but not used as outcome measure, since the intervention does specifically target stigma reduction. It is rather seen as an underlying condition potentially influencing the outcome behaviour, and would have to be measured at population level.

Overall achievement relating to the specific project objective 2:

The delays encountered during the development of the intervention and the difficulties during the recruitment phase for the trial study had an impact on the timely delivery of the overall TRP. But these delays did not affect the quality of the TRP developed. At the end of the project all deliverables relating to the specific objective 2 were available and disseminated. During the first project phase, a change of strategy was necessary in terms of the cooperation of the stakeholders, in order to obtain a meaningful involvement of the collaborative partners on the CISS development, the alternative strategy to work more closely with local community-based organisations enables us to develop the TRP in a participatory way. The TRP had been developed using a systematic health promotion-planning tool (i.e. the IMM framework), and was based on a participatory approach integrating stakeholder's feedback. We thus conclude that the TRP used an evidence-based and participatory approach, and that it presents the current state of the art with respect to behavioural interventions in the field of positive prevention.

Specific objective 3: Development of a policy tool for integration of SRH and positive prevention services in routine HIV care)

Within the framework of ES 6, we developed a policy tool which specifies the elements necessary to integrate SRH-related and positive prevention services in routine HIV care by defining mechanisms of effective task division, integration and specialisation, screening, local care pathways, and referral systems. This tool is part of the final TRP and provides guidance on

how to integrate specific positive prevention counselling in routine clinical care in HIV–settings will be delivered through the final TRP. As this tool had to be based on all the evidence accumulated throughout the project including the service providers' experiences during the CISS trial, the policy tool was finalised at the end of the project.

Table 9: Process indicators for specific objective 3 (i.e. to develop a policy tool)

Process indicator	Description
Involvement of stakeholders in the development of the policy tool	The policy tool, as integral part of the final TRO, was subjected to the same feedback mechanisms as the overall TRP. Thus, stakeholders were invited to give feedback, which was subsequently incorporated into the final policy tool. The e-survey results showed for instance, that 78% found the legal information provided through the policy tool helpful.

Table 10: Output indicators for specific objective 3 (i.e. to develop to develop a policy tool)

Output indicator	Description
1 policy tool (specifying mechanisms of effective task division, integration and specialisation, screening, local care pathways, and referral systems integrated in the final TRP	This tool tackles integration of HIV and SRH both on the policy- as well as on the programmatic level of service provision. The policy tools are provided with the *implementation manual* of the final TRP. They specify the key conditions for implementing an SRH intervention in HIV care service provision, by addressing issues such as how to inform stakeholders, installing an implementation group, describing the resources needed, discussing how to increase service providers' motivation on focusing on SRH issues in routine HIV care, and providing current up-to-date information on ethical, legal and cultural dimensions to be respected. In addition, the policy tool contains a toolkit for service providers with practical work- and fact-sheets on a variety of relevant issues, such as confidentiality and privacy, legal conditions, a referral guide and evaluation tools.

Table 11: Effect indicators for specific objective 3 (i.e. to develop a policy tool)

Effect indicator	Description
Improved capacity of HIV care settings to deliver SRH and positive prevention	The policy tool is a self-learning tool for service providers to effectively support them in better integration of SRH in routine HIV care. It contributes to the objective of the TRP to increase service providers' capacity to deliver meaningful SRH interventions for the

interventions	two target group (MSM and migrants). However, it was not suggested to measure this objective within the time framework of this project, thus no related indicators were assessed. According to the proposal submitted we put priority on evaluating the CISS' effectiveness on the level of the service users instead, because people living with HIV are the main beneficiaries of this project. However, for future research, evaluating the effect of the TRP on the service providers could be a useful indicator, in particular with respect to multi-level interventions.
A larger number of HIV service providers integrate SRH and positive prevention intervention in their routine services	Assessing this indicator during the project's life-time was not possible because the final TRP including the policy tool was only available at the end of the project. However, when up-scaling the intervention, indicators such assessing the number of service providers working with the intervention could be relevant. In order to assess an increase, however, a baseline measurement would be needed.

Table 12: Impact indicators for specific objective 3 (i.e. to develop a policy tool)

Impact indicator	Description
Reduction of onwards HIV transmission	Hard biological outcome indictors are seen as the best way to evaluate behavioural interventions using a randomised design. It must be acknowledged that self-reported data on sexual behaviour usually is subject to social desirability and to a certain degree will also depict the way people see themselves as sexual beings, thus not necessarily depicting the sexual behaviour but partly sexual norms. Compared to self-reported data, biological outcome data could reveal the true effect of a behavioural intervention. For the case of behavioural interventions, such as the CISS, the indicator could be onwards HIV infection, but due to practical and ethical issues this indicator would be challenging to measure. Another option could be STI testing among the participants. This could be a relevant outcome indicator for future trials to validate the self-reported data. However, longer follow-up periods must then be considered, to have sufficient power to yield meaningful results.
Target group members' improved health related quality of life	To measure impact, variables such as overall health-related quality of life could be assessed. In this project, we did not foresee such a global measure, since we were mainly interested in learning primarily which determinants of sexual risk behaviour can be changed with which type of intervention. However, for future research, it could be relevant to include more global health measures such as health-related quality of life.
Reduction of HIV-related societal stigma	Stigma could be another suggested impact measure. HIV-related stigma has been shown to also have an impact on sexual risk behaviour of PLHIV (Rojas et al. 2008). In the self-assessment of the scientific evaluation of study participants, some variables on HIV

	related stigma are integrated, but not used as outcome measure, since the intervention does specifically target stigma reduction. It is rather seen as an underlying condition potentially influencing the outcome behaviour, and would have to be measured at population level.

Overall achievement relating to the specific project objective 3:

Time-wise, the achievements of the specific objective 3 were also affected by the overall delay of the project in its initial development and implementation phase. However, it did not affect the quality of the policy tool developed. At the end of the project the policy tool was available and disseminated. Since the policy tool is an integral part of the TRP, it was developed using a systematic health promotion planning tool (i.e. the IMM framework), and was based on a participatory approach integrating stakeholder's feedback. We thus conclude that the policy used an evidence-based and participatory approach, and that it presents the current state of the art with respect to the integration of SRH and HIV, both from a policy - as well as a programmatic point of view.

Specific objective 4: Expanding and maintaining a network to promote SRH and positive prevention of both HIV and SRH field organisations in Europe.

Specific objective 4 was concerned with the expansion and the maintenance of the existing Eurosupport network, in order to facilitate mutual learning experience on the issues at stake (i.e. integration of SRH and HIV; positive prevention; and in a more focused sense sexual risk reduction and condom use) and to disseminate the TRP to a substantial number of stakeholders.

This specific objective aimed at increasing the number of stakeholders to be involved in the Eurosupport 6 network, which was gradually expanded throughout the projects running time. Specific tools such as the adapted website and the ES 6 newsletters served to disseminate information (including the TRP) and to facilitate mutual exchange of expertise. The TRP was disseminated electronically to all stakeholders at the end of the project, and is also available via the project website for download. The number of organisations reached, and the number of dissemination tools developed, served as indicators for reaching this specific objective.

Table 13: Process indicators for specific objective 4 (i.e. to expand and maintain the Eurosupport 6 network to promote SRH and positive prevention of both HIV and SRH field organisations in Europe

Process indicator	Description
Involvement of SRH/HIV stakeholders in the network	The stakeholders and organisations being part of the ES 6 network were gradually expanded from 360 organisations and the beginning of the project to 421 organisations and/or individual experts. In addition, associated partners set up their local networks for the service provision working individually with a small number of organisations for the implementation of the CISS. Some of them subsequently also became collaborative partners. → See table 21 in section 3.2 for more details on the local collaborations. The number of collaborative partners increased from 15 at the start of the project to 30 at the end of the project, among whom 11 stemmed from countries of Central and Eastern Europe. → see annex 5 for the list of collaborative partners.

Table 14: Output indicators for specific objective 4 (i.e. to expand and maintain the Eurosupport 6 network to promote SRH and positive prevention of both HIV and SRH field organisations in Europe

Output indicator	Description
ES 6 website adapted to the requirements of the project	The current ES 6 website www.eurosupportstudy.net was updated and maintained on a regular basis. In the first phase of the project (→ see specific objective 1) the strategy to integrate the CISS into a web-based environment was changed due to AP's concerns about internet access and how this would interfere with the delivery of the counselling. With increasing training and experience during the implementation phase, counsellors felt more confident about internet-based delivery. In addition, dissemination beyond the project's life-time can only be handled though a website. It's the most functional way to disseminate and upscale the intervention and the related TRP. At the end of the project, the CISS is available as a separate tool on a DVD, and the ES 6 website functions as a project-related tool for information dissemination including the TRP. In addition, the CISS website (www.cissweb.com), which is still under construction but contains the basic elements to serve as a dissemination tool, hosts the interactive intervention modules and the e-learning tool; it is also linked to the ES 6 website. Users are automatically referred to the basic CISS website if they click on the respective link.
Six ES 6 newsletters published and	Six ES 6 newsletters have been published and disseminated electronically. They are also available via the project's website.

disseminated	
> 360 organisations and individual experts receiving project-related information through the ES newsletter	More than 420 organisations received the Eurosupport 6 newsletter by the end of the reporting period.

Table 15: Effect indicators for specific objective 4 (i.e. to expand and maintain the Eurosupport 6 network to promote SRH and positive prevention of both HIV and SRH field organisations in Europe)

Effect indicator	Description
Improved exchange of expertise and mutual learning among network members	Through the website the self-learning tools for service providers are being disseminated (TRP, e-learning tools). They are intended to effectively support them in better integration of SRH in routine HIV care through the provision of information and tools that enhance their skills. The website may thus contributes to increasing service providers' capacity to deliver meaningful SRH interventions for this target group. As explained above, it was not suggested to measure this objective within the time framework of this project, thus no related indicators were assessed. According to the proposal submitted we put priority on evaluating the CISS' effectiveness on the level of the service users instead, because people living with HIV are the main beneficiaries of this project. However, for future research, this indicator could be measured for instance by assessing the frequency of occasions on which network members actually exchange expertise and to what extent such a network creates opportunities for mutual learning. This could be interesting, given the stark differences between European countries, not only with respect to the epidemiology of the HIV epidemic, but also its underlying fuelling factors and the perceptions and ideologies people hold, relating to potential solutions. Maintaining a web-based forum or a project-related blog, could for instance, inspire such a dialogue across Europe. However, these tools need to be maintained intensively, something that we could not achieve with the resources available, since we put our emphasis on the intervention development and testing its effectiveness. There are examples for such a dialogue on the web, mainly initiated by community-based organisations. One example is for instance the discussion forum on issues of criminalisation relating to HIV transmission and exposure maintained by the UK-based NAM. There may also be other means to measure the increase in exchange of expertise and mutual learning among network members, however, measuring this effect was not foreseen in the current project.

Increased knowledge of stakeholders with respect to SRH and positive prevention	The purpose of the Eurosupport networking initiative is to contribute to a better integration of SRH and HIV across Europe. This indicator could be suggested to measure the increased or changed knowledge, that potentially could be observed among network members. However, it would be difficult to actually assess if any changes observed can be attributed to their participation in the network. Being exposed to occasions of mutual exchange of knowledge and expertise, indeed could foster a new and different type of expertise. Since it is difficult if not impossible to discriminate between different influences, one would have to ask network members about their own perception of personal gains due to participation in the network. There may also be other means to measure the effect of network participation on knowledge in relation to SRH and positive prevention. However, measuring this effect was not foreseen in the current project.

Table 16: Impact indicators for specific objective 4 (i.e. to expand and maintain the Eurosupport 6 network to promote SRH and positive prevention of both HIV and SRH field organisations in Europe

Impact indicator	Description
Reduction of onwards HIV transmission	Ideally, through all its combined activities, the Eurosupport network would contribute to overall effective prevention and thus also to the reduction of new, onwards HIV infections. Hard biological outcome indictors are seen as the best way to evaluate behavioural interventions using a randomised design. It must be acknowledged that self-reported data on sexual behaviour usually is subject to social desirability and to a certain degree will also depict the way people see themselves as sexual beings, thus not necessarily depicting the sexual behaviour but partly sexual norms. Compared to self-reported data, biological outcome data could reveal the true effect of a behavioural intervention. For the case of behavioural interventions, such as the CISS, the indicator could be onwards HIV infection, but due to practical and ethical issues this indicator would be challenging to measure. Another option could be STI testing among the participants. This could be a relevant outcome indicator for future trials to validate the self-reported data. However, longer follow-up periods must then be considered, to have sufficient power to yield meaningful results.
Target group members' improved health related quality of life	If positive prevention intervention are effective, quality life would be a relevant indicator to measure their impact on the lives of people living with HIV. It would perhaps be the most relevant outcome measure. In this project, we did not foresee such a global outcome measure, since we were mainly interested in learning primarily which

	determinants of sexual risk behaviour can be changed with which type of intervention. However, for future research, it could be relevant to include more global health measures such as health-related quality of life.
Reduction of HIV-related societal stigma	If positive prevention intervention are effective, reduced HIV-related stigma, both internalised self-stigma as well as perceived external HIV-related stigma and discrimination would be relevant indicator to measure impact on the lives of people living with HIV. HIV-related stigma has been shown to also have an impact on sexual risk behaviour of PLHIV (Rojas et al. 2008). In the self-assessment of the scientific evaluation of study participants, some variables on HIV related stigma are integrated, but not used as outcome measure, since the CISS intervention does specifically target stigma reduction. It is rather seen as an underlying condition potentially influencing the outcome behaviour, and would have to be measured at population level.

Overall achievement relating to the specific project objective 4:

The indicators and their respective targets relating to maintaining and expanding the Eurosupport 6 network with the ultimate objective to disseminate the knowledge and expertise accumulated within the project were fully achieved. The expansion of both the group of collaborative partners and the Eurosupport 6 network progressed smoothly. The dissemination tools, such as the ES 6 newsletters were disseminated as planned and informed a large group of stakeholders (i.e. > 420 organisations beyond the Eurosupport network) about the project and its results. This group of stakeholders is a relevant starting point for future activities regarding the up-scaling the intervention (i.e. the dissemination of the TRP, and the training of interested stakeholders in its delivery).

3.2 Detailed description of activities relating to scientific evaluation of the intervention

In this part we focus in first instance on the evaluation of the risk reduction intervention developed in the framework of the Eurosupport project, i.e. the CISS, as it constitutes the core piece of the training and resource package for service providers in an integrated field of SRH and HIV. The rationale for this choice is that effect indicators were only measured on the level of the primary target group (i.e. people living with HIV; → see also figure 1: the intervention logic model), and not on the level of the service providers who were the project's intermediate target group.

Table 17 gives an overview of the milestones relating to the scientific evaluation of the intervention, i.e. the preparation of the CISS trial study and the respective milestones, as well as other activities relating to the evaluation of the project-related activities.

Table 17: Milestones relating to the project's evaluation

Date	*Milestone*
M3	Developing the IMM framework which establishes the evaluation plan
M8	Fine-tuning the evaluation plan and developing a scientific study protocol
M9	Approval of the study protocol by Ethical review board
M12	Developing the study tools (questionnaires, etc.)
M12	Evaluation of the first training workshop
M18+2	Midterm evaluation report
M45	CISS Intervention trial study results available
M48	Evaluation of the final training workshop/dissemination workshop
M48+2	Final evaluation report workshop

3.2.1 Evaluation approach and methods

Theoretical guidance

As mentioned initially, we used the Intervention-Mapping method (IMM) to guide the intervention development. IMM is an evidence-based public health planning method (Bartholomew et al., 2006), which guided us in fine-tuning all steps necessary to develop, implement, and evaluate the intervention and the accompanying training materials. IMM guided the TRP development as an *iteractive* process, and specified a number of concrete steps to be carried out in a systematic way during intervention development to achieve the desired outcome. For a more detailed description we refer to the IMM framework document (→ see deliverable D02; final technical implementation report). Each step in the IMM process is based on the outcome of the previous step. In addition, in the context of a European project with 10 different countries represented by the associated partners, IMM is used as an overall methodological framework to safeguard sufficient comparability of the intervention across the different settings. It should be stressed that IMM is a tool, not a theory per se. It is a guiding framework, in which the underlying scientific behavioural theories that were used to design the intervention, were integrated. For a description of these underlying theories we refer to the final technical implementation report and the IMM document, where these theories have been described in detail. Using IMM as a planning and development tool allows for adapting to unforeseen events and emergencies during the development and implementation phase due to its iteractive character. In addition, it allowed or sufficient room for target group specific and local/regional adaptations.

Table 18: Milestones relating to the theoretical guidance/IMM framework

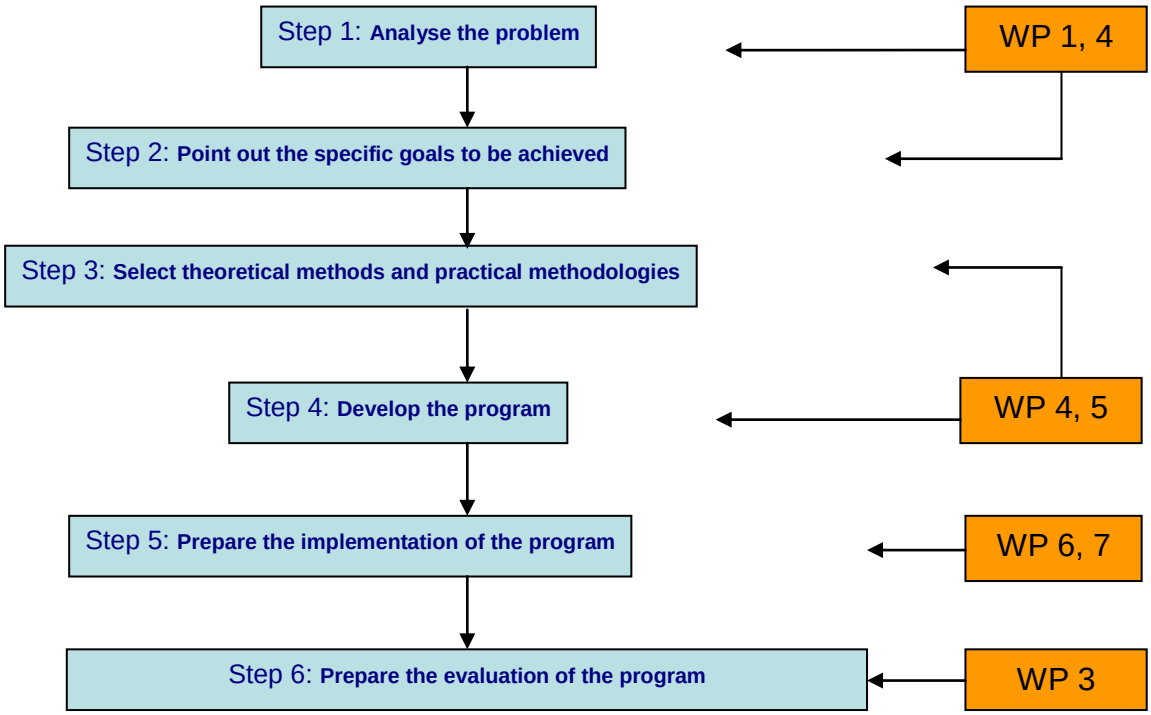
Date	*Milestone*
M3	Developing the IMM framework
M5	Disseminating of the IMM framework to APs
M10	Draft interventions available

Developing the IMM framework

IMM guides the TRP development as an iterative process (→ see figure 2 below), in which each step is based on the outcome of the previous step. Together, they contribute to the following envisaged outcomes:

- enabling service providers to deliver effective positive prevention interventions
- enabling people living with HIV (two main target groups: MSM and migrants living with HIV; the latter further distinguishing between male and female migrants paying attention to gender-specific needs and behaviours) to make informed decisions about sexual risk reduction and to adopt positive prevention principles (with particular emphasis on sexual risk reduction and condom use).

Figure 2: Linkages between IMM steps and Eurosupport 6 work-packages (WP)

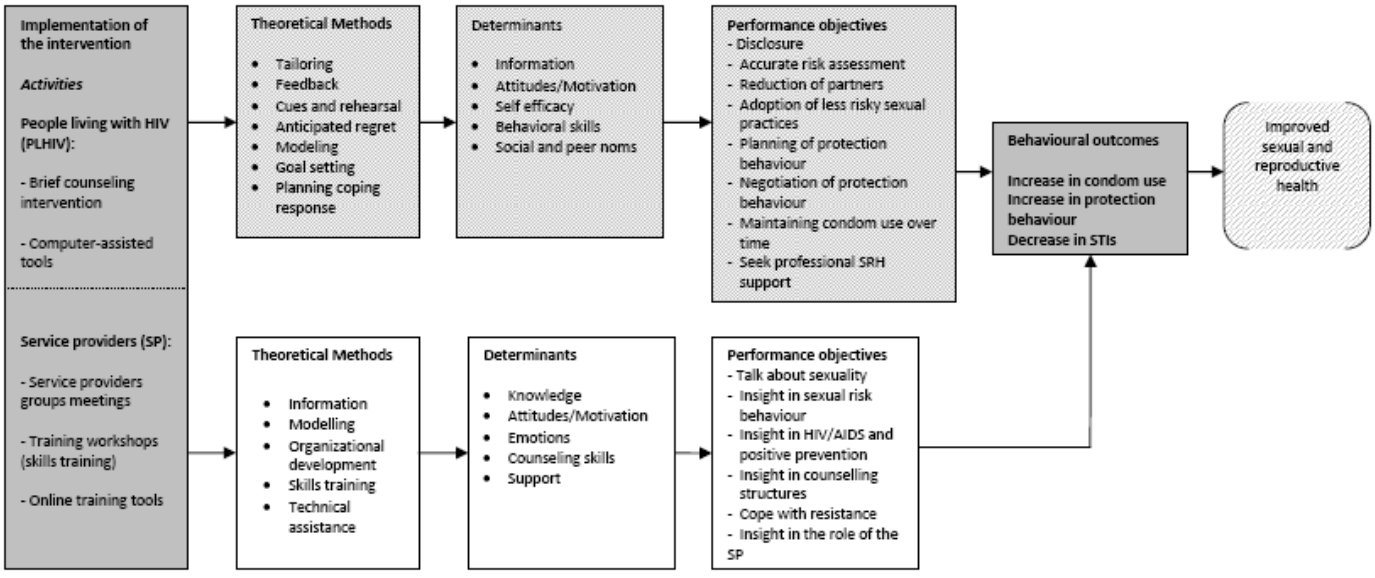


The IMM framework (→ D02; final technical implementation report) contains and describes the proximal programme objectives, the specification of the performance objectives, summarised in the IMM respective matrices; in addition, the intervention outcomes were formulated in terms of concrete change objectives. The evidence used for this step were the results of the previous project Eurosupport 5 (as described in the rationale and methodology

section of Annex I to the Grant Agreement), and a thorough literature review on SRH and HIV prevention interventions for people living with HIV with an emphasis on European studies. This evidence was scrutinised for an elaborated target group specific needs assessments. On the basis of this, theory-based strategies and tools were selected to implement the targeted intervention (brief face-to-face counselling interventions using elements of motivational interviewing with complementary computer assisted tools, leading to the intervention labelled as the CISS). The IMM framework document also operationalised the intervention plan, considering sufficient comparability and adaptation to settings requirements. A number of accompanying documents were also compiled up and distributed to the partners, which described the standard operating procedures for implementing the CISS intervention in their own settings. In addition, implementing partners were trained in the use of the CISS (i.e. see description of the first training workshop).

The IMM framework , as depicted in figure 2 above, stipulated the evaluation plan, and how to assess the interventions' effectiveness. It should be stressed that during the project, the IMM framework was a work in progress and as such was regularly updated through continuous feedback received from the associated partners. Its final version 1.6 was used to develop the study protocol for the evaluation study (→ see annex 7; final technical implementation report), defining the outcome behaviour, its underlying determinants and the specific behavioural sub-steps to reach the outcome behaviour.

Figure 3: Logic model for the intervention (CISS)



Methods: Assessing the intervention's effectiveness

This logic model was translated into the evaluation approach, consisting of two main components: an outcome evaluation and a process evaluation. For the former, a prospective experimental design with randomised assignment of people living with HIV to either intervention- or control group condition. Participants had to undergo screening for sexual risk behaviour during the last 3 months, based on specific screening questions (as displayed in table 19 below.

Table 19: Screening questions for recruitment

Variable	Question	Answers	Flow
Condom use at last sexual intercourse	Q1: "Did either you or your partner use a condom the last time you had vaginal or anal sex?"	Yes/No	Yes → go to Q2 No → go to Q3
Condom use in past 3 months	Q2: "Was this last episode of sex typical of sex for you over the last 3 months, i.e. did you always use a condom in the past 3 months?"	Yes/No	Yes → stop here. No → go to Q3
Importance of safer sex	Q3: "How important is it for you to be safe when you are sexually active?"	Scale "irrelevant to extremely important")	**Stop here!**

The experimental pre- and post-test design compared 2 conditions (a brief counselling intervention, i.e. the CISS consisting of three individual counselling session, in which the counsellor was supported by the CISS computer-assisted tools) with the 'treatment as usual' group (i.e. patients who were eligible to participate according to the inclusion criteria of the study, and who served as the control group).

The behavioural indicators relating to sexual risk behaviour (=the outcome variables) and other relevant variables, which could be hypothesised to influence sexual risk behaviour (e.g. disclosure, attitudes and motivation to sexual risk reduction, perceived self-efficacy in adopting sexual risk reduction,) were measured by validated tools, which allowed for pooling the data (pre-test at baseline, post-test and three and six months follow-up after completion of the intervention). Self-reported outcome measures were delivered as online tools using Snap®-software; this enhanced confidentiality. The study tools (→ see deliverable D8; final technical implementation report) measured frequency of condom use, perception and choice of partners, as well as meta-cognitions referring to sexual risk and sexual decision-making.

In addition, for the process evaluation (which we describe in more detail below and also in the study protocol) data were collected on the level of the service provider (only at the post test intervention) about feasibility, fidelity to the intervention, and specific questions to assess the

standard care condition in order to control for the comparability of the intervention across sites.

The study protocol contained not only a detailed description of the study variables (see table 20 below), and the measures used to assess them, but also a description of the procedures that study participants had to undergo (such as informed consent procedures, data collection, and storage, protecting the privacy of the participants; measures to safeguard confidentiality).

Procedures

Approval of the study protocol

The study protocol described in detail the study design, study procedures, and the ethical implications of the study including confidentiality and data safety issues, as well as the written informed consent procedures. The study protocol (→ see annex 7 to the final technical implementation report) was submitted by the main partner (ITM) to the Institutional review Board of ITM and the University of Antwerp. Approval was obtained in January 2010 (protocol ref. nr. 0947 5 690 IRB/ITM and Ethical Commission of the University of Antwerp). In addition, the following associated partners also submitted to their respective ethical review boards: Belgium (ITM, Antwerp), the Netherlands (University of Maastricht), Germany (Ludwig Maximilians University, Munich), Italy (Fondazione Centro San Raffaele del Monte Tabor, Milan), and the United Kingdom (Central North West London, NHS Trust).

Developing the study tools for the CISS trial

Table 20 gives an overview of the study variables and the measurement time-points.

Table 20: Overview of study variables and points of measurements

Variable	Screening	Baseline assessment	Post-intervention	3-months follow-up	6-months follow-up
Sexual risk behaviour	**X**	**X**		**X**	**X**
Socio-demographic information		**X**	Changes occurred?	Changes occurred?	Changes occurred?
Important life-events			**X**	**X**	**X**
Health-related characteristics		**X**		**X**	**X**
Reproductive health characteristics		**X**		**X**	**X**
Sexual Behaviour		**X**		**X**	**X**
Disclosure of HIV-status		**X**	**X**	**X**	**X**
Self-efficacy		**X**		**X**	**X**
Attitudes and motivation for safer sex		**X**	Only "Stages of change for condom use"	**X**	**X**
Social and peer norms		X		X	X
Behavioural skills		X		X	X
Mental Health		X		X	X
Evaluation of the intervention			X		
Exposure to prevention in standard care			X		

Wherever appropriate, we used empirically validated scales or questions developed in previous Eurosupport surveys, and therefore tested for feasibility and cognitive understanding. The Eurosupport study tools were translated into 8 European languages and back-translated by the associated partners for quality control. Questionnaires were transformed into online version using Snap®-software, and piloted with a small number of study participants at the UK partners study site. The study tools have been included as deliverable D08 in the final technical report.

Study procedures and implementation strategy

Before we present the results of the outcome evaluation we focus briefly on the experiences made during the implementation of the CISSS intervention trial.

As already indicated in the first part of this evaluation report (see section on specific objectives) we encountered major problems in recruiting a sufficient number of study participants. Recruitment also had started later than planned due to the complex process of intervention development. The reason for this was that the CISS intervention had become more comprehensive than originally thought due to the necessary integration of all the

theoretical elements stipulated to impact on sexual risk behaviour). Adding an additional theoretical construct based on available evidence such as the dual theory of affective decision-making, which acknowledged different learning modes for affective decision-making (Slovic et al., 2005; Kahnemann 2011), particularly in the area of sexual health, required additional modules to be developed and integrated into the CISS. This was believed to increase the potential effectivity of the intervention. Subsequently, the amount of translations required for the CISS material also increased substantially. In addition, in the initial phase some technical problems in translating the intervention into interactive modules were also encountered. All these factors contributed to a delayed start of actually implementing the CISS intervention in the clinical and CBO-settings. As a consequence, the evaluation study could not start as early During the implementation of the study, we also encountered substantial problems in the actual recruitment of study participants.

Starting from project month 24, i.e. February 2011, both MSM and migrants living with HIV living were continuously enrolled into the study. Participants were contacted individually, mostly by study nurses or treating HIV physician, who invited them to participate in the study. Recruitment strategies differed from setting to setting contingent on the way HIV care was organised. While this consecutive recruitment mode was adopted in most settings, in some selected settings (e.g. Poland, Portugal) a group consisting of the required number of participants (i.e. 32 study participants) was compiled and followed up throughout the overall study period. Seen retrospectively, this approach can be evaluated as more successful and less time consuming than the consecutive enrolment.

Participants were informed about the study mostly through their health care staff, various promotion material was developed, like flyers and posters for the waiting room areas, to improve recruitment as well as later on personal invitation cards. We also reported about the study in various patient newsletters of local service organisations, and used social media and websites where gay people search partners for instance such as “Gay Romeo”. If participants were interested in the study, a study nurse or counsellor took them step-by-step through the extensive informed consent procedure. Upon obtaining written informed consent to participate, participants were screened for the occurrence of sexual risk behaviour by answering the screening questions (see above). The screening procedure was conducted using an online tool on a PC provided at the clinic, using Snap®-software, as explained above. The same software was used for the baseline, the post-intervention and the follow-up questionnaires (three and six months after completion of the intervention).

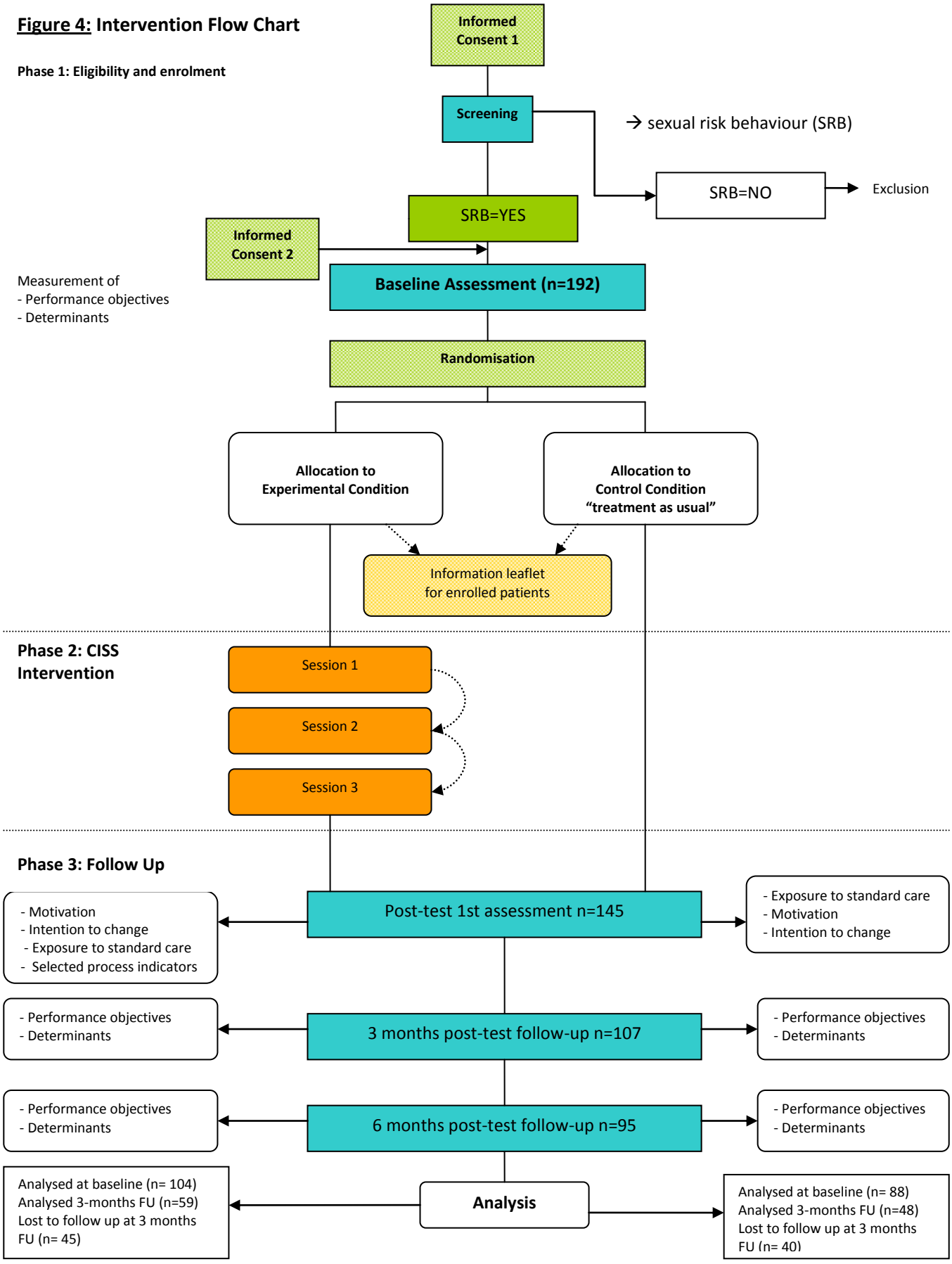
Box 1. Short description of the CISS intervention

Study participants took part in three individual counselling session, in which they were guided by the counsellor in working with the computerised tools of the CISS intervention. During the first session ('*Who am I?*') counsellor and participants explored the meaning of sex and sexuality as well as the individual barriers to safer sex using the various video-clips that were offered through the different menus of the CISS (see also work package 5 for a more detailed description). The second session ('*Working through'*), delivered about two weeks after the first session, explored potential individual solutions to overcome the barriers identified in session one. The second session was more structured and geared towards rational solutions, for instance focusing on partner-issues, existing resources and strategies that the participant could apply and anticipating partner' reactions, as well as on skills-building. The goal of the second session was to enable participants to envisage a personal solution to their problem, thus starting their own planning. Finally, in the third session counselors and participants moved on to using the discussed elements to make an individually tailored and personal risk reduction plan, either using pen and paper or a planning software that was included in the CISS DVD. In between sessions, participants could decide whether they would like to work with the CISS at home (and look at other topics included in the material), on the personal copy of the CISS DVD, in their possession.

Problems encountered during recruitment and solutions

The CISS intervention addressed a highly sensitive topic, namely unprotected sexual behaviour in the context of HIV, and overall the challenge to promote the intervention among people living with HIV and their service providers was greater than anticipated. The major problem encountered during the implementation period was slow uptake of the intervention. We had planned to deliver the CISS to about 440 people living with HIV, divided over MSM and migrants living with HIV (incl. 20% lost to follow up), randomly assigned over the two study arms comparing the intervention with standard care based on the sample size calculation (2 proportions, α=0.05; power=80%). We were not able to recruit the targeted number of study participants. At the end of project month 45, including the granted no cost extension over an additional 12 months, an overall of 192 study participants (112 MSM or 58,3% of the total study sample, and 80 migrants or 41.7% of the total study sample) were included. Overall, 104 people living with HIV were assigned to the intervention group, and 88 to the control group. The flow-chart on the next page shows the respective distribution.

Figure 4: Intervention Flow Chart



Recruitment was lower than expected due to a number of reasons: In some countries barriers were situated on a structural level, such as the legal context. For instance, in Slovakia, HIV positive people can be prosecuted by law if they are having unsafe sex. Also more general HIV- and MSM related stigmata may have hampered the recruitment. On the service provision level, apparently a general fear among HIV positive patients to discuss their sexual health, sexual behaviour, and difficulties with safer sex in HIV care settings may also have contributed to the low uptake. The fact that study counsellors emphasised confidentiality, i.e. assuring that regular health care providers were not informed about the content of the discussions during the counselling sessions and had no access to the data collected, was obviously not sufficient for patients to agree to participate in the study. It is worthwhile to note that associated partners who recruited participants via informal networks and community-based organisations encountered fewer difficulties in this respect. In some selected cases patients clearly had had risk behaviour, for instance when asking for a pregnancy test or documented through a recent infection with a sexually transmitted disease. Some of them though were not motivated to participate. They preferred a simple cure through STI treatment, and could not bring up the effort to invest in three counselling sessions to work on their risk reduction behaviour. While at individual level, this is a personal decision that has to be fully respected; it shows the impact of recent trends towards an overall medicalisation of HIV including HIV prevention, which may have contributed to such attitudes. Some gay men are part of a patient sub-population that has been prescribed as rather resistant against HIV prevention efforts, both with respect to primary prevention and positive prevention (Kalichman et al., 2010).

When these problems became apparent, a number of strategies to improve the enrolment were adopted resulting in applying for a project amendment with a no-cost extension of 12 months to maximise the data collection period. In the amendment, several strategies were described to revise the applied recruitment strategies (see below).

The above-mentioned legal constraints had particularly severe implications in the case of Slovakia, where recruitment failed. Several strategies were tried to improve recruitment also in this context, for instance promoting the study at community-based events, investing heavily in personally targeting individual patients and inviting them, and trying to strengthen ties with the MSM communities. In the case of Slovakia, at the time of recruitment, no patient organisation existed and the few initiatives of MSM self-organisations were not really willing to cooperate. HIV-related stigma among MSM communities, as described in the literature, may also have come into play here (Smit et al., 2011). In the specific case of Slovakia, we also consulted with a number of external experts on sexual health promotion in countries of

Central- and Eastern Europe, but no advice could improve the situation. Since none of these measures resulted into a single patient recruited, we had to decide to drop Slovakia as a setting for the field and to invest the resources that were saved in measures to potentially increase recruitment in other settings (i.e. allow costs for incentives).

In addition, it should be mentioned that the Italian partner encountered major financial problems wand was threatened with bankruptcy and thus could not participate in the no-cost extension. Another partner, i.e. the French AIDS service organisation AIDES, could not recruit anymore during the no cost extension period, because of other organisational commitments and priorities.

Given that the amendment was granted for 12 months, data collection ran until October 2012. The marked change in recruitment strategies resulted in enrolling another 32 MSM study participants and 28 migrants living with HIV during the time period from the second interim report delivered at project month 36 to the end of the data collection.

The proposed strategy on how to improve recruitment was worked out by the project's steering committee and approved by all partners. This included mainly a stronger collaborative effort at national/regional level to expand recruitment to other organisations, preferably to community-based organisations where we expected less perceived stigma and more trust in confidentiality being respected. The measures undertaken consisted of the following three main strategies (→ see the final technical report for more details on the changes in the recruitment strategy, which was applied for approval by EAHC by means of the second project amendment):

- consulting local service providers groups and local stakeholders to be able to expand recruitment to a larger number of organisations, among which collaboration with CBOs/NGOs was a main emphasis; organisations either referred study participants or had staff trained who could deliver the intervention at their facilities;
- paying incentives to study participants, i.e. to those who belonged to vulnerable groups and for whom transportation costs constituted a barriers;
- promoting the CISS intervention though various channels ranging from producing a flyer, personal invitation for patients and even promotion via gay websites (for the target group of MSM).

<u>Table 21:</u> Expanding the recruitment through local networks/collaborating organisations

Country	*Name of organisation*	*Type of organisation*
Belgium		
	Hospital St. Pierre	HIV-Clinic (public)
	Lhiving (service organisation for PLHIV)	NGO
	Muungano (HIV+ patient group for Africans living with HIV	CBO
	Hiv Vereniging België	NGO
Germany		
	Other departments within University Hospital (e.g. Dermatology)	Public hospital departments
Italy		
	Not active	
France		
	Regional AIDES satellite centres	NGO
The Netherlands		
	Maastricht University Medical Centre	Clinic (public)
	GGD Zuid-Limburg, Heerlen	Public Health Service
Poland		
	Warsaw's Hospital for Infectious Diseases.	Clinic (public)
Portugal		
	Positivo	NGO
	SER +	NGO
Slovakia		
	NGO Prima (Barbora Kucharova)	Prevention organisation (NGO)
Spain		
	Centro de Promoción de Hábitos Saludables, Instituto De Salud Pública Madrid Salud	Prevention service (public)
	Itsmo-Alma Ata, Madrid Salud Servicio De Prevención	Prevention service (public)
	Instituto de Adicciones. Madrid Salud Servicio De Prevención	Services for drug users (public)
	Centro Joven Instituto De Salud Pública, Madrid Salud	Youth services (public)
	Unidad de ITS. Hospital Clinico San Carlos, Madrid	Hospital (public)
	Apoyo Positivo	NGO for people living with HIV
	Prevención VIH Departamento de Salud- Cruz Roja Madrid (Red Cross)	Prevention service (private)
United Kingdom		
	Terence Higgins Trust	NGO
	Body & Soul	NGO
	Positive East	NGO
	Living Well	NGO
	Cara Life	NGO
	The Metro Centre	NGO

3.2.2 Evaluation Results: The CISS intervention

Study population

As indicated above, an overall of 192 participants were enrolled, of which 112 were gay men or MSM (58.3% of the total study sample), and 80 were migrants (41.7%). In terms of gender, the study population consisted of 148 men (77.1%), and 44 women (22.9%). The mean age of all participants was 40.5 years (ranging between 22 and 66 years), and was slightly higher among migrants (41.4 years), compared to the MSM group (39.8 years), although this difference was not statistically significant.

Table 22: Study participants per country

Country	MSM (%)	MIG (%)	Total number of participants (%)
BE	27 (24,1)	10 (12,5)	37 (19,3)
DE	14 (12,5)	0 (0,0)	14 (7,3)
ES	12 (10,6)	16 (20,0)	28 (14,6)
FR	3 (2,7)	4 (5,0)	7 (3,6)
IT	4 (3,6)	0 (0,0)	4 (2,1)
NL	6 (5,4)	1 (1,3)	7 (3,6)
PL	33 (29,5)	0 (0,0)	33 (17,2)
PT	0 (0,0)	33 (41,2)	33 (17,2)
UK	13 (11,6)	16 (20,0)	29 (15,1)
Total	**112 (100)**	**80 (100)**	**192 (100)**

Results at baseline assessment

In what is to follow, we present first the baseline results. We compared the baseline data (i.e. assessed before the intervention) between the two groups enrolled in the CISS evaluation study (MSM and migrants living with HIV), and we present the main characteristics of the participants pertaining to several domains: socio-demographic aspects, health, mental well-being, and selected features related to sexuality.

Socio-demographic and health-related characteristics

Migrants were more likely to be involved in a relationship compared to MSM (→see table 23; 64% vs. 45.5%; $p < .001$). More MSM than migrants were employed (→ see table 24; 65% vs. 34%; $p < .001$); this is reflected in financial difficulties, which are more prevalent among migrants, compared to MSM (87% vs. 45%). All these differences were significantly different between these two groups.

Table 23: Relationship status

	MSM (%)	MIG (%)	Total (%)
Single	61 (54,5)	29 (36,3)	90 (46,9)
With male partner	49 (43,7)	34 (42,5)	83 (43,2)
With female partner	2 (1,8)	17 (21,2)	19 (9,9)
Total	**112 (100)**	**80 (100)**	**192 (100)**

Table 24: Employment status

	MSM (%)	MIG (%)	Total (%)
Yes	73 (65,2)	27 (33,8)	100 (52,1)
No	39 (34,8)	53 (66,2)	92 (47,9)
Total	**112 (100)**	**80 (100)**	**192 (100)**

The majority of all study participants reported no physical complaints (65%, no significant distinction between the groups), and reported an undetectable viral load (65% overall; 68% among MSM and 61% among migrants).

Table 25: Physical health status

	MSM (%)	MIG (%)	Total (%)
No physical complaints	71 (63,4)	54 (67,5)	125 (65,1)
Physical complaints	41 (36,6)	26 (32,5)	67 (34,9)
Total	**112 (100)**	**80 (100)**	**192 (100)**

However, migrants were more likely to report that they did not know their viral load (27.5%) compared to MSM (4%). This difference was statistically significant (→ see table 26; p>.001).

Table 26: Self-reported viral load

	MSM (%)	MIG (%)	Total (%)
Undetectable	76 (67,8)	49 (61,2)	125 (65,1)
Detectable	32 (28,6)	9 (11,3)	41 (21,4)
I don't know	4 (3,6)	22 (27,5)	26 (13,5)
Total	**112 (100)**	**80 (100)**	**192 (100)**

Thirty-five percent of the MSM and 6% of the migrants reported that they had received a diagnosis of a sexually transmitted disease during the last three months (→ see table 27), which reflects a statistical significant difference between the two groups (p <.001). Such a diagnosis can serve as a proxy for the occurrence of sexual risk behaviour.

Table 27: STI diagnosis during the past 3 months

	MSM (%)	MIG (%)	Total (%)
Yes	39 (34,8)	5 (6,2)	44 (22,9)
No	68 (60,7)	71 (88,8)	139 (72,4)
I don't know	5 (4,5)	4 (5,0)	9 (4,7)
Total	**112 (100)**	**80 (100)**	**192 (100)**

In relation to mental health variables were no significant differences apparent between severity of symptoms related to depression, and anxiety between the two groups. While the mean and median scores for depression was 12.9 and 9.0 respectively among migrants (on a scale ranging from 0-42, with higher values indicated more severe levels of self-reported depression), this was 12.1 and 12 respectively among MSM. However, there was a larger group with extremely severe self-reported depression among migrants. Migrants reported to take significantly more antidepressants (25% vs. 14%, p <.05) and anxiety-reducing medication (27.5% vs. 15%, p < .03), compared to their MSM-counterparts (data not shown in tables).

Baseline data relating to sex life and sexual behaviour

More migrants than MSM reported having a main sexual partner (64.9% vs. 43.8%; p<.003). While the proportion of study participants who had an HIV-positive main partner was around

40% in both groups, migrants were more likely to be unaware of their main partner's HIV-status (28% vs. 12%).

Table 28. HIV status of main partner

	MSM (%)	MIG (%)	Total (%)
HIV-positive	20 (40,8)	21 (42,0)	41 (41,4)
HIV-negative	23 (46,9)	15 (30,0)	38 (38,4)
I don't know	6 (12,3)	14 (28,0)	20 (20,2)
Total	**49 (100)**	**50 (100)**	**99 (100)**

The vast majority (90%) of both migrants and MSM had disclosed their HIV status to their main partners. Condom use with main partners (measured at last intercourse) was not significantly different between the two groups, i.e. 75.5% of MSM and 76% of the migrants did not use a condom with their main partner.
Sexual activity (i.e. penetrative sex) with *casual partners* during the previous three months was more common among MSM (86%) compared to migrant participants (29%; p<.001). Condom use with casual partners also differed at last intercourse between these two groups, as shown in the table below.

Table 29. Condom use at last intercourse with casual partners

	MSM (%)	MIG (%)	Total (%)
Yes	40 (41,7)	14 (63,4)	54 (45,8)
No	56 (58,3)	8 (36,7)	64 (54,2)
Total	**96 (100)**	**22 (100)**	**118 (100)**

With respect to overall condom use, we found that a substantial proportion of MSM reported to never or almost never have used condoms in the past 30 days (43%), independent of partner type. For migrants, this proportion was (39%). The difference between the groups was statistically significant (p<.001; see table 30).

Table 30. Condom use in the past 30 days

	MSM (%)	MIG (%)	Total (%)
Never	19 (16,9)	24 (31,2)	43 (22,7)
Almost never	29 (25,9)	6 (7,8)	35 (18,5)
Sometimes	39 (34,8)	18 (23,3)	57 (30,2)
Almost every time	18 (16,1)	12 (15,6)	30 (15,9)
Every time	7 (6,3)	17 (22,1)	24 (12,7)
Total	**112 (100)**	**77 (100)**	**189 (100)**

However, it is encouraging that 22 % of the migrant participants reported that they always used condoms during this period, and 78% reported that they were planning to use condoms consistently (compared to 49% of the MSM, p<.001) in the future (→ see table 31 below).

Table 31. Intention to use condoms consistently in the future

	MSM (%)	MIG (%)	Total (%)
Yes	58 (51,8)	65 (84,4)	123 (65,1)
No	54 (48,2)	12 (15,6)	76 (40,2)
Total	**112 (100)**	**77 (100)**	**189 (100)**

Significant differences were also found between the groups with relation to using recreational drugs and drinking alcohol when having sex. While 45% of the MSM reported to (almost) always or sometimes have used alcohol before or during sex, this proportion was 36% among migrants (p<.001; data not shown in table). The proportion of MSM using drugs in connection with sex was 28.5 %, whereas this was only 4% of the migrant population (p<.001; data not shown in table). The use of erectile enhancing medication (EEM) also differed significantly: 49% of MSM had used them during the last 30 days, but none of the migrants reported use of EEM (p<.001).

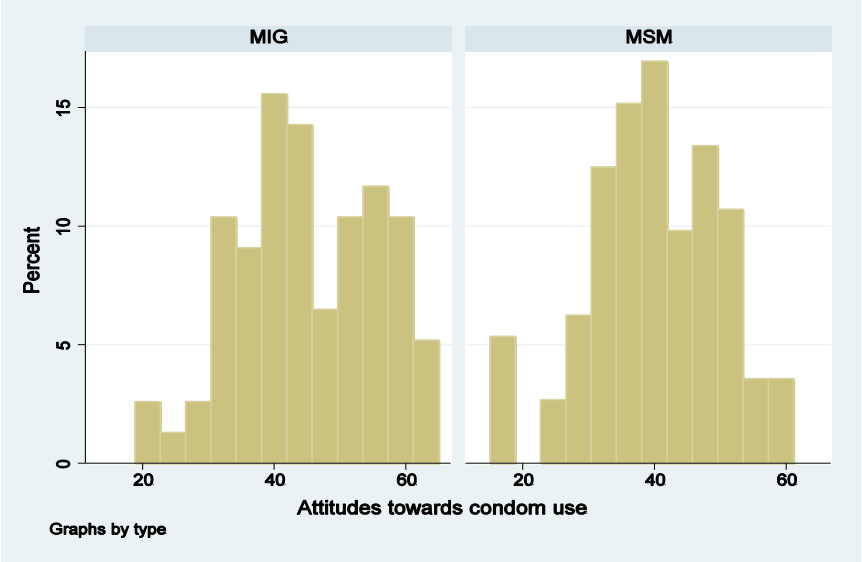
Attitudes towards condoms use and self-efficacy to use condoms

With respect to self-efficacy there were no statistical differences found between the target groups. Among migrants, the mean score was 35.8 (median score: 30) on a scale ranging from 0-50 (lowest-highest score). For MSM, the respective scores were 26.2 (mean) and 26.5 (median).

On terms of attitudes towards condom use, however, we found significant differences between the two groups. Migrants held more positive attitudes towards condoms than MSM, as can be seen in the following bar diagram (mean and median scores were 45.1 and 44 respectively for migrants and 39.8 and 39 for MSM respectively. The highest score, i.e. the

most positive attitudes towards condoms was 65. This difference was statically significant with p <.002.

Figure 5: Attitudes towards condoms



CISS effectiveness: comparison between baseline data and follow up measurements

In order to evaluate the effectiveness of the CISS-intervention, participants were randomly assigned to the CISS or control group. Because the main characteristics between intervention- and control group participants did not differ at baseline, we can assume that changes in sexual behaviour (assessed after the intervention at three- and six months follow-up measurements) can be attributed to the intervention itself.
We looked at differences between baseline and follow-up measurements for two outcome variables, i.e. condom use at last intercourse and the computed risk score as described above.

Differences between intervention and control group: 'condom use at last intercourse' as outcome variable

For condom use at last intercourse logistic mixed effect models were computed.

Table 32. Intervention effect (condom use at last intercourse)

	Odds ratio	Std. error	z	p	95% CI
Difference at baseline[a]	1.731	1.41	0.67	0.501	(0.35-8.57)
Difference at 3 months FU[a]	0.079	0.098	-2.05	**0.041***	(0.00-0.08)
Difference at 6 months FU[a]	0.135	0.153	-1.77	0.07	(0.00-1.23)

[a] Difference in 'Condom use at last intercourse' between intervention group and control group

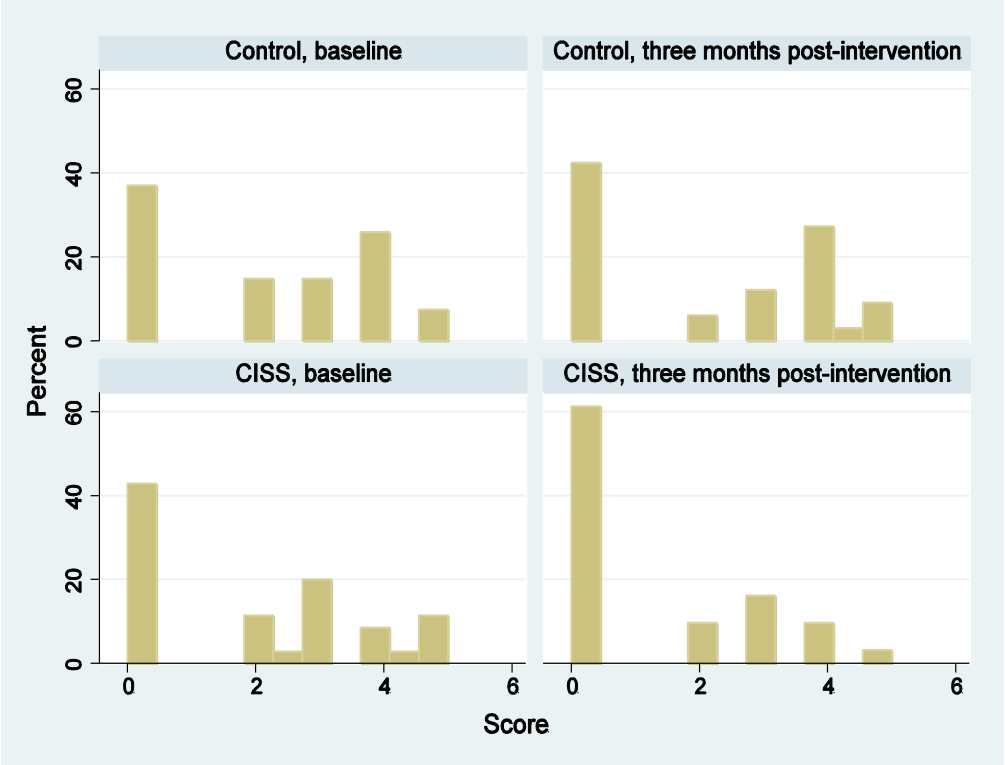
Among the participants from the control group, risk of unprotected intercourse was reduced with 0.7% between baseline and 3 months post-intervention. Among participants who were allocated to the CISS-intervention, this risk decreased much more, with 30%. This clear-cut difference in reduction of unprotected sexual intercourse demonstrates the effectiveness of the intervention. When looking at the indicator condom use at last intercourse, the likelihood

that participants of the CISS group would not use a condom three months after having completed the CISS intervention was much lower than of the controls (p< 0.04; OR: 0,08; 95% CI [0,01;0,90]). However, this effect was not sustained over the longer follow-up period. Six months after completion of the intervention, the difference between intervention- and control group failed to reach the level of significance (p=0.007). In addition, a mediation analysis was carried out. It showed that this increase in condom-use over the three months follow-up interval (as measured through the variable condom use at last intercourse) can be partially attributed to more positive attitudes towards condom-use (56%) and to improved self-efficacy in using condoms (13%).

Differences between intervention and control group using a risk profile score as outcome variable

In order to take the complexity of HIV transmission behaviour into account, we computed a composite risk profile (using Wilcoxon rank sum tests), taking into consideration the number of unprotected sexual encounters during the last three months (which will increase the transmission probability), the viral load (whether detectable or undetectable, as the latter would decrease the transmission probability as indicated by the Swiss Statement; Vernazza et al. 2008) and the knowledge of the sexual partner's HIV status, both in relation to main or casual partner. The figure below shows that also in respect for this outcome measure the intervention showed effectiveness over the three months follow-up period. While the CISS participants reached a score of 0, that of the controls was 3 (highest score to be achieved equalling greatest risk was 5).

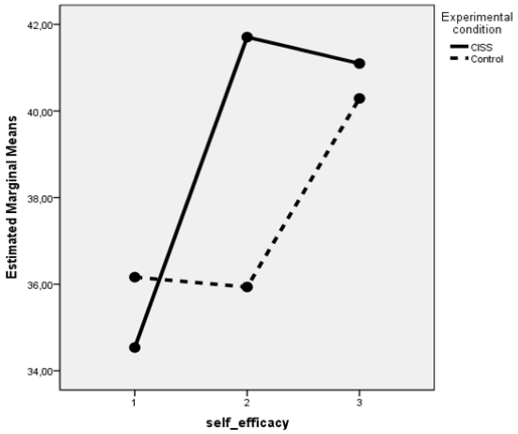
Figure 6. Intervention effect (condom use at last intercourse)



CISS effectiveness on underlying constructs

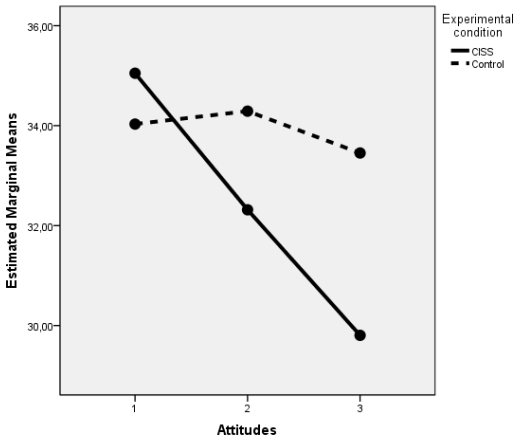
In the previous section, actual behaviour has been used as outcome variable. We also looked at other outcome measures, which are hypothesised of having been potentially modified by the CISS-intervention. Such underlying constructs could be hypothesised to eventually mediate the intervention effect. For this analysis, we used the answers from participants who filled in all questionnaires, up to 6 months follow-up (n=72). Results of this analysis, using ANOVA for repeated measures on quantitative variables, are presented below.
When looking at the effect of the intervention on self-efficacy, the scores at baseline assessment did not differ between participants from the CISS-group (i.e. the experimental condition) and those from the control group. Scores differed significantly at 3-months follow-up, however, this difference could not be sustained until the 6-months follow-up. Figure 6 shows the evolution of the mean self-efficacy scores at the 3 moments in time.

Figure 7: Evolution of self-efficacy scores



When looking at attitudes toward condom use, we see a different pattern. For this variable, the results at baseline and 3 months follow-up did not differ significantly between intervention and control group, but become significant at 6 months follow-up assessment, as shown in figure 7.

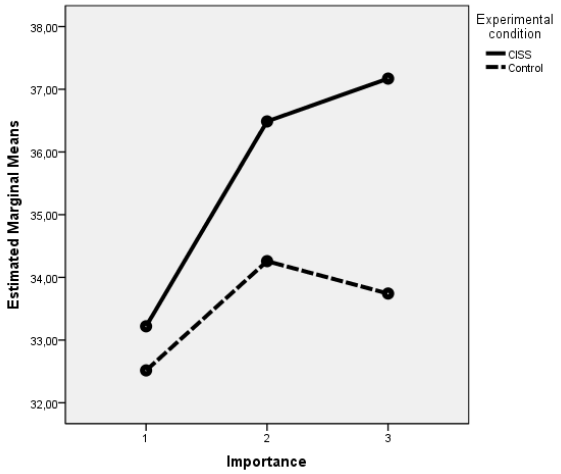
Figure 8: Evolution of scores on attitudes towards condom use



With respect to the perceived importance of using condoms, participants from the CISS group and control group differed significantly from each other. Importance of using condoms was

scored higher among participants who had been randomised into the intervention group, as shown in figure 8.

Figure 9: Evolution of scores on importance of using condoms



Summary of the outcome evaluation and conclusions

Overall, the CISS intervention study using an RCT design, showed that the CISS intervention was effective in increasing safer sex behaviour (as measured through condom use, operationalised in two different ways). However, it must be acknowledged that there were considerable problems in recruiting study participants, thus we acknowledge the study limitation that this evaluation was conducted with less scientific precision than originally planned.
The overall intervention effect could not be sustained up to the 6 months follow-up period. It is unclear whether the low number if study participants who had reached the 6 months follow-up – at the time when this data analysis was concluded - has contributed to this effect or not. We are currently completing the six months follow-up to improve the evidence base. An update of these results should give a better insight whether the intervention's effect can be maintained over a longer period or not.

The RCT study showed that the intervention significantly increased condom use three months post-intervention, and also fulfilled other criteria for good evidence of the intervention's effectiveness. According to the US-based Centers' for Disease Control (CDC) tier of evidence of behavioural interventions these criteria are (CDC: http://www.cdc.gov/hiv/dhap/prb/prs/tiers.html): existence of a comparison group, randomisation, follow-up period of at least three months or longer, and a high retention rate. At the time of concluding the study, however, the latter criteria of achieving a retention rate of 70% or higher was not achieved, i.e. as about 40% of the study participants had not been seen yet for a follow-up. Subsequently, we can conclude that according to the CDC tier of evidence of behavioural interventions the CISS sexual risk reduction intervention has to be graded good evidence. Should we succeed to include more study participants in the follow-up in the near future, eventually the evidence could be up-graded to best evidence, as the intervention does fulfill all the other criteria mentioned by the CDC.

A concrete recommendation to be drawn on the basis of the results is that - when implementing the CISS in regular service provision - it could be relevant to include a follow-up or booster session. This could in first place serve to discuss with clients whether the individual risk reduction plan developed in the third counselling session was useful to them in real life situations; and eventually adjust the plan to changing needs. Evidence has shown that such a booster session could contribute to making the intervention more effective over a longer follow-up period. It has been suggested that booster sessions focusing on prior skills learned during interventions or on new developmentally appropriate skills are needed to maintain positive outcomes (Nation et al., 2003; Kirby et al., 1997).

Results of the process evaluation

In addition to the effectiveness trial as describe above, the CISS did also undergo a process evaluation. It consisted of a systematic and continuous documentation and monitoring of key aspects of the program performance during the intervention implementation. The evaluation questions of this process evaluation to be answered were:

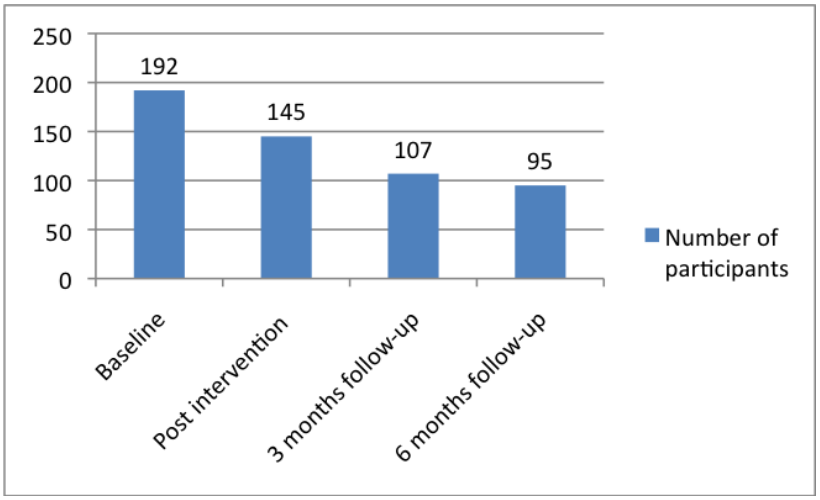
- *Is it feasible to implement a brief counselling intervention, using computer-assisted tools in HIV care settings?*
- *Is the intervention perceived as relevant by the key target groups of people living with HIV?*
- *Is the intervention delivered in a qualitative manner?*

These three evaluation questions were assessed though the following data:

Feasibility of the intervention

To assess the feasibility of the CISS, process data were collected about participant inclusion, follow-up and attrition. As describe above, difficult were encountered in participant inclusion. During the final meeting, partners agreed that the materials were very comprehensive, supported organisations to look critically at the SRH services they offered to people living with, and that they helped to improve current services in a feasible way. Despite this positive feedback obtained, several barriers for enrolment of participant have been faced during the implementation of CISS. These barriers can be clustered into legal, organisational, and individual barriers, and they have been described in more detail above, under the section 'procedures': an important legal issue preventing one associated partner (Slovak republic) from collaboration, was criminalisation of unprotected sexual behaviour for people living with HIV. Organisational aspects that complicated enrolment were time allocation and support from the team providing regular care, as well as referral from staff members. Personal issues among people living with HIV (fear of being judged, social desirability, practical and financial constraints) were also reported as a barrier for enrolment in the CISS-study. When participants were enrolled, there still was a substantial retention rate, as the figure below shows.

Figure 10. Proportion of participants retained at the different follow-up measurements



Despite difficulties to include a sufficient number of study participants in the follow-ups, fidelity to the intervention was very high. Ninety-five percent of participants completed all three sessions with their counsellor.

The use of the DVD outside the counselling setting differed quite a lot among participants. About 62% of the study participants had used it at home at some point, but use was not very extensive. Twenty-seven percent of the participants had used it at least once per week between the counseling sessions, as is shown in table 33.

Table 33: Frequency of the use of the DVD at home

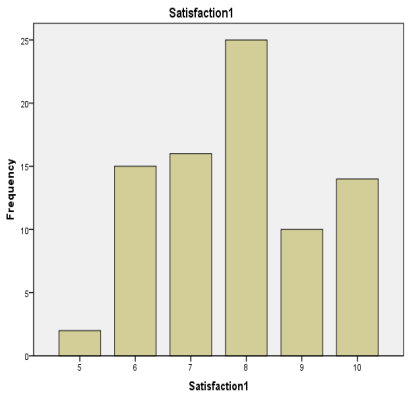
Time	Frequency	Percent
0 hours	31	38.3
Less than 1h/week	28	34.6
1h/week – 1h/day	18	22.2
At least 1h/day	4	4.9
Total	81	100.0

Counsellors who participated at the final project meeting expressed their views that the problems experienced during the enrolment phase of the CISS RCT would be less severe when delivering the intervention in regular service provision. It was believed that outside of the narrow framework and regulations of an RCT, there would be greater flexibility in promoting the intervention focusing on broader SRH issues than condom use alone, as well as in delivery format (for instance conducting more sessions, focusing on one specific topic during more sessions if needed, working with a booster sessions or working with couples, or even working with MSM with high risk behaviour instead of HIV positive MSM). However, the importance of stressing the theoretical foundations of the interventions was also stressed.

Satisfaction with the CISS intervention as perceived by service providers

Service providers (HIV counsellors) delivering the intervention were asked to assess whether the intervention was delivered as planned, and how satisfied they were with the intervention. After each cycle of three CISS intervention of sessions, that is for every participant, counselors were asked to fill in a brief survey. Counsellors from seven countries scored the sessions among 82 participants (47 MSM, 35 migrants). Mean satisfaction score with CISS-intervention was 7.8/10 (see the histogram shown in the figure below).

Figure 11. Histogram of satisfaction scores with the CISS-intervention

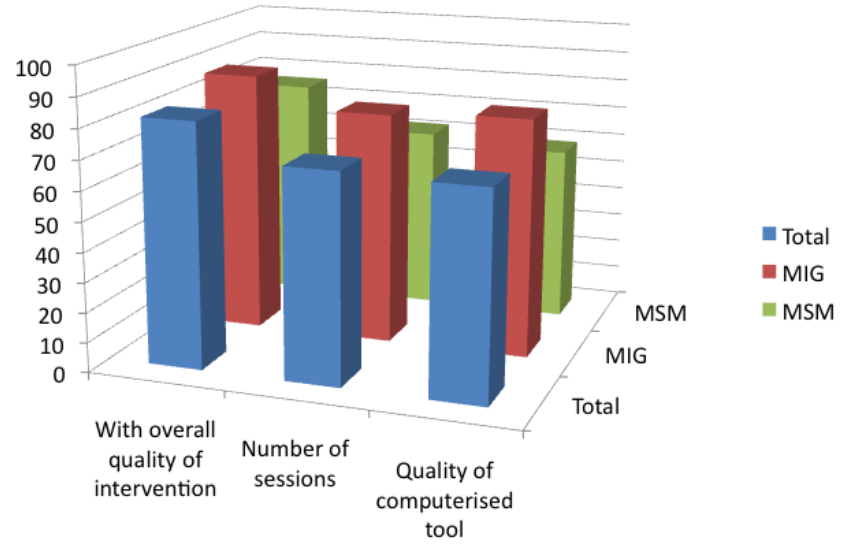


Service providers who had implemented the intervention found that the CISS had facilitated talking about sexuality with their clients. In 91.4% of the counselling interventions, service providers reported facilitation through the computer-assisted materials. Counsellors also reported that in 90.8% of the interventions completed out, the CISS had helped them to be more empathic with clients' sexual behaviour and the reported problems. The planning software on the DVD was believed to support counsellors to develop an individualised risk reduction plan, however, compared to the other indicators, this tool was appreciated somewhat less. In 78.9% of the counselling interventions, it was found useful to facilitate a risk reduction plan. Overall, 93.2% of the service providers reported that they would use CISS-materials with clients in similar situations in routine care.
These figures are promising in terms of usage of the CISS intervention materials outside a study context. According to the service providers the CISS materials will be useful tools in routine clinical care. In the above mentioned qualitative feedback obtained during the final training workshop, several participants even mentioned that the materials should be further developed to be used with other target groups, because the materials addressed basic attitudes and skills regardless of clients' HIV-status.

Study participants' perceived quality of the CISS intervention

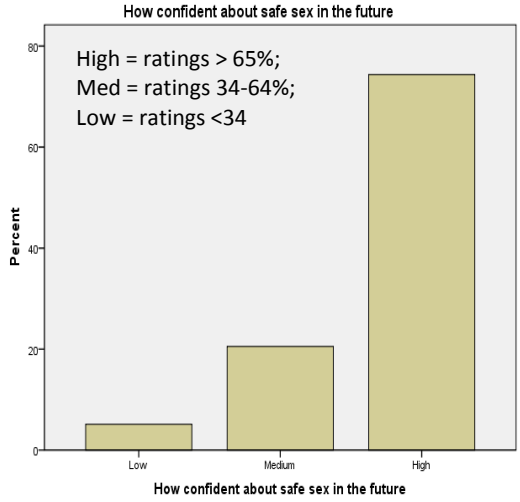
Study participants were also asked to score quality and relevance of the CISS intervention. They scored this on a scale from 0-10: '0' ="not at all satisfied/relevant" and '10' ="extremely satisfied/relevant". Presented below are the mean scores of participants on these questions.
In total, 78 participants (41 MSM, 37 migrants) who followed three sessions provided feedback after their third counselling session. Based on these data, we can conclude that overall participants were very satisfied with the intervention.
Participants were especially very positive about the counsellors. Quality of the counselling, as well as acceptance of sexual behaviour by the counselor, and collaboration with the counsellor, were all three scored between 9/10 and 9.1/10).
Scores for the materials (both helpfulness of the DVD in reducing risky behaviour, and quality of the materials on the DVD) were somewhat lower, but still high (both 6.9/10).
Scores for the operationalisation of the counselling varied, but were all in the higher range: satisfaction with the number of sessions was scored somewhat lower (6.9/10), whereas helpfulness of receiving an individualised risk reduction plan was scored higher (7.8/10).
Overall, participants scored the quality of the intervention high (8.2/10). Figure 12 below displays the perceived overall quality of the intervention, the satisfaction with the number of sessions, and with the quality of the computer-assisted tools, for both the complete sample, and divided into the two target groups.

Figure 12. Overall participants' satisfaction with quality of the CISS



As can be seen from the histogram, perceived quality was generally higher among clients stemming from ethnic minorities than among MSM. It should be stressed that study participants overall felt that they actually benefited from the intervention. This was expressed though their confidence that the CISS would help them to have a safer sex life in the future, as shown in figure 13 below.

<u>Figure 13.</u> Participants' confidence in being able to adopt safer sex in the future

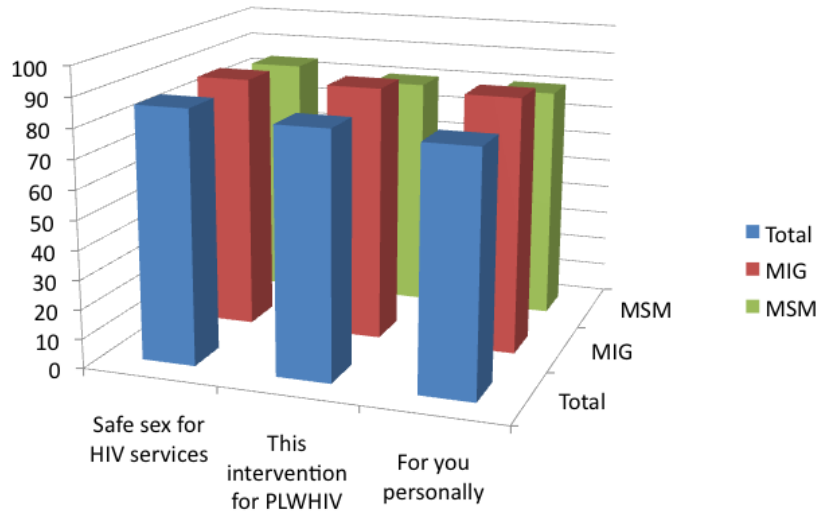


Relevance of the intervention as perceived by the study participants

The perceived relevance among the study participants was assessed through the following questions:

- How relevant was it that safer sex topics were being addressed in HIV service provision? (to be scored between 0-10: '0' =not at all relevant and '10' =extremely relevant).
- How relevant was it that prevention intervention in general for people living with HIV would support them in being safe? (same scoring as above).
- How relevant was the CISS to the study participants personally? (same scoring as above).

<u>Figure 14:</u> Perceived relevance



The figure above shows that overall, study participants found the integration of safer sex in regular HIV care provision a very relevant topic, both in general as well as for them personally. Again, this was slightly more pronounced for migrants than for MSM.

Summary and conclusions of the process evaluation

Based on the findings of the process evaluation, we can conclude that overall, the CISS achieved high levels of acceptability both among clients (i.e. people living with HIV) *and* among service providers (i.e. HIV counsellors) delivering the intervention. Considering that generally study participants found integration of safer sex topics in HIV care a relevant topic, it is positive that they regarded the CISS intervention as helpful and relevant in enabling them to adopt a safer sex life.

Outcomes to be highlighted include that 80% of the participants felt that they were enabled to adopt safer sex in the future, and 84% of the counsellors said that they would use the CISS with a similar client in the future.

Positive feedback was given on the combination of individual counselling and using the computer-assisted CISS materials. However, this process evaluation was limited in terms of assessing these two ingredients of the overall intervention-package. We did not differentiate between these two elements, therefore we are not able to assess the benefits of the counselling versus the materials. In general, both target groups were satisfied with the quality of the intervention, but there was a trend for greater benefits for the target groups consisting of ethnic minorities.

4. Evaluation of the training workshops

Evaluation of the first training workshop

The first training workshop was held on March 10-11, 2010 in Antwerp. It was both a feedback and training moment for the associated partners. The workshop was evaluated by the participants in terms of their satisfaction with the workshop and usefulness for preparing themselves to work with the intervention. To assess this, a short survey was developed by Sensoa for the participants. The detailed results of this evaluation are available on request and were sent to EAHC earlier (i.e. upon its completion).
Overall, participants were quite satisfied with the workshop and gave an average score of 7.7 (on a scale between 1-10) for the overall quality of the training workshop. Looking more closely at the specific components of the training workshop, participants rated the training on the CISS intervention (facilitated by the UK partner, CNWL) in the following way:

- Most of the participants found that the CISS presentation was clear and to the point (23% strongly agreed and 61.5% agreed, while 15%, i.e. 2 people disagreed)
- The goal of the first CISS session was clear (54% strongly agreed and 46% agreed)
- The goal of the second CISS session was clear (46% strongly agreed and 54% agreed)
- The goal of the third CISS session was clear (38.5% strongly agreed and 38.5% agreed)
- The presenter was responsive to participants (54% strongly agreed and 46% agreed)
- 85% agreed that the visual aids distributed were useful
- 70% felt confident to implement the CISS and 15% felt very confident (agreed strongly). Two people disagreed.

The second part of this training workshop was dedicated to general counselling skills. This was facilitated by Sensoa. Participants evaluated this second part also generally very positive:

- 93% found the exercises interesting (and 7% very interesting; agreed strongly)
- 93% found that the exercises had helped to practice counselling skills
- 100% found the visual aids useful
- 46% strongly agreed and 54% agreed that the presenters were responsive to the participants
- The same proportion of participants found that the exercises were well guided.

Logistic support before and during the workshop were evaluated positively (e.g. practical information, lunch and dinner arrangements, and sufficient time during the workshop related to practical aspects). In conclusion, the workshop was evaluated positively, considering the main draw-back that the intervention was not fully available as planned.

Evaluation of the second training workshop

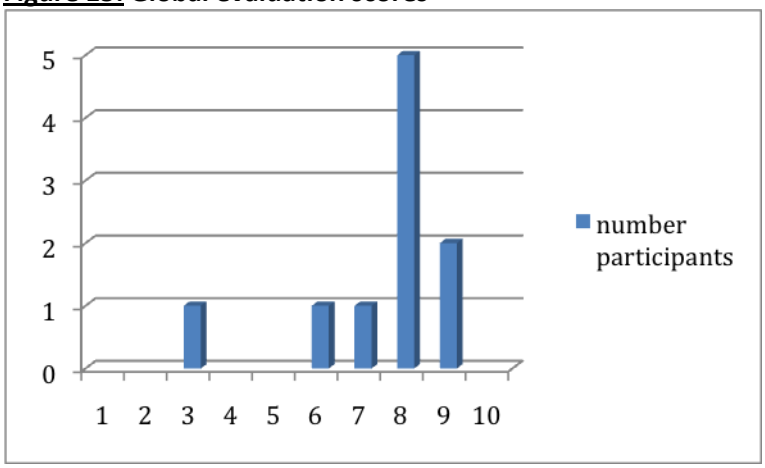
The second and final training workshop was held in Antwerp on February 7-8, 2013 and its objective was to familiarise collaborative partners with the TRP. An evaluation questionnaire was given at the end of the training workshop. The workshop on how to use the training and resource package (during the final meeting) was evaluated by 10 participants (from of the 14 collaborative partners who participated in the training).

Global evaluation of the training

Question 1: "What is your global evaluation score of this training?"

The global score of the training was high with an average of 7.6/10. There was one participant who scored the training very low (score 3/10). Unfortunately we do not know the reasons for this low score.

Figure 15: Global evaluation scores



Participants were also asked to fill in what they thought about following statements.
Statement 1: "I understand the goal of the TRP."

More than half of the participants (60%, 6/10) replied to have a very good understanding of the goal of the TRP after receiving the training. And 40% (4/10) had a good understanding of the TRP. All participants understand the goal good or very good after the training.
Statement 2:" I received the opportunity to ask questions."

Participants felt that they were sufficient opportunity to ask questions during the workshop. Half of the participants answered 'good', while 40% (4/10) perceived the opportunity to ask questions as "very good".
Statement 3: "The training met my expectations."

The majority (80%) of the participants said the training met their expectations in a good (60%) or sufficient (20%) way. One person had different expectations and one person did not have any expectations towards the training (not applicable).

Statement 4: "I can use the TRP (or parts of the TRP) in my country"

Almost all participants (90%) said that they can use the TRP (or parts of it) in their country (40%: very good; 50%: good).

Next, the participants were asked to fill in how they felt about following statements related to the trainer of the workshop.

Statement 5: "The trainer gave enough information."

Most of the participants (90%) agreed that the trainer gave enough information (very good 50%; good 40%; sufficient 10%). None of the participants answered that the information was not sufficient.

Statement 6: "The trainer was well prepared"

90% of the participants thought the trainer was very good prepared. One participant said the trainer was sufficient prepared for this workshop.

Statement 7: The handouts are clear and useful

90% of the participants thought the handouts distributed during the workshop were clear and useful (70% very good ; 20% good). One person disagreed (1% not sufficient).

Conclusion

All participants (except for one), who filled in the brief evaluation survey were very satisfied with the final training they had received. It should be noted that participant who gave a low global score for the training also answered to understand the goal of the TRP (good), perceived enough opportunities to ask questions (good), agreed that he/she can use the TRP (or parts) in his/her country, but had other expectations of the TRP training workshop.

5. Deliverables relating to the scientific evaluation

During the project period, the following deliverables were produced within WP 4 (numbers in brackets refer to the grant agreement; here we refer only to the deliverables as mentioned in the official grant agreement):

- Intervention map and IMM matrices (→ D02; final technical implementation report)
- Evaluation tools (→ D08; final technical implementation report)
- Interim evaluation report (D10; final technical implementation report)
- Final evaluation report (D14; final technical implementation)

6. Overall summary and conclusions

This interim self-evaluation report assessed the project's overall achievements. It describes the development over time of the respective indicators chosen, and assesses the level of achievement through those indicators that were adopted to measure the progress of this project. For the effect- and impact indicators, which cannot be measured during the project's running time, either due to methodological or resource-related constraints, we have elaborated them theoretically and suggested ways how to measure them. The others were worked out in detail in this report.

The major problem during this project was struggling with time. Ambitiously, we had set out to develop a comprehensive sexual risk reduction intervention, embedded in a positive prevention approach and targeting two varied key populations, MSM and migrants. Subsequently, the intervention development was complex, and the technical requirements added another dimension to this complexity. When the intervention was ready for implementation, recruitment became another barrier, with difficulties on the individual, the service-provision, and the contextual level levels. They have been described in detail in this report.

This delay had consequences on other project related activities, which were contingent on the main project-related output, i.e. the intervention development. A number of measures were introduced to safeguard the timely achievements during the second project phase, including the adoption of a parallel rather than a chronological working procedures, reducing the follow-up time of the CISS trial and applying for a no cost extension.

Based on the findings of the combined results of the outcome and the process evaluation as presented above, we conclude that:

- **The Eurosupport 6 project was carried out in an effective and qualitative manner:** This project has produced an evidence-based intervention (i.e. of good evidence) embedded in an overall training and resource package of high quality and relevance. It delivered also accompanying training materials and two training events that were perceived to be of high quality. While the project has encountered substantial delay resulting into a no-cost extension of 12 months, considerable efforts were made to achieve the project's objectives and produce all deliverables in a qualitative manner. At the end of the project all project related deliverables had been produced and disseminated.

- **The brief counselling intervention using computer-assisted tools (i.e. the 'CISS'), developed as core piece of the training and resource package (TRP) was found to be effective in reducing sexual risk behaviour.** This refers to the three months follow-up after the intervention was concluded, and was not fully sustained over a longer period of follow-up (i.e. 6 months). However, considering the multi-faceted barriers that were encountered during intervention implementation (i.e. individual, provider-related and contextual/structural) the Eurosupport 6 project produced *good evidence* for the effectiveness of the sexual risk reduction intervention.

The complexity of this rigorous intervention design applied in a multi-centre study conducted in nine participating sites raised some complex challenges during the implementation phase, , but produced good evidence for the intervention's effectiveness. We are currently working on further improving this evidence, which will be disseminated through scientific publications.

When up-scaling the CISS intervention, continuous training using the self-learning tool already developed, as well as face-to-face training events will be crucial to safeguard the theory-based behavioural constructs which are at the base of the intervention. This is crucial if we are to make sure that the CISS will be delivered in a wide range of European HIV care and community-based settings with appropriate quality and fidelity to the intervention.

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List of tables and figures: