Research in the framework of the ES 6 Project

Testing the effectiveness of a computer-assisted counselling intervention on safer sex (CISS) for people living with HIV (PLHIV)

The goal of this study is to design, implement, and evaluate an intervention to reduce HIV and STI transmission risk activities among people living with HIV (PLHIV). The intervention (labelled 'CISS', which stands for 'Computerised Intervention for Safer Sex), is delivered in HIV care settings by trained service providers and uses computer-assisted modules to support PLHIV in making informed decision on their sexual and reproductive health with an emphasis on safer sex and condom use. The CISS aims to enable PLHIV to protect themselves from contracting other sexually transmitted infections (STI), and to protect sexual partners from becoming HIV-infected.
The pilot version of the CISS consists of two target-group specific interventions (for HIV positive men having sex with men, MSM; and for HIV-positive migrants). It is obvious that they must undergo a sound evaluation before their dissemination.
This evaluation is performed by the Eurosupport 6 study group as a multi-centre study carried out by HIV care facilities in 10 European countries (see 'partners').

The study design (see flow-chart below) combines an outcome with a process evaluation.

Research questions and objectives

- To develop evidence-based and theory-guided target group specific interventions to improve the SRH of two specific groups of PLHIV, MSM and migrants, with particular emphasis on reduction of HIV transmission behaviour.

- To test the effectiveness of this intervention in real life settings on reduction of sexual risk behaviour (i.e. unprotected vaginal or anal intercourse) at 3 and 9 months post-intervention - as compared to baseline - in HIV clinical care and community-based settings.

Study design

Intervention development

The development of this behavioural intervention for PLHIV is partially based on the results of the previous study Eurosupport 5 (http://www.sensoa.be/eurosupport_5/euro_support.htm), which adapted the motivation-behavioural skills model (Fisher & Fisher 2002) to the specific needs of

PLHIV. It is also supported by other scientific evidence, such as the trans-theoretical model (Prochaska et al. 1992), which explains how people change their behaviour and what the necessary prerequisites are to support them in sustained behaviour change.
The intervention development is also based on additional evidence that risk management can be performed in two fundamentally different ways. 'Risk as analysis' brings logic, reason, and scientific deliberation to bear on risk management. Most behavioural theories build on such constructs. However, 'risk as feeling' refers to individuals' fast, instinctive, and intuitive reactions to risk (Slovic at al. 2005). Cognitive psychology examined how emotions and feelings influence decision taking relating to health bearing on this dual-process theory of information processing.

The intervention mapping model (Bartholomew 2006; Kok 2006) was used to guide our developmental work and to bring together these elements in a matrix that stipulates the intervention's learning objectives. To achieve them, the CISS brings together basic counselling elements stemming from the motivational interviewing and client-centred approaches (ie consciousness raising, tailoring of the counselling delivered to the acute needs of the client, decision making perspective, skill improvement through modelling, developing and supporting coping skills, stimulating self-efficacy and accessing social support, and dealing with other personal barriers). The intervention is being enhanced through the use of computer-assisted tools, which provide visual material (video-clips, personal stories, interactive quizzes, etc.). This is believed to bridge the gap between the rather rational counselling situation (in which one can reflect) and a situation, in which sexual risks are taken, in which one acts rather emotionally and sexually-driven. The CISS tools are expected to enhance the client-counsellor communication and to enable the counsellor to tailor the intervention to the clients' individual needs and priorities choosing with the client from a variety of computerised tools.

The CISS basically consists of three face-to-face counselling sessions (in which the counsellor guides the participant through the CISS), executed within a relative short time frame (e.g. 2 – 4 weeks between sessions). Each session takes approximately 50 minutes. The end-point of these sessions is an individualized risk reduction plan with clear goal setting of a targeted behaviour (consistent condom use). This plan, which is written down and handed to the client to support him/her, is developed together with the client based on his/her individual needs and personal resources.

The **CISS** aims at:

- Helping the individual to understand cognitive aspects of sexual (risk) behaviour
- Offering behavioural solutions based on peer models with video and audio 'stories' of dealing with difficulties and achieving change
- Affecting the evaluation of condoms through verbal and non-verbal means
- Engaging the participant in risk behaviour change
- Developing an individual "risk reduction plan"
- Motivating the participant to adhere to this plan

Outcome evaluation
To assess the CISS' effectiveness, we conduct a randomised clinical trial, which compares the CISS face-to-face counselling intervention consisting of 3 individually tailored sessions delivered by trained service providers to the condition of standard care (treatment as usual). The intervention is developed for use in a variety of clinical and community-based care settings and is therefore evaluated in these settings for feasibility and effectiveness. The effects of the intervention on sexual protection behaviour and on psychosocial mediators of sexual protection behaviour are compared to the standard care control condition (i.e. treatment as usual) three and nine months after completion of the intervention. For the control condition, treatment as usual is self-reported by the participating centres. According to sample size calculation, we aim to enrol 220 participants per target group, this a total of 440 adult study participants.

Process evaluation
The delivery of the CISS will be monitored during the implementation phase. Quality process indicators and providers' fidelity to the intervention will be collected after the completion of the intervention. The evaluation questions to be answered are:

- 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 PLHIV?
- Is the intervention delivered in a qualitative manner?

Outcome and results

The trials' **primary outcome** is sexual protection behaviour (self-reported frequency of sexual risk behaviour, i.e. subtracting the self-reported number of times using a condom from the number of times participants report having had vaginal/anal intercourse).

We also assess **secondary outcomes** relating to other sexual behaviours, such as reduction in number of sexual partners (considering the type of partner, i.e. main/steady or casual partner(s) and partner's HIV status), condom use at last sexual contact, and self-reported recent infections with other STI.
Medical records will not be checked on STI. This would require an explicit consent, which is believed to increase thresholds for eligible participants.

The study also allows assessing the effects of **psychosocial mediators** deriving from the underlying theoretic framework that may influence sexual protection behaviour: mental health correlates; motivation and attitudes; self-efficacy; behavioural skills to for protection behaviour; and social norms with respect to safer sex and condom use.

The outcome evaluation will show if using the CISS can effectively reduce sexual risk behaviour among HIV positive clients in our target groups; the pilot version of the CISS will be adapted based on the findings of the process evaluation.
If found to be effective, the CISS will be the core piece of the training and resource package (TRP), which will include the CISS intervention and its respective implementation manuals, a training manual, a reference guide/handbook for service providers and policy tools. In addition, online training tools will be developed aiming at sustained distribution after the projects' completion.

This TRP will be distributed to the ES 6 collaborative partners and other interested stakeholders during a European training workshop with different stakeholders at the end of the project.

Figure: Overview study design