Eurosupport 6: Testing the effectiveness of a computer-assisted counselling intervention on safer sex (CISS) for people living with HIV (PLHIV)

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- 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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON34668

Source
ToetsingOnline

Brief title
CISS for people living with HIV

Condition

- Viral infectious disorders

Synonym
human immuno-deficiency virus infection; HIV

Research involving
Human

Sponsors and support

Primary sponsor: Institute of Tropical Medicine

Source(s) of monetary or material Support: 2009 grant in the public health programme (PHP) 2008-2013 by the European Commission (EC)

Intervention

Keyword: computer-assisted counselling intervention, HIV, safer sex

Outcome measures

Primary outcome

Over the whole study period, data are collected on the primary and secondary outcomes. Data are collected using a computerised system, i.e. study participants fill out the questionnaire on a PC provided at the clinic, using Snap®-software.

Data assessments occur at 5 points in time: screening, baseline assessment, post-intervention assessment, and at 3- and 9-months after completion of the intervention.

Note that not all study variables are assessed at each assessment: overview of study variables and the moments of assessment are given in annex 5.

Secondary outcome

Seen Annex 5 of the study protocol

Study description

Background summary

Due to medical treatment advances, greater numbers of HIV-infected persons are living with HIV infection in good health for longer periods of time. The focus of medical care has thus shifted from preventing death to increasing the quality of life, of which sexual and reproductive health and rights (SRH&R) is an important part. Research has shown that PLHIV prioritize sexual well being as a topic. There is considerable evidence that women and men living with HIV need support in fulfilling their sexual and SRH&R, including support for HIV

transmission risk reduction, i.e. adoption of safer sex. Health care providers can play a critical role in providing this support.

Study objective

- 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 on reduction of sexual risk behaviour (i.e. unprotected vaginal or anal intercourse) at 3 months post-intervention - as compared to baseline - in HIV clinical care and community-based settings.
- Additionally, the sustainability of the behavioural change will be assessed at 9 months post-intervention.

Study design

This is a randomised clinical trial, which compares a face-to-face counselling intervention of 3 individually tailored sessions delivered by trained service providers to the condition of standard care.

Intervention

The CISS is to be provided as a CD-rom to all Eurosupport6 participating centres. It will provide the guided focus of the counselling intervention. The role of the counsellor will be to support the client in his or her use of the CISS with the objective to make informed decision on safer sex behaviour and achieve a reduction in HIV transmission risk reduction behaviour.
The CISS has different parts or modules which we will call *kisses* for now.
The CISS has certain underlying assumptions:
• It is important for clients to direct the way in which they choose which *kisses* they access as this provides an individually targeted approach.
• There is no need for the client to access all *kisses*.
• The CISS presents materials in a way which is informal, emotive and which reminds clients of sexual situations
• CISS presents materials in a culturally appropriate way. We recognize that *migrants* are a heterogeneous group, therefore CISS targets rather the specific vulnerabilities that migrants share with respect to HIV and SRH rather than representing a specific migrant culture.
• CISS presents materials for heterosexual migrants in a gender-sensitive way, i.e. materials contain specific issues adapted to the diverse needs of women and men living with HIV
• The role of the counsellor is to be accepting of the client*s difficulties with safer sex and to work in a collaborative way with the client on the CISS materials.

Different visual materials - pictures, audio transcripts, video suggestions will be included to support the non-directive, and client-centred counselling process that uses elements of motivational interviewing in terms of the counselling technique. The basic skills will be trained in the workshops and will also be integrated in the online training tool to be developed. Training intercultural competencies also forms an important part of the skills training for service providers in the ES 6 training workshop and training materials.

For further details of the CISS elements, see Annex 3 in the study protocol.

Study burden and risks

As in any trial, there is a potential risk involved relating to the randomisation to the treatment condition. Potential participants are informed of randomisation prior to enrolment, and an explanation of random assignment to the treatment group is being provided in the consent form. Referrals to other health care or community services providing counselling and support are available to all participants regardless of whether they are in the intervention or control condition. Assessment staff is trained to detect potential needs for referral and to provide such referrals throughout the course of the study.
The staff implementing the intervention is recruited among trained and experienced counsellors in HIV- or sexual health-care. On top of their general training and experience, they receive a specific two day training to help them to offer this intervention in an optimal way.

The first step is to fill out a computer questionnaire to see whether one is eligible to join the study. This will take about 5 minutes. At the end of this first brief questionnaire participants get immediate feedback to tell whether they are eligible. If they are not, nothing else will happen. If they are, they will have a new set of questions to do. This second questionnaire will take about 30 minutes. After having taken this questionnaire, they will be assigned - at random - either to the side of the study where you see and use the computer materials, with the support of someone here, or else to the side of the study where you don*t see the materials, but they get the support that is usually offered at the clinic.
In the CISS arm of the study participants will meet with a counsellor at the clinic to be introduced to the materials. There will be 3 meetings altogether over a period of about 6 weeks. The counsellor will show the participant how to use these materials and then give a CD-ROM which the participant can take home, so that he/she can look at it alone. One session will last about 45 - 50 minutes. There will also be some questionnaires to complete:
- At the beginning of the study;
- After 6 weeks (after the 3 counselling sessions);
- 3 months later;
- 6 months after the latter.
If the participant chooses this, he/she will be given the DVD to use by

him-/herself at home.
The participant will be asked personal questions about sex, about mood and other things that matter to him/her. By joining in the study, the participant agrees to answer these questions as best as he/she can, although the participant is also always free not to answer questions he/she doesn*t want to. Some of the questions and computer-materials may raise unpleasant feelings since they could be perceived as very intimate and personal, however, the utmost best has been done to phrase everything in a very sensitive way.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Being over 18 years of age;
-Having received their HIV-diagnosis a minimum of 6 months ago;

-Migrant status (man or woman) or man who has sex with other men (MSM)
-Understand the study goal, purpose and procedures involved;
-Having given their informed consent.

Exclusion criteria

-Being under 18 years of age;
-Having received their HIV diagnosis less than 6 months ago;
-No migrantstatus or MSM
-A language barrier prevents counselling possibility;
-Not understanding the study*s purpose and procedures and therefore unable to give informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2010

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30755.068.09