Increasing condom use in STI clinic clients: Promoting the formation of Implementation Intentions to overcome the discrepancy between motivation and action.

Published: 04-11-2008
Last updated: 10-08-2024

To assess whether a self-administered intervention to promote the formation of Implementation Intentions successfully promotes the use of condoms in both lower and higher risk clients of an STI clinic and reduces the well-known discrepancy between...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Interventional

Summary

ID

NL-OMON32185

Source
ToetsingOnline

Brief title
Implementation Intentions and condom use

Condition

- Ancillary infectious topics

Synonym
STD

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: condom use, HIV/AIDS, planning, prevention

Outcome measures

Primary outcome

The main parameter/endpoint of the study is the frequency of condom use for

penetrative vaginal or anal sex in the three months after the intervention.

This behavioural follow-up will be conducted online, via the Internet.

Secondary outcome

Not applicable.

Study description

Background summary

The number of people who contract a sexually transmitted infection (STI) in the Netherlands and other high-income countries has increased over the last decade. New behavioural interventions are required to contribute to the prevention of STI, in particular in so-called high risk groups, including men who have sex with men (MSM), young people and migrants. Current intervention approaches are known to be successful in promoting motivation and protective behaviour, but it has also been shown that the potential efficacy of prevention is limited because good intentions frequently do not result in protective behaviour. This study tests the efficacy of a brief intervention component that promotes the translation of intentions into behaviour and that provides an add-on to preventive counselling of clients seeking STI-treatment. The intervention that will be evaluated consists of the formation of implementation intentions, an approach that has proven to be highly effective in decreasing the intention-behaviour gap in multiple health behaviour domains, including smoking, diet and exercise, but that has not been tested with respect to protective sexual behaviours. Implementation intentions are specific plans that complement behavioural intentions, such as the plan to use condoms more

consistently, by specifying when and where condoms will be used. If it can be shown that this method successfully promotes condom use, as is expected, this would provide clinicians and nurses with a potent, innovative and easy-to-implement tool to strengthen current behavioural prevention of STI in health care settings. In addition, the intervention can potentially be used by other STI prevention professionals in a range of settings, including community outreach.

Study objective

To assess whether a self-administered intervention to promote the formation of Implementation Intentions successfully promotes the use of condoms in both lower and higher risk clients of an STI clinic and reduces the well-known discrepancy between intentions and behaviour with respect to condom use.

Study design

The study is conceived as a randomized controlled trial, with a 2 (lower risk vs. higher risk clients) x 2 (experimental vs. control intervention) design.

Intervention

The intervention is self-administered and will be conducted on a designated stand-alone personal computer placed in a private space of the clinic. After providing informed consent and adequate explanation by the researcher overseeing the study, participants will start the computer program designed for the study and intervention and first of all answer a series of questions to assess demographic characteristics, sexual behaviours, evaluations of condom use, and intention to use condoms. Half of the participants will then be randomly routed to the experimental intervention, while the other half is routed to a control intervention. In the experimental intervention participants a series of questions is presented that guides participants through the process of forming an Implementation Intention with respect to condom use. These questions will identify for which of the four main domains of condom related behaviours (i.e., getting condoms, carrying condoms, talking to a partner about using condoms, and using the condom; Sheeran, Abraham & Orbell, 1999) they want to get some advice and form a plan which will help them to actually use condoms. Subsequently, these questions will result in the formulation of an *If-then* plan or resolution that is characteristic of Implementation Intentions (e.g., *If I have sex with a new partner, I will bring up the issue of condom before starting to make out*). The participants will accomplish this by specifying what, were, when and how (they can choose which of these four factors they use in their plan). In the control intervention participants will be asked to think about situations in which they tend to engage in unsafe sex.

Study burden and risks

The study consists of answering a series of questions prompted by a tailored computer program. The only burden attached to this experiment is the investment of 30 minutes of time required for participation. This includes approximately 10 minutes related to providing informed consent, 15 minutes for the intervention, and 5 minutes to complete an online follow-up questionnaire. No other burdens or (health) risks are expected.

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

Participation is voluntary and based on informed consent and potential participants have to

be able to provide informed consent. Also, as the study and intervention will be conducted on a personal computer, participants need to feel competent in basic computer skills. Note that only minimal computer skills are required relating to the use of keyboard and mouse to enter responses and continue in the program. Furthermore, considering that the formation of Implementation Intentions is a method to promote acting on good intentions, the target population consists of individuals who intend to use condoms, but who have failed to act on that intention.

Exclusion criteria

Clients who are younger than the legal age of consent or who can otherwise not provide informed consent are excluded from the study. Also excluded are individuals who are in a monogamous relationship for three months or more and individuals who do not intend to use condoms (more often).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2009
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	04-11-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL23538.041.08