How to improve HIV prevention?

Development, implementation and evaluation of combination prevention interventions among key populations

Hoe kan hiv preventie beter?

Ontwikkeling, implementatie en evaluatie van interventies passend binnen combinatiepreventie bij sleutelpopulaties

Proefschrift

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CHAPTER 1

Introduction

Human immune deficiency virus (HIV) has been a health issue since its discovery in the early 1980s. Despite large improvements in treatment and accompanying improvement of quality of life among people living with HIV, prevention remains a critical element in the management of HIV. HIV prevention was traditionally a synonym for condom use, but has gradually changed over the years to a more comprehensive approach.

HIV

Human immune deficiency virus (HIV) is a virus causing acquired immune deficiency syndrome (AIDS). Most common transmission routes are condomless sex, injecting drugs, and mother to child transmission if no preventive actions (medication for the mother during pregnancy, medication for the baby) have been undertaken. When transmission occurs and HIV enters the body, the virus penetrates immune cells (CD4-cells), and by multiplying itself destroys affected CD4 cells. This process liberates new viruses able to infect more CD4 cells. The circulating virus is referred to as 'viral load'. Treatment for HIV consists of oral (antiretroviral) medication which suppresses the virus to an 'undetectable' level, which prevents the virus from affecting the immune system. The treatment is effective in suppressing viral load among HIV-positive persons over longer periods of time. Reduction in mortality is observed since the introduction of antiretroviral therapy (ART), and a continued reduction is accomplished until today (Antiretroviral Therapy Cohort Collaboration (ART-CC), 2017; Teeraananchai, Kerr, Amin, Ruxrungtham, & Law, 2017). In the first years of antiretroviral drugs development, this reduction was due to better regimens with increased effectiveness and improved tolerability. More recently, better life expectancy rates can be attributed to increased viral suppression, declines in viral failure, a wider range of treatment options, and simpler regimens, leading to an improved adherence to ART (Antiretroviral Therapy Cohort Collaboration (ART-CC), 2017). Yet, this improvement did not lead to a life expectancy that equals the life expectancy of the general population. Recent guidelines and efforts to start ART with high CD4 cell counts are not included in this review, and will probably influence the life expectancy further (Teeraananchai et al., 2017). In Switzerland, a high-income country, life expectancy of people living with HIV with higher education equals the estimated life expectancy of individuals from the general population with an educational level limited to compulsory education (Gueler et al., 2017). Life expectancy also differs between regions, and between men and women in low/middle-income countries (Teeraananchai et al., 2017; Wandeler, Johnson, & Egger, 2016). The dramatic diminution in circulating virus after ART not only prevents the virus from further infecting other CD4 cells, but also drastically decreases the transmission risk.

The risk of HIV transmission per sex-contact is estimated at 138/10,000 for condomless receptive anal sex, compared to 8/10,000 for condomless receptive vaginal sex (Patel et al., 2014). Oral sex is considered to pose less risk, even though reliable estimates of the actual risk are lacking (Landovitz & Currier, 2009). An elevated prevalence of HIV, and a higher risk of transmission via anal sex make men who have sex with men particularly vulnerable for HIV acquisition. This vulnerability is reflected in the epidemiological pattern throughout Europe.

In Europe, 29,747 people were newly diagnosed with HIV in 2015. This accounts for 6.3 newly diagnosed individuals per 100,000 inhabitants (European Centre for Disease Prevention and Control / WHO Regional Office for Europe, 2016). In Belgium, 1,001 people were diagnosed in 2015, a rate of 8.9 per 100,000 inhabitants (European Centre for Disease Prevention and Control / WHO Regional Office for Europe, 2016). This high rate in Belgium, compared with other European countries, was consistent over the past 10 years. In this period, Belgian rates ranged between 8.9 (2015) and 11.1 (2010; 2012) per 100,000 inhabitants, compared to 5.8 (2015) and 6.9 (2008) per 100,000 inhabitants for the EU/EEA region (European Centre for Disease Prevention and Control / WHO Regional Office for Europe, 2016).

The epidemiological situation varies strongly between European regions. Overall, sex between men is the most commonly reported transmission route in Europe, accounting for 42% of newly diagnosed HIV-infections, followed by heterosexual transmission accounting for 32% of new diagnoses. Injecting drug use was less frequently reported as transmission route (4%), and for a considerable proportion of newly diagnosed HIV-positive people (20%), transmission mode was not reported or unknown (European Centre for Disease Prevention and Control / WHO Regional Office for Europe, 2016). New HIV infections via sex between men is increasing in Western and Central Europe, whereas heterosexual transmission is more often observed in Eastern Europe. Transmission via injecting drug use still accounts for one third of new HIV infections in Eastern Europe, and more than half in Russia (European Centre for Disease Prevention and Control / WHO Regional Office for Europe, 2016).

A cure for HIV is probably possible but unrealistic to be available in the coming years. This makes prevention, early diagnosis and treatment, cornerstones of care and follow-up of HIV.

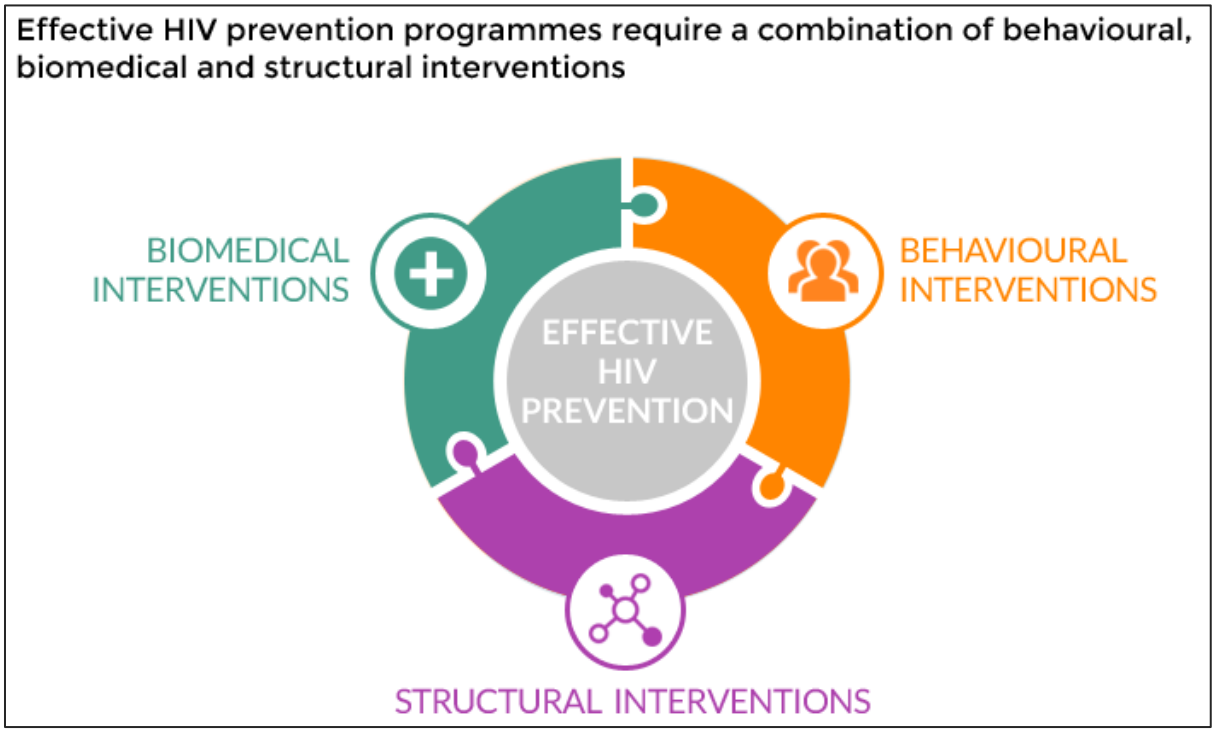
Prevention of HIV

Combination prevention

The preferred approach to achieve HIV prevention with the highest, sustainable impact is referred to as ‘combination prevention’ (Coates, Richter, & Caceres, 2008; Joint United Nations Programme on HIV/AIDS, 2010). An effective combination intervention for HIV-prevention involves

three dimensions: biomedical, behavioral and structural (Joint United Nations Programme on HIV/AIDS, 2010). Figure 1.1 shows an illustration of the three dimensions of effective HIV combination prevention.

Figure 1.1: Effective HIV prevention (AVERT, 2017)



Since the beginning of the epidemic, **biomedical** interventions have been tested as preventive activities. HIV treatment was an important focus of biomedical prevention. By reducing the viral load in individuals, and thereby reducing infectiousness (treatment as prevention; TasP), researchers demonstrated that transmission rates would decrease (Cohen et al., 2011, 2016; Strömdahl et al., 2015). Pre-exposure prophylaxis, the use of antiviral medication orally or topically (e.g., vaginal gel) prior to exposure to HIV (Abdool Karim et al., 2010; Shattock & Rosenberg, 2012) is also considered a highly effective prevention strategy to decrease HIV incidence in clinical trials and feasible to implement in real-life settings (Fonner et al., 2016; Krishnaratne, Hensen, Cordes, Enstone, & Hargreaves, 2016; Reyniers, Hoornenborg, Vuylsteke, Wouters, & Laga, 2016). Post-exposure prophylaxis, using oral antiviral medication after exposure to HIV, is considered efficacious despite the absence of randomized, placebo-controlled trial studies (Landovitz & Currier, 2009; Strömdahl et al., 2015). Prevention of mother to child transmission by using antiretroviral drugs in antenatal, perinatal and postnatal care, is highly effective (Padian et al., 2011). Increased uptake of HIV testing (and linkage to care) is considered effective (Strömdahl et al., 2015). Other highly effective biomedical interventions are condoms (Weller & Davis-Beaty, 2002), and needle and syringe

exchange (Abdul-Quader et al., 2013; Des Jarlais, Feelemyer, Modi, Abdul-Quader, & Hagan, 2013). Voluntary medical male circumcision showed to be an effective intervention for men (Auvert et al., 2005; E. Mills, Cooper, Anema, & Guyatt, 2008; Strömdahl et al., 2015). The inner surface of the foreskin contains Langerhans' cells with HIV receptors, an important entry point of the virus in the body (Szabo & Short, 2000). Additionally, traumata on foreskin and frenulum caused by sexual intercourse may facilitate HIV transmission (Auvert et al., 2005; Szabo & Short, 2000). As an indirect transmission risk, increased susceptibility of ulcerative lesions caused by other sexually transmitted infections (STI) of the highly vascularized frenulum are hypothesized (Auvert et al., 2005; Szabo & Short, 2000). As STI may facilitate HIV transmission, adequate control of STI is considered as a prevention intervention, though results are not convincing (Ng, Butler, Horvath, & Rutherford, 2011).

Behavioral interventions aim to reduce HIV transmission by addressing unsafe behavior. Obviously, for each new sexually transmitted HIV infection, an HIV-negative and an HIV-positive individual need to have unprotected dyadic sex. For many years, prevention focused on HIV-negative individuals (to protect themselves). Different counselling programs and strategies have been proven to be effective in HIV prevention (Johnson et al., 2008). Learning how to integrate the use of condoms in sexual encounters (Strömdahl et al., 2015), and reducing the number of sexual partners (Kalichman & Grebler, 2010; Wilson & Halperin, 2008), are highly effective interventions. Serosorting (choosing sexual partners based on their HIV status to reduce HIV transmission risk) or avoiding to receive semen in the mouth, generate insufficient evidence to be recommended (Strömdahl et al., 2015). Improvement of adherence to antiretroviral medication (PrEP), and an increase of the use of clean needles can be seen as a behavioral operationalization of effective biomedical interventions. An additional concept to increase prevention effectiveness is including people living with HIV in prevention, referred to as positive prevention (Kalichman, 2005). The same interventions as for HIV negative individuals apply to HIV-positive persons, including learning how to integrate condoms in sexual encounters (Strömdahl et al., 2015), a reduction in the number of sexual partners (Kalichman & Grebler, 2010; Wilson & Halperin, 2008), and improved adherence to antiretroviral medication.

Structural interventions aim to alter the physical, legal and social environment in which individual behavior takes place (Joint United Nations Programme on HIV/AIDS, 2015). Structural interventions tackle circumstances, which hinder people or make them vulnerable for HIV acquisition. Examples of structural barriers are discrimination (of sex work, same-sex relationships, or drug use), difficulties to access services or education, availability of condoms, gender inequality, etc. (World Health Organization, 2015b). Interventions that assess people's risk for HIV acquisition may be considered as structural interventions.

HIV testing as prevention intervention

HIV counselling and testing is mentioned as a preventive activity since the 1990's (Valdiserri, 1997). Testing, linkage to care and treatment can be considered as a continuum. It can foster prevention both at the individual and at the population level. People who receive an HIV diagnosis may adapt their behavior towards a less risky sexual lifestyle (Marks, Crepaz, Senterfitt, & Janssen, 2005). Effective testing, linkage to care and treatment of those tested positive will ultimately lead to a diminution of the community viral load in a population (Strömdahl et al., 2015), leading to a reduction of new HIV infections.

HIV testing is considered to be a cost-effective prevention approach. Indeed, a recent modelling study compared cost-effectiveness of three prevention activities in Belgium: intensified HIV testing, pre-exposure prophylaxis (PrEP), and treatment as prevention (Vermeersch & Annemans, 2016). Intensified testing showed to be by far the most cost-effective approach. The return on investment was many times higher compared to the other strategies. Despite the highest yield for intensified testing as stand-alone intervention, combined strategies were even more effective, consistent with the approach of overall (combination) HIV prevention (Vermeersch & Annemans, 2016) .

In order to eradicate HIV by 2030, UNAIDS developed an ambitious 90-90-90-strategy (Joint United Nations Programme on HIV/AIDS, 2014). To achieve these goals, 90% of all people living with HIV should be diagnosed; 90% of them should be on antiretroviral treatment; 90% of treated people living with HIV should be virally suppressed by 2020. Recent estimations from Belgium, with a 'diagnosed fraction' of 84.7%, show that the target of diagnosing 90% is not yet reached (Beckhoven, 2016). The European situation is comparable; the European Centre for Disease Prevention and Control (ECDC) estimates that in Europe, 15% of HIV-positive people are undiagnosed, which is often referred to as a 'hidden epidemic' (Drew et al., 2017; Pharris, Quinten, Noori, Amato-Gauci, & van Sighem, 2016).

Many efforts have been invested in increasing the number of individuals from key populations and undiagnosed people to take an HIV-test. This increase of uptake of testing requires tailored approaches to reduce existing barriers on personal, psychosocial or logistical levels (Lui et al., 2017). Despite the options, and efforts to reduce barriers, a paradigm switch towards a comprehensive testing approach in HIV testing seems necessary to achieve the first 90% mentioned in the ambitious UNAIDS goals (Joint United Nations Programme on HIV/AIDS, 2014).

Sexual health and HIV

Sexual health

Sexual health is a concept that was initiated by the World Health Organization (WHO) in 1975 (World Health Organization, 1975), and was updated in 2006 (World Health Organization, 2006). Sexual health is a positive concept that needs adopting a holistic approach of sexuality. It encompasses aspects of quality of sexual experiences and relationships (Wellings & Johnson, 2013), and recognizes the importance of pleasurable sexual experiences free of coercion, discrimination and violence (World Health Organization, 2006). Despite the broad focus of WHO's definition, sexual health research in the field of HIV and STI focuses mostly on 'risky' sexual behavior.

People living with HIV

Sexual transmission is for most HIV positive men (who have sex with men) the way they became infected. Adapting their sex life is therefore for many an important element of stopping ongoing HIV transmission. Despite effective treatment, the psychological impact of becoming HIV positive remains huge for many men. Treatment of HIV has dramatically changed the perspective of people living with HIV. Other aspects of their lives, such as their sexual activity, have also undergone dramatic changes since the beginning of the AIDS-epidemic. Until the 1990s, their sex life was characterized by a strong decrease of all sexual activity (Bogart et al., 2006). This has changed by the improved life expectancy and quality of life, with consequences for HIV transmission. A recent review showed an increase in sexual risk behaviors over time among men who have sex with men in high-income countries (Hess, Crepaz, Rose, Purcell, & Paz-Bailey, 2017). This increase was found in all different measures: condomless anal sex, with main and casual partners, and with partners of unknown HIV status (Hess et al., 2017).

Health care professionals will need to adapt to this evolution. Counselling as a behavioral prevention intervention is recommended as a support for safer sex to tackle risky sexual behavior and stigma, and increase health promotion strategies among people living with HIV (European Centre for Disease Prevention and Control, 2015a). Therefore, health care professionals should discuss potential issues and risks openly and non-judgmentally with patients. This respectful attitude is an integral aspect of qualitative HIV care. Qualitative care also comprises accessible, integrated, responsive and flexible care, provided by (a team of) health care providers who have up-to-date knowledge and technical expertise (Johnston, Kendall, Hogel, McLaren, & Liddy, 2015; Land, Nixon, & Ross, 2011).

People engaging in risky behavior for HIV/STI acquisition

Besides traditional risk groups for HIV and/or STI such as gay and bisexual men, migrants and people who use drugs, swingers have recently been identified to be at risk for acquiring STI (Spauwen, Niekamp, Hoebe, & Dukers-Muijrers, 2015). Swingers are defined as heterosexual couples who have sex with other couples, or singles. They are sexually very active, including engaging in multiple anonymous sexual partnerships and condomless anal sex, report inconsistent condom use with swing partners (sexual partners, other than their main partner), and alcohol and party drug use in a sexual context (Spauwen et al., 2015). Substance use in a sexual context has been increasingly reported among primarily gay men, and is referred to as 'chemsex' (Kirby & Thornber-Dunwell, 2013; Stuart, 2013). In a recent report from the Government of the United Kingdom (Her Majesty's or HM Government), it is defined as 'the use of drugs before or during planned sexual activity to sustain, enhance, disinhibit or facilitate the experience' (HM Government, 2017). It is considered as a catalyst for sexual risk behavior, but more research should focus on the magnitude of this phenomenon, as well as nature and pathways among specific groups in order to design adequate interventions (Bourne & Weatherburn, 2017). Despite a number of risk factors and an augmented STI incidence, HIV prevalence is likely to be low among swingers. Nevertheless, their sexual behavior is considered risky for HIV acquisition, making sensitization and information about potential risks particularly important in this group.

An important facilitator in the process of meeting casual sex partners, and negotiating (safer) sex, has been the introduction and accessibility of the Internet.

The Internet and sexual health (research)

Since its introduction, the Internet has facilitated the search both for sexual pleasure, including finding sexual partners, and for information on sexuality and sexual health (Grov, Breslow, Newcomb, Rosenberger, & Bauermeister, 2014).

Gay and bisexual men mainly sought sexual partners off-line until the early 1990s. Later, chat boxes, where people could register and use (anonymized) profile names, became the first available round the clock and easily accessible ways to find sexual partners online (Mills, 1998). In the first years of the twenty-first century, with increasing access to high-speed and wireless Internet connection, the number of young men who have sex with men meeting their first sexual partner on the internet increased significantly, from 2.6% in 1993 to 61.0% in 2002 (Bolding, Davis, Hart, Sherr, & Elford, 2007). Subgroups of these men with specific wishes (such as unprotected anal intercourse, and substance use in a sexual context), were able to connect at large scale leading towards more unprotected sexual encounters (Grov et al., 2014). In recent years, mobile technology and

applications, including GPS-tracking applications such as Grindr, were introduced. After a slow start their popularity boomed, and this technology has now become an alternative for the traditional online search for sexual partners (Grov et al., 2014).

Parallel to this evolution, research on sexual health through the Internet took ground since the 1990s. Initial research suggested that the use of Internet to find sexual partners facilitated HIV and STI transmission (Bull & McFarlane, 2000; McFarlane, Bull, & Rietmeijer, 2000). Later, in the early 2000s, mixed evidence on this association revealed that seeking partners online may not be associated with the actual risky behavior, but the ease and anonymity of Internet facilitated an efficient communication on condom use, directing towards both risky and less risky sexual behavior (Mustanski, 2007). This finding was confirmed in recent research that shows that using Internet or a mobile app to find a sexual partner is not necessarily associated with condomless anal sex (Whitfield, Kattari, Walls, & Al-Tayyib, 2017). Nonetheless, there are men who have sex with men who engage in condomless sex with a partner they met via Grindr. Of them, young men who use Grindr longer and more frequently and who present sexualized profiles, are more likely to have condomless sex with a partner they met via Grindr (Winetrobe, Rice, Bauermeister, Petering, & Holloway, 2014).

Mobile Internet connection, and GPS-tracking for mobile phones create opportunities to inform people about the availability and accessibility of sexual health services. Recent research suggests that smartphone apps can therefore serve as additional tools for the delivery of sexual health promotion messages (Jenkins Hall et al., 2017), and are feasible and acceptable (Holloway et al., 2014).

Objectives

'Know your epidemic, know your response' is a slogan that comprises the necessary process of improving and tailoring HIV prevention approaches (UNAIDS, 2007; Wilson & Halperin, 2008). The rationale of this slogan is that there's no single global HIV epidemic, but a multitude of diverse epidemics, each with its own drivers, obstacles and potential preventive actions.

Belgium has a concentrated epidemic, a stable high number of yearly diagnoses, and insufficient HIV testing approaches to achieve the first hurdle of the 90-90-90 goals. This work presents a set of research projects to improve different stages of HIV prevention for key populations. The focus lies on counselling and HIV testing as prevention activities. The general objective of this set of projects is the improvement of HIV prevention by targeting different stages of the HIV prevention process.

Specific objectives are to:

- Provide an overview of European targeted HIV testing activities;
- Assess acceptability and feasibility of new HIV testing approaches (outreach and online strategies) among key populations;
- Implement and evaluate outreach and online HIV testing approaches;
- Assess sexual activity among a group of people living with HIV in Europe;
- Assess effectiveness of a computerized intervention for safer sex for people living with HIV;
- Identify a potentially unidentified group affected with HIV in Belgium: swingers.

The presented studies meet the described objectives. The overarching general objective is operationalized in specific objectives.

Chapter 2 presents an overview of changes in HIV testing in Europe during the past decade. This manuscript is submitted for publication in HIV Medicine. Chapters 3 and 4 present the results of two consecutive HIV testing projects. Chapter 3 presents results of an outreach HIV testing project (Testing on Location) collecting blood samples during outreach activities, and communicating test results via cell phone messages (Platteau et al., 2012). A follow-up project, Swab2know, using outreach and online sampling collection and result communication via a secured website, is presented in chapter 4 (Platteau et al., 2015). We describe acceptability and feasibility, as well as an evaluation of both implemented projects.

Positive health, dignity and prevention encompasses strategies to protect sexual health. Chapter 5 presents results on sexual activity and inactivity among a European sample of people living with HIV, assessed via a questionnaire that was distributed among HIV-positive men who have sex with men in 14 European countries (Platteau et al., 2014). In chapter 6, these results are used to

develop a prevention intervention: a computerized intervention to support HIV-positive men who have sex with men towards a safer sex life (Nöstlinger et al., 2016). This psychological intervention, consisting of 3 counselling sessions is evaluated in a multicenter study using a prospective and randomized research design.

Chapter 7 presents results from an online survey on sexual health among a group of swingers to identify them as a key population for targeting HIV and STI prevention (Platteau, van Lankveld, Ooms, & Florence, 2016).

CHAPTER 2

HIV testing for men who have sex with men in Europe: A decade of technological innovation and patient empowerment complement the role of health care professionals

This chapter is co-authored by Jacques van Lankveld, Ludwig Apers, Katrien Fransen, Jürgen Rockstroh and Eric Florence and has been submitted for publication in HIV Medicine, under the same title.

Introduction

In the countries of the European Union and European Economic Area (EU/EEA), 29,747 people were newly diagnosed with HIV in 2015. This accounts for 6.3 (range 1.6 to 20.6) newly diagnosed people per 100,000 inhabitants (European Centre for Disease Prevention and Control / WHO Regional Office for Europe, 2016). The epidemiological situation varies between European regions, with sex between men as the main transmission mode in Western and Central Europe, and an epidemic driven via heterosexual transmission and injecting drug use in Eastern Europe (European Centre for Disease Prevention and Control / WHO Regional Office for Europe, 2016). To achieve the ambitious HIV '90–90–90' targets of the Joint United Nations Program on HIV/AIDS (UNAIDS), 90% of people living with HIV need to be diagnosed (Joint United Nations Programme on HIV/AIDS, 2014). The EU/EEA region does not achieve the first target with an estimated proportion of 83%, and only three out of 23 reporting countries having diagnosed 90% of people living with HIV (European Centre for Disease Prevention and Control, 2017c).

"Whatever the next hottest, scientifically proven HIV treatment or prevention strategies are, they will share a common denominator for implementation: the HIV test." (Walensky & Bassett, 2011, e1001101).

HIV testing has been offered in a centralized and medicalized way for many years. In this traditional approach, an HIV-test is offered voluntarily and confidentially during a face-to-face consultation by a medically trained health care professional in a healthcare setting. The test on a blood sample is executed in a laboratory, and in case of a reactive screening test result, the specimen is further confirmed using validated protocols. Communication of test results and subsequent counselling are provided by trained healthcare workers during a face-to-face consultation (World Health Organization, 2010). This traditional, provider-initiated approach has been dominant in HIV testing policies for many years. The World Health Organization refers to this strategy as the 5c's approach: Consent, Confidentiality, Counselling, Correct results and Connection (World Health Organization, 2015a).

With persisting high numbers of new HIV diagnoses, the traditional testing paradigm seems insufficient and has consequently been challenged in recent years. Testing for HIV has evolved from the traditional, health service centered strategy as described above, to a client initiated activity, with easier access to testing (facilitated by strong commitment and consequential initiatives in primarily gay communities), and even carried out by the client him or herself in a private environment. This process has been guided by adapted European legislation (European Centre for Disease Prevention and Control, 2017b), and subsequent recommendations and initiatives. Two factors play a crucial role

in this evolution: increased empowerment of the client, and the possibility of demedicalization of the test due to technological innovations, including almost ubiquitous access to Internet. These factors will be elaborated in this article.

Empowerment is defined as 'a multi-dimensional process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important' (European Patient Forum, 2015). Empowerment can be seen as a reaction against the paternalistic approach where the healthcare worker decides for the patient. It supports patients to become well-informed, autonomous clients, in charge of their own health, and deciding when and where to take a test. This tendency is observed in many other domains of medicine, especially in the management of chronic diseases. Combined with easily accessible information through specialized and customer-friendly websites, this leads to a form of personalized health care, in which the health worker becomes facilitator, rather than initiator of health acts. The traditional approach becomes one option, besides others, tailored to the needs of the clients.

This new paradigm of personalized health care requires complementary HIV testing approaches. Innovations in HIV testing technologies facilitated strategies to reach groups at highest risk for HIV acquisition. New technologies include the development and CE-labeling of reliable simple/rapid tests (enabling outreach testing with execution of a test on-site), the use of oral fluid specimen (Fransen et al., 2013), and the development, approval and distribution of self-tests for HIV (AAZ-LMB, 2017). These technologies facilitate and expand the ways of accessing the most vulnerable populations in getting an HIV test.

How did innovative technologies and increasing empowerment lead to tailored testing approaches?

Efficacious HIV testing approaches are well adapted and tailored to their focused population. Modern communication technologies and the evolving mind-set towards patient empowerment offer a variety of options to optimize HIV testing approaches. With increasing availability of new tools for HIV testing, international projects on earlier and optimal testing are emerging. Three approaches are very relevant to mention: community (based) testing, self-testing and self-sampling.

Community based testing

Community based testing refers to a strong involvement of communities in all aspects of the testing process. An inclusive consensus definition is presented by the European COBATEST-network: "CBVCT [community based voluntary counselling and testing] is any program or service that offers HIV counselling and testing on a voluntary basis outside formal health facilities and that has been

designed to focus on specific groups of the population most at risk and is clearly adapted for and accessible to those communities. Moreover, these services should ensure the active participation of the community with the involvement of community representatives either in planning or implementing HIV testing interventions and strategies" (Reyes-Urueña et al., 2017, p. 30). Results show that community based centers are effective and cost-effective in accessing, and linking undiagnosed people living with HIV to care (Meulbroek et al., 2013; Perelman et al., 2016). For instance, 56 Dean Street diagnoses one in four new HIV-positive people in London (Nwokolo, Whitlock, & McOwan, 2017), and Checkpoint Barcelona even detected 36.3% of new HIV-infections in Catalonia between 2009 and 2011 (Meulbroek et al., 2013).

Self-testing

For the user, the self-test has several benefits including convenience, privacy, non-invasiveness, and easiness to use. Linkage to care is the main concern about HIV self-testing from both an individual, and public health perspective (Figueroa, Johnson, Verster, & Baggaley, 2015). Besides linkage to care, concerns about lack of support, user error and a lower accuracy due to the prolonged window period of HIV self-tests, compared to clinic-based tests need to be mentioned (Figueroa et al., 2015). Mathematical modeling predicts that due to this prolonged window period, replacing clinic-based tests by home tests would increase HIV prevalence, even if testing frequency would increase (Katz, Cassels, & Stekler, 2014). This hypothesis, combined with a more complicated linkage to care, shows that the self-test is particularly beneficial for key populations, and cannot replace the traditional test with its characteristic personal contact, for most people.

Self-sampling

Using a self-sampling approach, people self-sample (blood or oral fluid) and send this sample to a laboratory, where the test is executed. Test results are communicated at a later time via a face-to-face consultation, telephone, cell phone message, email or a secured website. Research shows that acceptability of self-sampling, and intention to use this approach are high (Chen et al., 2010; Hottes et al., 2012). The approach is not widely implemented, but results from existing projects are promising (Elliot, Rossi, McCormack, & McOwan, 2016; Loos et al., 2016; Platteau et al., 2015). Self-sampling is convenient and easy to use, and linkage with care is more assured, compared to self-testing.

How to develop an HIV testing approach?

An HIV testing approach should be tailored to its focused population, and consists of a combination of four steps. Choosing a combination of effective steps is crucial in the design of an approach. An overview of these steps can be found in table 2.1.

Table 2.1: Overview of critical steps in the development of an HIV testing approach

Location	Health care provider	GP
		Other GP
		Designated testing center
		Specialist
	Community based center	
	Outreach	Mobile venue
		Venue
	At home	
Specimen	Blood sample	Whole blood
		Peripheral venous blood (whole blood, serum, plasma)
		Dried blood spot (whole blood, serum, plasma)
	Oral fluid sample	
Test used	Test in the laboratory	Immuno-essay (i.e. ELISA-test)
		Simple/Rapid test
	Test for personal use	Simple/Rapid test
Communication of test results	Face to face	Physician
		Counsellor
		Peer
	Phone call	
	Short text message	
	Secured website	

Discussion

Current landscape of HIV testing in Europe

In Europe, many non-traditional HIV testing approaches have been developed and implemented, reflecting the above-sketched evolution. They target different key populations and are developed using the four steps described above. Although many efforts have been made to reach out to key populations, international evidence shows that barriers are still faced at the level of the individual patient or health care provider, and the institutional or policy level (Deblonde et al., 2010). Barriers for HIV testing should be further decreased, in order to decrease the burden of the hidden epidemic and to achieve the first 90-target defined by UNAIDS (Joint United Nations Programme on HIV/AIDS, 2014).

Non-traditional approaches allow participants to receive their reactive (positive) screening result without a confirmatory test result. When participants receive a reactive orientation test result, this may induce uncertainty, anxiety and distress, when waiting for the final (confirmed) result. In case of a false reactive result, these feelings are even unnecessary. As Bayes' theorem predicts, the risk of a false reactive result, demonstrating low specificity of the employed method, decreases in groups with a higher prevalence of HIV. Orientation tests should therefore only be used in high-risk populations where the pre-test probability is high enough to minimize this effect. Even though very rare in high-risk populations, false reactive results cannot be fully excluded. Therefore, it should be discussed with the participant before taking an orientation test. Apart from the risk of false reactive test results, the window period poses a concern regarding the HIV orientation test. This period refers to the time to achieve a reactive test after the moment of infection. For some orientation tests, this period is longer compared to a traditional laboratory-based test (three months vs. six weeks as the standard laboratory test are also detecting antigens).

The future landscape of HIV testing in Europe

In Europe, legal frameworks for decentralized and demedicalized HIV testing differ strongly. In some European countries, written consent is required to execute an HIV test. Eight countries allow self-sampling HIV testing, and in only six the HIV self-test using finger prick blood is available (European Centre for Disease Prevention and Control, 2017a). Fourteen countries authorize non-medical staff to execute (community based) testing (European Centre for Disease Prevention and Control, 2017a). Despite these legal barriers, several CBVCT services have been implemented throughout Europe (Schmidt, Sander, & Noori, 2017). Effectiveness and cost-effectiveness of these centers is high.

Increasingly, community based centers offer testing for other sexually transmitted infections (STI). In the context of rising STI and the wish of people from the key populations to gain more control over their health, this offer has been an additional incentive for testing. The perspective to subsequently allow these centers to offer direct treatment of diagnosed STI makes them even more attractive. The extended testing portfolio and potential treatment may impact recruitment to testing in general within key populations, such as the gay community.

With the ongoing paradigm shift in HIV testing towards non-traditional approaches, the role of health care providers may seem to shrink. Nevertheless, for the majority of the people they remain the primary reference for an HIV test. Although the initiative for testing shifts towards patients, health care professionals need to stay updated about the local epidemiology of HIV ('who to test'), and indicator conditions for an HIV test to avoid 'missed opportunities' (Joore et al., 2016). A guide for health care providers, listing key populations and medical conditions that may mask an underlying HIV-infection, can be used as guideline for testing (Raben et al., 2015). Health care providers remain crucial actors in the process of testing and linkage to care by informing, counselling, and referring newly diagnosed people with HIV to specialized HIV care.

Although different approaches are accepted by key populations and individuals, none of the testing approaches described above are 'one size fits all' solutions. Each approach has advantages and disadvantages and should therefore be tailored to the targeted group, or even discussed individually with the client.

Conclusion: "Early diagnosis and treatment saves lives and prevents onwards transmission" (Delpech, 2017)

To increase diagnosis in the hidden epidemic, a range of testing approaches should be combined. The question guiding the efforts should not be 'which strategy works best?', but 'which strategy works best to diagnose people unaware of their HIV infection?'. Therefore, communities, clinicians, academics, and policy makers are urged to collaborate towards a highly effective combination testing approach to increase uptake and consequently reduce the proportion of undiagnosed people living with HIV.

Testing should be facilitated as much as possible. Yet, the quality of the testing processes should be safeguarded to preserve European quality standards. Emphasis should lie on the quality of the used materials, and the process of handling of the tests. Linkage to care remains a crucial aspect of a strategy's quality. For this purpose, a personal touch from dedicated healthcare professionals remains a prerequisite for a successful implementation strategy.

Overall, the evaluation of an HIV testing approach spans its different phases: reach the right people, test them in a reliable way, and link them to care in a respectfully and successfully.

CHAPTER 3

Voluntary outreach counselling and testing for HIV and STI among men who have sex with men in Antwerp

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Introduction

According to US surveillance data, 25% of all HIV cases remain undiagnosed (Marks, Crepaz, & Janssen, 2006). This percentage is even higher in some European countries (Hamers & Phillips, 2008). In the US, these undiagnosed infections account for 54% of new HIV-infections (Marks et al., 2006). Although recent estimations of undiagnosed HIV among men who have sex with men (MSM) in Australia are lower (9%), they account for an estimated 31% of newly diagnosed HIV-infections (Wilson, Hoare, Regan, & Law, 2009). These estimates indicate the importance of early detection from both a public health- and an individual perspective. Knowing one's HIV-status is a prerequisite not only for treatment itself, but also for starting prevention methods of HIV-transmission. Being ignorant of one's HIV-status may imply that an opportunity to discuss prevention and change in potentially dangerous sexual behavior could be missed.

Recently, several studies on outreach testing in high risk settings in the USA, UK and Australia have been published (A. C. Bailey et al., 2008; Daskalakis et al., 2009; Debattista et al., 2004; Huebner et al., 2006; Lambert et al., 2005). In Antwerp, known for its vivid gay-oriented night-life, however, no outreach testing was performed among men who have sex with men since the early 1980's (Coester, Avonts, Colaert, Desmyter, & Piot, 1984).

Venues, frequented by MSM, where sex anonymously takes place in darkrooms or cabins, present a high risk setting for transmission of HIV and sexually transmitted infections (STI). Recent prevention projects were especially developed to reach these settings (Mullens, Staunton, Debattista, Hamernik, & Gill, 2009). A number of men attending these venues request anonymous HIV/STI testing and report preferring not to discuss their sexual practices with their general practitioner (GP), because they fear prejudice and discrimination (Baber & Dayan, 2006). Studies also found that general practitioners encounter barriers in discussing their patient's sexual history (Khan, Plummer, Hussain, & Minichiello, 2007; Verhoeven et al., 2003).

Delivery of test results remains an important issue in clinical settings. In recent research of a sexual health clinic in Australia, 55% of patients had not collected their HIV-test results within 4 weeks after the test (Healey, O'Connor, & Templeton, 2010). Recently, novel approaches for test result delivery – mobile phone and text messaging – have been piloted (Buhrer-Skinner et al., 2009).

We hypothesized that a relatively high number of participants in local risk settings could potentially test positive for HIV/STI, as per-contact probability of HIV transmission in the HAART era for receptive unprotected anal intercourse (UAI) is estimated to be 1.43% if ejaculation occurred inside the rectum, and 0.65% if withdrawal prior to ejaculation took place (Jin et al., 2010).

Against this background, the rationale of our project was to lower the threshold for HIV/STI testing by offering voluntary, anonymous and free HIV/STI testing at places where men who have sex

with men socialize. The pilot study on 'Outreach Testing' had two objectives: firstly, investigating the feasibility and yield of outreach testing among men who have sex with men at risk for HIV and STI; secondly, assessing this target group's access to and use of the regular healthcare system.

Methods

Study site/population

To have access to a high number of MSM, two of the largest gay venues in the Antwerp area were selected for this project: a gay sauna and a fetish club. Men over 18 years of age -including foreign citizens- were eligible for testing.

Instruments

The specific STI tested for, were selected according to community and clinically relevant criteria: HIV, syphilis, hepatitis B and C and lymphogranuloma venereum (LGV) – because of their clinical complications, chronic condition, and long term transmissibility. For practical and feasibility reasons, no urethral/anal swab, nor urine samples were collected. In spite of potential difficulties in interpreting its results and based on evidence available, Chlamydia trachomatis serology (IgA and IgG for genotype L1, L2 and L3) was used to diagnose LGV (Forrester, Pawade, & Horner, 2006; van der Snoek, Ossewaarde, van der Meijden, Mulder, & Thio, 2007). If any abnormal result, the patient was informed to contact the sexual health center, where the results were discussed and appropriate action was taken (Table 3.1). Participants were also asked to complete a brief self-reported behavioral survey, which was linked to the test results. Participation was voluntary, but filling in the questionnaire was a prerequisite to access the test. This questionnaire collected information on socio-demographic data, service provision of general practitioners (GPs), and sexual activity. The latter section included a list of sexual practices: insertive and receptive anal sex, insertive and receptive fisting, and vaginal sex. Oral sexual practices were not addressed. Protective behavior was assessed as the proportion of sexual acts in the past 3 months during which a condom was used, and the proportion of acts during which gloves were used when fisting. 'Inconsistent protective behavior' was defined as < 100% protection. In the absence of a validated tool, we developed a brief questionnaire, including relevant covariates of sexual risk behavior that were selected from the literature. Participants were asked to rate a list of different ways to communicate the test results using a Visual Analogue Scale (0-10): text message, telephone, letter, appointment at the organizing sexual health center, or healthcare providers revisiting the venue.

Procedure

Two weeks prior to the test sessions, flyers announcing the initiative were disseminated in the respective venues.

A multidisciplinary team, consisting of a physician, a counsellor and an outreach worker, all trained and experienced in HIV/STI service provision, visited both venues 5 times over a period of 4 months between March and July 2008. Sessions took place during the busiest moments at the venues and lasted about 3 hours. Prevention messages, including safer sex messages, were delivered by a sexual health advisor and HIV service organization ('Sensoa'), partner in the project. Information and brief counselling on safer sex strategies were offered to all participants. In addition, on request of participants, free referral was offered for safer sex counselling by trained healthcare providers and a sexologist.

The outreach worker offered basic information on the test. The counsellor described the procedure, the tests and way of communicating the results to the participants. After giving written informed consent (IC) and filling in the survey, participants underwent a blood test. The physician collected two blood samples per participant: one for clinical results and the other for scientific analysis of the project. The processing of the samples for the clinical results was treated confidentially, as in routine clinical care. The second sample was coded, linked to the questionnaire and was treated completely anonymous.

Ten days after the test session, test results were communicated by means of a standardized text message. Participants received either of the following two messages: "All test results are normal; if you wish, you can discuss your results with a physician", or "At least one of the test results was positive. Please contact the sexual health center to discuss your results with a physician." When the patient consulted the sexual health center the results were interpreted and the patient was counselled and treated according to good clinical practice.

Ethical approval was obtained from the Institutional Review Board of ITM and the University Hospital of Antwerp.

Analysis

Statistical analysis was performed using SPSS 17.0. Descriptive and univariate analyses were carried out. Fisher's exact test, or Chi-Square test, were used for categorical variables and *t*-tests or non-parametric tests for continuous variables. A significance level of 5% was applied.

Table 3.1: Overview of the performed tests and results for which the patient was invited to contact the sexual health center.

Infection	*Tests performed*	*SMS message: 'please contact the sexual health center' when:*
HIV	Combined Ag/As test Confirmation INNO-LIA HIV1	Confirmation positive
Syphilis	RPR TPPA	RPR >= ¼
Hepatitis B	HBsAg HBcAb HBsAb	HbsAg+
Hepatitis C	HCAb Confirmation	Confirmation positive
LGV	IgG (ratio) IgA (ratio)	IgG > 3 and/or IgA > 3

Results

Sample description

Overall, 137 MSM underwent testing during 10 sessions (range 4 – 24 per session). Ninety-two men (67%) were tested in the sauna, 45 (33%) in the fetish club. Table 3.2 gives an overview of the respondents' main characteristics.

Table 3.2: Description of participants

Characteristic		*N (%)*
Age (years) Mean (SD): 41 (11.9)	=< 25	15/130 (11.6)
	26 - 35	33/130 (25.4)
	36 – 45	35/130 (26.9)
	46 - 55	33/130 (25.4)
	> 55	14/130 (10.8)
Relationship status	Single	68/135 (50.4)
	Male partner	62/135 (45.8)
	Female partner	5/135 (3.8)
HIV-tested in past year	Yes	53/134 (39.6)
	No	78/134 (58.2)
	I don't know	3/134 (2.2)
Regular (registered with a) GP	Yes	122/134 (91)
	No	12/134 (9)
Being under influence of alcohol during sex	(hardly) ever	88/133 (66.2)
	Sometimes	35/133 (26.3)
	(almost) always	10/133 (7.5)
Being under influence of drugs during sex	(hardly) ever	101/128 (78.9)
	Sometimes	18/128 (14.1)
	(almost) always	9/128 (7.0)

Fifty-three participants (40%) reported having taken an HIV-test in the past year. Of these men, 29 men (64%) had been tested by their own GP, whereas 9% (n = 4) was tested by another physician.

The vast majority of participating men had had penetrative sex in the past 3 months. Even though oral sexual practices were not addressed in the questionnaire, 37 men reported having had oral sex by using the 'Other'-category.

Table 3.3: Description of participants' sexual practices in the past six months

Sexual activity (in past 3 months)		*N (%)*	*Inconsistent protective behavior (%)*
Insertive anal sex	Yes	83/134 (61.9)	38/81 (46.9)
Receptive anal sex	Yes	78/134 (58.2)	42/76 (55.3)
Insertive fisting	Yes	30/134 (22.4)	15/27 (55.6)
Receptive fisting	Yes	24/134 (17.9)	13/23 (56.5)
Vaginal sex	Yes	6/134 (4.5)	4/6 (66.7)
None of the above	Yes	11/133 (8.3)	Not applicable

Facilitators of sexual risk behavior, such as being under influence of alcohol and drugs during sexual intercourse, were reported by 34% (n = 45) and 21% (n = 27), respectively.

Overall, 25 participants out of the 137 volunteers (18%) tested positive for an active, transmittable STI. Four of them (2.9%) were newly diagnosed with HIV. In addition, twelve participants (9%) showed serological signs of a known, or treated STI (HIV, syphilis, chlamydia). One HIV-positive man, diagnosed with HIV prior to the outreach testing intervention, tested also positive for hepatitis C, syphilis, and chlamydia. He also showed signs of a previous hepatitis B infection.

Thirty per cent of the participants were not immune to hepatitis B. A total of 43 (31%) participants were adequately vaccinated for hepatitis B (positive serology for HBs-Ab and negative titer for HBc-Ab).

Communication of test results

All participants, except one (due to incorrect phone number), received their test results. Twenty-two of these men received a positive test result by text message and were requested to contact the sexual health center to discuss their results. All reached participants were informed about their test result: either in a face-to-face consultation (n = 5), by phone (n = 15) or by email when not owning a cell phone (n = 1).

Participants evaluated the 'text message' as the best method of communication (median score 9/10; Q1 7/10, Q3 10/10), followed by 'phone' (median 8/10; Q1 6/10, Q3 9/10), 'letter' (median 7/10; Q1 4.5/10, Q3 9/10), 'consultation at sexual health center' (median 6/10; Q1 4/10, Q3 8/10), and 'healthcare providers revisiting the venue' (median 6/10; Q1 2/10, Q3 8/10) was evaluated as the least popular method.

Satisfaction with the primary healthcare system

Most of the participants (n=122; 91%) were registered with a fixed GP. In this group, satisfaction with their GP (again measured by a visual analogue scale ranging from 0-10) was significantly higher among STI-negative MSM, compared to their STI-positive counterparts (median scores 8/10 versus 6/10 respectively, $p = 0.012$).

Sexual risk

An analysis of the self-reported sexual practices showed that 53 (41%) of the tested MSM were at risk for acquiring STI. This was defined as having at least one unprotected sexual encounter (vaginal or anal sex, or fisting) in the past 3 months.

Significant differences were found comparing men reporting high sexual risk behavior – as defined above – and men reporting low risk behavior. An overview of these differences is shown in Table 3.4.

Table 3.4: Significant associations with sexual risk behavior

Outcome (% of participants)	*Significant risk factor*	*p-value*
Reported high risk (41% of participants)	Not having a GP	0.027
	Being under influence of drugs when having sex	0.008
	Being under influence of alcohol when having sex	0.044
	Being younger	0.042

Men reporting risky sexual practices in the past 3 months, were significantly younger, were more often under the influence of alcohol and drugs when having sex, and had less often a fixed GP compared to those not reporting risk behavior.

Discussion

Feasibility

If well-prepared and certain conditions are met, developing and implementing an outreach project is feasible in Flanders. This confirms the published findings from the US and the UK, where testing in bathhouses and saunas evolved to a regular clinical service, based on the experience

gained in successful pilot projects (A. C. Bailey et al., 2008; Daskalakis et al., 2009; Huebner et al., 2006). A thorough preparation, proper announcements and a structured co-operation on site are prerequisites for successful and effective outreach test sessions in high-risk venues for MSM.

The standardized text message to communicate test results was positively evaluated. Moreover, all but one of the participants received their test result. Having a cell phone number enabled us to contact the participant in case an appointment was not made. One participant, who tested HIV positive, was actively traced in this way. Modern communication techniques proved to be useful to reduce the loss to follow-up of clients who enter the health system in this way.

It should be stressed that the workload in this outreach project is high. A multidisciplinary team (3 professionals) had to work at the venue at night. Each session also had to be prepared substantially in advance.

Prevention benefits

Regular outreach testing may improve both primary and secondary HIV prevention. Twelve out of 137 participants (9%) showed signs of a previous STI, 18% had at least one result for which it was necessary to consult a sexual health clinic. Early detection of STI among HIV-infected individuals is important not only for treatment purposes, but also to prevent further spread of HIV, facilitated by concomitant infections (Morineau et al., 2011). The fact that one HIV-positive man -diagnosed with HIV prior to the outreach testing intervention- tested also positive for hepatitis C, syphilis, and chlamydia is a worrying finding.

Outreach testing in MSM may reduce the incidence of new HIV diagnoses (primary prevention) in two ways. It gives the opportunity to achieve behavioral change among people diagnosed with HIV, which has been demonstrated by recent studies (Camoni et al., 2009; Fox et al., 2009). In addition, counselling of MSM that tested negative may influence their risk behavior. Even though behavioral change is possible, research also suggests that maintaining behavioral changes remains difficult (Williamson, Dodds, Mercey, Hart, & Johnson, 2008).

The high rate (30%) of participants, not protected against hepatitis B infection, is remarkable. As an effective vaccine is available, this is a worrisome finding and demonstrates the need for more effective vaccine promotion campaigns, targeting MSM at highest risk.

Service delivery

This outreach project enhances the detection of HIV, but it should be seen as complementary to the state-of-the-art voluntary counselling and testing, being offered in sexual health centers, primary care services and by GPs. Proper (post-test) counselling and follow-up are essential elements

of any outreach testing program. Interestingly, the group at highest risk (measured by self-reported risk behavior as well as positive test results), was the group least covered by regular healthcare services. The reason why these participants are less likely to consult a GP is subject to further research.

The patient-GP relation should be encouraged during outreach test sessions. Participants were actively referred to their GP, to promote repeated STI-testing within the regular healthcare system to avoid the creation of a parallel circuit of STI case-finding in gay venues.

Some additional findings regarding risk behavior are worrying: the percentage of participants, engaged in unsafe sex practices, was considerable (41%), but again not different from the percentages found in similar pilot projects by Huebner et al. in San Francisco (38%) (Huebner et al., 2006) and Bailey et al. in Brighton (46%) (A. C. Bailey et al., 2008). Equally the proportion of clients that engaged in sex when under the influence of alcohol (34%) and drugs (21%) was consistent with other studies among MSM and remains a difficult to tackle barrier in efforts to change sexual behavior (Jorm, Korten, Rodgers, Jacomb, & Christensen, 2002; Morineau et al., 2011).

This project also contributed to HIV/STI awareness raising in the gay scene, due to the visible presence of the testing and prevention team, even when MSM decided not to take the test.

Study limitations

We acknowledge certain limitations of our study: the sample size is small and the study is based on a convenience sample of potential participants being present in the venues and volunteering to be tested. We estimate that 5-7% of the clients of the venues underwent testing. It is not possible to extrapolate the results to the risk group at large or to estimate the prevalence of STI in this population, but this was not the objective of the study.

Practical concerns swayed the choice towards collection of blood samples only. Additional testing methods such as swabs, could have led to the detection of additional STI. Lambert et al. showed that indeed the effectiveness of community based screening increases when more STI are included (Lambert et al., 2005).

Following the pilot intervention, the organizing center for sexual health integrated outreach HIV/STI testing for MSM as a routine activity – including screening for hepatitis A – during which one free vaccine for hepatitis A and B is offered to MSM who are not protected yet.

Although no cost-effectiveness analysis was done, the cost of this intervention is considered to be high: it requires thorough preparation and the presence of a team on site and it generates substantial laboratory and administration costs. To our knowledge, no cost per detected STI case by means of other screening methods is known in Belgium, to eventually compare with our method.

Conclusions

Outreach testing reaches the target group of MSM with a higher risk for acquiring STI, it detects a substantial number of clinically relevant STI, and it creates an opportunity to refer participants to the regular healthcare system. Finally, it increases visibility and awareness of HIV/STI prevention in specific gay venues.

CHAPTER 4

Swab2know: An HIV-testing strategy using oral fluid samples and online communication of test results for men who have sex with men in Belgium

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Introduction

HIV remains an important public health problem. In the European Union, 29,157 new HIV infections were reported in 2013, an incidence of 5.7 per 100,000 inhabitants (European Centre for Disease Prevention and Control & WHO Regional Office for Europe, 2014). A total of 42% of new infections were among men who have sex with men (MSM). Countries with the highest incidence were Estonia (24.6 per 100,000 inhabitants), Latvia (16.8), Portugal (10.4), and Belgium (10.0) (European Centre for Disease Prevention and Control & WHO Regional Office for Europe, 2014).

Promoting HIV testing is an integral part of the 90-90-90 Joint United Nations Programme on HIV/AIDS (UNAIDS) plan to end the AIDS epidemic by 2030. In terms of this plan, 90% of all people living with HIV should know their HIV status, 90% should be on treatment, and 90% of these should be virologically suppressed (Joint United Nations Programme on HIV/AIDS, 2014). Part of the rationale for this strategy is that intensified HIV testing contributes to earlier commencement of antiretroviral therapy (ART) which in turn leads to reduced HIV transmission via reducing the HIV viral load (Cohen et al., 2011). HIV diagnosis also leads to behavioral changes in sexual risk taking in a majority of newly diagnosed persons (Fox et al., 2009).

Increased HIV testing among those at risk is a key way of achieving the required target of 90% of HIV-infected people knowing their HIV status. The traditional HIV test is offered voluntarily and confidentially by a medically trained health care professional in a health care setting with a strong emphasis on the patient's informed consent (British HIV Association, British Association for Sexual Health and HIV, & British Infection Society, 2008). Counseling and test results are provided by trained health care workers during a face-to-face consultation (World Health Organization, 2010). This approach may remain the standard for most people. However, HIV has reached endemic proportions among MSM in the industrial world, with incidence rates of 2 to 3% per year, and prevalence between 10 and 30% (De Cock, Jaffe, & Curran, 2012). These men are generally well informed about HIV (S.-H. Lee & Sheon, 2008) and in certain groups of MSM, pretest counseling was found to be "repetitive" and "unnecessary" (Spielberg, Kurth, Gorbach, & Goldbaum, 2001). For these men, alternative HIV testing strategies can be considered. One study found that oral fluid testing is preferred by MSM above giving blood samples (Chen et al., 2010). It has also recently been found to be reliable for diagnostic use in groups with an HIV prevalence over 1% (Fransen et al., 2013) like MSM, and several research projects in clinical settings have shown promising results for HIV tests on oral fluid samples (Debattista et al., 2007; Pant Pai et al., 2012).

Rapid HIV tests, decentralized HIV testing (i.e., outreach and community-based testing), and self-testing are additional alternatives. Rapid tests are used in a variety of settings, including primary health care settings (Gauthier et al., 2012; Gennotte et al., 2013), emergency departments

(Christopoulos, Schackman, Lee, Green, & Morrison, 2010; D'Almeida et al., 2012), and in dental clinics (M. K. Hutchinson et al., 2012). Their advantage is that clients receive their results at the time of their visit (A. B. Hutchinson, Branson, Kim, & Farnham, 2006). A major disadvantage is that in low-HIV-prevalence settings they give a relatively high proportion of false positive results (Pant Pai et al., 2012). Outreach testing targeting MSM has been implemented in clubs, bars, and bath houses (Bowles et al., 2008; Mayer et al., 2012; Platteau et al., 2012), as well as at large-scale events, such as Gay Pride festivals (Manavi, Williams, & Newton, 2012). Community-based testing among MSM is increasing in recent years (Champenois et al., 2012; Thornton, Delpech, Kall, & Nardone, 2012). In Europe, an increasing number of community-based testing centers (i.e., Checkpoints) have been established (Gumy et al., 2012; Meulbroek et al., 2013).

Self-tests for HIV that can be ordered through the Internet are the most recent development in this field (Myers, El-Sadr, Zerbe, & Branson, 2013). The only US Food and Drug Administration (FDA)-licensed oral fluid-based rapid test is OraQuick ADVANCE Rapid HIV-1/2 Antibody test (US Food and Drug Administration, 2012). The FDA approved the use of this test for home use in July 2012 (US Food and Drug Administration, 2014), despite its relatively high risk of false positive results (Centers for Disease Control and Prevention, 2008), especially among lower-risk groups (Pant Pai et al., 2012). The quality of other test kits that can be ordered online is largely unknown due to their lack of certification. The advantages of self-testing include increased convenience and heightened privacy (Myers et al., 2013). The difficulty of ensuring linkage to care in the case of a positive result is a weakness of these tests. In a recent review, supervised and unsupervised self-testing strategies were found to be highly acceptable and preferred, but all studies lacked an evaluation of posttest linkage to counseling and care (Pant Pai et al., 2013). Internet-based testing can therefore be an alternative, where posttest linkage is part of the process. The willingness to use Internet-based HIV testing strategies was high in recently published quantitative and qualitative studies (Gilbert et al., 2013; Hottes et al., 2012). To address MSM's testing needs, we developed the Swab2know project (Institute of Tropical Medicine, n.d.-a). This project combines two strategies to increase HIV testing uptake among MSM: outreach HIV-test sessions and free online testing. In both strategies, samples are collected using oral fluid collection devices and test results are communicated via secured website.

This nonrandomized, prospective descriptive study aimed at detecting new HIV cases among groups at risk for HIV/sexually transmitted infection (STI) acquisition. The secondary objective was to assess the acceptability and feasibility of an HIV testing strategy with the use of self-administered oral fluid samples collected through outreach and online activities and Web-based delivery of test results.

Methods

Population and Settings

The project targeted two main risk groups for HIV infection in Belgium: MSM and sub-Saharan African migrants (SAM) socializing in community venues. Only the data from MSM were used for this analysis; the findings for SAM will be published elsewhere.

Outreach sessions for MSM were organized in five types of venues, mostly situated in Antwerp: saunas/bathhouses, fetish scene venues, dancing/discotheque venues, outreach sessions organized during the World Outgames in Antwerp targeting athletes and supporters, and large-scale gay events.

Inclusion criteria were that participants had to identify themselves as MSM and be 18 years of age or older. Additional criteria were that participants had to be accepting of oral fluid sampling, sign informed consent forms, provide minimal information, and understand that the test, if positive, would only be strongly indicative of HIV infection. Participants who were not willing to provide a mobile phone number or email address, were under 18 years of age, or were unable to sign the informed consent form were excluded from this project and redirected to standard testing facilities.

Website

A website, swab2know.be, has been specifically designed for this project (Institute of Tropical Medicine, n.d.-a). The main aim of the website is to provide a platform where visitors can find information, prevention messages, order test kits, and collect their test results. This website is secured by means of the Secure Sockets Layer protocol, and holds a security certificate provided by Belnet—Belnet is the federal government organization that provides high-bandwidth Internet connection and services to Belgian universities, research centers, and government departments. The certificate confirms the identity of, and encrypts the communication between, the Swab2know Web server and the computer where the information is requested.

All online materials described in the Methods section are available through the study website (Institute of Tropical Medicine, n.d.-a).

Sampling Procedures

Outreach sessions took place in various MSM leisure venues. Field workers of Sensoa, a local prevention organization, announced the Swab2know session at the entrance. If clients decided to participate, they visited the Swab2know team in a separate room. All materials were available in Dutch, English, and French. After being informed and signing the informed consent (IC) form,

baseline data using a self-administered pen-and-paper questionnaire (see Appendix 1) were gathered from participants and an online account was created. Each account was unique and linked with an email address and phone number. A generated password was sent automatically to the participant's email address. The oral fluid samples were self-collected by the participants under the supervision of study staff. All samples were identified by a unique sample code, which linked the sample with the personal account, the IC, and baseline data. Samples were kept at room temperature and were brought to the laboratory on the next working day.

Online recruitment happened on the website by occasional visitors who created an account and provided their email address and phone number. The project was advertised by prevention organizations and through articles and announcements in dedicated media, including gay-oriented websites and magazines and a Swab2know Facebook account. Participants provided consent by accepting the terms of the study. A sampling kit identified with a unique sample code was sent to the Belgian address of their choice. Participants took the oral fluid sample after having seen a short educational video on the website. Samples were sent to the lab with a prepaid envelope. The participants could also opt to collect their results during a face-to-face consultation.

HIV Test

The validation of the accuracy of the test has previously been evaluated in our AIDS Reference Laboratory at the Institute of Tropical Medicine (Fransen et al., 2013). Each sample underwent a two-step HIV-test procedure. First, all samples were tested for HIV using Genscreen HIV-1/2 Version 2 by Bio-Rad (BioRad, 2010). The results were classified as strong, weak, or nonreactive. In a second step, all nonreactive samples were checked for sample quality using a human IgG detection test. The quality of the oral fluid samples was measured using the IgG enzyme-linked immunosorbent assay (ELISA) quantification kit (Human IgG ELISA Immunology Consultants Laboratory, Inc, Portland, OR, USA). If the sample contained more than 3500 ng total IgG/mL, the nonreactive result was considered valid and ready to be communicated. Prior to uploading them onto the website, each result of the HIV test performed was technically validated by two persons, individually.

Communication of the HIV Test Results

Once the results of the HIV tests were known in the laboratory, they were uploaded onto the website. Upon uploading, participants received an email indicating that their result was available. Participants received one of four standardized messages (for full messages, see Appendices 2-5): (1) a strong reactive test result, strongly indicating HIV infection, to be confirmed by a blood sample, (2)

a weak reactive result, indicating a probable false positive result or an early infection, to be confirmed by a blood sample, (3) a nonreactive result, indicating the absence of HIV infection, taking into account a window period of 3 months, and (4) an invalid result, with the suggestion to repeat the oral fluid sample or to take a state-of-the-art HIV test. In the case of a reactive result, a mobile phone number was provided for emergency counseling by a trained paramedic.

Participants who did not check their results were contacted by phone or email. All participants with a reactive result were contacted by phone within 24 hours of having read their results. The purpose of the call was to offer counseling and to arrange a further confirmation test and guarantee linkage to care. If confirmation did not take place at the organizing health care center, participants were contacted after the confirmation procedure to collect the final result.

Repeated Testing

Participants with a nonreactive test result, both through outreach and online participation, were offered the possibility to order a sampling package to be delivered to a Belgian address every 4 to 6 months, allowing frequent and repeated testing. For this purpose, a reminder email was sent 4 to 6 months after participation to the email address linked with the personal account.

Acceptability of the Methodology

In the delivery message of the test result, participants were asked to fill out an online self-administered survey. In this survey, participants provided information on their impression of the project as a whole (not good, mixed feelings, good) and whether they would participate again in the future (no, not sure, without hesitation).

Statistical Analysis

Statistical analysis was performed using IBM SPSS version 22. Descriptive and univariate analyses were carried out. Chi-square tests were used for categorical variables and independent samples *t* tests for continuous variables. A significance level of 5% was applied.

Ethical Considerations

The methodology was conceptualized in close collaboration with community-based prevention organizations targeting MSM and African communities.

Ethical approval was obtained from the Institutional Review Board at the Institute of Tropical Medicine and the University Hospital in Antwerp.

Results

Number of Performed Tests

In a period of 17 months (December 2012-April 2014), 1,082 tests were executed on samples collected through outreach activities and online ordering of sampling kits. A total of 11 tests were excluded from the analysis because the participants disclosed their HIV-positive status during the baseline survey. Data from 1071 tests from 898 participants were used for this analysis. A total of 4 persons participated 4 times, 16 participated 3 times, and 129 participated twice in this period. A total of 53 persons participated during outreach activities and ordered a sampling kit later in the project.

During 23 outreach sessions, 553 out of a total 1,071 (51.63%) samples were collected. These sessions were organized in saunas/bathhouses (five sessions), fetish scene venues (four sessions), dancing/discotheque venues (eight sessions), during the World Outgames in Antwerp targeting athletes and supporters (three sessions), and at other gay events (three sessions). Additionally, 88 samples out of 1,071 (8.22%) were collected by two partner organizations who used the project's methodology to facilitate HIV testing within their regular activities during face-to-face consultations with MSM and male sex workers. For the analysis, these samples were added to the outreach group. These 641 samples out of 1,071 (59.85%) were collected from 609 men. From September 1, 2013, we offered people the possibility of ordering a sampling kit through the website. In the subsequent 8-month period, 430 samples out of 1,071 (40.15%) were ordered online by 289 participants.

Participant Characteristics

A description of the population with a comparison between the outreach and the online population is presented in Table 4.1.

Table 4.1: Characteristics of participants

Characteristic	*Online (N = 430) mean (SD) or n (%)*	*Outreach (N = 641) mean (SD) or n (%)*	*p-value*
Age (SD)	34.3 (10.2)	33.4 (11.4)	0.25
Sexual contacts with n (%)			0.07
Men	397 (92.3)	524 (81.7)	
Men and women	30 (7.0)	52 (8.1)	
Women *	3 (0.7)	0 (0.0)	
Has a general practitioner / family doctor n (%)	389 (90.5)	558 (87.1)	0.10
Never tested for HIV n (%)	43 (10.0)	111 (17.3)	0.001
Number of sexual partners in past 3 months mean (SD)	3.23 (5.02)	7.18 (13.53)	<0.001

* All participants reporting sexual contacts with women answered "transgender" on the question for gender

Results Communication

The vast majority (1,057/1,071, 98.69%) of test results were delivered through the website. A total of 14 out of 1,071 results (1.31%) were delivered either by phone (mainly because the participants did not have access to email or Internet) (8/1,071, 0.75%) or during a face-to-face consultation (6/1,071, 0.56%). All results that were not communicated through the website stemmed from samples collected through outreach activities.

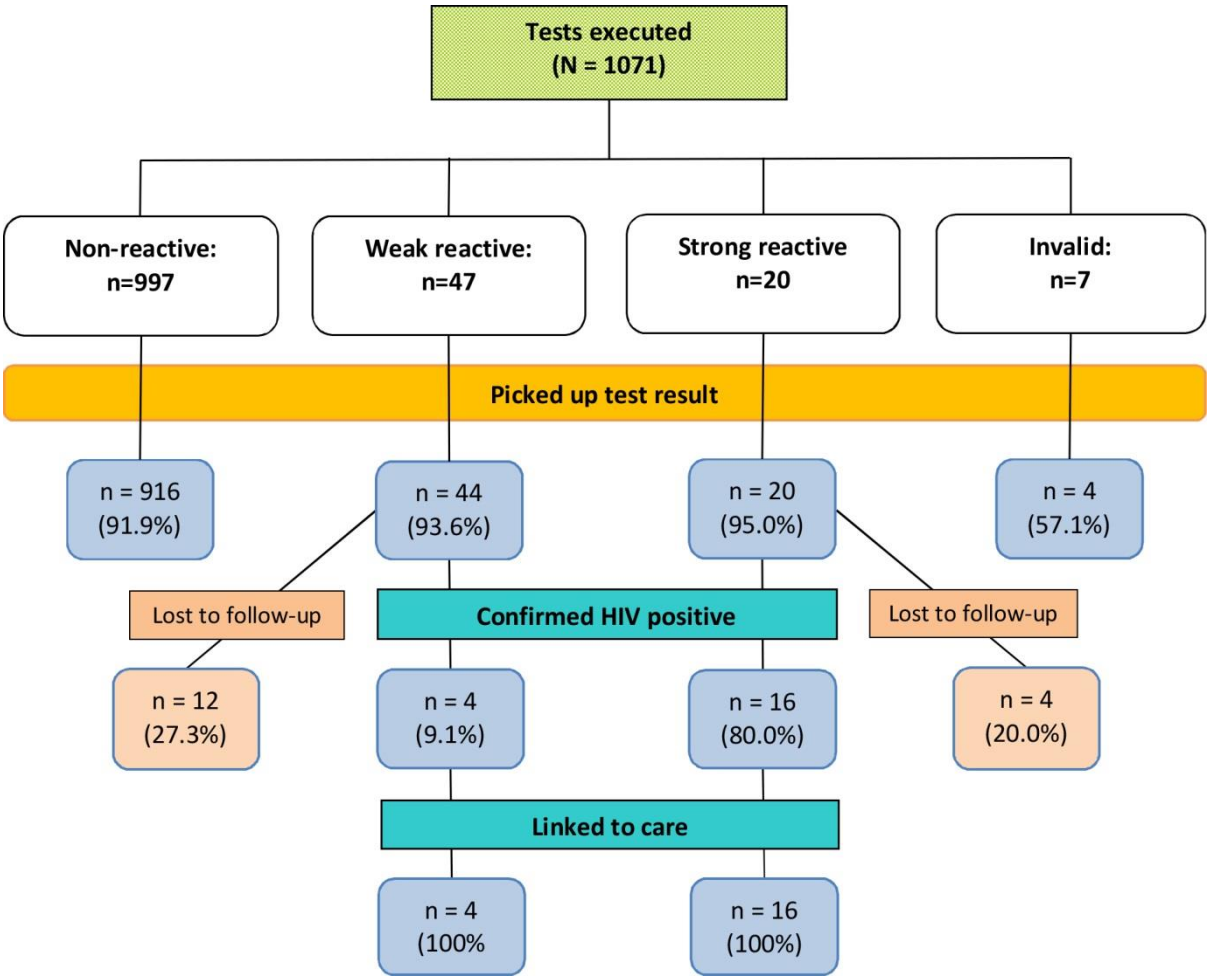
Overall, the results of 983 out of 1,071 (91.78%) tests were effectively collected from the website. The pickup rate was significantly higher when the test had been ordered online (421/430, 97.9%) compared to the test performed during outreach activities (559/641, 87.2%; $p < 0.001$).

Figure 4.1 shows the number of nonreactive, weak reactive, and strong reactive test results, with confirmation test results from blood and linkage to care.

A total of 28 out of 44 (64%) weak reactive test results were not confirmed HIV positive, and were thereby classified as false reactive results.

Overall, 20 participants were confirmed as newly diagnosed with HIV and all of them were linked to care; this represents 2.2% (20/898) of all participants tested. A total of six newly diagnosed participants ordered their sampling kit online, which put the new HIV infection rate in this group at 2.1% (6/289) while 14 were detected during outreach sessions; the new HIV infection rate for this group was 2.3% (14/609). This difference was not statistically significant ($p = 0.83$).

Figure 4.1: Flowchart of test results, confirmation, and follow-up for 1,071 tests executed among MSM in the swab2know study.



Acceptability

Of the 983 participants who collected their test results, 388 (39.5%) completed posttest surveys. The vast majority of participants (371/388, 95.6%) reported being very satisfied with the process while 17 out of 388 (4.4%) experienced mixed feelings taking part in the project. Whereas 48 out of 388 participants (12.4%) reported they would consider taking part again, most of the respondents (337/388, 86.9%) reported they would do so "without hesitation." Of the 388 respondents, 3 (0.8%) reported that they would not participate again in the future. One of them had been diagnosed with HIV through the project, which makes future participation redundant.

Discussion

Principal Findings

Results from recent surveys show that HIV self-testing is gaining momentum within the MSM community across the world (Hottes et al., 2012; Myers et al., 2014). This manuscript describes a low-threshold HIV-testing strategy combining oral fluid self-sampling, HIV testing in a specialized AIDS reference laboratory, and result delivery through a secured website with a solid linkage-to-care strategy.

Compared to the bulk of research on HIV self-testing and home-based testing, little has been published on the combination of self-sampling and the remote delivery of the test result. A recent project in the United Kingdom used a similar methodology to our project, but they performed tests on dried blood samples. Negative results were disclosed by text message while positive results were communicated by phone. They found a comparable rate of newly diagnosed HIV infections, successful linkage to care, and participant satisfaction (Brady et al., 2014).

We specifically chose oral fluid collection devices given their potential advantages: convenient and painless to collect, ideal for self-sampling, and very little risk of contamination during collection and sample transport. The potential problems associated with oral fluid testing are a lower sensitivity especially in detecting early infections and the fact that one cannot perform a confirmation test on the same sample because this needs to be done on a blood sample.

We also decided not to use a rapid test during outreach sessions despite good results described in similar settings (Bowles et al., 2008; Mayer et al., 2012). This choice was motivated by two reasons. First, when a session is organized in leisure venues, the idea of receiving an HIV diagnosis on the spot could prevent clients from participating. Second, a reactive result requires thorough counseling and support, which are hard to deliver in these types of venues, especially when other participants are waiting to be tested. Our alternative strategy was to deliver the results via an online tool.

Acceptability and intended uptake of Internet-based HIV/STI-screening programs are high among high-risk groups in various settings (Gilbert et al., 2013; Zou et al., 2013). Nevertheless using a website to communicate HIV test results has, to the best of our knowledge, not been reported before. It has several advantages over other communication strategies used in similar projects. The participant, not the health care provider, decides when to pick up the result. It is less time consuming and less intrusive than a phone call. It offers the possibility to provide information in addition to the HIV test result, such as information on the test window period, the importance of testing for other STIs, and the need to confirm the result in case of a reactive test. Compared to text messages,

website communication opens up possibilities to develop automated counseling strategies tailored to the test results and the patient's profile in the future.

The self-sampling procedure produced samples of acceptable quality. A small minority of participants (all through online testing) provided an invalid sample. Satisfaction with the project was very high among participants; however, given the incomplete response rate to the satisfaction survey, we cannot exclude the possibility of a selection bias.

The project helped us to reach the target population, both in terms of the number of tests executed, and in the number of newly diagnosed HIV infections. The percentage of newly diagnosed participants (2.2%) was higher than expected. As recently reported, 6% of Belgian MSM tested in a variety of nightlife settings are HIV positive (Vanden Berghe et al., 2011), of whom 14.3% are unaware of their HIV-positive status. Applying these figures, we expected to diagnose 9 new HIV infections (14.3% of 6% of 1,071 tests) compared to the 20 new HIV diagnoses in this project. This may be an indication that we succeeded in attracting the population at highest risk of acquiring HIV. All new cases were successfully linked to HIV care, which is a crucial aspect of the HIV treatment cascade, and a great asset of the project compared to self-testing. Moreover, with a yield of 2.2% of participants (20/898) newly diagnosed with HIV in this project, its method can be considered as cost effective—HIV testing in populations where the prevalence is greater than 0.1% is considered cost effective (Sanders et al., 2005; Walensky et al., 2005).

An additional benefit of the project was that the partners from 3 participants were newly diagnosed in the organizing health center during the course of the project. They were not included in this analysis.

The proportion of participants who were never tested before was considerable. Of 898 participants, 154 (17.1%) answered that they had never been tested for HIV before. This percentage indicates that online and outreach testing may facilitate HIV testing for MSM who experience difficulties in taking a test using the existing structures, and therefore do not get tested.

Limitations

As observed previously with oral fluid testing protocols, the proportion of false reactive test results was substantial (2.7%)(Pant Pai et al., 2012). Taking into account the impact of a reactive result on people’s lives, these false reactive results should be minimized. Despite this problem, four of six participants with a false reactive result who provided feedback using the acceptability questionnaire answered that they were "very satisfied" with the project and would "without hesitation" participate again. The other two participants reported "mixed feelings" about the project: one said he would not and one said he would consider participating again. It remains crucial that

participants with a weak reactive result see a physician to confirm or refute the result. A minority of participants with a weak reactive result were confirmed HIV positive (4/32, 13%).

A considerable number of participants were lost to follow-up in the course of the project. Whereas a loss to follow-up does not mean that participants were not linked to care (some may have visited their general practitioner), we should aim to minimize this proportion.

The yield of this screening project was high; however, contacting and motivating participants to pick up their results required more intensive follow-up than expected. Although the workload for the paramedical staff was much less than with the standard-of-care counseling method, this aspect should not be underestimated in such projects. Further studies should investigate whether such strategies are cost effective in detecting new HIV infections in high-risk groups.

Next Steps

We plan to continue the project in the coming years, with an increased emphasis on Internet-based testing and repeated testing for participants, as well as strong collaboration with community-based and prevention organizations to guide MSM toward the Swab2know project. On the basis of this experience, our methodology will be refined. First, the online counseling tool will be further developed and refined to support participants, with an increased emphasis on those with a reactive result. Comparable e-counseling tools have been developed and implemented in primary care (Adamson & Bachman, 2010). This could complement, and to some extent replace, the phone counseling, thereby reducing the staff workload. Second, we hope to reduce the number of false reactive results by the use of newly developed point-of-care oral fluid tests. Third, expanding the scope of sexually transmitted infections tests may improve the attraction of the project among MSM. One could consider performing syphilis or hepatitis C serology on oral fluid samples, or nucleic acid tests for the detection of chlamydia and gonorrhea on self-collected urethral and anal samples (Taylor et al., 2013), allowing a comprehensive STI checkup.

From a societal point of view, a legal framework needs to be developed. Self-testing is not officially recognized in Belgium: neither are online testing nor self-sampling activities.

In conclusion, we demonstrated that a low-threshold HIV-testing strategy combining self-sampling with oral fluid and online result delivery was acceptable. The HIV infection rate was higher than expected and the linkage to care was good. This strategy empowers individuals to manage their health, but at this stage it should be reserved for high-risk groups such as MSM where the incidence of HIV is high.

CHAPTER 5

Sexual inactivity among men who have sex with men living with HIV in Europe

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Introduction

HIV remains a public health problem in Europe. In the European Union [EU]/European Economic Area (EU Member States, Norway, Iceland, and Liechtenstein and Switzerland), 29,381 new HIV cases were reported in 2012, an incidence of 5.8 per 100,000 population (European Centre for Disease Prevention and Control & WHO Regional Office for Europe, 2014). Sex between men is the most common transmission mode in this region and accounts for 40.4% of new infections (European Centre for Disease Prevention and Control & WHO Regional Office for Europe, 2014).

Sexual relationships and sexual behavior are key components of well-being (Mercer et al., 2013). After being diagnosed with HIV (mostly acquired through sexual contact), being sexually active becomes more complicated for many people living with HIV (PLHIV). The ensuing changes in the person's sexual life may result in a reduced sense of well-being caused by psychological (including the fear of infecting a sexual partner and relational aspects) and sociological factors (HIV-related stigma and discrimination). Such factors may mutually influence and reinforce each other, thereby resulting in sexual difficulties.

It has been shown that fear of being rejected because of one's HIV status can prevent people from engaging in sexual intercourse (Bourne, Hickson, Keogh, Reid, & Weatherburn, 2012). Despite these complications, most PLHIV reengage in sexual activity and remain sexually active (Crepaz, Hart, & Marks, 2004; Crepaz & Marks, 2002). However, different studies have shown that substantial proportions of PLHIV remain sexually inactive for long periods after their HIV diagnosis. Studies that defined sexual inactivity as the absence of any oral or sexual intercourse among PLHIV and that were carried out after the large-scale introduction of antiretroviral therapy (ART) in the late 1990s showed that 31% of men and women (Bogart et al., 2006) and 22% of gay/bisexual men living with HIV in the respective samples reported no sexual activity in the previous six months (Ciccarone et al., 2003). More recent evidence showed a prevalence of 14% (Bouhnik et al., 2006) to 22% (Durham et al., 2013) of sexual inactivity among men who have sex with men (MSM) living with HIV.

HIV-related stigma and discrimination may additionally impact sexual activity. Stigma pertains to characteristics that convey a negative social identity (Goffman, 1963), and such negative attitudes against PLHIV have been well documented since the start of the HIV epidemic (Schuster et al., 2005). Many HIV-positive gay men experience stigma from both outside and within their own communities, regardless of their (sub)cultural background (Radcliffe et al., 2010; Smit et al., 2012). Stigma and discrimination may for instance have consequences on the decision to disclose one's HIV status. Some studies carried out among HIV-positive gay men have indeed documented widespread rejection by sexual partners after disclosure of HIV (Bourne, Dodds, Keogh, Weatherburn, & Hammond, 2009), which led them to take social and sexual distance.

PLHIV are more likely to suffer from mental health problems, including major depressive disorder (Hinkin, Castellon, Atkinson, & Goodkin, 2001), anxiety disorders (Hinkin et al., 2001; M. C. Sewell et al., 2000), and post-traumatic stress disorder (Joska, Fincham, Stein, Paul, & Seedat, 2010; Kelly et al., 1998; Olley, Zeier, Seedat, & Stein, 2005). The increased mental health problems of PLHIV should be seen in the background of an elevated prevalence of mood and anxiety disorders in MSM as opposed to heterosexual men (Burgess, Tran, Lee, & van Ryn, 2007; King et al., 2008; Meyer, 2003; Sandfort, de Graaf, & Bijl, 2003). Impaired mental health among gay men can be framed within the concept of minority stress. This theory stipulates that gay men are confronted with a social and contextual climate that leads to higher levels of internalized homophobia, perceived stigma, and prejudice. This in turn impacts on their overall health (Meyer, 1995, 2003). One example of this social context is the high level of homophobia in certain Central and Eastern European (C/EE) countries (Berg, Ross, Weatherburn, & Schmidt, 2013; Ross et al., 2013; Stulhofer & Rimac, 2009).

Mental health problems may be more common in these areas with high levels of homophobia, and this may in turn lead to sexual inactivity of MSM living with HIV, as argued (Bancroft, 2009). He described the impact of negative mood states on sexual functioning among HIV-negative persons (Bancroft, 2009). A majority of both heterosexual and homosexual individuals suffering from a negative mood state report less sexual interest and responsiveness, but a minority experience the opposite effect (Bancroft, Janssen, Strong, Carnes, et al., 2003; Bancroft, Janssen, Strong, & Vukadinovic, 2003; Lykins, Janssen, & Graham, 2006). Likewise, for HIV-positive individuals, it has also been suggested that the relationships between depressive symptoms and level of sexual activity and sexual risk behavior are mixed and complex (Bradley, Remien, & Dolezal, 2008).

In the context of various potential risk factors of HIV-positive MSM (fear of rejection, stigma and discrimination, and mental health), determinants of sexual inactivity have not been systematically explored. In this study, we explore sexual inactivity among a European clinical convenience sample of MSM living with HIV. It concerns a subsample of Eurosupport 5 (ES5), a European multicenter study, which investigated sexual and reproductive health among PLHIV in Europe (Nöstlinger et al., 2010, 2011). The aim of our study was to investigate the prevalence of sexual inactivity and to identify factors associated with sexual inactivity. This knowledge is relevant as sexual activity and sexual satisfaction are important for the wellbeing of PLHIV. We hypothesized that the following factors might be associated with sexual inactivity: mental health, the region where people live, and HIV-related discrimination. Additionally, several demographic and general health aspects were tested for their potential association with sexual inactivity. By identifying relevant associated factors, interventions can be developed to improve (sexual) wellbeing of PLHIV.

Methods

Study Site/Population

The ES5 network consisted of 17 HIV treatment and research centers in 14 European countries. A self-administered anonymous questionnaire (SAQU) was distributed as a paper-and-pencil version to consecutive patients from March 2007 to October 2007 at all collaborating ES5 sites, mostly adult HIV outpatient clinics. The SAQU had been translated and back-translated (for quality check) into 12 languages. Health care providers (physicians, nurses) from the participating centers invited eligible patients to voluntarily and anonymously fill in the SAQU and return it to the coordinating center using prepaid envelopes. Participants did not receive any incentives for participation. Responding to the questionnaire took 30 min to 45 min. No information was collected on patients who received their SAQU but did not send it back. Only the total number of questionnaires distributed was noted. Inclusion criteria for the study were being able to understand the study goals and objectives, providing informed consent, and having been diagnosed as HIV-positive for at least six months. The questionnaires were distributed to all eligible patients in the different study sites during the course of the study.

For this article, we limited the analysis to the MSM participants. MSM were self-identified homosexual or bisexual men.

Instruments

The SAQU was piloted in a small sample of PLHIV at the coordinating center for clarity and feasibility. Ethical approval was obtained at the coordinating site (Institute of Tropical Medicine/ University Hospital Antwerp). The SAQU assessed different aspects, including information on demographic background, general health, mental health, sexual health, and duration since HIV diagnosis. As part of the sexual health assessment, respondents provided information on their sexual activity during the previous six months and answered detailed questions on vaginal, anal, and oral sex. The definition we used for sexual inactivity is derived from these behavioral measures: Participants who reported not having engaged in any vaginal, anal, or oral sexual activities were classified as “sexually inactive.” Validated scales (21-item scale of the Depression Anxiety Stress Scale) were used to measure mental health (Lovibond & Lovibond, 1995). Satisfaction with sexual desire was assessed with a single question: “How satisfied have you been with your sexual desire during the past 6 months?” Sexual desire was scored from “0” (not at all satisfied) to “10” (completely satisfied). Satisfaction with general health was assessed with the question “In general, how satisfied are you with your current state of health?” and used the same response categories.

Discrimination was assessed as “Did you experience any discrimination in relation to your HIV infection during the last three years?”

Table 5.1 shows an overview of the selected independent variables and how they were assessed.

Table 5.1: Overview of independent variables

SAQU-domain	*Variable*	*Assessment*
Demographic variables	Age	Years
	Relationship situation	Being single / Having a relationship
General health variables	Satisfaction with general health	Visual Analogue Score (0-10)
	Duration of HIV-infection	Years
Mental health variables	Depressive symptoms	Depression score DASS 21[*] – Ordinal Scale (Non-clinical, Subclinical, Clinical)[**]
	Anxiety symptoms	Anxiety score DASS 21[*] – Ordinal Scale (Non-clinical, Subclinical, Clinical)[**]
	Stress symptoms	Stress score DASS 21[*] – Ordinal Scale (Non-clinical, Subclinical, Clinical)[**]
Sexual health variables	Satisfaction with sexual desire	Visual Analogue Score (0-10)
Regional differences	Region	Western Europe
		Southern Europe
		Central/Eastern Europe
	Feeling discriminated against	Yes / No

[*] DASS21: 21-item scale of the Depression-Anxiety-Stress Scale (Lovibond & Lovibond, 1995)

[**] According to percentile cut-offs (Lovibond & Lovibond, 1995); Non-clinical (normal, or mild symptoms), subclinical (moderate symptoms), clinical (severe, or extremely severe symptoms)

To explore regional and/or cultural differences between participants from the different countries, countries were clustered into three European regions (i.e., Western Europe [WE], which included Austria, Belgium, Germany, Switzerland, and the United Kingdom; Southern Europe [SE], which included Greece, Italy, Portugal, and Spain; and C/EE, which included the Czech Republic, Hungary, Latvia, Poland, and Slovak Republic) to conduct further comparative analyses.

Statistical Analysis

Statistical analysis was performed using the IBM Statistical Package for the Social Sciences Version 20. Descriptive and univariate analyses were carried out. Chi-square tests were used for categorical variables, and Mann-Whitney *U* Tests were used for continuous variables (or Kruskal-Wallis for variables with more than two categories). A significance level of 5% was applied. Using logistic regression, an associated model for sexual inactivity was developed. All variables that were tested in univariate analysis were entered into a logistic regression using a backward step model (*p*-in value was .05, *p*-out was .10). In a second step, retained variables from this regression analysis were entered into a new logistic regression model. This included relevant interaction factors for all remaining main effects.

Results

Overall, 838 MSM living with HIV from 14 countries completed and returned their questionnaires. An overview of participating countries and centers and the number of returned questionnaires per country are provided in Table 5.2.

Among all participants who returned their questionnaires, the median age was 43 years (interquartile range [IQR] = 37–50 years), and the median duration of living with HIV was seven years (IQR = 3–14 years).

Table 5.2: Participating countries, centers and numbers of returned questionnaires

Country	*Center*	*N (%)*
Austria	European Centre, Vienna	30 (3.6)
	University of Innsbruck	
Belgium	Institute of Tropical Medicine, Antwerp	210 (25.1)
	Sensoa, Antwerp	
Czech Republic	Charles University, Prague	20 (2.4)
Germany	Ludwig Maximilian University, Munich	163 (19.5)
Greece	SYNTHESIS, Athens	54 (6.4)
Hungary	Semmelweis University, Budapest	46 (5.5)
Italy	University of Padova, Padua	37 (4.4)
	San Raffaele Scientific Institute, Milan	
Latvia	Association for family planning and sexual health, Riga	16 (1.9)
Poland	University of Zielona Gora	28 (3.3)
Portugal	Hospital Santa Maria, Lisbon	14 (1.7)
Slovak Republic	National reference center for HIV/Aids prevention, Bratislava	11 (1.3)
Spain	Complutense University, Madrid	22 (2.6)
Switzerland	University of Aargau	165 (19.7)
UK	Pennine Acute Hospitals, NHS Trust, Manchester	22 (2.6)
Total		838 (100.0)

Of participants who answered the question on sexual activity during the previous six months (n = 833), 97 men (11.6%) did not report any partnered sexual activity. Respondents who were sexually inactive were asked for the reasons for their inactivity. They were allowed to indicate multiple reasons. Ninety-three men (96% of the sexually inactive respondents) answered this question. The most cited reasons were: “I was afraid of infecting somebody else” (n = 25; 27%), followed by “I wasn’t in the mood for sex” (n = 24; 26%), “I had no opportunity for sex” (n = 20; 22%), and “I wanted to avoid a new HIV infection or [sexually transmitted infection]” (n = 17; 18%). Somewhat less reported was “I was afraid of being disclosed when I was having sex” (n = 7; 8%).

Univariate analysis revealed several significant differences between sexually active and inactive respondents (see Table 5.3).

Being older, having had an HIV diagnosis for a longer time, and being single were associated with sexual inactivity. Moreover, respondents who were less satisfied with their general health status and less satisfied with their level of sexual desire were more likely to report sexual inactivity. Mental health variables such as depression, anxiety, and stress levels did not differ between sexually active and inactive respondents. Experiences with discrimination did not differ between sexually active and inactive respondents.

Median satisfaction with sexual desire was higher among sexually active respondents (7; IQR = 4–8) compared with sexually inactive respondents (5; IQR = 3–8; $p = 0.017$). Respondents from WE were older (median age = 44 years; IQR = 38–51) than those from SE (median age = 42 years; IQR = 37–46) and C/EE (median age = 36 years; IQR = 30–45). However, no significant differences were found in sexual (in)activity between the geographical regions.

Table 5.3: Factors associated with sexual inactivity: Univariate analysis

Characteristics	*N(%)*		*Median (IQR)*		*p-value*	*Total*
	Sex. active	*Sex. inactive*	*Sex. active*	*Sex. inactive*		
Age			42 (36-48)	49 (43-06)	<0.001*	43 (37-50)
Relationship status					<0.001*	
Single	295 (82.4)	63 (17.6)				358 (43.2)
In a relationship	438 (93.0)	33 (7.0)				471 (56.8)
Satisfaction with general health			8 (6-9)	7 (5-9)	<0.015*	8 (6-9)
Duration of HIV-infection			7 (3-13)	11 (3-16)	<0.016*	7(3-14)
Depression					0.501	
Non-clinical	623 (88.9)	78 (11.1)				701 (85.8)
Subclinical	63 (86.3)	10 (13.7)				73 (8.9)
Clinical	36 (83.7)	7 (16.3)				43 (5.3)
Anxiety					0.799	
Non-clinical	637 (88.3)	84 (11.7)				721 (88.2)
Subclinical	53 (86.9)	21 (13.1)				61 (7.5)
Clinical	32 (91.4)	3 (3.2)				35 (4.3)
Stress					0.672	
Non-clinical	642 (88.6)	83 (11.4)				725 (88.8)
Subclinical	48 (88.9)	6 (11.1)				54 (6.6)
Clinical	31 (83.8)	6 (16.2)				37 (4.6)
Region					0.787	
WE	514 (87.9)	71 (12.1)				585 (70.2)
SE	114 (89.8)	13 (10.2)				127 (15.3)
C/EE	108 (88.4)	13 (11.6)				121(14.5)
Satisfaction with sexual desire			7 (4-8)	5 (3-8)	<0.017*	7 (4-8)
Felt discriminated	221 (90.2)	24 (9.8)			0.240	245 (30.5)

* significantly associated with sexual inactivity ($p < 0.05$)

In the first step of the multivariable analysis, in which all variables were entered into the model, age, relational status, satisfaction with general health, and satisfaction with sexual desire were retained. In the second step, the interaction variables were added to the model. None of these interactions were retained in the model after regression analysis. Being sexually inactive was found to be significantly related to older age, being single, lower satisfaction with general health status, and lower satisfaction with sexual desire (Table 5.4).

Discussion

In our sample, 12% of MSM living with HIV reported that they had been sexually inactive according to the study's definition. This prevalence is similar to the rate of 8% found among a large group of MSM (not specifically HIV-positive MSM) in The Netherlands (Hospers, Dörfler, & Zuilhof, 2008). However, it is lower than the prevalence of 22% found in a previous study of MSM living with HIV using similar definitions and reference periods for sexual inactivity (Ciccarone et al., 2003). Since the introduction of ART, life expectancy of PLHIV has increased to near-normal figures (May & Ingle, 2013), which may reduce the fear for many MSM to become HIV-infected. Moreover, PLHIV on ART with an undetectable viral load are at very limited risk for transmitting the virus, thereby reducing the fear of infecting a sexual partner (Donnell et al., 2010). The study by Ciccarone and colleagues (2003) was conducted earlier in the ART era, and our finding of a lower prevalence of sexual inactivity may reflect the normalization of sex lives among MSM living with HIV in the ART era.

Table 5.4: Factors associated with sexual inactivity: Multivariate analysis

Characteristics	*Univariate*			*Multivariate*		
	O.R.	*(95% C.I.)*		*O.R.*	*(95% C.I.)*	
Age*	1.07	1.05	1.09	1.07	1.05	1.10
Time HIV-positive	1.05	1.02	1.08			
Relationship status*						
Single	1.00			1.00		
In a relationship	0.35	0.23	0.55	0.49	0.29	0.81
Satisfaction with general health*	0.88	0.81	0.96	0.89	0.81	0.98
Satisfaction with sexual desire*	0.90	0.84	0.97	0.93	0.86	1.00

* factor retained in multivariate analysis

The individual living conditions of PLHIV, the level of societal acceptance of HIV (European Centre for Disease Prevention and Control, 2010b), HIV-related discrimination (Peretti-Watel, Spire, Obadia, Moatti, & VESPA Group, 2007; Sprague et al., 2011), and access and quality of HIV care (European Centre for Disease Prevention and Control & WHO Regional Office for Europe, 2009; Platteau et al., 2013) are not homogeneous throughout Europe. Despite this, we found no differences in the degree of sexual activity between regions. This indicates that societal and juridical aspects are limited in influencing people's individual choices for being sexually active.

This study has several limitations. Firstly, there is possible inaccuracy due to response bias (differences between responders and non-responders could not be assessed). Secondly, there are limitations in the generalizability of the results due to the convenience sampling and the absence of a comparison group of HIV-negative people. A third limitation is the absence of a question on participants' satisfaction with sexual activity/inactivity in addition to their satisfaction with sexual desire in order to assess its impact on PLHIV's quality of life. Despite these limitations, our results provide a snapshot of the phenomenon of sexual inactivity among MSM living with HIV in Europe in the more recent ART period.

Multivariable analysis showed four variables that may predict sexual inactivity: being older, single, and less satisfied with one's general health and current level of sexual desire. This list of associated variables from the multivariable analysis indicates a complex relation between biological (age), psychological (satisfaction with aspects of health, satisfaction with sexual desire), and social (relationship status) components of sexual inactivity. Predictive factors in this model are similar to results from other studies. Older age, for example, was expected to be associated with sexual inactivity (Bogart et al., 2006; Schiltz, Bouhnik, & Peretti-Watel, 2008). This association is also found in many studies, regardless of the study population's HIV status (Mitchell et al., 2013). Being single implies that people have to find a new sex partner with whom they have sex. For some PLHIV, this is a step they find hard to take because of their fear of infecting the partner (Schiltz et al., 2008) and the fear of rejection (Bourne et al., 2012) by a sexual partner, and due to internalized stigma (R. S. Lee, Kochman, & Sikkema, 2002). In our study, duration since HIV diagnosis was significantly associated with sexual inactivity in the univariate analysis but not the multivariable analysis. This may be due to its significant correlation with age ($r = 0.45$, $p < .001$), which itself is correlated to sexual inactivity.

Median scores of satisfaction with sexual desire were significantly lower among sexually inactive respondents, compared with their sexually active counterparts. However, it should be stressed that the multivariate model cannot attribute causality nor determine the direction of the relationship between sexual inactivity and satisfaction with sexual desire due to the cross-sectional design. Yet, we hypothesize that being dissatisfied with (reduced) sexual desire may negatively

influence one's sexual activity and prevent someone from searching for sexual partners. A similar pattern may be hypothesized for satisfaction with general health: when PLHIV are dissatisfied with their (general) health condition, this may influence their sexual desire negatively and thereby impact sexual behavior. Poor satisfaction with general health may also prevent people from searching for sexual partners. In a recent British population-based study among 15,162 participants (Mitchell et al., 2013), poor health status was also found to be associated with low sexual function.

By demonstrating the importance of biological, psychological, and social factors, we argue that helping people rebuild their sex life should be framed in a multidisciplinary approach. By discussing sexuality with individual patients, health care providers in HIV clinics can support patients in setting up an individual trajectory to improve their sex life while involving peers, physicians, psychologists, sexologists, and paramedic health care providers.

CHAPTER 6

Computer-assisted intervention for safer sex in HIV-positive men having sex with men: Findings of a European randomized multi-center trial

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Introduction

HIV infection is a major public health concern in Europe. In 2013, 30 countries in the European Union / European Economic Area (including European Union Member States, Norway, Iceland, and Liechtenstein) reported 29,157 new HIV cases. Of those, 42% were reported among men having sex with men (MSM), accounting for the majority of new HIV cases with unprotected sex between men as the predominant HIV transmission mode (European Centre for Disease Prevention and Control & WHO Regional Office for Europe, 2014). Among MSM living with HIV, growing numbers of other sexually transmitted infections (STI) such as gonorrhea and syphilis have also been observed, attributed to condomless sex (Crepaz et al., 2009; Ostrow et al., 2002; Stolte, Dukers, de Wit, Fennema, & Coutinho, 2002). Several European studies reported such evidence. For instance, a European multicenter study found that 42% of 705 sexually active, HIV-positive MSM in 14 European countries reported at least one occasion of unprotected vaginal or anal intercourse with a casual partner in the previous six months (Mueller et al., 2013; Nöstlinger et al., 2011). The European MSM internet survey, an online survey with more than 180,000 MSM from 38 European countries participating, reported that almost twice as many HIV-positive MSM had unprotected sexual encounters with casual partners, compared with HIV-negative, and untested MSM (The EMIS Network, 2013).

Unprotected sexual intercourse has been linked with biological, psychological, social, and contextual determinants often interacting with each other (Baral, Logie, Grosso, Wirtz, & Beyrer, 2013; Vanden Berghe, Nöstlinger, & Laga, 2014). Among psychological determinants, mental health (e.g., depressive symptoms and substance abuse)(Kaltenthaler, Pandor, & Wong, 2014), negative attitudes towards condom use (Widman, Golin, Grodensky, & Suchindran, 2013), and low self-efficacy to adopt protective behavior (Omrod, 2006) were shown to correlate with unprotected sex. Self-efficacy or the perceived ability to exert personal control over behavior change (Bandura, 1977) is a central construct in empirically validated behavior change theories such as social cognitive theory (SCT)(Bandura, 1997) and the Information-Motivation-Behavioral skills (IMB) model (Fisher & Fisher, 1992), and was found to highly correlate with individuals' health behaviors including sexual activity for MSM (Jemmott III et al., 2015). Treatment optimism, i.e., a decreased concern about HIV transmission because of the availability of effective combination antiretroviral treatment (cART), treatment fatigue eventually leading to declined adherence over time, and improved quality of life of HIV-infected MSM may also contribute to increased sexual risk behavior (European Centre for Disease Prevention and Control, 2015a). More recently, the widespread use of the internet for partner selection may have facilitated online initiation of condom less sex (European Centre for Disease Prevention and Control, 2015c; Lewnard & Berrang-Ford, 2014).

Studies systematically testing the effectiveness of behavioral interventions to increase safer sex among MSM (Higa et al., 2013; Lewnard & Berrang-Ford, 2014; Lorimer et al., 2013) reported larger intervention effects for people living with HIV (PLHIV) compared with uninfected MSM (Crepaz et al., 2006). In general, reviews consistently identified that intervention effects are bigger when interventions are theory-based, include participants' skill building, and delivered by trained professionals (Lorimer et al., 2013). It has been recognized that for behavioral interventions to be effective, delivery channels must be appealing to the target group's needs and preferred lifestyles. Increasing evidence also shows that the use of internet-based tools and mobile technology can effectively contribute to the achievement of health objectives (J. V. Bailey et al., 2012; Crepaz et al., 2006; Lopez, Otterness, Chen, Steiner, & Gallo, 2013; Noar et al., 2011; World Health Organization, 2011; Zule et al., 2013). However, few interventions targeting MSM (Bachmann et al., 2013; Carpenter, Stoner, Mikko, Dhanak, & Parsons, 2010) or PLHIV (Gilliam & Straub, 2009; Klein, Lomonaco, Pavlescak, Card, & El, 2013; Kurth et al., 2014) have used randomized controlled designs as the gold standard for their evaluation. None of them were conducted in a European context (Lewnard & Berrang-Ford, 2014).

To fill this void, we developed and evaluated a theory-guided computer-assisted safer sex intervention for PLHIV. The intervention was based on complementary behavioral theories, i.e., SCT (Bandura, 1997), the IMB model (Fisher & Fisher, 1992), and dual process approaches in health risk decision making (Gerrard, Gibbons, Houlihan, Stock, & Pomery, 2008; see methods section for more details). It targeted 2 key populations most affected by HIV in Europe, HIV-positive MSM and HIV-positive women, and men from ethnic minorities. To the best of our knowledge, this is the first behavioral intervention addressing safer sex for PLHIV in Europe which has been evaluated using a randomized controlled design.

This paper presents only the effectiveness results obtained in the target group of HIV-positive MSM, looking at whether the intervention can support them effectively in improving condom use. Because of target-group specific behavioral patterns and their underlying determinants, the results for heterosexual PLHIV are analyzed and reported separately. The trial results are further explored using mediation analysis (Hardnett et al., 1974; Vanderweele & Vansteelandt, 2009), an approach that identifies which specific aspects of the intervention lead to its outcome. In line with the intervention's underlying theories, we hypothesized that the intervention effect is not only achieved directly but also indirectly through improving specific psychological constructs that facilitate behavior change (i.e., self-efficacy, attitudes)(Bandura, 1977; Fishbein & Ajzen, 1975; Rimal, 2000), and mood which likely influences protection motivation (Kaltenthaler et al., 2014). More specifically, the following hypotheses were tested:

- Study participants receiving the intervention report have decreased condomless sex compared with individuals receiving regular treatment at three and six months after completion of the intervention.
- The intervention effect can be explained by potential mediators. The intervention effectively increases self-efficacy to negotiate condoms and favorably changes condom use attitudes, which in turn increase condom use. Also the role of depressed mood as a mediator is explored (Kaltenthaler et al., 2014), i.e., if the intervention can improve the participant's mood, it may also increase condom use.

Methods

This multicenter, simple-randomized controlled parallel-group study was conducted in eight European countries (i.e., HIV care centers serving MSM patient populations in Belgium, Italy, France, Germany, The Netherlands, Poland, Spain, and England). Investigators belonged to the Eurosupport 6 network (i.e., a multidisciplinary consortium of HIV clinics, community-based and research organizations).

Development and Delivery of the Brief Computer-Assisted Counseling Intervention

The intervention mapping protocol (Bartholomew, Parcel, Kok, Gottlieb, & Fernández, 2011) facilitated intervention development, implementation, and evaluation across the sites through a series of systematic steps including a needs assessment (focus group research with PLHIV and service providers; Nöstlinger et al., 2008), resulting in identification of main determinants influencing sexual risk behavior. Target-group specific change objectives were formulated and practical intervention strategies were selected based on empirical evidence (Bartholomew et al., 2011). The systematic approach to intervention development, the detailed content, and the main results of the process evaluation were reported elsewhere (Nöstlinger et al., 2015). Several complementary theories informed the intervention development. Guided by the IMB model, an empirically validated HIV behavior change theory (Cornman et al., 2008; Fisher et al., 2004; Fisher & Fisher, 1992; Kahneman, 2011; Nöstlinger et al., 2011), the intervention addressed motivations and behavioral skills including self-efficacy. We further built on SCT to address relevant influencing factors from the participant's personal and social environment such as attitudes and social norms, and to induce behavior change through role modelling and guided practice (Bandura, 1977, 1997). In addition, theories emerging from cognitive neuroscience provided insight into how behaviors are emotionally driven. "System 1 – System 2 Thinking" (Kahneman, 2011; Slovic, Peters, Finucane, & MacGregor, 2005) differentiates between intuitive decision-making in affect-laden situations (i.e., automated brain processing or fast

thinking), and a rational, analytical decision-making (slow thinking). Dual process theories have been surprisingly absent from research on sexual risk (Rendina, 2014). Yet, they can contribute to explaining the gap between safer sex knowledge and practice. This particular theory base led to developing computer-assisted tools depicting personal stories about safer sex acted by role models using sexualized images rather than traditional methods of cognitive "education." We hypothesized that this approach addresses emotions and affects facilitated insight into the effects of sexual arousal on sexual decision making, which subsequently would improve motivation for using condoms (Ariely & Loewenstein, 2006).

The intervention, labelled as "CISS" (computer-assisted intervention for safer sex) consisted of three semi structured counseling sessions delivered by service providers, who worked with the participants through a series of video materials and interactive slide shows available on a DVD (for the time of the study period). Counseling sessions took about 50 minutes, with an interval of three weeks between sessions. Session one, "Who am I?" focused on exploring participants' emotional response to individual problems with safer sex, using the filmed role models. Participants could choose the personally most relevant clips addressing barriers to safer sex from a menu with five relevant topics congruent with the determinants identified in the needs assessment: relationship issues, emotions and mood, sexuality and pleasure, drugs/alcohol and sex, HIV, health and sex (including sexual problems and infectiousness). Session two, "Working Through" focused on developing personal solutions for the identified problems that would fit participants' context and lifestyles using video clips and interactive slide shows featuring self-assessment tools (e.g., a thermometer to measure the "risk temperature") and educational slides. Counselors guided the participants in working though these materials. Session three, "Making your plan" identified the necessary steps to achieve the behavioral goal through the counseling interaction and resulted in a personalized risk reduction plan. The counseling style adopted a motivational interviewing (MI) approach, with problem solving and cognitive behavioral goal setting strategies to identify personally tailored solutions with safer sexual behaviors (Malouff, Thorsteinsson, & Schutte, 2007).

Three different versions of the DVD were available, each with tailored recognizable role models, and relevant topics: one designed for MSM, one for heterosexual migrant women, and one for heterosexual migrant men. The combination of personally relevant computer-assisted materials and MI counseling achieved a high degree of individual tailoring through matching participants' needs in a cross-cultural perspective, while using the same theory base to ensure coherence across settings. All staff delivering the intervention received a two day training facilitated by the intervention developers.

Study Setting and Participants

Seven HIV treatment centers and one community-based organization from eight European countries providing HIV care for MSM delivered the intervention. Participants were recruited between February, 2011 and February, 2013. All consecutive patients were invited to participate in the screening procedure if they met the following criteria: aged 18 or above, diagnosed HIV-positive for at least 6 months, able to understand the study goal and procedures involved, fluency in one of the study languages (Dutch, English, German, French, Italian, Polish, Portuguese, Slovak, Spanish), and providing written informed consent. MSM self-identified as men having (regular or occasional) sexual contacts with other men. According to the sample size calculation, we needed a sample of 182 participants to detect a difference in intervention effect of 20% in the control group and 40% in the intervention group with a power of 80%.

Procedures

Participants were enrolled through a two-step procedure. An online screening instrument assessed eligibility (see Table 6.1). Participants who reported any condomless sex, and at least "some importance" to be safe when having sex, were automatically directed to the baseline questionnaire, a computer-administered self-interview. Figure 6.1 describes the flow of participants through the study.

Upon completing the baseline questionnaire, participants were randomly assigned to the intervention (CISS) or control condition using a computerized randomization procedure concealed from study investigators. Participants in the control group received sexual health counseling as part of the regular care offered at their clinic. Each participant received an information leaflet providing information on local sexual health services. Controls were also offered to receive the intervention after completion of the study. Participants allocated to the intervention group received three CISS counseling sessions as described above.

Study participants completed computer-administered self-interview questionnaires at three consecutive time points (see Fig. 1): at T2 (after completion of the intervention) only process evaluation data were collected (results are presented elsewhere; Nöstlinger et al., 2015), and at T3 and T4 (three and six months after completion of the intervention respectively) a questionnaire assessed variables to compare with the baseline instrument. Participants did not receive any incentives for their study participation. The coordinating center's ethics committee (Institute of Tropical Medicine, University of Antwerp, Belgium) provided ethical approval.

Measures

The baseline and the three and six months follow-up questionnaires assessed the outcome variable condom use and relevant socio-demographic and health-related variables. In addition, psychosocial variables were assessed such as HIV disclosure, substance use, mental health, and the psychological constructs attitudes and self-efficacy related to condom use as relevant mediators. Table 6.1 presents these variables and their measurements.

Table 6.1: Measures used

Domain	*Variable assessed*	*Question*	*Answer*
Screening questions		"Over the last 3 months have you always used a condom with all partners on all occasions of anal or vaginal sex?"	Yes / No
		"How important is it for you to be safe when you are having sex?"	Five-point Likert scale from "irrelevant" to "extremely important"
Socio-demographic variables	Relationship status	"Do you currently have a steady sexual relationship?"	No, single / Yes, male partner / Yes, female partner
	Highest educational level	"What is your highest education completed?"	Lower secondary / Higher secondary / Apprenticeship / Higher education
	Employment status	"Are you currently employed?"	Yes / No
Health-related variables	Physical condition	"How would you describe you HIV-related health?"	No physical complaints / Physical complaints
	HIV-treatment	"Are you currently on antiretroviral treatment?"	Yes / No
	Viral Load	"What was your most recent viral load?"	Undetectable / Detectable / I don't know
HIV-disclosure	HIV-disclosure to main partner	"Does your partner know you're HIV-positive?"	Yes / No
	HIV-disclosure to casual partners	"Do casual sexual partners know you are HIV-positive?"	(almost) no one / some of them / (almost) all of them
Substance use		"How often have you been under influence of alcohol when you have had sex?"	(almost) never / sometimes / (almost) always
		"How often have you been high on drugs when you have had sex?"	(almost) never / sometimes / (almost) always
Mental health	Depression	DASS 21 depression scale *	
	Anxiety	DASS 21 anxiety scale *	
	Stress	DASS 21 stress scale *	
Psychological constructs	Attitudes towards condom use	Sexual Risks Scale – Attitudes toward condom use ** 13 items rated on a 5 point Likert scale	"Strongly agree" – "Strongly disagree"
	Condom Use Self-Efficacy	Self-efficacy for negotiating condom-use, 5 items rated on a 1-10 scale ***	"Cannot do at all" – "Certain that I can do"
Intention to use condoms		"Are you intending to start using condoms consistently within the next 30 days?"	Yes / No

* (Lovibond & Lovibond, 1995) ** (DeHart & Birkimer, 1997) *** (Rotheram-Borus et al., 1997)

The primary outcome variable was condom less sex at the three months follow-up assessment measured in two ways: “condom use at last sexual intercourse,” and a refined HIV transmission risk score. The rationale for introducing such a score rests on two considerations. Firstly, HIV-infected persons are 96% less likely to transmit HIV to uninfected sexual partners, if viremia is suppressed under effective antiretroviral treatment (Cohen et al., 2011; Rodger et al., 2014). Secondly, the occurrence of STI other than HIV facilitates HIV infection through local ulcers of the receptive partner, thereby increasing the risk of HIV transmission (Ng et al., 2011). Given the increasing incidence of STI among MSM (Crepaz et al., 2009; Ostrow et al., 2002; Stolte et al., 2002), we combined several variables into a score reflecting a nuanced individual HIV transmission risk profile: numbers of unprotected sexual contacts (with main and casual sexual partners with HIV-negative or unknown status), participants’ viral load, and self-reported STI diagnosis in the previous three months (see Table 6.2 for details). This score was developed to account for available evidence on reduced infectivity of PLHIV treated effectively with cART (Ng et al., 2011; Rodger et al., 2014), their awareness of viral load and its implication on transmission risk (Hasse et al., 2010; Persson, 2010; Rojas Castro et al., 2012), and increasing STI incidences among MSM (Crepaz et al., 2009; Ostrow et al., 2002; Stolte et al., 2002).

Scores from participants who reported no condom less encounters were automatically set to “0” because there was no transmission risk, regardless of their current viral load and STI diagnoses. For further analysis, we dichotomized this outcome variable into “high transmission risk” vs. “low transmission risk” (score > 1 vs. score ≤ 1).

All study instruments were developed in English and translated into eight study languages using appropriate quality checks (Guillemin, Bombardier, & Beaton, 1993).

Statistical Analysis Plan

Stata version 12.1 was used for statistical analysis. Descriptive statistics for socio-demographic, health-related, mental health variables, and HIV disclosure, as well as for the additionally computed outcome variables (“transmission risk score”, “lower transmission risk”) were calculated using baseline data and subsequently compared between the intervention and control groups.

To compare the CISS intervention and control group, we modelled the evolution over time for the outcome variables by linear or logistic mixed effects model including a random intercept. Tests for a difference in time evolution between intervention groups were applied at 5% significance level. We then used mediation analysis (Hardnett et al., 1974; Vanderweele & Vansteelandt, 2009) to explore the intervention effect at the three months follow-up assessment. Mediation analysis is a

model seeking to identify the mechanism that underlies an observed relationship transmitting the effect of an independent variable on dependent variables (i.e., the outcome behavior). In line with the above mentioned theories, we explored the operationalized constructs self-efficacy to negotiate condom use and attitudes towards condoms as potential mediators, because they have been shown to be highly correlated with condom use, and to be modifiable through behavior change interventions (Rimal, 2000). Likewise, based on previous research (Kaltenthaler et al., 2014) and our needs assessment (Nöstlinger et al., 2008), assuming that people who had depressed mood were not motivated to use condoms, we explored depressed mood as a potential mediator. For the outcome variable condom use at last intercourse, three generalized linear regression models were used to test the effect of theoretically grounded mediator variables (i.e., condom use self-efficacy measured by the Self-efficacy for Negotiating Condom-use Scale; attitudes towards condom use measured by the Sexual Risk Scale; depression measured by the Depression Anxiety and Stress Scale 21; for measures see Table 6.1). This allowed for splitting the total intervention effect into one pathway where the intervention is associated with the outcome by changes in the different mediators (i.e., indirect effects) and another pathway with directly observed changes.

Figure 6.1: Flowchart

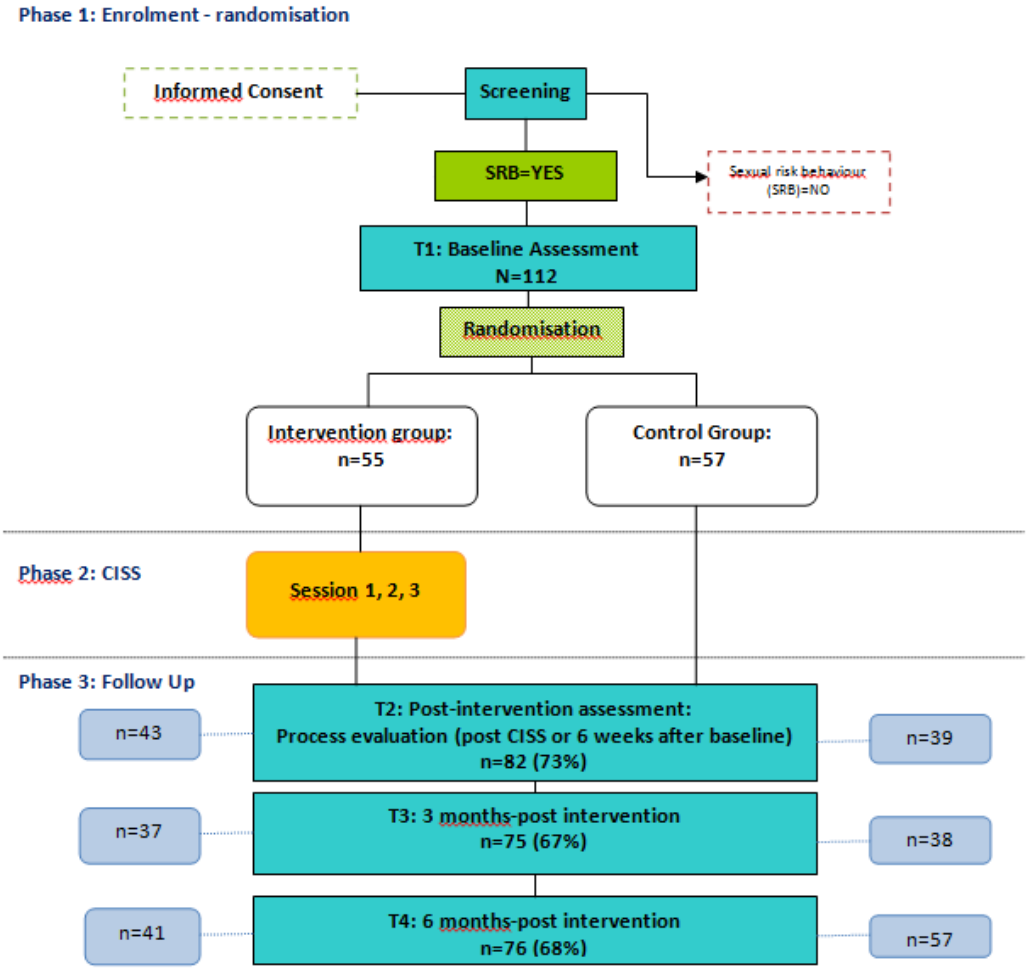

Table 6.2: HIV transmission risk score at baseline

Score indicator	*Number / category*	*Value assigned*	*Intervention group (CISS)*	*Control group*
			n (%)	*n (%)*
Number of occasions of unprotected sexual encounters with main partner with HIV-negative or unknown status	0	0	46 (85.2)	47 (83.9)
	1-6	1	4 (7.4)	4 (7.1)
	7 - 12	2	3 (5.6)	0
	> 12	3	1 (1.9)	5 (8.9)
Number of occasions of unprotected sexual encounters with casual partners with HIV-negative or unknown status	0	0	29 (54.7)	28 (50.0)
	1-6	1	16 (30.2)	18 (32.1)
	7 - 12	2	4 (7.6)	3 (5.4)
	> 12	3	4 (7.6)	7 (12.5)
Viral Load	Undetectable	0	38 (69.1)	38 (66.7)
	Unknown	1	2 (3.6)	2 (3.5)
	Detectable	3	15 (27.3)	17 (29.8)
STI diagnosis reported (past 3 months)	No	0	36 (65.5)	32 (56.1)
	Unknown	0.5	2 (3.6)	3 (5.3)
	Yes	1	17 (30.9)	22 (38.6)
Total Score: median (Q1; Q3)	Range: 0-10	0 – 10	1 (0; 3.5)	1 (0; 3.0)

Results

Descriptive Analysis

As displayed in Figure 6.1, we enrolled a total of 112 MSM across eight study sites, which was lower than the calculated sample size. Fifty-five men (49%) were assigned to the CISS group, and 57 men (51%) to the control group. Eighty-two men (73%) filled in the post intervention process evaluation questionnaire. At the 3 and 6 months follow-up, 75 (67%) and 76 men (68%), respectively, were retained in the study. Thirty-six men (32%) were lost to follow-up at the six months follow-up assessment; they were comparable with those retained with respect to the variables “intervention group,” “having a partner,” “health status,” “viral load,” “stress,” “anxiety,” “depression,” and “transmission risk score” at baseline, suggesting a non-differential drop-out.

At baseline, participants in the intervention- and control group were compared for socio-demographic, health-related and psychological variables, HIV disclosure, and the different outcome variables including the indicators that were used for computing the HIV transmission risk score (see Table 6.2). Rates of condomless sex at last intercourse with all partner types were 65% and 70%, respectively, for CISS and control group participants (see Table 6.3). Median age of the participants in the CISS group at baseline was 40 years (interquartile range 32–47), and in the control group 42 years (interquartile range 33–45).

Table 6.3: Baseline differences for selected variables between participants in intervention group and control group (n = 112)

Variable assessed	*Intervention group (CISS)*	*Control group*
	n (%)	*n (%)*
Relationship status		
Single	29 (52.7)	32 (56.1)
With a male partner	26 (47.3)	23 (40.4)
With a female partner	0 (0.0)	2 (3.5)
Education		
Lower secondary (9 years education)	2 (3.6)	7 (12.3)
Higher secondary (12 years education)	17 (30.9)	11 (19.3)
Apprenticeship	11 (20.0)	13 (22.8)
Higher education (university/college)	25 (45.5)	26 (45.6)
Employment status		
Unemployed	18 (32.7)	21 (36.8)
Employed	37 (67.3)	36 (63.2)
Under influence of alcohol when having sex		
(Almost) always	3 (5.5)	6 (10.5)
Sometimes	19 (34.6)	22 (38.6)
(Almost) never	33 (60.0)	29 (50.9)
Under influence of drugs when having sex		
(Almost) always	7 (12.7)	3 (5.3)
Sometimes	8 (14.6)	14 (24.6)
(Almost) never	40 (72.7)	40 (70.2)
No physical HIV-related complaints	32 (58.2)	39 (68.4)
On antiretroviral treatment	46 (83.6)	49 (86.0)
HIV-disclosure to main partner	24 (88.9)	20 (90.9)
HIV-disclosure to casual partners		
(Almost) all of them	13 (26.0)	13 (25.0)
Some of them	5 (10.0)	16 (30.8)
(Almost) none of them	32 (64.0)	23 (44.2)
Considering consistent condom use	31 (56.4)	27 (47.4)
Planning consistent condom use	25 (45.5)	30 (52.6)
Condom use at last intercourse	19 (34.5)	17 (29.8)
Transmission risk score (median + IQR) *	1 (0 – 3.5)	1 (0 – 3)
Lowered transmission risk	34 (65.4)	32 (58.2)

* IQR, interquartile range

Intervention Effect

Table 6.4 provides an overview of the odds ratio (OR) at the different follow-up assessments compared with baseline of reported condom use at last intercourse, and of low transmission risk. For the transmission risk score, mean change from baseline is shown.

Participants from both groups had improved at three months follow-up compared to baseline, but CISS-participants were more likely than controls to report condom use at last intercourse [i.e., yielding an OR of 3.83 between CISS and control participants; 95% confidence interval (CI): 1.15 to 12.76]. This difference was statistically significant (p = 0.03). Six months after the intervention, the OR of protected sex was 2.15; 95% CI: 0.69 to 6.78), which was not significant (p = 0.19).

The proportions of men using a condom at last intercourse were 35% (n = 19; 95% CI: 23% to 48%) at baseline in the CISS group and 30% (n = 17; 95% CI: 20% to 43%) in the control group (data not shown in table). This increased to 68% (n = 25; 95% CI: 51% to 80%) and 45% (n = 17; 95% CI: 30% to 60%) respectively at the three months follow-up assessment. At the six months follow-up assessment, it dropped to 66% (n = 27; 95% CI: 51% to 78%) for CISS participants, whereas among controls the rate was 49% (n = 17; 95% CI: 33% to 64%).

Table 6.4: Risk difference between intervention and control group at three and six months follow-up assessments for three outcome measures

Characteristic	*Intervention group (CISS)*		*Control group*		
	Estimate	*95% CI*	*Estimate*	*95% CI*	*p-value*
	%	*%*	*%*	*%*	
Three months follow-up					
Condom use at last intercourse, both partners (OR)	6.77	2.48, 18.52	1.77	0.72, 4.32	0.03*
Transmission risk score (mean difference)	-1.19	-1.80, -0.57	-0.68	-1.27, -0.09	0.20
Low HIV transmission risk (OR)	11.53	2.58, 51.52	1.28	0.50, 3.28	0.008*
Six months follow-up					
Condom use at last intercourse, both partners (OR)	5.46	2.16, 13.79	2.53	0.98, 6.52	0.19
Transmission risk score (mean difference)	-0.67	-1.25, -0.09	-0.51	-1.14, 0.12	0.70
Low HIV transmission risk (OR)	1.64	0.64,4.22	1.25	0.47, 3.36	0.67

* significant difference between intervention and control group (p < 0.05)

We also compared the two groups with respect to the outcome measure HIV transmission risk score. We observed no significant intervention effect on the score three months post intervention (difference in mean change from baseline of 20.51; 95% CI: 1.29 to 0.28; $p = 0.20$). Likewise, the difference observed at the six months follow-up assessment was not significant (difference in mean change from baseline of 20.16; 95% CI: 0.94 to 0.63; $p = 0.70$)(see Appendix 6).

Using "lower transmission risk" as outcome variable yielded a significant difference between the two groups, three months after the intervention. The OR of success at three months compared with baseline was 1.28 in the control group and 11.53 in the CISS group (ratio of ORs 9.01, CI: 1.78 to 45.71; $p = 0.008$). This effect became nonsignificant at the six months follow-up assessment (ratio of ORs 1.31, CI: 0.38 to 4.54; $p = 0.67$).

Exploration of the Intervention Effect Using Mediation Analysis

We explored the significant intervention effect for condom use at last intercourse at three months post intervention. Mediation analysis was used to divide the total intervention effect into a direct intervention effect (i.e., not mediated by improvements on the proximal variables), and indirect effects through changes in the mediator. Comparing CISS with control group participants, the average increase in self-efficacy was 6.36, in attitudes 3.12, and in depression 2.34.

Improved self-efficacy accounted for 43% of the total effect ($p = 0.02$), whereas favorable changes in attitudes towards condom use accounted for 22% ($p = 0.16$). Improvements on negative mood states did not mediate the intervention effect; only 2% of the overall effect was explained by changes in depressive mood states ($p = 0.71$)(see Appendix 7).

Discussion

This brief computer-assisted safer sex intervention for HIV-positive MSM showed short-term effectiveness at three months post intervention in increasing condom use at last intercourse and in increasing the proportion of men with lower HIV transmission risk. This was mainly explained by an improvement in participants' self-efficacy to negotiate condom use, on which the intervention had a positive effect. Our results add to a growing body of evidence on effective computer-assisted interventions delivered by health care providers to support risk reduction in HIV-positive patients (Bachmann et al., 2013).

In the treatment as prevention-era for PLHIV, safer sex encompasses more than just condom use, as HIV-positive MSM employ a variety of harm reduction strategies (Gupta et al., 2013). Although the tailored CISS approach can be used for working on different aspects of safer sex, we measured condom use as the primary outcome of this study. The difference in risk detected between

the two groups was roughly as expected, i.e., 23% for condom use at last intercourse (at the three months follow-up). However, condom use also improved over time for the controls. The fact that all participants were motivated to work on safer sex, independent of which group they were allocated to, may have influenced the outcome behavior. Many studies have shown that sustaining safer sexual behavior over time is challenging (Coates et al., 2008). In our study, the difference in condom use rates (at last intercourse) dropped from 23% difference achieved at the three months follow-up to 17% difference at the six months follow-up assessment, which is an almost comparable effect in the range of the 20% difference expected. The CISS concluded with an individualized risk reduction plan in session three. There was no follow-up opportunity for participants to assess its usefulness in real life with their counselors. A reinforcing booster session to evaluate and adapt the personalized risk reduction plan if needed, could potentially contribute to sustaining behavior change. Although the added value of adding such a booster session has been documented elsewhere (Koblin, Chesney, Coates, & EXPLORE Study Team, 2004), future research should determine if it could also improve the CISS effectiveness.

A review of computer-based interventions found similar efficacy levels as interventions delivered by service providers (Noar, Black, & Pierce, 2009), with rather small effect sizes for condom use. All but two interventions included in this review had follow-up periods of six months or less. Because no meta-analytic reviews for computer-assisted interventions delivered in HIV care exist, we compare our findings with single studies using similar approaches. Our results compare favorably with recent studies combining counselor-facilitated interventions with computer messaging, which were successful in reducing both the rate of condomless sexual encounters and the number of sexual partners (Bachmann et al., 2013; Carpenter et al., 2010).

The mediation analysis showed that the proximal variables, self-efficacy and —to a lesser extent—attitudes partially mediated the intervention effect, as has been shown in other domains of health behavior (DiIorio, McCarty, & Denzmore, 2006); for instance, interpersonal communication in mass media campaigns for smoking cessation (Southwell & Yzer, 2007; van den Putte, Yzer, Southwell, de Bruijn, & Willemsen, 2011). This confirms the importance of self-efficacy and attitudes as mediators of condom use, as found in other research (Bandura, 1997; Jemmott III et al., 2015; O'Leary et al., 2005). Because they can successfully be modified through tailored counseling strategies, they can be seen as potent intervention components. The CISS provided opportunities for increasing self-efficacy through role-modeling and adequate counselor feedback, and setting up step-wise behavioral goals. Because the CISS was not designed to reduce depressive symptoms in HIV-positive people, the small intervention effect explained through an observed change in depressive mood seems reasonable.

Study Limitations

Study participation was voluntary and motivation was an inclusion criterion. Self-reported outcome data may potentially be biased, e.g., because of under-reporting sexual risk behavior or false assumptions about partner's HIV status. Randomization was not blinded, which lies in the nature of the intervention. The overall number of HIV-positive MSM screened was not registered, therefore, we can neither compare participants with nonparticipants nor assess the reasons for declining participation. More importantly, we could not recruit the desired number of participants, resulting in reduced power. Barriers to recruitment related to both the individual level (e.g., motivation, fear to discuss problems with condom use in HIV care settings) and structural issues (e.g., legal barriers in countries where HIV transmission can be legally prosecuted, HIV-stigma). As observed elsewhere, even individual-focused interventions face challenges in addressing multilevel factors (Kaufman, Cornish, Zimmerman, & Johnson, 2014). Loss-to-follow-up can be a source of bias, especially if participants who return differ from those who drop out, but this was not the case in our study. Our retention rates (67% at the three months and 68% at the six months follow-up) are within an acceptable range for prospective studies (Eaton, Kalichman, O'Connell, & Karchner, 2009). Nevertheless, difficulties to recruit and, to a lesser degree, to retain patients in the study make generalization of the study results difficult. The transmission risk score represents an approach to measure outcome reflecting the complexity of risk reduction strategies in line with current harm reduction practices (Kamb et al., 1998). It could represent an important addition to using a simple measure of epidemiological risk (i.e., any act of condomless sex)(Golub, 2014), but the score needs validation in future research.

Clinical Implications

Model predictions have shown that in the long run, the positive impact of effective cART may be outweighed by an increase in risk behavior of at least 30% for MSM (Mei, Quax, van de Vijver, Zhu, & Sloot, 2011). Therefore, in the era of biomedical prevention strategies, behavior change to increase safer sex among MSM is an important tool in combination prevention. Despite the study limitations, we conclude that our intervention was effective in the short-term in changing some of the factors influencing safer sexual behaviors (i.e., attitudes and self-efficacy) and thereby improving condom use. The CISS could thus be a valuable tool for future combination prevention, particularly when integrated in regular HIV care to further reduce thresholds.

The strength of this study lies in its pan-European approach, demonstrating the intervention's effectiveness under "real-life" conditions. Because this multicenter trial included MSM from different European contexts and HIV care settings, we expect that the CISS could generally

benefit heterogeneous MSM populations in Europe despite socio-cultural differences because of its high degree of tailoring (Berg et al., 2013), which has been described as a success factor for effective interventions (Noar, Benac, & Harris, 2007). Tailoring results in prevention messages, with a higher chance to be perceived as personally relevant leading to behavior change (Petty, Barden, & Wheeler, 2002). The CISS achieves tailoring through the combination of visually appealing target-group specific computer-assisted tools, which give an important role to the counselor for guiding participants through the materials, and for creating an accepting, nonjudgmental, and empathic atmosphere. The CISS has been designed to be delivered by professionals in three sessions, however, with a minimum amount of specific training to ensure fidelity to the intervention and work with limited resources. As shown in other research, MI-counseling interventions using the right dosage of three to four sessions can indeed strengthen clients' safer sex self-efficacy (Chariyeva, Golin, Earp, & Suchindran, 2012). The DVD has been translated into an open-source online program to support positive prevention strategies in HIV care and prevention settings.

In conclusion, our computer-assisted intervention for safer sex showed short-term effectiveness. However, the intervention should be replicated in other settings, eventually investigating if booster-counseling sessions would yield a longer lasting effect.

CHAPTER 7

Sexual behavior and sexually transmitted infections among swingers: results from an online survey in Belgium

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Introduction

Western culture traditionally prescribes monogamy as the behavioral norm for heterosexual relationships (Grunt-Mejer & Campbell, 2016). Interviews among 15,162 participants in the United Kingdom during the period 2010-2012 (NATSAL-3) showed low tolerance of non-exclusivity in marriage, in 62.5% of male and 69.8% of female responders, respectively (Mercer et al., 2013). In contradiction with this finding, heterosexual men and women frequently report extradyadic sexual relations. In population-based surveys in the USA, 25.2% of males and 14.5% of females reported having had sexual intercourse with another partner while time they were in a steady relationship (Laumann, Gagnan, Michael, & Michaels, 1994). In Belgium, 23.7% of 1,637 men and women from the general population reported extradyadic sex (Buysse et al., 2013).

Despite the norm of monogamy, some couples experiment with alternative sexual lifestyles, including consensual nonmonogamy. In literature, three types of consensual nonmonogamy are distinguished: polyamory, open relationships, and swinging (Rubel & Bogaert, 2015). Polyamorous relationships are defined as the practice, belief or willingness to engage in multiple romantic and/or sexual relations with everyone's consent (Easton & Hardy, 2009; Taormino, 2008). Open relationships are relationships in which partners explicitly agree that they can have extradyadic sex (Buunk, 1980). Swinging can be defined as the practice of having extradyadic sexual relations as a couple with other swingers (Jenks, 1998). The swingers' subculture is defined by locations and venues where swingers meet their sexual partners: in clubs, and at (home) parties after contacting each other via specific websites. Swingers are perceived more negatively than polyamorists due to the merely sexual character of their nonmonogamy, in contrast with the romantic attachment with more than one person of polyamorists (Matsick, Conley, Ziegler, Moors, & Rubin, 2014).

No recent estimations of the prevalence of swinging are published. Estimations are drawn from survey results dating from the 1970s (Bartell, 1970; Cole & Spaniard, 1974; Hunt, 1974), providing estimates that between 1-2% of all married couples swing. Weiss (1983) estimated that around 4% of married couples swing. One of the major obstacles to engage in swinging that were mentioned in older research, namely 'finding people', is dramatically reduced with the increased use of Internet (Jenks, 1998).

With the above described changing norms and increased use of Internet, the question arises whether estimations of the number of swingers are still reliable.

Sexual concurrency, engaging in overlapping sexual relations involving different sexual partners (Morris & Kretzschmar, 1997), is considered to be an important risk factor for acquiring (Fenton et al., 1851; Rosenberg, Gurvey, Adler, Dunlop, & Ellen, 1999), and transmitting STI (Koumans et al., 2001; Potterat et al., 1999), even though this notion is sometimes challenged (Lurie

& Rosenthal, 2010; Sawers & Stillwaggon, 2010). Monogamy is considered to be and promoted as an effective strategy for STI prevention (Misovich, Fisher, & Fisher, 1997). Apart from the mutual monogamy (monogamy by both partners) that is a prerequisite for its effectiveness, individuals' interpretation of monogamy undermines its real-life effectiveness (Conley, Moors, Ziegler, & Karathanasis, 2012). From a behavioral perspective, both consensual nonmonogamy and nonconsensual nonmonogamy (infidelity) can be considered as sexual concurrency. However, with regards to condom use and sexually transmitted infections (STI) testing, different patterns have been described for people who adopt consensual nonmonogamy and those who report infidelity, with higher levels of condom use reported among consensual nonmonogamists (Conley et al., 2012; Lehmiller, 2015).

Despite these increased levels of condom use, a link between sexually transmitted infections (STI) and swingers has been mentioned in older research (Jenks, 1992). More recently, a series of studies on the prevalence and correlates of STI among swingers has been published by a Dutch research team from an STI-clinic (Dukers-Muijrers, Niekamp, Brouwers, & Hoebe, 2010; Niekamp, Hoebe, Spauwen, & Dukers-Muijrers, 2011; Spauwen et al., 2015; van Liere, Hoebe, Niekamp, Koedijk, & Dukers-Muijrers, 2013). In their research projects, they conclude that swingers, with an emphasis on older and frequent swingers, and swingers who engage in group sex, are vulnerable groups for STI-acquisition. Multiple drug use may facilitate risky sexual behaviors. In their STI-clinic, they found substantial numbers of swingers diagnosed with an STI, and suggested universal Chlamydia- and Gonorrhea-testing strategy for swingers.

Data on the process how couples start swinging suggest that one partner usually vocalizes his or her sexual fantasies to the other partner. After discussing these fantasies as a couple, agreements are made on the conditions under which these fantasies and desires can be fulfilled (Kimberly & Hans, 2017, published online 2015). Psychological impact of swinging on the dyadic relationship seems positive: there's no evidence that swingers differ from monogamists in terms of psychological well-being, and quality of their relationships (Rubel & Bogaert, 2015). Despite this growing body of evidence on swinging and its psychological impact (Kimberly & Hans, 2017; Rubel & Bogaert, 2015), few data are available on the swingers' sexual risk profile and the relation of swinging with STI (Lehmiller, 2015). Apart from the above mentioned concurrent sexual relations, swingers report inconsistent condom use (Spauwen et al., 2015). Swingers also report common use of party drugs (Spauwen et al., 2015), known for facilitating unsafe sex encounters (Mayer, Colfax, & Guzman, 2006). This project has therefore been designed to obtain insight in the sexual health and lifestyle of swingers and to review risk factors associated with an STI-diagnosis in the past, including gender differences. Additionally, characteristics associated with sexual risk behavior for STI-acquisition are investigated.

Methods

Participants

For this project, we aimed to reach a broad sample of swingers in Belgium. It was deliberately decided not to recruit swingers through an STI-clinic, as this may result in overrepresentation of the subgroup running with the highest sexual risk profile and swingers with STI infections. Instead the survey was advertised in swinger clubs and chat- and dating websites targeting swingers. The entire project and the survey were developed in an ongoing collaboration with stakeholders, including 23 interviewed swingers, and owners of dating websites and swinger clubs.

Visitors of the project's website who have 'multiple sexual partners, and identify as swinger' were invited to participate by completing the survey (Institute of Tropical Medicine, n.d.-b). Participants with exclusively same-sex sexual relations were excluded from the analysis.

Materials

A survey had been developed by the investigators on the basis of previously published research projects (Niekamp et al., 2011; Spauwen et al., 2015), and of information gathered in semi-structured interviews of swingers seeking medical advice for STI test or care at the outpatient department of the Institute of Tropical Medicine. A set of maximum 38 questions covered a broad array of topics including socio-demographic information, sexual health (including sexual behavior, and condom use), and HIV and STI testing experiences. Answer driven filters were used to avoid irrelevant or redundant questions. The Formsite® software was used to design the online version of the survey (Vroman Systems, n.d.).

The survey was pilot-tested in a subset of 12 volunteers from the swinger community. Filling in the complete survey took maximum five minutes for most pilot-testers.

The survey was available in Dutch, and accessible through the study website during the study period (Institute of Tropical Medicine, n.d.-b).

Party drug use was defined as: use of XTC, GHB, speed, cocaine, cannabis, ketamine, and/or poppers when swinging.

Procedure

Ethical approval had been obtained from the Institutional review board of the Institute of Tropical Medicine in Antwerp, Belgium.

A banner to advertise the project and the survey was published on six (out of eight that were approached) chat-, and dating websites targeting swingers. All of the approached swinger club

owners (10/10) volunteered to distribute business cards in their clubs to promote the study. Interested participants were directed to a website (Institute of Tropical Medicine, n.d.-b), where background information on the project was provided, and a direct link to the survey was available.

By completing the survey, respondents could win 25 x two movie tickets as an incentive for participation.

By filling in the survey, swingers implicitly consented in participation. The survey was completely anonymous, unless respondents wanted to receive information on the general results or if they wanted to win movie-tickets; then they were asked to provide an email address.

Statistical analysis

Statistical analysis was performed using IBM SPSS 22. Descriptive and univariate analyses were carried out. Chi-Square tests were used for categorical variables, independent samples *t*-test for continuous variables. Two logistic regression analyses have been performed, one with 'sexual risk behavior' (defined as 'vaginal or anal sex without condom'), and one with 'ever diagnosed with an STI' as dependent variable. Independent variables in the first analysis were gender, age, relationship status, length of swinging history, frequency and location of swinging, number of partners during swinging, same-sex swing partners, and alcohol and party drug use when swinging. For the second analysis, inconsistent condom use during vaginal and anal sex were added as independent variables. For these analyses, no theoretical model was developed. There was opted for an explorative approach, where all independent variables were kept in the model.

A significance level of 5% was applied.

Results

Between May and August 2015, 480 swingers started the survey, of whom 392 (81.6%) fully completed it. More men (n = 334; 69.6%) than women (n = 146; 30.4%) started the survey. Mean age was slightly, but not significantly, higher among male respondents, compared to their female counterparts (46.1 (SD = 9.4) vs. 43.8 (SD = 20.1) years, $t = 1.67$, $p = 0.097$). Men swing longer than women (10.2 (SD = 10.2) vs. 6.8 (SD = 6.7) years; $t = 1.97$, $p = 0.049$), and reported more partners per swing date, even though the latter difference was not statistically significant (2.1 (SD = 5.5) vs. 1.9 (SD = 1.9); $t = 0.33$, $p = 0.75$).

In table 7.1 an overview of respondents' relationship characteristics and their swinging behaviors is presented by gender.

Table 7.1: Socio-demographic information

Characteristic	*Men*	*Women*	*χ^2 (p-value)*
	n (%)	*n (%)*	
Relationship status			0.002 (0.967)
Single	43 (12.9)	19 (13.0)	
In a relationship	291 (87.1)	127 (87.0)	
Frequency of swinging			8.758 (0.013)
Occasional	34 (11.0)	9 (7.0)	
Regular	185 (59.9)	64 (49.6)	
Frequent	90 (29.1)	56 (43.4)	
Place of swinging			1.914 (0.590)
In a swinger club	56 (18.2)	29 (22.5)	
At home	87 (28.2)	31 (24.0)	
Both (club + home)	157 (51.0)	67 (51.9)	
Elsewhere	8 (2.6)	2 (1.6)	

Respondents were asked about their sexual behavior. A description of sexual practices among respondents is provided in table 7.2. For comparison reasons, percentages from population-based research in Belgium (Buysse et al., 2013), The Netherlands (de Graaf, 2012), and United Kingdom (Mercer et al., 2013) are presented in table 7.2.

Table 7.2: Sexual behavior

Characteristic	*SWING*			*Belgium (Buysse, et al., 2013)*		*The Netherlands (de Graaf, 2012)*		*United Kingdom (Mercer, et al., 2013)*	
	Men N=334	*Women N=146*	*χ^2 (p-value)*	*Men N=839*	*Women N=846*	*Men N=3,927*	*Women N=4,137*	*Men N=6,293*	*Women N=8,869*
	n (%)	*n (%)*		*%*	*%*	*%*	*%*	*%*	*%*
Engaged in oral sex	293 (97.7)	122 (96.8)	0.250 (0.617)	46.4	37.7	NA	NA	67.1	59.9
Engaged in vaginal sex	287 (95.7)	118 (93.7)	0.769 (0.380)	69.7	60.8	74.3	69.2	62.9	58.4
Engaged in anal sex	184 (61.3)	57 (45.2)	9.356 (0.002)	6.2	5.7	13.0	8.1	13.4	10.5
Same sex sexual contacts	93 (30.1)	98 (76.0)	77.873 (<0.001)	8.6	9.1	8.7	8.0	5.5	6.1

Several factors that are associated with increased risk for HIV/STI transmission were assessed. A more detailed overview of these risk factors by gender is provided in table 7.3.

Table 7.3: Risk factors for STI transmission

Risk factor (… at least sometimes) when swinging	*Men*	*Women*	*χ^2 (p-value)*
	n (%)	*n (%)*	
Inconsistent condom use when having oral sex	281 (95.9)	116 (95.1)	0.140 (0.708)
Inconsistent condom use when having vaginal sex	124 (43.2)	33 (28.0)	8.181 (0.004)
Inconsistent condom use when having anal sex	23 (12.5)	8 (14.0)	0.091 (0.762)
Being under influence of alcohol	140 (46.7)	83 (65.9)	13.122 (<0.001)
Use of party drugs	51 (17.0)	26 (20.6)	0.792 (0.374)
Diagnosed STI			
Chlamydia	26 (12.0)	19 (19.6)	3.100 (0.078)
Gonorrhea	16 (7.4)	4 (4.1)	1.207 (0.272)
Genital warts	14 (6.5)	7 (7.2)	0.058 (0.810)
Syphilis	4 (1.9)	0 (0.0)	1.820 (0.177)
HIV	0 (0.0)	0 (0.0)	n/a
Any STI	56 (25.9)	25 (25.8)	0.001 (0.997)

Three hundred and ninety-two swingers (81.7% of the total sample) provided information on STI testing history, including self-reported test results. Most of them (313; 79.8%) had been previously tested for STI, and 282 (71.9%) were tested in the previous year. An overview of the STIs they have been diagnosed with is provided in table 7.3.

Results show that inconsistent condom use was most common for oral sex, followed by vaginal sex, and anal sex. Party drug use was reported by 17% of men, and 20.6% of women (table 7.3). Overall 20.7% of participants (25.7% of those ever tested for STI) had ever been diagnosed with an STI.

Multivariate analysis

A significant regression model was found (model χ^2 (10) = 39.425; $p < 0.001$) when sexual risk behavior was used as outcome variable. Being male (OR = 1.938; $p = 0.014$), older (OR = 1.032; $p = 0.016$), and single (OR = 2.475; $p = 0.005$) were associated with sexual risk behavior. The use of drugs in a sexual context (OR = 2.051; $p = 0.009$) was a strong predictor for sexual risk behavior. Although there was an association between the frequency of swinging and an STI diagnosis in the past (OR =

1.924; p = 0.046), no significant model could be found (model χ^2 (12) = 14.292; p = 0.282) with STI diagnosis in the past.

Finally, we tested the association between both possible outcome variables, sexual risk behavior and an STI diagnosis in the past. Using a Chi-square test, there was a significant association between both variables (χ^2 = 6.47; p = 0.011).

Table 7.4: Logistical regression analysis with sexual risk and STI-diagnosis as dependent variable

Characteristic	*Sexual risk*		*Ever diagnosed with an STI*	
	OR	*β-coefficient (p-value)*	*OR*	*β-coefficient (p-value)*
Gender (female/male)	0.516	-0.662 (0.014)	0.874	-0.134 (0.757)
Age	1.032	0.031 (0.016)	0.995	-0.005 (0.861)
Relationship status (relationship/single)	0.404	-0.905 (0.005)	1.158	0.147 (0.780)
Length of swinging history	1.006	0.006 (0.448)	0.999	-0.001 (0.958)
Frequency swinging	1.233	0.209 (0.258)	1.742	0.654 (0.046)
Number of partners during swinging	1.033	0.033 (0.420)	1.020	0.020 (0.472)
Same-sex swing partners	0.987	-0.013 (0.956)	1.637	0.493 (0.183)
Location swinging	1.041	0.041 (0.745)	0.975	-0.025 (0.906)
Alcohol use	1.491	0.400 (0.069)	0.891	-0.116 (0.752)
Party drug use	2.051	0.718 (0.009)	1.369	0.314 (0.441)
Inconsistent condom use during vaginal sex	n/a	n/a	1.548	0.437 (0.246)
Inconsistent condom use during anal sex	n/a	n/a	1.772	0.572 (0.275)
Constant	0.697	-0.360 (0.712)	0.053	-2.938 (0.085)

Discussion

A convenience sample of swingers participated in this study. Participants were recruited for an online survey on sexual health. This could have led to an underrepresentation of participants with a high risk profile and fewer attention for their sexual health. This hypothesis is supported by the finding that testing rates were higher, and party drug use was lower among participants compared to participants who were recruited when they consulted the STI clinic and were interviewed during the development process of the survey.

Swingers who completed the survey reported high frequency of oral, vaginal and anal sex compared to national samples from the general population in Belgium (Buysse et al., 2013), The Netherlands (de Graaf, 2012), and United Kingdom (Mercer et al., 2013), as presented in table 7.3. These studies are difficult to compare. Study population and methodologies are different, therefore statistical tests should be applied carefully. Hence, we chose to present the main findings side by side. Nevertheless, differences are substantial. Several reasons can account for these differences: swingers might have generally higher sexual desire, could be more open for new experiences, talk more openly and honestly about sexuality and sexual fantasies, and mainly female swingers might be more likely to experience bisexual feelings compared to their counterparts from the general population.

Male and female swingers were similar regarding most aspects of their swinging behavior, such as relationship status, place of swinging, sexual behavior when swinging, and risk factors for STI-acquisition. Significant gender differences were found with regard to the frequency of swinging (women swing more frequently), engaging in anal sex (more men report this), inconsistent condom use (more prevalent among men), and same-sex swing activities (more prevalent among women). The proportion of women reporting same-sex activities was very high (76%), but consistent with other research (Spauwen et al., 2015).

In addition to inconsistent condom use when swinging, several other risk factors for acquisition of STI were reported frequently: being under influence of alcohol (52.3%), and using party drugs when swinging (XTC, and GHB, were the most commonly reported drugs, 12%, and 10% respectively). Intentional sex with different partners when being under the influence of psychoactive drugs is referred to as 'chemsex', and has been reported among men who have sex with men (MSM) in the previous years (Stuart, 2013). Chemsex is considered to play a facilitating role in the transmission of HIV and STI in a group of MSM (Bourne, Reid, Hickson, Torres-Rueda, & Weatherburn, 2015; McCall, Adams, Mason, & Williw, 2015). Future research should focus on the magnitude of this phenomenon among swingers, in order to design adequate interventions.

Sexual risk behavior was significantly associated with STI diagnosis in the past' ($\chi^2 = 6.469$, $p = 0.011$). This finding seems logical whereas sexual risk may lead to an STI, but due to the cross-sectional design this could also indicate that swingers who received an STI diagnosis in the past didn't change their behavior towards safer sex.

Chlamydia was found to be the most frequently reported STI among swinger respondents (14.4%), followed by gonorrhea (6.4%). These results are in line, although higher, with European findings among the general population, where chlamydia and gonorrhea are the most commonly diagnosed STI (European Centre for Disease Prevention and Control, 2015b, 2016). No HIV diagnoses were reported.

Overall, the proportion of swingers who reported an STI was high (25.9% of those tested, 20.7% of all respondents). This proportion is higher than in samples from general population (3.6% of respondents) in Belgium (Buysse et al., 2013). It is lower than the proportion found among swingers in The Netherlands (39%), but in the latter study, participants were recruited at an STI clinic, whereas this was deliberately avoided in the present study (Spauwen et al., 2015).

Future research with this population using validated measures of sexual behavior should be encouraged. It would be worthwhile to examine motivations for engaging in swinging, including the process of initiating a (individual) sexual fantasy into a (partnered) decision to engage in swinging, and the impact of swinging on a marital relationship.

Limitations

We cannot ensure that the sample described here is representative for the total population of swingers in Belgium. Participation bias may have played a role in enrollment in the study. The refusal rate could not be measured, because the number of swingers whose attention was drawn to the survey (through an online banner or a business card) could not be determined. Social desirability effects cannot be excluded in answering some of the questions (e.g. on illicit drug use, or explicit sexual behavior), despite offering anonymous participation. The forced entry method of all independent variables for the logistical regression analysis may reduce the stability of the predictive model. As statistical prediction models tend to be overfitted, validation of the observed model predicting sexual risk behavior in new samples of swingers is recommended.

Conclusions

Despite these limitations, the current results based on 480 swingers provide a good starting point to assess swingers' sexual lifestyle and risk for STI acquisition in Belgium. The studied group was sexually very active, compared to the general population. The reported behavior that holds serious risks for acquiring HIV/STI and self-reported STI diagnoses were high. Although a majority of respondents had found their way to STI testing, STI testing guidelines targeting swingers should be developed, addressing specific sexual behavior and drug use in a non-normative way. Lastly, untested swingers should be motivated to get tested, starting with the subpopulation identified to present a higher sexual risk profile. Strengthening the existing testing structures is crucial, and additional low-threshold testing strategies should be considered.

CHAPTER 8

General discussion

A combination prevention approach may tackle the persisting high numbers of new infections with human immune deficiency virus (HIV) in Belgium. In chapters 2 to 7, a set of research projects is presented that contribute to knowledge and practice on different levels of the combination prevention for HIV. The overarching purpose of these research projects was to improve HIV prevention by providing evidence for different stages of the combination HIV prevention, in order to (1) reach out to the people most at risk, (2) adapt to their prevention needs, and (3) evaluate HIV prevention approaches. Increasing the effectiveness of prevention, and diagnose more people unaware of their HIV infection, is crucial in reaching the first target of UNAIDS's 90-90-90 strategy (Joint United Nations Programme on HIV/AIDS, 2014).

An overview of HIV testing approaches that have been implemented during the past decade in Europe is provided in chapter 2. Huge progresses in HIV testing technologies and strategies have been made parallel to the advances in antiviral therapy. Yet, availability and access to testing differs between European countries (European Centre for Disease Prevention and Control, 2017b). In Europe (EU/EEA countries), an estimated number of 122,000 of all people living with HIV (15%) are not yet diagnosed. Of those diagnosed, nearly half (47%) are diagnosed late, defined as CD4 cell count < 350/mm³ (European Centre for Disease Prevention and Control, 2017b). Additional efforts are required to reduce the persisting high number of newly diagnosed people living with HIV in Europe and Belgium (European Centre for Disease Prevention and Control / WHO Regional Office for Europe, 2016).

HIV testing is an integral part of HIV prevention, and cannot be seen as a separate entity. It should always be embedded in a preventive approach that is designed for and by a specific population. New technologies facilitate novel HIV testing approaches, and will need to be further developed in order to increase the uptake of HIV testing among key populations. Early adoption of new technologies, and turning them into practice are crucial elements for researchers and health care providers to remain relevant and attractive for users they aim to reach.

Once people are diagnosed with HIV and linked to care, people living with HIV should receive qualitative HIV care. Health care providers should strive for high standards at all levels of HIV care to optimize people's quality of life. On an organizational level, access to services and treatment are important indicators for quality of HIV care. Quality in care also implies a supportive environment, free of discrimination, and a non-judgmental attitude and communication skills among health care providers allowing open discussions on all aspects of the lives of people living with HV, regardless of their background. Quality will improve patients' wellbeing, and satisfaction with care, leading ultimately to retention. Retention is a prerequisite for effective treatment of HIV. Treatment is a valuable outcome in HIV prevention, reflected in WHO's second 90-goal (Joint United Nations Programme on HIV/AIDS, 2014).

Satisfaction with the quality of sexual and reproductive health services in HIV care varies between European regions (Platteau et al., 2013). Differences in satisfaction between regions were observed at the level of the relationship between the patient and the health care provider, as well as at the level of the organization (Land et al., 2011; Platteau et al., 2013). Improvement of sexual and reproductive health services in HIV care should lead to a holistic approach, focused on HIV-positive people's quality of life, including a satisfying sexual health. Sexual health is an important driver for quality of life. This is also true for people living with HIV.

The sexual life of people living with HIV has changed dramatically over the years. Until the late 1990s, it was characterized by a significant reduction in sexual activity, observed in up to 31% for men and women living with HIV (Bogart et al., 2006). Later, their sex life changed again, with an observed increase of sexual activity (Bouhnik et al., 2006), which was confirmed in a survey research project among 838 European men who have sex with men living with HIV, as presented in chapter 5 (Platteau et al., 2014). Their sexual activity rose to a comparable level of sexual activity among a group of HIV-negative counterparts in the same era (Hospers et al., 2008). Higher levels of sexual activity are still accompanied by a persistent HIV-related stigma (Radcliffe et al., 2010; Smit et al., 2012). When people living with HIV experience this stigma, for instance by being rejected as sexual partner after disclosing their HIV status (Bourne et al., 2009), they may engage in risky sexual behavior (Smit et al., 2012). This can account for an increase in HIV incidence over time.

What has been done in Belgium to reduce the number of undiagnosed people living with HIV in the past decade?

Biomedical interventions in Belgium

Biomedical interventions have been dominating HIV prevention (Horton & Das, 2008). Belgian health authorities have always adapted to the most up-to-date scientific evidence for most biomedical approaches. Voluntary medical male circumcision is the only biomedical intervention described in Chapter 1 that has not structurally been implemented in Belgium. Other biomedical interventions, such as reducing mother-to-child transmission, condom availability, needle and syringe exchange programs and control and management of sexually transmitted infections (STI), have been adopted since their scientific value has been proven. Below, implementation in Belgium of the use of antiretroviral treatment (ART), and interventions on HIV testing as preventive biomedical interventions are described more detailed.

Antiretroviral treatment as prevention intervention

Treatment as prevention (starting ART shortly after diagnosis for individual and public health benefits) has been applied as soon as it was proven effective. Belgian health authorities reimbursed treatment following international guidelines since the introduction of antiretroviral treatment. Post-exposure prophylaxis (PEP) after occupational exposure has been reimbursed since it was considered effective and international guidelines were compiled. More recently, since 2009, PEP is reimbursed for people following non-occupational (sexual) exposure.

Since June 1st 2017, pre-exposure prophylaxis (PrEP) is available for persons from key populations at risk for HIV acquisition. As for now, only physicians working in HIV treatment centers are allowed to prescribe PrEP. The reduction of transmission risk of HIV among people taking PrEP has been observed (McCormack et al., 2016; Molina et al., 2015). Its effect in real world situations was acknowledged when a reduction of new HIV-diagnoses was observed and attributed to PrEP after its introduction in London. Yet, this attribution was recently contested by collaborators from a large sexual health clinic, responsible for one in four new HIV-diagnoses in London (Nwokolo et al., 2017). They argue that not only the introduction of PrEP, but the combination of PrEP with accessible and attractive services for HIV and STI testing and treatment, promotion of regular HIV testing among key populations, prescribing PEP, and rapid treatment after diagnosis with HIV account for this decrease of new diagnoses (Nwokolo et al., 2017).

Indeed, in line with the combination prevention approach, prescription of PrEP should be accompanied by regular HIV/STI testing, and support to guide behavior change towards less risky sexual behavior should be offered. Using this holistic approach, potential underlying aspects of sexual risky behavior, such as mental health issues, and drug use, could be tackled. Unfortunately, as it looks now, the focus of the legal frame in Belgium lies merely on the biomedical aspect of PrEP. Only the PrEP-medication is reimbursed, and accompanying regular testing for HIV and STI is promoted and required to receive PrEP. Yet, no psychosocial support or counseling is foreseen within the framework of reimbursement. This may give the impression that prevention consists solely of 'taking a pill', and denies the holistic vision on prevention. PrEP may prevent people from becoming HIV positive, but it doesn't support them if their risky sexual behavior is a consequence of underlying issues, such as mental health issues or drug use, which in itself might be a coping strategy for underlying issues. Another potential unintended side-effect is the reduction in condom use among people who take PrEP, accounting for an increase of other STI. Researchers from a large-scale PrEP-trial concluded that risk compensation did not occur because either no difference or a decrease in risk behavior was observed (Marcus et al., 2013). This conclusion was contested (Alaei, Paynter, Juan, & Alaei, 2016; Scott & Klausner, 2016), by reviewing results from findings observed in real-life situations. Additionally, an increase of STI could ultimately lead to the development of multi drug

resistant bacteria, as reported very recently for gonorrhea (Wi et al., 2017). As it is not yet clear in what sense HIV and STI epidemics will evolve with the introduction of PrEP, monitoring, research on its consequences are crucial. Gay activists who fought successfully for the availability for PrEP, should therefore also fight for the availability of accompanying support. To paraphrase Freddy Mercury, an icon of the gay community: "I want it all, and I want it now!"

HIV testing as prevention intervention

Despite a world-wide paradigm shift towards normalization of HIV testing, several barriers remain (Deblonde et al., 2010; Flowers, Estcourt, Sonnenberg, & Burns, 2017). Among them counselling, conceived as an essential element of the HIV testing process (World Health Organization, 2015a). Counselling may become a barrier for testing for both health care providers (European Centre for Disease Prevention and Control, 2010a) and potentially members of key populations who are recommended to take a test on a regular basis. One way to deal with this barrier is to integrate an opt-out approach. This approach implies that people are informed that HIV testing is a part of the STI testing package, and they routinely get tested unless they refuse. An opt-out strategy is less time-consuming than a traditional approach, whereas no counselling nor specific informed consent procedure is required. It should therefore only be implemented in settings where this approach is culturally and legally acceptable (European Centre for Disease Prevention and Control, 2015a). This could be the case in Belgium for a group of men who have sex with men who test regularly.

Another way of dealing with the 'barrier of counselling' is shifting HIV testing service delivery towards a more convenient and accessible model for members of key populations. Apart from free and anonymous HIV testing for key populations in three designated testing facilities in the largest Belgian cities (Brussels, Antwerp, Liège), the HIV self-test was introduced in Belgian pharmacies in December 2016. The self-test has several benefits for the users, including convenience, privacy, non-invasiveness, and easiness to use. Linkage to care is the main concern about HIV self-testing (Figueroa et al., 2015). Besides linkage to care, concerns about counseling, user error and the prolonged window period of HIV self-tests, compared to clinic-based tests need to be mentioned. Despite these concerns and disadvantages, some men who have sex with men use the HIV self-test as an additional tool for prevention.

Two consecutive HIV testing projects are presented in this work in chapter 3 and 4 (Platteau et al., 2012, 2015). The first project, called 'Testing on Location', ran between 2007 and 2011. Project collaborators collected blood samples during outreach interventions in two gay venues, one fetish bar and one bathhouse, where visitors can have sex. Collected samples were tested for HIV, Syphilis, Hepatitis B and C, and Chlamydia serologies. Participants were provided informed consent prior to participation, and received test results via standardized cell phone messages (Platteau et al., 2012).

We used our results and experiences to develop and refine the approach of our follow-up project, 'Swab2know' (presented in chapter 4). We decided to adapt the method to a web-based delivery of test results, despite high acceptance of cell phone messages among participants in the Testing on Location project. This decision was taken for two reasons: the opportunity to offer more and better tailored information, and strengthening empowerment by laying the decision when to check the result with the participant, not the health care provider. Collecting oral fluid samples instead of blood samples made the presence of a physician (which is legally obligatory during blood sampling in Belgium) unnecessary. This adaptation of the approach could only be achieved after the validation of an oral fluid test for diagnostic use, which has been executed in the laboratory of the Institute of Tropical Medicine (Fransen et al., 2013). We decided to maintain the delayed communication of test results (not using a simple/rapid test on site with immediate result) for two reasons: receiving an immediate result could become a barrier for clients of the venues, and a reactive result requires thorough counselling and support, which are hard to deliver in these venues. On top of our sample collection during outreach activities, we added a self-sampling approach where members from key populations could order sampling kits online. Both research projects provided evidence for feasibility, and acceptance . Limitations and weaknesses mainly concern workload during outreach activities and follow-up, and false reactive test results when using oral fluid samples (Platteau et al., 2012, 2015). Both approaches were successful in reaching the right people, both in the executed number of tests as in the number of newly diagnosed people with HIV or STI. The proportion of newly diagnosed HIV infections in these projects was 2.9% (Testing on Location) and 2.2% (Swab2know) respectively (Platteau et al., 2012, 2015). With these figures, both projects yielded in effectiveness and cost-effectiveness, as a level of 0.1% newly diagnosed HIV infections is usually considered as cost-effective (Sanders et al., 2005; Walensky et al., 2005).

Regarding testing as prevention intervention, additional efforts should be made to test more people unaware of their HIV infection. Innovative testing approaches by adopting the newest technology should guide the development of testing projects. Online activities, convenience and easiness to use will gain importance, and health care workers and community based organizations should follow this evolution. Experiences with our projects show that novelty attracts new users. In line with marketing strategies of other products, an HIV testing approach should be updated when (parts of) the approach are perceived outdated. Constantly adapting the testing approach to the newest technology, both digital and biomedical, is therefore key to a successful project.

Behavioral interventions in Belgium

Behavioral interventions targeting behavior change have been integrated in HIV prevention since the beginning of the epidemic. Theory-based interventions, that include participants' skills building, and delivered by trained professionals are most effective (Lorimer et al., 2013). Effective interventions should be delivered based on the envisaged group's needs and preferred lifestyles. Internet-based tools and mobile technology can also contribute to the achievement of health objectives (J. V. Bailey et al., 2012; Crepaz et al., 2006; Lopez et al., 2013; Noar, 2011; World Health Organization, 2011; Zule et al., 2013). Behavioral interventions appealing to key populations are time consuming to develop and implement in a rapidly evolving technological era. Behavioral interventions tend to be overshadowed by a predominant emphasis on biomedical prevention (of which PrEP is the newest innovative exponent) among both communities and health care professionals. Yet, behavior change remains an additional and sustainable tool in effective HIV prevention. Compared to biomedical interventions, they are less dependent on compliance, price of drugs, and medical follow-up.

Counselling is integrated in the management of HIV in Belgium. People living with HIV receive multidisciplinary support provided in designated treatment centers (Aids Reference Center, ARC). This multidisciplinary approach is financially supported by Belgian health authorities and consists of social and psychological support, sexual health advice, therapy counseling, and dietary advise. This implies that people living with HIV in follow-up in one of these centers can benefit for free from multidisciplinary follow-up.

Apart from this routine support, project-based counselling interventions have been evaluated in order to improve quality of life, and a safer sex life of people with HIV. In chapter 6, results from a computerized intervention for safer sex (CISS) are presented. This European multicenter, simple-randomized parallel group study evaluated condom use among men who have sex with men living with HIV. Men were assigned to a specifically designed, client driven, counsellor guided counselling intervention using a DVD, or a control condition offering local standard sexual health care. By using a DVD, we could include learning methods such as modelling. Yet, the use of a DVD was (for some users) not appealing enough. An online tool would have been more appealing, but slow Internet connections in some participating countries complicated its implementation. Three months after completion of the intervention, condom use among participants who received the intervention was higher, compared to participants from the control group. The protective effect could not be maintained up to six months after the intervention. Booster counselling sessions could potentially improve the consolidation of condom use over time (Nöstlinger et al., 2015, 2016).

Structural interventions in Belgium

Structural interventions aim to change physical, legal and social circumstances in which individual behavior takes place. They may aim to remove barriers to protective action or to create constraints to behavior that include risk for HIV acquisition (Joint United Nations Programme on HIV/AIDS, 2015).

Structural HIV prevention interventions are effectively implemented in Belgium conform the standard of the WHO (World Health Organization, 2015b). Since 2002, a law on gender equality, the prohibition to discriminate on the basis of gender, culture, religion or sexual orientation is implemented. Same-sex marriage is legalized since 2003. Compared to other European countries, Belgian situation is among the most tolerant for lesbian, gay, bisexual and transsexual (LGBT) communities (ILGA Europe, 2016). Theoretically, this would imply that less profit can be gained in this field. In reality, the situation is more nuanced. Despite existing regulation in Belgium, gay, bisexual and transgender men and women experience negative reactions, and even homophobic violence. Sensitization, and legislation to safeguard rights of each individual remain a crucial first step. Turning legislation into daily practice is an equally relevant second step. Therefore, regulation and the surveillance of compliance of this regulation in order to eradicate stigma (including self-stigma) and discrimination are cornerstones of structural prevention efforts.

Identifying unrecognized key populations in order to improve the HIV and STI prevention can also be considered as a structural intervention. A research project to assess swingers' risk for HIV and STI acquisition has been carried out and is presented in chapter 7 (Platteau et al., 2016). In this study, we assessed sexual health and lifestyle of swingers and reviewed risk factors associated with sexual risky behavior and STI diagnoses in the past. Results from our online survey among 472 swingers demonstrated that up to date, there are no indications that HIV is an issue yet among swingers (Platteau et al., 2016). However, our results confirm previous findings of multiple sexual partnerships, inconsistent condom use, and substance use in a sexual context (Platteau et al., 2016; Spauwen et al., 2015). Taking into account these findings, swingers are considered to be at risk for acquiring STI (Platteau et al., 2016; Spauwen et al., 2015). It is therefore important to monitor this group and offer tailored services to prevent an increase of STI and the emergence of HIV among swingers. There's need to find a balance between not problematizing the current situation, and avoiding regret, caused by waiting until the situation might become problematic ('If we had reacted earlier, this wouldn't have happened').

To get a more detailed insight of swingers' existing needs in sexual health care, we executed a follow-up qualitative research project, interviewing 40 swingers in depth about their sexual health (unpublished data). An important finding is that swingers sense a societal taboo on swinging. This

taboo prevents them from discussing their sexual health, including STI testing, with other swingers, and health care providers. It also raises barriers and concerns that are similar to other key populations: (1) a perceived low risk of STI acquisition, (2) swingers' relation with health care providers, and related stigma, and (3) accessibility of integrated sexual health care services. Informing and sensitizing swingers in an appealing way (social media), and improving availability of reliable information may meet the first issue. The second issue may be tackled by training health care providers to openly discuss sexual health needs and issues. To meet the third issue, we established a 'swinger consultation' where swingers can consult a counsellor for counselling and HIV/STI testing, and sensitized our physicians in the HIV clinic to discuss sexual behavior with swingers in an open and non-judgmental way by informing them about the swinging lifestyle.

What can additionally be done in testing to reduce the number of undiagnosed people living with HIV?

Despite many preventive efforts to reach out to the groups at highest risk for HIV acquisition, numbers of newly diagnosed HIV-positive people remain high. Four aspects may be helpful to tackle the persisting high numbers of new HIV diagnoses in Belgium.

Better identification of the key populations driving the HIV epidemic in Belgium

Do we sufficiently know the groups at highest risk for HIV acquisition? Or those driving the epidemic? Do we not succeed in testing them, or testing them enough? This would make them a subpopulation that is not identified (enough), and reached sufficiently with current HIV testing programs. Or is it a different population? This knowledge would help to develop effective and cost-effective strategies to test, diagnose and link to care the hidden epidemic.

The need to implement existing international evidence and recommendations

Community based testing is proven to be effective and cost-effective (Perelman et al., 2016; Schmidt et al., 2017). Community based centers diagnosed one in four new HIV-positive people in London (Dean Street; Nwokolo et al., 2017) and 36.3% of new HIV-infections in Catalonia between 2009 and 2011 (Checkpoint Barcelona; Meulbroek et al., 2013). Community based testing in its most narrow definition (peer-driven voluntary counselling and testing) is implemented throughout Europe, but not in Belgium (Schmidt et al., 2017). A new legal framework that authorizes non-medical staff to execute (community based) testing is expected in 2017. This framework would allow to implement community based testing activities in Belgium.

Anonymized online partner notification is a tool to reach out to those at risk for acquiring HIV and STI. It seems crucial to integrate this tool in the national prevention toolbox in a structured way. Even though there's 'not enough' to 'moderate' evidence of its effectiveness due to a lack of scientific studies (Down et al., 2012; Strömdahl et al., 2015; Woodward et al., 2010; World Health Organization, 2016), the European Centre for Disease Prevention and Control (2015a) recommends, and The World Health Organization (World Health Organization, 2016) even strongly recommends voluntary and anonymous partner notification for HIV. To achieve a successful implementation of partner notification, sensitization of key populations about the importance and relevance of partner notification is required in Belgium. Developing a tool to facilitate partner notification is essential, but unless the tool is (widely) used by the community, it will not fulfill its preventive potential. Bearing this need in mind, we are currently developing a website for anonymous voluntary partner notification for HIV and STI in collaboration with prevention and community organizations. In order to send anonymous emails or cell phone messages, a person diagnosed with HIV/STI will receive a code from his treating health care provider. Using this unique code, he can notify sexual partners by sending anonymous emails or cell phone messages via the website. Subsequently, access and availability of an HIV test is crucial for notified partners.

Study and response to new trends

For some men who have sex with men, safer sex remains a challenge, and they keep engaging in unsafe sexual behavior. For these men, PrEP is very beneficial as (biomedical) HIV prevention intervention.

Chemsex, 'the use of drugs before or during planned sexual activity to sustain, enhance, disinhibit or facilitate the experience' (HM Government, 2017) has been described in recent years (Kirby & Thornber-Dunwell, 2013; Stuart, 2013). Engaging in chemsex seems increasing among subgroups and populations, such as men who have sex with men and swingers. Several studies report substantial proportions of men who have sex with men who engage in chemsex, as well as its association with condomless sex, post-exposure prophylaxis in the past, more sexual partners and STI acquisition (Hegazi et al., 2017; J. Sewell et al., 2017). Little is known about potential underlying issues, such as coping behavior, personality characteristics or mental health issues (Bourne & Weatherburn, 2017). Therefore, fully adequate support cannot be provided.

The question rises whether people who take PrEP and those who engage in chemsex are the same people? And are those people the ones who previously took post-exposure prophylaxis? This would potentially imply that there's a group with a 'high risk lifestyle'. Additional research is needed to gain a better insight in the relation between these trends. This research should result in a more

qualitative care tackling issues leading to the risky behavior by coping via chemsex or PrEP. Designated or specialized centers should be established in order to support these people in an optimal way. This includes an open, non-judgmental approach toward people who engage in high-risk sexual behavior.

HIV testing has been considered as a prevention tool, also by users. From their perspective, it has been conceived away from a purely individualistic focus towards couple testing in recent years (Lui et al., 2017). Couple testing is facilitated by the availability of HIV self-tests. A related concept is 'partner self-testing', testing sexual partners for HIV. By some, partner self-testing is executed prior to sexual contact to decide whether or not to use a condom. Acceptability of partner self-testing is high (Pant Pai et al., 2013). 'What can couple testing add to the existing prevention toolbox?' is a relevant research question for exploration using qualitative research methods. These findings and evidence can be used to tailor prevention messages. These messages should contain minimal information on the window period, during which an HIV test result is negative while the person is actually HIV-positive (false negative test result). Although the newest HIV tests are more reliable for recent risk compared to older tests, some oral fluid tests maintain a prolonged window phase (up to three months). Being related to self-testing, a concern for partner and couple self-testing is obviously linkage to care for confirmatory testing and follow-up. Yet, the use of self-tests for couple and partner testing seem additional and promising HIV prevention tools.

Embrace computerized technologies

Computer games are ubiquitous and played by millions around the world (Entertainment Software Association, 2017). Two concepts derived from games are very promising in the field of e-Health: 'serious gaming' and 'gamification'. Gamification uses gaming elements outside of a gaming context (Fleming et al., 2016; Sardi, Idri, & Fernández-Alemán, 2017). Serious games are computer games that have the purpose to educate, train, or improve health (Lau, Smit, Fleming, & Riper, 2016). Though very promising, empirical evidence on serious gaming's effectiveness is scarce, and yield solely short-term effect (Sardi et al., 2017). Serious gaming and gamification are also introduced to support people in mental health care. A recent meta-analysis of nine studies on a variety of mental health issues showed effective reduction of disorder-related symptoms, although numbers were small (Lau et al., 2016). In the field of sexual heath, HIV and STI, some projects and trials are ongoing (Mejia et al., 2017; Mustanski et al., 2017), but no results are available to our knowledge. Gamification and serious gaming may be effective approaches, yet more evidence is required to explore their potential in adapting sexual behavior. Development of gamification and serious gaming interventions, and integration of these interventions in sexual health care require a close

collaboration between researchers, health care providers, program developers, communities, and information technologists who can turn conceptual ideas into functioning programs. The common goal of these collaborations is to effectively support people, including those who are hard to reach in a traditional, face-to-face strategy.

Key messages, recommendations and challenges

Recommendations on further research

- Gain better insight in the phenomenon of chemsex, its consequences and effective support;
- Gain insight in the use of PrEP, its consequences on safer sex behavior and effective support;
- Develop and evaluate behavioral prevention interventions that use appealing and attractive modes of intervention delivery, such as serious gaming and gamification.

Recommendations on prevention

- Establish specialized services for people who engage in chemsex to cope with this behavior and its consequences;
- Establish comprehensive services for people who use PrEP;
- Invest in behavioral interventions. Behavioral interventions may include condom use and reduction of the number of partners should, and need to be relevant and appealing, available and accessible;

Recommendations on policy

- Secure the rights of key populations, even though legislation and regulation guarantee minorities' rights in Belgium. Changing societal values should compromise structural HIV prevention as little as possible. Strong commitment from both policy makers and communities remains a prerequisite to achieve this ambitious goal.
- Secure access to services through legislation (including non-traditional approaches, such as online approaches) as much as possible. Access to testing and treatment are crucial in HIV and STI management and control.

Challenges

In virtually every country where progress in prevention of ongoing HIV-infections is reported, a combined biomedical, behavioral and structural approach has been used (Joint United Nations Programme on HIV/AIDS, 2010). However, incorporating these different classes of interventions into

project design and delivery remains a challenge. There is a tendency to view technology, behavior and social factors as different entities, and even opposing approaches (Hargreaves et al., 2016). Despite these issues and limitations, it is crucial to effectively translate interventions (knowledge) into efficacious project programs and delivery to the key population (practice)(Hargreaves et al., 2016).

Final Conclusions

Many of the above mentioned elements are interconnected and should be acknowledged as tools for a highly active prevention strategy, not a stand-alone strategy. An integrated approach of tailored prevention interventions on different levels is a prerequisite for successful prevention. These prevention interventions with a holistic approach should be developed with a strong involvement and collaboration of all actors.

To increase HIV-diagnosis among the hidden epidemic, testing approaches should be offered simultaneously. The question should not be which strategy works best, but how people, primarily from key populations, who are unaware of their HIV infection can be diagnosed. Therefore, we urge communities, clinicians, academics, and policy makers to collaborate for a highly effective comprehensive testing approach.

Whereas we are convinced that testing should be facilitated as much as possible, the quality of the testing processes should be safeguarded to preserve Belgian quality standards in healthcare, with emphasis on the quality of the used materials, and the process of handling of the tests. Linkage to care remains a crucial aspect of a strategy's quality. For this purpose, a personal touch from dedicated healthcare professionals remains a prerequisite for a successful implementation strategy.

Once linked to HIV care, people should benefit from optimal HIV care. People living with HIV should be able to benefit from an accessible, integrated, responsive and flexible HIV care, provided by (a team of) health care providers who have up-to-date knowledge and technical expertise, and at the same time show a respectful attitude. By showing a respectful attitude, open discussions on all aspects of people's lives may occur, which ultimately optimize care, both in terms of satisfaction, health outcome and preventive attitudes.

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Table of abbreviations

Abbreviation	*In full*	*Chapter*
Ab	Antibody	3
Ag	Antigen	3
AIDS	Acquired Immune Deficiency Syndrome	1, 2
ARC	Aids Reference Center	8
ART	Antiretroviral Treatment	1, 4, 5, 8
As	Antistof	3
cART	Combination Antiretroviral treatment	6
CBVCT	Community Based Voluntary Counselling and Testing	2
C/EE	Central/Eastern Europe	5
CE	Conformité Européenne	2
CI	Confidence Interval	6
CISS	Computer-assisted Intervention for Safer Sex	6, 8
COBATEST	Community Based Testing	2
DASS 21	21-item scale of the Depression-Anxiety-Stress-Scales	5
DVD	Digital Video Disk	6, 8
ECDC	European Centre for Disease Prevention and Control	1, 2
EEA	European Economic Area	1, 2
ELISA	Enzyme Linked Immuno Sorbent Assay	2, 4
EMIS	European MSM Internet Survey	6
ES5	Eurosupport 5	5
ES6	Eurosupport 6	6
EU	European Union	1, 2, 5
FDA	(US) Food and Drug Administration	4
GHB	*γ*-hydroxybutyrate	7
GP	General Practitioner	2, 3
GPS	Global Positioning System	1
HAART	Highly Active Antiretroviral Treatment	3
HIV	Human immune deficiency virus	1, 2, 3, 4, 5, 6, 7, 8
HM	Her Majesty's	1, 8
IC	Informed Consent	3, 4

IgA	Immunoglobulin A	3
IgG	Immunoglobulin G	3, 4
IMB [model]	Information-Motivation-Behavioral skills [model]	6
INNO-LIA	Confirmation test for HIV by Fujirebio	3
IQR	Inter Quartile Range	5, 6
IT	Information Technology	1, 8
ITM	Institute of Tropical Medicine	3, 4
LGBT	Lesbian, gay, bisexual, transsexual	8
LGV	Lymphogranuloma Venereum	3
MI	Motivational Interviewing	6
MSM	Men who have sex with men / Men having sex with men	2, 3, 4, 5, 6, 7
NHS	National Health System (United Kingdom)	5
OR	Odds Ratio	5, 6
PEP	Post-exposure Prophylaxis	1, 8
PLHIV	People Living with HIV	5, 6
PrEP	Pre-exposure Prophylaxis	1, 8
PRP	Rapid Plasma Reagin	3
Q	Quartile	3, 6
SAM	Subsaharan African Migrants	4
SAQU	Self-administered Anonymous Questionnaire	5
SCT	Social Cognitive Theory	6
SD	Standard Deviation	3, 4, 7
SE	Southern Europe	5
SMS	Short Message Service	2
SPSS	Statistical Package for Social Sciences (IBM)	3, 4, 7
STATA	General-purpose statistical software package. Syllabic abbreviation of the words statistics and data	6
STI	Sexually Transmitted Infection	1, 3, 4, 6, 7, 8
SWING	Swingers in Gesprek	7
T	Timepoint	6
TasP	Treatment as Prevention	1
TPPA	Treponema pallidum particle agglutination assay (Serological test for Syphilis)	3

UAI	Unprotected Anal Intercourse	3
UK	United Kingdom	3, 5
UNAIDS	Joint United Nations Programme on HIV/AIDS	1, 2, 4
US/USA	United States of America	3, 7
WE	Western Europe	5
WHO	World Health Organization	1, 2, 4, 5, 6, 8
XTC	Ecstasy	7

Summary

Infections with the human immune deficiency virus (HIV) remain an important health issue. In Europe and Belgium, high numbers of new HIV diagnoses persist. Without the prospect of a cure for HIV within the coming years, prevention, early diagnosis, linkage and access to specialized care and treatment are cornerstones of the management of HIV. Effective HIV prevention has been prioritized since the beginning of the HIV epidemic. An approach with a high and sustainable impact is combination prevention. Combination prevention for HIV covers a set of prevention interventions involving three dimensions: biomedical, behavioral and structural.

The general objective of this thesis was to improve HIV prevention across all three dimensions of the HIV combination prevention concept. In the different chapters, we presented projects that aimed to provide evidence on the effectiveness of innovative prevention activities on HIV prevention. On the **biomedical** dimension, testing has been highlighted as a prevention intervention. After having provided an overview of innovation and evolution of HIV testing activities in Europe in chapter two, we presented results of two consecutive HIV testing projects in Belgium in chapters three and four. Both projects used outreach approaches for sample collection. In the second project, we added a self-sampling approach allowing people to order a sampling kit via a website. We combined collection of blood and oral fluid samples with a test executed in the laboratory and delayed communication of HIV test results using cell phone messages (chapter three) and a secured website (chapter four). Although we aimed for innovation in both projects, safeguarding quality in all aspects of the HIV testing approach was fundamental. Both testing interventions were found to be effective as 2.9% and 2.2% of participants were newly diagnosed with HIV respectively. These proportions are higher than the consensus of 0.1% newly diagnosed participants as cut-off for cost-effectiveness in HIV testing projects.

Regarding the **behavioral** dimension of HIV combination prevention, results from a survey research project were presented in chapter five. We observed a decline in sexual inactivity among a group of European men who have sex with men living with HIV since the introduction of antiretroviral treatment for HIV. This finding suggests a tendency towards normalization of the sex life of people living with HIV. This implies investment to support people living with HIV in their sexual health. In chapter six, we presented results from a project studying the effectiveness of a computer-assisted counselling intervention for safer sex for people living with HIV. This intervention was tested among a group of European men who have sex with men, and consisted of three individual counselling sessions with a trained counsellor using computer-assisted tools (including video clips and interactive slide shows) to increase condom use in sexual encounters. A significant increase in condom use was observed three months after completion of the intervention, providing evidence for

short term effectiveness. This effect could not be sustained up to six months after completion. Booster sessions may yield a longer term effect.

Structural prevention interventions aim to tackle circumstances that hinder people to practise safer sex, or make them vulnerable for HIV acquisition. In this light, identifying groups at risk for HIV acquisition may be considered as a structural prevention intervention. Using an online survey, we assessed the sexual health of a group of swingers, their risk for acquisition of HIV and sexually transmitted infections (STI), and testing experiences, as presented in chapter seven. Compared to the general population, swingers were sexually very active, and several risk factors for acquisition of HIV and STI were identified. Swingers were more likely to have been diagnosed with an STI. Although swingers found their way to existing structures for testing, strengthening these structures and providing alternative testing options should be considered.

The different projects presented in chapters two to seven provided evidence on the effectiveness of a combination approach in HIV prevention. Turning this knowledge into practice is a key element to success of prevention. Therefore, a collaboration between policy makers, program officers, health care providers, researchers and communities is required to ensure access to qualitative support and functioning programs. Improving quality and functionality may also include innovation to find appealing ways of the delivery of services and programs. Computerized technologies may attract new users, and should receive attention in research and practice. Adapting prevention to new trends, their consequences and responses, is important in effective prevention. In chapter eight, effects and responses to pre-exposure prophylaxis, chemsex and couple testing were discussed.

Combination prevention for HIV covers a range of interventions on a structural, behavioral and biomedical level. All three levels are necessary to achieve highly effective prevention. Securing rights of key populations to reduce stigma and discrimination, and safeguarding or improving access to services are crucial structural ambitions. Investment in the development and evaluation of effective behavioral interventions using appealing ways of program delivery is a challenge on the behavioral dimension. An important biomedical goal is to diagnose as many people living with HIV unaware of their status as possible by expanding HIV and STI testing approaches. Although testing for HIV is critical, linkage to care, and retention in care should be integrated in the evaluation of each testing approach. Optimizing linkage and retention requires qualitative HIV care. Quality is reflected in accessibility, and a team of professional health care providers with medical and psychological expertise who treat patients with an open and respectful attitude.

Samenvatting

Besmetting met het humaan immunodeficiëntie virus (hiv) blijft een belangrijk gezondheidsprobleem. In Europa en België blijven veel mensen met hiv gediagnosticeerd worden. Zonder het vooruitzicht op een curatieve behandeling voor hiv in de komende jaren blijven preventie, vroege diagnostiek, toeleiden naar en toegang tot gespecialiseerde zorg en behandeling hoekstenen van hiv-zorg. Effectieve hiv-preventie is een prioriteit sinds het begin van de epidemie. Een aanpak met een hoge en duurzame impact is combinatiepreventie. Combinatiepreventie voor hiv omvat een set van preventieve interventies die binnen drie dimensies passen: biomedisch, gedragsmatig en structureel.

De algemene doelstelling van deze thesis was het verbeteren van hiv preventie overheen alle drie dimensies van combinatiepreventie. In de verschillende hoofdstukken presenteerden we projecten waarmee we wetenschappelijk bewijs probeerden aan te leveren over de effectiviteit van innovatieve activiteiten binnen preventie voor hiv. Op **biomedisch** vlak werd testen als preventieve interventie uitgelicht. Nadat we in hoofdstuk twee een overzicht hebben gegeven over innovatie en evolutie van de activiteiten rond hiv testing in Europa, presenteerden we in hoofdstukken drie en vier twee opeenvolgende projecten rond hiv testing in België. In beide projecten gebruikten we een outreach aanpak om stalen te verzamelen. In het tweede project voegden we de mogelijkheid van het bestellen van een pakket via een website toe, waarna het pakket naar de deelnemers thuis werd opgestuurd. Ze namen het staal bij zichzelf af en stuurden het op naar het laboratorium. We combineerden het verzamelen van bloed- en speekselstalen met een test die in het laboratorium werd uitgevoerd waarna mensen hun testresultaat ontvingen via een sms (hoofdstuk drie) en een beveiligde website (hoofdstuk vier).
Hoewel innovatie in beide projecten op de voorgrond stond, bleef het waarborgen van kwaliteit in alle aspecten van de hiv testing strategie fundamenteel. Beide testing interventies werden effectief bevonden gezien respectievelijk 2.9% en 2.2% van de deelnemers met hiv gediagnosticeerd werden. Deze percentages liggen hoger dan de consensus van 0.1% als grens voor kosteneffectiviteit binnen hiv testing projecten.

Met betrekking tot de **gedragsmatige** dimensie van combinatiepreventie voor hiv werden de resultaten van een vragenlijstonderzoek gepresenteerd in hoofdstuk vijf. We vonden een vermindering in seksuele inactiviteit sinds de introductie van antiretrovirale behandeling voor hiv bij een groep Europese hiv-positieve mannen die seks hebben met mannen. Deze bevinding suggereert een tendens naar normalisatie van het seksleven van mensen met hiv. Dit impliceert dat geïnvesteerd moet worden in de ondersteuning en begeleiding van mensen met hiv rond hun seksuele gezondheid. In hoofdstuk zes bespraken we de resultaten van een onderzoeksproject naar

de effectiviteit van een counseling interventie bij mensen met hiv. Deze interventie werd getest bij een groep Europese mannen die seks hebben met mannen, en bestond uit drie individuele gesprekken bij een counselor waarbij gebruik gemaakt werd van computermaterialen (inclusief videoclips en interactieve diapresentaties) om condoomgebruik tijdens seksuele contacten te versterken. Een significante verhoging van condoomgebruik werd waargenomen drie maanden na het beëindigen van de interventie, wat bewijs aanlevert voor korte termijn effectiviteit. Dit effect kon niet vastgehouden worden tot zes maanden na de interventie. Booster sessies zouden een effect op langere termijn kunnen bewerkstelligen.

Structurele preventieve interventies streven ernaar omstandigheden te verbeteren die het mensen moeilijker maken om veiliger seks te hebben, of hen kwetsbaar maken om hiv op te lopen. In dit licht kan het identificeren van groepen die een verhoogd risico lopen op hiv als structurele preventie-interventie opgevat worden. Door middel van een online vragenlijst hebben we de seksuele gezondheid van een groep swingers gemeten, alsook hun risico om hiv en seksueel overdraagbare aandoeningen (soa) op te lopen en hun ervaringen met testing. De resultaten van dit onderzoek werden gepresenteerd in hoofdstuk zeven. In vergelijking met de algemene bevolking waren swingers seksueel erg actief, en konden we verschillende risicofactoren opsporen die hen kwetsbaar maken om hiv en soa op te lopen. Swingers hadden een verhoogde kans om ooit soa te hebben opgelopen in vergelijking met mensen uit de algemene bevolking. Ondanks het feit dat swingers hun weg vonden naar bestaande gezondheidsstructuren om zich te laten testen, dienen het uitbouwen van deze structuren en het aanbieden van alternatieve opties voor testen overwogen te worden.

De verschillende projecten –beschreven in hoofdstukken twee tot zeven- droegen bij tot het inzicht over de effectiviteit van een gecombineerde aanpak in hiv-preventie. Deze theoretische kennis vertalen naar de praktijk is de sleutel tot het succes van preventie. Daarom is een samenwerking tussen beleidsmakers, projectverantwoordelijken, gezondheidswerkers, onderzoekers en communities noodzakelijk om toegang tot kwalitatieve zorg en effectieve projecten te voorzien. Het verbeteren van de kwaliteit en effectiviteit kan ook door innovatieve manieren te vinden om diensten en programma's aan te bieden. Gecomputeriseerde technologieën kunnen nieuwe gebruikers aantrekken, en zouden aandacht moeten krijgen in onderzoek en de klinische praktijk. Preventie afstemmen op nieuwe trends, de gevolgen ervan en de antwoorden erop is ook een belangrijk element in effectieve preventie. In hoofdstuk acht werden effecten en respons op pre-exposure profylaxis, chemsex en koppeltesting besproken.

Combinatiepreventie voor hiv omvat een geheel aan interventies op een structureel, gedragsmatig en biomedisch niveau. Alle drie de niveaus zijn noodzakelijk om de meest effectieve preventie te bereiken. Waarborgen van rechten om stigma en discriminatie tegen te gaan, en

verzekeren of verbeteren van de toegang tot de zorg zijn cruciale ambities op een structureel niveau. Investeringen in de ontwikkeling en evaluatie van effectieve gedragsinterventies waarbij gebruik gemaakt wordt van aantrekkelijke manieren om de interventie aan te bieden is een uitdaging op het gedragsmatige niveau. Een belangrijke biomedische doelstelling is het diagnosticeren van zoveel mogelijk mensen met hiv die hun status niet kennen door een verscheidenheid aan teststrategieën voor hiv en soa aan te bieden. Hoewel testen voor hiv erg belangrijk is, moeten mensen toeleiden naar de zorg en ze blijven opvolgen en begeleiden onderdeel uitmaken van de evaluatie van elke teststrategie. Een kwalitatieve hiv-zorg is een noodzakelijke voorwaarde om dit te bereiken. Deze kwaliteit wordt bepaald door de toegankelijkheid, en door een team van gezondheidswerkers met medische en psychologische expertise die hun patiënten behandelen met een open en respectvolle attitude.

Curriculum vitae

Tom Platteau was born on the 21st of April, 1974. He's married to Sandra Van Genechten, with whom he has 4 children.

Tom completed his secondary school in 1992 in Sint-Lievenscollege in Antwerp. He obtained a bachelor degree (BSc) in (Social) Nursing in 1996. Consequently, he started working as a nurse in an elderly home for people suffering from severe dementia, and worked later as a social worker in a social service (OCMW). In 2000, he started to work at the Institute of Tropical Medicine (ITM) as social counsellor for people living with HIV. While working, he obtained a master's degree (MSc) in Mental Health Sciences at Maastricht University in 2005, and subsequently finalized a post-academic training in sexology in 2007. Since then, he works as a sexologist at ITM where people consult him for issues related to sexual health and HIV/STI. He also collaborates on the development and co-ordination of projects on HIV testing, behavior change and novel phenomena, such as chemsex and increased interest in sexual health among swingers. More recently, he started an implementation project for voluntary and online partner notification in Belgium.

Tom is involved in teaching activities for short courses and seminars organized by the department of Clinical Sciences at ITM, and is asked as lecturer in the training of nurses (Karel de Grote Hogeschool) and sexologists (Ghent University).

Tom is member of the Steering Committee of the 'HIV in Europe' initiative, and expert for the Belgian Superior Health Council (Hoge Gezondheidsraad).

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Appendices

Appendix 1: Baseline questionnaire filled in by all participants.

SWAB 2 KNOW

Take your test swab2know.be

Questionnaire

1. How old are you? ..... years old
2. What is your sex? male / female / transgender

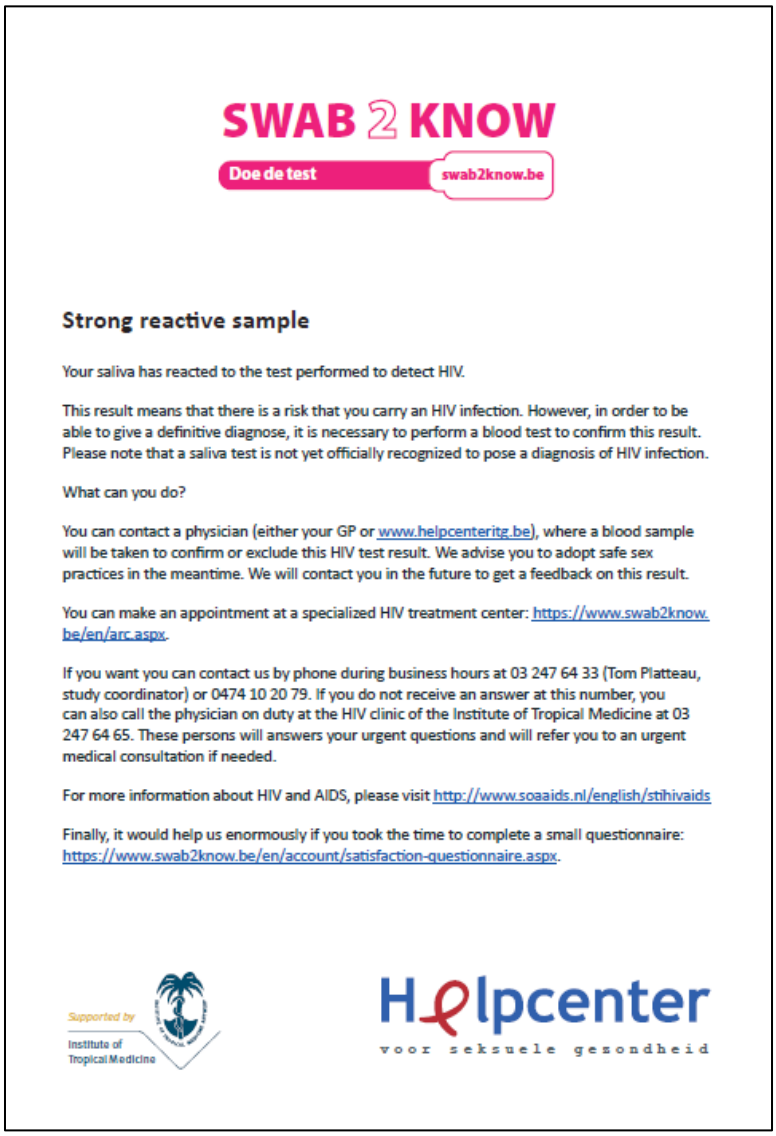
   With whom do you have sexual contacts? men / women / men and women
3. Provide your contact details. e-mail : .....@.....

   mobile phone : 04 ..... / .....
4. How would you like to receive your test result? website / consultation at Helpcenter
5. In which country do you live? .....
6. What is your country of origin? .....
7. Are you aware of your HIV-status? not aware / HIV-positive / HIV-negative.
8. When did you take your last HIV test?

   o no, this is the first time

   o yes, the latest test was around ..... months / ..... years ago
9. Do you have a family doctor? yes / no
10. During the last 3 months, how many different sexual partners did you have? .....

Appendix 2: Full message that was communicated in the case of a strong reactive test result.



SWAB 2 KNOW

Doe de test swab2know.be

Strong reactive sample

Your saliva has reacted to the test performed to detect HIV.

This result means that there is a risk that you carry an HIV infection. However, in order to be able to give a definitive diagnose, it is necessary to perform a blood test to confirm this result. Please note that a saliva test is not yet officially recognized to pose a diagnosis of HIV infection.

What can you do?

You can contact a physician (either your GP or www.helpcenteritg.be), where a blood sample will be taken to confirm or exclude this HIV test result. We advise you to adopt safe sex practices in the meantime. We will contact you in the future to get a feedback on this result.

You can make an appointment at a specialized HIV treatment center: https://www.swab2know.be/en/arc.aspx.

If you want you can contact us by phone during business hours at 03 247 64 33 (Tom Platteau, study coordinator) or 0474 10 20 79. If you do not receive an answer at this number, you can also call the physician on duty at the HIV clinic of the Institute of Tropical Medicine at 03 247 64 65. These persons will answers your urgent questions and will refer you to an urgent medical consultation if needed.

For more information about HIV and AIDS, please visit http://www.soaaids.nl/english/stihivaids

Finally, it would help us enormously if you took the time to complete a small questionnaire: https://www.swab2know.be/en/account/satisfaction-questionnaire.aspx.

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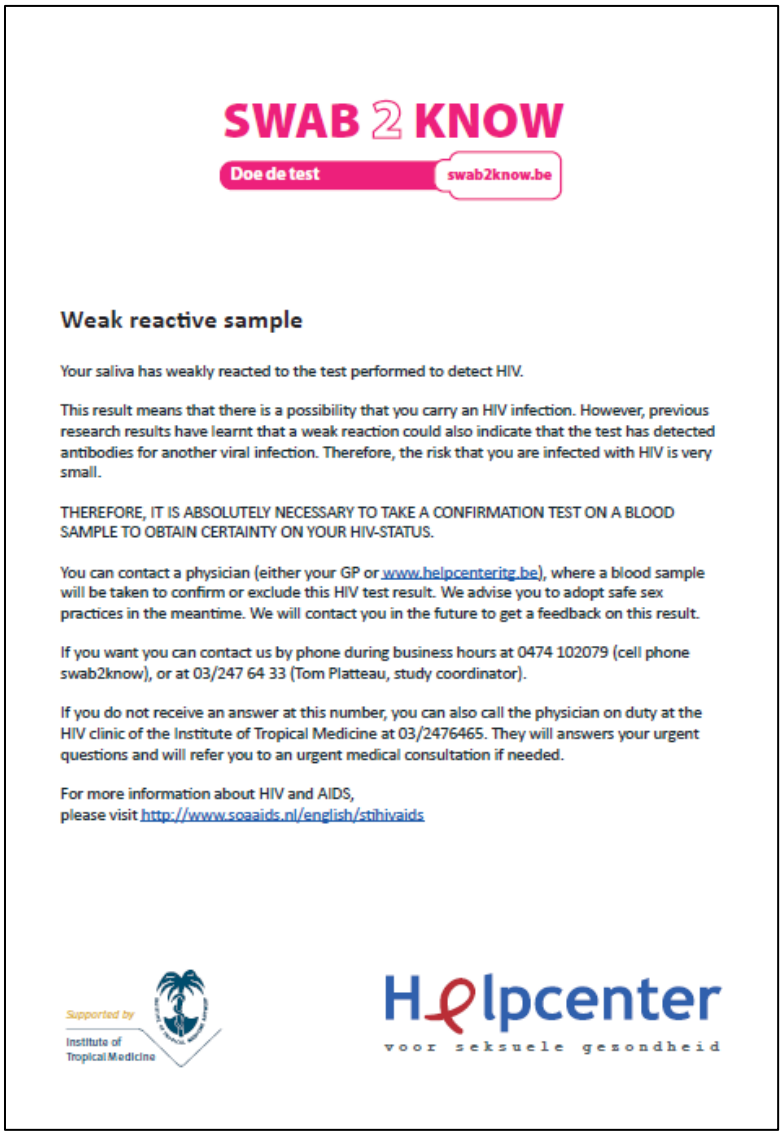
Appendix 3: Full message that was communicated in the case of a weak reactive test result.



SWAB 2 KNOW

Doe de test swab2know.be

Weak reactive sample

Your saliva has weakly reacted to the test performed to detect HIV.

This result means that there is a possibility that you carry an HIV infection. However, previous research results have learnt that a weak reaction could also indicate that the test has detected antibodies for another viral infection. Therefore, the risk that you are infected with HIV is very small.

THEREFORE, IT IS ABSOLUTELY NECESSARY TO TAKE A CONFIRMATION TEST ON A BLOOD SAMPLE TO OBTAIN CERTAINTY ON YOUR HIV-STATUS.

You can contact a physician (either your GP or www.helpcenteritg.be), where a blood sample will be taken to confirm or exclude this HIV test result. We advise you to adopt safe sex practices in the meantime. We will contact you in the future to get a feedback on this result.

If you want you can contact us by phone during business hours at 0474 102079 (cell phone swab2know), or at 03/247 64 33 (Tom Platteau, study coordinator).

If you do not receive an answer at this number, you can also call the physician on duty at the HIV clinic of the Institute of Tropical Medicine at 03/2476465. They will answers your urgent questions and will refer you to an urgent medical consultation if needed.

For more information about HIV and AIDS,
please visit http://www.soaaids.nl/english/stihivaids

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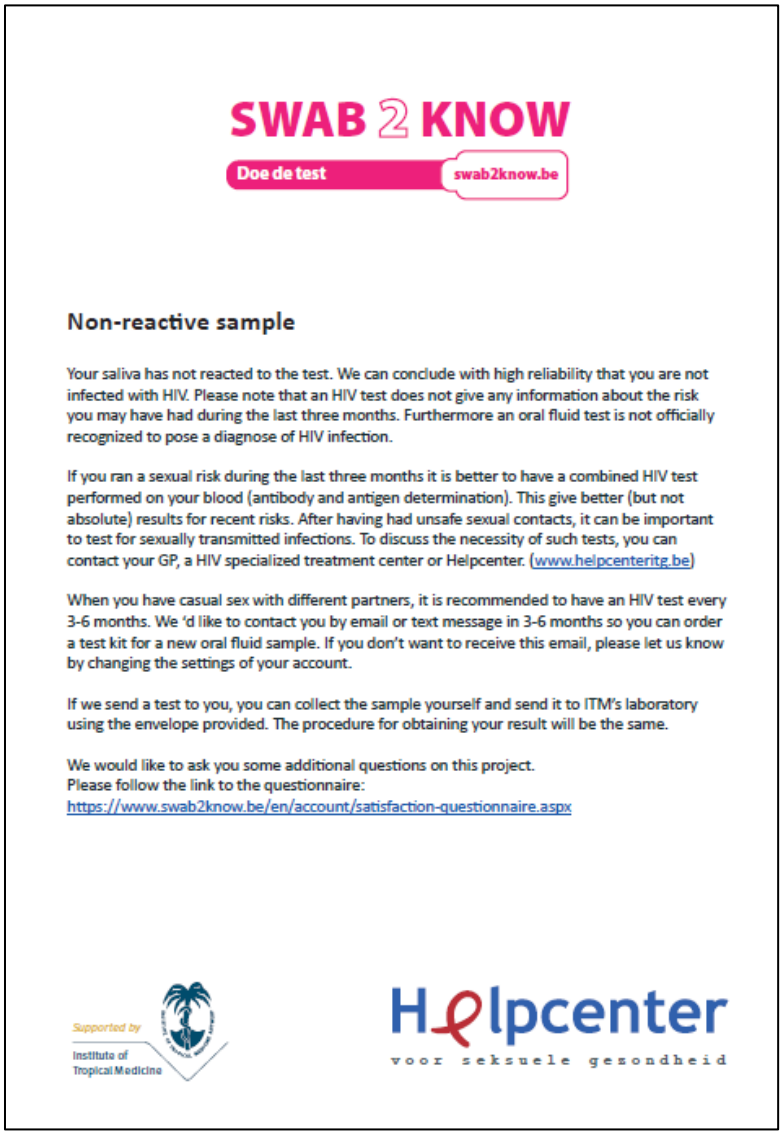
Appendix 4: Full message that was communicated in the case of a nonreactive test result.



SWAB 2 KNOW

Doe de test swab2know.be

Non-reactive sample

Your saliva has not reacted to the test. We can conclude with high reliability that you are not infected with HIV. Please note that an HIV test does not give any information about the risk you may have had during the last three months. Furthermore an oral fluid test is not officially recognized to pose a diagnose of HIV infection.

If you ran a sexual risk during the last three months it is better to have a combined HIV test performed on your blood (antibody and antigen determination). This give better (but not absolute) results for recent risks. After having had unsafe sexual contacts, it can be important to test for sexually transmitted infections. To discuss the necessity of such tests, you can contact your GP, a HIV specialized treatment center or Helpcenter. (www.helpcenteritg.be)

When you have casual sex with different partners, it is recommended to have an HIV test every 3-6 months. We 'd like to contact you by email or text message in 3-6 months so you can order a test kit for a new oral fluid sample. If you don't want to receive this email, please let us know by changing the settings of your account.

If we send a test to you, you can collect the sample yourself and send it to ITM's laboratory using the envelope provided. The procedure for obtaining your result will be the same.

We would like to ask you some additional questions on this project.
Please follow the link to the questionnaire:
https://www.swab2know.be/en/account/satisfaction-questionnaire.aspx

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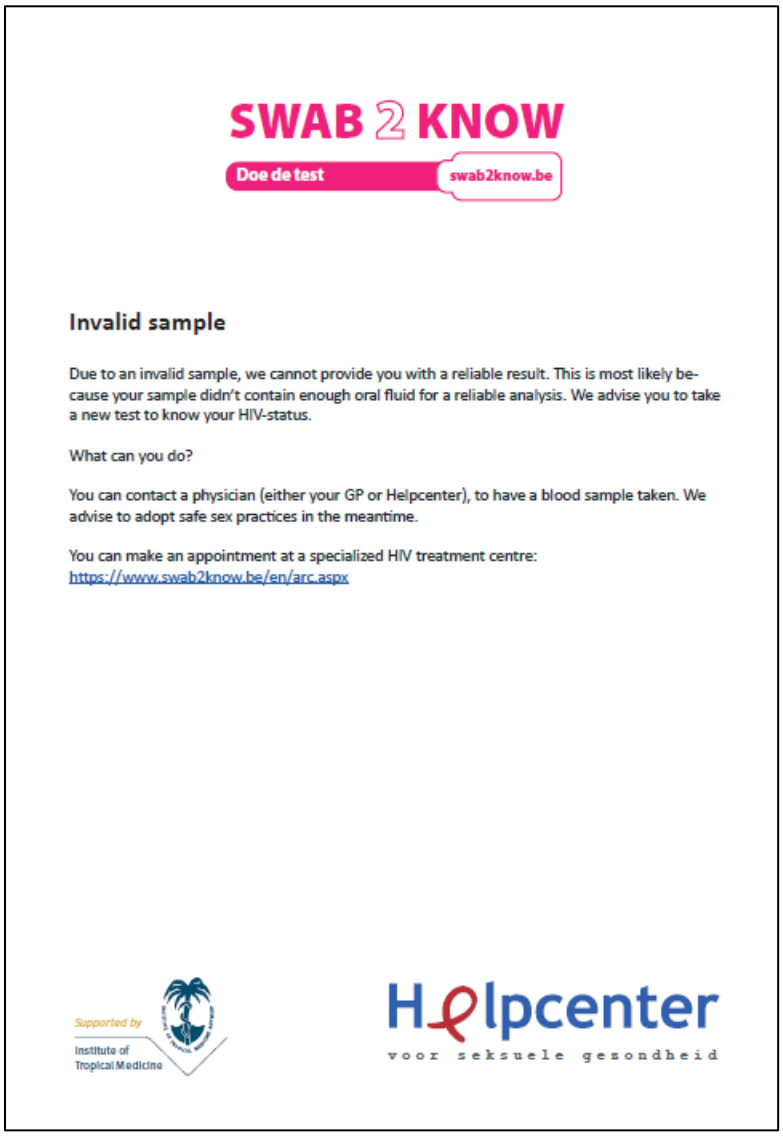
Appendix 5: Full message that was communicated in the case of an invalid test result.



SWAB 2 KNOW

Doe de test swab2know.be

Invalid sample

Due to an invalid sample, we cannot provide you with a reliable result. This is most likely because your sample didn't contain enough oral fluid for a reliable analysis. We advise you to take a new test to know your HIV-status.

What can you do?

You can contact a physician (either your GP or Helpcenter), to have a blood sample taken. We advise to adopt safe sex practices in the meantime.

You can make an appointment at a specialized HIV treatment centre:
https://www.swab2know.be/en/arc.aspx

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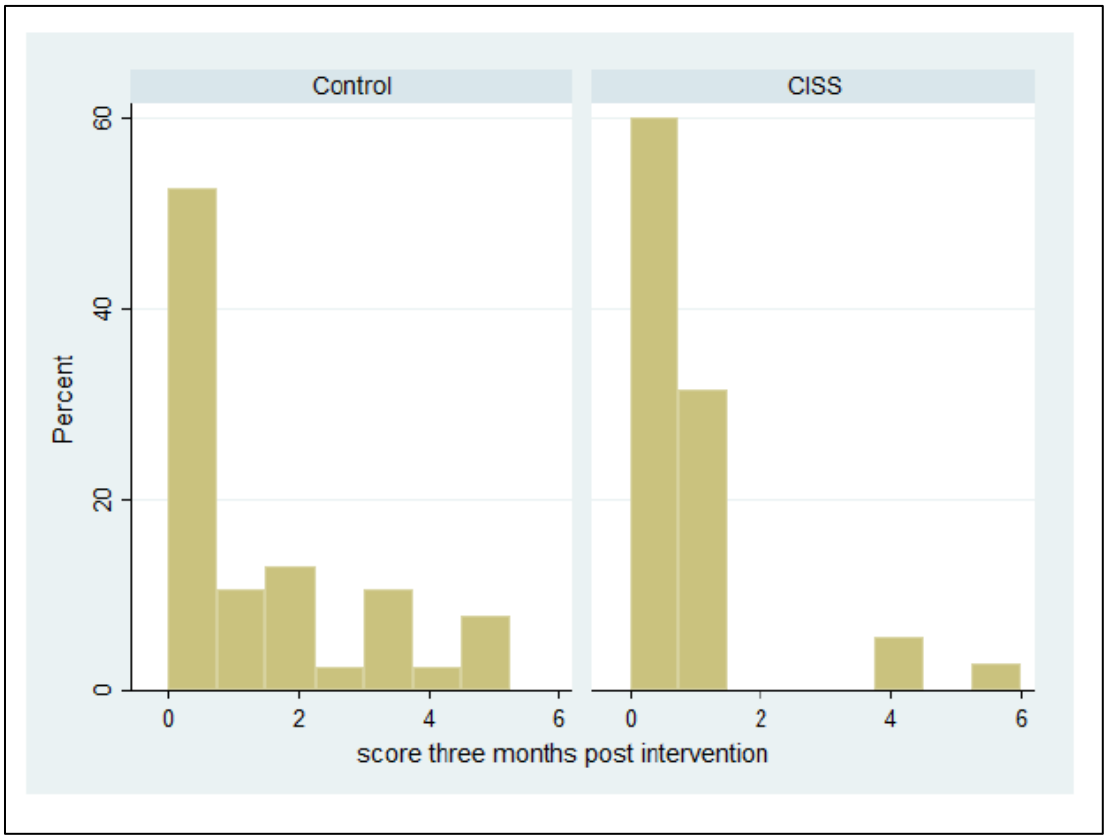
Appendix 6: Distribution of HIV transmission risk score at the three months follow-up assessment



Appendix 7: Mediation analysis