

HIV Voluntary Counseling and Testing (VCT-HIV) effectiveness for sexual risk-reduction among key populations: A systematic review and meta-analysis

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Summary

Background HIV disproportionately affects people who inject drugs, transgender people, sex workers, men who have sex with men, and incarcerated people. Recognized as key populations (KP), these groups face increased impact of HIV infection and reduced access to health assistance. In 1990, the Center for Disease Control and Prevention organized technical guidance on HIV Voluntary Counseling and Testing (VCT-HIV), with subsequent trials comparing intervention methodologies, no longer recommending this strategy. However, KP needs have not been explicitly considered.

Methods We assessed VCT-HIV effectiveness for sexual risk-reduction among KP (PROSPERO 2020 CRD42020088816). We searched Pubmed, EMBASE, Global Health, Scopus, PsycINFO, and Web of Science for peer-reviewed, controlled trials from February, 2020, to April, 2022. We screened the references list and contacted the main authors, extracted data through Covidence, applied the Cochrane Risk-of-Bias tool, and performed the meta-analysis using Review Manager.

Findings We identified 17 eligible trials, including 10,916 participants and evaluated HIV risk behaviors. When compared to baseline, VCT-HIV reduced unsafe sex frequency ($Z=5.40$; $p<0.00001$, $I^2=0\%$).

Interpretation While our meta-analysis identified VCT-HIV as protective for sexual risk behaviors for among KP, the results are limited to MSM and PWID, demonstrating the paucity of data on the other KP. Also, it highlights the importance of applying a clear VCT-HIV guideline as well as properly training the counselors.

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Keywords: HIV Voluntary Counseling and Testing (VCT-HIV); Key populations (KP); People who inject drugs (PWID); Transgender people (TW); Sex workers (SW); Men who have sex with men (MSM); Incarcerated people (IC)

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Abbreviations: FSW, Female Sex Worker; IC, Incarcerated people; KP, Key populations; MSM, Men who have sex with men; PWID, People who inject drugs; SW, Sex workers; TW, Transgender people; VCT-HIV, HIV Voluntary Counseling and Testing

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Introduction

When first implemented by the Centers for Disease Control and Prevention (CDC), HIV counseling did not have a clear guideline.^{1,2} In 1992, CDC organized technical guidance on HIV Voluntary Counseling and Testing (VCT-HIV) and started gathering data on VCT-HIV effectiveness through a trial named Project RESPECT.^{2,3} Project RESPECT was a multicentric, randomized controlled trial that compared two HIV and other STIs counseling interventions: enhanced counseling (four interactive theory-based sessions), brief counseling (two interactive risk-reduction sessions), and two control groups (didactic

Research in context

Evidence before this study

HIV Voluntary Counseling and Testing (VCT-HIV) provides counseling before and after testing aiming to promote risk reduction strategies (such as condom use and disclosure of status), to foster support (*e.g.*, peer-groups), and to guarantee linkage to care (*e.g.*, antiretroviral therapy [ART]). Pre-test counseling consists of briefly describing the benefits of testing, the meaning of results, and the possibilities in case of an HIV-positive diagnosis.

In contrast, post-test counseling varies according to the result. For those who assessed HIV-negative, post-test counseling encompasses explaining the results and the window period, teaching about HIV prevention, providing preservatives, and in some cases referring to HIV preventive services. For those who tested HIV-positive, VCT-HIV is particularly relevant: it provides support after a life-changing event. Using a client-centered approach, the counselor should assure referral to specialized care and encourage HIV-testing of sexual partners. Assessment of mental health outcomes, especially suicide ideation, must be included in the post-test counseling.

The impact of VCT-HIV on sexual risk behavior was evaluated from 1985 to 1997. Exposure to VCT-HIV diminished the frequency of unprotected intercourse and increased the frequency of condom use exclusively among HIV-positive participants and serodiscordant couples. In addition, while reducing the incidence of Sexually Transmitted Infections (STIs) among HIV-positive participants, VCT-HIV increased it among HIV-negative and untested participants. One systematic review and meta-analysis evaluated the effectiveness of VCT-HIV in modifying risk behaviors (number of sexual partners and unprotected sex) in developing countries. VCT-HIV did not affect the number of sex partners; however, being exposed to VCT-HIV reduced the odds of engaging in unprotected sex. Again, the largest impact was seen among HIV-positive individuals.

Subsequently, other reviews identified that VCT-HIV reduced the odds of reporting increased numbers of sexual partners and enhanced the odds of engaging in protected sex exclusively among HIV-positive participants. Populations particularly vulnerable to HIV infection, as the Joint United Nations Program on HIV/AIDS (UNAIDS) key populations (KP), were not considered in these reviews.

Added value of this study

The present systematic review and meta-analysis pioneers in assessing VCT-HIV effectiveness on multiple sexuality related outcomes among KP: people who inject drugs (PWID), transgender people (TW), sex workers (SW), men who have sex with men (MSM), and incarcerated people (IC). Even considering the heterogeneity, low quality, and divergent results of the included studies, currently, we recommend VCT-HIV as an evidence-based health policy among populations with a high risk of HIV infection; MSM and PWID.

Nevertheless, two potentially negative outcomes should be considered: VCT-HIV may also have a deleterious impact, given a false sense of security and enabling sexual risk behaviors right after the test result, as well as demanding counseling without properly training the counselors.

Implications of all the available evidence

In the early 21st century, VCT-HIV was an essential part of the HIV prevention spectrum. With the advancement of biomedical strategies (such as pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and highly active antiretroviral therapy (HAART)), the necessity of providing counseling along with testing was seen as delaying the implementation of biomedical strategies. Currently, counseling is considered dispensable. KP necessities were neither assessed nor considered in the decision making.

Our study points out that VCT-HIV is an effective tool to reduce HIV risk behaviors among KP (MSM and PWID). Also, it highlights the importance of applying a clear VCT-HIV guideline as well as properly training the counselors.

material).² Both interventions augmented condom use frequency and reduced STIs incidence. Although having methodological limitations (*e.g.*, not including key vulnerable groups among participants), Project RESPECT showed that short counseling intervention, using personal risk reduction plans, was capable of modifying behaviors. Easy-to-use intervention kits, based on Project RESPECT protocol, were distributed to health departments and community organizations along with specific training to counselors.

During the following years, VCT-HIV became an essential part of the HIV prevention toolkit implemented worldwide.⁴ In the 2000s, the Joint United Nations Program on HIV/AIDS (UNAIDS) highlighted the benefits of VCT-HIV, as well as the importance of identifying and understanding the particularities of specific groups.⁵ Twenty years after Project RESPECT, circumstances have changed: rapid HIV test can be offered in the most diverse contexts; biomedical prevention strategies, such as PrEP and post-exposure prophylaxis (PEP), are available and accessible; and highly active antiretroviral therapy (HAART) treatment is highly effective in reducing HIV-associated mortality. Bearing in mind the biomedical prevention strategies' enormous potential to control the HIV epidemic, and its dependence on serum status awareness.

VCT-HIV effectivity was questioned by three systematic reviews suggesting that it did not affect the sexual risk behavior of HIV-negative participants.^{4,6,7} In 2013, Project AWARE did not find statistical differences between participants receiving and not receiving counseling.⁸ Although none of the previous reviews

focused on key populations particularly vulnerable to HIV infection, CDC suspended all training based on Project RESPECT: the necessity of providing counseling along with testing was seen as delaying the implementation of biomedical strategies.³

According to UNAIDS, key populations (KP) are groups disproportionately affected by HIV infection.⁹ UNAIDS recognizes five KP: people who inject drugs (PWID), transgender people (TW), sex workers (SW), men who have sex with men (MSM), and incarcerated people (IC). Different from populations vulnerable to HIV infection, that are at risk in certain situations or contexts (for example, young women in sub-Saharan Africa), KP have an increased risk of HIV infection independently of the epidemic type or context.¹⁰ Globally, in 2020, KP and their sexual partners represented 65% of HIV infections.¹¹ More precisely, the risk of acquiring HIV was 35 times higher among PWID; 34 for TW; 26 for SW; 25 for MSM; and 5 for IC. After HIV acquisition, KP also faced a higher prevalence of pretreatment HIV drug resistance.¹² Nevertheless, historically, VCT-HIV guidelines did not consider KP' particularities, nor did the trials that marked counseling as disposable.

Given that KP face greater difficulty in accessing HIV-related health than the general population,¹³ as well as deal with a higher prevalence of mental health disorders,¹⁴ counseling may be determinant in guaranteeing linkage to care and avoiding adverse health outcomes of a HIV positive test.¹⁵ Assuming that VCT-HIV is always conducted for the same purposes, and under the same circumstances, is naive and potentially misleading. Even though VCT-HIV may not be a cost-effective alternative for populations at low risk of HIV infection, it may handle a significant reduction of sexual risk behavior within KP. Therefore, the present systematic review and meta-analysis aim to assess VCT-HIV evidence of effectiveness on multiple VCT-HIV related outcomes among KP.

Methods

Search strategy and selection criteria

For this systematic review and meta-analysis we applied four different approaches to search articles: 1- systematically searching online databases PubMed, EMBASE, Global Health, Scopus, PsycINFO, and Web of Science from January 01, 2010, to 21 April, 2022, 2- manually searching the journals Lancet HIV, AIDS, AIDS Care, AIDS Education and Prevention, AIDS and Behavior, American Journal of Public Health, Journal of Acquired Immune Deficiency Syndromes (1999), Sexually Transmitted Infections (STI), and Journal of the International AIDS Society from January 01, 2010 to 21 April, 2022, 3- manually checking the citation list of all included articles, as well as previously published meta-analysis,^{4,6,7}

and 4- contacting authors from the included articles, requesting data and references that meet the eligibility criteria (see appendix 1 for more details).

All included articles supplied data concerning VCT-HIV applied but not necessarily adapted to KP. According to UNAIDS, VCT-HIV is “the process by which an individual undergoes counseling enabling him or her to make an informed choice about being tested for HIV”.⁵ For this review, however, an operationalized concept of VCT-HIV was applied. Based on Fonner et al. (2012), VCT-HIV was defined as 1- volition for HIV testing (meaning that the participant sought the HIV test), 2- pre-test counseling, 3- being tested for HIV, and 4- post-test counseling and test results.⁴ We only included indexed peer-reviewed articles, that have been written in English and contained a comparator (*e.g.*, pre- and post-VCT-HIV, VCT versus non-VCT-HIV) and a quantitative outcome. Furthermore, exclusively studies published after 2010 were evaluated because, in 2010, the Global Health Sector Strategy on HIV/AIDS 2011–2015, aiming to optimize HIV prevention, diagnosis, treatment, and care outcomes, recommended special attention to KP.¹⁰ From then on, the term gained space in HIV/AIDS literature.

Articles that did not assess an outcome to VCT-HIV or did not show results of a direct evaluation of VCT-HIV for KP (*e.g.*, an analysis of government programs for the population as a whole) were excluded. Studies that did not provide meaningful data concerning KP were also excluded. For example, studies where KP were a part of a larger sample and, thus, were not represented independently in the results, as well as have not had their specificities considered in the study design and discussion were excluded. Furthermore, studies that had incomplete or ambiguous methods, were not a complete article (*e.g.*, poster or abstract) or were not available for download, and assessed an intervention outside the HIV-testing context (such as a risk reduction focus group) were excluded. Cross-sectional studies without control groups were excluded. Finally, cross-sectional studies in which VCT-HIV was part of a larger analysis (*e.g.* a logistic regression), among multiple other variables, without the unadjusted results were not included in the present review.

Data analysis

All references were extracted to Mendeley or EndNote software on February 05, 2020. Afterward, the search was updated twice: on November 11, 2021, and on April 4, 2022. All references from February 2020 to November 2021 and from November 2021 to April 2022 were extracted to Mendeley or EndNote. The references were uploaded to Covidence,¹⁶ online screening and data extraction tool designed for Cochrane authors. The studies' inclusion and exclusion were conducted in Covidence.

For each study, three judges (AF, LHV, or MF) independently extracted data on study characteristics (first

author, year of publication, sponsorship source, country, sample size, and setting), details about the population identification (eligibility criteria to select participants, the financial support provided to the participant, the strategy applied to identify the key population, and dropout rates), the intervention applied (study design and the VCT guideline or theoretical framework applied, as well as details on follow-up), the comparison (groups, main group differences), and the outcomes (HIV knowledge, linkage to care, and sexual behavior).

The risk of bias was assessed using the Cochrane Risk-of-Bias tool.¹⁷ More precisely, selection, performance, detection, attrition, and reporting bias were evaluated. Since the studies were mostly uninformative, the corresponding authors were contacted to explain unavailable and unclear data.

The meta-analysis was performed using Review Manager (Revman) 5.4. Mantel-Haenszel method was applied with an analysis model of random effects. The Mantel-Haenszel method is a technique that generates an estimate of the association between an exposure and an outcome after adjusting for, or taking into account, confounding factors. Heterogeneity, or Inconsistency (I^2), was calculated by combining Risk Ratio (RR), and 95% confidence intervals (CI) ($p < 0.05$) and by using the funnel and forest plot. Dichotomous and/or continuous data were extracted from each study and used for analysis to calculate RRs which were adjusted by the Mantel-Haenszel test. Low inconsistencies were assigned for values of $I^2 < 25$, intermediate $I^2 > 25$ and < 75 , and great inconsistency $I^2 > 75$. The frequency of unprotected anal and unsafe sex acts, as the most common and homogeneous outcome, before and after VCT-HIV, was used for the meta-analysis. Additionally, as we considered individually each KP, we provided both total and subtotal overall effect estimation for each analysis, named subgroup analysis in the forest plot. This can elucidate if some interventions for a KP (e.g. incarcerated people) were not as effective as in another KP (e.g. MSM) comparing heterogeneity and overall effect for each of them.

From the 7,182 references imported for screening, 1,845 duplicates were removed. The 5,337 remaining studies had their titles and abstracts screened by three independent reviewers (AF, LHV, or MF). Any discrepancy was resolved through discussion among the three reviewers (AF, LHV, and MF). After applying the inclusion criteria, the full text from 17 articles was retrieved and independently assessed for eligibility by the three independent reviewers (AF, LHV, and MF). At this point, the exclusion criteria were applied (Appendix 2 contains a list of studies excluded at the full-text screening stage, with brief reasons). Seventeen articles were included in the systematic review from sixteen different studies, including 10,916 participants. See Figure 1 for the PRISMA flow chart, Table 1 for more details on study characteristics, and Appendix 3 for the Prisma checklist.

There were five main outcomes evaluated: sexual risk behaviors ($n=14$),^{18–31} HIV incidence ($n=7$),^{18,20,21,23,24,26,32} HIV knowledge ($n=3$),^{29,33,34} social consequences of HIV status disclosure ($n=2$),^{31,33} linkage to referred facilities for HIV confirmatory testing ($n=1$),³⁴ and mental health ($n=1$).¹⁸ Only sexual risk behaviors presented comparable results. For the meta-analysis, sexual risk behaviors were classified into two groups: 1) studies that considered individuals that had, at least, one sex act versus participants that disclosed not having engaged in sexual activity (labeled as unsafe sex acts and considered as dichotomous, yes/no, variable); and 2) studies that provided the number of unprotected sex acts of a group in a period of time (labeled as the frequency of unsafe sex and used as a continuous variable). Therefore, we conducted two different meta-analyses considering unsafe sex acts (dichotomous variable) and frequency of unsafe sex (continuous variable) as outcomes. For both analyses, we used two comparators: before versus after VCT-HIV (mostly a 6 months follow-up), and brief versus standard VCT-HIV.

Role of the funding source

Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) (CNPQ/MS-DIAHV No. 24/2019) and Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) provided financial support through scholarships. The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

As described above, five main outcomes were assessed: sexual risk behaviors ($n=14$),^{18–31} HIV incidence ($n=7$),^{18,20,21,23,24,26,32} HIV knowledge ($n=3$),^{29,33,34} social consequences of HIV status disclosure ($n=2$),^{31,33} linkage to referred facilities for HIV confirmatory testing ($n=1$),³⁴ and mental health ($n=1$).¹⁸ Sexual risk behaviors were those associated with sex under the influence of a substance, unprotected sex (anal and/or vaginal), number of sex partners, HIV disclosure, and others. They were assessed by different strategies: from directly asking the number of sexual partners in the past months to inquiring specifically about the number of unprotected insertive or receptive anal sex acts with the two most recent anal sex partners. Most authors chose the direct approach by simply asking the frequency of sexual acts. In these cases, the type of sexual act questioned differed greatly between articles: insertive anal sex, receptive anal sex, anal sex in general, unprotected anal sex, anal sex with different partners, anal or vaginal sex, “unprotected anal sex and sex while drunk or high”. One study considered safe sex behavior abstaining from sex (or 100% use of condoms during vaginal or anal sex). Although the studies differed by their

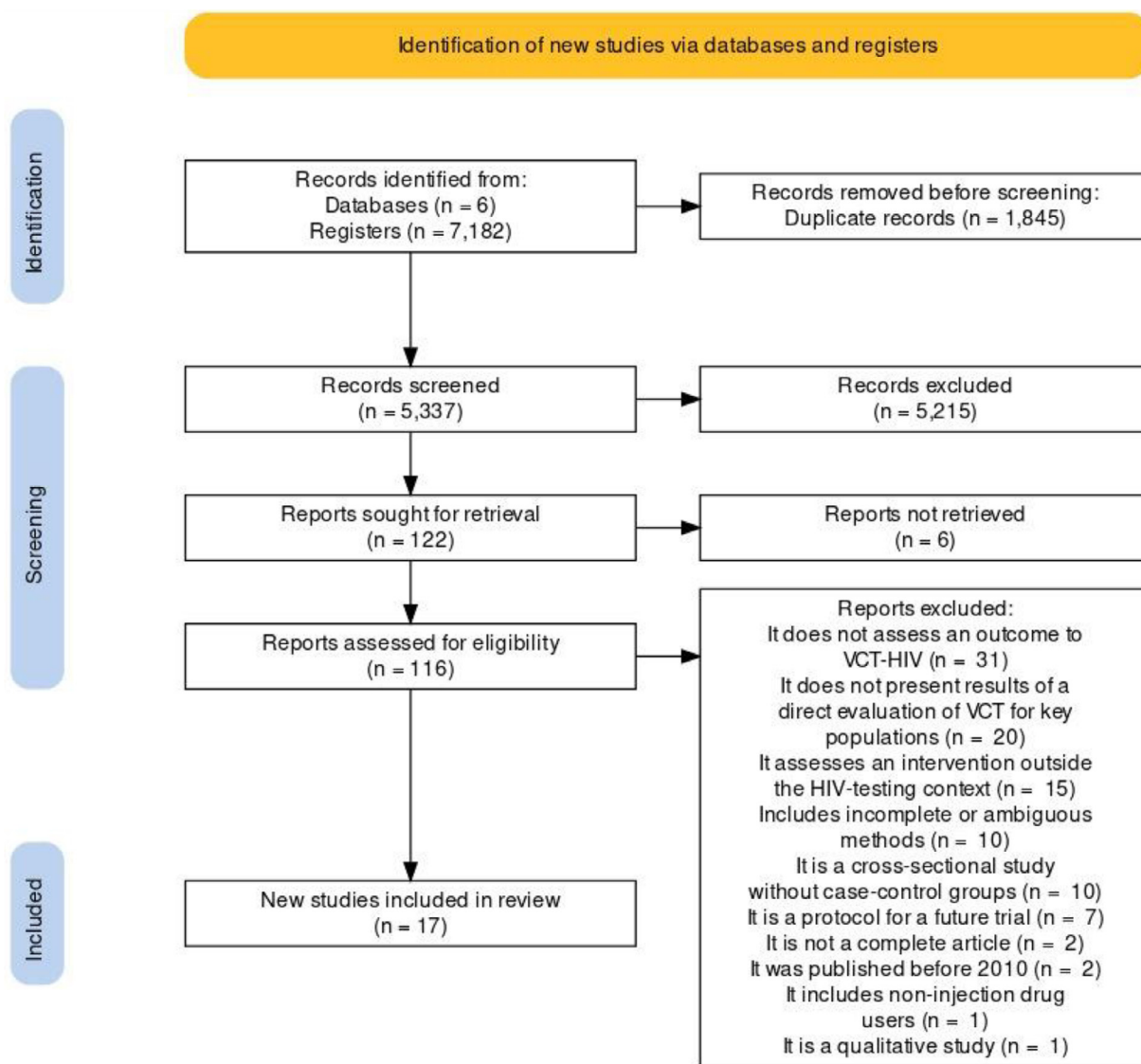


Figure 1. Study selection. PRISMA flow chart reporting studies involving voluntary counseling and testing for HIV among key populations.

Notes. PRISMA flow diagram was generated using the ShinyApp online version.

approach to the information, they divided groups in two by counting patients' sexual risk behavior by none (o) and those with at least one risk exposure (1 or more events). Other studies used frequency of risk exposure by counting the number of events for unsafe sex.

As described in Table 2, eight articles did not clarify the VCT-HIV protocol applied.^{22,23,26,29–33} From the remaining articles, five cited a specific protocol that, when consulted online, was unavailable.^{20,21,24,25,34} We contacted the authors to have access to unpublished data, which was eventually unsuccessful. Thus, only three articles used a clear and accessible VCT-HIV protocol, all based on Project RESPECT.^{18,27,28}

For most articles, the duration of each VCT-HIV session was indeterminate. Exclusively three articles provided data about it: it varied from 30 min to one and half hours each session (pre and post-test).^{22,28,29} Furthermore, the training received by the counselors was not clearly described. Only four articles referred counselors' training to a specific institution (State of California's and Project ASSERT's licensed counselors); however, precise details, such as workload, and focus on KP, were not described nor available online.^{20–22,24} It is noteworthy that none of the included articles disclosed applying protocols, and training counselors, to address KP's particularities regarding, for example, sexual behaviors, social risks of revealing

Author	Setting	Key population	Design	Recruitment	Sample Size	Drop out rate	Main outcomes measured	Main results
Aho et al. (2011)	Guinea; clinic-based.	FSW	PCS with a 12-months follow up	CS	421	47%	Social consequences of HIV status disclosure and HIV knowledge.	It is noteworthy that seronegative women were more likely to report status disclosure than seropositive women. The outcomes were not shown separately by HIV serostatus. Positive consequences of testing were far more frequent than negative consequences (98% vs. 2%, respectively); however, the negative life events were more deleterious (such as, banishment from the worksite and verbal abuse). Furthermore, considering exclusively seropositive women, only 11.7% searched for medical care and 7.8% received psychological assistance after VCT-HIV.
Beckwith et al. (2010)	USA; clinic-based.	IP	NRS with a 6-weeks follow up	CS	264	59%	HIV risk behaviors.	The rapid VCT-HIV intervention was not found to reduce HIV risk behavior when compared to the standard VCT-HIV. There was an overall decrease in sexual risk behavior after jail release in both arms.
Bernstein E, Ashong D et al. (2012)	USA; emergency department.	PWID	RCT	CS	1030	31%	HIV incidence and risk behaviors.	Self-reported HIV risk behaviors declined in both groups (HIV-VCT was performed in both groups) with no significant between-group differences in behaviors or STI/HIV incidence.
Bernstein E, Heeren T et al. (2012)	USA; emergency department.	PWID	PCS with a 12-months follow up	CS	1030	31%	HIV incidence and risk behaviors.	There was a reduction in the percentage of unprotected sex acts over time. HIV-positive patients were more likely to use condoms in their sexual encounters.
Booth et al. (2011)	USA; program for drug or alcohol abuse.	PWID	RCT with a 6-months follow-up	CS	632	37%	HIV risk behaviors.	Significant reductions in HIV risk behaviors occurred over a 6-month follow-up period. VCT-HIV participants reported significantly greater rates of attending an HIV testing appointment, but this was not associated with HIV risk reduction.
Coulaud et al. (2019)	Mali, Cote d'Ivoire, Burkina Faso and Togo; community-based organization.	MSM	PCS with a 18-months follow-up	CS	621	57%	HIV risk behaviors and HIV incidence.	VCT-HIV reduced HIV risky behaviors among HIV-negative MSM.
Hao et al. (2012)	China; clinic-based.	MSM	RCT with a 6-months follow-up	RDS	295	28%	HIV risk behaviors and HIV incidence.	No significant differences were found between standard and enhanced VCT-HIV when considering the HIV incidence. However, participants exposed to enhanced VCT-HIV reported lower prevalence of unprotected anal intercourse.

Table 1 (Continued)

Author	Setting	Key population	Design	Recruitment	Sample Size	Drop out rate	Main outcomes measured	Main results
Huebner et al. (2010)	USA; bathhouse.	MSM	ITS with a 3-months follow-up	CS	1020	Does not apply.	HIV risk behaviors.	Rapid testing offers an important advantage over standard testing in that a far larger proportion of individuals in the rapid testing condition actually received their test results. Both VCT-HIV approaches reduced HIV risk behaviors. However, behavior change following counseling in a rapid testing context was somewhat less clear.
Lau et al. (2015)	China; non-governmental organization.	MSM	PCS with a 21-months follow-up	CS	809	37%	HIV incidence and HIV risk behaviors.	VCT-HIV did not reduce risk of HIV seroconversion and HIV risk behaviors.
McMahon et al. (2013)	USA; community-based organization.	PWID	RCT with a 9-months follow-up	RDS	660	32%	HIV risk behaviors.	VCT-HIV administered jointly to both male and female members of drug-using couples is more effective in reducing HIV risk among women with primary partners than VCT-HIV administered exclusively to women.
Metsch et al. (2012)	USA; program for drug or alcohol abuse.	PWID	RCT with a 6-months follow-up	CS	1281	6%	HIV risk behaviors.	No beneficial effect of brief risk reduction counseling on reducing unprotected intercourse was seen.
Pantin et al. (2013)	USA; community-based organization.	PWID	ITS with a 4-weeks follow up	CS	60	3%	HIV knowledge and HIV risk behaviors.	VCT-HIV enhanced condom use and STI knowledge, as well as reduced safe-sex risk fatigue and number of same- and opposite-sex partners.
Phanuphak et al. (2020)	Thailand; community-based organization.	MSM and TW	PCS with a 12-months follow up	CS	571	37%	Linkage to referred facilities for HIV confirmatory testing and HIV knowledge.	All three groups received VCT-HIV: online, offline or mixed. Successful ART initiation in the online group (52.8%) was lower than the offline (84.8%) and mixed groups (77.8%).
Pollack et al. (2014)	USA; bathhouse.	MSM	ITS	CS	852	Does not apply.	HIV risk behaviors.	VCT-HIV was associated with a lower prevalence of unprotected insertive anal intercourse.
Sullivan et al. (2014)	USA; community-based organization.	MSM	RCT with a 3-months follow up	CS	144	20%	Social consequences of HIV status disclosure and HIV risk behaviors.	VCT-HIV, applied to couples, was not associated with a higher incidence of intimate partner violence or relationship dissolution when compared to individual VCT-HIV.

Table 1: Study characteristics.

Notes. FSW= female Sex Worker, MSM= men who have sex with men, PWID= people who inject drugs, IP= incarcerated people, PCS= prospective cohort study, RCT= randomized controlled trial, ITS= interrupted time series analysis, NRS= non-randomized controlled study, CS= convenience sampling, RDS= respondent-driven sampling.

All correspondent authors were contacted by email in order to explain the unclear data.

Author	VCT definition	VCT duration	Counselors training
Aho et al. (2011)	Unclear.	Unclear.	Unclear.
Beckwith et al. (2010)	Unavailable (HIV C&T per RIDOC protocol).	Unclear.	Unclear.
Bernstein E, Ashong D et al. (2012) and Bernstein E, Heeren T et al. (2012)	Unavailable (described as the Standard VCT-HIV).	Unclear.	Project ASSERT's licensed addiction counselors.
Booth et al. (2011)	Unclear.	30 min pretest and post-testing counseling sessions.	Intervention experts conducted a 3-day, centralized training of 50 interventionists and supervisors from the eight detoxification centers.
Coulaud et al. (2019)	Unclear.	Unclear.	Unclear.
Hao et al. (2012)	Unavailable (VCT-HIV organized by CMOH & China CDC).	Unclear.	Four clinicians provided pre-test counseling and post-test counseling to all of the participants. These clinicians had at least 1 year of VCT experience and had attended an 8-h training session which was delivered by an experienced trainer working in an HIV prevention non-government organization in Hong Kong.
Huebner et al. (2010)	Unavailable (VCT-HIV established by the California Office of AIDS).	Unclear.	Unclear.
Lau et al. (2015)	Unclear.	Unclear.	Unclear.
McMahon et al. (2013)	A Community-Based Outreach Model, which is a manualized HIV counseling and testing protocol for substance users.	Unclear.	Unclear.
Metsch et al. (2012)	Individual risk-reduction counseling based on that in the RESPECT-2 study.	Pre-testing (30 min), waiting for the test result (20–40 min), and post-test counseling (10 min).	Unclear.
Pantin et al. (2013)	Unclear.	Two sessions each lasting 1 and half hours.	Unclear.
Phanuphak et al. (2020)	Unavailable (Thailand National Guidelines).	Unclear.	Unclear.
Pollack et al. (2014)	Unclear.	Unclear.	Counselors were trained and certified to deliver counseling and testing according to protocols promulgated by the State of California.
Sullivan et al. (2014)	Unclear.	Unclear.	Unclear.

Table 2: VCT-HIV characteristics.

Notes. FSW= female Sex Worker, MSM= men who have sex with men, PWID= people who inject drugs, IP= incarcerated people, PCS= prospective cohort study, RCT= randomized controlled trial, ITS= interrupted time series analysis, NRS= non-randomised controlled study, CS= convenience sampling, RDS= respondent-driven sampling.

All correspondent authors were contacted by email in order to explain the unclear data. VCT-HIV characteristics.

their serostatus, and challenges in accessing health care.

Besides not having a clear and uniform protocol for VCT-HIV application, the eligibility criteria of each KP also varied within studies. For example, as shown in Table 3, MSM was defined as people who self-identify as MSM, as well as men who self-reported having had

(protected or unprotected, according to the study) anal sex with men in the last few months (ranging from three to 12 months before enrolment).

As the interventions encompassed specific activities, none of the included articles blinded participants or personnel. Most articles showed an elevated risk of attrition bias related to drop-out rates as well as to differences

Author	Key-population	Key-population definition
Aho et al. (2011)	FSW	Women who admitted having had sexual relations in exchange for money in the preceding month.
Beckwith et al. (2010)	IP	Recruitment occurred on jail entry.
Bernstein E, Ashong D et al. (2012) and Bernstein E, Heeren T et al. (2012)	PWID	Drug abuse severity test scores.
Booth et al. (2011)	PWID	A recent history of injection drug use via self-report and signs of recent drug injection or the ability to correctly describe injection procedures.
Coulaud et al. (2019)	MSM	Self-identify as MSM and report, at least, one episode of anal intercourse with another man within the 3 months prior to enrolment.
Hao et al. (2012)	MSM	Men who self-reported having had anal sex with men in the last 12 months.
Huebner et al. (2010)	MSM	Self-identify as MSM and attend a bathhouse.
Lau et al. (2015)	MSM	Reported anal intercourse with at least one man in the last 6 months.
McMahon et al. (2013)	PWID	Self-reported use of crack/cocaine or heroin (injected or noninjected) in the prior 30 days. A half have ever injected illicit drugs.
Metsch et al. (2012)	PWID	Seeking or receiving drug treatment services.
Pantin et al. (2013)	PWID	Confirmatory test to determine recent drug-use eligibility was determined by rapid urine testing for drug metabolite using the On-Trak test. 21% injected these drugs alone or together.
Phanuphak et al. (2020)	MSM and TW	Engaged in unprotected anal sex with men at least once in the past six months.
Pollack et al. (2014)	MSM	Unclear.
Sullivan et al. (2014)	MSM	Unclear.

Table 3: Definition of key population.

Notes. FSW= female Sex Worker, MSM= men who have sex with men, PWID= people who inject drugs, IP= incarcerated people, PCS= prospective cohort study, RCT= randomized controlled trial, ITS= interrupted time series analysis, NRS= non-randomised controlled study, CS= convenience sampling, RDS= respondent-driven sampling.

All correspondent authors were contacted by email in order to explain the unclear data. VCT-HIV characteristics.

between intervention and comparison groups. Furthermore, most trials were not previously registered online, enabling (and making it difficult to identify) selective reporting bias. For more details on risk of bias, see Appendix 4, 5, 6 and 7.

Nine studies showed dichotomic data on unsafe sex acts. When including all studies, no significant overall effect was observed when comparing data before and after VCT-HIV, as shown on Appendix 8 and 9. Comparison between brief and standard VCT-HIV yielded a significant overall effect of $Z = 2.11$ ($p=0.04$; $I^2=75\%$). Due to the high heterogeneity, we chose to consider exclusively randomized controlled trials that provided data before and after VCT-HIV. As result of scarcity of data, only PWID and MSM populations were included in the analyses. This strategy provided a significant overall effect of $Z = 5.40$ (Figure 2; $p<0.00001$) with no inconsistency ($I^2=0\%$). No significant overall effect was observed in subgroup analysis.

Five studies, encompassing exclusively MSM and PWID, provided data on frequency of unsafe sex. Considering exclusively randomized controlled trials, VCT-HIV had a beneficial impact in reducing the frequency of unsafe sex (Figure 3; $Z=4.72$, $p<0.00001$, $I^2=0\%$). Again, no significant overall effect was observed in subgroup analysis. It's noteworthy that brief and standard

VCT-HIV had the same impact on modifying risk behaviors (Appendix 10, 11 and 12).

Discussion

Although surprisingly sparse and, at times, contradictory, most of the included articles showed that VCT-HIV is an effective tool to reduce sexual risk behaviors among KP.^{20,21,23,27,29,30} Bearing in mind the heterogeneity, low quality, and divergent results of the included studies, currently, we recommend VCT-HIV as an evidence-based health policy among populations with a high risk of HIV infection. VCT-HIV may be effective in environments where it is possible to adequately train the counselors with standardized protocols. Well-supervised peer counseling may present itself as a creative solution to access KP. Importantly, while our meta-analysis identified VCT-HIV as protective for sexual risk behaviors, the results are limited to MSM and PWID, demonstrating the paucity of data on the other KP. Even though VCT-HIV may have a positive effect on reducing sexual risk behaviors among KP, two potentially negative outcomes should be considered. First, most studies assessed VCT-HIV applied once or twice; repeated VCT-HIV may have a different impact.²⁶ For example, by giving a false sense of security and enabling sexual risk behaviors right after the test result.³⁵ In bathhouses,

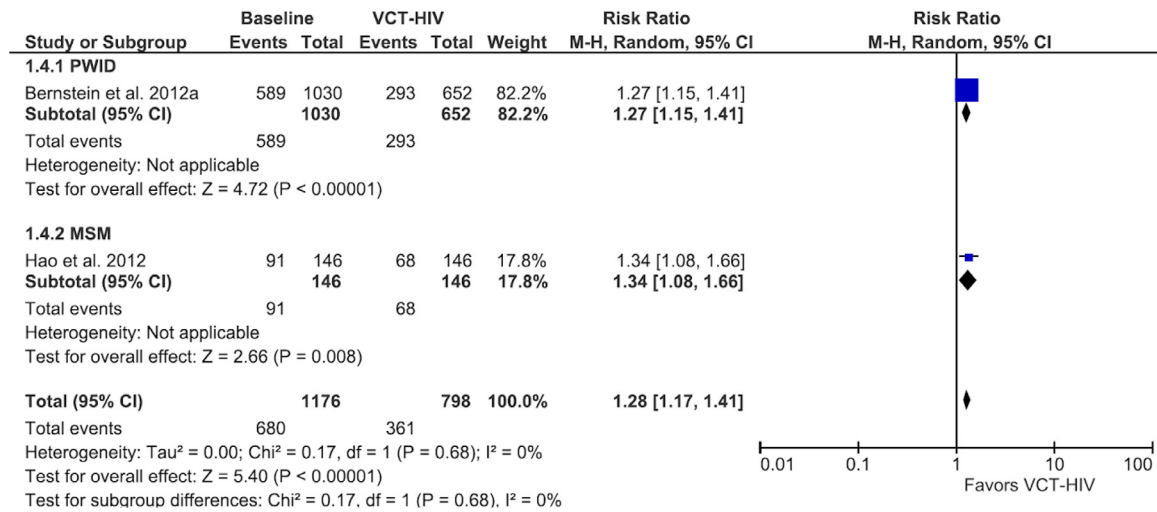


Figure 2. Unsafe sex acts (yes or no) before and after VCT-HIV.

Notes. PWID = People Who Inject Drugs; MSM = Men Who Have Sex with Men.

Exclusively randomized controlled trials were included.

Bernstein et al. (2012) evaluated a single 30-min brief motivational interview and had a 6 months follow-up, with a timeframe of the last 30 days.

Hao et al. (2012) assessed a 10-minute enhanced posttest counseling add to a 6-min video and a cloth bracelet for the reminder of safe sex as intervention, with a 6-month follow-up, and a timeframe of the last 6 months.

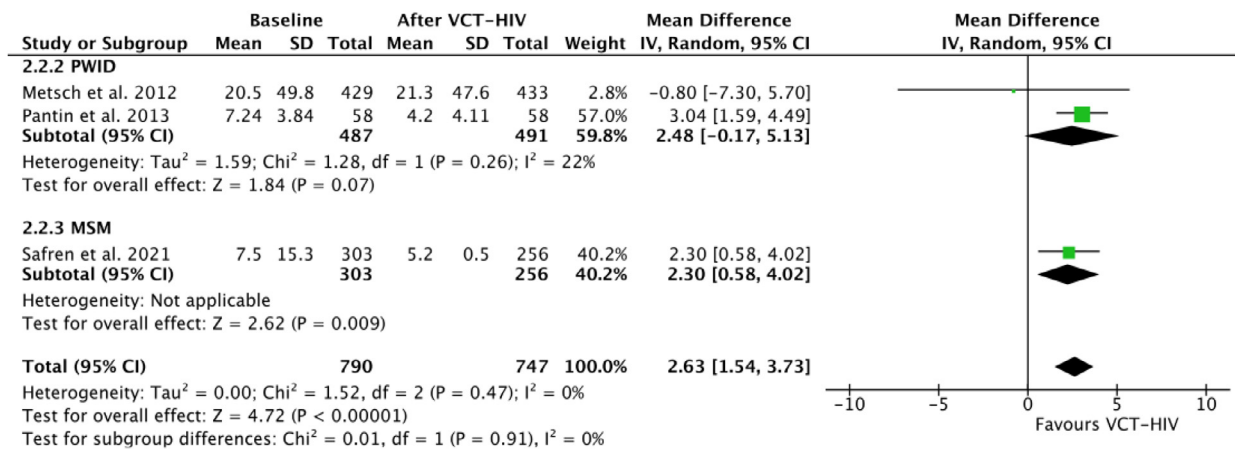


Figure 3. Frequency of unsafe sex before and after VCT-HIV.

Notes. PWID = People Who Inject Drugs; MSM = Men Who Have Sex with Men.

Metsch et al. (2012) had a follow-up visit at 1 and 6 months, but data about risk behavior was retrieved only for the last 6 months. VCT-HIV sessions lasted for 30 minutes.

Pantin et al. (2013) had a 30 days follow-up and timeframe of the last 30 days. VCT-HIV was structured in two sessions, each one lasting 1 and a half hours.

Safren et al. (2021) had a 12 months follow-up without more details on VCT-HIV duration.

clients who receive negative test results might assume that other clients have also tested negative and, thus, engage in unprotected sex more frequently.^{36,37}

Second, counseling, especially without proper training, may aggravate the already vulnerable situation that KP usually have by reproducing prejudices and lacking the promised anonymity. HIV high-risk groups are more likely to use home-based HIV self-testing to avoid experiences of stigma and discrimination.^{38,39} Accordingly, previous experiences of stigma and discrimination are an important barrier to HIV testing among female SW (FSW).⁴⁰ Some FSW reported fear of breaches in anonymity due to the social repercussions of having their HIV serostatus revealed. Indeed, women living with HIV have a higher risk of being neglected or disowned by their families,⁴¹ as well as suffering partner violence.⁴² Therefore, the counseling's quality is a determining factor on HIV prevention outcomes: it may enhance self-efficacy and change HIV-related attitudes as well as worse KP vulnerability; nevertheless, none of the included studies considered whether the counseling took into account KP particularities. VCT-HIV is not risk-free: when provided by unprepared counselors, it may aggravate prejudice and social exclusion; anticipating discrimination, in turn, may hinder access to effective biomedical HIV-prevention strategies (such as PrEP and ART). Also, requiring the presence of professionally trained counselors can delay access to testing and, so, to the current HIV prevention and treatment possibilities.

An complicating factor must be considered: sex work, substance use and sexual and gender minorities are highly stigmatized or, even, criminalized in some contexts. Bearing in mind that considering KP's particularities is essential to provide relevant counseling, in contexts where VCT-HIV focusing on KP specificities may entail risks for both the participant and the counselor, it may not be feasible. In this sense, VCT-HIV may have a deleterious impact, carrying the risk of reinforcing stigma and prejudice, delaying access to the currently available medical strategies.

VCT-HIV structures itself on two pillars: non mandatory and counseling. Despite being an essential part of VCT-HIV, it's clear that guaranteeing participants' willingness is especially tricky among KP. For example, in the included studies, FSW could choose between joining an adapted healthcare center from Guinea by themselves, by nongovernmental organizations, or even by the police, who verified their attendance during police raids.³³ VCT-HIV was also applied among IP.¹⁹ Although participants could refuse to join the study, voluntariness in the prison context is controversial.

Besides nonmandatory VCT-HIV, the occurrence of counseling before and after testing was also essential. Indeed, in the eighties, counseling preceded the antibody test: during a public health crisis, volunteers from lesbian, gay, bisexual and transgender (LGBT) communities offered emotional support and information through

counseling.³ Counseling, however, is a generic term with many different meanings.¹ The standard counseling consisted of fact-based didactic messages to enhance the client's knowledge about HIV infection.² In the Project RESPECT, three distinctive styles of counseling were evaluated: four individual sessions (with a total of 200 min), a brief (40 min) theory-based counseling session, and didactic messages. Brief and enhanced counseling was more effective than didactic messages in increasing condom use and decreasing ISTs incidence. In the included articles, the Project RESPECT protocol was the only clearly found guideline applied to guide counseling. Therefore, it remains unclear the ideal approach to perform VCT-HIV with KP, as well as whether a single session, with rapid testing, is as effective as the standard two-session model.³⁶ For instance, Safren et al. (2021) found that there is no statistical difference in the frequency of unprotected anal sex between groups with people that received the standard VCT alone with those who participated in both groups (four sessions) and individual (six sessions) interventions.¹⁸

VCT-HIV implementation was not based on a previous theoretical framework. This *atheoretical* approach that seems to have guided the VCT-HIV strategies applied in the included studies is perhaps the most important difference between VCT-HIV and an actual intervention focused on modifying sexual risk behaviors. According to the Information-Motivation-Behavioral Skills (IBM) model of HIV preventive behavior,⁴³ behavioral changes are dependent on obtaining specific abilities. Providing information and, maybe, even motivation may not be enough to empower the participant with the ability to, for example, negotiate condom use with their partner.⁴⁴ While a well-informed and well-motivated MSM may use his knowledge and motivation to unilaterally use a preservative, an aware and motivated SW may not be capable of engaging in complex and skilled behavioral performance to guarantee safe sex with an obstinate male partner.

The present review has four main limitations. First, ten studies provided financial support for the interviewees. It should be stressed that financial incentives, especially for participants from a place of vulnerability, may affect their autonomy. Therefore, both positive and negative results regarding VCT-HIV should be considered for selection bias.

Second, although the present review had the hope to examine data from across the globe, more than half of the included studies have samples from the US. In certain countries (such as Indonesia) stigma and discrimination drive populations of sex workers, people who inject drugs and men who have sex with men underground.^{45,46} Laws tableted to outlaw, for example, same sex behavior, enabling police crackdowns, make these highly vulnerable populations invisible. Furthermore, we exclusively included articles published in English. Thus, generalizations should be made carefully.

Third, bearing in mind that there isn't a precise date in which the term *key populations* became widespread, choosing to include studies published after 2010 may have left important studies aside. Indeed, selecting the ideal terminology for identifying KP was challenging. Taking into account the overlap between sexual orientation and gender identity, that occurs in some contexts, was specially arduous. For example, only one study provided data concerning TW.³⁴ The data, however, was provided together with a larger sample of MSM.³⁴ This overlap is problematic because it is based on the assumption that all transgender women have sex with men and that anal sex is the main determinant to HIV infection, disregarding the importance of gender identity. Nevertheless, all terms suggested by MeSH terms were included. Also, it's not impossible that studies applying HIV testing and some form of counseling, but not citing VCT-HIV, were not identified by our team.

Finally, from the VCT-HIV protocols and the KP's definition to the measurements applied to estimate sexual risk behaviors, the included articles are highly heterogeneous and showed an elevated risk of bias. Due to the small number of articles identified, we chose to include high risk of bias studies in our meta-analysis. The quality of these studies limits the quality of the present review, demanding some caution when interpreting the results.

The present systematic review and meta-analysis pioneers in assessing VCT-HIV effectiveness on multiple sexuality related outcomes among some KP. Our results show that VCT-HIV for KP, even considering high risk of bias and heterogeneity of the studies, and limitations in the protocols construction and the training of the counselors, is indeed effective in reducing sexual risk behaviors only for MSM and PWID. Future research on VCT-HIV should make it noticeably clear the VCT-HIV guideline applied as well as the training provided to the counselors regarding all KP. Also, clearly defining the studied population is essential to guarantee reproducibility and enable the generalization of results.

Contributors

ABC and AMVF designed the project and protocols. AMVF, MF, and LHV, conducted the searches, extracted the data, and excluded duplicates. AMVF, MF, and LHV, screened studies, conducted quality appraisal and extracted data. LHV performed the meta-analysis, accessing the raw data. AMVF led the preparation of the manuscript. All authors analyzed and interpreted the data, as well as drafted the manuscript, reviewed and approved the article prior to submission.

Data sharing statement

All data extracted for this study are available upon request to the corresponding author.

Declaration of interests

The authors declare that they have no conflict of interest.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:[10.1016/j.eclinm.2022.101612](https://doi.org/10.1016/j.eclinm.2022.101612).

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