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Voluntary counseling and testing (VCT) for changing HIV-related risk behavior in developing countries

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Abstract

Background—Voluntary Counseling and Testing (VCT) continues to play a critical role in HIV prevention, care and treatment. In recent years, different modalities of VCT have been implemented, including clinic-, mobile- and home-based testing and counseling. This review assesses the effects of all VCT types on HIV-related risk behaviors in low- and middle-income countries.

Methods—We updated a previous review from 1990–2005 by searching for eligible studies through July 6, 2010 on electronic databases, reference lists, and four key journals. To be included, studies had to evaluate pre-post or multi-arm biological, behavioral, or psychological results from an intervention in a developing country in which participants voluntarily received HIV testing and counseling and were administered pre-test counseling, HIV testing, and post-test counseling.

Results—An initial search yielded 2808 citations. After excluding studies failing to meet the inclusion criteria, 19 were deemed eligible for inclusion. Of these studies, two presented duplicate data and were removed. The remaining 17 studies were included in the qualitative synthesis and 8 studies were meta-analyzed. Twelve studies offered clinic-based VCT, 3 were employment-based, 1 involved mobile VCT, and 1 provided home-based VCT. In meta-analysis, the odds of reporting increased number of sexual partners were reduced when comparing participants who received VCT to those who did not, OR= 0.69 (95% CI: 0.53–0.90, p=0.007). There was an insignificant increase in the odds of condom use/protected sex among participants who received VCT compared to those who did not, OR=1.39 (95% CI: 0.97–1.99, p=0.076). When stratified by HIV status, this effect became significant among HIV-positive participants, OR= 3.24 (95% CI: 2.29–4.58, p<0.001).

Conclusions—These findings add to the growing evidence that VCT can reduce HIV-related risky sexual behaviors, thus confirming its importance as an HIV prevention strategy. To maximize the effectiveness of VCT, more studies should be conducted to understand which modalities and counseling strategies produce significant reductions in risky behaviors and lead to the greatest uptake of VCT.

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Background

HIV voluntary counseling and testing (VCT) is an important component of HIV prevention programs and a critical entry point into HIV care and treatment. As a prevention strategy, it is believed that VCT can influence behavior change through a process involving individualized counseling, acquisition of HIV/AIDS knowledge and awareness, and learning one's HIV status. Previous reviews have found that VCT can reduce risky sexual behaviors, thus reducing the likelihood of virus transmission, especially among serodiscordant couples (1, 2). In addition, results from a meta-analysis conducted by Weinhardt et al. (1999) substantiated evidence that VCT can be an effective behavior change strategy for people infected with HIV(3). The majority of studies included in these earlier reviews, however, were from developed countries. Given that implementing VCT programs in resource-limited settings can pose significantly different challenges from those presented in developed countries (4), Denison et al. (2008) conducted a systematic review and meta-analysis of VCT evaluations from low and middle-income countries that were published between 1990 and April 2005 (5). Results of this meta-analysis from seven studies provide evidence in support of VCT as a moderately effective strategy for reducing sexual risk behavior in developing country contexts.

Since the publication of the Denison et al. (2008) review, the field of VCT has continued to expand with the number of facilities globally offering VCT services increasing 35% from 2007 to 2008 alone. Despite this expansion, the majority of individuals worldwide remain unaware of their HIV status (6). In order to increase access and promote awareness of one's HIV status, different models of VCT delivery have been developed to reach individuals, couples and families not only through different clinic settings and provider-initiated testing(7), but also by bringing VCT closer to people in their communities and homes through mobile and home-based testing approaches. More recently it has been debated whether HIV testing should become a routine part of medical care while still remaining voluntary and confidential. In 2007 the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) created guidelines for provider-initiated testing and counseling (PITC) which, as opposed to client-initiated testing and counseling, is performed in health facility as a standard service for all patients in a generalized epidemic and for high-risk patients in a concentrated epidemic setting (7).

This expansion and diversification reflects progress made towards achieving the Sixth Millennium Development Goal of providing HIV treatment to all who need it by 2015, as knowledge of one's HIV infection status is necessary for accessing lifesaving antiretroviral therapy. The importance of VCT as an HIV prevention strategy, however, was reiterated in a resolution passed by the UN General Assembly in 2006(8), and the rapidly expanding field of HIV testing and counseling has provided new opportunities for evaluation of the service as an HIV prevention tool. This review seeks to examine the effectiveness of VCT, including these newer VCT delivery models such as mobile and home-based testing, on reducing sexual risk behaviors in low- and middle-income countries as a means of preventing future HIV infections.

This review updates the results originally published by Denison et al. in 2008 using updated inclusion criteria that take into consideration the distinction PITC and VCT. Interventions originally included in the Denison et al. review that took place as a routine part of health services, such as receiving HIV testing and counseling at an antenatal care visit, are excluded from this review and analyzed separately in a review of PITC(9).

Objectives

The primary objective of this review is to systematically examine the literature on the efficacy of VCT in reducing HIV-related risk behaviors in developing countries. This review compares the effectiveness of different approaches to VCT. The three specific aims are as follows:

1. To systematically identify and review all available literature examining the efficacy of VCT interventions in developing countries.
2. To describe studies evaluating the effects of VCT on behavioral, biomedical, and psychological outcomes relating to HIV prevention in developing countries, and if warranted, stratify studies based on the type of VCT provided (e.g. home-based, mobile, etc.) and/or the type of population under study.
3. To conduct a meta-analysis that synthesizes comparable outcomes across eligible studies in order to evaluate the overall effectiveness of VCT in reducing HIV-related risk behaviors.

Methods

Inclusion Criteria

Types of studies—We included studies conducted in low- and middle-income countries as defined by the World Bank (2010) (10). The period of inclusion for studies was January 1, 1990 through July 6, 2010. Articles published in any language were included if they met the inclusion criteria. Only peer reviewed articles were eligible; conference abstracts and unpublished reports were excluded from the review. We strove to include studies that maintained a high level of methodological rigor, such as randomized controlled trials, but also included interventions with weaker study designs. Specifically, the following study designs were eligible for inclusion: (1) *Randomized trial (individual)*: Minimum two study arms; random assignment of individuals to study arm; (2) *Randomized trial (group):* Minimum two study arms; random assignment of groups (couples, classrooms, towns, etc.) to study arm; (3) *Non-randomized "trial" (individual):* Minimum two study arms; assignment of individuals to study arm, but not done randomly; (4) *Non-randomized "trial" (group)*: Minimum two study arms; assignment of groups to study arm, but not done randomly; (5) *Before-after study*: Pre- and post-intervention assessment among the same individuals. One study arm and one follow-up assessment period; (6) *Time series study*: Pre-intervention and several post-intervention assessments among the same individuals. One study arm and multiple follow-up assessment periods; (7) *Case-control study*: Two groups defined by outcome measures, one consisting of cases and one consisting of controls. To be included, the study must compare outcomes between those who got the intervention and those who did not; (8)*Prospective cohort*: Two or more groups defined by exposure measures and followed over time; (9) *Retrospective cohort*: Two or more groups defined by exposure measures, but uses previously collected or historical data; (10)*Cross-sectional*: Exposure and outcome determined in the same population at the same time. To be included, the study must compare outcomes between those who got the intervention and those who did not; (11) *Serial cross-sectional:* When a cross-sectional survey is conducted in a population at multiple points in time with different people in that population.

Among the eligible study designs, we only included studies that presented the results of comparisons made between participants who received VCT to those who did not receive VCT or ones that made a pre-post test comparison before and after VCT was provided. We also included studies that compared more and less intensive versions of a VCT intervention. Studies that did not meet the inclusion criteria but presented relevant qualitative data, cost-

effectiveness data, or other review articles/meta-analyses were collected and included in the review as background articles; a brief data abstraction was conducted for these studies.

Types of participants—This review included studies conducted with a variety of different populations; therefore, we had no restrictions on the types of participants. We only required that participants reside in the low- or middle-income country where the study took place and voluntarily consented to receive HIV testing and counseling, and participate in the study. We included both individual and couples- based VCT interventions. However, we did not include studies that compared individual to couples-based VCT as this comparison addresses a separate research question not posed in our current review.

Types of interventions—Studies were included in the review if they evaluated a VCT intervention adhering to the international standards for VCT as initially presented by the US Centers for Disease Control and Prevention (CDC) and UNAIDS (11, 12). For the purposes of this review, we operationalized these guidelines into a concise definition of VCT, which consists of three criteria: (1) receiving pre-test counseling, (2) being tested for HIV, and (3) receiving post-test counseling and test results. In addition, this review included interventions where the client, as opposed to the provider, initiated the HIV test either directly or as a result of outreach services. Studies which are conducted in a healthcare setting where the provider initiates the HIV test for clients seeking other services were not included in this review as this is considered provider initiated testing and counseling (PITC) and was analyzed in a separate review (9).

Types of outcome measures—This review focused on primary outcomes measured post-intervention where results are presented for either a pre/post test comparison or a comparison between at least two study arms. All other outcomes were considered secondary endpoints and were not emphasized in the analysis.

This review included studies reporting at least one outcome measure directly related to HIV prevention, including behavioral, biological, and psychosocial outcomes. Behavioral outcomes included indicators that measure participants' risk reduction knowledge, attitudes, beliefs, and behaviors regarding HIV. Examples of behavioral outcomes include use of male/female condoms, frequency of having unprotected sex and number of sex partners. Biological outcomes included indictors, such as HIV/STI prevalence and pregnancy incidence, that relate to the biological manifestations of practicing or not practicing protective behaviors related to HIV transmission. Psychosocial outcomes included aspects of behavior or mental health influenced by social factors and includes examples such as self-efficacy, stigma, and support from family and friends. If additional behavioral, biological, or psychosocial outcomes were presented within the studies, we recorded these outcomes as well.

Search Methods

Three different approaches were used to identify eligible articles for inclusion. First, five electronic databases – PubMed, Excerpta Medica Database (EMBASE), PsycINFO, Sociological Abstracts, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) – were searched using predetermined key words and phrases. These search terms were identical to those used for the Denison et al. (2008) review and were as follows: "HIV counseling and testing" OR "HIV VCT" OR "HIV voluntary counseling and testing" OR "HIV anonymous counseling and testing" OR "HIV ACT" OR "HIV testing and counseling and evaluation" OR "HIV testing and counseling and interventions" OR "HIV counseling and efficacy." Second, hand-searching was conducted in four key journals including *AIDS*, *AIDS and Behavior*, *AIDS Education and Prevention*, and *AIDS Care*; the tables of contents

of these four journals during the included time period were individually screened for relevant articles. Third, the reference lists of all articles included in the review were screened to identify any additional studies; this process was iterated until no additional articles were found.

Since the search methods were identical to those used in the Denison et al. 2008 review, a new search was conducted from April 2005 through July 2010. These search results were combined with the original search conducted by Denison et al. (2008) that covered dates from January 1990 through April 2005.

Data collection and analysis

Screening and Data Abstraction—Search results from each database were merged and duplicate citations were removed. Trained staff (who received 15 hours of training on systematic review methods and training and practice with the specific methods for this review) screened the titles and abstracts of all search results to eliminate clearly unrelated citations. After preliminary screening, two senior study staff independently screened the remaining records for eligibility. These assessments were merged and discrepancies discussed until consensus was reached. Following this process, citations appearing to fit the inclusion criteria were retrieved and read thoroughly. Once a complete list of eligible articles was compiled, two trained staff independently abstracted the relevant data from the studies using a highly-detailed standardized form with fifteen content sections: (1) citation information, (2) inclusion criteria, (3) study methods, (4) study population characteristics, (5) setting, (6) sampling strategies, (7) study design, (8) unit of analysis, (9) attrition rates, (10) study group (arms or comparison populations), (12) intervention specific questions, (13) outcome measures, (14) outcome results, (15) additional information (e.g. costs and limitations).

All behavioral, biological, or psychosocial outcome variables reported in each study were recorded; however, only outcomes for which there is a pre/post test or multi-arm comparison were extracted in detail. Eligible outcome results were reported in a league table format and included the following: (1) the statistical analysis used, (2) the effect size and base rate, (3) the independent variables analyzed, (4) follow-up times (if applicable), (5) the confidence interval and/or P value, (6) the page number where the results are located, and (7) any additional information deemed of importance. After the two staff members independently coded a study, they compared their coding forms and discussed any discrepancies in data abstraction. If no resolution could be reached, they discussed the issue with a member of the senior project staff until all differences were resolved. We contacted authors if certain aspects of studies needed further clarification. Once resolution was completed, the two data abstractors created a final coding form, and all data were entered into a statistical database (SPSS^{TM}, Chicago, IL) for analysis.

Assessing Study Rigor—To standardize comparisons of rigor across studies, we used a rigor table previously developed for the synthesis project. This table recorded the following aspects related to study rigor: (1) *Prospective Cohort* analyses presented data from the same subjects followed over time; (2)*Control or comparison groups* compared those who received VCT to those who did not (including a more-versus-less intensive intervention); (3) *Pre/post intervention data* assessed participants before and after receiving VCT; (4) *Random assignment of treatment groups* of study subjects; (5) *Random selection of subjects* for assessment; (6) *Attrition* determined if the follow-up rate was 80% or more; (7) *Comparison groups matching* assesses if there were statistically significant differences in socio-demographic variables across study arms; and (8) *Comparison group matching on outcome measures* assesses whether studies had a statistically significant baseline difference in study

outcomes. For articles reporting the results of randomized controlled trials, risk of bias was assessed using the Cochrane Collaboration's tool for assessing risk of bias (13).

Meta-analytic Methods—Standard meta-analytic methods (14) were used to standardize effect sizes of study outcomes that were comparable across studies using the software package Comprehensive Meta-Analysis (CMA) V.2.2. We assessed a study's eligibility for inclusion in the meta-analysis based on a set of meta-analytic guidelines for social and behavioral interventions developed for the project Effect estimates from included studies were converted to the common metric of an odds ratio for studies that compared two groups (either intervention/control groups or before/after groups) using dichotomous outcome variables. If outcomes were presented as continuous variables, the effect size was entered into CMA and standardized as an odds ratio. If studies presented categorical data for an outcome of interest, the outcome was dichotomized when possible to utilize the common metric of the odds ratio. For example, if a study reported the number of sexual partners in the last year as 0–1, 2–3, or >3, the categories were collapsed into 0–1 or >1. When studies reported an outcome of interest in multiple ways, such as providing information on consistent condom use with primary partners and non-primary partners, the two outcomes were combined so that a singular effect size for consistent condom use reported among all partners could be utilized in meta-analysis. When studies presented results from more than one follow-up time period, data from one time point was selected for inclusion in meta-analysis based on its similarity to the follow-up times utilized in other included studies.

Because this review built on the findings of the Denison et al. (2008) review, we employed similar meta-analytic methods and included the same outcome measures in meta-analysis: number of sex partners and condom use, which is the inverse of the unprotected sex variable used in the Denison review. However, since slightly different inclusion criteria and meta-analytic methods were used, not all studies meta-analyzed in the Denison review were included in this update. Additionally, many studies were not included in the meta-analysis because the effects were too heterogeneous to be synthesized. Sub-group analyses by modality of VCT were not feasible given that the majority of included studies took place in a clinic setting. Sub-group analyses based on gender and HIV status were possible and the results of these meta-analyses are presented below.

Results

After searching the literature, 2808 records were identified, 2668 were eliminated during initial screening, and 85 additional records were eliminated after a second round of screening. The full texts of the remaining 55 articles were obtained to ascertain their eligibility. In total 19 articles met all inclusion criteria for the review. Among these 19 articles, two articles (14, 15) analyzed data from the same cohort study in eastern Zimbabwe. To avoid double-counting data from the same population, we only included the later article, Cremin et al., 2010, because this article provided data from a longer period of follow-up (from 3 time points instead of 2). Additionally, the later article recalculated the statistical analyses to take into account the degree of change between behavioral outcomes over time and the analyses were stratified by HIV infection status to provide a more accurate comparison group (15). Importantly, the earlier article found that VCT was associated with increased risk behavior among individuals who tested HIV-negative in terms of numbers of partnerships in the last month, the last year, and in concurrent partnerships (16). However, in the revised analyses, no increase in risk behavior was found for individuals who tested HIV-negative.

Two additional articles (17, 18) analyzed data from the same cohort of participants in Rakai, Uganda; however, the Matovu et al. 2007 article included a comparison of participants who

had repeatedly gone through VCT as compared to first-time acceptors and those who refused (17). Since our research question does not address repeat testing and counseling, we choose to only include the Matovu et al., 2005 study as it was most comparable to the other studies included in the review (18).

The VCT Efficacy Study (2000) and the Grindstead et al. (2001) articles utilized data from the same randomized trial, but since the two articles assessed different behavioral outcomes, results from both articles were included in the review (19, 20). Each article presents outcomes separately for those who were randomized to individual VCT and those who were randomized to couples VCT; therefore, we considered individual VCT and couples VCT to represent two separate study populations and each was considered a separate study. Additionally, these studies took place in three locations: Trinidad, Tanzania, and Kenya. Although Trinidad is currently considered a high-income country (10), it was considered a middle-income country when the studies took place in 1995–1998; therefore, we included these two studies in the review.

After these decisions were made, 17 studies from 17 articles were included in the review (Figure 1). Nine of these studies were originally identified in the Denison et al. (2008) review; the remaining eight studies were found during the updated search.

Description of Studies

Of the 17 articles included in the review, 10 took place in Sub-Saharan Africa, including four in Zimbabwe(15, 21–23), two in Uganda(18, 24), two in Zambia(25, 26), one in Mozambique (27), and one in Kenya (28). Two studies, one among individuals and one among couples, were multi-site, with locations in Trinidad, Kenya, and Tanzania (19, 20). The remaining five studies took place in the following locations: two in China (29, 30), two in Thailand (31, 32), and one in Guatemala (33). Most studies (N=12) took place in an urban location, while three took place in rural settings (15, 18, 30), one took place in a peri-urban setting (31), and one took place in a mixed setting involving both urban and rural locations (28). Combined, the 17 studies included a total baseline population of 40,309 participants. Study designs included one individual-randomized trial (19, 20), two group-randomized trials (19–21), three prospective cohort studies (15, 18, 27), eight before/after studies with no comparison group (23–25, 28–31, 33), one time-series study (22), and two cross-sectional studies (26, 32).

Nine included studies targeted sexually active adult men and women in the general population (15, 18–20, 27–28, 31–33). Five studies focused on couples (19, 20, 25, 26, 30), and three studies focused on employees (21–23). One workplace-based intervention in Zimbabwe included only male employees (22), whereas the other workplace-based interventions included both male and female employees (21, 23). Only one study focused on injection drug users (29). One study (32) focused solely on behavior among individuals who tested HIV-positive, whereas the remaining studies included both HIV-positive and HIV-negative participants. Table 1 presents study locations, target populations, participant demographics, and intervention descriptions for the included studies.

Risk of Bias of Included Studies

Risk of bias was assessed for the three articles (3 studies in total) that utilized a randomized study design (19–21). In all studies, participants and personnel were not blinded as the intervention arms included activities, such as VCT or health information, that were impossible to conceal. Due to the nature of the interventions, we do not believe the lack of blinding greatly influenced the study outcomes. In all five studies, it is unclear whether interviewers collecting behavioral information from participants were blinded; however,

Corbett et al. states that lab staff members were blinded during specimen analysis. The VCT Efficacy studies (19, 20) showed low risk of attrition bias and selective reporting bias, whereas Corbett et al., 2007 demonstrated a risk of attrition bias as attrition rates differed between intervention and comparison groups. Additionally, Corbett et al., 2007 was not powered to detect differences in HIV incidence, which was the main outcome presented in the study. Risk of bias assessments are presented in Table 2.

Quality of Evidence—For the remaining 15 studies that utilized non-random study designs, the quality of the evidence varied. All but three studies (26, 31, 32) studied a cohort of participants over time. Seven studies included some type of a control or comparison group (15, 18, 22, 26, 27, 31, 32) and 12 studies included data from pre- and post-intervention (15, 18, 21, 22–25, 27–30, 33). Only two studies randomly selected individuals for assessment (18, 26). Among studies that followed one group of people through time, three studies (22, 29, 30) reported an overall follow-up rate of 80% or greater. Quality assessment results are presented in Table 3.

Publication Bias—There were not enough studies to assess publication bias in this review.

Descriptions of Interventions—Despite the various implementation modalities for VCT, including clinic-based, mobile, and home-based approaches, the vast majority of included studies were clinic-based (19, 20, 25, 26, 27, 28, 30, 31, 32, 33). One study in China was specifically geared toward couples obtaining a marriage license (30). Although HIV testing and counseling is currently not required in China, this program sought to test the feasibility of integrating VCT into the existing required premarital counseling and health exams (30). One study, Matovu et al., 2005, offered VCT in the participants' homes or in a venue of their choosing; however, the article did not report how many participants received VCT in their home versus at a clinic or other setting (18). Cremin et al., 2010 provided mobile VCT services; however, participants who reported having had VCT through other means (e.g. at government clinics or non-governmental organizations) were categorized as having "received VCT" (15). The article does not specify the percentage of participants who received VCT through mobile services and the percentage of those that received VCT through other modalities (15). Three studies (21–23) offered VCT in worksites. The remaining 12 studies offered clinic-based VCT.

The length of time between being tested for HIV and receiving test results varied across studies. Only seven studies reported that participants received same-day HIV test results (21, 23, 25–26, 28–30). However, many studies took place prior to the availability of rapid HIV testing.

Effects of Interventions-qualitative synthesis

HIV incidence: Three studies measured HIV incidence as a primary outcome (18, 21, 22). Corbett et al., 2007 utilized data from a cluster-randomized trial among 22 businesses in Harare, Zimbabwe to assess HIV incidence among employees in businesses randomized to receive rapid on-site VCT as compared to employees in businesses randomized to receive paid vouchers for VCT with an external provider. The results showed no statistical difference between unadjusted HIV incidence in the intervention group (1.37/100 person-years) as compared to the control group (0.95/100 person-years) after the completion of follow-up (average 1.7 years between HIV tests). The adjusted incidence rate ratio was 1.49 (95% CI 0.79–2.80). However, uptake of VCT was quite different across sites; in the rapid, on-site group, VCT uptake was 70.7% compared to only 5.2% in the group receiving off-site vouchers. Machekano et al., 1998 (N=1683) examined HIV incidence among a cohort of

male factory workers in Harare, Zimbabwe and observed that participants who completed VCT and decided to receive their test results had a higher HIV incidence, IR= 3.29 (2.31–4.56) per 100 person-years, as compared to those who chose not to receive their test results, IR= 1.76 (1.01–2.86) per 100 person-years, IRR= 1.87 (1.01–3.61, p=0.030). However, this study also found that among those who received their results, HIV incidence was lower following the period after obtaining the results, IR=3.04 (1.86–4.70) per 100 person-years as compared to the period prior to obtaining results, IR=4.82 (2.75–7.81) per 100 person years, IRR= 0.63 (0.31–1.30, p=0.180). Matovu et al., 2005 followed a cohort of participants (n=10,694) to assess their willingness to participate in VCT and compared HIV incidence among participants who accepted VCT to those who refused. This study observed no significant difference between those who accepted VCT (IR= 1.6/100 person-years) and those who refused (IR= 1.4/100 person-years), p=0.60.

STI incidence/prevalence: Five studies measured STI prevalence or STI incidence (19–22, 28). Arthur et al., 2007 (N=401) found that the proportion of participants reporting any STI symptom decreased 6 months after receiving VCT (15.3%) as compared to baseline (39.7%), p<0.02. Matambo et al., 2006 (N=366) observed no significant pre-to post-intervention difference in participants reporting a genital ulcer or discharge (1.3% and 1.6%, respectively, p=0.73). Machekano et al., 1998 (N= 2060) detected no pre/post difference in STI incidence among participants who completed VCT and received their test results (IRR=1.30, 95% CI 0.95–1.80, p =0.100); however, the authors did find that subjects who went through VCT and received their test results had a significantly higher incidence of STIs than those who went through VCT but chose not to receive their test results (IRR=4.37, 95% CI=3.47, 2.51–4.89, p=0.001).

Positive and negative life events: Only three studies (19, 28) presented outcomes related to positive and negative life events associated with VCT. Grinstead et al., 2001 (n= 3120 enrolled as individuals, 1173 enrolled as couples) found that among participants receiving individual and couples VCT, positive life events were relatively common, such as strengthening a sexual relationship (42% overall) and negative life events, such as physical abuse (4.5% overall), were relatively rare. The most common negative life event was the break-up of a sexual relationship (27% overall). Arthur et al., 2007 (n=401) found no significant changes in the rates of life events following VCT, regardless of HIV status. Both studies (19, 28) found that rates of HIV serostatus disclosure were significantly higher among those who tested HIV-negative as compared to those who tested HIV-positive.

Effects of Interventions- Meta-Analysis

Description of study outcomes used in meta-analysis: Meta-analysis was conducted on two primary outcomes: number of sexual partners and condom use. The VCT Efficacy Study (2000) measured unprotected sex with primary and non-primary partners among individuals and unprotected sex with enrollment partner and with non-enrollment partners among couples. To include this outcome in meta-analysis, the two effects were combined using CMA to obtain one overall effect. Muller et al., 1995 and Matovu et al., 2005 differentiated between consistent, inconsistent, and no condom use. To dichotomize this outcome for meta-analysis, we compared consistent condom use to inconsistent or no condom use. Mola et al., 2006 contained several different condom use outcomes including: condom use at last sex, condom use at last sex among those reporting having had sex with friends/prostitutes in the last month and always/sometimes condom use. We chose to include the effect size for always/sometimes condom use as we felt this was the most comparable outcome to the other included studies. Additionally, the VCT Efficacy Study (2000) measured unprotected sex at two time-points—the first follow-up visit occurring on average 7.3 months after baseline and the second follow-up visit occurring on average 13.9 months

after baseline. Mola et al., 2006 also included two follow-up times: 4 and 6 months after receiving the intervention. To have the most accurate comparison, we chose to use the 1st follow-up time for the VCT Efficacy study (2000) (avg. 7.3 months after baseline) and the 2nd follow-up time for Mola et al., 2006 (6 months after baseline).

Condom use/protected sex: Twelve studies reported condom use or unprotected sex as a primary outcome (15, 18, 20, 23–24, 27–29, 31–33). For studies that reported unprotected sexual activity (20, 28), we took the inverse of this outcome to make it comparable to condom use outcomes presented in other studies. Of studies reporting either condom use or protected sex, seven were considered eligible for meta-analysis: VCT Efficacy 2000 (2 studies), Muller et al., 1995, Matovu et al., 2005, Mola et al., 2006, Arthur et al., 2007, and Cremin et al., 2010. After disaggregation by sex and HIV status within the results of these seven studies, a total of 14 discrete effects were used to calculate an overall effect size estimate (N= 23923). The random-effects pooled odds ratio across all studies showed a positive but not statistically significant effect of VCT on condom use (OR: 1.39, 95% CI: 0.97–1.99, p=0.076). There was significant heterogeneity, Q=94.10, p<0.001, which indicates the findings across studies were inconsistent. When stratified by gender, the random-effects pooled odds ratio for condom use was not statistically significant for either men (OR: 1.31, 95% CI: 0.64–2.67, p=0.46) or for women (OR: 1.17, 95% CI: 0.76–1.80, p=0.49). However, when stratified by HIV status, the random-effects pooled odds ratio for HIV-positive participants, combining males and females, was statistically significant (OR=3.24, 95% CI: 2.29–4.58, p<0.001). These results suggest that participants who received VCT and were given positive results had greater odds of using condoms than HIV-positive participants who did not receive VCT. However, these results should be interpreted with caution as this analysis contained only two studies (N=8873) (15, 32). Since there was only one study (15) that provided results separately for HIV-negative participants, this outcome could not be meta-analyzed.

Only one study, Matovu et al., 2005, found that participants who received VCT had reduced odds of condom use as compared to participants who did not receive VCT (18). Self-selection bias was an issue in this study as participants either agreed to receive VCT or refused; there was no randomization. The authors suggest that condom users may exhibit more risky behaviors, leading to increased fear they are HIV infected and discouraging them from accepting VCT (18). Cremin et al., 2010 also showed that the odds of condom use were reduced among HIV-negative female participants who received VCT compared to those who did not, especially with non-regular partners; however, the confidence interval for this outcome is extremely large, suggesting a high degree of imprecision and a non-significant effect (15). Results from all analyses related to the condom use/protected sex outcome are detailed in Figure 2 and Table 4.

The VCT Efficacy Study (2000) was the only randomized controlled trial that reported results on protected sex. For both individual and couples-based VCT, the results from this trial show that receiving VCT did not have a significant effect on protected sex comparing those who received the intervention to those who did not (20).

Number of sex partners: Six studies reported on the number of sexual partners, either comparing the same individuals before- and after- receiving VCT (28, 31, 33) or comparing intervention groups who received VCT to comparison groups who did not receive VCT (15, 18, 32). Of these, five studies were included in the meta-analysis: Arthur et al., 2007, Matovu et al., 2005, Muller et al., 1995, Samayoa et al., 2010, and Cremin et al., 2010 (N=18573). The overall pooled random effect odds ratio was 0.69 (95% CI: 0.53–0.90, p=0.007), demonstrating that participants who did not receive VCT had significantly higher odds of reporting greater numbers of sexual partners as compared to participants who did

receive VCT. The Q statistic, 61.84, was significant ($p<0.001$), which suggests substantial amounts of heterogeneity between study results. When stratified by gender, the effect of VCT on the number of sexual partnerships became statistically insignificant; the random-effects pooled odds ratio was 0.86 (95% CI 0.57–1.29, p=0.46) for males and 0.70 (95% CI: 0.47–1.04, p=0.08) for females. When stratified by HIV status, the random-effects pooled odds ratio was 0.61 (0.37–0.997, p=0.048) for HIV-positive individuals and 0.90 (95% CI: 0.77–1.10, p=0.195) for HV-negative individuals. All individual studies, including all sub-populations, showed a positive trend toward reduced number of partners for those participants receiving VCT compared to those not receiving VCT; no results suggested that receiving VCT increased the number of sexual partners of participants. Results for number of partners are presented in Figure 3 and Table 4 below.

Discussion

This systematic review and meta-analysis synthesized results across 17 studies and 5 HIV-related biological, behavioral, and psychological outcomes, including HIV incidence, STI prevalence/incidence, positive and negative life events, condom use/protected sex, and number of sex partners. Overall, there were no significant differences in HIV incidence and STI incidence/prevalence comparing participants who received VCT and those who did not. The two studies reporting on positive and negative life events suggest that individuals who receive VCT do not experience a significant increase in negative life events as compared to those not receiving VCT. However, these studies also found that reported disclosure of HIV status was more common among participants who received VCT and tested negative as compared to those who tested positive. As disclosure of one's HIV status remains an important strategy for HIV prevention (34), VCT counselors should work with clients, especially those who test HIV positive, to discuss ways of disclosing their HIV status to sexual partners, and should refer clients to further counseling if necessary.

For outcomes relating to HIV-related risk behavior, results from our meta-analysis demonstrate that people who received VCT were more likely to report reducing their number of sexual partners than those who did not receive VCT. This result stands in contrast to the random-effects pooled odds ratio in the Denison et al., 2008 review, which found no significant difference in odds of reported number of sex partners comparing those who received VCT to those who did not. However, the current meta-analysis incorporated only two studies originally included in the Denison et al., 2008 review for this outcome (18, 32) and added three new studies (15, 28, 33). Therefore, it is possible that the inclusion of additional studies enhanced the statistical power necessary to detect a significant difference in the reported number of sex partners comparing participants and non-participants of VCT interventions. This result is encouraging in that it shows VCT can have a significant effect on reducing HIV related risk behaviors for all participants, regardless of serostatus.

For the condom use/protected sex outcome, results from the meta-analysis show that VCT had no significant overall effect. Although VCT was not statistically effective in increasing condom use across all VCT participants, those who received a positive test result were significantly more likely to report condom use than HIV positive participants who did not receive VCT. The significant effect of VCT on condom use for HIV-positive individuals has been demonstrated in previous findings (3) and also among serodiscordant couples (1, 2). The Denison et al., 2008 review also found a significant effect of VCT on increased condom use, including both HIV positive and negative participants (5). In contrast, this meta-analysis found an insignificant effect of VCT on condom use when combining both HIV-positive and HIV-negative participants. As a potential explanation for this discrepancy, the Denison et al., 2008 review included studies that took place in antenatal settings. In the current review, these studies were moved into a separate category comprising provider-initiated testing and

counseling (PITC), which is being analyzed in another review (9). Additionally, the current review comprised 4 studies originally analyzed in the Denison et al., 2008 review: VCT Efficacy 2000—2 studies, Matovu et al. 2005, and Muller et al. 1995, in addition to including three new studies: Cremin et al. 2010, Arthur et al. 2007, and Mola et al. 2006. Estimated effects from the current review and the previous review (Denison 2008) show similar results, as the odds of condom use/protected sex were increased for VCT participants as compared to non-participants; however, significant heterogeneity was found in both analyses, suggesting inconsistent results across studies.

Originally this study aimed to assess the behavioral effects of different VCT modalities, including clinic-, mobile-, and home-based testing and counseling. However, since the vast majority of studies took place in clinic-based settings, differences in effects by modality could not be meta-analyzed. Although our review contained mostly clinic-based VCT, some studies demonstrated a much higher uptake of VCT when different modalities were offered. For example, one included study demonstrated that VCT uptake was 70.1% for onsite employment-based testing as compared to only 5.2% for offering vouchers for an off-site provider (21). Given the increasing importance of testing and counseling in accessing HIV care and treatment, more research should be conducted to assess which modalities are most successful at both increasing uptake of VCT and influencing behavior.

There are several limitations to this systematic review and meta-analysis that should be considered. Firstly, it is possible that our extensive search methods failed to identify eligible studies. We sought to minimize this limitation by searching not only electronic databases but also the reference lists of included articles as well as hand-searching the table of contents of four relevant journals. Additionally, since this review only included published studies, it is possible that unpublished studies exist that show negative findings, thus resulting in publication bias. This review spans two decades of HIV interventions related to testing and counseling. During this time, there have been numerous advances in the field of HIV, including increased availability of anti-retroviral therapy (ART) and increased availability of rapid, same-day VCT services. Therefore, it is possible that participants who volunteered for VCT prior to the wide availability of ART and rapid-testing are different in some aspects from those that volunteered in more recent years. Additionally, VCT interventions must be understood in the context of the larger HIV prevention efforts that have been underway since the early 1990s. The majority of studies in this review have relatively short follow-up time periods of one year or less. Therefore, we were not able to assess any larger time trends surrounding HIV prevention or any long-term effects of VCT. Finally, outcomes presented in the included studies often varied. For example, some studies reported consistent condom use in the past two weeks while others reported the amount of unprotected sex in the past month. In the future, developing standardized HIV-related behavioral outcomes would make comparisons between studies more valid.

In conclusion, results from this review and meta-analysis bolster the growing evidence (1–3, 5) that VCT reduces risky behaviors related to HIV by significantly reducing the number of sex partners of participants. Additionally, people living with HIV who received VCT exhibited increased odds of using condoms and engaging in protected sex than people living with HIV who did not receive VCT.

In the past year, innovative, effective interventions for HIV prevention have been discovered, including treatment as prevention (35) and pre-exposure prophylaxis (PrEP) (36). However, these interventions will only succeed if more people become aware of their HIV status, highlighting the continued importance of VCT in preventing HIV and accessing care and treatment. Although this review adds to the evidence that VCT reduces risky behaviors, relatively few details are known about which modalities of VCT are most

effective. Additionally, the included studies revealed little information about how intervention components were implemented, such as which counseling strategies were employed during pre- and post-test counseling. These details are precisely what must be understood in order to maximize the effectiveness of VCT in regards to changing sexual risk behavior, thus maximizing this intervention's ability to prevent HIV, and for those who test positive, increasing the uptake of HIV care and treatment.

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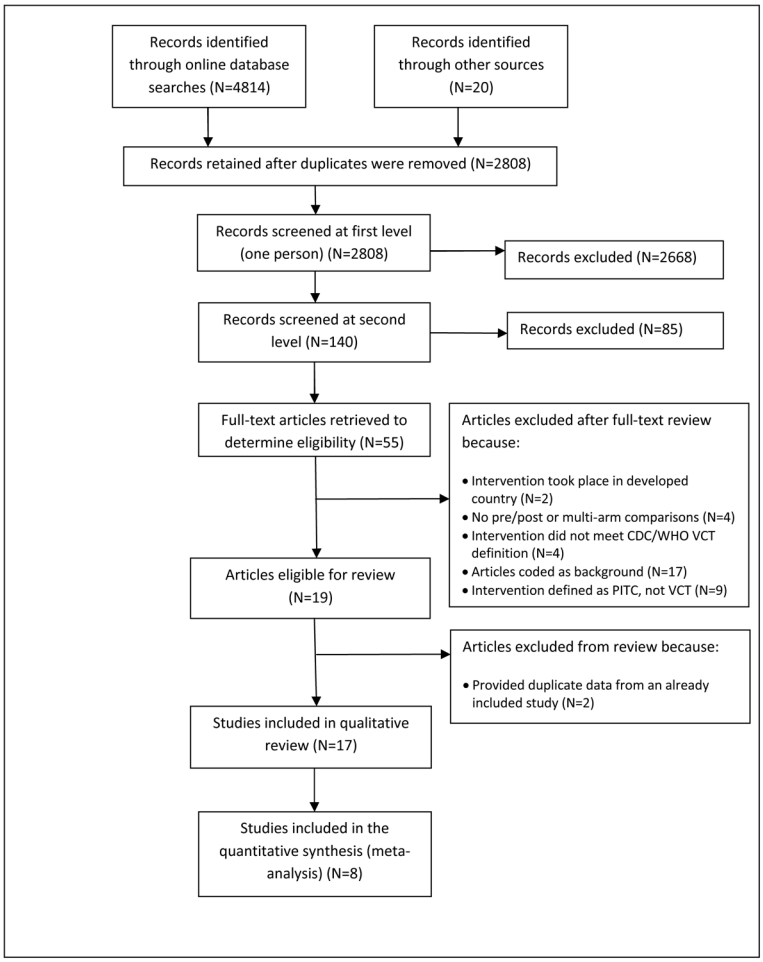


FIGURE 1.
Flow chart depicting disposition of study citations (2005–2010)

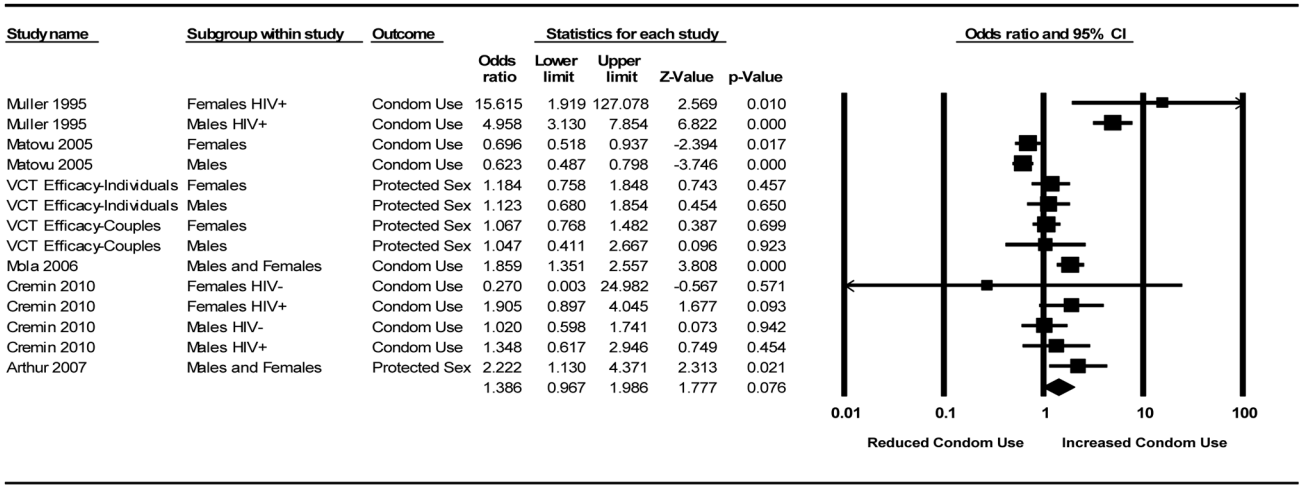
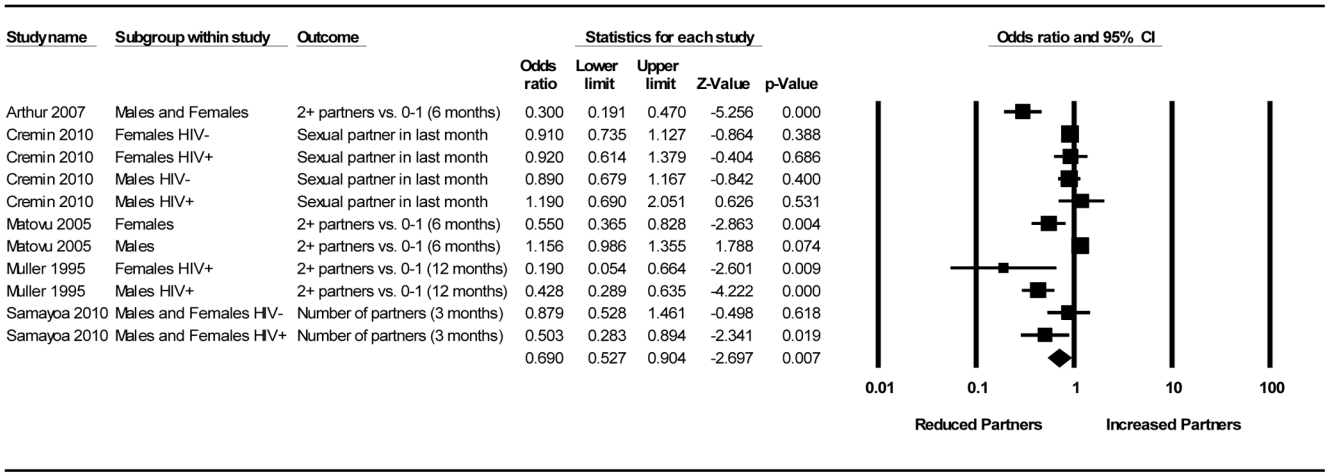


FIGURE 2.

Meta-analysis: Random effects model—Condom use/protected sex



Study name	Subgroup within study	Outcome	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Arthur 2007	Males and Females	2+ partners vs. 0-1 (6 months)	0.300	0.191	0.470	-5.256	0.000
Cremin 2010	Females HIV-	Sexual partner in last month	0.910	0.735	1.127	-0.864	0.388
Cremin 2010	Females HIV+	Sexual partner in last month	0.920	0.614	1.379	-0.404	0.686
Cremin 2010	Males HIV-	Sexual partner in last month	0.890	0.679	1.167	-0.842	0.400
Cremin 2010	Males HIV+	Sexual partner in last month	1.190	0.690	2.051	0.626	0.531
Matovu 2005	Females	2+ partners vs. 0-1 (6 months)	0.550	0.365	0.828	-2.863	0.004
Matovu 2005	Males	2+ partners vs. 0-1 (6 months)	1.156	0.986	1.355	1.788	0.074
Muller 1995	Females HIV+	2+ partners vs. 0-1 (12 months)	0.190	0.054	0.664	-2.601	0.009
Muller 1995	Males HIV+	2+ partners vs. 0-1 (12 months)	0.428	0.289	0.635	-4.222	0.000
Samayoa 2010	Males and Females HIV-	Number of partners (3 months)	0.879	0.528	1.461	-0.498	0.618
Samayoa 2010	Males and Females HIV+	Number of partners (3 months)	0.503	0.283	0.894	-2.341	0.019
			0.690	0.527	0.904	-2.697	0.007

FIGURE 3.
Meta-analysis: Random effects model—Number of sexual partners

TABLE 1

Study Description table

Study	Setting	Population Characteristics	Intervention Description	Study Design	Outcomes Used in Meta-Analysis
Allen et al., 2003	Zambia Lusaka Clinic-based VCT	HIV serodiscordant couples Gender: 50% female; 50% male Age: Mean male age: 35 Mean female age: 29	Couples recruited from a same-day VCT center. The same-day couples' VCT services included free treatment for syphilis, condom skills training, and free condoms.	Cohort study with before-after data presented on extramarital sex among male and female participants. Individual unit of analysis. Non-random selection of participants.	none
Arthur et al., 2007	Kenya Thika & Nairobi Districts Clinic-based VCT	At least 18 years old or married, never tested for HIV and regular partner never tested. Gender: % male: 52% % female: 48% Age: Mean by Gender Men 29 Women 28	The new free counselling and simple rapid on-site testing service used existing infrastructure to mirror future government services. Each had one project-salaried counsellor, with testing performed by nurses and counsellors. Condom demonstrations and free condoms were provided. Counselling sessions used a client-centred approach involving personalized, interactive counselling, and included risk assesment and coping strategies.	Single-arm prospective cohort study with before-after design. Assessments took place at baseline (N=540) and at follow up (6-months; mean=7.5 months; N=401) post-intervention. Participants were selected based on the three health clinics which were selected systematically.	Unprotected sex with any partner type (in the analysis, this outcome was flipped to reflect protected sex)
Bakari et al., 2000	Zambia Lusaka Clinic-based VCT	Couples and individuals invited and/or attending VCT clinics Gender: not reported Age Range 16–56	Zambia-UAB HIV research project (ZUHRP) invited couples for same-day HIV counseling and testing. Participants were also recruited from Kara Counseling without same-day test results.	Cross-sectional data analyzed using cross-tabulations stratified by four categories: a) couples invited for same-day VCT at ZUHRP but did not attend; b) couples who attended ZUHRP but chose not to test; c) couples who attended ZUHRP and were tested; and d) individuals tested at Kara counseling (results were not same-day results). Random selection of participants. Individual unit of analysis.	none
Chen et al., 2007	China Guangxi Province Clinic-based VCT	Adult IDUs in southern China Gender: 89.8% male 10.2% female Age: Range: 20 – 50+	Participants received HIV pre-test counseling, HIV testing, post-test counseling and referral. Pre-test counseling was conducted one-on-one and covered fundamentals of AIDS knowledge, risk reduction and demonstration of effective use of bleach and condoms. Post-test counseling was conducted after participant finished the HIV testing and was informed of his/her HIV antibody status. Post-test counseling was tailored to serostatus and consissted of a risk	Before-After study design with no control group. Assessments took place at baseline (N=226) and at 3 months (N=217) post-intervention. Participants were non-randomly selected.	none

Study	Setting	Population Characteristics	Intervention Description	Study Design	Outcomes Used in Meta-Analysis
			reduction "booster" and information about referral services. HIV positive participants received more intensive information regarding referral services.		
Corbett et al., 2007	Zimbabwe Harare Employment-based VCT	Employed HIV-negative adults in Africa. Gender: I: 90.5% male; 9.5% female C: 88.4% male; 11.6% female Age: Mean: I = 36.3; C =36.7	Participants received either Intensive VCT or standard VCT. Intensive VCT included pre-test counseling, risk asssessment, testing, results and pre-test counseling with risk reduction planning all on the same day. Follow-up counseling and repeat VCT were available. Standard VCT participants received pre-test counseling and risk assessment and were then given a pre-paid voucher to a chain of free-standing VCT providers. All participants had access to free condoms.	Randomized group trial study design. Assessments took place at baseline (N=4316) and at approx. 2 years (N =2966) post-intervention. Participants were non-randomly selected.	none
Cremin et al., 2010	Zimbabwe Manicaland province of Eastern Zimbabwe Mobile VCT	Zimbabweans in rural areas and small towns. Gender: 42% male 58% female Age: 15–54 with a median of 29 for males and 30 for females	Participants were offered free HIV counseling and testing at each survey. This service was available at a mobile clinic which was present within the study site at the time the survey was being conducted. Participants receiving VCT from the research program did so after completing the survey questionnaire. During the baseline and second surveys, VCT clients were asked to return 2 weeks after testing, to receive their results and post-test counseling. Counseling was provided by trained male and female nurse counselors.	Prospective cohort study. Assessments taken place at baseline (N= 8,273) and at 3 years (N= 6,559) and 5 years (N=12,553) post-intervention. Participants were non-randomly selected.	Consistent condom use in past 2 weeks with regular and non-regular partners Sexual partner in the past month
Grinstead et al., 2001	Nairobi, Kenya; Dares salaam, Tanzania; and Port of Spain, Trinidad. Clinic-based VCT	Individual and couples seeking VCT at a free-standing VCT center	VCT based on the CDC client-centered model. Counseling included personalized risk assessment, development of a personalized risk-reduction plan, role plays and condom demonstrations. Test results available 2 weeks after the blood draw. The participants in the health information (HI) arm watched a 15 minute video and participated in a group discussion about HIV transmission and condom use led by a health information officer. At the first follow-up HI participants were offered VCT.	Randomized controlled pre-/post trial comparing amount of sex and amount of unprotected sex at the 1st follow-up among adults who received VCT to adults who attended the HI session. Individual unit of analysis. Non-random selection of participants.	none
Kawichai et al., 2004	Thailand Chiang Mai City Clinic-based VCT	Thai citizens living in Chiang Mai between the ages of 19–35 years. Gender: 41% male 59% female Age: Mean male age: 28 Mean female age: 29	Group pre-test counseling provided by trained counselors at community sites. Topics covered include HIV/STDs, routes of infection, risk assessment, risk reduction and the meaning of an HIV test. After blood draw the questionnaire was administered. Participants received confidential post-test counseling individually 2 to 3 weeks later at health clinics or hospitals.	Cross sectional analysis comparing risk behaviors among I=previously tested participants vs. C=untested participants, measured at baseline. Individual unit of analysis. Non-random selection of participants.	none
Machekano et al., 1998	Zimbabwe Employment-based VCT	Male factory workers 100% Male	Pre-test counseling, provided at the factories during the study recruitment, consisted of	Time series study design comparing HIV and STI	none

Study	Setting	Population Characteristics	Intervention Description	Study Design	Outcomes Used in Meta-Analysis
		Age not reported	individual risk assessment, meaning of the test results and availability of treatment and support. Subjects encouraged to obtain their test result from a project clinic located off factory premises 2 weeks after the blood draw. STD treatment and condoms provided free of charge. Post-test counseling covered topics such as the meaning of test results and disclosure.	incidence between: a) men who returned for their test results at the project clinic and men who did not come in for their test results; and b) before and after data among men who received their HIV test result. Analysis conducted on subjects who were HIV-negative at the time of enrollment. Factories were visited every six months to repeat serological tests and interviews. Individual unit of analyses. Non-random selection of participants.	
Matambo et al., 2006	Zimbabwe Harare Employment-based VCT	Employed individuals in Harare Gender: 87% male 13% female Age: Mean of 36	Participants received pretest counseling, including risk assessment and a risk reduction plan. Same-day results and posttest counseling were provided. For those with negative test results, posttest counseling routinely included discussion of the window period phenomenon, advice on how to tell sex partner(s) and ask them to consider voluntary counseling and testing as well, and advice on reducing their risk of acquiring HIV in the future. At the 3-month follow-up, a questionnaire, including a repeat risk assessment, was administered by the clinic nurse.	This was a before and after study. Assessments took place at baseline (N=388) and at 3 months (N=388) post-intervention. Participants were non-randomly selected.	none
Matovu et al., 2005	Uganda Rakai Home-based VCT	HIV negative adults in rural Uganda Gender: 57% female Ag range 15–49	Participants were interviewed and had a blood draw, followed by pre-test counseling. Participants could request free VCT as individuals or couples, either at the time of the interview or during the inter-survey period. Participants who choose to learn their HIV status received post-test counseling and verbally told their HIV test result.	Prospective cohort of initially HIV-negative respondents who completed the baseline interview in 1999 and the follow-up interview in 2000. All participants received pre-test counseling and had their blood drawn. Authors compared respondents who I=accepted VCT (received their VCT test result) vs. C= did not accept VCT (respondents who did not receive their VCT test result) in terms of number of sexual partners and condom use behaviors at baseline and follow-up. Census sampling.	Condom use (comparing consistent use to anything less than consistent use) Number of sex partners (dichotomized at 0–1 partner vs. ≥2 partners)

Study	Setting	Population Characteristics	Intervention Description	Study Design	Outcomes Used in Meta-Analysis
Mola et al., 2006	Mozambique Beira, Chimoio Clinic-based VCT	Individuals seeking VCT in central Mozambique Gender: I: 52% male C: 48% male Age: I: 43% < 21 years, 51%: 21–40 years, 6% >40 years C: 31% < 21 years, 64% 21–40 years, 5% >40 years	Voluntary counseling and testing for HIV (no detailed description of the intervention provided)	Prospective cohort study. Assessments took place at baseline (N=1220), 4 months (N=1052), and 6 months (N=954 post-intervention. Participants were not randomly selected to participate.	Condom use (sometimes/always)
Muller et al., 1995	Thailand Bangkok Clinic-based VCT	Adults seeking VCT Gender: 17% female 83% male Age: 15 to 66 years	HIV positive patients, who received their test result at the anonymous clinic (AC), were referred to the immune clinic (IC) for care and treatment after the post-test counseling. This outpatient clinic has cared for patients with HIV/AIDS since 1985 and newly attending patients receive counseling by specially trained Red Cross health workers.	Cross-sectional study comparing condom use and number of sex partners among HIV infected men and women who had previously sought VCT on average 23 months earlier and were attending an immune clinic to HIV infected age and gender-matched controls receiving VCT for the first time. Individual unit of analysis. Non-random selection of participants.	Condom use during last 3 sexual encounters (comparing always use to less than always use) Number of sex partners in past 12 months (dichotomized at 0–1 partners vs. ≥2 partners)
Roth et al., 2001	Rwanda Kigali Clinic-based VCT	Male cohabiting partners of women Gender: 100% male Age (mean): Females: 32 years Males: 39 years	Male counseling for the partners of previously tested women. Each man watched a video on HIV risk/safer sexual practices and participated in small group discussions led by trained social workers. Trained counselors gave individuals their HIV test results during a return visit.	Pre-/post intervention trial comparing condom use among men before and after having received the male counseling intervention. Individual and couple unit of analyses. Non-random selection of participants.	None
Samayoa et al., 2010	Guatemala Guatemala City Clinic-based VCT	Adults seeking HIV test in Guatemala Gender: 43.1% male 56.9% female Age range: 18–83 years	Voluntary pre-test and post-test counseling regarding HIV infection, transmission, prevention, and interpretation of HIV test results. Those who tested positive received psychological support; those who tested negative received further behavioral recommendations to reduce likelihood of infection.	Before-After (stratified by HIV status) study. Assessments took place at baseline (N=144) and at 3 months (N=90). Non-random selection of participants	Number of sexual partners in past 3 months (reported mean and standard deviation)
VCT Efficacy Study Group, 2000	Nairobi, Kenya; Dares salaam, Tanzania; and Port of Spain, Trinidad. Clinic-based VCT	Individual and couples seeking VCT at a free-standing VCT center Gender-Individuals 51% female 49% male Gender-Couples 50% female 50% male	VCT based on the CDC client-centered model. Counseling included personalized risk assessment, development of a personalized risk-reduction plan, role plays and condom demonstrations. Test results available 2 weeks after the blood draw. The participants in the health information (HI) arm watched a 15 minute video and participated in a group discussion about HIV transmission and	Randomized controlled pre-/post trial. Participants were randomly assigned to the study arms as individuals or couples. HI participants were offered VCT during the 1st follow-up visit (2nd follow-up data not shown). Because there	Unprotected sex with primary and non-primary partners (outcome flipped to reflect protected sex)

Study	Setting	Population Characteristics	Intervention Description	Study Design	Outcomes Used in Meta-Analysis
			condom use led by a health information officer. At the first follow-up HI participants were offered VCT.	was no effect of study site on intervention-group outcome, data were pooled for all analyses. Individual unit of analysis. Non-random selection of participants.	
Wu et al, 2005	China Townships in three counties in Fuyang city of Anhui province: Yingzhou, Lingquan, and Jieshou. Clinic-based VCT	Couples in mandatory premarital counseling Gender: 50% males; 50% females Age: not reported	The intervention included the provision of information about HIV/AIDS, including methods of transmission and strategies to protect oneself and one's partner from being infected. The program included a demonstration of condom use with a model. Each participant was given a risk–profile questionnaire to complete, which included a list of possible HIV exposures. The counseling sessions and questionnaires were administered to each person separately to ensure confidentiality. All participants were informed their test results would be made available to their partners only if they so desired. Local health professionals were trained to conduct all parts of the study program, including providing information about HIV/AIDS, obtaining blood samples for HIV testing, carrying out the rapid test, and providing pretest and posttest counseling for both HIV–negative and –positive individuals.	Before and after study with no control group. Assessments at baseline (N=319), and one year (N=319). Random selection of participants (25%) for one year follow up.	none

TABLE 2

Cochrane Risk of Bias Table (for randomized studies)

Study Author and year: Corbett et al., 2007		
Item	**Judgment (low risk/high risk/ uncertain risk)**	**Support for Judgment (description)**
Random sequence generation (selection bias)?	Unclear risk	Authors do not specify how the 22 businesses were randomly allocated to receive intense or standard VCT (pg 484)
Allocation concealment (selection bias)?	Unclear risk	Since the authors do not report their allocation method, it is impossible to discern whether or not allocation concealment (selection bias) was an issue
Blinding of participants and personnel (performance bias)?	Low risk	Participants were not blinded to treatment. However, laboratory personnel were blinded. Given the nature of the intervention, it is unlikely that the lack of blinding affected study outcomes.
Blinding of outcome assessment (detection bias)?	Unclear risk	Authors do not state whether or not interviewers administering follow-up surveys were blinded but laboratory staff were blinded for specimen analysis.
Incomplete outcome data addressed (attrition bias)?	High Risk	There were different attrition rates between intervention and control arms of the study.
Selective reporting (reporting bias)?	Low Risk	Note: Authors measure HIV incidence, but state that “HIV incidence was not an outcome of the VCT trial, and so no power studies were performed before analysis”. Thus, the study may not have had enough power to detect differences in HIV incidence between the two arms.
Other bias?	Low risk	No other biases detected
Study Author and year: Grinstead et al., 2001		
Item	**Judgment (low risk/ high risk/ uncertain risk)**	**Support for Judgment (description)**
Random sequence generation (selection bias)?	Low risk	Although the randomization process was not specified in the article, data utilized in the study came from the VCT Efficacy Trial in which the random sequence generation is detailed.
Allocation concealment (selection bias)?	Low Risk of Bias	Recruitment and allocation were sufficiently separated and concealed (NOTE: this was not explicitly stated in the article but this was mentioned in the VCT Efficacy Study)
Blinding of participants and personnel (performance bias)?	Low Risk of Bias	Participants were not blinded, but it is unlikely that the lack of blinding influenced the study outcomes
Blinding of outcome assessment (detection bias)?	Unclear Risk	“Interviewers needed to be blinded to the baseline serostatus of participants during the follow-up interview; therefore, several series of questions assessing life events and disclosure of HIV serostatus were deferred from the interview and ascertained later by a counselor” No mention is made whether the interviewers were blinded to the participants’ treatment group.
Incomplete outcome data addressed (attrition bias)?	Low Risk of Bias	No differences were found between retained and non-retained participants at second follow-up on any baseline sexual behaviour variables.
Selective reporting (reporting bias)?	Unclear risk	It is not clear whether study addressed outcomes pre-specified in study protocol (no baseline measures for negative and positive life events were measured)
Other bias?	Low risk	No other biases detected
Study Author and year: VCT Efficacy Study Group, 2000		

Study Author and year: Corbett et al., 2007		
Item	**Judgment (low risk/high risk/ uncertain risk)**	**Support for Judgment (description)**
Item	**Judgment (low risk/high risk/ uncertain risk)**	**Support for Judgment (description)**
Random sequence generation (selection bias)?	Low Risk of bias	"Randomisation was stratified by site, sex, and couple or individual status. Participants were assigned VCT or health information by allocation of sealed envelopes. Couples were always randomised together."
Allocation concealment (selection bias)?	Low Risk of Bias	Recruitment and allocation were sufficiently separated and concealed
Blinding of participants and personnel (performance bias)?	Low Risk of Bias	Participants were not blinded to treatment allocation. Participants assigned to VCT agreed to testing after being assigned to groups. It is unlikely that the lack of blinding influenced study results.
Blinding of outcome assessment (detection bias)?	Unclear Risk of Bias	Specification of blinding lab technicians and interviewers were not provided
Incomplete outcome data addressed (attrition bias)?	Low Risk of Bias	No differences were found between retained and non-retained participants at second follow-up on any baseline sexual behaviour variables. At 1st follow-up, VCT − 82% (n=1281); HI − 81.5% (n=1269) At 2nd follow-up, VCT − 70.7% (n=1105); HI − 70.1% (n=1091)
Selective reporting (reporting bias)?	Low Risk of Bias	All outcomes specified in the paper were measured and results were reported.
Other bias?	Low Risk of Bias	No other bias detected

TABLE 3

Study Quality Assessment (all studies)

Study	Cohort	Control or comparison group	Pre/post intervention data	Random assignment of participants to intervention	Random selection of participants for assessment	Follow-up rate of 80% or more	Comparison groups equivalent on socio-demographics	Comparison groups equivalent at baseline on outcome measure
VCT Efficacy Group, 2000-indviduals	yes	yes	yes	yes	no	yes	yes	no
VCT Efficacy Group, 2000-couples	yes	yes	yes	yes	no	yes	yes	no
Grinstead et al., 2001-individuals	NA	yes	no	yes	no	NA	yes	NR
Grinstead et al., 2001-couples	NA	yes	no	yes	no	NA	yes	NR
Muller et al., 1995	no	yes	no	no	no	NA	yes	NA
Kawichai et al., 2004 Analysis 1	no	yes	no	no	no	NA	NR	NA
Allen et al., 2003	yes	no	yes	no	no	NR	NA	NA
Bakari et al., 2000	no	yes	no	no	yes	NA	NA	NA
Matuvo et al., 2005	yes	yes	yes	no	yes [a]	no	NR	yes
Mola et al. (2006)	yes	yes	yes	no	no	no	no	no
Arthur et al., 2007	yes	no	yes	no	no	no	NA	NA
Samayoa et al., 2010	yes	no	yes	NA	no	no	NA	NA
Cremin et al., 2010	yes	yes	yes	no	no	NR	NR	NR
Corbett et al., 2007	yes	yes	yes	yes [c]	no	no	yes	yes
Machekano et al., 1998	yes	yes	yes	no	no	yes	NR	NR
Matambo et al., 2006	yes	no	yes	NA	no	NR	NA	NA
Chen et al., 2007	yes	no	yes	no	no	yes	NA	NA
Wu et al, 2005	yes	no	yes	no	yes [d]	yes	NA	NA
Roth et al., 2001	yes	no	yes	no	no	NR	NA	NA

[a] Census sampling was used

[b] Pre/post intervention data is available for only one of the primary outcomes measured

[c] Random assignment was by group, not individual participants

[d] The intervention was mandatory for all couples seeking a marriage license, but the participants who were followed-up were randomly selected

TABLE 4

Summary of meta-analysis results stratified by gender and HIV status

	Number of studies	Odds ratio	95% confidence interval	Q-statistic	p-value for Q-statistic	I-squared
Condom use/protected sex						
Overall condom use/protected sex (all studies)	7	1.39	(0.97–1.99)	94.10	<0.001	86.19
Males	5	1.31	(0.64–2.66)	61.24	<0.001	91.84
Females	5	1.17	(0.76–1.80)	16.04	0.007	68.82
HIV-positive participants (males and females)	2	3.24	(2.29–4.59)*	12.19	0.007	75.39
HIV-positive males	2	2.69	(0.75–9.62)	7.92	0.005	87.37
HIV-positive females	2	4.30	(0.58–32.08)	3.426	0.064	70.81
Number of sex partners						
Overall number of sex partners (all studies)	5	0.69	(0.53–0.90)*	61.84	<0.001	83.83
Males	3	0.86	(0.57–1.29)	22.10	<0.001	86.42
Females	3	0.70	(0.47–1.04)	10.11	0.018	70.33
HIV-positive participants (males and females)	3	0.61	(0.37–1.00)*	16.36	0.003	75.54
HIV-negative participants	2	0.90	(0.77–1.06)	0.025	0.987	0.00

*Significant at p<0.05