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Manuscripts

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3 **Relationship between Social Cognitive Theory Constructs and Self-Reported Condom Use:**
4 **Findings from the *Safe in the City* Trial**
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31 The findings and conclusions in this article are those of the authors and do not necessarily
32 represent the official position of the Centers for Disease Control and Prevention.
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Abstract

Objectives: Previous studies have found Social Cognitive Theory (SCT)-framed interventions are successful for improving condom use and reducing sexually-transmitted infections (STIs). We conducted a secondary analysis of behavioral data from the *Safe in The City* intervention trial (2003–2005) to investigate the influence of social cognitive theory constructs on study participants' self-reported use of condoms at last intercourse.

Methods: The main trial was conducted from 2003–2005 at 3 public US STI clinics. Patients (n = 38,635) were either shown a “safer sex” video in the waiting room, or received the standard waiting room experience, based on their visit date. A nested behavioral assessment was administered to a subsample of study participants following their index clinic visit and again at 3 months follow-up. We used multivariable modified Poisson regression models to examine the relationships among SCT constructs (sexual self-efficacy, self-control self-efficacy, self-efficacy with most recent partner, hedonistic outcome expectancies, and partner expected outcomes) and self-reported condom use at last sex act at the 3-month follow-up study visit.

Results: Of 1252 participants included in analysis, 39% reported using a condom at last sex act. Male gender, homosexual orientation, and single status were significant correlates of condom use. Both unadjusted and adjusted models indicate that sexual self-efficacy (adjusted relative risk [RRa] = 1.50, 95% confidence interval [CI] = 1.23–1.84), self-control self-efficacy (RRa = 1.67, 95% CI = 1.37–2.04), self-efficacy with most recent partner (RRa = 2.56, 95% CI = 2.01–3.27), more favorable hedonistic outcome expectancies (RRa = 1.83, 95% CI = 1.54–2.17), and more favorable partner expected outcomes (RRa = 9.74, 95% CI = 3.21–29.57) were significantly associated with condom use at last sex act.

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3 **Conclusions:** Social cognitive skills, such as self-efficacy and partner expected outcomes, are an
4 important aspect of condom use behavior.
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10 11 12 **Article Summary**

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15 • Social cognitive skills are an important aspect of condom use behavior for the
16 participants in *the Safe in the City* trial.
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21 • Self-efficacy and partner expected outcomes are associated with self-reported
22 condom use at last sex act.
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27 • Prevention programs that seek to increase condom use should consider social
28 cognitive skills (such as self-efficacy and partner expected outcomes).
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32 **Strengths and limitations of this study**

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35 • A strength of our study is that the study sample size was large consisting of a
36 geographically, ethnically and socio-culturally diverse group of STI clinic attendees.
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41 • A potential limitation is that the analysis included only those subjects who participated in
42 the behavioral component of the SITC trial, and, consequently, may not be representative
43 of the overall patient population included in the larger trial, or generalizable to all STI
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INTRODUCTION

Sexually transmitted infections (STI) affect approximately 19 million people annually in the US[1, 2]. Used consistently and correctly, condoms are an important strategy for reducing sexually transmitted infections (STI) and human immunodeficiency virus (HIV)[3]. Several studies have demonstrated that Social Cognitive Theory (SCT)-framed interventions are successful at improving condom use and reducing sexually transmitted infection (STI) incidence[4-8]. SCT-framed interventions are thought to improve condom use and reduce sexual risk behavior by improving individuals' behavioral skills and perceptions of their ability to use condoms (self-efficacy)[8]. *Safe in the City* (SITC), a 23-minute STI prevention video, was such an intervention. It used an integrated theoretical approach, including core elements of SCT to achieve health behavior change[9]. While a previous multi-site controlled trial demonstrated a decrease in the overall incidence of infection among the STI clinic participants who viewed the video[9], it remains unclear how the SITC intervention affected individuals' behavior that led to reductions in STI incidence. In this account, we examine the question of do SCT constructs influence sexual risk behaviors such as condom use. We used information collected from individuals who were a subgroup of clinic patients participating in the nested behavioral study conducted during the larger SITC trial.

METHODS

The Institutional Review Board at each participating site and the Centers for Disease Control and Prevention reviewed and approved all study procedures. The SITC trial was conducted from

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3 2003 to 2005, at 3 publicly funded STI clinics in the US. Approximately 40 000 clinic patients
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5 either viewed a theory-based intervention video while in the waiting room, or not; selection was
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7 based on their clinic visit date[9]. For this analysis, we used data from a subset of participants
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9 who completed the behavioral assessment both immediately following their index clinic visit
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11 (baseline) and at 3 months follow-up. In total, 217 persons were lost to follow-up, 130 were not
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13 sexually active at follow-up, and 10 were excluded from this analysis due to incomplete or
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15 missing demographic information. The remaining 1252 participants were included in the
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17 analysis. The behavioral assessments were conducted using an audio/computer assisted self-
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19 interview (A-CASI) technology (QDS, Nova Research Company, Bethesda, Maryland). Each
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21 assessment measured sexual behaviors, condom use, and psychosocial factors related to condom
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23 use (eg, condom use self-efficacy).
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30 Asked at the 3-months follow-up visit, our primary outcome was self-reported condom
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32 use at the most recent sexual encounter. We chose this time frame (ie, last sex act) because self-
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34 reported sexual history and condom use are thought to be more reliable and less prone to recall
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36 bias when specific and recent[10]. We selected SCT constructs as potential factors affecting
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38 condom use, including condom use self-efficacy, self-control self-efficacy, sexual self-efficacy,
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40 hedonistic condom outcome expectancies, expected partner reaction outcomes, and also risk
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42 perception; all were asked at the 3-month follow-up visit[8,11-12]. For each construct, responses
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44 to the related questions were reverse-scored if necessary, (such that all questions and responses
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46 were in the same direction, if negatively or positively phrased), then responses were cumulated,
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48 averaged, and then re-calculated to a binary variable to indicate either a positive (1) or
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50 ambivalent/negative (0) attitude toward condom use (Table 1). For example, for each theoretical
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52 construct, if a respondent's average score was greater than 2, then it was re-calculated to "1". If a
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respondent's average score was 2 or below, then the score was recalculated to "0" to create a binary variable indicating either a positive (1) or ambivalent/negative attitude toward condom use (0). We examined models with both rescored and unscored constructs. Since the variables that were statistically significant did not change, we decided to use the binary coded variables. We assessed internal consistency for each construct and all Cronbach's alpha scores were $>.80$.

TABLE 1. Items Included in Each Social Cognitive Theory Construct

SCT Constructs		Items	Responses				
			Strongly Disagree 0-----	1	2	3	Strongly Agree -----4
1. Self-Efficacy (most recent partner)	Can use a condom even if most recent sex partner does not want to	0	1	2	3	4	
	Can use a condom every time you have sex with most recent sex partner	0	1	2	3	4	
	Can use a condom even if want to feel close with most recent sex partner	0	1	2	3	4	
	Can use condom even if you are making up with most recent sex partner after a fight	0	1	2	3	4	
	Can use condom even high or drunk with most recent sex partner	0	1	2	3	4	
2. Self-Control	I could stop having sex:						
Self-Efficacy	To get a condom even if I'm really turned on	0	1	2	3	4	
	If no condom was available	0	1	2	3	4	

Even if it meant getting dressed and going to the store	0	1	2	3	4
Even with a really hot new partner	0	1	2	3	4
Even with someone I want to have a relationship with	0	1	2	3	4
Even with someone I am in love with	0	1	2	3	4

3. Sexual

Self-Efficacy

I am sure that I can:

Talk with partner about sexual past and our risk of getting STDs and AIDS from each other

0	1	2	3	4
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Go without sex until partner has had check up for STDs and doesn't have any

0	1	2	3	4
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break-up with a partner who puts me at risk of getting STDs

0	1	2	3	4
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Avoid having sex when I am drunk, or high on drugs.

0	1	2	3	4
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Get to know potential partners better before having sex with them

0	1	2	3	4
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Have fewer sex partners in the next 3 months, than in the past 3 months.

0	1	2	3	4
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Have sex with only one partner in the next 3 months

0	1	2	3	4
---	---	---	---	---

Go without having sex for the next 3 months

0	1	2	3	4
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Discuss using condoms with my partners

0	1	2	3	4
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3 Keep condoms where I will have them 0 1 2 3 4
4 nearby when I need them

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7 Use condoms more often 0 1 2 3 4
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11 Use condoms until my partner has had a 0 1 2 3 4
12 check-up for STDs, and doesn't have any

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14 Use condoms until my partner has been 0 1 2 3 4
15 tested for HIV, (AIDS), and is HIV negative
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19 Use a condom with my MAIN partner 0 1 2 3 4
20 EVERY TIME we have vaginal or anal sex
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22 Use a condom with partners OTHER THAN 0 1 2 3 4
23 my main partner, EVERY TIME we have
24 vaginal or anal sex
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29 **4. Hedonistic**
30 **Outcomes**

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32 Condoms ruin the mood 0 1 2 3 4
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34 Sex doesn't feel as good when you use a 0 1 2 3 4
35 condom
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37 Sex with condoms doesn't feel natural 0 1 2 3 4
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39 Using condoms breaks up the rhythm of sex 0 1 2 3 4
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**5. Partner
Expect
Outcomes**

**(most recent
partner)**

I think my most recent sex partner would:

Be proud of me if I asked to use condoms	0	1	2	3	4
Be supportive if I asked to use condoms	0	1	2	3	4
Appreciate it if I asked to use condoms	0	1	2	3	4
Be mad at me if I asked to use condoms	0	1	2	3	4
Break up with me if I asked to use condoms	0	1	2	3	4
Think I have other partners if I asked to use condoms	0	1	2	3	4
Be jealous if I asked to use condoms	0	1	2	3	4

**6. Risk
Perception**

If I don't use condoms, I could get infected with an STD or HIV in the next 3 months	0	1	2	3	4
Unless I change my behavior, I am likely to get an STD or HIV	0	1	2	3	4
If I don't reduce the number of people I have unprotected sex with, I could get infected with a STD or HIV	0	1	2	3	4
If I keep having unprotected sex with my partner(s), I could get infected with a STD or HIV	0	1	2	3	4
Sometimes I think that it's only a matter of time before I get an STD or HIV	0	1	2	3	4

Statistical Analysis

We used counts and percentages in order to describe the sociodemographic and self-reported condom use characteristics (Table 2). We constructed multivariable Poisson regression models with robust error variances to estimate the relative risks (RR) and associated 95% confidence intervals (CIs) in order to determine if the specified SCT constructs, and demographic and intervention variables were associated with self-reported condom use at last sex act. Specifically, six models were constructed (Table 1), for each SCT construct and risk perception (1 = self-efficacy, 2 = self-control self-efficacy, 3 = sexual self-efficacy, 4 = hedonistic outcome expectancies, 5 = partner expected outcomes, and 6 = risk perception), and we assessed the effects of each on reported condom use at last sex act. The constructs were first evaluated in unadjusted models, and again after adjusting for demographic and study-related variables (receipt of intervention, study site, age, race, gender, marital status, education, and sexual orientation). Analyses were performed with SAS version 9.3 (SAS Institute Inc., Cary, North Carolina, USA).

TABLE 2. Sociodemographic Characteristics Among Participants in the “*Safe in The City*” Study Behavioral Assessment

	N	(%)
	1252	
Study Arm		

Control	614	(49)
Intervention	638	(51)

Study Site

Denver	515	(41)
San Francisco	280	(22)
Long Beach	457	(37)

Age (years)

≤ 25	530	(42.3)
26–34	380	(30.4)
≥ 35	342	(27.3)

Race/Ethnicity

White (non-Hispanic)	467	(37)
Black (non-Hispanic)	318	(25)
Other (non-Hispanic)	182	(15)
Hispanic	285	(23)

Marital Status

Single	931	(74)
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Married/Domestic Part/Cohabiting	238	(19)
Separated/Divorced/Widowed	82	(7)

Education

≤ 12 years of school	429	(34)
Some college	367	(29)
College degree	283	(23)
Post college	173	(14)

Gender

Male	809	(65)
Female	443	(35)

Sexual Identity

Homosexual	171	(14)
Heterosexual	973	(78)
Bisexual/Not sure	108	(8)

Used a Condom at Last Sex Act

No	758	(61)
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Yes	494	(39)
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RESULTS

Participant Characteristics

Forty-nine percent of participants were in the control arm of the study; 51% were in the intervention group. Participants were from all study sites: Denver (41%), San Francisco (22%), and Long Beach (37%). Forty-two percent of the participants were 25 years of age or younger, 30% were 26–34 years and 27% were over 35 years of age. Approximately two-thirds of the participants were male. Twenty-five percent self-identified their race ethnicity as black non-Hispanic, 37% as white non-Hispanic, 15% as other non-Hispanic, and 23% as Hispanic. Approximately three-quarters of respondents reported that they were single (Table 2). Fourteen percent of participants reported their sexual identity as homosexual, 78% as heterosexual, and 8% as not sure or bisexual.

Correlates of Condom Use at Last Sex Act

Thirty-nine percent of participants reported using a condom at last sex act (Table 2).

Multivariable analyses revealed that several sociodemographic variables were significantly associated with condom use at last intercourse (Table 3). Being male (RR = 1.23, 95% CI = 1.05-

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3 1.45), single (RR = 1.64, 95% CI = 1.35-1.99), and self-identifying as homosexual (RR = 1.34,
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5 95% CI = 1.12-1.60) were significantly associated with condom use at last sex. All 6 constructs
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7 (1 = self-efficacy, 2 = self-control self-efficacy, 3 = sexual self-efficacy, 4 = hedonistic outcome
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9 expectancies, 5 = partner expected outcomes, and 6 = risk perception) were significantly
10
11 associated with self-reported condom use at last sex act in unadjusted models (Table 4). After
12
13 adjusting for the intervention arm and demographic variables, all of the construct associations
14
15 remained significant, except risk perception (Table 4). In particular, participants who scored
16
17 positively on condom-use self-efficacy with their most recent partner (e.g., who indicated that
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19 they can use a condom even if the partner did not want to or even if “high” or drunk, etc.) were
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21 significantly more likely to have reported they used a condom during the last sex act (RRa =
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23 2.56, 95% CI = 2.01-3.27).
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30 **TABLE 3.** Relationship Between Selected Sociodemographic Characteristics and
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32 Condom Use at Last Sex Act Among Participants in the “Safe in The City” Study Behavioral
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34 Assessment
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Sociodemographic Variables [^]	Relative Risk	95% C L	
Age < 25 years	1.11	.96	1.27
Black race	1.15	.98	1.36
Single	1.64	1.35	1.99***
Education (less than college degree)	.90	.78	1.04

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2				
3	Male	1.23	1.05	1.45**
4				
5				
6	Sexual orientation (homosexual)	1.34	1.12	1.60***
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10 ^ The analyses were also adjusted for study arm and study site. Results not shown.
11 CL: Confidence levels; * $P \leq .05$, ** $P \leq .01$, *** $P \leq .001$
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TABLE 4. Unadjusted and Adjusted Social Cognitive Theory Constructs and Condom Used at Last Sex Act Among Participants in the Safe in The City Study Behavioral Assessment

Social Cognitive Theory Constructs	% condom use at last sex act		Unadjusted RR	Confidence Levels		Adjusted[^] RR	Confidence Levels	
1. Self-efficacy with most recent partner	0	17	2.72	2.13	3.48***	2.56	2.01	3.27***
	1	47						
2. Self-control Self-efficacy	0	26	1.72	1.41	2.10***	1.67	1.37	2.04***
	1	44						
3. Sexual Self-efficacy	0	29	1.45	1.18	1.78***	1.50	1.23	1.84***
	1	42						
4. Hedonistic outcome expectancies	0	27	1.73	1.46	2.06***	1.83	1.54	2.17***
	1	46						
5. Partner expected outcomes	0	4	11.04	3.63	33.56***	9.74	3.21	29.57***
	1	42						

6. Risk perception	0	44	.84	.73	.97*	.88	.76	1.02
	1	37						

RR: Relative Risk; ^ Adjusted for socio-demographic characteristics: Study arm, study site, age, race, gender, marital status, sexual orientation, and education. * $P \leq .05$, ** $P \leq .01$, *** $P \leq .001$

Similarly, those with positive self-control self-efficacy, (RRa = 1.67, 95% CI = 1.37-2.04), positive sexual self-efficacy (RRa = 1.50, 95% CI = 1.23-1.84), more favorable hedonistic outcome expectancies, (RRa = 1.83, 95% CI = 1.54-2.17), or more favorable partner expected outcomes with their most recent sex partner (RRa = 9.74, 95% CI = 3.21-29.57) were also significantly more likely to have reported that they used a condom during the last sex act (all $P \leq 0.001$) in adjusted models.

DISCUSSION

Social cognitive theory (SCT) is based on the theoretical work of Bandura¹³ and includes conceptual components such as self-efficacy and outcome expectancies, such as an expected outcome for acquiring an STI or HIV. These conceptual components have been studied as correlates of sexual behavior. Self-efficacy has been found to be an important correlate of self-reported condom use[8,14-15], and to mediate the effectiveness of risk-reduction interventions.^{16,17} Previous studies have demonstrated this especially for women[8,14-15] and HIV-positive gay and bisexual men[17]. Other conceptual components within the social cognitive theoretical framework that have been found to influence or mediate condom use are outcome expectancies and from the health belief model risk perceptions. Outcome expectancies

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3 are also a major construct within other social psychological theories, such as the theory of
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5 reasoned action[19].For example, hedonistic outcome expectancies have been found to be related
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8 to both intention to use and self-reported use of condoms[6,14]. Risk perceptions have been
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10 evaluated among HIV-positive MSM and while being on a highly active antiretroviral therapy
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12 (HAART) did not increase risky behaviors, men who had low risk perceptions reported more
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14 unprotected sex[20].
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18 All six constructs evaluated in this analysis of data from the SITC trial were significantly
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20 associated with condom use at last sexual intercourse. For all models, three sociodemographic
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22 characteristics—being male, single, and of homosexual orientation—were significantly
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24 associated with condom use at last sex. Such participants also scored higher on condom use self-
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26 efficacy with their most recent partner, self-control self-efficacy, sexual self-efficacy, and had
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28 more positive condom use outcome expectancies as compared with their counterparts. These
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30 findings are consistent with previous reports, as described above[14,21-22].
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36 A particular strength of our study is that the study sample included a geographically,
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38 ethnically and socio-culturally diverse group of STI clinic attendees. However, there are some
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40 limitations. The analysis included only those subjects who participated in the behavioral
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42 component of the SITC trial, and, consequently, may not be representative of the overall patient
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44 population included in the larger trial, or generalizable to all STI clinic attendees. Additionally,
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46 although social desirability in responding is always a concern when collecting self-reported data
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48 on sexual risk behaviors[23], the use of A-CASI technology in the trial to collect sensitive
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50 information on the most recent act of intercourse may alleviate some of these concerns.
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3 Independent of the SITC intervention, women and heterosexual men in particular did not
4 seem to have social cognitive characteristics that facilitated condom use at last sex act. Rather,
5 condom use was more influenced by the social cognitive construct scores and individual
6 participant characteristics. It is possible that these individual socio-cognitive characteristics
7 predated any effects of the intervention,` as we did not measure socio-cognitive characteristics
8 prior to the intervention; the initial assessment occurred at the end of the baseline visit where the
9 video would have already been played while participants were waiting for their visit.` This
10 finding suggests future research directions; in particular, how best to determine the ways in
11 which SCT-framed interventions influence specific behaviors such as condom use.
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25 Can such interventions reshape or reinforce particular socio-cognitive characteristics and
26 thus change behavior? Future studies should consider measuring SCT components
27 longitudinally, i.e., before, during and after an intervention so that the pathway of how such
28 interventions affect SCT components can be clearly elucidated, particularly since SCT-framed
29 interventions can be an important tool for decreasing rates of STIs. Prevention programs that
30 seek to increase condom use should consider social cognitive constructs (such as self-efficacy
31 and partner expected outcomes) as important mediators of condom use, and they should be
32 included along with condom provision work to increase social cognitive skills.
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48 **Footnotes**

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51 **Contributors** All authors participated in the interpretation of the study and drafting of the
52 manuscript. All authors have seen and approved the final version. MCS, LW, AML, MGM,
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3 CAR, CKM, and LO contributed to the overall study design and concept. JDK, CAR, and CKM
4 participated in acquisition of data. MGM and JW performed the statistical analysis.
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19 **Competing Interests** None.
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23 **Ethics** The institutional review boards at each site and the Centers for Disease Control and
24 Prevention reviewed and approved the study protocol.
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29 **Data Sharing Statement** The Safe in the City Study Group has a project-specific web site that
30 provides additional details about the study and data. <http://www.stdcentral.org/SitC/> (please
31 click on 'contact' for additional information or to initiate a request). You may request data by
32 emailing Kees.Rietmeijer@dhha.org
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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	NA the trial has been published previously (Warner 2009)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Yes
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Yes
	2b	Specific objectives or hypotheses	Yes
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	NA the trial has been published previously (Warner 2009)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	Yes
	4b	Settings and locations where the data were collected	Yes
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	NA the trial has been published previously (Warner 2009)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	NA

		were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	Yes
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA the trial has been published previously (Warner 2009)
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Yes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Yes
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	NA the trial has been published previously (Warner 2009)
	13b	For each group, losses and exclusions after randomisation, together with reasons	Yes
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Yes
	14b	Why the trial ended or was stopped	Yes
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Yes
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	NA

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		by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Yes
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Yes
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Yes
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	NA the trial has been published previously (Warner 2009)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	NA
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	NA
Other information			
Registration	23	Registration number and name of trial registry	NA
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Yes

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Relationship between social cognitive theory constructs and self-reported condom use: assessment of behaviour in a subgroup of the Safe in the City Trial

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Manuscripts

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3 **Relationship between social cognitive theory constructs and self-reported condom use:**
4 **assessment of behaviour in a subgroup of the Safe in the City Trial**
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32 represent the official position of the Centers for Disease Control and Prevention.
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For peer review only

Abstract

Objectives: Previous studies have found Social Cognitive Theory (SCT)-framed interventions are successful for improving condom use and reducing sexually-transmitted infections (STIs). We conducted a secondary analysis of behavioral data from the *Safe in The City* intervention trial (2003–2005) to investigate the influence of social cognitive theory constructs on study participants' self-reported use of condoms at last intercourse.

Methods: The main trial was conducted from 2003–2005 at 3 public US STI clinics. Patients (n = 38,635) were either shown a “safer sex” video in the waiting room, or received the standard waiting room experience, based on their visit date. A nested behavioral assessment was administered to a subsample of study participants following their index clinic visit and again at 3 months follow-up. We used multivariable modified Poisson regression models to examine the relationships among SCT constructs (sexual self-efficacy, self-control self-efficacy, self-efficacy with most recent partner, hedonistic outcome expectancies, and partner expected outcomes) and self-reported condom use at last sex act at the 3-month follow-up study visit.

Results: Of 1252 participants included in analysis, 39% reported using a condom at last sex act. Male gender, homosexual orientation, and single status were significant correlates of condom use. Both unadjusted and adjusted models indicate that sexual self-efficacy (adjusted relative risk [RRa] = 1.50, 95% confidence interval [CI] = 1.23–1.84), self-control self-efficacy (RRa = 1.67, 95% CI = 1.37–2.04), self-efficacy with most recent partner (RRa = 2.56, 95% CI = 2.01–3.27), more favorable hedonistic outcome expectancies (RRa = 1.83, 95% CI = 1.54–2.17), and more favorable partner expected outcomes (RRa = 9.74, 95% CI = 3.21–29.57) were significantly associated with condom use at last sex act.

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3 **Conclusions:** Social cognitive skills, such as self-efficacy and partner expected outcomes, are an
4 important aspect of condom use behavior.
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10 11 12 **Article Summary**

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15 • Social cognitive skills are an important aspect of condom use behavior for the
16 participants in *the Safe in the City* trial.
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21 • Self-efficacy and partner expected outcomes are associated with self-reported
22 condom use at last sex act.
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27 • Prevention programs that seek to increase condom use should consider social
28 cognitive skills (such as self-efficacy and partner expected outcomes).
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32 **Strengths and limitations of this study**

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35 • A strength of our study is that the study sample size was large consisting of a
36 geographically, ethnically and socio-culturally diverse group of STI clinic attendees.
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41 • A potential limitation is that the analysis included only those subjects who participated in
42 the behavioral component of the larger SITC trial, and, consequently, may not be
43 representative of the overall patient population included in the larger trial, or
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INTRODUCTION

Sexually transmitted infections (STI) affect approximately 19 million people annually in the US[1, 2]. Used consistently and correctly, condoms are an important strategy for reducing sexually transmitted infections (STI) and human immunodeficiency virus (HIV)[3]. Several studies have demonstrated that Social Cognitive Theory (SCT)-framed interventions are successful at improving condom use and reducing sexually transmitted infection (STI) incidence[4-8]. SCT-framed interventions are thought to improve condom use and reduce sexual risk behavior by improving individuals' behavioral skills and perceptions of their ability to use condoms (self-efficacy)[8]. *Safe in the City* (SITC), a 23-minute STI prevention video, was such an intervention. It used an integrated theoretical approach, including core elements of SCT to achieve health behavior change[9]. While a previous multi-site controlled trial demonstrated a decrease in the overall incidence of infection among the STI clinic participants who viewed the video[9], it remains unclear how the SITC intervention affected individuals' behavior that led to reductions in STI incidence. In this account, we examine the question of whether SCT constructs influence sexual risk behaviors such as condom use. We used information collected from individuals who were a subgroup of clinic patients participating in the nested behavioral assessment conducted during the larger SITC trial.

METHODS

The Institutional Review Board at each participating site and the Centers for Disease Control and Prevention reviewed and approved all study procedures. The SITC trial was conducted from

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2
3 2003 to 2005, at 3 publicly funded STI clinics in the US. Approximately 40 000 clinic patients
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5 either viewed a theory-based intervention video while in the waiting room, or not; selection was
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7 based on their clinic visit date[9]. The behavioral assessment component of the larger SITC trial
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9 was a nonrandomized control trial where select clinic patients were invited to participate from
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11 the group of patients who attended clinic waiting rooms during the study period. For this
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13 analysis, we used data from a subset of participants who completed the behavioral assessment
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15 both immediately following their index clinic visit (baseline) and at 3 months follow-up. In total,
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17 217 persons were lost to follow-up, 130 were not sexually active at follow-up, and 10 were
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19 excluded from this analysis due to incomplete or missing demographic information. The
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21 remaining 1252 participants were included in the analysis.
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27 Participants received an incentive worth \$35-\$45 at the enrollment / baseline visit and an
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29 incentive worth \$45-\$60 at follow-up, depending on locality. The value of these incentives takes
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31 into account the time spent at the clinic as well as related costs of participation, such as travel to
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33 the clinic site, child care arrangements, and work time lost.
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36 The behavioral assessments were conducted using an audio/computer assisted self-
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38 interview (A-CASI) technology (QDS, Nova Research Company, Bethesda, Maryland). Each
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40 assessment measured sexual behaviors, condom use, and psychosocial factors related to condom
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42 use (eg, condom use self-efficacy). Asked only at the 3-months follow-up visit, our primary
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44 outcome was self-reported condom use at the most recent sexual encounter. We chose this time
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46 frame (ie, last sex act) because self-reported sexual history and condom use are thought to be
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48 more reliable and less prone to recall bias when specific and recent[10]. We selected SCT
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50 constructs as potential factors affecting condom use (also asked at the 3-months follow-up visit),
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52 including condom use self-efficacy, self-control self-efficacy, sexual self-efficacy, hedonistic
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condom outcome expectancies, expected partner reaction outcomes, and also risk perception; all were asked at the 3-month follow-up visit[8,11-12]. For each construct, responses to the related questions were reverse-scored if necessary, (such that all questions and responses were in the same direction, if negatively or positively phrased), then responses were cumulated, averaged, and then re-calculated to a binary variable to indicate either a positive (1) or ambivalent/negative (0) attitude toward condom use (Table 1). For example, for each theoretical construct, if a respondent's average score was greater than 2, then it was re-calculated to "1". If a respondent's average score was 2 or below, then the score was recalculated to "0" to create a binary variable indicating either a positive (1) or ambivalent/negative attitude toward condom use (0). We examined models with both rescored and unscored constructs. Since the variables that were statistically significant did not change, we decided to use the binary coded variables. We assessed internal consistency for each construct and all Cronbach's alpha scores were >.80.

TABLE 1. Items Included in Each Social Cognitive Theory Construct

SCT Constructs						
	Items	Responses				
		Strongly Disagree 0-----	1	2	3	Strongly ---Agree -----4
1. Self-Efficacy (most recent partner)	Can use a condom even if most recent sex partner does not want to	0	1	2	3	4
	Can use a condom every time you have sex with most recent sex partner	0	1	2	3	4
	Can use a condom even if want to feel close	0	1	2	3	4

with most recent sex partner

Can use condom even if you are making up with most recent sex partner after a fight	0	1	2	3	4
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Can use condom even high or drunk with most recent sex partner	0	1	2	3	4
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2. Self-Control

I could stop having sex:

Self-Efficacy

To get a condom even if I'm really turned on	0	1	2	3	4
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If no condom was available	0	1	2	3	4
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Even if it meant getting dressed and going to the store	0	1	2	3	4
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Even with a really hot new partner	0	1	2	3	4
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Even with someone I want to have a relationship with	0	1	2	3	4
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Even with someone I am in love with	0	1	2	3	4
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3. Sexual

Self-Efficacy

I am sure that I can:

Talk with partner about sexual past and our risk of getting STDs and AIDS from each other	0	1	2	3	4
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Go without sex until partner has had check up for STDs and doesn't have any	0	1	2	3	4
--	---	---	---	---	---

break-up with a partner who puts me at risk of getting STDs	0	1	2	3	4
--	---	---	---	---	---

Avoid having sex when I am drunk, or high	0	1	2	3	4
---	---	---	---	---	---

on drugs.

Get to know potential partners better before having sex with them 0 1 2 3 4

Have fewer sex partners in the next 3 months, than in the past 3 months. 0 1 2 3 4

Have sex with only one partner in the next 3 months 0 1 2 3 4

Go without having sex for the next 3 months 0 1 2 3 4

Discuss using condoms with my partners 0 1 2 3 4

Keep condoms where I will have them nearby when I need them 0 1 2 3 4

Use condoms more often 0 1 2 3 4

Use condoms until my partner has had a check-up for STDs, and doesn't have any 0 1 2 3 4

Use condoms until my partner has been tested for HIV, (AIDS), and is HIV negative 0 1 2 3 4

Use a condom with my MAIN partner EVERY TIME we have vaginal or anal sex 0 1 2 3 4

Use a condom with partners OTHER THAN my main partner, EVERY TIME we have vaginal or anal sex 0 1 2 3 4

4. Hedonistic Outcomes

Condoms ruin the mood 0 1 2 3 4

Sex doesn't feel as good when you use a condom 0 1 2 3 4

	Sex with condoms doesn't feel natural	0	1	2	3	4
	Using condoms breaks up the rhythm of sex	0	1	2	3	4
5. Partner Expect Outcomes (most recent partner)	I think my most recent sex partner would:					
	Be proud of me if I asked to use condoms	0	1	2	3	4
	Be supportive if I asked to use condoms	0	1	2	3	4
	Appreciate it if I asked to use condoms	0	1	2	3	4
	Be mad at me if I asked to use condoms	0	1	2	3	4
	Break up with me if I asked to use condoms	0	1	2	3	4
	Think I have other partners if I asked to use condoms	0	1	2	3	4
	Be jealous if I asked to use condoms	0	1	2	3	4
6. Risk Perception	If I don't use condoms, I could get infected with an STD or HIV in the next 3 months	0	1	2	3	4
	Unless I change my behavior, I am likely to get an STD or HIV	0	1	2	3	4
	If I don't reduce the number of people I have unprotected sex with, I could get infected with a STD or HIV	0	1	2	3	4
	If I keep having unprotected sex with my partner(s), I could get infected with a STD or HIV	0	1	2	3	4
	Sometimes I think that it's only a matter of time before I get an STD or HIV	0	1	2	3	4

Statistical Analysis

We used counts and percentages in order to describe the sociodemographic and self-reported condom use characteristics (Table 2). We constructed multivariable Poisson regression models with robust error variances to estimate the relative risks (RR) and associated 95% confidence intervals (CIs) in order to determine if the specified SCT constructs, and demographic and intervention variables were associated with self-reported condom use at last sex act. Specifically, six models were constructed (Table 1), for each SCT construct and risk perception (1 = self-efficacy, 2 = self-control self-efficacy, 3 = sexual self-efficacy, 4 = hedonistic outcome expectancies, 5 = partner expected outcomes, and 6 = risk perception), and we assessed the effects of each on reported condom use at last sex act. The social cognitive constructs were evaluated as continuous for the 5 point scales (data not shown) and also as dichotomous variables. The constructs were further evaluated in unadjusted models, and then again after adjusting for demographic and study-related variables (receipt of intervention, study site, age, race, gender, marital status, education, and sexual orientation). Analyses were performed with SAS version 9.3 (SAS Institute Inc., Cary, North Carolina, USA).

TABLE 2. Sociodemographic Characteristics Among Participants in the “*Safe in The City*” Study Behavioral Assessment

	N	(%)
	1252	
Study Arm		
Control	614	(49)
Intervention	638	(51)
Study Site		
Denver	515	(41)
San Francisco	280	(22)
Long Beach	457	(37)
Age (years)		
≤ 25	530	(42.3)
26–34	380	(30.4)
≥ 35	342	(27.3)
Race/Ethnicity		
White (non-Hispanic)	467	(37)
Black (non-Hispanic)	318	(25)
Other (non-Hispanic)	182	(15)

Hispanic	285	(23)
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Marital Status

Single	931	(74)
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Married/Domestic Part/Cohabiting	238	(19)
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Separated/Divorced/Widowed	82	(7)
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Education

≤ 12 years of school	429	(34)
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Some college	367	(29)
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College degree	283	(23)
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Post college	173	(14)
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Gender

Male	809	(65)
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Female	443	(35)
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Sexual Identity

Homosexual	171	(14)
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Heterosexual	973	(78)
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Bisexual/Not sure	108	(8)
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Used a Condom at Last Sex Act		
No	758	(61)
Yes	494	(39)

RESULTS

Participant Characteristics

Forty-nine percent of participants were in the control arm of the study; 51% were in the intervention group. Participants were from all study sites: Denver (41%), San Francisco (22%), and Long Beach (37%). Forty-two percent of the participants were 25 years of age or younger, 30% were 26–34 years and 27% were over 35 years of age. Approximately two-thirds of the participants were male. Twenty-five percent self-identified their race ethnicity as black non-Hispanic, 37% as white non-Hispanic, 15% as other non-Hispanic, and 23% as Hispanic.

Approximately three-quarters of respondents reported that they were single (Table 2). Fourteen percent of participants reported their sexual identity as homosexual, 78% as heterosexual, and 8% as not sure or bisexual.

The subgroup of participants in the behavioral assessment differed from all patients who attended the participating clinics during the study period (and whose records were reviewed) as

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3 they were significantly less likely to be male (65.4% vs 69.7%); aged 25 years or older (62.5%
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5 vs. 68.9%); white, non-Hispanic (36.8% vs 45.9%) and reside in San Francisco (35.2% vs
6
7 51.0%).
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10 11 12 13 14 15 16 17 **Correlates of Condom Use at Last Sex Act**

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20 Thirty-nine percent of participants reported using a condom at last sex act (Table 2).

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22 Multivariable analyses revealed that several sociodemographic variables were significantly
23
24 associated with condom use at last intercourse (Table 3). Being male (RR = 1.23, 95% CI = 1.05-
25
26 1.45), single (RR = 1.64, 95% CI = 1.35-1.99), and self-identifying as homosexual (RR = 1.34,
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28 95% CI = 1.12-1.60) were significantly associated with condom use at last sex. All 6 constructs
29
30 (1 = self-efficacy, 2 = self-control self-efficacy, 3 = sexual self-efficacy, 4 = hedonistic outcome
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32 expectancies, 5 = partner expected outcomes, and 6 = risk perception) were significantly
33
34 associated with self-reported condom use at last sex act in unadjusted models (Table 4). After
35
36 adjusting for the intervention arm and demographic variables, all of the construct associations
37
38 remained significant, except risk perception (Table 4). In particular, participants who scored
39
40 positively on condom-use self-efficacy with their most recent partner (e.g., who indicated that
41
42 they can use a condom even if the partner did not want to or even if “high” or drunk, etc.) were
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44 significantly more likely to have reported they used a condom during the last sex act (RRa =
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46 2.56, 95% CI = 2.01-3.27).
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TABLE 3. Relationship Between Selected Sociodemographic Characteristics and Condom Use at Last Sex Act Among Participants in the “Safe in The City” Study Behavioral Assessment

Sociodemographic Variables[^]	Relative Risk	95% C L	
Age < 25 years	1.11	.96	1.27
Black race	1.15	.98	1.36
Single	1.64	1.35	1.99***
Education (less than college degree)	.90	.78	1.04
Male	1.23	1.05	1.45**
Sexual orientation (homosexual)	1.34	1.12	1.60***

[^] The analyses were also adjusted for study arm and study site. Results not shown.
CL: Confidence levels; * $P \leq .05$, ** $P \leq .01$, *** $P \leq .001$

TABLE 4. Unadjusted and Adjusted Social Cognitive Theory Constructs and Condom Used at Last Sex Act Among Participants in the Safe in The City Study Behavioral Assessment

Social Cognitive Theory Constructs	% condom use at last sex act		Unadjusted Confidence Levels			Adjusted[^] Confidence Levels		
	0	1	RR			RR		
1. Self-efficacy with most recent partner	0	17	2.72	2.13	3.48***	2.56	2.01	3.27***
	1	47						
2. Self-control	0	26	1.72	1.41	2.10***	1.67	1.37	2.04***
Self-efficacy	1	44						
3. Sexual Self-efficacy	0	29	1.45	1.18	1.78***	1.50	1.23	1.84***
	1	42						
4. Hedonistic outcome expectancies	0	27	1.73	1.46	2.06***	1.83	1.54	2.17***
	1	46						
5. Partner expected outcomes	0	4	11.04	3.63	33.56***	9.74	3.21	29.57***
	1	42						

6. Risk perception	0	44	.84	.73	.97*	.88	.76	1.02
	1	37						

RR: Relative Risk; ^ Adjusted for socio-demographic characteristics: Study arm, study site, age, race, gender, marital status, sexual orientation, and education. * $P \leq .05$, ** $P \leq .01$, *** $P \leq .001$

Similarly, those with positive self-control self-efficacy, (RRa = 1.67, 95% CI = 1.37-2.04), positive sexual self-efficacy (RRa = 1.50, 95% CI = 1.23-1.84), more favorable hedonistic outcome expectancies, (RRa = 1.83, 95% CI = 1.54-2.17), or more favorable partner expected outcomes with their most recent sex partner (RRa = 9.74, 95% CI = 3.21-29.57) were also significantly more likely to have reported that they used a condom during the last sex act (all $P \leq 0.001$) in adjusted models.

DISCUSSION

Social cognitive theory (SCT) is based on the theoretical work of Bandura¹³ and includes conceptual components such as self-efficacy and outcome expectancies, such as an expected outcome for acquiring an STI or HIV. These conceptual components have been studied as correlates of sexual behavior. Self-efficacy has been found to be an important correlate of self-reported condom use[8,14-15], and to mediate the effectiveness of risk-reduction interventions.^{16,17} Previous studies have demonstrated this especially for women[8,14-15] and HIV-positive gay and bisexual men[17]. Other conceptual components within the social cognitive theoretical framework that have been found to influence or mediate condom use are outcome expectancies and from the health belief model risk perceptions. Outcome expectancies

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3 are also a major construct within other social psychological theories, such as the theory of
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5 reasoned action[19].For example, hedonistic outcome expectancies have been found to be related
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8 to both intention to use and self-reported use of condoms[6,14]. Risk perceptions have been
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10 evaluated among HIV-positive MSM and while being on a highly active antiretroviral therapy
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12 (HAART) did not increase risky behaviors, men who had low risk perceptions reported more
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14 unprotected sex[20].
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18 All six constructs evaluated in this analysis of data from the SITC trial were significantly
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20 associated with condom use at last sexual intercourse. For all models, three sociodemographic
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22 characteristics—being male, single, and of homosexual sexual orientation—were significantly
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24 associated with condom use at last sex. Such participants also scored higher on condom use self-
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26 efficacy with their most recent partner, self-control self-efficacy, sexual self-efficacy, and had
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28 more positive condom use outcome expectancies as compared with their counterparts. These
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30 findings are consistent with previous reports, as described above[14,21-22].
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36 A particular strength of our study is that the study sample included a geographically,
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38 ethnically and socio-culturally diverse group of STI clinic attendees. However, there are some
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40 limitations. The analysis included only those subjects who participated in the behavioral
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42 component of the SITC trial, and, consequently, may not be representative of the overall patient
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44 population included in the larger trial, or generalizable to all STI clinic attendees. Additionally,
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46 although social desirability in responding is always a concern when collecting self-reported data
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48 on sexual risk behaviors[23], the use of A-CASI technology in the trial to collect sensitive
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50 information on the most recent act of intercourse may alleviate some of these concerns.
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3 Independent of the SITC intervention, women and heterosexual men in particular did not
4 seem to have social cognitive characteristics that facilitated condom use at last sex act. Rather,
5 condom use was more influenced by the social cognitive construct scores and individual
6 participant characteristics. It is possible that these individual socio-cognitive characteristics
7 predated any effects of the intervention,` as we did not measure socio-cognitive characteristics
8 prior to the intervention; the initial assessment occurred at the end of the baseline visit where the
9 video would have already been played while participants were waiting for their visit.` This
10 finding suggests future research directions; in particular, how best to determine the ways in
11 which SCT-framed interventions influence specific behaviors such as condom use.
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25 Can such interventions reshape or reinforce particular socio-cognitive characteristics and
26 thus change behavior? Future studies should consider measuring SCT components
27 longitudinally, i.e., before, during and after an intervention so that the pathway of how such
28 interventions affect SCT components can be clearly elucidated, particularly since SCT-framed
29 interventions can be an important tool for decreasing rates of STIs. Prevention programs that
30 seek to increase condom use should consider social cognitive constructs (such as self-efficacy
31 and partner expected outcomes) as important mediators of condom use, and they should be
32 included along with condom provision work to increase social cognitive skills.
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48 **Footnotes**

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51 **Contributors** All authors participated in the interpretation of the study and drafting of the
52 manuscript. All authors have seen and approved the final version. MCS, LW, AML, MGM,
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3 CAR, CKM, and LO contributed to the overall study design and concept. JDK, CAR, and CKM
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12 and interpretation of the data; and preparation, review, and approval of the manuscript.
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19 **Competing Interests** None declared.
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23 **Ethics** The institutional review boards at each site and the Centers for Disease Control and
24 Prevention reviewed and approved the study protocol.
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29 **Data Sharing Statement** The Safe in the City Study Group has a project-specific web site that
30 provides additional details about the study and data. <http://www.stdcentral.org/SitC/> (please
31 click on 'contact' for additional information or to initiate a request). You may request data by
32 emailing Kees.Rietmeijer@dhha.org
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Relationship between Social Cognitive Theory Constructs and Self-Reported Condom Use: Findings from a Behavioral Assessment of a Nonrandomized Control Trial of a Video Based Intervention

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9 Key Words: Condom use, social cognitive theory, risk perception, sexual risk, self-efficacy,
10 partner expected outcome, hedonistic outcome expectancy
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13 Word Count: 1773
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For peer review only

Abstract

Objectives: Previous studies have found Social Cognitive Theory (SCT)-framed interventions are successful for improving condom use and reducing sexually-transmitted infections (STIs). We conducted a secondary analysis of behavioral data from the *Safe in The City* intervention trial (2003–2005) to investigate the influence of social cognitive theory constructs on study participants' self-reported use of condoms at last intercourse.

Methods: The main trial was conducted from 2003–2005 at 3 public US STI clinics. Patients (n = 38,635) were either shown a “safer sex” video in the waiting room, or received the standard waiting room experience, based on their visit date. A nested behavioral assessment was administered to a subsample of study participants following their index clinic visit and again at 3 months follow-up. We used multivariable modified Poisson regression models to examine the relationships among SCT constructs (sexual self-efficacy, self-control self-efficacy, self-efficacy with most recent partner, hedonistic outcome expectancies, and partner expected outcomes) and self-reported condom use at last sex act at the 3-month follow-up study visit.

Results: Of 1252 participants included in analysis, 39% reported using a condom at last sex act. Male gender, homosexual orientation, and single status were significant correlates of condom use. Both unadjusted and adjusted models indicate that sexual self-efficacy (adjusted relative risk [RRa] = 1.50, 95% confidence interval [CI] = 1.23–1.84), self-control self-efficacy (RRa = 1.67, 95% CI = 1.37–2.04), self-efficacy with most recent partner (RRa = 2.56, 95% CI = 2.01–3.27), more favorable hedonistic outcome expectancies (RRa = 1.83, 95% CI = 1.54–2.17), and more favorable partner expected outcomes (RRa = 9.74, 95% CI = 3.21–29.57) were significantly associated with condom use at last sex act.

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9 **Conclusions:** Social cognitive skills, such as self-efficacy and partner expected outcomes, are an
10 important aspect of condom use behavior.
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12 13 14 15 16 **Article Summary**

- 17
18 • Social cognitive skills are an important aspect of condom use behavior for the
19 participants in *the Safe in the City* trial.
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23 • Self-efficacy and partner expected outcomes are associated with self-reported
24 condom use at last sex act.
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28 • Prevention programs that seek to increase condom use should consider social
29 cognitive skills (such as self-efficacy and partner expected outcomes).
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32 **Strengths and limitations of this study**

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34 • A strength of our study is that the study sample size was large consisting of a
35 geographically, ethnically and socio-culturally diverse group of STI clinic attendees.
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39 • A potential limitation is that the analysis included only those subjects who participated in
40 the behavioral component of the larger SITC trial, and, consequently, may not be
41 representative of the overall patient population included in the larger trial, or
42 generalizable to all STI clinic attendees.
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INTRODUCTION

Sexually transmitted infections (STI) affect approximately 19 million people annually in the US[1, 2]. Used consistently and correctly, condoms are an important strategy for reducing sexually transmitted infections (STI) and human immunodeficiency virus (HIV)[3]. Several studies have demonstrated that Social Cognitive Theory (SCT)-framed interventions are successful at improving condom use and reducing sexually transmitted infection (STI) incidence[4-8]. SCT-framed interventions are thought to improve condom use and reduce sexual risk behavior by improving individuals' behavioral skills and perceptions of their ability to use condoms (self-efficacy)[8]. *Safe in the City* (SITC), a 23-minute STI prevention video, was such an intervention. It used an integrated theoretical approach, including core elements of SCT to achieve health behavior change[9]. While a previous multi-site controlled trial demonstrated a decrease in the overall incidence of infection among the STI clinic participants who viewed the video[9], it remains unclear how the SITC intervention affected individuals' behavior that led to reductions in STI incidence. In this account, we examine the question of ~~whether~~ SCT constructs influence sexual risk behaviors such as condom use. We used information collected from individuals who were a subgroup of clinic patients participating in the nested behavioral ~~assessment~~ study conducted during the larger SITC trial.

METHODS

The Institutional Review Board at each participating site and the Centers for Disease Control and Prevention reviewed and approved all study procedures. The SITC trial was conducted from

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9 2003 to 2005, at 3 publicly funded STI clinics in the US. Approximately 40 000 clinic patients
10 either viewed a theory-based intervention video while in the waiting room, or not; selection was
11 based on their clinic visit date[9]. The behavioral assessment component of the larger SITC trial
12 was a nonrandomized control trial where select clinic patients were invited to participate from
13 the group of patients who attended clinic waiting rooms during the study period. For this
14 analysis, we used data from a subset of participants who completed the behavioral assessment
15 both immediately following their index clinic visit (baseline) and at 3 months follow-up. In total,
16 217 persons were lost to follow-up, 130 were not sexually active at follow-up, and 10 were
17 excluded from this analysis due to incomplete or missing demographic information. The
18 remaining 1252 participants were included in the analysis.

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27 Participants received an incentive worth \$35-\$45 at the enrollment / baseline visit and an
28 incentive worth \$45-\$60 at follow-up, depending on locality. The value of these incentives takes
29 into account the time spent at the clinic as well as related costs of participation, such as travel to
30 the clinic site, child care arrangements, and work time lost.

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The behavioral assessments were conducted using an audio/computer assisted self-interview (A-CASI) technology (QDS, Nova Research Company, Bethesda, Maryland). Each assessment measured sexual behaviors, condom use, and psychosocial factors related to condom use (eg, condom use self-efficacy).

Asked only at the 3-months follow-up visit, our primary outcome was self-reported condom use at the most recent sexual encounter. We chose this time frame (ie, last sex act) because self-reported sexual history and condom use are thought to be more reliable and less prone to recall bias when specific and recent[10]. We selected SCT constructs as potential factors affecting condom use (also asked at the 3-months follow-up visit), including condom use

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self-efficacy, self-control self-efficacy, sexual self-efficacy, hedonistic condom outcome expectancies, expected partner reaction outcomes, and also risk perception; all were asked at the 3-month follow-up visit[8,11-12]. For each construct, responses to the related questions were reverse-scored if necessary, (such that all questions and responses were in the same direction, if negatively or positively phrased), then responses were cumulated, averaged, and then re-calculated to a binary variable to indicate either a positive (1) or ambivalent/negative (0) attitude toward condom use (Table 1). For example, for each theoretical construct, if a respondent's average score was greater than 2, then it was re-calculated to "1". If a respondent's average score was 2 or below, then the score was recalculated to "0" to create a binary variable indicating either a positive (1) or ambivalent/negative attitude toward condom use (0). We examined models with both rescored and unscored constructs. Since the variables that were statistically significant did not change, we decided to use the binary coded variables. We assessed internal consistency for each construct and all Cronbach's alpha scores were $>.80$.

TABLE 1. Items Included in Each Social Cognitive Theory Construct

SCT Constructs		Responses				
		Strongly Disagree	0	1	2	3
1. Self-Efficacy (most recent partner)	Can use a condom even if most recent sex partner does not want to	0	1	2	3	4
	Can use a condom every time you have sex with most recent sex partner	0	1	2	3	4

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	Can use a condom even if want to feel close with most recent sex partner	0	1	2	3	4
	Can use condom even if you are making up with most recent sex partner after a fight	0	1	2	3	4
	Can use condom even high or drunk with most recent sex partner	0	1	2	3	4
2. Self-Control	I could stop having sex:					
Self-Efficacy	To get a condom even if I'm really turned on	0	1	2	3	4
	If no condom was available	0	1	2	3	4
	Even if it meant getting dressed and going to the store	0	1	2	3	4
	Even with a really hot new partner	0	1	2	3	4
	Even with someone I want to have a relationship with	0	1	2	3	4
	Even with someone I am in love with	0	1	2	3	4
3. Sexual						
Self-Efficacy	I am sure that I can:					
	Talk with partner about sexual past and our risk of getting STDs and AIDS from each other	0	1	2	3	4
	Go without sex until partner has had check up for STDs and doesn't have any	0	1	2	3	4
	break-up with a partner who puts me at risk of getting STDs	0	1	2	3	4

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Avoid having sex when I am drunk, or high on drugs.	0	1	2	3	4
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Get to know potential partners better before having sex with them	0	1	2	3	4
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Have fewer sex partners in the next 3 months, than in the past 3 months.	0	1	2	3	4
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Have sex with only one partner in the next 3 months	0	1	2	3	4
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Go without having sex for the next 3 months	0	1	2	3	4
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Discuss using condoms with my partners	0	1	2	3	4
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Keep condoms where I will have them nearby when I need them	0	1	2	3	4
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Use condoms more often	0	1	2	3	4
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Use condoms until my partner has had a check-up for STDs, and doesn't have any	0	1	2	3	4
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Use condoms until my partner has been tested for HIV, (AIDS), and is HIV negative	0	1	2	3	4
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Use a condom with my MAIN partner EVERY TIME we have vaginal or anal sex	0	1	2	3	4
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Use a condom with partners OTHER THAN my main partner, EVERY TIME we have vaginal or anal sex	0	1	2	3	4
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4. Hedonistic Outcomes

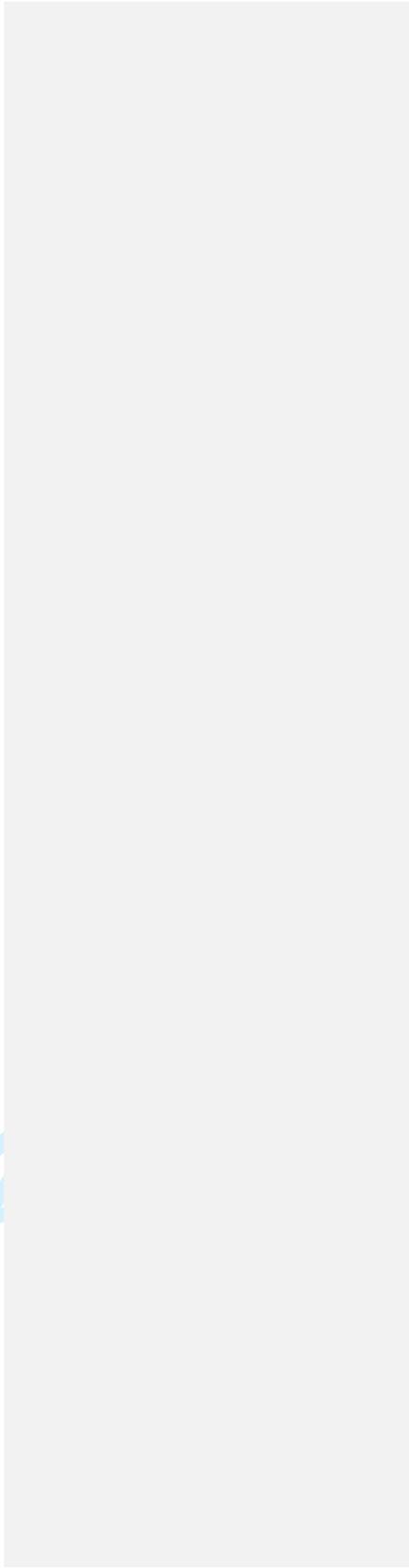
Condoms ruin the mood	0	1	2	3	4
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Sex doesn't feel as good when you use a condom	0	1	2	3	4
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Sex with condoms doesn't feel natural	0	1	2	3	4
Using condoms breaks up the rhythm of sex	0	1	2	3	4

For peer review only



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60**5. Partner
Expect
Outcomes**

I think my most recent sex partner would:

**(most recent
partner)**

Be proud of me if I asked to use condoms	0	1	2	3	4
Be supportive if I asked to use condoms	0	1	2	3	4
Appreciate it if I asked to use condoms	0	1	2	3	4
Be mad at me if I asked to use condoms	0	1	2	3	4
Break up with me if I asked to use condoms	0	1	2	3	4
Think I have other partners if I asked to use condoms	0	1	2	3	4
Be jealous if I asked to use condoms	0	1	2	3	4

**6. Risk
Perception**

If I don't use condoms, I could get infected with an STD or HIV in the next 3 months	0	1	2	3	4
Unless I change my behavior, I am likely to get an STD or HIV	0	1	2	3	4
If I don't reduce the number of people I have unprotected sex with, I could get infected with a STD or HIV	0	1	2	3	4
If I keep having unprotected sex with my partner(s), I could get infected with a STD or HIV	0	1	2	3	4
Sometimes I think that it's only a matter of time before I get an STD or HIV	0	1	2	3	4

Statistical Analysis

We used counts and percentages in order to describe the sociodemographic and self-reported condom use characteristics (Table 2). We constructed multivariable Poisson regression models with robust error variances to estimate the relative risks (RR) and associated 95% confidence intervals (CIs) in order to determine if the specified SCT constructs, and demographic and intervention variables were associated with self-reported condom use at last sex act. Specifically, six models were constructed (Table 1), for each SCT construct and risk perception (1 = self-efficacy, 2 = self-control self-efficacy, 3 = sexual self-efficacy, 4 = hedonistic outcome expectancies, 5 = partner expected outcomes, and 6 = risk perception), and we assessed the effects of each on reported condom use at last sex act. The social cognitive constructs were evaluated as continuous for the 5 point scales (data not shown) and also as dichotomous variables. The constructs were further~~first~~ evaluated in unadjusted models, and then again after adjusting for demographic and study-related variables (receipt of intervention, study site, age, race, gender, marital status, education, and sexual orientation). Analyses were performed with SAS version 9.3 (SAS Institute Inc., Cary, North Carolina, USA).

TABLE 2. Sociodemographic Characteristics Among Participants in the “*Safe in The City*” Study Behavioral Assessment

	N	(%)
	1252	

Study Arm		
Control	614	(49)
Intervention	638	(51)

Study Site		
Denver	515	(41)
San Francisco	280	(22)
Long Beach	457	(37)

Age (years)		
≤ 25	530	(42.3)
26–34	380	(30.4)
≥ 35	342	(27.3)

Race/Ethnicity		
White (non-Hispanic)	467	(37)
Black (non-Hispanic)	318	(25)
Other (non-Hispanic)	182	(15)
Hispanic	285	(23)

Marital Status		
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Single	931	(74)
Married/Domestic Part/Cohabiting	238	(19)
Separated/Divorced/Widowed	82	(7)

Education

≤ 12 years of school	429	(34)
Some college	367	(29)
College degree	283	(23)
Post college	173	(14)

Gender

Male	809	(65)
Female	443	(35)

Sexual Identity

Homosexual	171	(14)
Heterosexual	973	(78)
Bisexual/Not sure	108	(8)

Used a Condom at Last Sex Act

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No	758	(61)
Yes	494	(39)

RESULTS

Participant Characteristics

Forty-nine percent of participants were in the control arm of the study; 51% were in the intervention group. Participants were from all study sites: Denver (41%), San Francisco (22%), and Long Beach (37%). Forty-two percent of the participants were 25 years of age or younger, 30% were 26–34 years and 27% were over 35 years of age. Approximately two-thirds of the participants were male. Twenty-five percent self-identified their race ethnicity as black non-Hispanic, 37% as white non-Hispanic, 15% as other non-Hispanic, and 23% as Hispanic. Approximately three-quarters of respondents reported that they were single (Table 2). Fourteen percent of participants reported their sexual identity as homosexual, 78% as heterosexual, and 8% as not sure or bisexual.

The subgroup of participants in the behavioral assessment differed from all patients who attended the participating clinics during the study period (and whose records were reviewed) as they were significantly less likely to be male (65.4% vs 69.7%); aged 25 years or older (62.5% vs. 68.9%); white, non-Hispanic (36.8% vs 45.9%) and reside in San Francisco (35.2% vs 51.0%).

Correlates of Condom Use at Last Sex Act

Thirty-nine percent of participants reported using a condom at last sex act (Table 2).

Multivariable analyses revealed that several sociodemographic variables were significantly associated with condom use at last intercourse (Table 3). Being male (RR = 1.23, 95% CI = 1.05-1.45), single (RR = 1.64, 95% CI = 1.35-1.99), and self-identifying as homosexual (RR = 1.34, 95% CI = 1.12-1.60) were significantly associated with condom use at last sex. All 6 constructs (1 = self-efficacy, 2 = self-control self-efficacy, 3 = sexual self-efficacy, 4 = hedonistic outcome expectancies, 5 = partner expected outcomes, and 6 = risk perception) were significantly associated with self-reported condom use at last sex act in unadjusted models (Table 4). After adjusting for the intervention arm and demographic variables, all of the construct associations remained significant, except risk perception (Table 4). In particular, participants who scored positively on condom-use self-efficacy with their most recent partner (e.g., who indicated that they can use a condom even if the partner did not want to or even if “high” or drunk, etc.) were significantly more likely to have reported they used a condom during the last sex act (RRa = 2.56, 95% CI = 2.01-3.27).

TABLE 3. Relationship Between Selected Sociodemographic Characteristics and Condom Use at Last Sex Act Among Participants in the “Safe in The City” Study Behavioral Assessment

Sociodemographic Variables [^]	Relative	95% C L
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	Risk		
Age < 25 years	1.11	.96	1.27
Black race	1.15	.98	1.36
Single	1.64	1.35	1.99***
Education (less than college degree)	.90	.78	1.04
Male	1.23	1.05	1.45**
Sexual orientation (homosexual)	1.34	1.12	1.60***

^ The analyses were also adjusted for study arm and study site. Results not shown.

CL: Confidence levels; * $P \leq .05$, ** $P \leq .01$, *** $P \leq .001$

TABLE 4. Unadjusted and Adjusted Social Cognitive Theory Constructs and Condom Used at Last Sex Act Among Participants in the Safe in The City Study Behavioral Assessment

Social Cognitive Theory Constructs	% condom use at last sex act		Unadjusted RR		Confidence Levels		Adjusted^ RR		Confidence Levels	
	0	1	0	1	0	1	0	1	0	1
1. Self-efficacy with most recent partner	0	17	2.72	2.13	3.48***	2.56	2.01	3.27***		
	1	47								
2. Self-control Self-efficacy	0	26	1.72	1.41	2.10***	1.67	1.37	2.04***		
	1	44								
3. Sexual Self-efficacy	0	29	1.45	1.18	1.78***	1.50	1.23	1.84***		
	1	42								
4. Hedonistic outcome expectancies	0	27	1.73	1.46	2.06***	1.83	1.54	2.17***		
	1	46								
5. Partner expected outcomes	0	4	11.04	3.63	33.56***	9.74	3.21	29.57***		
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6. Risk perception	0	44	.84	.73	.97*	.88	.76	1.02
	1	37						

RR: Relative Risk; ^ Adjusted for socio-demographic characteristics: Study arm, study site, age, race, gender, marital status, sexual orientation, and education. * $P \leq .05$, ** $P \leq .01$, *** $P \leq .001$

Similarly, those with positive self-control self-efficacy, (RRa = 1.67, 95% CI = 1.37-2.04), positive sexual self-efficacy (RRa = 1.50, 95% CI = 1.23-1.84), more favorable hedonistic outcome expectancies, (RRa = 1.83, 95% CI = 1.54-2.17), or more favorable partner expected outcomes with their most recent sex partner (RRa = 9.74, 95% CI = 3.21-29.57) were also significantly more likely to have reported that they used a condom during the last sex act (all $P \leq 0.001$) in adjusted models.

DISCUSSION

Social cognitive theory (SCT) is based on the theoretical work of Bandura¹³ and includes conceptual components such as self-efficacy and outcome expectancies, such as an expected outcome for acquiring an STI or HIV. These conceptual components have been studied as correlates of sexual behavior. Self-efficacy has been found to be an important correlate of self-reported condom use[8,14-15], and to mediate the effectiveness of risk-reduction interventions.^{16,17} Previous studies have demonstrated this especially for women[8,14-15] and HIV-positive gay and bisexual men[17]. Other conceptual components within the social cognitive theoretical framework that have been found to influence or mediate condom use are outcome expectancies and from the health belief model risk perceptions. Outcome expectancies

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9 are also a major construct within other social psychological theories, such as the theory of
10 reasoned action[19].For example, hedonistic outcome expectancies have been found to be related
11 to both intention to use and self-reported use of condoms[6,14]. Risk perceptions have been
12 evaluated among HIV-positive MSM and while being on a highly active antiretroviral therapy
13 (HAART) did not increase risky behaviors, men who had low risk perceptions reported more
14 unprotected sex[20].
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21 All six constructs evaluated in this analysis of data from the SITC trial were significantly
22 associated with condom use at last sexual intercourse. For all models, three sociodemographic
23 characteristics—being male, single, and of homosexual sexual orientation—were significantly
24 associated with condom use at last sex. Such participants also scored higher on condom use self-
25 efficacy with their most recent partner, self-control self-efficacy, sexual self-efficacy, and had
26 more positive condom use outcome expectancies as compared with their counterparts. These
27 findings are consistent with previous reports, as described above[14,21-22].
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35 A particular strength of our study is that the study sample included a geographically,
36 ethnically and socio-culturally diverse group of STI clinic attendees. However, there are some
37 limitations. The analysis included only those subjects who participated in the behavioral
38 component of the SITC trial, and, consequently, may not be representative of the overall patient
39 population included in the larger trial, or generalizable to all STI clinic attendees. Additionally,
40 although social desirability in responding is always a concern when collecting self-reported data
41 on sexual risk behaviors[23], the use of A-CASI technology in the trial to collect sensitive
42 information on the most recent act of intercourse may alleviate some of these concerns.
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9 Independent of the SITC intervention, women and heterosexual men in particular did not
10 seem to have social cognitive characteristics that facilitated condom use at last sex act. Rather,
11 condom use was more influenced by the social cognitive construct scores and individual
12 participant characteristics. It is possible that these individual socio-cognitive characteristics
13 predated any effects of the intervention,` as we did not measure socio-cognitive characteristics
14 prior to the intervention; the initial assessment occurred at the end of the baseline visit where the
15 video would have already been played while participants were waiting for their visit.` This
16 finding suggests future research directions; in particular, how best to determine the ways in
17 which SCT-framed interventions influence specific behaviors such as condom use.
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26 Can such interventions reshape or reinforce particular socio-cognitive characteristics and
27 thus change behavior? Future studies should consider measuring SCT components
28 longitudinally, i.e., before, during and after an intervention so that the pathway of how such
29 interventions affect SCT components can be clearly elucidated, particularly since SCT-framed
30 interventions can be an important tool for decreasing rates of STIs. Prevention programs that
31 seek to increase condom use should consider social cognitive constructs (such as self-efficacy
32 and partner expected outcomes) as important mediators of condom use, and they should be
33 included along with condom provision work to increase social cognitive skills.
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45 **Footnotes**

46
47 **Contributors** All authors participated in the interpretation of the study and drafting of the
48 manuscript. All authors have seen and approved the final version. MCS, LW, AML, MGM,
49 APK, ADG, JW and DJJ participated in the design and analysis for the manuscript. LW, JDK,
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9 CAR, CKM, and LO contributed to the overall study design and concept. JDK, CAR, and CKM
10 participated in acquisition of data. MGM and JW performed the statistical analysis.

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12
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14 Control and Prevention (CDC), where technical assistance was provided through a federal
15 cooperative agreement in the design and conduct of the study; collection, management, analysis,
16 and interpretation of the data; and preparation, review, and approval of the manuscript.

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21 **Competing Interests** None declared.

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24 **Ethics** The institutional review boards at each site and the Centers for Disease Control and
25 Prevention reviewed and approved the study protocol.

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29 **Data Sharing Statement** The Safe in the City Study Group has a project-specific web site that
30 provides additional details about the study and data. <http://www.stdcentral.org/SitC/> (please
31 click on 'contact' for additional information or to initiate a request). You may request data by
32 emailing Kees.Rietmeijer@dhha.org

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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Reported on Page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Title Page
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Pages 3-4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 5
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5
Methods			
Study design	4	Present key elements of study design early in the paper	Page 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pages 5-6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	Page 5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6-7
Bias	9	Describe any efforts to address potential sources of bias	Page 6
Study size	10	Explain how the study size was arrived at	Page 5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pages 5-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 11
		(b) Describe any methods used to examine subgroups and interactions	N/A

		(c) Explain how missing data were addressed	Page 5
		(d) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 5
		(b) Give reasons for non-participation at each stage	Page 5
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Pages 11-12
		(b) Indicate number of participants with missing data for each variable of interest	Page 5
Outcome data	15*	Report numbers of outcome events or summary measures	Pages 14-17
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Pages 14-17
		(b) Report category boundaries when continuous variables were categorized	Pages 14-17
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	Pages 18-20
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Pages 18-20
Interpretation	20	Give a cautious overall interpretation of results considering objectives,	Pages 18-20

		limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	Pages 18-20
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 21

*Give information separately for exposed and unexposed groups.(supplemental analyses)

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.