PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Relationship between social cognitive theory constructs and self-reported condom use: assessment of behaviour in a subgroup of the Safe in the City Trial
AUTHORS	Snead, Margaret (proxy) (contact); O'Leary, Ann; Mandel, Michele; Kourtis, Athena; Wiener, Jeffrey; Jamieson, Denise; Warner, Lee; Malotte, Kevin; Klausner, Jeffrey; O'Donnell, Lydia; Rietmeijer, Cornelius; Margolis, Andrew

VERSION 1 - REVIEW

REVIEWER	Laureen Lopez FHI 360, USA
REVIEW RETURNED	31-Jul-2014

GENERAL COMMENTS	p. 6, L 8. Please provide more detail on how the subset was selected for this behavioral assessment. The potential influence of the selection process should be noted more clearly. p 7, L 27. Table 1. I am often curious why 5-point item responses are used and then analyzed as dichotomous. Did other investigators develop the tool for another purpose in the original study? If these represent constructs, why not score the 'scales' and analyze as continuous variables? Perhaps they have not been test for validity or reliability? p 14, L 23. Did the respondents in any way reflect the participants in the intervention or the clinic population? p 19, L 43. Why did the authors not compare the demographics or other data for questionnaire respondents with that of intervention participants and of clinic attendees? p 20, L 13. Why were the SCT constructs not assessed initially if they formed (part of) the basis for the intervention? The intervention was reportedly theory-based. Were any knowledge or attitude constructs assessed pre-intervention? Perhaps determined not feasible in such a clinic situation. What incentive did the questionnaire respondents have for completing the assessment and returning for follow up? p 20, L 28. The authors note that such components or constructs should be assessed longitudinally. Please clarify for the reader why this was not done. I do not have any basis for addressing #14 without doing research on the authors' and others' publications. I'm not clear why the authors used CONSORT checklist unless the editors required it. The original trial was controlled, not randomized. More importantly, the comparison groups here did not necessarily represent the original groups.

REVIEWER	Ivo Rakovac WHO Regional Office for Europe
REVIEW RETURNED	22-Sep-2014

GENERAL COMMENTS	In this interesting and well written paper Snead and colleagues examine the cross sectional association between social cognitive theory (SCT) constructs and self reported condom use at the last intercourse. Findings of this study are in line with the available evidence, showing that higher scoring in SCT dimensions is associated with more frequent condom use at the last intercourse. In my opinion, there are several points that author could consider as they might potentially improve the manuscript: - Could you please clarify which SCT measurement have you used to asses the condom use: the one at the index visit or the one at the follow up visit three months afterwards? In first case, this study would be evidence that SCT predicts condom use and is not only associated with it. However, it seems to me that you have used the SCT measurement from follow up assessment in your paper. Could you please explain the rationale for using SCT measured at follow up and not at index visit? - It would be interesting to know if the STC scores differ between the study subjects who did and did not receive the STIC intervention (saw and did not saw the intervention movie). Although the SCT questionnaire was filled only at the end of the visit, after the movie has potentially been already seen, it can be assumed that this difference is due to the intervention (because of the randomisation). - In my opinion, it would be interesting if you could present the results of regression analysis in table 4 also for covariates you adjusted for, namely sex, age, study site, race, gender, marital status, sexual orientation and education and study arm (presenting the results for study arm would be similar to previously raised issue to compare the difference in SCT for persons in intervention and control arm) and to briefly discuss the findings. This would allow identifying characteristics of the persons that are at particular risk of low scores in individual dimensions of SCT. - Authors have submitted the filled CONSORT statement with the manuscript. However, as this is either cross sectional (if the SCT assessment was done on the follow up visit) or cohort (if SCT assessment was done on the index visit) evaluation of the patients included in the randomized controlled trial, I believe that the appropriate STROBE statement should be completed and attached to the paper. - If the SCT was assessed at both index and follow up visit, it would be interesting if you could report on intra-personal stability / consistency of obtained SCT scores.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Please state any competing interests or state 'None declared': None declared
Thank you. We have added none 'declared' to the manuscript footnotes on page 21 and noted this in the e-system.

p. 6, L 8. Please provide more detail on how the subset was selected for this behavioral assessment. The potential influence of the selection process should be noted more clearly.
respondents were STI clinic patients who were systematically sampled from the larger group of patients who attended waiting rooms in the participating clinics during the study period.

We added: "The behavioral assessment component of the larger SITC trial was a nonrandomized control trial where all respondents were STI clinic patients who were invited from the group of patients who attended waiting rooms in the participating clinics during the study period." To page 6, L 4

p 7, L 27. Table 1. I am often curious why 5-point item responses are used and then analyzed as dichotomous. Did other investigators develop the tool for another purpose in the original study? If these represent constructs, why not score the 'scales' and analyze as continuous variables? Perhaps they have not been test for validity or reliability?
Thanks for raising this point, we did use dichotomous covariates in this paper instead of the ordinal scales, because they were easier to interpret for the reader. We ran the models both ways (with a binary outcome and with a continuous outcome) and are providing these results in our response. This analysis demonstrates that the results are similar. See supplemental Analyses A (not included in the paper).
p 14, L 23. Did the respondents in any way reflect the participants in the intervention or the clinic population?
At line 10- we have included a sentence about the differences between subgroup participants in the behavioral assessment as compared with all patients who attended the participating clinics during the study period (and whose medical records were reviewed). In short, participants in the behavioral assessment were less likely to be male (65% vs 70); aged 25 years or older (63% vs. 68.9%); white, non-Hispanic (37% vs 46%) and reside in San Francisco (35% vs 51%).

p 19, L 43. Why did the authors not compare the demographics or other data for questionnaire respondents with that of intervention participants and of clinic attendees?
We used the intervention variable in the adjusted models (along with demographic variables. We are providing comparisons of the scores by study arm and appreciate the suggestion (the chi-squared p-values comparing the dichotomous social cognitive score variables by study arm "intervention"). The intervention was not statistically significant in any of the adjusted multivariate models. See supplemental Analyses B (not included in the paper.
p 20, L 13. Why were the SCT constructs not assessed initially if they formed (part of) the basis for the intervention? The intervention was reportedly theory-based. Were any knowledge or attitude constructs assessed pre-intervention? Perhaps determined not feasible in such a clinic situation. What incentive did the questionnaire respondents have for completing the assessment and returning for follow up?
The overall intervention was based on a multi-theoretical model, one of which was SCT, so it is not feasible to break out further. For more information, see the attached companion paper by Harshbarger et al r (Am J Prev Med 2012;42(5):468–472) about the development of SITC. Unfortunately, evaluation of constructs in the pre-intervention period was not feasible with the study design, where the intervention was administered in the waiting room prior to thebehavioral assessment

Regarding incentives, we have added this information to page #6. Patients who enrolled in the study completed the survey on a computer after they have enrolled in the study. Participants received an incentive worth $35-$45 at the enrollment / baseline visit and an incentive worth $45-$60 at follow-up, depending on locality. The value of these incentives takes into account the time spent at the clinic as well as related costs of participation, such as travel to the clinic site, child care arrangements, and work time lost.

p 20, L 28. The authors note that such components or constructs should be assessed longitudinally. Please clarify for the reader why this was not done.
Please see above. Unfortunately, pre-intervention assessments of SCT constructs was not feasible with this trial due to the study design Future studies may want to take this into consideration during study design (if feasible in the clinic setting).

I do not have any basis for addressing #14 without doing research on the authors' and others' publications. I'm not clear why the authors used CONSORT checklist unless the editors required it. The original trial was controlled, not randomized. More importantly, the comparison groups here did not necessarily represent the original groups. Thank you. We agree. We have attached the STROBE statement

Reviewer: 2
Please state any competing interests or state 'None declared': None declared
Thank you. We have added "none declared' to the manuscript footnotes on page 21 and noted this in the e-system.

In this interesting and well written paper Snead and colleagues examine the cross sectional association between social cognitive theory (SCT) constructs and self reported condom use at the last intercourse. Findings of this study are in line with the available evidence, showing that higher scoring in SCT dimensions is associated with more frequent condom use at the last intercourse.

In my opinion, there are several points that author could consider as they might potentially improve the manuscript:
- Could you please clarify which SCT measurement have you used to asses the condom use: the one at the index visit or the one at the follow up visit three months afterwards? In first case, this study would be evidence that SCT predicts condom use and is not only associated with it. However, it seems to me that you have used the SCT measurement from follow up assessment in your paper. Could you please explain the rationale for using SCT measured at follow up and not at index visit?
We used the SCT measurements to assess condom use at the follow up visit only (three months after the administration of the intervention). Both were asked at 3 months and clarifications have been added to the text on page #6. Unfortunately, pre-intervention assessments of the SCT constructs was not feasible with the study design used to evaluate the sitc intervention. Future studies may want to take this into consideration during study design (if feasible in the clinic setting).

- It would be interesting to know if the STC scores differ between the study subjects who did and did not receive the STIC intervention (saw and did not saw the intervention movie). Although the SCT questionnaire was filled only at the end of the visit, after the movie has potentially been already seen, it can be assumed that this difference is due to the intervention (because of the randomisation).
I have attached supplemental analyses (B) for your review. The intervention arm was not associated with the SCT variables

- In my opinion, it would be interesting if you could present the results of regression analysis in table 4 also for covariates you adjusted for, namely sex, age, study site, race, gender, marital status, sexual orientation and education and study arm (presenting the results for study arm would be similar to previously raised issue to compare the difference in SCT for persons in intervention and control arm) and to briefly discuss the findings. This would allow identifying characteristics of the persons that are at particular risk of low scores in individual dimensions of SCT.
We agree these are interesting results. The results in Table 3 show the effects of the adjusted variables on the condom use outcome. These were included in the adjusted models for each SCT in Table 4. , We opted to discuss those that were significant in the model in table 3 (gender, marital status & sexual orientation) in text (Page 19) rather than presenting repeatedly for the 6 models in table 4.
"All six constructs evaluated in this analysis of data from the SITC trial were significantly associated with condom use at last sexual intercourse. For all models, three sociodemographic characteristics—being male, single, and of homosexual orientation—were significantly associated with condom use at last sex. Such participants also scored higher on condom use self-efficacy with their most recent partner, self-control self-efficacy, sexual self-efficacy, and had more positive condom use outcome expectancies as compared with their counterparts."

- Authors have submitted the filled CONSORT statement with the manuscript. However, as this is either cross sectional (if the SCT assessment was done on the follow up visit) or cohort (if SCT assessment was done on the index visit) evaluation of the patients included in the randomized controlled trial, I believe that the appropriate STROBE statement should be completed and attached to the paper.
Thank you. We agree. We have attached the STROBE statement
- If the SCT was assessed at both index and follow up visit, it would be interesting if you could report on intra-personal stability / consistency of obtained SCT scores.
Thanks. We only assessed the SCT at follow-up visit. We agree this is of interest, but beyond the scope of the present paper. Perhaps subsequent & more sophisticated analyses may capture the intra-personal stability / consistency of obtained SCT scores.

VERSION 2 – REVIEW

REVIEWER	Laureen Lopez FHI 360, USA
REVIEW RETURNED	21-Oct-2014

GENERAL COMMENTS	Authors have addressed my comments. I have no further comments. Thank you.

REVIEWER	Ivo Rakovac WHO Regional Office for Europe
REVIEW RETURNED	03-Nov-2014

GENERAL COMMENTS	Yes and I have performed this review Thank you very much for addressing all the issues raised during the review process.

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

Snead MC, O'Leary AM, Mandel MG, *et al*. Relationship between social cognitive theory constructs and self-reported condom use: assessment of behaviour in a subgroup of the Safe in the City trial. *BMJ Open* 2014;4:e006093.

The trial registration number in this article is incorrect and should be: NCT00137370.

BMJ Open 2016;**6**:e006093corr1. doi:10.1136/bmjopen-2014-006093corr1