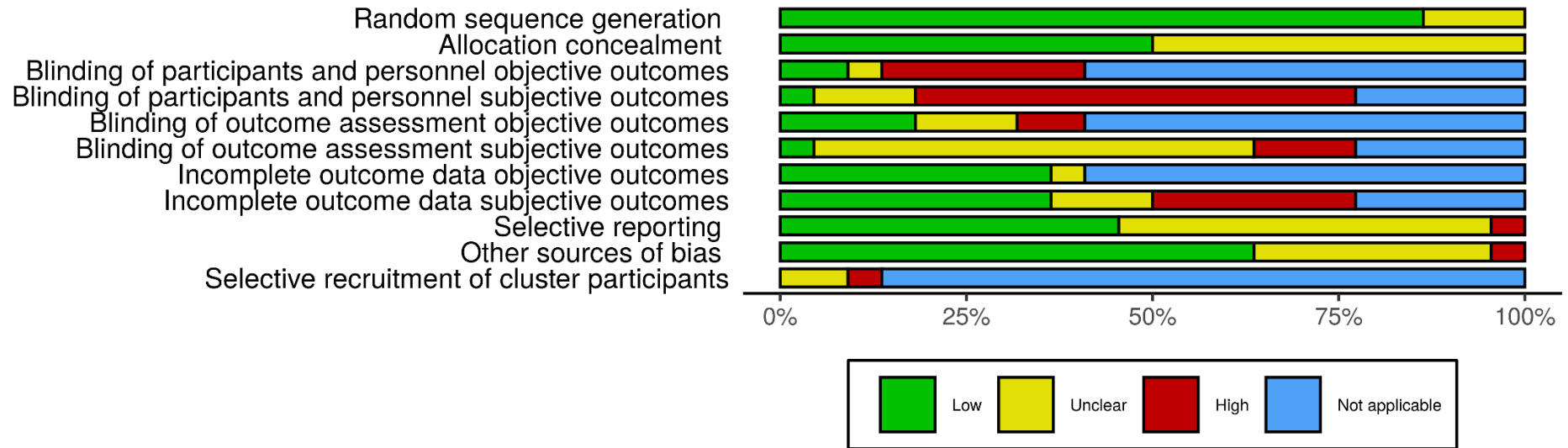


Supplementary File 7 – Risk of bias assessments of included studies

Fig. S7.1 - Overall risk of bias for all studies included in systematic review (summary plot, non-weighted)



Source of assessment and visualization tools: Higgins et al. 2011; McGuinness and Higgins 2020

Fig. S7.2 – Risk of bias summary by study & subjective vs objective outcome (Traffic light plot)

Study	Risk of bias										
	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11
de Tolly (2012)	-	-	○	✗	○	-	○	✗	-	-	○
Delamere (2006)	-	-	○	-	○	-	○	✗	-	-	○
Downing (2013)	+	-	✗	○	+	○	+	○	-	+	○
Free (2016)	+	+	✗	✗	+	-	+	+	+	+	○
Gold (2011)	-	-	○	✗	○	✗	○	✗	-	✗	○
Govender (2019)	+	+	○	+	○	-	○	-	-	+	○
Kelvin (2019a)	+	+	+	○	-	○	+	○	+	+	○
Kelvin (2019b)	+	+	+	○	-	○	+	○	+	+	○
Lim (2012)	+	+	○	✗	○	-	○	✗	✗	+	○
Mimiaga (2017)	+	-	○	✗	○	-	○	+	-	+	○
Mugo (2016)	+	+	✗	○	✗	○	+	○	+	+	○
Nielsen (2019)	+	+	○	✗	○	-	○	-	+	+	○
Parkes-Ratanshi (2018, 2020)	+	+	✗	○	✗	○	-	○	+	-	○
Reback (2019a)	+	-	○	✗	○	-	○	+	+	+	○
Rinehart (2019)	+	+	○	✗	○	-	○	✗	+	+	○
Rokicki (2017)	+	-	○	✗	○	✗	○	+	-	+	✗
Suffoletto (2013)	+	-	○	✗	○	✗	○	✗	-	-	○
Tang (2018)	+	-	○	✗	○	-	○	-	+	-	-
Trent (2019)	+	+	✗	✗	+	-	+	+	+	-	○
Ybarra (2017)	+	+	○	-	○	+	○	+	-	+	○
Young (2013)	+	-	-	-	-	-	+	+	-	-	-
Zhu (2019)	+	-	✗	✗	+	-	+	+	-	+	○

- D1: Random sequence generation
- D2: Allocation concealment
- D3: Blinding of participants and personnel objective outcomes
- D4: Blinding of participants and personnel subjective outcomes
- D5: Blinding of outcome assessment objective outcomes
- D6: Blinding of outcome assessment subjective outcomes
- D7: Incomplete outcome data objective outcomes
- D8: Incomplete outcome data subjective outcomes
- D9: Selective reporting
- D10: Other sources of bias
- D11: Selective recruitment of cluster participants

Judgement

- ✗ High
- Unclear
- +
- Not applicable

Source of assessment and visualization tools: Higgins et al. 2011; McGuinness and Higgins 2020

Table S7 - Detailed risk of bias assessment by study and objective vs subjective outcome

de Tolly (2012)

Random sequence generation (selection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> No information on sequence generation provided, mentions only "A randomized control trial study design was used for the evaluation with four experimental options"</p>
Allocation concealment (selection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> No information on allocation concealment provided.</p>
Blinding of participants and personnel, subjective outcomes (performance bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Not possible to blind participants. No information provided on blinding of personnel.</p>
Blinding of outcome assessment, subjective outcomes (detection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> Not possible to blind participants. No information provided on blinding of personnel. Outcome assessment seemed not to involve direct interaction with staff - quote: "an SMS was sent requesting all groups to indicate whether they tested or not (see Table 1 for details of the SMSs). Two separate "please-call-me" (PCM) lines were set up: one captured PCMs from participants indicating that they had tested since the start of the intervention, while the other captured PCMs from participants who had not tested since that date."</p>
Incomplete outcome data, subjective outcomes (attrition bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> High level of attrition, and reasons for attrition had not been assessed. "Overall, there was a retention rate of 54.1% (i.e., 54.1% indicated whether they had tested)."</p>
Selective outcome reporting (reporting bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> No protocol or trial registration entry available; also limited information on outcomes in methods section [TCC: Denominators analysed were not clearly reported and it was not possible to tell from the brief description of methods whether all planned outcomes were reported. In addition, a small proportion of participants (2.0%) self-reported as having tested for HIV]</p>
Other sources of bias (e.g. contamination)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> No baseline data presented; data do not add up, and failed attempt to seek clarification from author.</p>

Delamere (2006)

Random sequence generation (selection bias)	<i>Judgement:</i> Unclear <i>Support:</i> No information on sequence generation provided, mentions only "randomized controlled study".
Allocation concealment (selection bias)	<i>Judgement:</i> Unclear <i>Support:</i> Not information on allocation concealment provided.
Blinding of participants and personnel, subjective outcomes (performance bias)	<i>Judgement:</i> Unclear <i>Support:</i> Not reported
Blinding of outcome assessment, subjective outcomes (detection bias)	<i>Judgement:</i> Unclear <i>Support:</i> Not reported
Incomplete outcome data, subjective outcomes (attrition bias)	<i>Judgement:</i> High risk <i>Support:</i> Quote: "Total response rate to telephone interview 48% of whom 55% received texts (see table)."
Selective outcome reporting (reporting bias)	<i>Judgement:</i> Unclear <i>Support:</i> Protocol not available; no trial registration reported
Other sources of bias (e.g. contamination)	<i>Judgement:</i> Unclear <i>Support:</i> No information to allow judgement

Downing (2013)

Random sequence generation (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Quote: "the chief investigator consecutively allocated study participants to a randomised list of numbers, generated using Excel software"</p>
Allocation concealment (selection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> No details on allocation concealment provided. (Only statement: "Neither the clinicians recruiting the participants nor the participants themselves were informed of the randomisation outcome")</p>
Blinding of participants and personnel, objective outcomes (performance bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Quote: "Neither the clinicians recruiting the participants nor the participants themselves were informed of the randomisation outcome"; nevertheless, it is likely that most of the participants will have guessed that they were in one of the intervention groups, after receiving messages/ promise of incentive.</p>
Blinding of outcome assessment, objective outcomes (detection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Quote: "options for re-testing - a booked appointment or a walk-in appointment where they were reviewed by a member of nursing staff or they could simply provide a urine sample (arranged by the reception staff) without a formal clinical review."; Quote: "Neither the clinicians recruiting the participants nor the participants themselves were informed of the randomisation outcome"; nevertheless, it is likely that most of the participants will have guessed that they were in one of the intervention groups; Given that the test was done via urine sample bias is unlikely, although it is not clear whether the personnel who performed the test were blinded, but it is likely that they were.</p>
Incomplete outcome data, objective outcomes (attrition bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> For 6 of 23 participants in SMS arm, texts were undelivered, but intention to treat analysis done</p>
Selective outcome reporting (reporting bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> Protocol not available; no trial registration reported</p>
Other sources of bias (e.g. contamination)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> No baseline differences; Intention-to-treat analysis and per-protocol-analysis both yield statistically significant results favouring intervention arms; The "CSHS relocated during the study period, and this may have influenced whether participants returned for re-testing or not", but this should not have had differential effect.</p>

Free (2016)

Random sequence generation
(selection bias)

Judgement: Low risk

Support: Quote: "An independent online randomisation system [see www.sealedenvelope.com/ (accessed 22 July 2016)] generated the 1 : 1 allocation sequence, stratified by site, using random permuted block sizes of 2, 4 and 6. Staff were not aware of the block sizes."

Allocation concealment
(selection bias)

Judgement: Low risk

Support: Quote: "The online randomisation system generated the allocation sequence, which meant that staff enrolling participants into the trial could not have known in advance which treatment allocation the next participant would receive.";

"The online randomisation system randomised participants immediately after the recruiting staff entered their baseline data onto the online trial database system."

Blinding of participants and
personnel, objective outcomes
(performance bias)

Judgement: High risk

Support: Quote: "Because of the nature of the intervention, participants could have been aware of their treatment allocation; they would have expected frequent text messages (intervention) or one text message a month (control). Thus, the participants were unmasked. The trial manager (OM) required access to treatment allocation to monitor the incoming texts and identify intervention participants for the qualitative interviews. However, the risk of bias associated with this unmasking is low as the intervention was prescribed and delivered by the bespoke texting software, directly to participants' mobile phones; OM was not involved in the delivery of the intervention. Laboratory staff assessing chlamydia infection and researchers assessing the outcomes were masked to treatment allocation. Staff performing the statistical analysis were also masked to treatment allocation. Data were double entered with one researcher masked to allocation. The treatment allocation variable in the data set was coded 1 or 2 and this was kept undisclosed until the full analysis was complete."

Blinding of participants and
personnel, subjective outcomes
(performance bias)

Judgement: High risk

Support: Same quote as above for 'Blinding of participants and personnel, objective outcomes'

Blinding of outcome assessment, objective outcomes (detection bias)

Judgement: Low risk

Support: Quote: "Because of the nature of the intervention, participants could have been aware of their treatment allocation; they would have expected frequent text messages (intervention) or one text message a month (control). Thus, the participants were unmasked. [...] Laboratory staff assessing chlamydia infection and researchers assessing the outcomes were masked to treatment allocation."

Blinding of outcome assessment, subjective outcomes (detection bias)

Judgement: Unclear risk

Support: Same quote as above for 'Blinding of participants and personnel, objective outcomes'

Comment: Outcomes were self-reported with most participants completing paper-based questionnaires and sending them back in a return envelope, some participants completing the questionnaires online, and a small fraction of participants using other ways of self-reporting results.

Incomplete outcome data, objective outcomes (attrition bias)

Judgement: Low risk

Support: Quote: "In total, 86% (171/200) provided a chlamydia test sample at 3 months. Of the 171, 98% (167/171) returned the sample by post and 2% (4/200) provided the sample at the clinic"; "We obtained an 81.0% (162/200) follow-up rate for the cumulative incidence rate of chlamydia [at 12 months], with a rate of 81.2% (82/101) in the control group and 80.8% (80/99) in the intervention group." *Comment:* ITT analysis performed for the cumulative incidence rate of chlamydia at 1 months.

Incomplete outcome data, subjective outcomes (attrition bias)

Judgement: Low risk

Support: Quote: "In total, 92% (183/200) provided questionnaire outcome data at 1 month."; "In total, 82% (163/200) provided questionnaire outcome data at 12 months."; "We analysed by randomised arm and conducted a complete case analysis only."

Selective outcome reporting (reporting bias)

Judgement: Low risk

Support: Full HTA report and trial registration available. No reason to suspect selective reporting.

Other sources of bias (e.g. contamination)

Judgement: Low risk

Support: Quote: "There was a small amount of contamination (sharing messages) between the intervention group and the control group"; Author clarified: "The amount of contamination was only 2%." *Comment:* We therefore think the risk of bias arising from this is low.

Gold (2011)

Random sequence generation (selection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> Quote: "The randomisation was performed by the telecommunications provider, who assigned groups by listing participants' mobile phone numbers in numerical order and assigning alternate numbers to each group. No blinding was performed." It seems unlikely that this could have led to bias, but not entirely clear.</p>
Allocation concealment (selection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> Quote: "The randomisation was performed by the telecommunications provider, who assigned groups by listing participants' mobile phone numbers in numerical order and assigning alternate numbers to each group. No blinding was performed."</p>
Blinding of participants and personnel, subjective outcomes (performance bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Quote: "No blinding was performed." (Participants cannot be blinded to message content.)</p>
Blinding of outcome assessment, subjective outcomes (detection bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Quote: "No blinding was performed." (Participants cannot be blinded to message content.)</p>
Incomplete outcome data, subjective outcomes (attrition bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> High withdrawal rate, only case analysis available [Withdrew from mobile advertising subscription by message five - Interv.: n=423, Contr.: n=362; Excluded from analysis as resided interstate -at baseline: n=67; - at follow-up- Interv.: n=27, Contr.: n=10]; Quote: "From the 7606 individuals enrolled at baseline, we received 620 (8.2%) completed baseline and 395 (5.2%) completed follow-up surveys."</p>
Selective outcome reporting (reporting bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> All outcomes detailed in methods section were reported in the results section, but no protocol/ trial registration entry available</p>
Other sources of bias (e.g. contamination)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> High risk of contamination- Quote: "a number of individuals who completed the follow-up questionnaire reported receiving messages for the group to which they were not assigned. We attempted to verify these reports by contacting a subset of individuals once survey data had been examined in detail (August 2009) but were unable to clearly ascertain if contamination in groups had occurred"; also only few baseline characteristics reported, unclear if differences between groups exist.</p>

Govender (2019)**Govender (2019)**

Random sequence generation
(selection bias)

Judgement: Low risk

Support: No info on sequence generation provided in paper (Quote: "Upon completing the baseline interview, the fieldworker opened a sealed envelope with the randomisation assignment. Participants were randomised to either the control arm or the SMS arm.") The corresponding author clarified though via email that random numbers had been "computer-generated".

Allocation concealment
(selection bias)

Judgement: Low risk

Support: Full paper mentions use of sealed assignment envelopes, but unclear whether envelopes were opaque and sequentially numbered (Quote: "Upon completing the baseline interview, the fieldworker opened a sealed envelope with the randomisation assignment.") After seeking clarification on "how exactly it was decided to which trial arm the next participant should be assigned to", the corresponding author responded via email - quote: "Upon completing the baseline interview (including taking down mobile phone numbers) with subject, the fieldworker opened a sealed envelope that contained a computer-generated randomised assignment number. The number was written on an allocation sheet by fieldworker and given to research manager. The research manager then independently checked the random number against an existing database to determine which arm the subject/number fell into (SMS or control arm). Training occurred for all field staff to ensure independence of procedures. Site investigators undertook regular quality assurance checks to ensure uniformity of procedures." The author further clarified that the envelope had been opaque and that the envelope contained a number (rather than the treatment arm allocation) to mask the fieldworker to the allocation of participants. The research manager had no field work interaction with participants.

Blinding of participants and
personnel, subjective outcomes
(performance bias)

Judgement: Low risk

Support: Participants can probably be rated as blinded ("Participants were not informed about the specific research questions or the fact that they would be randomised to different study arms in order to avoid bias."), and no interaction with personnel until follow-up.

Blinding of outcome assessment, subjective outcomes (detection bias)

Judgement: Unclear

Support: Participants can probably be rated as blinded ("Participants were not informed about the specific research questions or the fact that they would be randomised to different study arms in order to avoid bias."), but unclear whether personnel was blinded. Clarification from author (response to question: "Could you please describe all measures used, if any, to ensure blinding of key trial personnel from knowledge of which intervention a participant had received?"): "Unfortunately, it was not possible to blind clinic personnel in this study because they had to be aware of what study arm the client was in (if any) in order to offer them the HIV-testing options appropriate for that study arm. However, the data analysis was conducted blind until complete, when we checked the randomization assignment codes to write the paper. [...] And while participants knew what text messages they received and what HIV tests they were offered when in a clinic, they did not know about the other study arms, unless they heard something from other clients, so they were sort-of blind as well." Unclear though what influence the fact that personnel was not blinded might have had on the subjective outcome assessment.

Incomplete outcome data, subjective outcomes (attrition bias)

Judgement: Unclear

Support: High proportion of participants lost to follow-up in both arms (49% in SMS arm, 44% in control arm), but likely related to high proportion of mobile populations, which at baseline was slightly higher in the SMS arm (76.% Truck driver/assist.) than the control arm (72.8% Truck driver/assist.); "the ability to retain study respondents was hampered by their mobility, hence the low response rate at follow-up" It cannot be excluded though that some of the losses to follow-up were also related to outcomes; intention to treat analysis was performed (we do not include dosage analysis results in this review); The authors did not attempt to make an assessment of reasons for missing data; The outcome events are not rare.

Selective outcome reporting (reporting bias)

Judgement: Unclear

Support: No protocol/ trial registration entry available.

Other sources of bias (e.g. contamination)

Judgement: Low

Support: No reason to suspect other sources of bias

Kelvin (2019a)**Kelvin (2019a)**

Random sequence generation
(selection bias)

Judgement: Low risk

Support: No details on sequence generation provided in paper, (Quote: "The eligible individuals who remained in the sample after the consent process were randomized to one of three study groups."), but info obtained from author - quote: "The assignment to "treatment" group/arm was done completely randomly via a computer program (SAS software). Basically, what we did was download [records of] all those truckers/FSWs who met eligibility criteria from the North Star Alliance electronic medical record database and then run the SAS randomization syntax that randomized each person in the database to either the intervention, SOC or enhanced SOC arm. So everyone was randomized at the same time."

Allocation concealment
(selection bias)

Judgement: Low risk

Support: Randomization of all participants done at the same time and no intermediary step involving staff prior to intervention start, so that allocation concealment was not an issue. (Email communication quote: "The assignment to "treatment" group/arm was done completely randomly via a computer program (SAS software). Basically what we did was download records of all those truckers/FSWs who met eligibility criteria from the North Star Alliance electronic medical record database and then run the SAS randomization syntax that randomized each person in the database to either the intervention, SOC or enhanced SOC arm. So everyone was randomized at the same time."

Blinding of participants and
personnel, objective outcomes
(performance bias)

Judgement: Low risk

Support: Participants blinded ("Participants were not informed about the specific research question or that they would be randomized to different HIV testing programs in order to avoid bias."), but unclear whether personnel was blinded. The corresponding author said "Unfortunately, it was not possible to blind clinic personnel in this study because they had to be aware of what study arm the client was in (if any) in order to offer them the HIV-testing options appropriate for that study arm. However, the data analysis was conducted blind until complete, when we checked the randomization assignment codes to write the paper." It is unlikely though that the delivery of the intervention is influenced by a lack of blinding of personnel.

Blinding of outcome assessment, objective outcomes (detection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> Participants blinded ("Participants were not informed about the specific research question or that they would be randomized to different HIV testing programs in order to avoid bias."), but paper did not indicate whether personnel was blinded. The corresponding author said "Unfortunately, it was not possible to blind clinic personnel in this study because they had to be aware of what study arm the client was in (if any) in order to offer them the HIV-testing options appropriate for that study arm. However, the data analysis was conducted blind until complete, when we checked the randomization assignment codes to write the paper." Unclear whether the persons who entered the HIV testing status onto the EHRS system were aware of the allocation while doing so.</p>
Incomplete outcome data, objective outcomes (attrition bias)	<p><i>Judgement:</i> Low</p> <p><i>Support:</i> Only 2 participants lost to follow up (2/750 in Enhanced SOC group)</p>
Selective outcome reporting (reporting bias)	<p><i>Judgement:</i> Low risk; <i>Support:</i> All expected outcomes reported in the methods and in trial registration are reported as planned.</p>
Other sources of bias (e.g. contamination)	<p><i>Judgement:</i> Low</p> <p><i>Support:</i> No reason to suspect other sources of bias</p>

Kelvin (2019b)

Random sequence generation (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> No details on sequence generation provided in paper, (Quote: "The eligible individuals who remained in the sample after the consent process were randomized to one of three study groups."), but info obtained from author - quote: "The assignment to "treatment" group/arm was done completely randomly via a computer program (SAS software). Basically, what we did was download [records of] all those truckers/FSWs who met eligibility criteria from the North Star Alliance electronic medical record database and then run the SAS randomization syntax that randomized each person in the database to either the intervention, SOC or enhanced SOC arm. So everyone was randomized at the same time."</p>
Allocation concealment (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Randomization of all participants done at the same time and no intermediary step involving staff prior to intervention start, so that allocation concealment was not an issue. (Quote: "The eligible individuals who remained in the sample after the consent process were randomized to one of three study groups."), but info obtained from author - quote: "The assignment to "treatment"</p>

group/arm was done completely randomly via a computer program (SAS software). Basically what we did was download [records of] all those truckers/FSWs who met eligibility criteria from the North Star Alliance electronic medical record database and then run the SAS randomization syntax that randomized each person in the database to either the intervention, SOC or enhanced SOC arm. So everyone was randomized at the same time."

Blinding of participants and personnel, objective outcomes (performance bias)

Judgement: Low risk

Support: It is likely that participants were blinded, as in the linked Kelvin 2019a paper (same study among truckers) it was reported that "participants were not informed about the specific research question or that they would be randomized to different HIV testing programs in order to avoid bias." In this paper though, only the text message content seeking passive consent was included: "North Star Alliance is evaluating our programs for their improvement using client information from our system. The information we use for this evaluation will not be linked to your name and you will not be contacted or have any expenses related to your inclusion. If you have questions about the use of your data call [phone number of clinic where they had last been seen]. To have your data excluded, reply "NO" to this text." The corresponding author confirmed via email, that procedures were the same as in the linked Kelvin 2019a paper and that they did not tell participants "anything about the study or randomization or research questions." In neither article information on the blinding of personnel or researchers was provided, but the corresponding author said "Unfortunately, it was not possible to blind clinic personnel in this study because they had to be aware of what study arm the client was in (if any) in order to offer them the HIV-testing options appropriate for that study arm. However, the data analysis was conducted blind until complete, when we checked the randomization assignment codes to write the paper." It is unlikely though that the delivery of the intervention is influenced by a lack of blinding of personnel.

Blinding of outcome assessment, objective outcomes (detection bias)

Judgement: Unclear

Support: Participants likely blinded as previously explained, but paper did not indicate whether personnel was blinded. The corresponding author said "Unfortunately, it was not possible to blind clinic personnel in this study because they had to be aware of what study arm the client was in (if any) in order to offer them the HIV-testing options appropriate for that study arm. However, the data analysis was conducted blind until complete, when we checked the randomization assignment codes to write the paper." Unclear whether the persons who entered the HIV testing status onto the EHRS system were aware of the allocation while doing so.

Incomplete outcome data, objective outcomes (attrition bias)

Judgement: Low

Support: No cases of loss to follow up or missing data reported

Selective outcome reporting (reporting bias)

Judgement: Low risk

Support: All expected outcomes reported in the methods and in trial registration are reported as planned.

Other sources of bias (e.g. contamination)

Judgement: Low risk

Support: No reason to suspect other sources of bias

Lim (2012)

Random sequence generation (selection bias)

Judgement: Low risk

Support: Quote: "After recruitment, participants were randomly allocated to either the control or intervention group (using Microsoft Excel's random number function) by a study researcher."

Allocation concealment (selection bias)

Judgement: Low risk

Support: After asking author to "describe all measures used, if any, to ensure blinding of key trial personnel from knowledge of which intervention the next participant would be assigned to /which intervention a participant had received", the author responded among other things - quote: "The recruitment staff were blinded to intervention group because the groups were not assigned until post recruitment and baseline survey."
After the recruitment phase, all participants were randomized at the same time by a researcher using the Microsoft Excel random number function.

Blinding of participants and personnel, subjective outcomes (performance bias)

Judgement: High risk

Support: Quote: "Owing to the nature of the intervention it was not possible to blind participants as to whether they were in the intervention group or the control group."

Blinding of outcome assessment, subjective outcomes (detection bias)

Judgement: Unclear

Support: Comment: Participants were not blinded, outcomes assessed by completion of online surveys; Quote: "Owing to the nature of the intervention it was not possible to blind participants as to whether they were in the intervention group or the control group."

Incomplete outcome data, subjective outcomes (attrition bias)

Judgement: High risk

Support: Comment: Only 34% completed all three follow-up questionnaires (39% completed final questionnaire); statistical methods (weighted analysis) were used to try to control for potential bias due to missing data.

Selective outcome reporting (reporting bias)

Judgement: High risk

Support: Comment: All outcomes detailed in methods section were reported in the results section, but outcomes described in trial registration entry (ACTRN12605000760673) were partly different:

1) Primary outcome in trial registration - quote: "Significantly increased self-reported condom use with casual or new partners during the intervention period in participants receiving the intervention", but paper reports condom use with "new or casual partners, or two or more partners within 12 months"

2) Primary outcomes in trial registration also read "self reported (and validated by contacting doctor) chlamydia testing", but paper did not report results 'validated by doctor' and only reported self-reported STI testing; the author clarified: "We did attempt to validate testing at an additional 18 month follow up survey, but this survey and the validation results were not included in the paper due to low response rate."

3) Paper also reports STI knowledge score among main outcomes, which has not been mentioned in the trial registration.

Other sources of bias (e.g. contamination)

Judgement: Low risk

Support: Comment: No reason to suspect other sources of bias.

Selective recruitment of cluster participants (selection bias)

Judgement: n/a *Support:* n/a

Mimiaga (2017)

Random sequence generation (selection bias)	<i>Judgement:</i> Low risk <i>Support:</i> Quote: "they were randomly assigned to the experimental condition (n = 50) or to the SOC comparison condition (n = 50) (both described below) using a computerized randomization program."
Allocation concealment (selection bias)	<i>Judgement:</i> Unclear <i>Support:</i> No information provided, apart from quote: "The study interviewer was blinded to the assigned study condition for all participants."
Blinding of participants and personnel, subjective outcomes (performance bias)	<i>Judgement:</i> High risk <i>Support:</i> "The study interviewer was blinded to the assigned study condition for all participants." Blinding of participants not possible.
Blinding of outcome assessment, subjective outcomes (detection bias)	<i>Judgement:</i> Unclear <i>Support:</i> "The study interviewer was blinded to the assigned study condition for all participants." Blinding of participants not possible. Primary outcome data assessed using audio-computer assisted self-interview.
Incomplete outcome data, subjective outcomes (attrition bias)	<i>Judgement:</i> Low risk <i>Support:</i> Only 2 participants withdrawn from intervention group for reasons unrelated to outcome (one participant moved out of the area, another participant had a serious smpm-study related accident.)
Selective outcome reporting (reporting bias)	<i>Judgement:</i> Unclear <i>Support:</i> No protocol or trial registration entry available
Other sources of bias (e.g. contamination)	<i>Judgement:</i> Low risk <i>Support:</i> No reason to suspect other sources of bias

Mugo (2016)

Random sequence generation (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Shuffling opaque sealed envelopes; Quote: "Participants were randomized to either standard appointment or enhanced appointment on a 1:1 ratio using the sealed opaque envelope method. Envelopes were prepared by a data manager not involved in screening, enrolment and follow-up of participants. Randomization was stratified by study site. Un-numbered envelopes were supplied to study sites in shuffled batches of twenty, 10 for standard appointment and 10 for enhanced appointment. When fewer than 6 envelopes were remaining at a study site, a new set of 20 envelopes was supplied. After enrolment, HIV testing, and all other enrolment visit procedures, the attending clinician asked the participant to pick one envelope at random"</p>
Allocation concealment (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Sealed opaque envelopes (see also comment on random sequence generation)</p>
Blinding of participants and personnel, objective outcomes (performance bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Quote: "Neither participants nor study staff were blinded to the assigned group, as blinding was not feasible given the nature of the intervention."</p>
Blinding of outcome assessment, objective outcomes (detection bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Quote: "Neither participants nor study staff were blinded to the assigned group, as blinding was not feasible given the nature of the intervention." Unclear whether clinic staff who recorded attendance for HIV testing were blinded, but it is likely that they knew about the assignment, as the researchers regularly asked them whether intervention group participants had attended for re-testing to know whether further reminders had to be sent - quote: "For purposes of determining the need for reminder escalation, visit attendance was confirmed from the participant file through daily visits or phone calls to the attending clinicians."</p>
Incomplete outcome data, objective outcomes (attrition bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Four acutely HIV infected participants withdrawn from control arm after randomization, as test results found positive for p24 antigen. These were excluded in 'intent-to-treat analysis' by study authors. Given that n=4 out of N=211 is a relatively small number, and the outcome is relatively frequent (this study reports HIV re-testing appointment attendance outcome only, and not HIV diagnosis) we judge the risk of bias as low.</p>

Selective outcome reporting (reporting bias) *Judgement:* Low risk
Support: Reported outcome as in protocol and trial registration

Other sources of bias (e.g. contamination) *Judgement:* Low risk
Support: No reason to suspect other sources of bias

Nielsen (2019)

Random sequence generation (selection bias) *Judgement:* Low risk
Support: "Eligible participants were individually randomised in a 1:1 ratio to either control or intervention arms. Stratified randomisation by sex was performed. Within each stratum, block randomisation (blocks of 4 and 6) ensured balanced representation in the two treatment arms as recruitment progressed. A remote central randomisation site generated the sequences by computer and ensured allocation concealment"

Allocation concealment (selection bias) *Judgement:* Low risk
Support: Quote: "A remote central randomisation site generated the sequences by computer and ensured allocation concealment. Each participant was provided personal log in details, in sealed envelopes according to randomisation number."

Blinding of participants and personnel, subjective outcomes (performance bias) *Judgement:* High risk
Support: Quote: "Research staff at the site were available to assist in the download and train participants in the use of the app. The trial was therefore open label at the clinical sites; however, the analysis was conducted blind."

Blinding of outcome assessment, subjective outcomes (detection bias) *Judgement:* Unclear risk
Support: Participants cannot be blinded. (Although control group participants received 'dummy' app with questionnaires only, it is likely that they have realized that they have not received the intervention.) Personnel was not blinded, but outcomes were self-reported via questionnaires embedded into the app not during interview with personnel.

Incomplete outcome data, subjective outcomes (attrition bias) *Judgement:* Unclear
Support: Relatively high lost to follow up rate - Quote: "Overall, loss to follow-up was 29.6% (128/433). Disproportionally more men (60/141, 42.5%) than women (68/292, 23.3%) were lost to follow-up. Baseline characteristics between those who completed the study and those lost to follow-up were similar." Results were presented as ITT (table 2) and numbers missing were similar in both

arms (only slightly higher in intervention arm at 6 months). No reasons for losses to follow up reported though, so that it is unclear whether they might have been related to outcomes.

Selective outcome reporting (reporting bias)	<i>Judgement:</i> Low risk
	<i>Support:</i> All expected outcomes reported in the methods are reported as planned; trial registration and published protocol available that listed same outcomes.
Other sources of bias (e.g. contamination)	<i>Judgement:</i> Low risk
	<i>Support:</i> No reason to suspect other sources of bias
Parkes-Ratanshi (2018, 2020)	
Random sequence generation (selection bias)	<i>Judgement:</i> Low risk
	<i>Support:</i> Quote: "Participants were randomised by a computer-generated block randomisation algorithm of different sized blocks in a ratio of 1:1:1 by an independent member of the IDI statistics team."
Allocation concealment (selection bias)	<i>Judgement:</i> Low risk
	<i>Support:</i> Quote: "The randomisation schedule was provided to the site in a box of sequentially numbered, opaque, sealed envelopes to the enrolling study nurses. The sequential randomisation codes were recorded on the study entry case report form to ensure randomisation adherence."
Blinding of participants and personnel, objective outcomes (performance bias)	<i>Judgement:</i> High risk
	<i>Support:</i> No blinding reported; Blinding of participants not possible.
Blinding of outcome assessment, objective outcomes (detection bias)	<i>Judgement:</i> High risk
	<i>Support:</i> No blinding of participants or personnel (confirmed by author via email)
Incomplete outcome data, objective outcomes (attrition bias)	<i>Judgement:</i> Unclear
	<i>Support:</i> It is not clear how many participants/ data were lost from each of the study groups, and/or what the reasons for missing data were; The study flow diagram only shows lost to follow-up of women up to the postpartum visit overall, which was relatively small (n=46/442). It seems an intention-to-treat analysis was done, although not explicitly stated.

Selective outcome reporting
(reporting bias)

Judgement: Low risk

Support: Trial registration entry indicates same primary outcome; the secondary outcomes are not relevant to our review

Other sources of bias (e.g.
contamination)

Judgement: Unclear

Support: In the trial register, the estimated enrolment number was 1752 participants, but only 442 participants were actually enrolled. The following explanation was provided: "An interim futility analysis suggested that there would be no significant difference seen in the arms of the study with the original sample, which led to cessation of enrolment before the original sample size of the study was reached." No details on the futility analyses provided, which would have been useful, as the difference of 21.5% (SOC plus SMS) vs. 15.1% (SOC) does not seem that small.

Reback (2019a)

Random sequence generation
(selection bias)

Judgement: Low risk

Support: No details on sequence generation provided in paper (only says that it is a randomized controlled trial), but author provided the following info via email: "Participants were assigned to a study arm through the computer-based "urn" randomization procedure. To provide multivariate balance across conditions, the urn randomization procedure included the following characteristics: age, ethnicity, HIV status, severity of methamphetamine use."

Allocation concealment
(selection bias)

Judgement: Unclear

Support: No information provided.

Blinding of participants and
personnel, subjective outcomes
(performance bias)

Judgement: High risk

Support: No information provided in article, but author responded to enquiry email: "The study was not blinded. Both participants and research staff knew the study arm assignment."

Blinding of outcome
assessment, subjective
outcomes (detection bias)

Judgement: Unclear

Support: No information on blinding provided in article, but author responded to enquiry email: "The study was not blinded. Both participants and research staff knew the study arm assignment." Given that assessments were done via Audio Computer Assisted Self-Interview (ACASI), the risk of detection bias is unclear.

Incomplete outcome data,
subjective outcomes (attrition
bias)

Judgement: Low risk

Support: Relatively high retention rates (At 9 months: TXT-PHE: 95%, TXT-Auto: 90%, AO/Control: 93%)

Selective outcome reporting
(reporting bias)

Judgement: Low risk

Support: All expected outcomes reported in the methods are reported as planned; no protocol available, but relevant outcomes in trial registration (done prior to study start) similar (although slightly less specific)

Other sources of bias (e.g.
contamination)

Judgement: Low risk

Support: No reason to suspect other sources of bias

Rinehart (2019)

Random sequence generation
(selection bias)

Judgement: Low risk

Support: Quote: "A statistical software program was used to randomly allocate study ids to intervention condition and study envelopes were premade that contained intervention assignment."

Allocation concealment
(selection bias)

Judgement: Low risk

Support: Unclear whether premade envelopes were sequentially numbered, opaque, and sealed. Quote: "study envelopes were premade that contained intervention assignment. The researcher, blinded to this assignment, opened the envelope after the baseline interview and discussed intervention assignment with the participants." In email correspondence, we asked author to "provide more details about these premade envelopes and the relating procedures", and author clarified - quote: "We used SAS to randomly allocate 300 unique study IDs to the intervention or control condition [...]. Prior to starting study recruitment, 300 envelopes that contained a letter describing the intervention assignment were created based on the condition the study ID was randomized to; that is, the envelope either contained an intervention letter or control group letter. The envelopes were prepared and sealed by a non-study team staff member, thus researchers were blinded to assignments before enrolling a participant. Once a participant consented to the study, they were allocated a study ID and this ID was assigned sequentially based on the order in which they enrolled. Based on the study ID they were given, the corresponding envelope was opened by the researcher and thus group assignment was assigned after the baseline interview was completed." Author also further clarified that it was "white business envelopes – opaque/couldn't see through. The study ID was on the upper right hand corner" and "They assigned the next sequential study number/folder/envelope as participants were identified and consented to participate"

Blinding of participants and personnel, subjective outcomes (performance bias)

Judgement: High risk

Support: The article only mentioned that researcher were blinded to the assignment at the point of allocation, but not whether blinding was maintained, i.e. if personnel administering the follow-up questionnaires were blinded. Participants were likely not blinded. We therefore asked the author to describe "all measures used, if any, to ensure blinding of key trial personnel and also of trial participants from knowledge of which intervention a participant had received (throughout the study period)."

Response - quote: "Researchers were blinded from knowing which envelope contained which assignment, however; after the participant consented, completed the baseline, and the researcher opened the assignment envelope, both the researcher and participant knew their assignment. Our study team was comprised of researchers who did not have any clinical relationship to participants and the intervention was delivered electronically, so it was not possible for a control group participant to receive the automated text intervention."

Blinding of outcome assessment, subjective outcomes (detection bias)

Judgement: Unclear

Support: Comment: Participants likely not blinded, unclear whether personnel blinded (only blinding of researchers at assignment stage reported, but not clear whether blinding has been maintained.)

We sought clarification from author, who responded:

"after the participant consented, completed the baseline, and the researcher opened the assignment envelope, both the researcher and participant knew their assignment. Our study team was comprised of researchers who did not have any clinical relationship to participants and the intervention was delivered electronically, so it was not possible for a control group participant to receive the automated text intervention"

Most participants seemed to have completed the self-assessment online (without interacting with personnel), but those who failed to do so were given the option to do the survey over the phone - unclear though, how many participants took on this offer.

Quote: "Participants were first sent a text to prompt them to look for an email with a link to the online survey that was collected using Research Electronic Data Capture (REDCap). For participants who did not complete the survey online, reminder phone calls were made and participants were also offered the option to complete the survey over the phone"

Incomplete outcome data,
subjective outcomes (attrition
bias)

Judgement: High

Support: Losses to follow up of 25% (contr. arm) and 28% (interv. arm) at 3 month, and of 36% (contr. arm) and 34% (interv. arm) at 6 months. Quote: "Significant baseline demographic differences between 6-month follow-up completers and non-completers included current grade level (with completers having a higher grade level, $P = .01$), sharing a telephonic device (with completers less likely to share a device, $P = .04$), ever had oral sex (with completers more likely to have had oral sex, $P = .01$), and having ever used birth control (with completers more likely to have used birth control, $P = .03$). Six-month completers had higher overall baseline knowledge ($P = .05$) and condom use self-efficacy ($P = 0.02$) as compared to non-completers."

Selective outcome reporting
(reporting bias)

Judgement: Low risk

Support: Comment: Outcomes listed in the protocol and paper are very similar, apart from biologic outcomes. The protocol indicates (under outcome measures) that urine tests will be assessed for chlamydia, gonorrhoea and pregnancy (p.4/5) and a "preliminary assessment of the effect of the intervention on STD incidence (urine test for chlamydia)" (as Hypothesis 4, p.2). Similarly, the trial registration indicates under secondary outcomes "incidence of unintended pregnancy and STDs", measured via urinalysis at 6 months. The author clarified via email that they had been unable to collect urine samples at the 6 month follow-up and explained - quote: "as part of the 6 month follow-up interview we asked [participants] to come by the community health clinic to complete a study UA (STI test). However, very few completed this step and we did not want to tie compensation to this piece for fear of not getting any of the FU data (the self-report) interview."

Other sources of bias (e.g.
contamination)

Judgement: Low risk

Support: No reason to suspect other sources of bias

Rokicki (2017)

Random sequence generation (selection bias)	<i>Judgement:</i> Low risk <i>Support:</i> Quote: "Randomization was based on a computer-generated random number draw randomization by school category (a measure of quality designated by the Ghana Education Service) and by whether the school had a home economics class."
Allocation concealment (selection bias)	<i>Judgement:</i> Unclear <i>Support:</i> Not clearly stated
Blinding of participants and personnel, subjective outcomes (performance bias)	<i>Judgement:</i> High risk <i>Support:</i> Quote: "Study participants and data collection staff could not be masked because the intervention required overt participation."
Blinding of outcome assessment, subjective outcomes (detection bias)	<i>Judgement:</i> High risk <i>Support:</i> Quote: "Study participants and data collection staff could not be masked because the intervention required overt participation."
Incomplete outcome data, subjective outcomes (attrition bias)	<i>Judgement:</i> Low risk <i>Support:</i> Quote: "A total of 756 participants enrolled in the study, of which 716 (95%) were successfully followed up at 3 months and 721 (95%) were successfully followed up at 15 months."
Selective outcome reporting (reporting bias)	<i>Judgement:</i> Unclear <i>Support:</i> No protocol available, and primary and secondary outcomes in trial registration entry are partly vague and vary slightly for original and final entries.
Other sources of bias (e.g. contamination)	<i>Judgement:</i> Low risk <i>Support:</i> No reason to suspect other sources of bias
Selective recruitment of cluster participants (selection bias)	<i>Judgement:</i> High risk <i>Support:</i> Cluster RCT - recruitment of participants (students) occurred after randomisation of clusters (schools).

Suffoletto (2013)

Random sequence generation (selection bias)	<i>Judgement:</i> Low risk <i>Support:</i> Quote: "After completing the baseline questionnaire, participants were randomized to either the intervention or control group using a computer-generated random sequence"
Allocation concealment (selection bias)	<i>Judgement:</i> Unclear <i>Support:</i> No information provided.
Blinding of participants and personnel, subjective outcomes (performance bias)	<i>Judgement:</i> High risk <i>Support:</i> Blinding of participants and of personnel providing feedback on risk behaviour not possible.
Blinding of outcome assessment, subjective outcomes (detection bias)	<i>Judgement:</i> High risk <i>Support:</i> Comment: Blinding of participants and of personnel providing feedback on risk behaviour not possible. Outcome self-assessment via web-based follow-up survey.
Incomplete outcome data, subjective outcomes (attrition bias)	<i>Judgement:</i> High risk <i>Support:</i> Quote: "Out of the 52 persons who enrolled in the study, 29 (56%; 95% CI 41%-70%) completed the 3-month web-based follow-up."
Selective outcome reporting (reporting bias)	<i>Judgement:</i> Unclear risk <i>Support:</i> No protocol available, and insufficient detail in trial registration entry
Other sources of bias (e.g. contamination)	<i>Judgement:</i> Unclear <i>Support:</i> Quote: "we cannot account for the potential effect of frequent SMS queries about risk behavior on differential recall bias compared with the control group. SMS queries could have "educated" individuals through assisted self-monitoring, thus potentially making their recall more "accurate" than control group."

Tang (2018)

Random sequence generation (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Quote; "We randomly assigned the order of intervention for each of the four cities in Guangdong province and Shandong province, then paired the cities by order of intervention (S1 Table). Prior to receiving the intervention, cities were considered to be in the control state. We initiated the intervention for each pair at 3-month intervals, and each pair of cities received the intervention for 3 consecutive months. In total, we collected data at baseline followed by four data collection points over 12 months." Additional info obtained from author: "We used SAS to generate a random sequence of implementation."</p>
Allocation concealment (selection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> No information provided.</p>
Blinding of participants and personnel, subjective outcomes (performance bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Comment: Blinding of participants and personnel not possible (confirmed by author).</p>
Blinding of outcome assessment, subjective outcomes (detection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> Comment: Blinding of participants not possible (confirmed by author). Participants self-reported outcomes via online surveys.</p>
Incomplete outcome data, subjective outcomes (attrition bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> Quote: "306 did not finish our last survey, with a loss-to-follow-up rate of 23% (306/1,313, Fig 4). Loss-to-follow-up rates were similar between the four intervention groups. Characteristics of participants lost to follow-up differed in age and income from participants who completed the last follow-up (S2 Table)." Individual-level missing data for each of four timepoints for all four groups/cities shown in Fig.4; No reasons for losses to follow up reported; Intention-to-treat analysis was done</p>
Selective outcome reporting (reporting bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Reported outcomes as in protocol, trial registration and methods section</p>

Other sources of bias (e.g. contamination)

Judgement: Unclear

Support: "the implementation of HIV self-testing was delayed in two cities because of logistical problems. This may explain why HIV testing rates were lower in the earlier groups, which would bias our effect estimates towards the null, suggesting that reported results are even more conservative than the true effect"
"Finally, there may have been contamination between the intervention and control periods, especially among participants of the crowdsourcing contest and designathon who may have viewed intervention materials in advance. We did not collect information on whether men participated in contests used to develop the intervention. Because it would be impossible to determine if control groups had inadvertently seen the intervention without exposing them to the intervention, we did not collect information on potential spillover effects. However, given that the intraclass correlation for participants within each city was low, we anticipate that the impact of the spillover would also be small."

Selective recruitment of cluster participants (selection bias)

Judgement: Unclear

Support: Cluster RCT, recruitment of participants occurred after randomization - it occurred online/via social media

Trent (2019)

Random sequence generation (selection bias)

Judgement: Low risk

Support: "At baseline, participants [...] were randomized to intervention and standard of care control groups based on a computer-generated block randomization sequence that was generated by the study's data analyst (S.C.) and sealed in an envelope until sequential enrollment.¹⁶"

ref 16- Matts JP, Lachin JM. Properties of permuted-block randomization in clinical trials. *Control Clin Trials*. 1988;9(4):327-344. doi:10.1016/0197-2456(88)90047-5

Allocation concealment (selection bias)

Judgement: Low risk

Support: Envelopes were sequentially numbered, and sealed, but unclear whether opaque.

"At baseline, participants [...] were randomized to intervention and standard of care control groups based on a computer-generated block randomization sequence that was generated by the study's data analyst (S.C.) and sealed in an envelope until sequential enrollment.¹⁶" [ref 16: Matts JP, Lachin JM. Properties of permuted-block randomization in clinical trials. *Control Clin Trials*. 1988;9(4):327-344. doi:10.1016/0197-2456(88)90047-5]

Corresponding author clarified when asked to specify how the envelopes looked like and how exactly the sequential enrolment was implemented that "After consent, the RA would select the

envelope that matches the next SUBID containing the group assignment" and that "The SUBID is on the outside and you cannot see through the business envelopes."

Blinding of participants and personnel, objective outcomes (performance bias)

Judgement: High risk *Support:* Blinding of participants and counsellors not possible.

No blinding of interviewers, but blinding of PI (with minor exceptions)

Quote (main paper, limitations): "The outreach worker who collected the 2-week, 30-day, and 90-day data was a single individual and was not blinded to group assignment information. It is possible that interactions with the outreach worker may have influenced the longitudinal behavior of adolescents in the control group, but this individual did not interact with participants during the 14-day intervention period."

Quote (protocol): "All data will be managed by an institutional data management service. While the principal investigator is blinded to individual study assignment; per protocol if a patient has a clinical problem while the CHN is in the field individual assignment will be unblinded so that Drs. Butz and/or Trent will can assist with patient management"

Blinding of participants and personnel, subjective outcomes (performance bias)

Judgement: High risk

Support: Blinding of participants and counsellors not possible.

No blinding of interviewers, but blinding of PI (with minor exceptions)

Quote (main paper, limitations): "The outreach worker who collected the 2-week, 30-day, and 90-day data was a single individual and was not blinded to group assignment information. It is possible that interactions with the outreach worker may have influenced the longitudinal behavior of adolescents in the control group, but this individual did not interact with participants during the 14-day intervention period."

Quote (protocol): "All data will be managed by an institutional data management service. While the principal investigator is blinded to individual study assignment; per protocol if a patient has a clinical problem while the CHN is in the field individual assignment will be unblinded so that Drs. Butz and/or Trent will can assist with patient management"

Blinding of outcome assessment, objective outcomes (detection bias)

Judgement: Low risk

Support: Blinding of participants and counsellors not possible, but PI and of lab staff were blinded:

According to author (personal email correspondence) STI samples at 90 days "were self-collected in the field by participants and given to staff to return to the lab" and the lab "staff who performed the testing were blinded to group assignment. They only have subject IDs."

Blinding of outcome assessment, subjective outcomes (detection bias)

Judgement: Unclear

Support: Comment: Blinding of participants and counsellors not possible.

No blinding of interviewer, but blinding of PI (with minor exceptions) - Quote (main paper, limitations): "The outreach worker who collected the 2-week, 30-day, and 90-day data was a single individual and was not blinded to group assignment information..."; Quote (main paper, measures): "Core measures used for this analysis included the [...] sexual and reproductive history data from the audio computer assisted self-interview, self-reported adherence measures (partner notification and treatment, sexual abstinence, and self-medication adherence from the 14-day visit).

Incomplete outcome data, objective outcomes (attrition bias)

Judgement: Low risk

Support: Withdrawals are unlikely to have an effect on outcome: n=6 individuals (1 in SOC and 5 in intervention arm) excluded after enrollment, "because they did not meet the enrollment criteria (eg, hospitalized after doxycycline treatment, later revealed an out-of-state address)"; 91% retention rate for objective outcome (both arms)

Incomplete outcome data, subjective outcomes (attrition bias)

Judgement: Low risk

Support: Withdrawals are unlikely to have an effect on outcome: n=6 individuals (1 in SOC and 5 in intervention arm) excluded after enrolment, "because they did not meet the enrollment criteria (eg, hospitalized after doxycycline treatment, later revealed an out-of-state address)";

Quote: "in the intervention, 16 refused the community health nurse visit. The effective intervention delivery rate achieved was 89.6% (138 of 154 patients), and 90.9% (260 of 286 patients) of the effective sample was retained at 3 months"

Footnote to table 2: "Number of measurements vary slightly because of participant nonresponse, sample leakage, and indeterminate diagnostic results."

Comment: The variations are not high though, with relatively few other losses to follow up/ missing data, which are not very likely to lead to bias, given that the subjective outcomes were relatively common.

Selective outcome reporting (reporting bias)

Judgement: Low risk

Support: Protocol available (although published only post-trial), and Trial registration (original version published pre-trial) and no significant changes made to primary and secondary outcomes.

Other sources of bias (e.g. contamination)

Judgement: Unclear *Support:* Baseline imbalance in Chlamydia prevalence ($p=.01$); use of blocked randomization in only partly blinded trial (PI was blinded, but other study personnel seems not to have been blinded.)

Ybarra (2017)

Random sequence generation (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Quote: "Participants were randomly assigned [...] by using a computer program designed to minimize the likelihood of an imbalance between the study arms with respect to sexual experience and sexual identity."</p>
Allocation concealment (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> National online recruitment, then telephone screening and informed consent, then email sent with link to online survey. Then, quote: "After survey completion, youth were randomly assigned and began receiving text messages."; Quote: "Participants were randomly assigned [...] by using a computer program designed to minimize the likelihood of an imbalance between the study arms with respect to sexual experience and sexual identity." Thus unlikely that researchers knew what individual participants allocation may be prior to allocation. "Participants, but not researchers, were blind to arm allocation" most likely refers to after allocation.</p>
Blinding of participants and personnel, subjective outcomes (performance bias)	<p><i>Judgement:</i> Unclear risk</p> <p><i>Support:</i> Quote: "Participants, but not researchers, were blind to arm allocation." Unclear, if the fact that researchers had not been blinded might have led to bias, given that there was no personal interaction between personnel and participants during intervention or data collection.</p>
Blinding of outcome assessment, subjective outcomes (detection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Quote: "Participants, but not researchers, were blind to arm allocation." Unlikely that the fact that personnel was not blinded might have led to bias, given that there was no personal interaction between personnel and (blinded) participants during intervention or data collection, and given that assessments were self-reported via text message and online surveys.</p>
Incomplete outcome data, subjective outcomes (attrition bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> High level of retention at 90-days postintervention: Intervention arm - 137/150, Control arm - 146/152</p>
Selective outcome reporting (reporting bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> All outcomes mentioned in methods reported, but no protocol available, and outcomes in original trial registration vague and slightly different from more specific final outcomes.</p>

Other sources of bias (e.g. contamination)

Judgement: Low

Support: Imbalances of age at baseline, but statistical analyses adjusted for these imbalances, apart from for condom outcome, where it was not possible to use adjusted measure for pooling

Young (2013)

Random sequence generation (selection bias)

Judgement: Low risk

Support: Randomization of participants and facebook groups - Quote: "Facebook was used to create closed groups (unable to be accessed or searched for by persons who were not group members) for the 2 control and 2 intervention groups. Participants were randomly and blindly assigned to 1 of 2 intervention or control groups and then randomly assigned to 2 peer leaders within that group. Each group was designed to have 28 participants and 4 peer leaders. Randomization was performed by a random-number generator with participants blinded to assignment and unable to be placed in a group or condition at their request." We assume that randomization of peer leaders was also done by random-number generator - Quote: "Peer leaders who satisfied enrollment criteria were informed about the study design and were randomly assigned to the HIV (intervention) group or general health (control) group."

Allocation concealment (selection bias)

Judgement: Unclear

Support: No details on allocation concealment provided. (Only statements: "Peer leaders [...] were randomly assigned to the HIV (intervention) group or general health (control) group." and "Participants were randomly and blindly assigned to 1 of 2 intervention or control groups and then randomly assigned to 2 peer leaders within that group.")

Blinding of participants and personnel, objective outcomes (performance bias)

Judgement: Unclear

Support: Quote: "Randomization was performed by a random-number generator with participants blinded to assignment...". Not possible to blind peer educators, and no information on blinding of study personnel. Author email response: "Groups clustered were numbered rather than labeled with intervention or control; also study staff had limited/no interaction with participants other than to remind them to complete surveys and to send them HIV testing kits they had offered, making it unlikely they could have influenced groups."

Blinding of participants and personnel, subjective outcomes (performance bias)

Judgement: Unclear

Support: Quote: "Randomization was performed by a random-number generator with participants blinded to assignment...". Not possible to blind peer educators, and no information on blinding of study personnel.

Author email response: "Groups clustered were numbered rather than labeled with intervention or control; also study staff had limited/no interaction with participants other than to remind them to complete surveys and to send them HIV testing kits they had offered, making it unlikely they could have influenced groups."

Blinding of outcome assessment, objective outcomes (detection bias)

Judgement: Unclear

Support: Quote: "Randomization was performed by a random-number generator with participants blinded to assignment...". Not possible to blind peer educators, and no information on blinding of study personnel who recorded requests for home-testing kits

Quote: "Primary intervention end points were based on verifiable behavior change from baseline to follow-up: requesting a home-based testing kit, returning the kit, and following up for test results." - "Home Access Health provided the personal identification numbers on the testing kits that were returned along with data on rates of participant follow-up to receive test results."

Author email response: "Groups clustered were numbered rather than labeled with intervention or control; also study staff had limited/no interaction with participants other than to remind them to complete surveys and to send them HIV testing kits they had offered, making it unlikely they could have influenced groups."

Blinding of outcome assessment, subjective outcomes (detection bias)

Judgement: Unclear

Support: Quote: "Randomization was performed by a random-number generator with participants blinded to assignment...". Not possible to blind peer educators and no information on blinding of study personnel.

Quote: "Secondary end points were self-reported reduction in number of sexual partners [...]."

Author email response: "Groups clustered were numbered rather than labeled with intervention or control; also study staff had limited/no interaction with participants other than to remind them to complete surveys and to send them HIV testing kits they had offered, making it unlikely they could have influenced groups."

Incomplete outcome data, objective outcomes (attrition bias)

Judgement: Low risk

Support: "A total of 105 participants (93.8%) completed the follow-up survey."

Incomplete outcome data, subjective outcomes (attrition bias)

Judgement: Low risk

Support: "A total of 105 participants (93.8%) completed the follow-up survey."

Selective outcome reporting
(reporting bias)

Judgement: Unclear

Support: No protocol available and trial registration number (NCT01701206) for this pilot trial provided in the article and confirmed by author indicates different actual enrolment number (558 instead of 112 participants)

Other sources of bias (e.g.
contamination)

Judgement: Unclear

Support: Author response to email inquiring about intra-cluster coefficient or design effect: "The analysis presented used a contrast on cluster means, which indirectly takes the intracluster correlation into account."

Imbalances in some of the participant characteristics at baseline: "The control group had more single participants than the intervention group (91% vs. 75%), and the intervention group had more persons who completed postsecondary education than the control group (65% vs. 56%). ", but paper reports that "adjusted regressions that included age and marital status did not change the conclusion.

Comment: In this review we did not include data on outcomes for which the authors had been unable to conduct statistical analyses (due to sparse data) that indirectly took intracluster correlations into account.

Selective recruitment of cluster
participants (selection bias)

Judgement: Unclear

Support: Social networking study/ cluster RCT - recruitment of participants occurred after randomisation of peer leaders, but before randomisation to intervention vs control group and randomization to facebook groups within intervention or control group. There were also baseline differences that could have possibly been related to problems in randomization. Quote: "The control group had more single participants than the intervention group (91% vs. 75%), and the intervention group had more persons who completed postsecondary education than the control group (65% vs. 56%)."

Zhu (2019)

Random sequence generation (selection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> No details provided in paper on random sequence generation (quote: "The research assistant then assigned participants to intervention or control groups, based on an a priori randomization sequence that was managed by the study statistician."), but one of the authors clarified via email that a "research team member used a computer algorithm to create an a priori randomization sequence."</p>
Allocation concealment (selection bias)	<p><i>Judgement:</i> Unclear</p> <p><i>Support:</i> Insufficient detail provided to allow judgement of allocation concealment. Quote: "The research assistant then assigned participants to intervention or control groups, based on an a priori randomization sequence that was managed by the study statistician."</p>
Blinding of participants and personnel, objective outcomes (performance bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Blinding of participants not possible. Unclear whether personnel was blinded. Clinical trial registry entry reads: "Masking: Single (Outcomes Assessor)" In email correspondence one of the authors indicated that - quote: "Assessors were blind to condition. Participants were not."</p>
Blinding of participants and personnel, subjective outcomes (performance bias)	<p><i>Judgement:</i> High risk</p> <p><i>Support:</i> Blinding of participants not possible. Unclear whether personnel was blinded. Clinical trial registry entry reads: "Masking: Single (Outcomes Assessor)"; In email correspondence one of the authors indicated that - quote: "Assessors were blind to condition. Participants were not."</p>
Blinding of outcome assessment, objective outcomes (detection bias)	<p><i>Judgement:</i> Low risk</p> <p><i>Support:</i> Blinding of participants not possible. Unclear whether personnel was blinded. Clinical trial registry entry reads: "Masking: Single (Outcomes Assessor)"; In email correspondence one of the authors indicated that - quote: "Assessors were blind to condition. Participants were not."</p>

Blinding of outcome assessment, subjective outcomes (detection bias)

Judgement: Unclear

Support: Comment: Blinding of participants not possible. Paper does not report whether personnel was blinded, but irrelevant, given that assessment via self-reported online survey. Clinical trial registry entry reads: "Masking: Single (Outcomes Assessor)"; In email correspondence one of the authors indicated that - quote: "Assessors were blind to condition. Participants were not."

Incomplete outcome data, objective outcomes (attrition bias)

Judgement: Low risk

Support: Zero withdrawals and zero losses to follow-up

Incomplete outcome data, subjective outcomes (attrition bias)

Judgement: Low risk

Support: Zero withdrawals and zero losses to follow-up

Selective outcome reporting (reporting bias)

Judgement: Unclear

Support: No protocol available; Clinical trial registration around primary completion date (nine months after study start)

Other sources of bias (e.g. contamination)

Judgement: Low risk

Support: No reason to suspect other sources of bias

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