The TREND Checklist (Version 1.0)

Paper Section/Topic	Item No.	Descriptor	Examples From HIV Behavioral Prevention Research
Title and abstract	1	• Information on how units were allocated to interventions	Example (title): A nonrandomized trial of a clinic-based HIV counseling intervention for African American female drug users
		• Structured abstract recommended	
		• **Information on target population or study sample**	
Introduction		• Scientific background and explanation of rationale	
Background	2	• **Theories used in designing behavioral interventions**	Example (theory used): the community-based AIDS intervention was based on social learning theory
Methods			
Participants	3	• Eligibility criteria for participants, **including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)**	
		• Method of recruitment (e.g., referral, self-selection), including the **sampling method** if a systematic sampling plan was implemented	Example (sampling method): using an alphanumeric sorted list of possible venues and times for identifying eligible subjects, every tenth venue–time unit was selected for the location and timing of recruitment
		• **Recruitment setting**	Examples (recruitment setting): subjects were approached by peer opinion leaders during conversations at gay bars
		• Settings and locations where the data were collected	
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	
		Content: what was given?	
		Delivery method: how was the content given?	
		Unit of delivery: how were subjects grouped during delivery?	Example (unit of delivery): the intervention was delivered to small groups of 5–8 subjects
		Deliverer: who delivered the intervention?	
		Setting: where was the intervention delivered?	Examples (setting): the intervention was delivered in the bars; the intervention was delivered in the waiting rooms of sexually transmitted disease clinics
		Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Examples (exposure quantity and duration): the intervention was delivered in five 1-hour sessions; the intervention consisted of standard HIV counseling and testing (pretest and posttest counseling sessions, each about 30 minutes)
		Time span: how long was it intended to take to deliver the intervention to each unit?	Examples (time span): each intervention session was to be delivered (in five 1-hour sessions) once a week for 5 weeks; the intervention was to be delivered over a 1-month period.
		Activities to increase compliance or adherence (e.g., incentives)	Example (activities to increase compliance or adherence): bus tokens and food stamps were provided
Objectives	5	• Specific objectives and hypotheses	
Outcomes	6	• Clearly defined primary and secondary outcome measures	
		• **Methods used to collect data** and any methods used to	Examples (method used to collect data):

		enhance the quality of measurements	self-report of behavioral data using a face-to-face interviewer-administered questionnaire; audio-computer-assisted self-administered instrument
		• Information on validated instruments such as psychometric and biometric properties	
Sample size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	
Assignment method	**8**	• **Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)**	Example 1 (assignment method): subjects were assigned to study conditions using an alternating sequence wherein every other individual enrolled (e.g., 1, 3, 5, etc.) was assigned to the intervention condition and the alternate subjects enrolled (e.g., 2, 4, 6, etc.) were assigned to the comparison condition
		• **Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)**	
		• **Inclusion of aspects employed to help minimize potential bias induced due to nonrandomization (e.g., matching)**	
			Example 2 (assignment method): for odd weeks (e.g. 1, 3, 5), subjects attending the clinic on Monday, Wednesday, and Friday were assigned to the intervention condition and those attending the clinic on Tuesday and Thursday were assigned to the comparison condition; this assignment was reversed for even weeks
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding **was accomplished** and how it was assessed	Example (blinding): the staff member performing the assessments was not involved in implementing any aspect of the intervention and knew the participants only by their study identifier number
Unit of analysis	**10**	• **Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)**	Example 1 (unit of analysis): since groups of individuals were assigned to study conditions, the analyses were performed at the group level, where mixed effects models were used to account for random subject effects within each group
		• **If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)**	Example 2 (unit of analysis): since analyses were performed at the individual level and communities were randomized, a prior estimate of the intraclass correlation coefficient was used to adjust the standard error estimates before calculating confidence intervals
Statistical methods	11	• Statistical methods used to compare study groups for primary outcome(s), including complex methods for correlated data	
		• Statistical methods used for additional analyses, such as subgroup analyses and adjusted analysis	
		• **Methods for imputing missing data, if used**	
		• **Statistical software or programs used**	
Results			
	12	• Flow of participants through each stage of the study:	

Participant flow		enrollment, assignment, allocation and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	
		Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	
		Assignment: the numbers of participants assigned to a study condition	
		Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	
		Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition	
		Analysis: the number of participants included in or excluded from the main analysis, by study condition	
		• Description of protocol deviations from study as planned, along with reasons	
Recruitment	13	• Dates defining the periods of recruitment and follow-up	
Baseline data	14	• Baseline demographic and clinical characteristics of participants in each study condition	
		• **Baseline characteristics for each study condition relevant to specific disease prevention research**	Example (baseline characteristics specific to HIV prevention research): HIV serostatus and HIV testing behavior
		• **Baseline comparisons of those lost to follow-up and those retained, overall and by study condition**	
		• **Comparison between study population at baseline and target population of interest**	
Baseline equivalence	**15**	• **Data on study group equivalence at baseline and statistical methods used to control for baseline differences**	Example (baseline equivalence): the intervention and comparison groups did not statistically differ with respect to demographic data (gender, age, race/ethnicity; P > .05 for each), but the intervention group reported a significantly greater baseline frequency of injection drug use (P = .03); all regression analyses included baseline frequency of injection drug use as a covariate in the model
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	Example (number of participants included in the analysis): the analysis of condom use included only those who reported at the 6-month follow-up having had vaginal or anal sex in the past 3 months (75/125 for intervention group and 35/60 for standard group)
		• Indication of whether the analysis strategy was “intention to treat” **or, if not, description of how noncompliers were treated in the analyses**	Example (“intention to treat”): the primary analysis was intention to treat and included all subjects as assigned with available 9-month outcome data (125 of 176 assigned to the intervention and 110 of 164 assigned to the standard condition)
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each study condition, and the estimated effect size and a confidence interval to indicate the precision	
		• Inclusion of null and negative findings	
		• **Inclusion of results from testing prespecified causal pathways through which the intervention was intended to operate, if any**	

Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are prespecified or exploratory	Example (ancillary analyses): although the study was not powered for this hypothesis, an exploratory analysis shows that the intervention effect was greater among women than among men (although not statistically significant)
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	Example (adverse events): police cracked down on prostitution, which drove the target population, commercial sex workers, to areas outside the recruitment/sampling area
Discussion			
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	
		• **Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations**	
		• **Discussion of the success of and barriers to implementing the intervention, fidelity of implementation**	
		• Discussion of research, **programmatic, or policy implications**	
Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, **incentives, compliance rates, specific sites/settings involved in the study,** and other contextual issues	
Overall evidence	22	• General interpretation of the results in the context of current evidence and current theory	

Note: Masking (blinding) of participants or those administering the intervention may not be relevant or possible for many behavioral interventions. Theories used to design the interventions (see item 2) could also be reported as part of item 4. The comparison between study population at baseline and target population of interest (see item 14) could also be reported as part of item 21. Descriptors appearing in boldface are specifically added, modified, or further emphasized from the CONSORT statement. Boldface topic and descriptors are not included in the CONSORT statement but are relevant for behavioral interventions using nonrandomized experimental designs. The CONSORT statement[11] or the explanation document for the CONSORT statement[18] provides relevant examples for any topic or descriptor that is not in boldface. A structured format of the discussion is presented in Annals of Internal Medicine (information for authors; www.annals.org, accessed September 16, 2003).