S1 CONSORT checklist of information to include when reporting a randomised trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Information on how unit were allocated to interventions	**N.A.**
	1b	Structured abstract recommended	**2**
	1c	Information on target population or study sample	**2**
Introduction			
Background	2a	Scientific background and explanation of rationale	**3-4**
	2b	Theories used in deigning behavioural interventions	**N.A.**
Methods			
Participants	3a	Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	**5**
	3b	Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	**5**
	3c	Recruitment setting	**5**
	3d	Settings and locations where the data were collected	**5**
Interventions	4a	Details of the interventions intended for each study condition and how and when they were actually administered, specifically including	**5-6**
		- Content: what was given?	**5**
		- Delivery method: how was the content given?	**5**
		- Unit of delivery: how were the subjects grouped during delivery?	**N.A.**
		- Deliverer: who delivered the intervention?	**6**
		- Setting: where was the intervention delivered?	**6**
		- Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	**5**
		- Time span: how long was it intended to take to deliver the intervention to each unit?	**N.A.**

		- Activieties to increase compliance or adherence (e.g., incentives)	**6**
Objectives	5	Specific objectives and hypotheses	**4**
Outcomes	6a	Clearly defined primary and secondary outcome measures	
	6b	Methods used to collect data and any methods used to enhance the quality of measurements	**6-9**
		Information on validated instruments such as psychometric and biometric properties	**6-7**
Sample size	7a	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	**5**
Assignment Method	8a	Unit of assignment	**N.A.**
	8b	Methods used to assign units to study conditions, including details of any restriction	**N.A.**
	8c	Inclusion of aspects employed to help minimize potential bias induced due to non-randomization	**N.A.**
Blinding	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.	**9-10 1**
Unit of Analysis	10a	Description of the smallest unit that is being analysed to assess intervention effects	**5**
	10b	If the unit of analysis differs from the unit of assignment, the analytical method used to account for this	**N.A.**
Statistical methods	11a	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	**9**
	11b	Statistical methods used for additional analyses, such as a subgroup analysis and adjusted analysis.	**N.A.**
	11c	Methods for imputing missing data, if used	**N.A.**
	11d	Statistical software or programs used	**9**

Results			
Participant flow	12a	Flow of participants through each stage of the study: enrolment, assignment, allocation, and intervention exposure, follow-up, analysis	**Fig. 1**
	12b	Description of protocol deviations from study as planned, along with reasons	**Fig. 1**
Recruitment	13	Dates defining the periods of recruitment and follow-up	**6**
Baseline data	14a	Baseline demographic and clinical characteristics of participants in each study condition	**N.A.**
Numbers analysed	14b	Baseline characteristics for each study condition relevant to specific disease prevention research	**N.A.**
	14c	Baseline comparison of those lost to follow-up and those retained, overall and by study condition	**N.A.**
	14d	Comparison between study population at baseline and target population of interest	**9-20**
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	**9-20**
Numbers analyzed	16a	Number of participants 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	**5**
	16b	Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses.	**N.A.**
Outcomes and estimation	17a	For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	**N.A.**
	17b	Inclusion of null and negative findings	**N.A.**
	17c	Inclusion of results from treating pre-specified causal pathways through which the intervention was intended to operate, if any	**9-20**

Ancillary analyses	18	Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	**N.A.**
Adverse events	19	Summary of all important adverse events or unintended effects in each study condition	**6**
Discussion			
Interpretation	20a	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	**21-24**
	20b	Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	**21-24**
	20c	Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	**21-24**
	20d	Discussion of research, programmatic, or policy implications	**24**
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	**24**