Recommendations for the reporting of smoking cessation randomised control trials: Initial outcomes from an expert consensus meeting

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OBJECTIVES

To develop recommendations for improved reporting of randomised control trials of smoking cessation interventions.

METHODS

Followed the Guidance for Developers of Health Research Reporting Guidelines (Moher, 2010).

Existing checklists for design and reporting of RCTs in behavioural medicine were identified. Additionally, items from the IC-SMOKE database with the most missing data were selected.

Using the CONSORT-SPI (Social and Psychological Interventions) reporting tool as the backbone, potential additions were identified from other tools and input from experts.

An online questionnaire was developed and experts were asked to vote on the importance of 10 proposed changes to the CONSORT-SPI.

Results were compiled and an expert meeting was held at Trimbos Institute, Utrecht, Netherlands on May 2nd 2019. All items were voted either critical for inclusion on new guidelines or not critical. 75% consensus was required to constitute agreement.

Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c869.

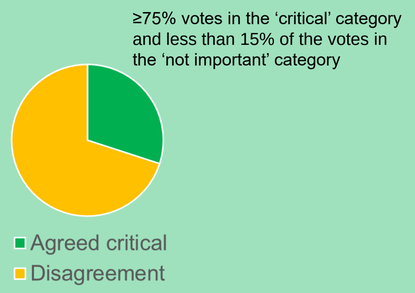
RESULTS

Online questionnaire

17 experts completed this, voting on the importance of 10 proposed changes to the CONSORT checklist using a 9 point Likert scale.

Items that reached agreement:

- Agreed to be included (n=3)
- Disagreement (n=7)

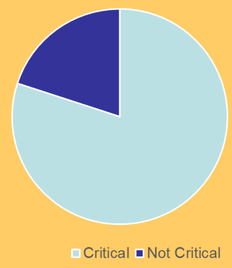


Expert meeting

The results of the questionnaire were discussed with 15 international experts attending the meeting. Agreement was reached on 11 additions to CONSORT-SPI (three agreed from the online phase and 8 additional items)

Consensus was reached on all items:

- Critical (to be included, n=9)
- Not critical (not included, n=2)



	CONSORT 2010 + CONSORT-SPI 2018	Proposed addition for reporting
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered§	**The interventions for each group (as well as any comparator, including usual care) are described in sufficient detail to allow replication, including what was provided, why , how, by whom, when & how much, and where (see the TIDieR recommendations for the minimum characteristics to report)**
5d		**What the rationale is behind selecting the comparator intervention. In case of treatment-as-usual comparator, why these treatment-as-usual sites were recruited.**
11a	Who was aware of intervention assignment after allocation (for example, participants, providers, those assessing outcomes), and how any masking was done	**Specify for each outcome, whether and how outcome assessors were blinded to treatment assignment**
11b	If relevant, description of the similarity of interventions	
3a	Description of trial design (such as parallel, factorial), including allocation ratio§ If the unit of random assignment is not the individual, please refer to CONSORT for Cluster Randomised Trials (ref 33)	**Justification and rationale for trial design, including timing of follow up measurements**
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reason	
4a	Eligibility criteria for participants§ When applicable, eligibility criteria for settings and those delivering the interventions	
4b	Settings and locations where the data were collected	
4c		**How, where, when and by whom participants were recruited**
5b	Where other informational materials about delivering the intervention can be accessed, such as intervention protocols, training manuals or other materials (e.g. worksheets and websites)	**Where all the intervention materials for each group (and any comparator, including usual care) and, in case of in-person delivered interventions, training materials can be accessed**
13a	For each group, the numbers randomly assigned, receiving the intended intervention, and analysed for the outcomes§ Where possible, the number approached, screened, and eligible prior to random assignment, with reasons for non-enrolment	
13b	For each group, losses and exclusions after randomisation, together with reasons	**For each group at each time point, specify non-response, dropout, and exclusions; together with reasons**
14a	Dates defining the periods of recruitment and follow-up	
14b	Why the trial ended or was stopped	**Why the trial ended or recruitment was stopped before the pre-specified sample size or follow-up was achieved; or why trial recruitment was continued beyond the pre-specified sample size or follow-up duration**
15	A table showing baseline characteristics for each group. Include socioeconomic variables where applicable.	**Recommend minimum core data set with variables (e.g. nicotine dependence, motivation to quit, physical or mental illness etc.), and measures.**
17c		**Availability of the statistical scripts for running the analysis over the outcome dataset and of the statistical outputs**
20a	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	**Discuss outcomes of planned sensitivity analyses and how these attest (or do not attest) to the robustness of findings**

CONCLUSIONS

The consensus exercise identified 11 additional items of information that should be included in reports of randomised controlled trials of smoking cessation interventions.

The next stage is to draft guidance on how these items can best be applied to randomised controlled trials of smoking cessation interventions.

Details on how these can best be applied to smoking cessation trials are currently being outlined. It is hoped that this work will assist trialists in the design and reporting of smoking cessation trials, as well as enabling comparability of trials in evidence synthesis studies, implementation in clinical practice and reproducibility of the trial.

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