

Outline for Writing Up Clinical Studies in Smoking

See CONSORT document as well

1. Title- Include study method
2. Abstract – structured? Usually rationale, aims, methods, results, discussion
3. Introduction – should be logical rationale not literature review, early one pose question, brief describe prior most relevant studies (and put into a table), why need new study, state significance, can end with hypotheses
4. Design – optional brief overview of hypotheses, setting, basic research design, comments on why design chosen, blindness
5. Methods – include rationale for any unusual aspects
6. Participants – how recruited, inclusion criteria, external validity, CONSORT flow chart, justification of sample size, ethical issues?, randomization info sufficient for Cochrane risk of bias, human Ss approval, registered
7. Procedures – in chronological order, use table/figure to illustrate,
8. Interventions – contents, dose, duration; training and monitoring of txists,
9. Measures – major outcomes, how operationalized, what not being measured, moderators and mediators, clinical relevance, psychometrics, blinding of assessments, adequacy of proxy measures
10. Data Analysis – tied to hypotheses, parametric vs nonparametric, handling of missing data, analysis of AEs,
11. Results – intro section on missing data, etc, internal validity of tx, major outcomes, secondary outcomes, adverse events, moderators, mediators, magnitude of effects
12. Discussion – summarize results, compare with prior studies, liabilities and assets and qualifiers, internal/external validity, alternate explanations, theoretical and clinical significance, adequacy of test, future studies, end with positive statement.