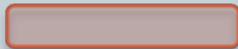
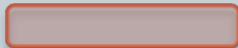
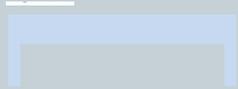


CONSORT: Consolidated Standards of Reporting Trials



- Evidence-based, *minimum* set of recommendations for reporting clinical trials
- Rennie (JAMA) urged the consolidation of SORT and Asilomar recommendations -- 1995
 - Evolving document; latest in 2010
 - Over 600 journals endorse and use it
 - Evidence suggest its use improves reporting of randomized trials (Plint et al., Med J 2006, 185:236-7)
- One of many such sets of recommendations used: STROBE (observational), STARD (diagnostics), PRISMA (Reviews/Meta-Analyses), STREGA (genetic associations), etc.

CONSORT Checklist Content, in part

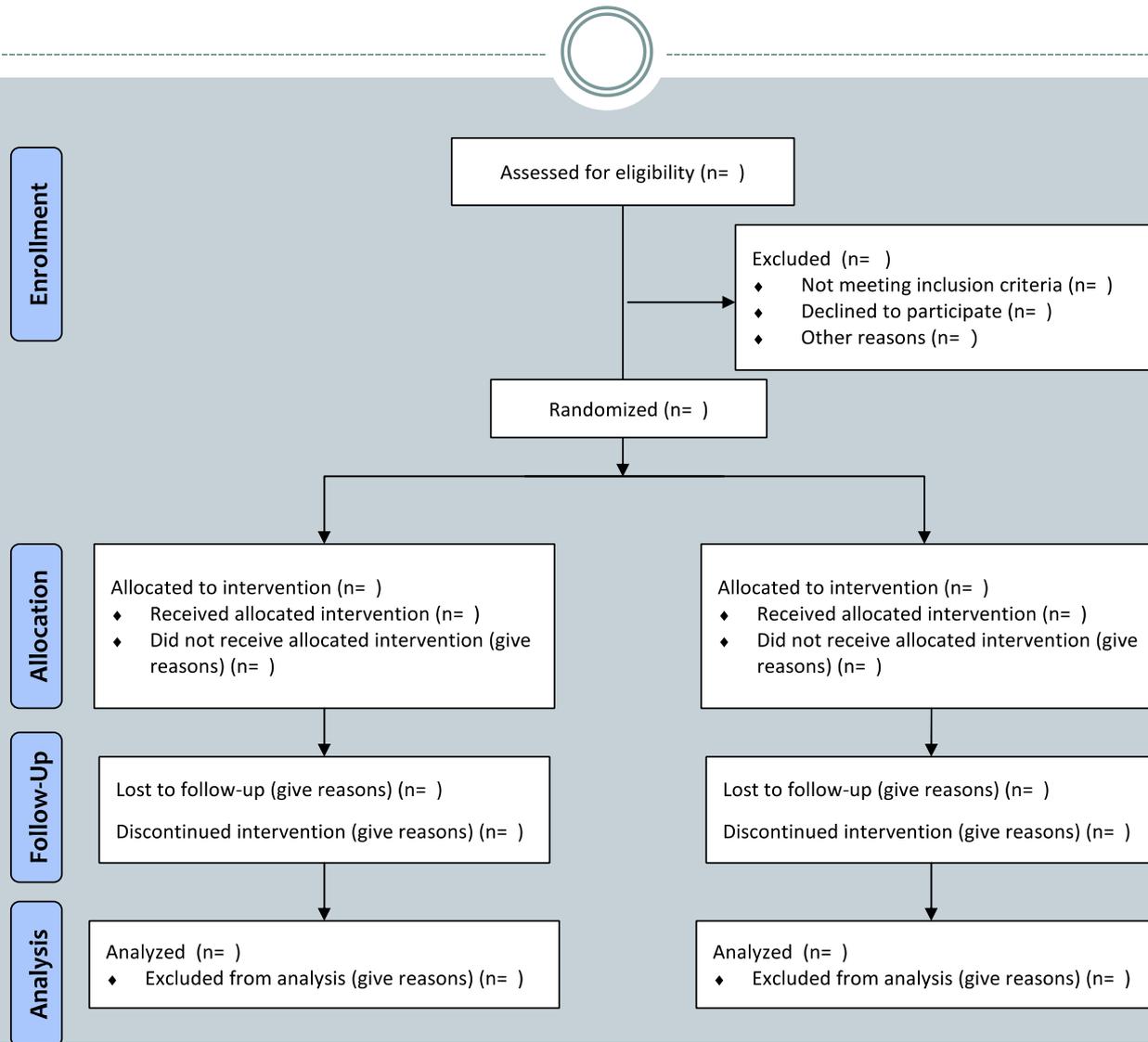


CONSORT Checklist Content, in part (2)



		assessing outcomes) and how	_____
	11b	If relevant, description of the similarity of interventions	_____
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	_____
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	_____
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	_____
Recruitment	13b	For each group, losses and exclusions after randomisation, together with reasons	_____
	14a	Dates defining the periods of recruitment and follow-up	_____
	14b	Why the trial ended or was stopped	_____
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	_____
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	_____
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	_____
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	_____
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	_____
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	_____
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	_____
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	_____
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	_____
Other information			
Registration	23	Registration number and name of trial registry	_____
Protocol	24	Where the full trial protocol can be accessed, if available	_____
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	_____

CONSORT Flow Diagram



Application to Basic Science?



- **False-Positive Psychology : Undisclosed Flexibility in Data Collection and Analysis Allows Presenting Anything as Significant:** Joseph P. Simmons, Leif D. Nelson and Uri Simonsohn, *Psychological Science* published online 17 October 2011
- **Researcher degrees of freedom create laxity in design and reporting**
 - EG: gathering more samples to assure significance (participants)
 - EG: combining or transforming measures (set analysis in advance)
 - EG: excluded data? On what basis? (inclusion, exclusion criteria)
- **The natural tendency is to report the positive findings, not to report the negative; no one (including researchers) is a good judge of their own conflicts of interest or bias.**