Specialist Unit for Review Evidence (SURE)

Questions to assist with the critical appraisal of randomised controlled trials and other experimental studies[1]

Citation:
Study Design:

1. Does the study address a clearly focused question/hypothesis	Yes/Can't tell/No
Population/Problem? Can you identify the setting & eligibility criteria? Intervention? Comparator/control? Outcomes? Can you identify the primary outcome?	
2. Was the population randomised? If YES, were appropriate methods used? Eg: random number tables, opaque envelopes Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week	
3. Was allocation to intervention or comparator groups concealed? Is it possible for those allocating to know which group they are allocating people to? As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.	
4. Were participants/investigators blinded to group allocation? If NO, was assessment of outcomes blinded?	
5. Were interventions (and comparisons) well described and appropriate? Aside from the intervention, were the groups treated equally? Was exposure to intervention and comparison adequate? Was contamination acceptably low?	
6. Was ethical approval sought and received? Do the authors report this?	
7. Was a trial protocol published?	

Was a protocol published in a journal or clinical trial registry before participants were recruited? If a protocol is available, are the outcomes reported in the paper listed in the protocol?	
8. Were the groups similar at the start of the trial? Are baseline characteristics provided and discussed (eg age, sex, social class, life style etc.)? Are there any significant differences that may influence study outcomes?	
9. Was the sample size sufficient? Were there enough participants? Was there a power calculation? If YES, for which outcome? Were there sufficient participants?	
10. Were participants properly accounted for? Was follow-up ≥ 80%? Were patients analysed in the groups to which they were randomised? Was an Intention to Treat analysis conducted? Was the follow-up period long enough?	
11. Data analysis Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	
12. Results Were all important outcomes assessed? Were outcome measures reliable (eg objective or subjective measures)? Are effect sizes, confidence intervals/standard deviations provided? Were all outcome measurements complete? Are the authors' conclusions adequately supported by the results?	
13. Is any sponsorship/conflict of interest reported?	
14. Finally…consider: Did the authors identify any limitations? Are the conclusions the same in the abstract and the full text?	
Summary *Add comments relating to areas of concern that were avoidable and a statement indicating if the results are reliable and/or useful.*	

This checklist should be cited as: Specialist Unit for Review Evidence (SURE) 2018. Questions to assist with the critical appraisal of randomised controlled trials and other experimental studies available at: http://www.cardiff.ac.uk/specialist-unit-for-review-evidence/resources/critical-appraisal-checklists

[1] Adapted and updated from the former Health Evidence Bulletins Wales (HEBW) checklist (http://www.cardiff.ac.uk/insrv/libraries/sure/doc/Project%20Methodology%205.pdf) with reference to the NICE Public Health Methods Manual (2012) and previous versions of the Critical Appraisal Skills Programme (CASP) checklists, with reference to the CONSORT statement.