## Specialist Unit for Review Evidence (SURE)

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

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### Citation:

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### Study Design:

1. **Does the study address a clearly focused question/hypothesis**
   - Population/Problem?
   - 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?**
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
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<tr>
<td>8. Were the groups similar at the start of the trial?</td>
<td>Are baseline characteristics provided and discussed (e.g. age, sex, social class, lifestyle etc.)? Are any differences &gt;10%?</td>
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<td>9. Was the sample size sufficient?</td>
<td>Were there enough participants? Were there a power calculation? If YES, for which outcome? Were there sufficient participants?</td>
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<tr>
<td>10. Were participants properly accounted for?</td>
<td>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?</td>
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<tr>
<td>11. Data analysis</td>
<td>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.</td>
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<tr>
<td>12. Results</td>
<td>Were outcome measures reliable (e.g. objective or subjective measures)? Were all outcome measurements complete? Were all important outcomes assessed? Are the authors' conclusions adequately supported by the results?</td>
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<tr>
<td>13. Is any sponsorship/conflict of interest reported?</td>
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<td>14. Finally...consider:</td>
<td>Did the authors identify any limitations? Are the conclusions the same in the abstract and the full text?</td>
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</table>

This checklist should be cited as: Specialist Unit for Review Evidence (SURE) 2016. 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](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](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.