

**CASP Randomised Controlled Trial Standard Checklist:**

The questions on this checklist will help you make sense of a randomised controlled trial (RCT). If you would like additional guided practice before attempting this assignment, we recommend viewing Module Three: Appraise >Therapy of the DukeHealth Evidence Based Practice Series available at: <https://guides.mclibrary.duke.edu/ebptutorial/therapy>. If you have any questions about the assignment, please reach out to the FAU Medical Librarians at LibraryMed@health.fau.edu.

**Main issues for consideration:** Several aspects need to be considered when appraising a randomised controlled trial:

 Is the basic study design valid for a randomised controlled trial? (Section A)

 Was the study methodologically sound? (Section B)

 What are the results? (Section C)

 Will the results help locally? (Section D)

**How to use this appraisal tool:** The first three questions (Section A) are screening questions about the validity of the basic study design and can be answered quickly. If the answer to both is yes, it is worth proceeding with the remaining questions. *For this assignment, please continue regardless of your answers on the first two questions.*

**Record ‘Yes’, ‘No’ or ‘Can’t tell’ in response to the questions.** Prompts below all but one of the questions highlight the issues it is important to consider. **Type a narrative explanation for all of your answers in the space provided.** As CASP checklists were designed to be used as educational/teaching tools in a workshop setting, we do not recommend using a scoring system.

**About CASP Checklists:** The CASP RCT checklist was originally based on JAMA Users’ guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL and Cook DJ), and piloted with healthcare practitioners. This version has been updated taking into account the CONSORT 2010 guideline (<http://www.consort-statement.org/consort-2010>, accessed 16 September 2020).

**Citation:** CASP recommends using the Harvard style, i.e., *Critical Appraisal Skills Programme (2021). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: insert URL. Accessed: insert date accessed.*

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**Study and citation:**
**Grobman WA et al. Labor Induction versus Expectant Management in Low-Risk Nulliparous Women.
N Engl J Med 2018;379:513-523**

**Section A: Is the basic study design valid for a randomised controlled trial?**

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| **1**. | **Did the study address a clearly focused research question?***CONSIDER:* * *Was the study designed to assess the outcomes of an intervention?*
* *Is the research question ‘focused’ in terms of:*
* *Population studied*
* *Intervention given*
* *Comparator chosen*
* *Outcomes measured?*
 | Yes No Can’t tell “The study was designed to test the hypothesis that elective induction of labor at 39 weeks would result in a lower risk of a composite outcome of perinatal death or severe neonatal complications among low-risk nulliparous women (women who have never given birth)” (p. 514) |
| **2**. | **Was the assignment of participants to interventions randomised?***CONSIDER:* * *How was randomisation carried out? Was the method appropriate?*
* *Was randomisation sufficient to eliminate systematic bias?*
* *Was the allocation sequence concealed from investigators and participants?*
 | Yes No Can’t tellx “Women who met the inclusion criteria were randomly assigned in a 1:1 ratio to either labor induction or expectant management. The randomization sequence, prepared by an independent data coordinating center, used the simple urn method, with stratification according to clinical site” (p. 515)The participants were randomized and according to Table 1, it seems that randomization was successful butthe authors do not specify if the allocation sequence was concealed, so there’s potential for selection bias. |
| **3**. | **Were all participants who entered the study accounted for at its conclusion?***CONSIDER:* * *Were losses to follow-up and exclusions after randomisation accounted for?* [*https://www.youtube.com/watch?v=dMfC-SSBZi0*](https://www.youtube.com/watch?v=dMfC-SSBZi0)

* *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* [*https://www.youtube.com/watch?v=Kps3VzbykFQ*](https://www.youtube.com/watch?v=Kps3VzbykFQ)
* *Was the study stopped early? If so, what was the reason?*
 | Yes No Can’t tell“Three women in the induction group and 7 in the expectant-management group were lost to follow-up or withdrew consent. (p.516) This number is below the recommended 10% threshold.“Analyses were performed according to the intention-to-treat principle” but they should have kept in the patients who were lost to follow-up and withdrew consent*. Once randomized, always analyze.* (p. 516)The study was not stopped early. |

**Section B: Was the study methodologically sound?**

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| **4**. | * Were the **participants** ‘blind’ to intervention they were given?
* Were the **investigators** ‘blind’ to the intervention they were giving to participants?
* Were the **people assessing/analysing outcome/s** ‘blinded’?
 | Yes No Can’t tell“Records of all infants who met the primaryperinatal outcome were reviewed centrally toverify that the primary outcome had occurred…Reviewers were unaware of the trial-group assignments” (p. 515-516). This is describing the outcome adjudicators. This is the only group the authors explicitly state are blinded. |
| **5**. | **Were the study groups similar at the start of the randomised controlled trial?***CONSIDER:* * *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?*
* *Were there any differences between the study groups that could affect the outcome/s?*
 | Yes No Can’t tell“The two groups were similar at baseline, except that fewer women in the induction group than in the expectant-management group had had a previous pregnancy loss (22.8% vs. 25.6%, P = 0.01) (Table 1)” (p. 516)Though there was a difference between the groups, it was unlikely to affect the outcome, probably because the groups that are different are underpowered and these are all considered low-risk patients. |
| **6.** | **Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)?***CONSIDER:* * *Was there a clearly defined study protocol?*
* *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?*
* *Were the follow-up intervals the same for each study group?*
 | Yes No Can’t tell“because masking was not feasible, ascertainment bias is possible” (p. 522)Authors also mention they did not have a specific study protocol for the intervention arm. They mention in discussion that this was to assist in generalizability of the study but could lead to bias. |

 **Section C: What are the results?**

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| **7**. | **Were the effects of intervention reported comprehensively?** *CONSIDER:* * *Was a power calculation undertaken?*
* [*https://www.youtube.com/watch?v=IH5maUyyX4w*](https://www.youtube.com/watch?v=IH5maUyyX4w)

* *What outcomes were measured, and were they clearly specified?*
* *How were the results expressed? For binary outcomes, were relative and absolute effects reported?*
* *Were the results reported for each outcome in each study group at each follow-up interval?*
* *Was there any missing or incomplete data?*
* *Was there differential drop-out between the study groups that could affect the results?*
* *Were potential sources of bias identified?*
* *Which statistical tests were used?*
* *Were p values reported?*
 | Yes No Can’t tellA power calculation was undertaken but “the trial was not powered to detect differences in infrequentoutcomes, and most individual adverseperinatal outcomes were relatively uncommon” (p. 522)“The primary outcome was a composite of perinatal death or severe neonatal complications. The main secondary outcome was caesarean delivery” (p. 515) Relative risk (RR) and p-values for each outcome in each study group was reported in Table 2, Table 3, and Figure 2 (p. 519-521). Absolute risk (AR) was not reported. Number needed to treat (NNT) was reported on p. 522. However, if AR was not reported, we’re not sure we can believe the NNT, especially because authors only reported RR.There was no differential drop-out between the study groups but other limitations are noted on p. 522The statistical tests used in the study were reported on p. 516 |
| **8.** | **Was the precision of the estimate of the intervention or treatment effect reported?***CONSIDER:* * *Were confidence intervals (CIs) reported?*

[*https://www.youtube.com/watch?v=v0FXSAdYCkQ*](https://www.youtube.com/watch?v=v0FXSAdYCkQ) |  Yes No Can’t tell Confidence intervals of the relative risk for each outcome were reported in Table 2, Table 3, and Figure 2 (p. 519 – 521). |
| **9**. | **Do the benefits of the intervention outweigh the harms and costs?***CONSIDER:* * *What was the effect size of the intervention or treatment effect?* [*https://www.youtube.com/watch?v=5GuXKJl5CyY*](https://www.youtube.com/watch?v=5GuXKJl5CyY)
* *Were harms or unintended effects reported for each study group?*
* *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*
 | Yes No Can’t tell The authors state, “our data suggest that 1 caesarean delivery may be avoided for every 28 deliveries among low-risk nulliparous women who plan to undergo elective induction of labor at 39 weeks” (p.522) However, this was a population of low-risk patients and likely was underpowered to find the primary or secondary outcome because those outcomes are uncommon.No harms or unintended effects were reported.The authors mention in discussion that “the cost-effectiveness of labor induction in low-risk nulliparous women at 39 weeks will need to be evaluated in further analyses” (p. 522) |

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| **Section D: Will the results help locally?** |

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| **10**. | **Can the results be applied to your local population/in your context?***CONSIDER:** *Are the study participants similar to the people in your care?*
* *Would any differences between your population and the study participants alter the outcomes reported in the study?*
* *Are the outcomes important to your population?*
* *Are there any outcomes you would have wanted information on that have not been studied or reported?*
* *Are there any limitations of the study that would affect your decision?*
 | Yes No Can’t tell The results may not be broadly generalizable because the study participants were young and overweight (Table 1, p. 518). Additionally, only 27% of the eligible women chose to participate in the study (Figure 1, p. 517). This small percentage of participants may not be truly representative of a larger population.Also think about your specific patient here – are there any other outcomes they might be concerned about that aren’t reported in this study?The authors did not mention whether the pregnancy was planned vs. unplanned and if the participants had consistent prenatal care throughout the pregnancy, both of which could change the risk of outcomes. |
| **11.** | **Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?***CONSIDER:* * *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?*
* *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*
 | Yes No Can’t tell It would be helpful to know more about the cost analysis for the intervention to be able to better answer this question. Would also be helpful to know more about why patients elected not to participate (over 50K women were identified but only 6100+ ended up going through with the study). |
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| **12. APPRAISAL SUMMARY/APPLICATION TO PATIENT CARE:** *What is your conclusion about the paper? Do you feel confident that the results are trustworthy and that they can be applied to the standard patient’s care? Consider the medical knowledge you’ve gained so far. Consider the evidence provided in the clinical research article. Consider your patient’s circumstances, values, believes, abilities, wishes – financial situation, insurance costs, family obligations, transportation challenges. Would you use it to change your practice or to recommend changes to care/interventions used?*We appreciate that the authors were upfront about the limitations in this paper. However, there are some concerns that make the results from this paper difficult to generalize to other patients outside of the study. First, the participants were young and overweight and only 27% of the eligible women chose to participate. Second, the results for the primary outcome (perinatal death or severe neonatal complications) were underpowered due to the rarity of that outcome. Finally, only the outcome adjudicators were able to be blinded due to the nature of the study and the authors did not specify if allocation sequence was concealed from investigators and participants. The results of this study could be discussed with a patient, but the unique characteristics and desires of the patient should be considered. |