11 questions to help you make sense of a trial

How to use this appraisal tool

Three broad issues need to be considered when appraising the report of a randomised controlled trial:

- **Are the results of the trial valid? (Section A)**
- **What are the results? (Section B)**
- **Will the results help locally? (Section C)**

The 11 questions on the following pages are designed to help you think about these issues systematically.
The first two questions are screening questions and can be answered quickly. If the answer to both is ***yes***, it is worth proceeding with the remaining questions.

There is some degree of overlap between the questions, you are asked to record a ***yes***, ***no*** or ***can't tell*** to most of the questions. A number of prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

There will not be time in the small groups to answer them all in detail!

These checklists were designed to be used as educational tools as part of a workshop

(A) Are the results of the trial valid?

Screening Questions

1. Did the trial address a clearly focused issue? ☑ Yes ☐ Can't tell ☐ No

Consider: An issue can be 'focused' In terms of

- The population studied
- The intervention given
- The comparator given
- The outcomes considered

Trial focused on children below 18 years old. There was a placebo group and each participant was taking IU or oral antibiotics.

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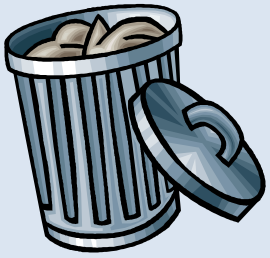
2. Was the assignment of patients to treatments randomised? ☑ Yes ☐ Can't tell ☐ No

Consider:

- How was this carried out, some methods may produce broken allocation concealment
- Was the allocation concealed from researchers?

A computer-generated randomization list was prepared that allocated the patients. All of the investigators caregivers, outcome assessors and person responsible for the statistical analysis remained blinded.

Is it worth continuing?



Detailed questions

3. Were patients, health workers and study personnel blinded?

☑ Yes ☐ Can't tell ☐ No

Consider:

- Health workers could be; clinicians, nurses etc
- Study personnel – especially outcome assessors

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4. Were the groups similar at the start of the trial?

☐ Yes ☐ Can't tell ☑ No

Consider: Look at

- Other factors that might affect the outcome such as age, sex, social class, these may be called baseline characteristics

Baseline characteristics:

Antibiotic classes pt. were taking
- Aminopenicillins
- cephalosporins (2/3)
- Macrolide
- Lincosamides
- combo therapy

Reason for therapy
- Respiratory tract
- UTI
- otolaryngology
- unknown source
- Skin

Although these were the baseline characteristic it was not equally distributed between these characteristics.

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5. Aside from the experimental intervention, were the groups treated equally?

☑ Yes ☐ Can't tell ☐ No

The experimental group was given L. reuteri DSM 17938 daily dose 2×10^8 CFU BID in drops.

Placebo included medium chain triglyceride and sunflower oil.

Both formulations were identical

6. Were all of the patients who entered the trial properly accounted for at its conclusion?

☑ Yes ☐ Can't tell ☐ No

Consider:

- Was the trial stopped early?
- Were patients analysed in the groups to which they were randomised?

Trial lasted from 12/2016 to 03/2018. 250 children were enrolled -125 randomized to placebo and 125 to experimental group.
One child from placebo and two from experimental were dropped.

(B) What are the results?

7. How large was the treatment effect?

Consider:

- What outcomes were measured?
- Is the primary outcome clearly specified?
- What results were found for each outcome?
- Is there evidence of selective reporting of outcomes?

primary outcome =

	Placebo	vs. Treat.
3 or more watery stools per day (48h)	16	25
3 or more loose watery stools (24h)	26	27
2 or more loose stools per day (24h)	26	27

8. How precise was the estimate of the treatment effect?

Consider:

- What are the confidence limits?
- Were they statistically significant?

	CI	95% CI
3 or more watery stools per day (48h)	1.58 .9-2.79	-0.07 .17- .021
3 or more loose watery stools (24h)	1.05 .65-1.68	-0.01 .11 -.09
2 or more loose stools per day (24h)	1.05 .65- 1.68	-0.01 .11- .09

not clinically significant

(C) Will the results help locally?

9. Can the results be applied in your context? (or to the local population?)

☐ Yes ☐ Can't tell ☑ No

The results are not equally distirbuted. Average age was 25.8 moths for placebo and 25.7 for L. reutri.

Consider:

- Do you have reason to believe that your population of interest is different to that in the trial
- If so, in what way?

variable dist. blw ages →

Age	Placebo	L reutri
< 6 months	43	49
≥ 6 to 24 months	36	31
≥ 24 to 48 months	26	21
≥ 48 to 5 years	7	11
≥ 5 years	13	13

There were more patients that were between <6 months and 48 months. Therefore, results cannot be applied completely to all age groups

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10. Were all clinically important outcomes considered?

☐ Yes ☐ Can't tell ☑ No

Although the outcome of diarrhea was evaluated completely, only one probiotic was evaluated. Other probiotics should be used to evaluate if it decreases the chances of diarrhea.

Consider:

- Is there other information you would like to have seen?
- Was the need for this trial clearly described?

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11. Are the benefits worth the harms and costs?

☑ Yes ☐ Can't tell ☐ No

There aren't harms to taking probiotics. Even if the results aren't clinically significant the slight chance they might be helpful.

Consider:

- Even if this is not addressed by the trial, what do you think?