The Association for Child and Adolescent Mental Health

CAMHS around the Campfire
Virtual journal club
#CAMHScampfire

The Mental Elf

#CAMHScampfire

Critical appraisal workshop on

Early language screening and intervention can be delivered successfully at scale: evidence from a cluster randomized controlled trial.

Critical appraisal process

1. What is the research question?
2. Are the methods valid?
3. Are these valid results important?
4. Are these valid, important results applicable to my setting?

Bias in health research

Around 50% of published studies don't do enough to eliminate potential bias

- Fail to recruit adequate sample size (underpowered)
- Fail to ensure comparable groups (selection bias)
- Fail to ensure comparable care (performance bias)
- Fail to ensure adequate follow-up (attrition bias)

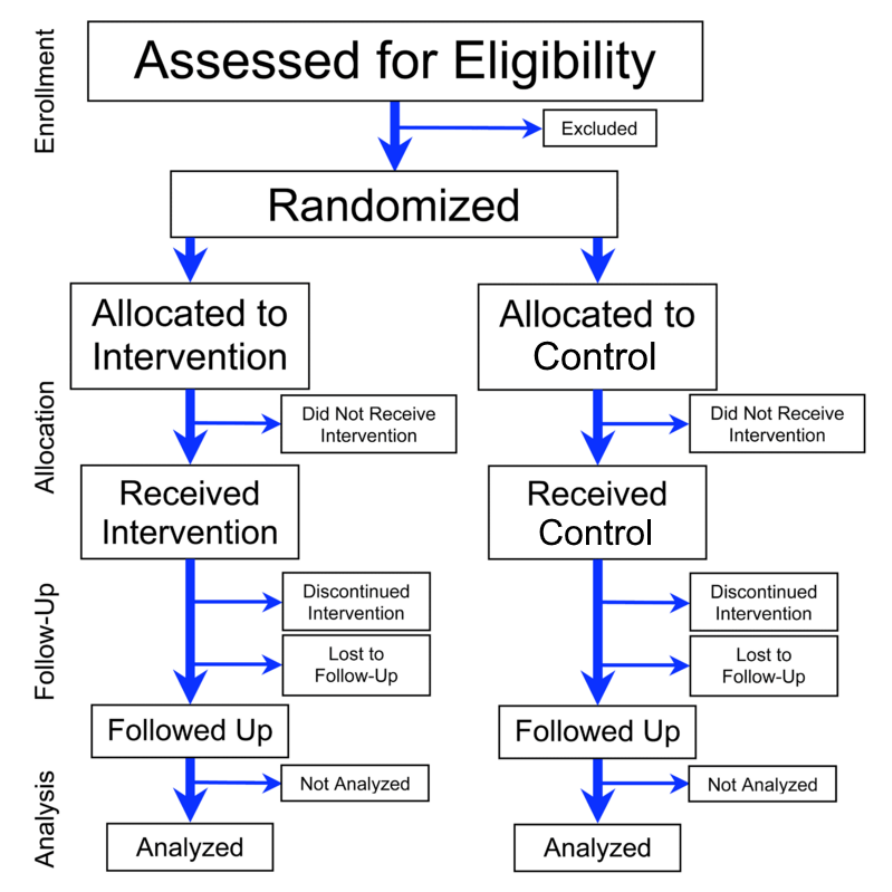
Around 50% of studies don't even get published

- "negative" trials are less likely to be published than "positive" ones

Most bias works in favour of interventions

Chalmers I, Glasziou P. The Lancet 2009;9683:86-89
Superb PDF by Liz Wager here; see also the Catalogue of Bias

About RCTs



Fair comparisons are essential for understanding the effects of interventions.

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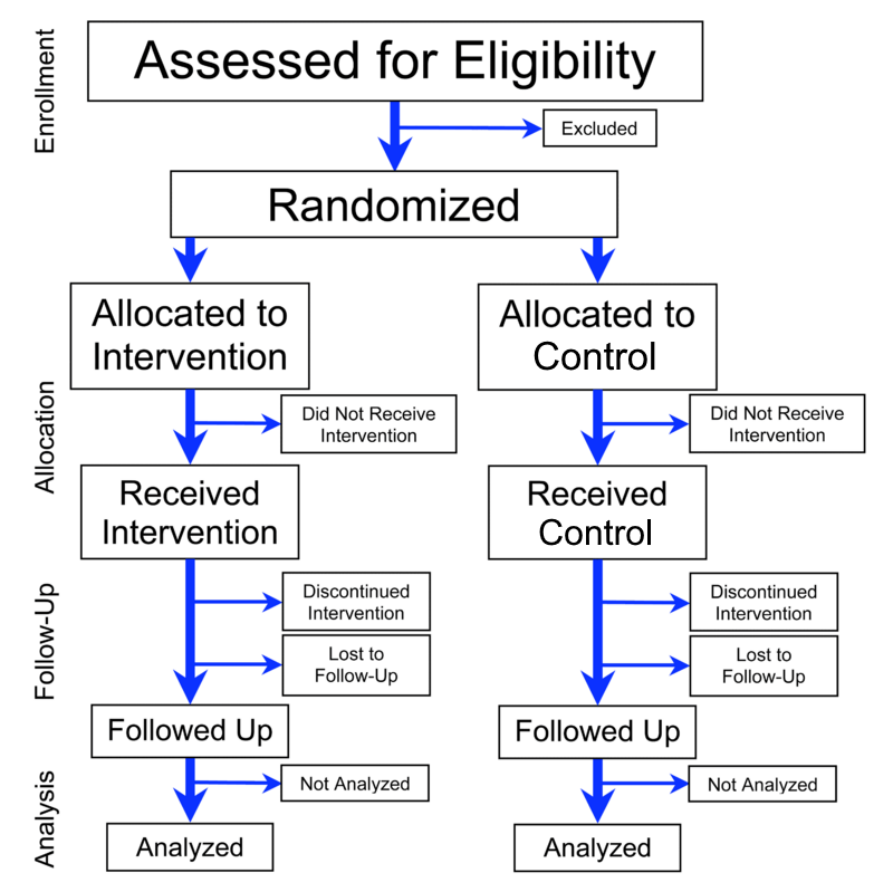

Fair comparisons are essential for understanding the effects of interventions.

Randomization ensures the groups start out the same, even for (confounders) stuff we don't know about.

The comparison groups should receive equal treatment throughout the trial, apart from the intervention.

Follow-up should include enough people to draw valid conclusions. The original group allocation should be retained (intention-to-treat).

The study

Check for updates

The Journal of Child Psychology and Psychiatry

Journal of Child Psychology and Psychiatry **:* (2021), pp **–** doi:10.1111/jcpp.13415

Early language screening and intervention can be delivered successfully at scale: evidence from a cluster randomized controlled trial

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Cluster Randomized Trial

An RCT in which the unit of randomization is a group of people rather than the individual participant, e.g. a class, school, hospital, etc

- Good for system-level interventions such as guidelines or procedures
- Prevents "contamination" by including all individuals in a group the same allocation
- See NIH Living Textbook of Pragmatic Trials https://rethinkingclinicaltrials.org/chapters/design/experimental-designs-randomization-schemes-top/cluster-randomized-trials/

The study

- Children in reception classes (age 4-5)
- Screened with LanguageScreen
  - Some participants excluded at this stage
- Five children in each class with the lowest scores were eligible for NELI (mostly)
- N= 1,173, validated by SLTs assessment
- Randomization was stratified by geography

The intervention

- Nuffield Early Language Intervention (NELI)
- 20-week programme for children with poor language skills
- Training for teachers and teaching assistants
- Control group was “business as usual”
  - They received credit to buy the programme after the trial
  - “Waiting list” control

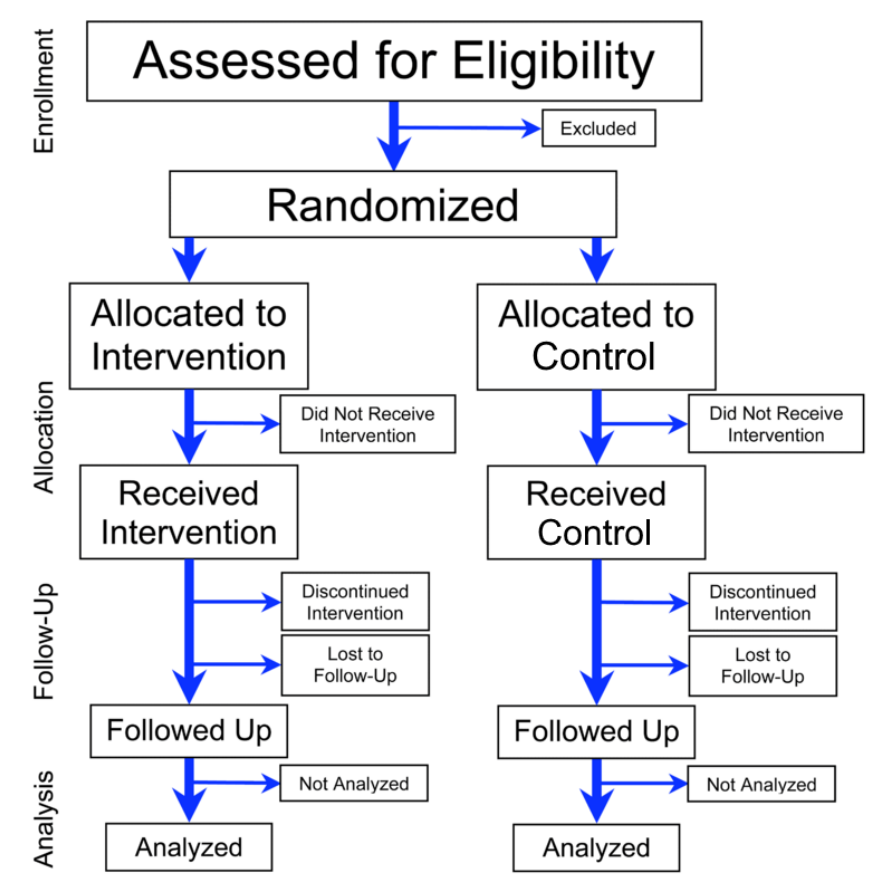
Outcome measures

- Children would be expected to improve language ability anyway, so they needed to compare the *improvement* between groups
- A combined assessment using standardised measures of language ability (i.e. CELF expressive vocabulary, CELF recalling sentences and APT information and grammar scores)
- At the end of the academic year, outcome data was analysed in a statistical model to compare NELI with the control group using Cohen's d scores.

The Research Question

P	In children aged 4-5 with relatively poor language skills
I	does the Nuffield Early Language Intervention
C	compared with usual teaching practice
O	improve language scores after one academic year?

Biases affecting RCTs



Selection biases:
Is the sample representative?
Was there good allocation concealment?
Were the groups similar at the start of the trial?

Performance biases:
Were the groups treated equally apart from the intervention?
Were participants and investigators blind to treatment?

Measurement biases:
Were assessors blind to treatment group?

Attrition biases:
Were there any losses to follow-up?
Were participants analysed in their original groups?

Critical appraisal checklist

Question	Yes	DK	No	
1. Did the trial address a clearly focused question?	X			The protocol was published in advance.
2. Was the assignment of participants to interventions randomised?	X			Randomised in clusters, stratified by location and size; allocation was concealed at recruitment.
3. Were all participants accounted for at the end?	X			5-6% drop-out rate, no evidence of bias; analysis by intention-to-treat.
4. Were participants, investigators and outcome assessors blinded to treatment?		X		Not possible. The app may provide blinding for secondary outcomes.
5. Were the study groups similar at the start of the trial?	X			They tested their assumptions using sensitivity analysis and statistical heterogeneity tests.
6. Were the study groups treated equally (apart from the experimental intervention)?		X		It's possible there's co-interventions in taking part in the active intervention group.

Results

The results show consistent small-to-medium benefits from NELI

- The experimental group improved more than the control group
  - Improvements were independent from baseline language scores, gender, English as an Additional Language
- Cohen's d=0.26, for the primary outcome of the combined score
  - 95% Confidence Interval 0.017 to 0.36
  - = These results are unlikely to have occurred by chance

Cohen's d

Measuring the effect size from the standardised difference between two means.

- In our case, the mean improvement in language skills
- You divide the difference between the means by the standard deviation

Effect size	*d*
Very small	0.01
Small	0.20
Medium	0.50
Large	0.80
Very large	1.20
Huge	2.0

Interpreting this evidence

- Consistent with previous studies
- More moderate effect size than seen previously
- Included speakers of English as a second language
- Worked just as well independently of initial language ability
- Shows that NELI can be practical and effective

- Full appraisal with links in the Mental Elf blog here.

Questions for the team

- Recruitment strategy: five per class rather than a setting a cut-off score for inclusion?
- Choice of outcomes: the SMD and Cohen's d instead of event rates (e.g. "what % improved by X amount?")
- Conflict of interest: not-for-profit organisation; can be delivered by independent professionals
- What advice do you have about implementing NELI?
- What happens after NELI?