

Designing a multi-centre RCT:

From initial good idea to team building
and obtaining funding.

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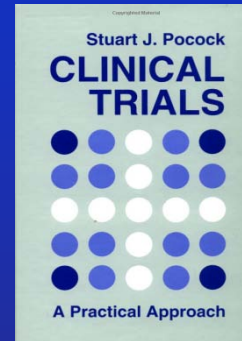
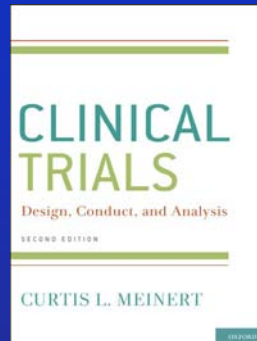
Perspective

- Framed by information from the two top text books on the subject
- I am going to talk about my own experiences and beliefs



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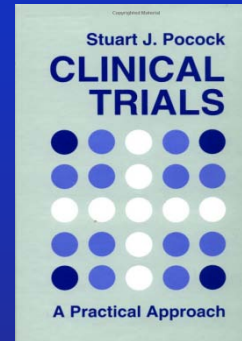
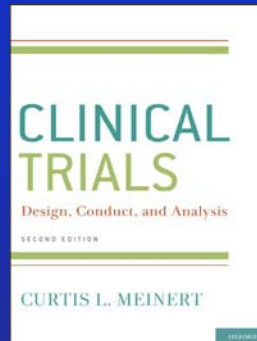


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Key lessons I have learned

- 1) Your research question must be important.*
- 2) Know your Funding Agency.*
- 3) Demonstrate your clinical expertise.*
- 4) Demonstrate your research expertise.*
- 5) Choose your team members wisely.*
- 6) Your written grant must be clear and concise.*



Choosing your research question



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When should you conduct a multi-centre RCT?



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Maybe not the single best reason....



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This level of complexity makes multi-centre trials *very expensive*.



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Lesson #1. Your research question must be important.



What is important?



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At work, your *boss* defines what is important!



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- To be considered 'important', I must show the NHMRC my project will:
 - 1) Improve health and well-being *and*
 - 2) Change practice or policy.



What is important?

*Lesson #2. At work, your Boss defines what is important.
Your Funding Agency is your Boss! Know your Funding Agency.*



Example



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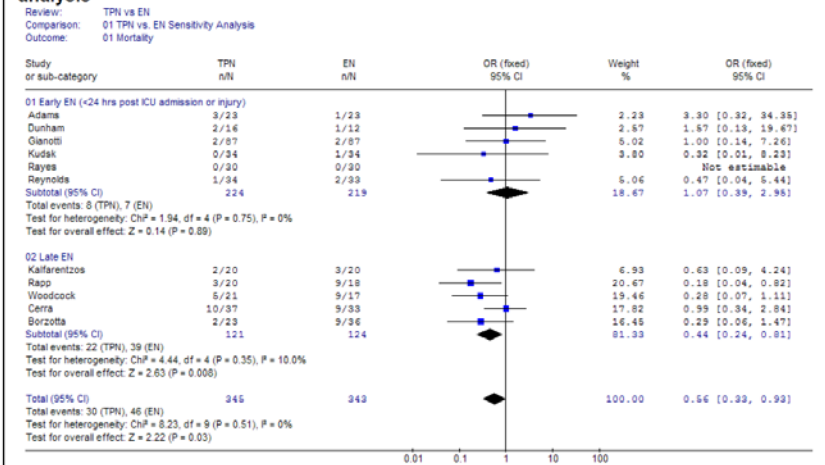
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subgroup analysis, this overall benefit was attributable to trials that compared the use of early PN to delayed EN (OR=0.29, p=0.006).

Figure 1: Standard TPN versus EN. Effect on mortality: Sensitivity analysis and subgroup analysis



Legend: EN: Enteral nutrition, TPN: Total parenteral nutrition, OR: Odds ratio, N: Total number of people in the group, n: Number of people that died in the group

Although infection complication was significantly increased with the use of extended PN.



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A database composed of 13 representative control hospitals, obtained from a recent 27 hospital Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) Endorsed cluster randomised controlled (cRCT) trial of evidence-based ICU feeding guidelines conducted over a six-month period, identified 354 patients who would qualify for recruitment into the current trial. Of these potentially eligible patients, **166 (46.9%)** did not receive enteral or parenteral nutritional support during their ICU stay, which averaged 4.7 ± 2.2 days. An additional



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You may think that a highly-cited publication in a major journal is the end-deliverable for your project. Members of your Funding Agency may be more focussed on health change in the real world.



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Use methods papers to demonstrate knowledge of good RCT conduct.



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Lesson #4. Publish methods papers to demonstrate **your** research expertise!

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Or, show that you have been learning how to succeed!!!



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 - This team **must have clinical and research expertise.**
 - **Must include senior biostatistician or academic clinical trialist.**



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- 2) A data management team
 - Collaborate with a recognised Data Management Centre.
 - Led by biostatistician or academic trialist who is named on your grant.



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 - This can be the most difficult aspect of a multi-centre RCT!
 - Make friends. Agree to help your friends in the future if they help you now!



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To ensure the success of your grant, you must assemble three teams:

- 1) An experienced grant writing team
 - 2) A data management team
 - 3) A network of participating sites
- These teams should be identified *before* you write your grant.
 - Few people will be members of all three teams.
 - Members should be selected because skills are appropriate for specific team.
 - Do not make your teams too big.

Lesson #5. Choose your team members wisely!



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Start putting these elements together 2 to 3 years in advance of writing your grant!



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Good Luck!!!



Questions?



*A pdf version of this talk can be downloaded from the **Talks** section of our outreach education web site (www.EvidenceBased.net).*

