THE UNIVERSITY OF MELBOURNE

Faculty of Medicine, Dentistry and Health Sciences

Statistics for your grant applications

MISCH *Hub*

Methods and Implementation Support for Clinical and Health Research

Diana Zannino

MISCH Biostatisician/Research Fellow

MACH Melbourne Academic Centre for Health

Housekeeping

- Please keep your microphone switched off during the presentation.
- You are welcome to leave your video on or off as you prefer.
- If you have any questions, please feel free to enter them in the chat box. We will review them throughout the presentation.
- Note that this presentation will be recorded and a link will be provided after the webinar.
- A copy of the slides will also be provided.

MISCH Hub

Collaborate with MISCH to maximise your research impact

Methods and **I**mplementation **S**upport for **C**linical and **H**ealth research Hub

Our aim is to provide support to researchers and affiliated researchers of the University of Melbourne in clinical and health research.

We provide support on core research methods of:

- Biostatistics and Clinical Epidemiology
- Health Economics
- Clinical Trials
- Implementation Effectiveness and Co-Design
- Health Informatics (REDCap)

MISCH *Staff*


Clinical Trials Lead
Adam Deane
MISCH Manager
Shaie O'Brien
Co-Lead MISCH Biostatistics
Sabine Braat
Biostatistician
Patty Chondros
Biostatistician
Emily Karahalios
Health Economist
Kim Dalziel
Epidemiologist
Mark Jenkins
Co-Design and Consumer Involvement Lead
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Biostatistics Lead, Austin Hospital
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Biostatistician
Peixuan Li
Biostatistician
Anurika De Silva
Biostatistician
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Health Informatics Lead
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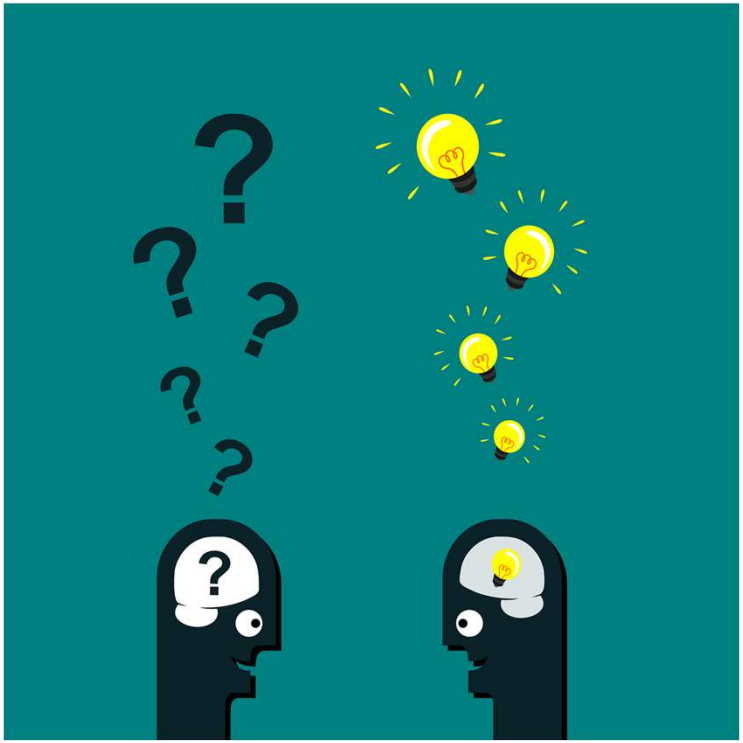
Why you need statistics for grant applications

- Getting the statistical sections of your grant correct can be critical to the success of your application.
- Often only the **sample size calculation** and **statistical analysis sections** are considered when researchers think about the statistics for a grant application.
- Statistics is not solely about deciding what analysis method (e.g. regression, survival analysis) to use.
- A well crafted grant has statistical elements throughout.

Why you need statistics for grant applications

- Statistics (and statisticians) are important for the **design**, **conduct**, **analysis** and **interpretation** of study findings.
- Statisticians supporting grant applications check that the **grant flows** clearly from the research question and hypotheses to the study design to the methods.
- Our MISCH team provides support to researchers to ensure that the design is appropriate to answer the proposed research question.



PICOTs

- Consider **PICOT** to help frame your **research question**

[See recording of seminar by Karen Lamb: *Kicking off your research question: how to craft a well-defined research question* https://machaustralia.org/emcr-research-design-webinars/]

- This helps identify important statistical information to include in your grant

Population	Who should be in the study?
Intervention	Intervention/Exposure
Comparator	Control
Outcome	What is the outcome of interest?
Time	Over what time period?
(**s**tudy design)	Study design features (e.g. parallel-group RCT)

Study design (PICOTs)

- It is essential to provide details of the methods proposed to tackle the research question.
- Reviewers need to see not only that the question under investigation is important but that it is **methodologically sound** and **feasible**.
- The topics that should be covered depend on the nature of the study.
- It is necessary to clearly state the overall **study design** early in the grant proposal (e.g., cohort study, cluster randomised controlled trial).

[See recording of seminar by Julie Simpson: *Alternative (fixed) trial designs* https://machaustralia.org/emcr-research-design-webinars/]

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/describ.htm#intro

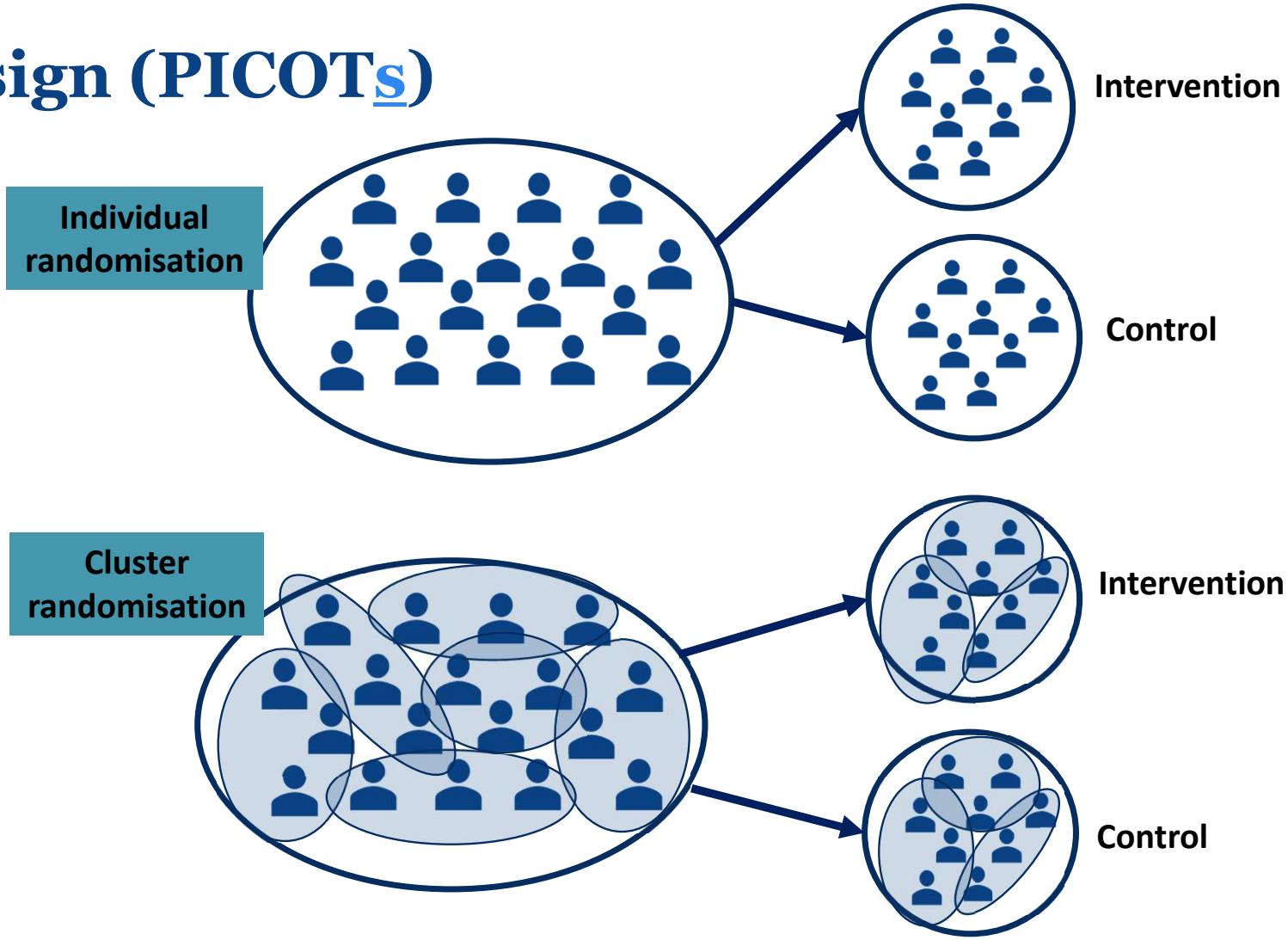
Study design (PICOTs)

- There are many elements to include to clearly specify the study design.
- If a randomised controlled trial will be used, will the study be **blinded**?
- Blinding reduces bias in estimating the treatment effect but it may not be possible to have a double blinded study.
- For example, participant blinding would not be possible if comparing a new surgical intervention to an existing non-invasive treatment.

Study design (PICOTs)

- Can the treatment be allocated at an **individual** or a **cluster** level?

- For example, a trial designed to improve the physical activity of children using active lessons would allocate treatment at a class or school level rather than an individual level.



Pilot and exploratory studies (PICOTs)

- While funding may be sought for pilot or exploratory studies, it is important to be clear on what these studies are seeking to determine and why a fully powered study cannot be conducted at this stage.
- A pilot study is a small study designed to gather information prior to a larger study.
- A well-designed pilot study should improve the quality of the final study.
- Importantly, a pilot study is not a study which is too small to provide an answer to the research question.

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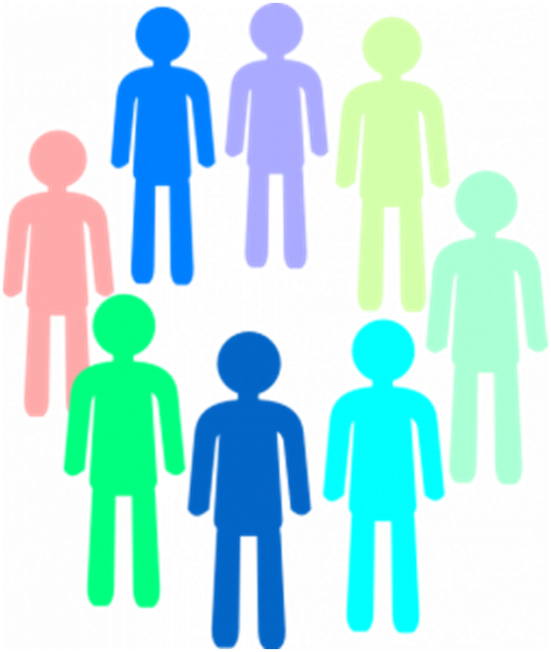
Population/Participants (PICOTs)



- It is important to clearly state who will be taking part in the study.
- Are the **participants appropriate** to answer the research question? For example, adults aged 65 years and over will be recruited as the health condition is common in this age group.
- How will participants be **selected** or **recruited**? For example, a random sample from the population or all patients presenting to a particular hospital ward during a pre-defined period of time.
- What are the **inclusion/exclusion** criteria?

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Population/Participants (PICOTs)

- While a **sample size calculation** should be provided to justify that sufficient numbers will be available, it is important to make it clear that these numbers can be recruited.
- How many patients or subjects will be **invited** to participate and how many are **expected** to take part?
- The **sample size** is the number who **agree to participate**, not the number invited.
- Provide figures where possible to make it clear how many participants are in the population of interest and how many may take part, justified based on other studies.

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Population/Participants (PICOTs)

- If designing a prevalence study to estimate the **prevalence** of a particular disease, condition or characteristic in a population, it is critical to highlight how you will ensure the sample will be **representative** of the population of interest.

- Poor **response rate** could bias the study so highlight how the study will be conducted to ensure a good response rate.

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/describ.htm#obsorex

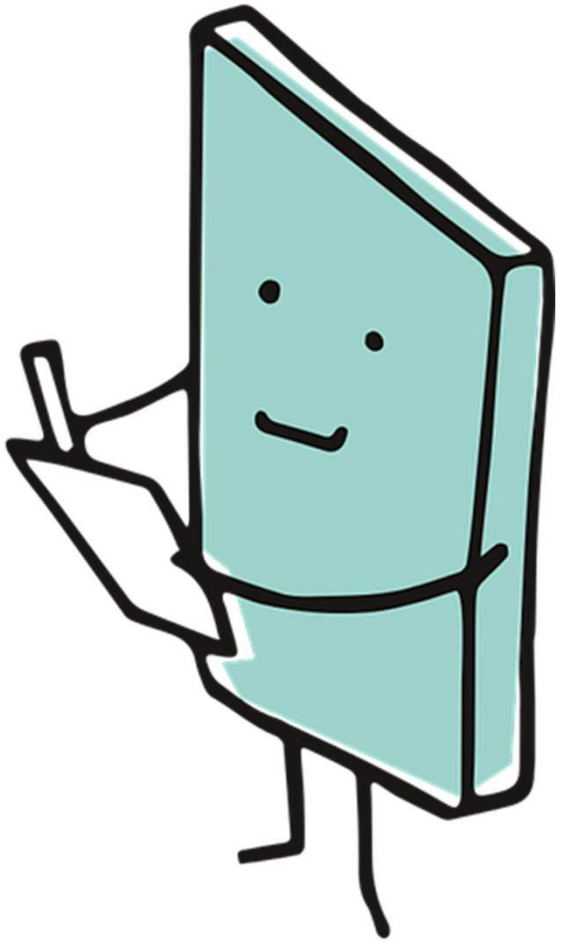
The data (PICOTs)

- What data are you collecting and why?
- What is your **outcome** variable?
- What is your **intervention** or **exposure**?
- What is your **comparator** (if appropriate)?
- Are there other important variables (e.g., strata, confounders)?

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/describ.htm#intro

The data (PICOTs)

- Study quality can depend on how data are collected.
- It is important to clearly specify how the information will be obtained.
- How will your data be **measured** (e.g., questionnaire, blood test)?
- If a questionnaire is used, how will it be administered (e.g., postal or interviewer administered)?



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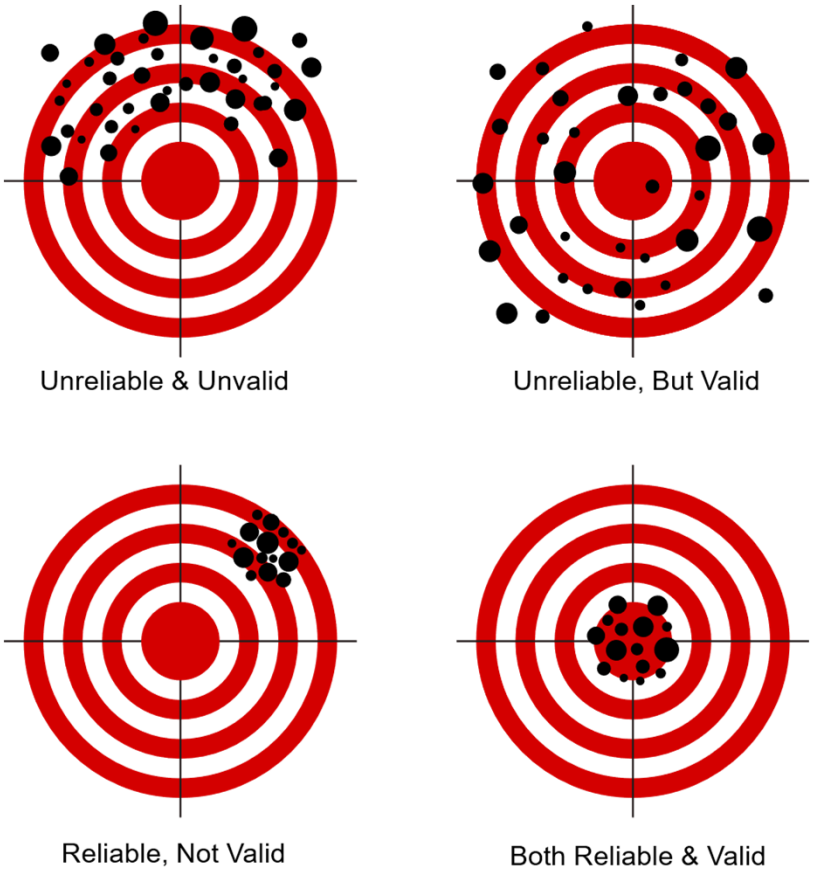
The data (PICOTs)

- Is the proposed method of measurement **valid** and **reliable**?
- Validity refers to whether the method actually measures what it is designed to measure.
- For example, does a questionnaire designed to measure self-efficacy (i.e. belief in ones ability to cope) actually measure self-efficacy?
- If validity has been demonstrated elsewhere, has it been demonstrated in an appropriate setting (e.g., people of the same age group from a similar context)?

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/describ.htm#intro

The data (PICOTs)



- Reliability refers to the extent to which the measurements are **consistent** when the experiment is repeated more than once.
- Measurements should not only be valid but also reliable.

The data (PICOTs)

- It is common to propose only one key outcome for a trial, although some may have another key outcome of interest.
- This outcome is known as the **primary outcome** or **primary endpoint**.
- The sample size calculation should be conducted for the **primary outcome** (or outcomes if more than one primary is specified).
- The statistical analysis section should make it clear how the primary outcome will be analysed.

The data (PICOTs): trials

- The treatment description must be easy to understand by those outside your field.
- The type of treatment may have implications for the trial design so it is important to be clear about this (e.g., blinding may not be possible depending on treatment type).
- To determine the effect of a new treatment, it is necessary to compare a group of participants on the new treatment with a group of participants who do not receive the new treatment (the **control** or **comparator**).
- The control group should be comparable to the treated group in all respects (i.e., in the **same place**, at the **same time**, **same distribution of disease severity and prognosis**, and receiving the **same care apart from the treatment** of interest).

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/trials.htm

The data (PICOTs): trials

- There usually is a clear idea of what the new intervention or treatment will be when designing a study.
- However, choosing the **control** or **comparator** group can be challenging.
- If no current treatment is available to compare to the treatment then the control group will be untreated (a placebo could be used to maintain blindness).
- If there is an existing treatment, you may decide to test the new treatment in addition to an existing treatment while the control group receive only the existing treatment (with a suitable placebo in addition where appropriate).

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/trials.htm

The data (PICOTs): observational studies

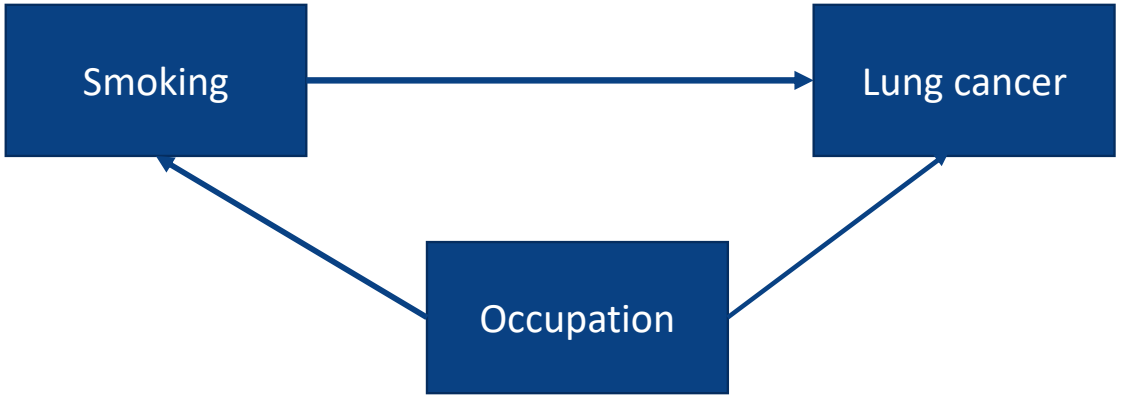
- Rather than an *intervention*, we typically think of **exposure(s)** in observational studies.
- Exposure variables can take different forms.
- For example, in an observational study of smoking and lung cancer, smoking could be **binary** (e.g., smoker or non-smoker), **categorical** (e.g., smoker, ex-smoker, non-smoker) or **continuous** (e.g., cigarettes smoked per day).
- It is important to be clear in your grant on the form your exposure(s) will take. This is important for your sample size calculation.

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/trials.htm

The data (PICOTs): observational studies

- In addition to the outcome and exposure, it can be important to consider **confounders** in observational studies.

- A confounder is an alternative explanation for an observed association between an exposure and outcome. Confounders are undesirable as they obscure the 'real' effect of an exposure.



- Asbestos mining is a known risk factor for lung cancer
- Smoking is a risk factor for lung cancer
- Miners tend to smoke more cigarettes due to job stress

Rothman (2008) Modern Epidemiology (3rd Edition) Lippincott Williams & Wilkins; Skelly (2012) Evid Based Spine Care J 3(1): 9-12

The data (PICOTs): observational studies

- When writing a grant involving an observational study, such as a **cohort study**, it is important to acknowledge:

  - Confounders may affect the relationship of interest
  - Potential confounders will be measured (and how this information will be collected)
  - How the statistical analysis will take into account these potential confounders

The data (PICOTs)

- What is the **data type** (e.g., continuous, ordinal, categorical)?
- This should be specified for both the **outcome** and the **exposure** (where appropriate)
- This information is critical to inform both the **sample size calculation** and how the **statistical analysis** should be conducted.

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/describ.htm#obsorex

Time (PICOTs)

- When will you be collecting the data?
- Most randomised controlled trials and cohort studies are prospective so participants will be followed over time.
- Bland et al. from St George's Hospital Medical School highlight that the length of follow-up in a study is often left out of grant proposals. This is critical information to understand feasibility, costs, etc.
- Need to clearly specify **how many** measurements will be taken over the course of the study.
- **How often** will measurements be taken?
- What is the **primary time-point** of interest?

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/describ.htm#follow

Sample size section

Sample size section

- Sample size calculations are required for **most quantitative studies**.
- Failing to include a sample size calculation for a quantitative study is a common reason for rejecting a grant application so be sure to prioritise this aspect of your grant.
- If you have multiple primary outcomes, the sample size has to be sufficient to detect the effect of interest for **all** outcomes (i.e., you have to choose the larger of the sample sizes from the calculations to ensure sufficient power for all outcomes).
- Sample size considerations for Pilot and Feasibility studies - **[See recording of seminar by Sabine Braat: *What's it going to take to get your study started? Pilot and Feasibility studies.* https://machaustralia.org/emcr-research-design-webinars/]**

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/size.htm

Sample size section - Quiz Question 1

Which of the following are excellent examples of the sample size text in a grant application?

a) A previous trial in this same area recruited 150 patients and found significant results (p=0.014), and therefore a sample size of 150 patients has been selected for the proposed study.

b) Sample sizes are not provided for this trial because there is no information on which to base them.

c) The clinic attends to around 50 patients per year, of whom 10% may refuse to take part in the study. Therefore over the 2 years recruitment phase of the study, the sample size will be 90 patients.

d) All of the above

e) None of the above

Sample size section – what NOT to do

"A previous study in this area recruited 150 subjects and found significant results (p=0.014), and therefore a similar sample size should be sufficient here."

- This does NOT mean the prior study was sufficiently powered!
- This could be a chance finding.
- Sample size calculations must be calculated for your specific study and the effect you wish to detect.

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/size.htm

Sample size section – what NOT to do

- This is something statisticians commonly hear when working with researchers.
- It is important to make a concerted effort to find prior relevant published information.
- Alternatively, a small study could be conducted to obtain the required information.
- General sample sizes can still be undertaken if some information (e.g., standard deviation of the outcome) is not available.

"Sample sizes are not provided because there is no information on which to base them."

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/size.htm

Sample size section – what NOT to do

"The throughput of the clinic is around 50 patients a year, of whom 10% may refuse to take part in the study. Therefore over the 2 years of the study, the sample size will be 90 patients."

- This is valuable information to include in your grant and helps highlight the **feasibility** of the study being undertaken.
- It does **NOT** mean your study will be **powered**. Underpowered studies are a waste of resources and are unlikely to get funded.
- A sample size calculation is required to determine the power to detect differences of interest.
- If the sample size is too small, you may want to extend the study length or collaborate with other centres.

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/size.htm

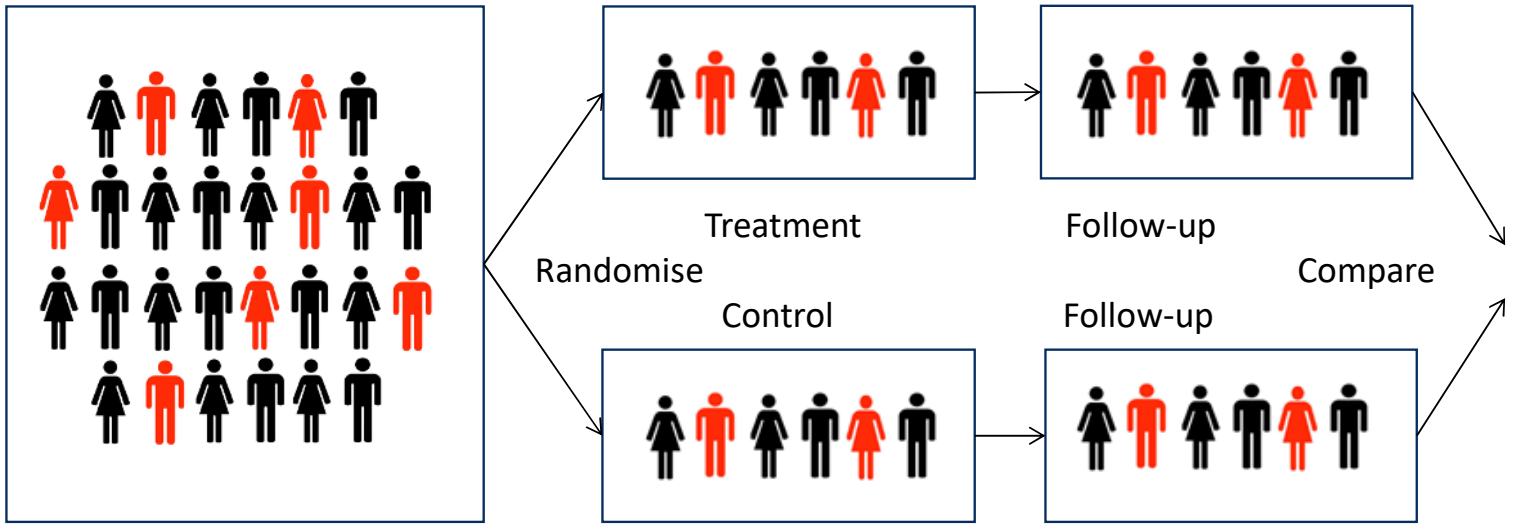
How many participants do I need in my study?

- In order to think about sample size for a study, there must be a clearly articulated **research question.**

- Sample size estimates are based on the **primary outcome** that the study is investigating, so
  - ***Outcome*** measure must be clearly articulated
  - How will the ***outcome*** be measured?
  - Is the ***outcome*** categorical or numerical?
  - How will the o***utcome*** be analysed?

- Sample size depends on the researcher's knowledge & assumptions such as those arising from systematic reviews (as much as technical statistical calculations).
  - It is important to carry out sample size calculations for several different scenarios, not just one.

Sample size: Demonstration for a RCT



Aim: – To compare some outcome measure between treatment and control group

- randomised at individual level

- superiority trial

Sample size: Demonstration for a RCT
- randomised at individual level
- superiority trial

REVAMP trial – *Mwangi M et al. BMJ Open, 2021*

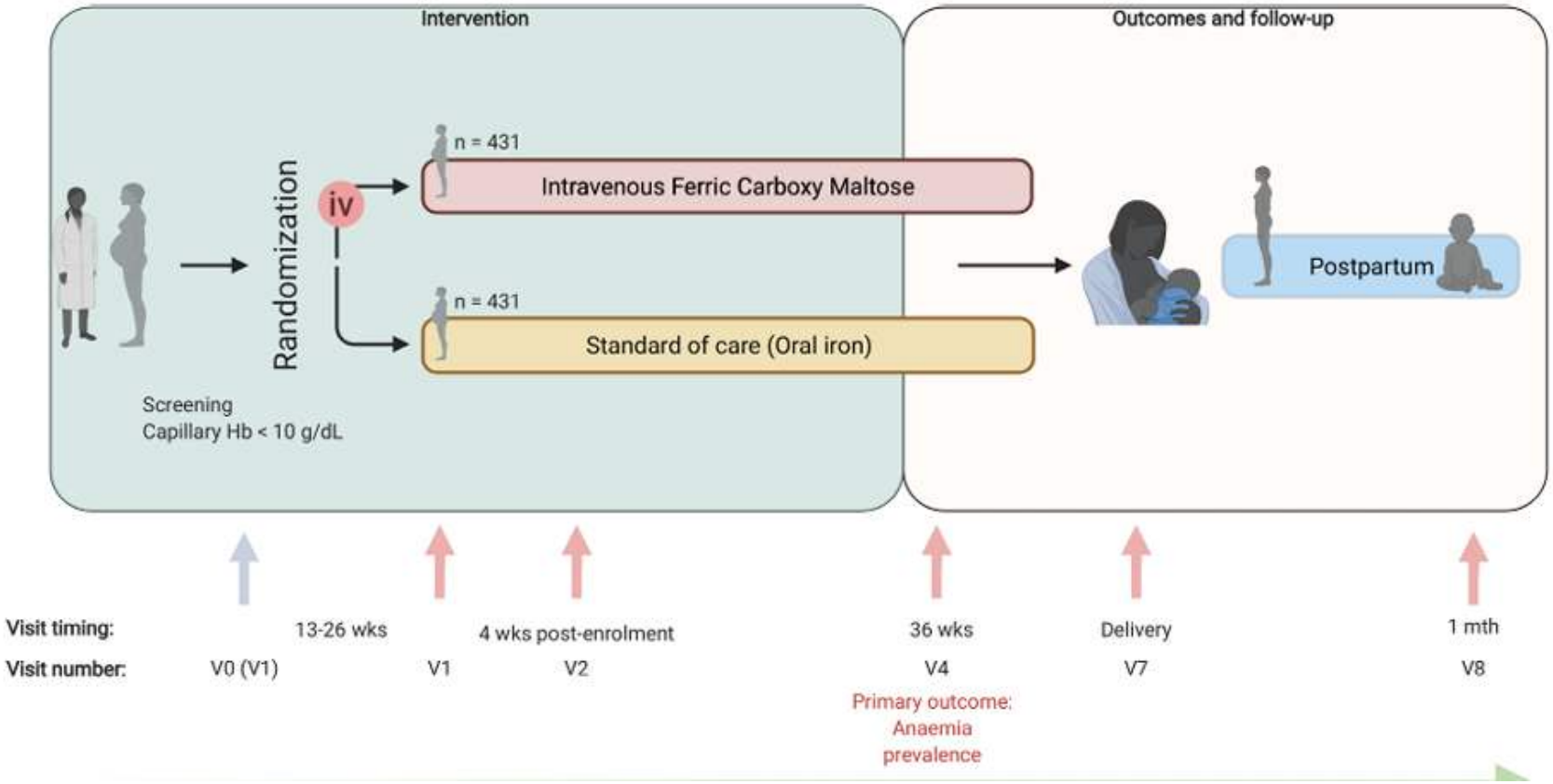
Population	Malawian pregnant women (recruited at 13-26 weeks' gestation)
Intervention	Intra-venous iron (once over 15 minutes after randomisation)
Comparator	Standard of care – oral iron treatment course (two times per day for 90 days)
Outcome	Prevalence of maternal anaemia (venous haemoglobin concentration < 110 g/L) at 36 weeks gestation
Time	Primary outcome assessed at 36 weeks gestation (note:- follow-up until 1 month post-partum for secondary outcomes)
(study design)	Randomised Controlled Trial (*multi-centre, open-label, superiority, two-arm, parallel group, individually randomised*)

Sample size: Demonstration for a RCT

- randomised at individual level

- superiority trial

REVAMP trial – *Mwangi M et al. BMJ Open, 2021*



Sample size: Demonstration for a RCT

- randomised at individual level
- superiority trial

Information (ingredients) required for a power-based sample size calculation:

1. Baseline information	**Categorical outcome:** The proportion with the feature in the control group *or* **Numerical outcome:** Measure of variability in the control group *- published data, pilot data, guess-timate of range*
2. Minimum clinically important difference	The smallest difference in outcome between the treatment and control groups that would be deemed to be of 'clinical/public health' relevance. *- must be based on clinical (substantive) considerations*
3. Relative sizes of the two groups	Ratio of number of treatment / control (Usually 1:1 in most trials)
4. Significance level	Near-universal convention to set this at 0.05 (5% two-sided)
5. Power	Typically between 80% or 90%

Sample size – *information needed for REVAMP trial*

1) Baseline information

We need…..

Outcome - **Prevalence** of maternal anaemia (venous haemoglobin concentration < 110 g/L) at 36 weeks gestation

Control group - Standard of care – oral iron treatment course (two times per day for 90 days)

→Set at 60% (based on study in Gambia)

Source picture: https://www.mdedge.com/obgyn/article/153051/obstetrics/recognize-and-treat-iron-deficiency-anemia-pregnant-women

Sample size – *information needed for REVAMP trial*

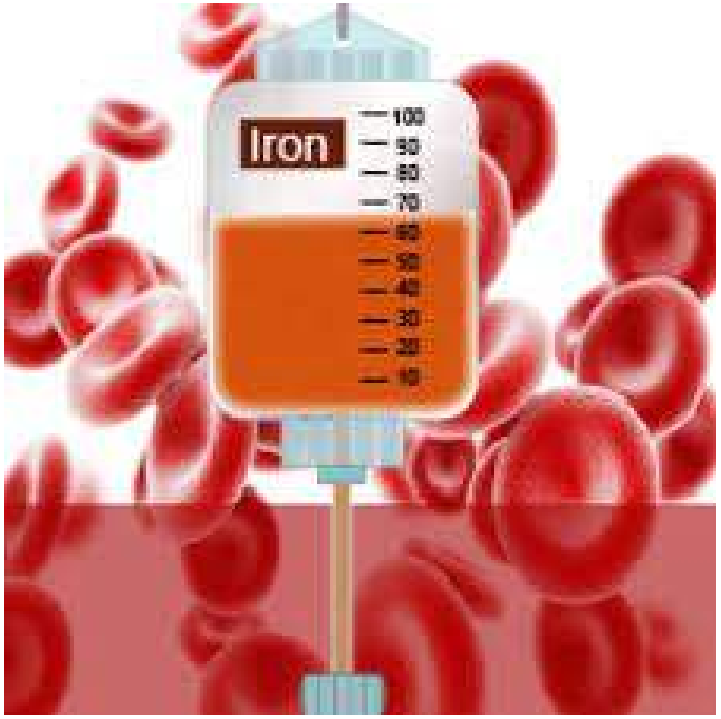
2) Minimum clinically important difference

Hypothesise that intra-venous iron will result in an absolute decrease of 10% units in prevalence of anaemia at 36 weeks gestation.

[10% - justified based on a similar trial in a high income setting that observed 14%]

IV group – prevalence of 50%

Standard of care oral group – prevalence of 60%



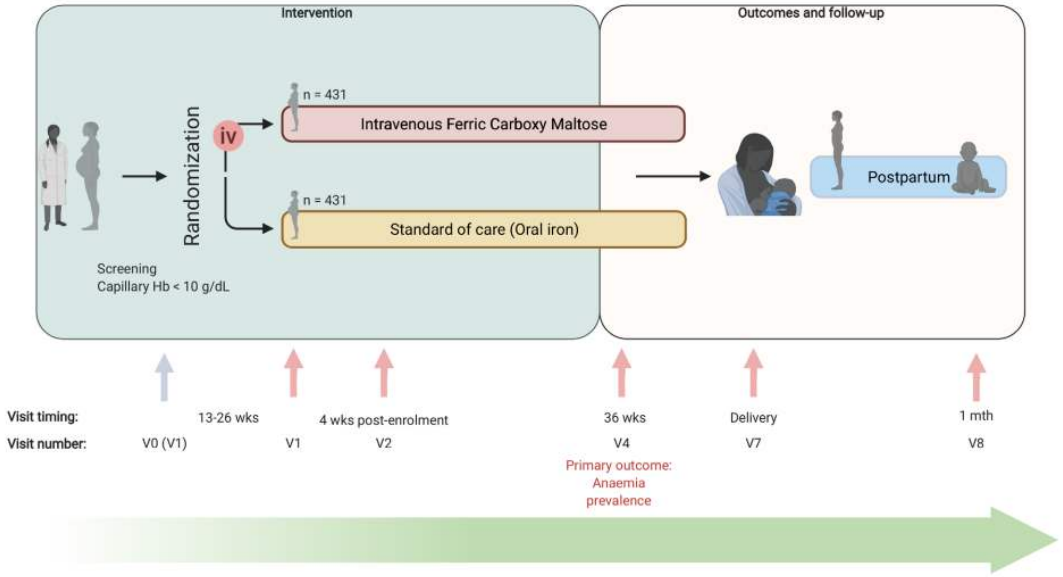
Source picture: https://podtail.com/podcast/dr-chapa-s-obgyn-pearls/iv-vs-oral-iron-therapy-in-pregnancy/

Sample size – *information needed for REVAMP trial*

3) Relative sizes of the two groups

Ratio of number of pregnant women randomised to IV versus oral iron

1:1



Sample size – *information needed for REVAMP trial*

4) Significance level & 5) Power

Null hypothesis in superiority question

A null hypothesis is one that proposes there is no difference in population parameter between groups

REVAMP null hypothesis:

- The prevalence of anaemia at 36 weeks gestation is the same for those in the population who receive IV iron or oral iron.

Hypothesis testing

Type I error

Investigator concludes from sample:
"IV iron reduces the prevalence of anaemia at 36 weeks gestation compared to standard oral iron"
(i.e. reject the null hypothesis)

WHEN

There is NO difference in prevalence of anaemia at 36 weeks gestation between IV and oral iron in the population
(i.e. null hypothesis is true)

Type II error

Investigator concludes from sample:
"There is no difference between the prevalence of anaemia at 36 weeks gestation for IV and oral iron groups"
(i.e. do not reject the null hypothesis)

WHEN

There is a REAL difference in prevalence of anaemia at 36 weeks gestation following IV iron compared to oral iron in the population
(i.e. null hypothesis is not true)

Hypothesis testing

Type I error (α)

Convention to fix at 5%

Two-sided significance level = α = 5%†

We will incorrectly interpret a difference as a real difference on less than 5% of occasions

(false positive)

Type II error (β)

Convention to fix at 10 or 20%

Power = 1-β
= 90% or 80%

We will be able to detect an important difference on 80/90% of occasions and will miss it on 20/10% of occasions

(false negative)

† - leads to $p<0.05$ convention for "statistical significance", note that $p=0.049$ & $p=0.051$ are not in reality different, but for planning purposes it is necessary to have a cut-off.

Sample size – *information needed for REVAMP trial*

1. Baseline information	The proportion of anaemia at 36 weeks gestation for standard oral iron group 60%
2. Minimum clinically important difference	A decrease of 10% (i.e., prevalence of anaemia in the IV iron group = 50%)
3. Relative sizes of the two groups	1:1
4. Significance level	5%
5. Power	80%

Sample size – *information needed for REVAMP trial*

1. Baseline information	The proportion of anaemia at 36 weeks gestation for standard oral iron group 60%
2. Minimum clinically important difference	A decrease of 10% (i.e., prevalence of anaemia in the IV iron group = 50%)
3. Relative sizes of the two groups	1:1
4. Significance level	5%
5. Power	80%

Resulting sample size per group: 388 patients

(776 patients in total)

REVAMP sample size – grant application

Grant application statement:-

> *"This study, with 388 pregnant women per group, has 80% power, i.e. an 80% chance of producing a statistically significant finding at a two-sided 5% significance level, to detect an absolute difference in prevalence of anaemia at 36 weeks gestation of 10% between IV and oral iron groups, assuming a prevalence of 60% in the oral iron group (i.e. 50% versus 60% respectively)."*

Note: *You need to provide further text in the grant application to justify the values of 60% for the control (standard of care) group, and the absolute reduction of 10%.*

Factors important in sample size calculations

In addition to be incorporated:

- Missing data: - (illustrated no loss-to-follow-up)
  - Predicted response &/or loss to follow-up rates, e.g. REVAMP - loss to follow-up expected to 10%, increased sample size by 100/90.
  - Of note, beware of non-random dropout leading to *bias* (larger samples do not correct for bias)

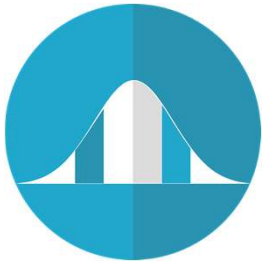
- Study design:- (illustrated parallel group, individual level design)
  e.g. cross-over trial, cluster randomised trial

- Study question:- (illustrated difference question - superiority)
  to show difference, equivalence or non-inferiority

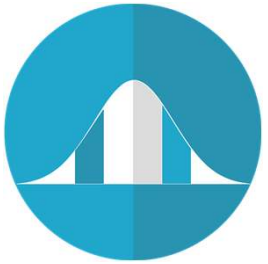
Finally:

- It is important that you calculate the sample size using the same/similar techniques to the primary analysis presented in your grant application.

Statistical methods



Statistical methods



- The statistical methods should include **sufficient details** about how each of the research questions posed will be addressed.

- The reviewer should be made aware that the researchers have spent time thinking about how the data collected will be used.

- A grant is unlikely to be funded with only statements like:

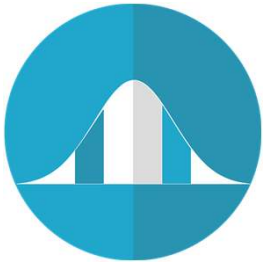
A statistician will be employed to conduct the statistical analysis.

OR

Statistical analysis will be conducted using Stata.

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/methods.htm

Statistical methods



- The statistical methods section should include **unambiguous statements** about how analyses will be conducted.

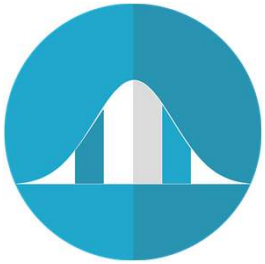
- For example:

Linear regression will be used to compare the mean difference in body mass index (primary outcome) between the two treatment arms at 6 month follow-up, controlling for baseline body mass index.

- The method described should be **appropriate for the study design** (e.g., clustered designs need to take into account clustering in the analysis) and the **data type of outcome** (e.g., continuous, categorical).

St George's University of London 'Statistics Guide for Research Grant Applications' https://www-users.york.ac.uk/~mb55/guide/methods.htm

Statistical methods



- Importantly, the statistical methods used for the primary outcome(s) should directly align with the sample size calculation included in the grant.

- If the primary outcome is continuous (e.g., body mass index) but the statistical analysis section includes only methods for dealing with a binary outcome (e.g., overweight or not overweight), this raises a red flag to reviewers.

- The grant should be **consistent** throughout.

Statistical methods

REVAMP Trial – Statistical method for primary outcome

"Anaemia will be analysed using a log-binomial regression model. The model will include the standard-of-care (oral iron) group as the reference group. The primary maternal hypothesis will be evaluated by obtaining the estimate of the prevalence ratio of intravenous iron versus standard-of-care (oral iron), 95% CI at 36 weeks' gestation, and p value."

Statistical methods – Quiz Question 2

Is the following paragraph sufficient for the statistical methods section in a grant application?

"Treatment groups will be compared using a t-test (continuous outcomes) or chi-squared test (binary/categorical outcomes). We will declare our intervention successful if the p-value is less than 0.05."

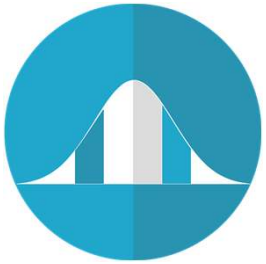
a) Yes

b) No

c) Maybe

d) Don't know

Statistical methods



- Topics typically covered in the statistical methods sections are:
  - Analysis sample
  - Model for primary and key secondary outcomes
  - Handling missing data
  - Handling multiple testing
  - Subgroup analyses
- The grant should allow for sufficient space to cover the above topics in the statistical methods section...

Funding

- It is important to consider the funding required to support the data and statistical aspects of your study.
- Do you need support with **data management** (e.g., database set up and design)?
- Will you need **ongoing statistical support** for the design, conduct, analysis and reporting of your study?
- Statisticians and data managers require funding to ensure they can continue to support research.
- It is important that these costs are built into the budget.

[See recording of seminar by Sabine Braat: Effective collaboration with biostatisticians in randomised controlled trials https://machaustralia.org/emcr-research-design-webinars/]

Ensure sufficient time for statistics!

- It is important to think about the statistics as early as possible in the planning stage.
- Statisticians can assist with framing the research question(s) and identifying the best design.
- This can take time!

Thank you

- Recording:- https://machaustralia.org/
- Website:-https://clinicalresearch.mdhs.unimelb.edu.au/
- MISCH Newsletter:- https://clinicalresearch.mdhs.unimelb.edu.au/collaborate/contact-us/misch-newsletter-sign-up
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