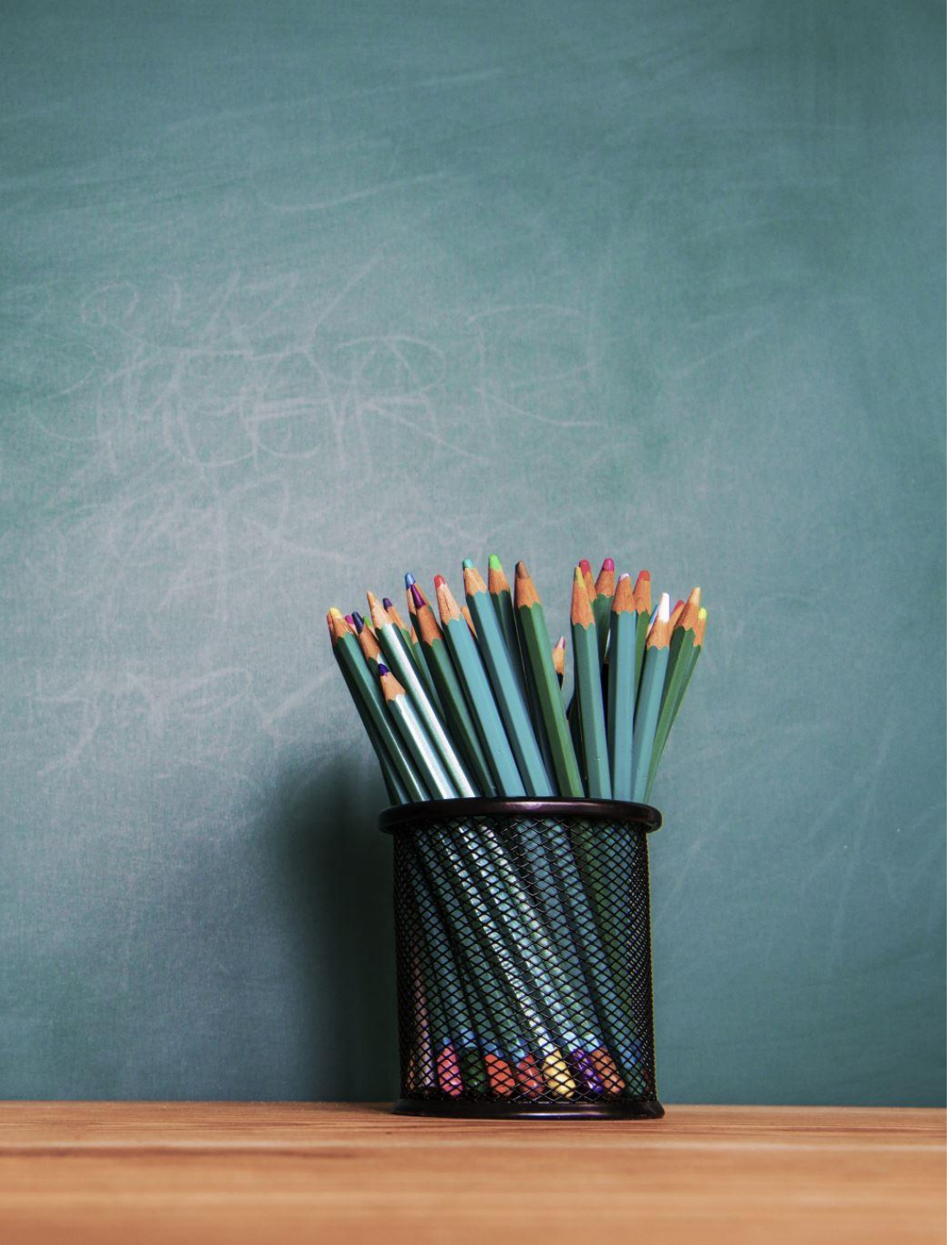

Taranaki Medical Foundation

Tips & traps for common research designs

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Summary

- Choosing a method
- Literature reviews
- Qualitative research designs
- Diagnostic tests
- Transversal studies
- Case-control studies
- Controlled trials

Choosing a method – tips

- Your research question is:
  - *Descriptive: What? Who? When? Where?*

  →Literature reviews, qualitative research, transversal studies, case-control studies
  - *Analytic: Why?*

  →Literature reviews, qualitative research, cohort studies, case-control studies, controlled trials
  - *About an intervention: For what?*

  → Meta-analyses, controlled trials, health economics

Choosing a method - tips

- **Always start ‘theoretically’:** what should be the best method for my objectives?
- **Then confront it to reality:**
  - How can I source the data?
  - How much time and money is available?
  - Is it an ethical study?
  - Where and when can I conduct a study?
- **It is always a compromise**

Choosing a method - traps

- **Never start by the method** or the dataset
  - A good research question is always relevant, even if your method is not able to find the answer
  - A bad research question is irrelevant, sometimes even fraudulent
- **Never be too optimistic:**
  - Research is hard and takes time!
  - Calculate how many patients / how much data to include beforehand
- **Do not change your research design at mid-course**

Literature reviews

- 3 main types of literature reviews:
  - **Systematic review**: a lot of work but if done properly, can be published in good journals
  - **Scoping review**: mostly to identify gaps in research
  - **Narrative review:** can have a lot of value if done properly – but not easily published

Grant, M.J. & Booth, A. (2009). A typology of reviews: An analysis of 14 review types and associated methodologies. Health Information & Libraries Journal, 26(2), 91-108. https://doi.org/10.1111/j.1471-1842.2009.00848.x

Systematic literature reviews tips

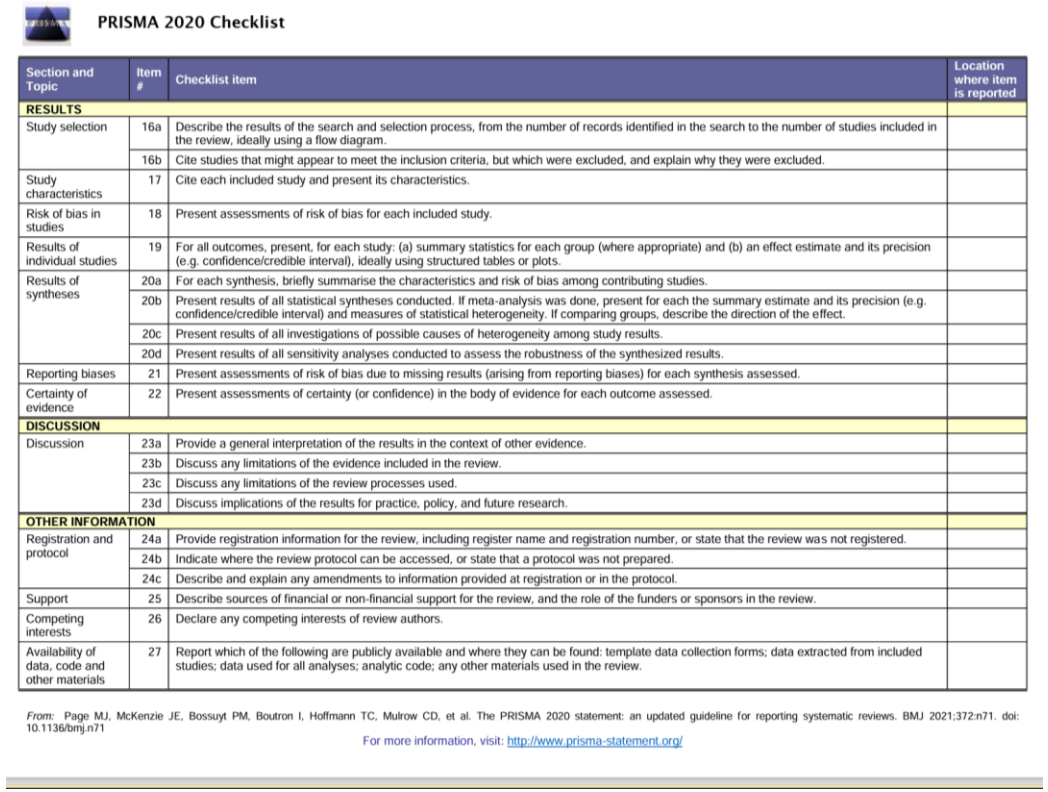
- **Use PRISMA** checklist for systematic reviews
- Specify **your criteria of inclusion and exclusion** before starting the review – but be flexible you can always change them and restart from scratch

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	

Systematic literature reviews tips

- Decide how you are going to handle **disparities** between researchers before starting
- And stick to it!
- Know how to **grade the quality of evidence**
- Use a reference manager (e.g. Endnote, Zotero, Mendeley)



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

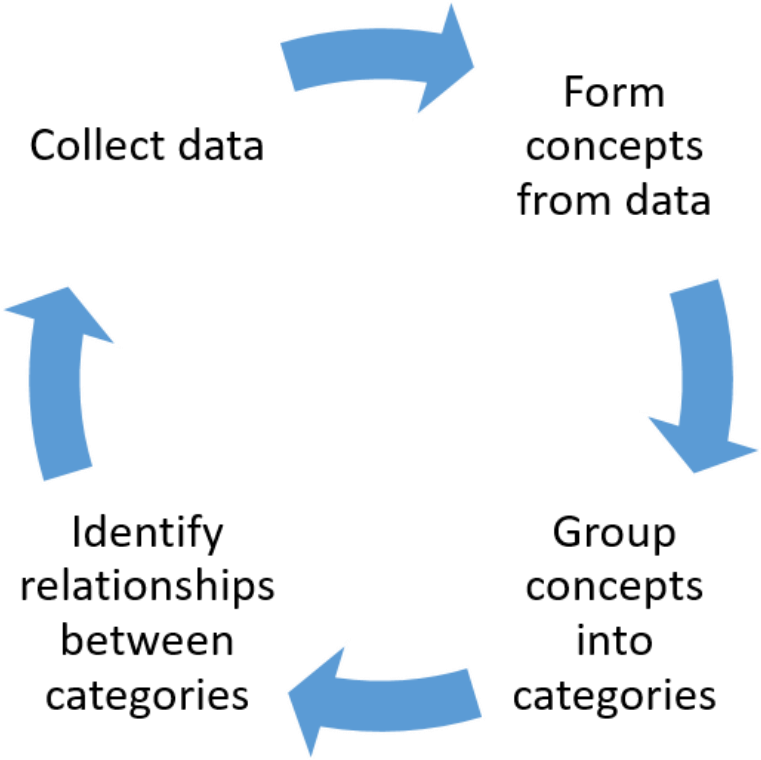
For more information, visit: http://www.prisma-statement.org/

Systematic literature reviews traps

- **Be careful with the choice of data** you include for your research:
  - Specific databases: Psycinfo, CINAHL, Sportdiscus etc.
  - ‘Grey literature’: guidelines, government publications, WHO, OECD etc.
- **Be aware of the limits of titles and abstracts**
- Use the **skills of your librarian**...
  - But do not rely exclusively on them
- **Get a second author** that will be as much involved in it as you – and have a backup plan
- **Do not attempt meta-analyses** unless you have 10+ years of experience in research

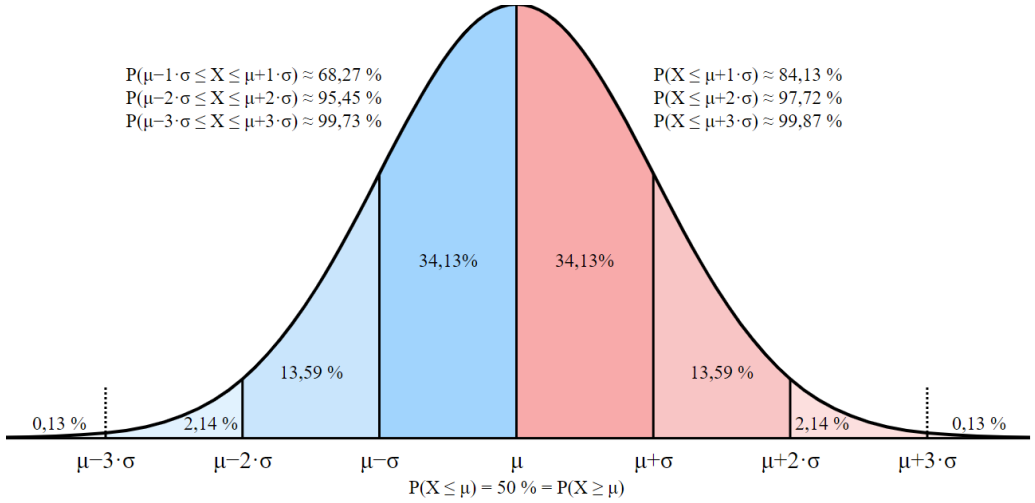
Qualitative research

- 2 main methods:
  - **Interviews**
    - Semi-structured
    - Focus group
  - **Observations**
    - Direct: participative or not
    - Indirect: videos, recordings, reports etc.
- Needs a theoretical framework for analysis:
  - **Grounded theory** most often used in medical research



Qualitative research

- Objectives:
  - To understand why
  - To gather the largest possible range of opinions on a topic



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Qualitative research designs tips

- Be prepared for a good amount of work – it’s not easier because it is qualitative research
- Always get a co-researcher for **data triangulation**
- Grounded theory:
  - Define your limits for achievement of **data saturation** before starting interviews
  - Use your interviewees to extend your perimeter of interviews
- **Use software for thematic analysis**: nVivo, Atlas, maxQDA

Qualitative research designs traps

- Using your results in a quantitative way
- **Not achieving saturation**: ‘pseudo’-saturation
- **Context** of observations and interviews is important ++
- **High risk of personal bias** in data collection and interpretation of data
- More difficult to publish in high-impact journals

Diagnostic tests tips

- **Check literature:** it is likely somebody had a similar idea
- **Determine your sample with high precision**:
  - How many patients to include – linked to the prevalence of the disease
  - Where to recruit patients – context-dependent
  - Availability of the ‘gold standard’ (MRI scans, post-mortems etc.)
- **For composite scores**:
  - Do sensitivity analyses to determine which questions are actually relevant

Diagnostic tests traps

- **Not choosing the right ‘gold standard’** to compare your test:
  - Histology or post-mortem at best
  - Lab/imaging are only intermediate unless pathognomonic
  - Seek consensus if using clinical features only (e.g. psychiatry)
- **Not getting meaningful results:**
  - Prevalence lower than expected
  - Difficulties for recruitment
  - Surrogate endpoints

Transversal studies tips

- Determine your main objective and your secondary objectives
- **Calculate your sample size on your main objective only**
- Transversal studies can be done over a range of time:
  - Make sure your study population does not change over time (e.g. teenagers)
- Surveys:
  - Avoid open-ended questions
  - Precision vs. adherence to questionnaire

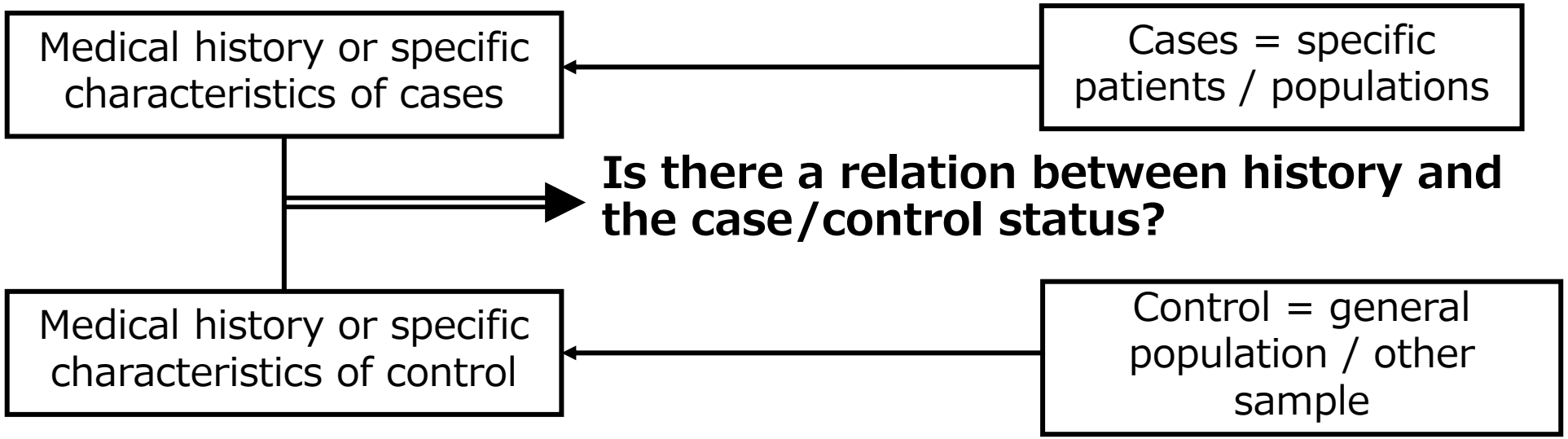
Transversal studies tips

- Always start with **comparing your sample to the general population:**
  - Demographic parameters at least
  - If available, health conditions, social status etc.
- **2-step approach** for data analysis:
  - Univariate methods first
  - Multivariate only if dataset is good enough

Transversal studies traps

- **P-value hacking**
  - Stick to your original study plan
  - Sometimes no statistically significant difference is of equal value than an artificial difference
- **Correlation is not causality**
- **Reproducibility of the study**

Case-control studies



Case-control studies tips

- **Definition of population of interest** for both cases and control:
  - Some degree of homogeneity in cases
- **Sampling size:**
  - Recommended to have 2-4 times more control than cases
- **Data source:**
  - Medical records are not always available
  - Memory recall bias
- Look for **confounding variables**

Case-control studies traps

- **Stability of study population** over time for both cases and controls = ‘lost-of-sight’ = deaths, people moving out, not answering anymore
- **Risk of selection bias**
- **Change of definition of cases** over time (e.g. diagnostic definitions)
- **Do not infer causality** out of a case-control study

Controlled trials

- The gold-standard of medical evidence?
- Different types of intervention:
  - Before/after (pre-post)
  - Here/there (different locations, same intervention)
  - Multiple arms (with or without placebo)
- Controlled = selective inclusion
- Randomized = random inclusion in one of the study arms
- Simple/double/triple-blinded

Controlled trials tips

- Team effort, including high-level statistical competencies
- Prospective design: **anticipate the problems**
  - Usually better to do a feasibility study before starting a controlled trial
- **Training of the investigators** is crucial, notably if multicentric
- Not necessarily against placebo, **can be against established practice**
- Ethical approval can be difficult to obtain sometimes: **long-term effort**
- **Publish protocol** for feedback, publishing and funding

Controlled trials traps

- **Selection bias**, notably if clinicians decide to include or not
- **Non-homogeneous or non-comparable populations**
- **Early withdrawal of participants** – ITT analyses are almost always better
- **Monitoring of complications**
- **Deviation** from initial protocol

General advice

- Choosing a method is always a **compromise** between expected results and feasibility
- Always keep in mind the **potential impact of the evidence** you want to produce: do you really need to do that complicated?
- **Do not dismiss qualitative research methods**, especially in new fields of research
- **Good scientific practice on small-scale research** beats scientific fraud at a large scale
- Think about **your publication** as soon as you start your research
- **Always list your biases and limitations when publishing**