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Melbourne Academic
Centre for Health

2026 Research Design Webinar Series




MACH acknowledges the Traditional Owners of the land on which it works, the Wurundjeri People of the Kulin Nation, and we pay our respects to Elders past, present and emerging.
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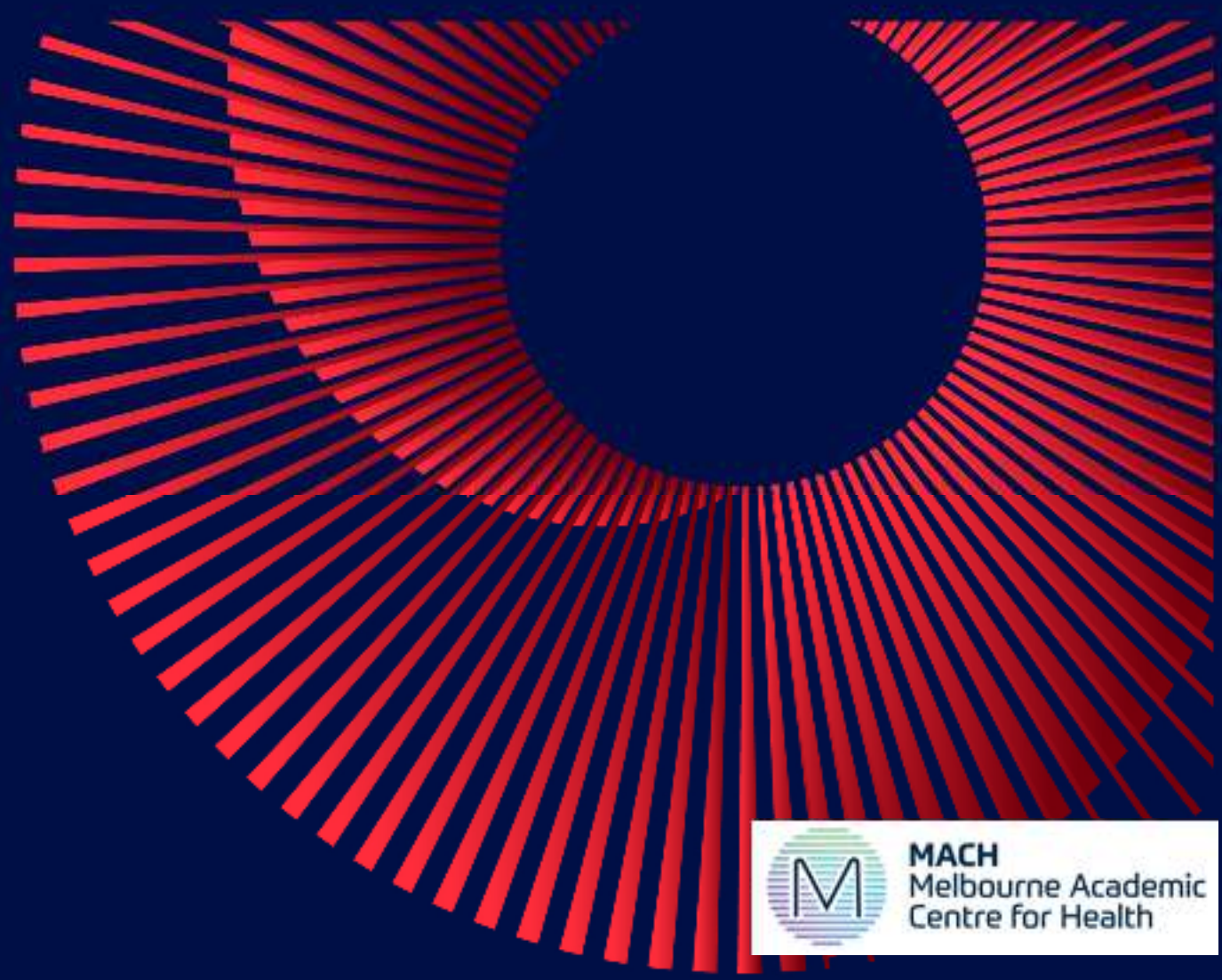

MACH
Melbourne Academic
Centre for Health
2026 Research Design Webinar Series
MISCH Hub
Methods and Implementation Support
for Clinical and Health research
Centre for Digital Transformation
of Health
MELBOURNE
DATA ANALYTICS
PLATFORM

THE UNIVERSITY OF MELBOURNE

Faculty of Medicine, Dentistry and Health Sciences

MISCH *Hub*

Methods and Implementation Support for Clinical and Health Research



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MISCH Hub Structure



MISCH
Staff


Clinical Trials Lead
Adam Deane
Co-Lead MISCH Biostatistics
Sabine Braat
Biostatistician
Ximena Camacho
Co-Design and Consumer Involvement
Jess Kirwan
Health Economist
Kim Dalziel
Co-Design and Implementation Effectiveness Co-Lead
Cathy Vaughan
MISCH Manager
Shane O'Brien
Biostatistician
Emily Karahalios
Health Economist
Bianca Lau-Goodchild
MISCH Operations Manager
An Nguyen
Biostatistician
Lidaje Koroveva
Biostatistics Lead, Austin Hospital
Leonid Churilo
Biostatistician
Dominic Italiano
Biostatistician
Fiona McManus
Biostatistician
Vee-Foong Wok
Health Economist Lead
An Duy Tran
Director of MISCH
Julie Simpson
Biostatistician
Rob Maher
Epidemiologist and Biostatistician
Digau Kaya
Biostatistician
Alistair McLean
Biostatistician
Peixuan Li
Biostatistician
Diana Zarsino
Biostatistician
Anurika De Silva
Co-Lead MISCH Biostatistics
Karen Lamb
Biostatistician
Sophie Zaloumis
Biostatistician
Phoebe Fitzpatrick
Clinical Trials Manager
Katie Ozdowska
Health Informatician
David Ormiston-Smith
Biostatistician
Hannah Johns
Health Informatics Lead
Douglas Boyle
Health Economist
Peter Lee
Biostatistician
Nadine Phillips
Co-Design and Consumer Involvement
Mary Stathopoulos
Communications Coordinator
Jessie Lu-Lee

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MACH EMCR Observational Research Seminar

How your observational research study can benefit from biostatistical guidance

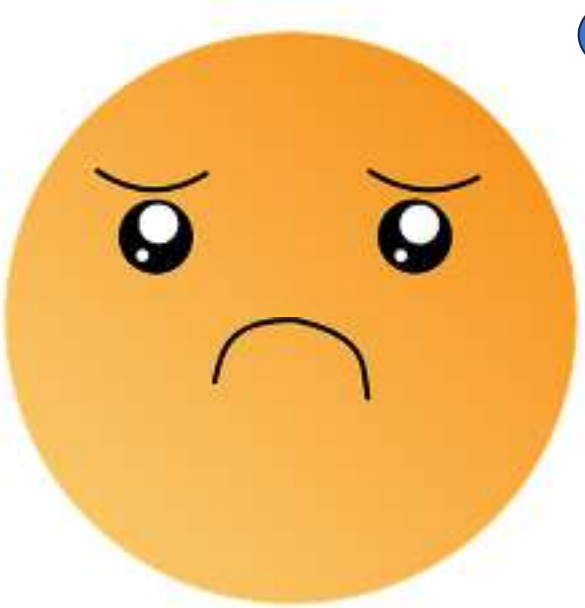
A/Prof Karen Lamb
Dr Sophie Zaloumis
MISCH Biostatisticians



Statistics: the science of disappointment?

You don't have enough participants

Your study design isn't right



You have not collected the data you need

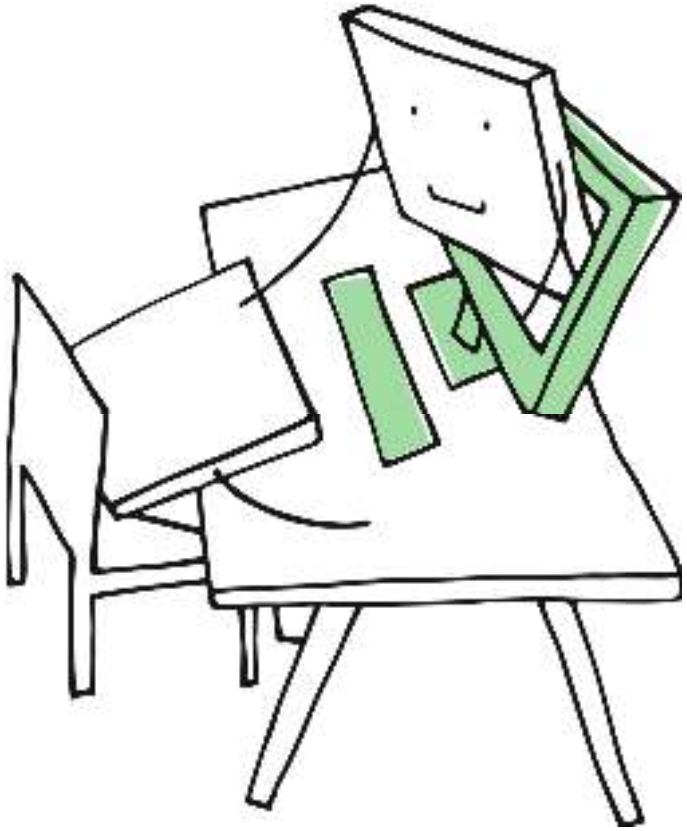
You have too much missing data

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Avoiding disappointment

- Involve a biostatistician as **early as possible** when developing your quantitative research study!
- We can identify the **appropriate design** and help determine the **number of participants needed** and the **data to capture**
- Biostatisticians are often considered critical in randomised controlled trials but are not consulted for observational research.



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Communicating with biostatisticians during your research study

- Important to ensure biostatisticians are consulted at appropriate points during the design, data capture and analysis of observational studies

- The aims of this presentation:
    - To describe how biostatisticians can assist with observational research
    - To provide case studies of different observational research studies we have supported



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What is observational research?

- Observational research in clinical and health research can include:
    i. prospectively capturing information/data for people
    ii. using data already collected

- A key feature of observational research is that these do not typically involve any intervention component.

Cross-sectional studies

Ecological studies



Case-control studies

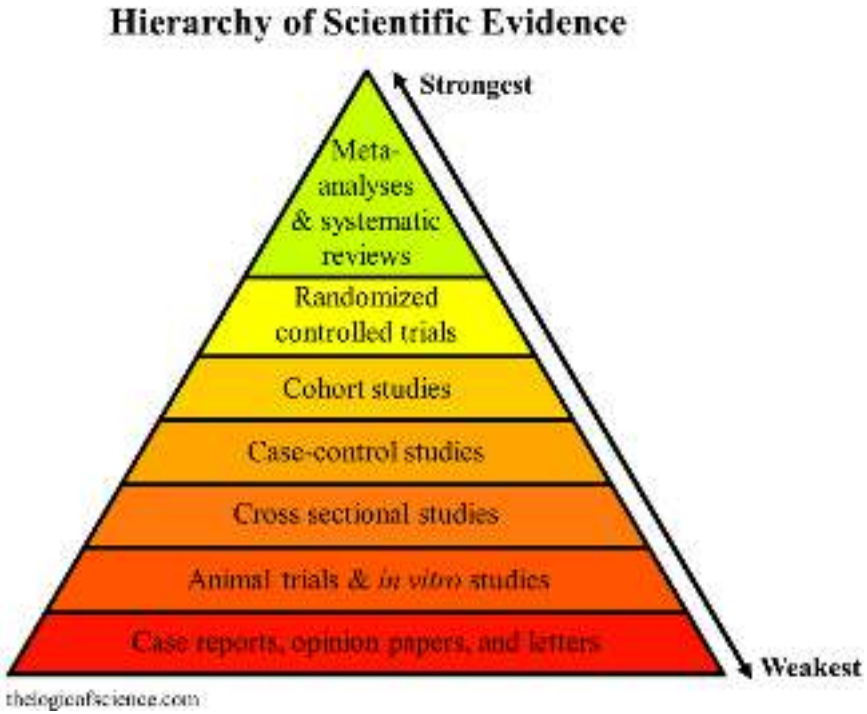
Cohort studies

National Institutes of Health – Observational Research https://irbo.nih.gov/protocol-development/observational-research/

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Why conduct observational research?



- Research question may only require observational data
  (e.g., prevalence study)

- May not be ethical or feasible to undertake RCT
  (e.g., study of smoking and lung cancer)

Hess (2023) Observational Studies. *Respiratory Care* 68(11) 1585-1597

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Observational Research Support Requests

Descriptive

Case or case-series reports

Prevalence studies

Surveillance

Cohort

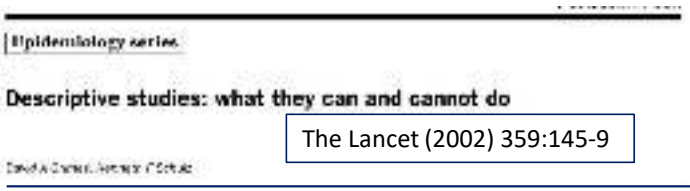
Follow people over time to learn about how exposures affect outcomes

Challenges of confounding and loss to follow-up

Prediction

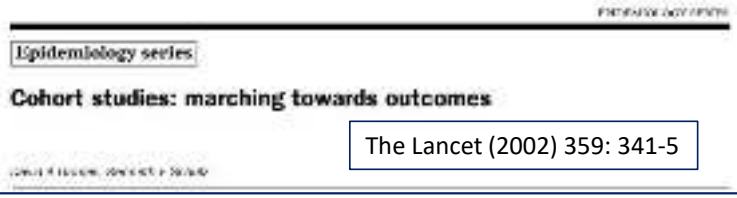
Aim to develop and apply a model to predict new or future observations

Can be used to support clinical decisions


Epidemiology series

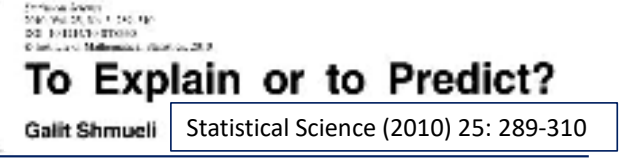
Descriptive studies: what they can and cannot do

The Lancet (2002) 359:145-9


Epidemiology series

Cohort studies: marching towards outcomes

The Lancet (2002) 359: 341-5


To Explain or to Predict?

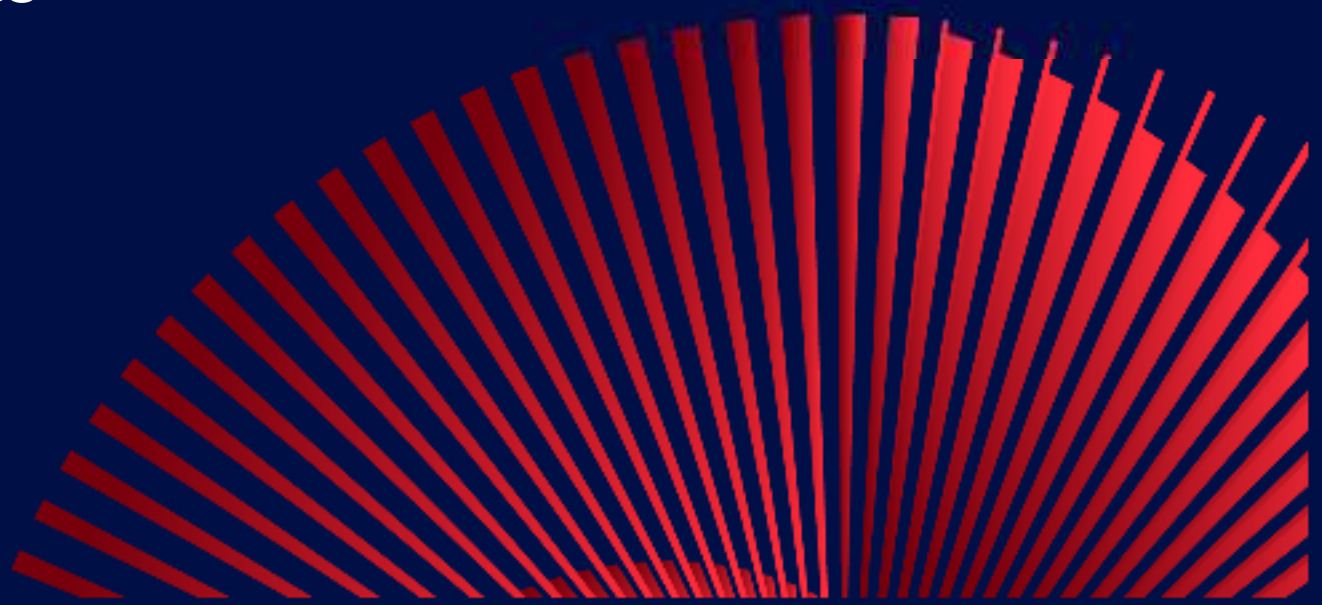
Galit Shmueli

Statistical Science (2010) 25: 289-310

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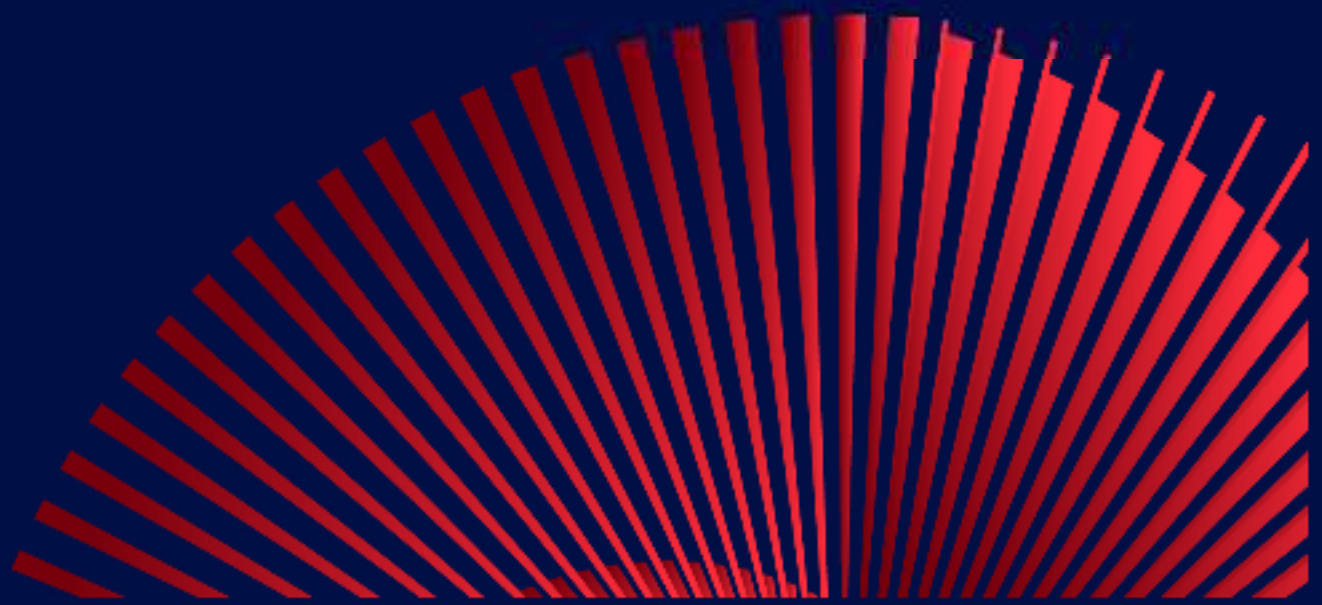
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Case studies: Impact of MISCH statistical consulting on observational studies



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Part 1: Descriptive study example



Case studies: Descriptive study


Research

Ethics guidelines use and Indigenous governance and participation in Aboriginal and Torres Strait Islander health research: a national survey

Abstract

Burchill et al. (MJA, 2023)

Background

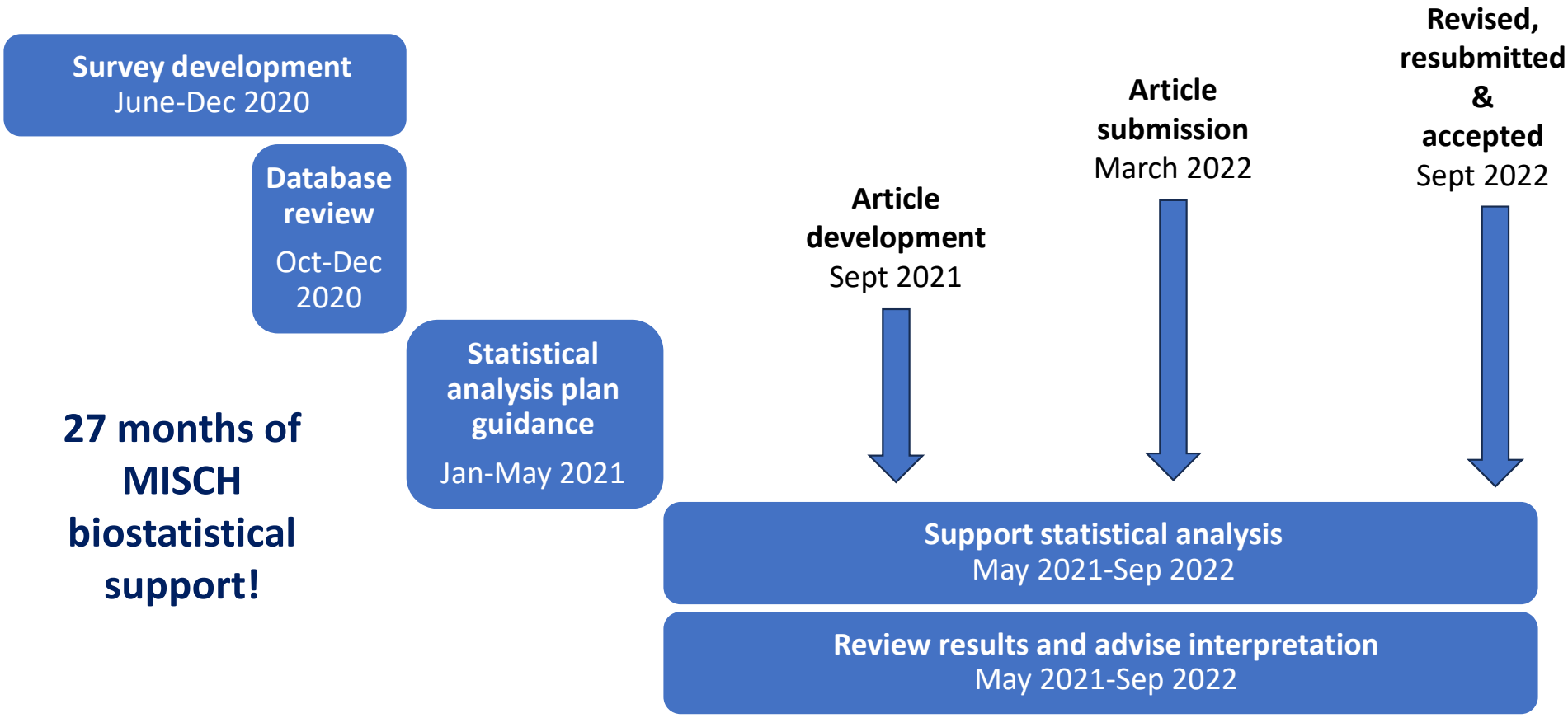
- NHMRC guidelines '*Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities*' published 2018
- Recommend Indigenous oversight and participation in Indigenous health research
- Guidelines not mandatory so extent of implementation unknown

Aims

- To assess the use of these guidelines by Australian researchers
- To assess degree of Aboriginal and Torres Strait Islander governance and participation in Indigenous health research

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Descriptive Study: Burchill et al.



27 months of MISCH biostatistical support!

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MISCH contribution: Survey development

3 draft surveys



Draft 1

Refining scope

"The survey is open to all Australian researchers undertaking Aboriginal and Torres Strait Islander research."

Question: Is the research restricted to health research or any research context?

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MISCH contribution: Survey development

3 draft surveys



Draft 1

Clarifying population of interest

"The definition of 'researchers' is inclusive of graduate students and Aboriginal and Torres Strait Islander health care professionals and community members whose contribution to research is vital."

Comment: Need to think about how to capture all groups. If looking to NHMRC for those doing Indigenous research, may miss those doing unfunded research or research funded by other bodies.

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MISCH contribution: Survey development

3 draft surveys



Draft 1

Aligning survey measures with objectives

"Objectives
- To describe the demographic and organisational profile of researchers undertaking Aboriginal and Torres Strait Islander health research
- To understand researchers' perceptions of the NHMRC Guidelines including their purpose, importance, barriers to implementation, and institutional oversight."

Comment: Good to have these outlined. Need to clearly specify the primary outcomes/measures that will be used for each objective.

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MISCH contribution: Survey development

3 draft surveys



Draft 2

Refinement of survey questions

"Which of the following themes does your Aboriginal and Torres Strait Islander research explore?

- *Culture and Heritage*
- *Governance and Public Policy*
- *Health and Wellbeing*
- *Land and Water*
- *Languages and Cultural Expression*
- *Native Title and Traditional Ownership*
- *Other (free text)"*

Question: Will this be a tick all that apply question?
If so, perhaps indicate this in brackets after the question.

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MISCH contribution: Survey development

3 draft surveys



Draft 2

Avoiding ambiguities

"2.5. Age group (years)
- <25
- 25-45
- 46-66
- >67"

Questions:

- Is this age group of respondent or age group of research participants studied?
- What should be selected for those aged 67 years?

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MISCH contribution: Survey development

3 draft surveys



Draft 3

Examples from 29 outcome measures listed!

Further clarification of outcome definitions

"To identify organisational profiles suggesting higher versus lower levels of active commitment to ethical research with Aboriginal and Torres Strait Islander people ."

Possible analysis outcome measures:

- *NHMRC guideline use (3.1)*
- *Organisation has Indigenous representation on board (4.1)*
- *Organisation has an Indigenous advisory board (4.2)*
- *Organisation has Indigenous ethics committee (4.3)*

Questions: *Will a final variable be created from these outcomes for high/low organisation commitment?*

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MISCH contribution: Database review



- Cross-check paper questionnaire with database
  - All questions in database?
  - Wording consistent with paper questionnaire?
  - Any new questions added?
- Check survey flow/branching logic

CDI number	Item	Question/Note
Participant consent	By proceeding with this survey, you are providing consent to participate. Do you consent?	If you select 'No' to this option, it is still possible to complete the survey. Anyone that selects 'No' does not consent so should be redirected to a page that says thank you for your consideration and then stops them from proceeding through the survey.

- Check for survey errors

Page 2	Survey errors	When proceeding to page 2 of the survey after completing page 1, an error message appears. "SURVEY ERRORS EXIST. CANNOT CONTINUE! Please contact your survey administrator and let them know that Branching Logic errors exist on this survey for the field "responsible for ethics review." This survey will not function correctly until these errors have been fixed. Sorry for any inconvenience."

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MISCH contribution: Statistical analysis plan

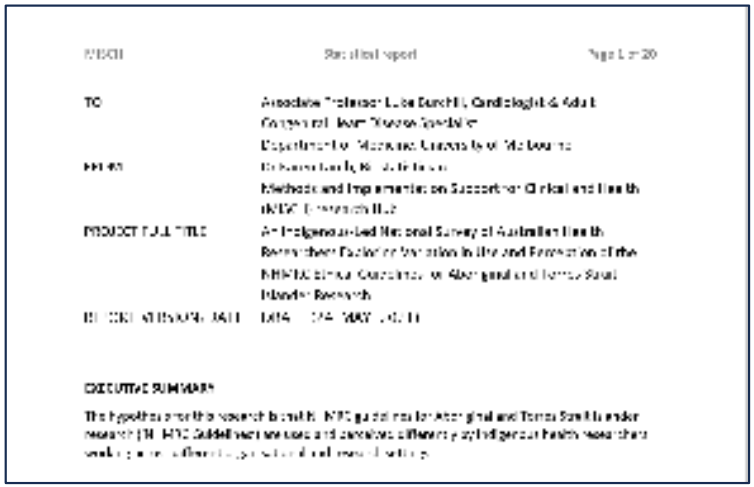


- Clear outline of all research objectives and survey items aligned with these
- Description of recruitment process
- Description of analysis population
- Analysis details
    - Descriptive statistics
    - Planned tables
    - Planned figures

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MISCH contribution: Statistical analysis



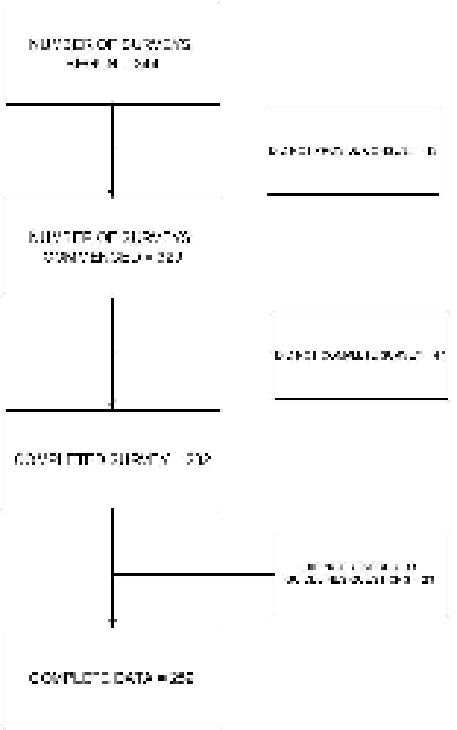


Figure 1. Flowchart of participation in the Indigenous health research survey.

Do you use the NHMRCs Ethical conduct in research with Aboriginal and Torres Str	Aside from the NHMRC Guidelines, do you use any other ethical guidelines when un Yes - ple	No	Total
All of the time	136 63.26	79 36.74	215 100.00
Some of the time	24 61.54	15 38.46	39 100.00
None of the time	1 20.00	4 80.00	5 100.00
Total	161 62.16	98 37.84	259 100.00

Table 2. Cross-tabulation of NHMRC ethical guideline use against other guideline use (N=259).

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MISCH contribution: Interpretation

- Dot point summary of key findings
- Description of participant characteristics
- Focus on key objectives; for example:
  - **24%** reported **no Aboriginal or Torres Strait Islander representatives at highest level** of organisation (15% 'don't know')
  - **28%** reported **Aboriginal or Torres Strait Islander advisory boa**rd in organisation (16% 'don't know')
  - **40%** reported primary organisation had its own **Aboriginal and/or Torres Strait Islander research ethics committee** (21% 'don't know')
  - Higher proportion of Aboriginal and/or Torres Strait Islander respondents indicate no Aboriginal or Torres Strait Islander representatives at highest level (32% vs. 22%)

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MISCH contribution: Publication

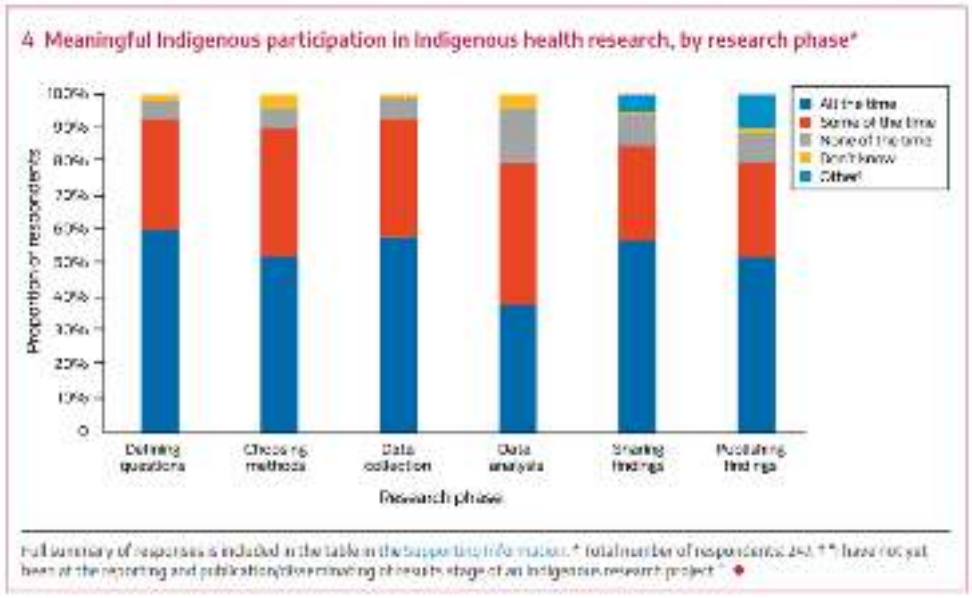

Ethics guidelines use and Indigenous governance and participation in Aboriginal and Torres Strait Islander health research: a national survey

- Support write-up
- Publication quality tables
- Figures in style requested by publication
- Response to reviewers



3 Participation of Indigenous people in Indigenous health research, and the perceived importance of such participation

Survey question	Responses
Total number of respondents	247
Do you currently have Aboriginal and/or Torres Strait Islander people on your research team?	
Yes	205 (83%)
No	20 (8%)
Not currently undertaking Indigenous health research	22 (9%)
How important is it that Aboriginal and/or Torres Strait Islander people play a leading role in the governance of Aboriginal and/or Torres Strait Islander research?	
Very important	234 (95%)
Somewhat important	11 (4%)
Not important	2 (1%)

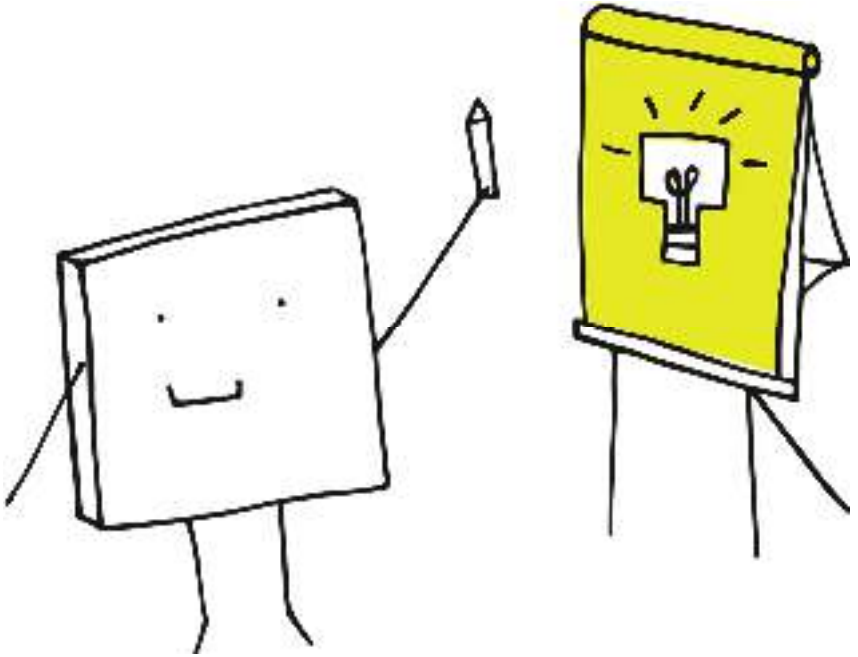


*Note that journal requested reporting of only 247 participants who responded to ALL survey questions resulting in revised analysis

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Findings from descriptive study support

- MISCH biostatisticians can provide valuable contributions to descriptive studies
- Substantial work in refining research objectives and survey questions
- Database review essential to ensure survey usable
- Brief statistical analysis plan helpful to ensure all research objectives clear, can be measured in the survey and will be analysed descriptively
- Despite descriptive study, much more statistical support required than anticipated in analysis stage!

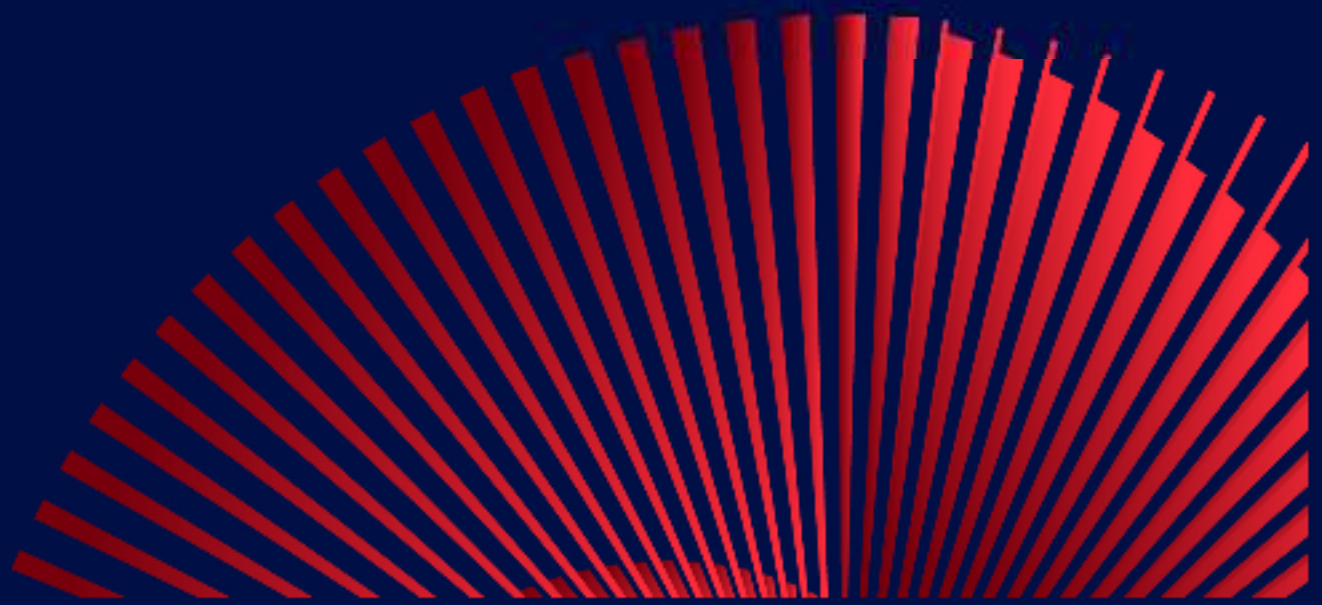


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Part 2: Cohort and prediction examples



Case studies

Tan et al. (BJA Open, 2022)

- **Inferential cohort study** with confounder control

Metcalf et al. (Eur J Psychotraumatol, 2025)

- **Predictive**, longitudinal wearable + Ecological Momentary Assessment (EMA) data

Projects illustrate that observational studies can benefit from early and sustained statistical support

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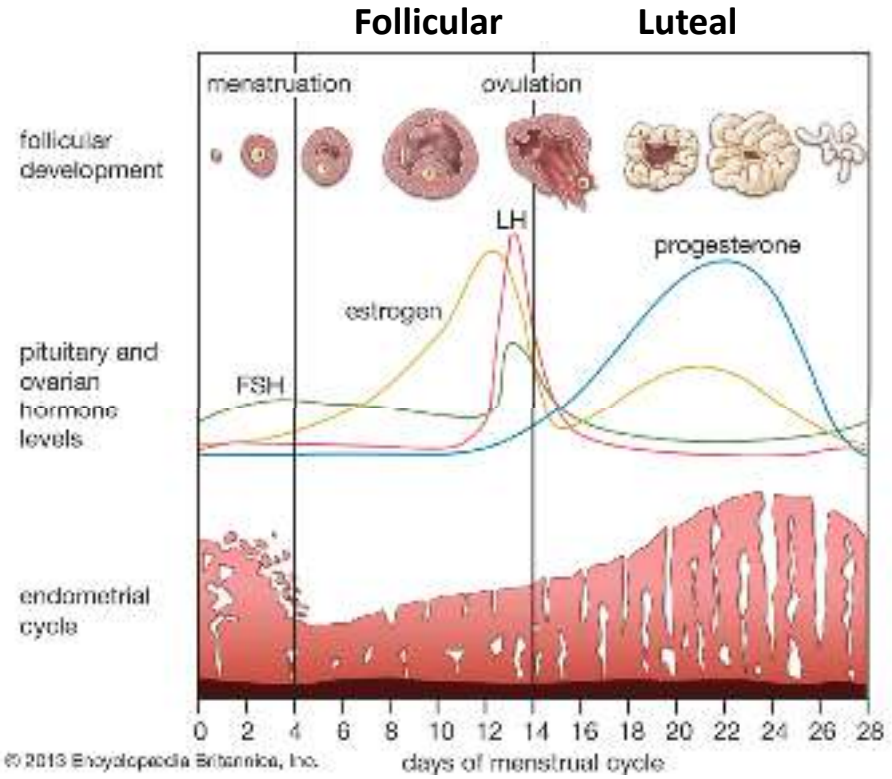
Cohort Study: Tan et al.

Background:

- Women have poorer quality of postoperative recovery from general anaesthesia than men
- Persists for at least 3 days postoperatively
- More pronounced in premenopausal women
- Studies of menstrual cycle effects on pain or postoperative nausea and vomiting (PONV) report conflicting results

Aim:

- To determine whether menstrual cycle phase is associated with quality of recovery after surgery in premenopausal women.



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Cohort Study: Tan et al.

Prospective single-centre cohort; Epworth Richmond (May 2019–Oct 2021)

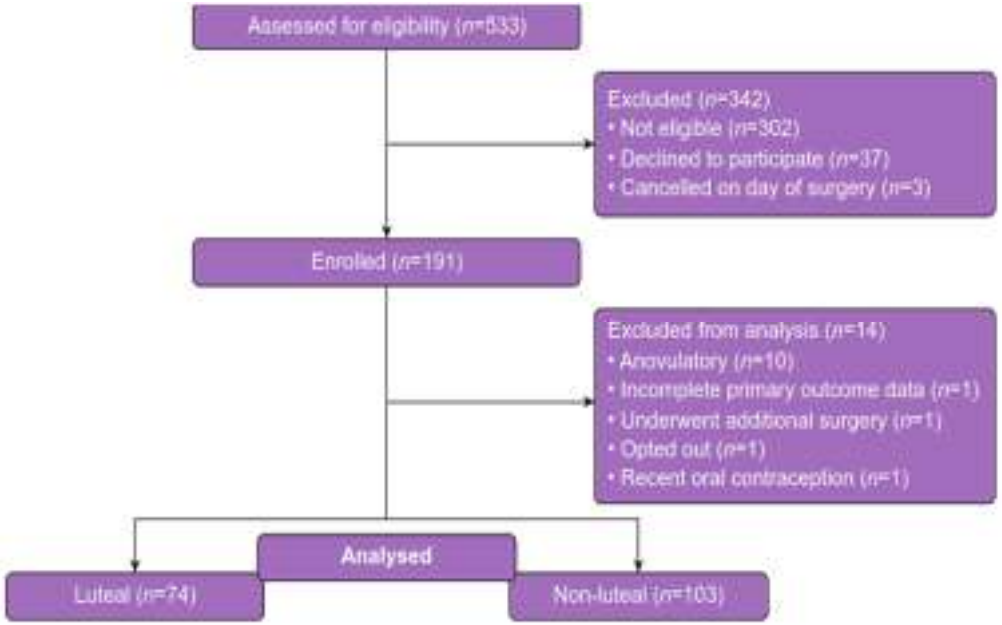
Eligibility

- Women aged 18 to 45 yr
- Wisdom teeth extraction or laparoscopic cholecystectomy under general anaesthesia with volatile agents

Analysed n = 177 premenopausal women (74 luteal, 103 non-luteal)

- Determined using a combination of patient-reported menstrual cycle history and preoperative blood progesterone level

Primary outcome: Quality of Recovery-15 (QoR-15) at 24 hours



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MISCH contribution: Protocol

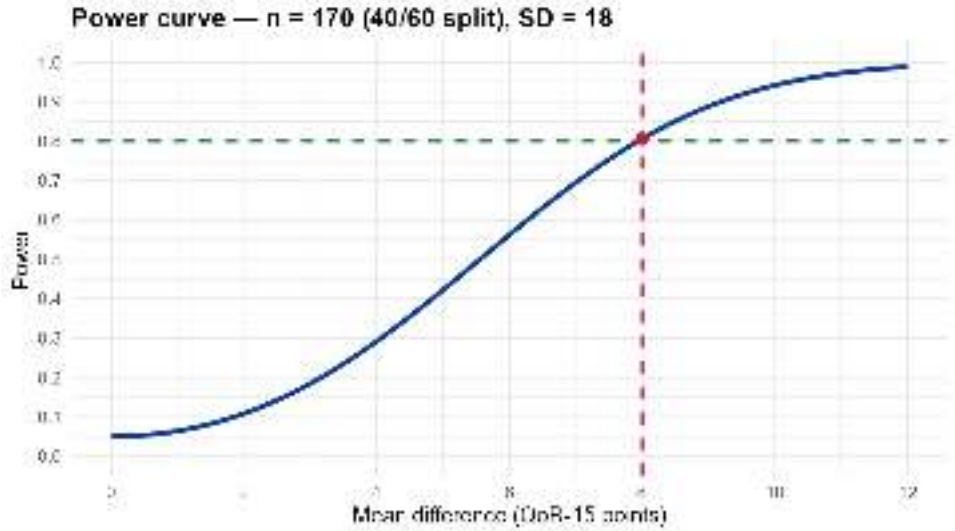
- Contribution to protocol development
- Pre-specified primary and secondary objectives and outcomes
- Defined study population, inclusion/exclusion criteria, recruitment timing and follow-up schedule
- Planned complete-case primary analysis with explicit sensitivity plan for multiple imputation if >20% missing



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MISCH contribution: Power & Sample Size

- **Two-sample means** test (luteal vs non-luteal groups)
- **Target effect:** MCID*=**8 points** on QoR-15 (primary outcome, 24 h)
- **Power and significance:** **80% power**; two-sided **5% significance** level
- **Assumed group allocation:** **40/60** imbalance (≈ 68 vs 102 participants)
- **Assumed variability:** equal **SD=18** points in both groups
- No correlation between baseline QoR-15 and 24-h score
- **Missingness allowance:** anticipated **5% missing** → increase from 170 → 180 participants
- **Final recruitment target:** increased to 191 (Ethics-approved) to allow for anovulatory participants who cannot be classified



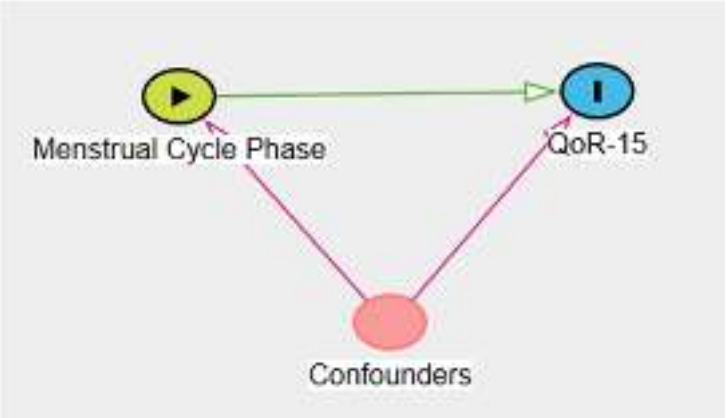
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*minimum clinically important difference

MISCH contribution: Statistical Analysis Plan

- **Primary analysis population:** complete cases (consented, underwent surgery); anovulatory excluded from primary analysis
- **Pre-specified subgroup analysis** if numbers allowed: surgery type
- **Pre-specified confounder set** to be included in adjusted models:

  Age, BMI, surgery type, current smoker, history of PONV, history of motion sickness, number of antiemetics in theatre, number of antiemetics in recovery, opioids in theatre, and opioids in recovery

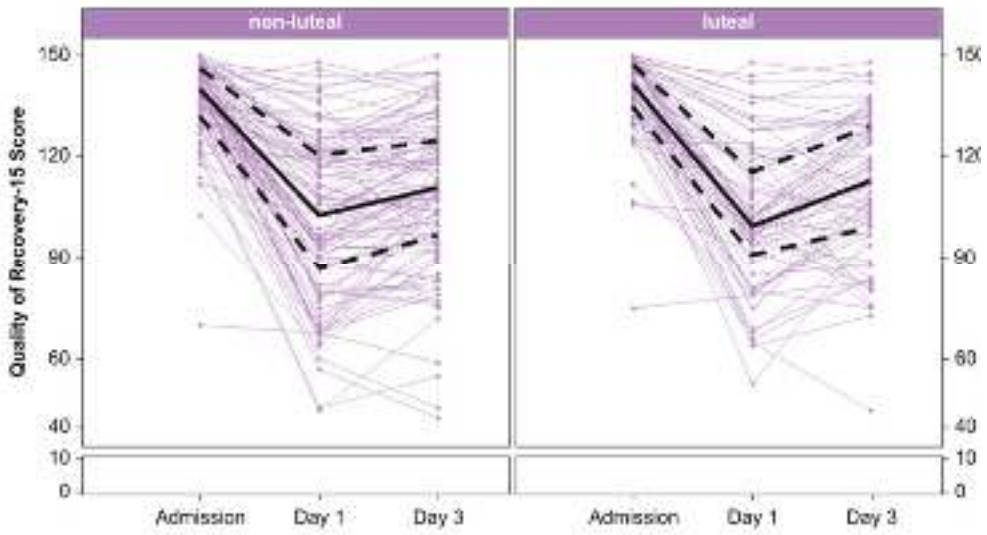


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MISCH contribution: Statistical Analysis Plan

- **Primary model:**
  - Linear mixed model with random intercept (accounts for within-patient clustering)
  - Estimated absolute mean difference (luteal vs non-luteal) with two-sided 95% CI at 24 h (primary) and Day 3 (secondary)

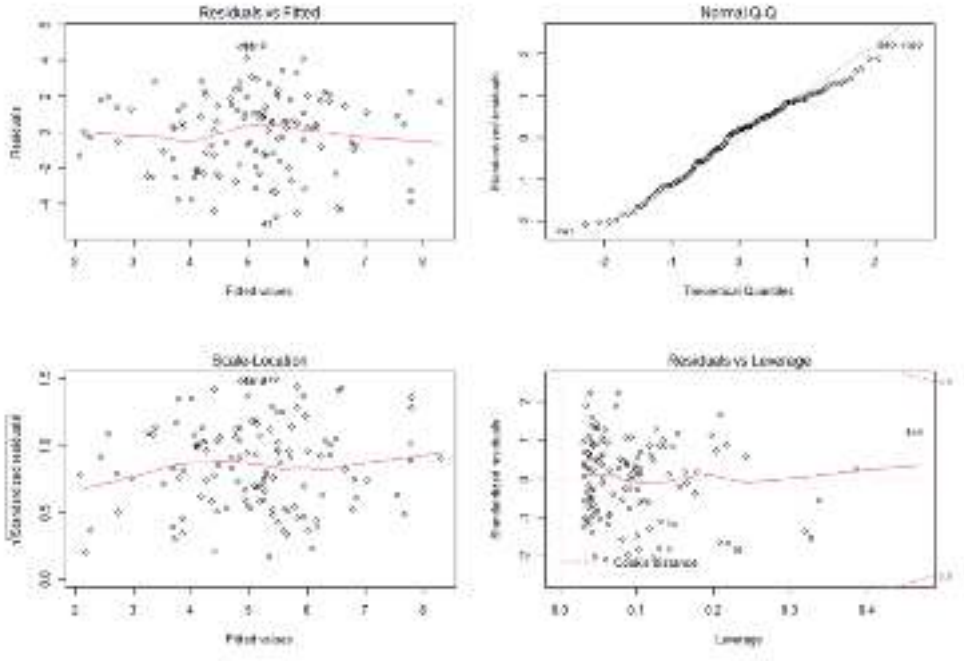
- **Surgery-type effect:**
  - Interaction term (surgery type × cycle phase) included if subgroup sample sizes permitted



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MISCH contribution: Statistical Analysis Plan

- **Secondary outcomes*:**
  - Pain Numeric Pain Rating (continuous; linear regression)
  - Subjective Analgesic Effect (ordinal; ordinal logistic regression)
  - PONV impact (binary; logistic regression);
  - Unplanned/prolonged admission (binary, logistic regression)
- **Assumption checks and diagnostics:**
  - Brant test to assess proportional-odds assumption for ordinal models
  - Diagnostic plots (e.g. linearity, residual vs fitted, influential observations, normality of residuals and random effects etc.)



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*Unadjusted and adjusted models fitted

Deliverables MISCH provided

Final SAP and reproducible R scripts (modelling and diagnostics)

- **Minimizes Bias**
- **Prevents P-Hacking**
- **Valid inference**

Sample size/Power calculation

Final report summarising the statistical analyses and assisting with manuscript preparation.

Publication-quality figures and tables

Methods text and tables aligned with reporting guidelines

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Predictive: Metcalf et al.

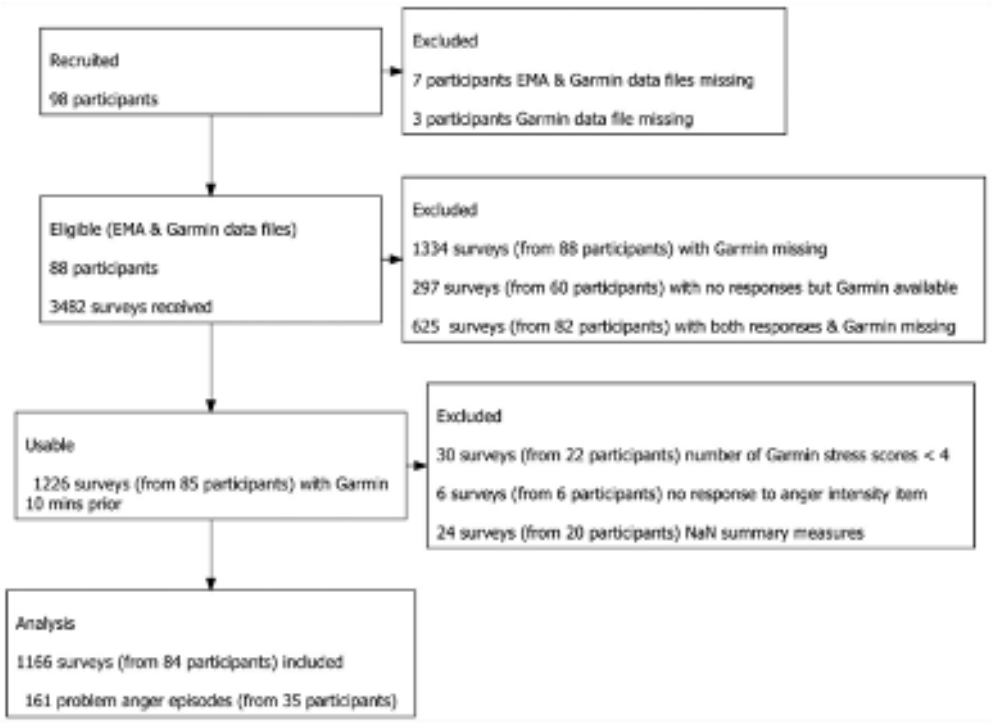
- **Background:**
  - >70% of adults will experience a traumatic event in their lifetime, with problem anger a common mental health issue in individuals who have experienced trauma
  - Characterized by rapid, frequent, and disproportionate escalations in anger that harms individuals and their relationships
  - Linked to severe harms. e.g., suicidality, cardiovascular disease, dangerous and illegal driving, and relationship violence
  - Triggers the body's "fight or flight" response, leading to physiological changes, e.g., faster heart rate, increased blood pressure, and tense muscles
- **Aim:**
  - Examine whether continuously measured physiological stress captured by wearable sensors can predict self-reported anger intensity



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Study Design

- Cohort study using ambulatory assessment
- Gather data as participants go about their daily life via repeated self-report surveys or wearable devices
- 100 adults (>18 years) with problem anger who have experienced a previous traumatic event
- Data collected at three time points:
  - Time 1: Pre-ambulatory self-report surveys
  - **Time 2: Ambulatory assessment (for a 10-day period)**
  - Time 3: Post-ambulatory self-report surveys and qualitative interviews



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Ambulatory Assessment

- Self-reported **anger intensity**, **anger frequency/duration**, **verbal aggression**, **physical aggression**, **pain**, **sleep**, **alcohol use**, and **rumination**
- Surveys delivered to each participant's smartphone via an app
- Four times a day with an individualised schedule
  - Nominated daily waking time prior to study commencement
  - First survey occurs randomly within one hour of the waking window
  - Second, third and fourth surveys occur randomly within four-hour intervals after the first
- Commercial wearable device (Garmin Vivofit 4) continuously records **heart rate**, **inter-beat interval**, **stress**, **steps per day**, and **GPS location**



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Outcome: Problem Anger



Derived from anger intensity item in ambulatory assessment



Participants asked to “Rate the overall intensity of the anger or irritability that they felt right now”

10-point Likert scale

1 (lowest intensity) to 10 (highest intensity)



Problem anger was defined as an intensity score ≥ 7

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Predictor: Garmin Stress Score

Stress scores captured by a Garmin wearable device

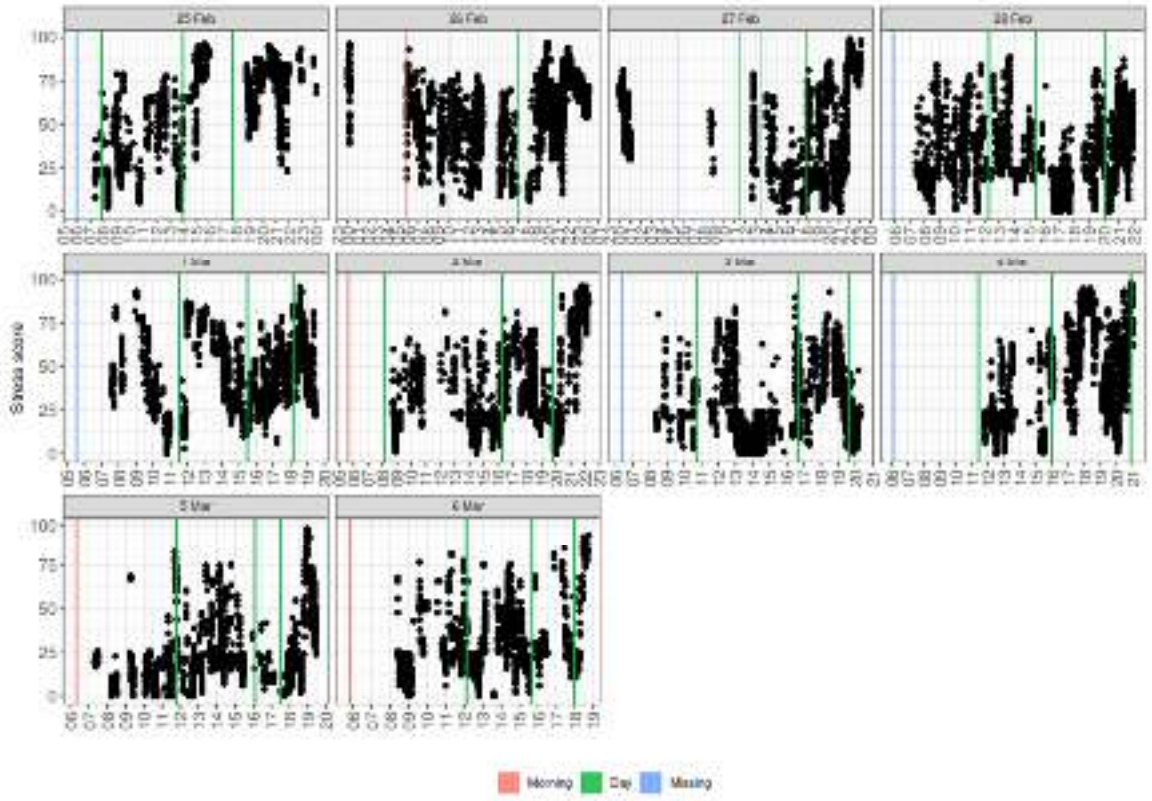
Garmin devices use heart rate variability (HRV) to calculate stress level based on an algorithm from Firstbeat Analytics

- Device takes a baseline HRV measurement when the participant is inactive
- Compares subsequent values to resting value to determine stress scores on a range from 0 to 100 (higher values = greater stress)

Stress scores captured within 10 mins prior to a completed survey were included in the analysis

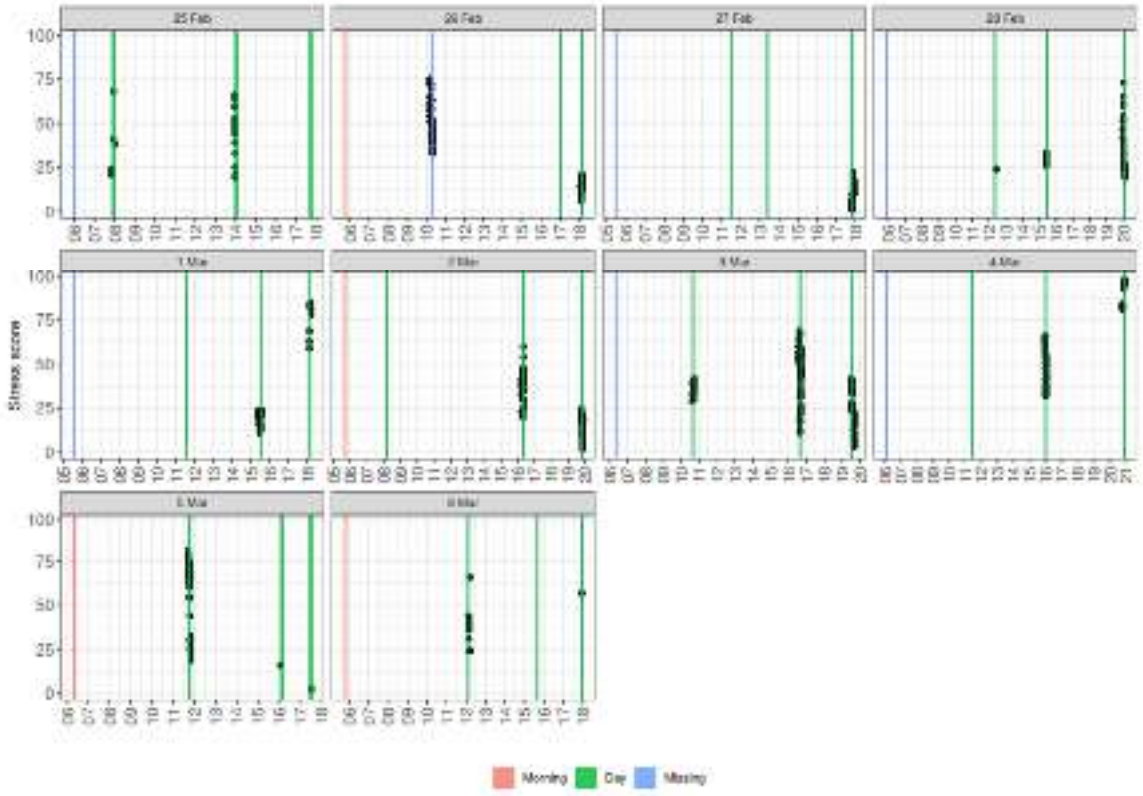
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Garmin Stress Score



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Garmin Stress Score - 10 Mins Prior



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MISCH contribution: Sample Size



Planned n = 100 participants → 40 measurement occasions each → 4,000 possible outcome observations



Missingness assumption: up to 30% missing → ~2,800 usable observations (≈28 per participant)



Outcome prevalence assumption: 25% of recorded observations are high-intensity anger (≥7)



Effective sample size ≈ 200 for prediction analyses

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MISCH contribution: Sample Size

Prediction-modelling sample-size approach

- Evaluated against three criteria — shrinkage, overfitting and precision

Detectable signal:

- With effective n ≈ 200, minimum detectable Cox–Snell R2 ≈ 0.04 for a single predictor (wearable stress score, range 1–100) while ensuring shrinkage = 0.9
- Overfitting criterion: satisfied for a plausible maximum Cox–Snell R2 ≈ 0.53 based on null-model log-likelihood estimates
- Precision (margin of error): estimated margin of error for baseline risk ≈ 0.06

[Riley et al. (Statistics in medicine, 2019)]

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MISCH contribution: Preprocessing & Feature Selection

Data pipeline and quality checks:

- Built reproducible pipelines to processing/clean Garmin data, align timestamps with EMAs, quantify missingness patterns

Feature selection:

- Implemented Leffondré et al. (Journal of Clinical Epidemiology, 2004) summary measures (24 candidates) and factor analysis to select 5 non-redundant features
- Capture nonlinearity/linearity, inconsistency in changes (many short-term fluctuations), large peak/spike or valley
- Features standardised so comparisons between features reflect relative importance.

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MISCH contribution: Modelling & Validation

Modelling framework:

- Generalised Linear Mixed Model (logistic)
- Two random effects structures examined (participant; day-within-participant) to respect clustering

Robust validation strategy:

- Implemented temporally aware CV to avoid information leakage:
  - train/test splits,
  - forward-chaining, and
  - population-informed forward chaining

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MISCH contribution: Modelling & Validation

Calibration:

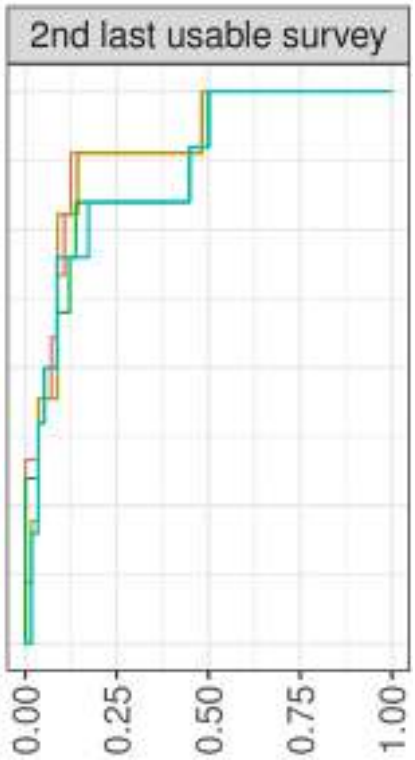
- Assessed calibration intercept/slope

Discrimination:

- Area under the receiver operating curve (AUC)
- Reported balanced accuracy and confusion matrix

Sensitivity analyses:

- Explored GAMMs for nonlinearity, alternative time windows, different thresholds, and inclusion of covariates



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Deliverables MISCH provided

End-to-end reproducible pipeline:

- Data processing/cleaning
- Feature selection
- Temporally aware validation: train/test splits, forward-chaining CV, and population-informed forward-chaining
- Interpretation, reporting & manuscript support
- Model fit diagnostics and sensitivity analyses

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Introduction to Prediction Modelling

TOP ORGANIZER
by **MISCH**
73 followers • 49 events • 5y hosting • 1.5k total attendees

Follow

School of Population and Global Health (Level 5 Room 515) · Parkville, VIC
Monday, November 9-Tuesday, November 10 • 1 PM-5 PM

Overview

This short course provides a practical introduction to prediction modelling over two half days 1-5pm.

The course starts with an overview of the main types of quantitative research questions in which data analysis plays a central role, and how to distinguish betwen descriptive, predictive and causal questions. It then presents a roadmap to addressing predictive research questions, and explains the key concepts and tools needed to develop diagnostic and prognostic prediction models, assess predictive model performance, and carry out internal and external validation.

https://clinicalresearch.mdhs.unimelb.edu.au/training-resources/events/introduction-to-prediction-modelling

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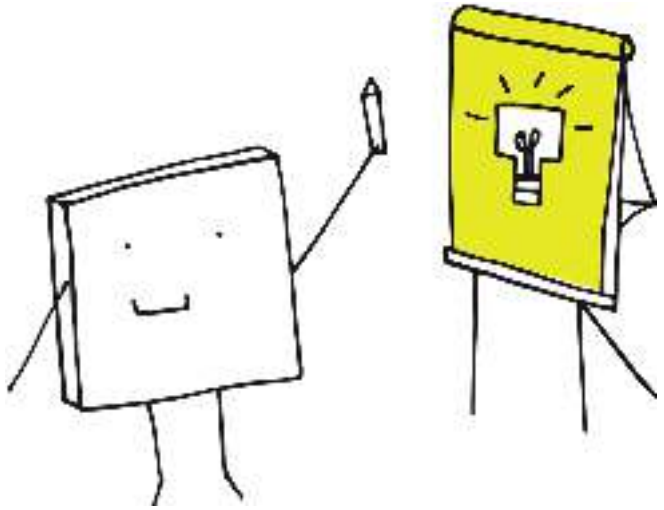
Concluding remarks

- Biostatisticians can and should be involved in observational quantitative studies in health research!

- Biostatisticians can help determine whether a descriptive, causal or prediction study is needed

- As in trials, biostatisticians help with:

  Research question refinement
  Study design
  Protocol development
  Survey/database development and review
  Statistical analysis plan
  Data cleaning and analysis
  Reporting and interpretation



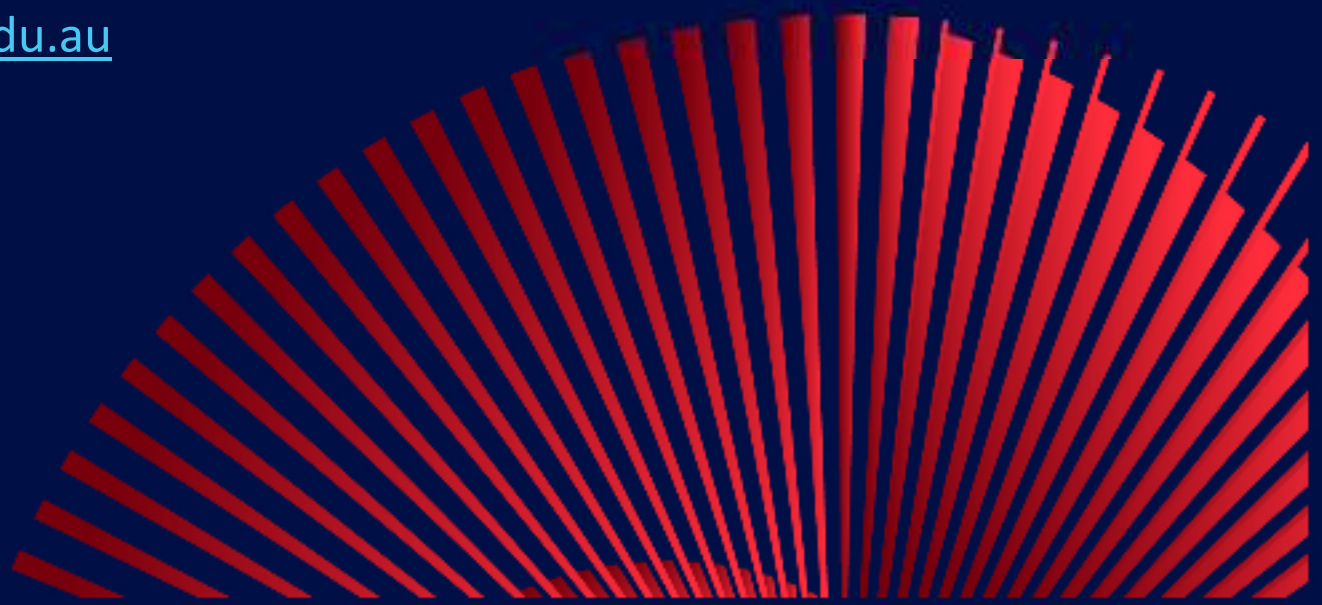
- Involve a biostatistician early to avoid disappointment!

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Thank you

- :-https://clinicalresearch.mdhs.unimelb.edu.au/
- :- misch-info@unimelb.edu.au
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