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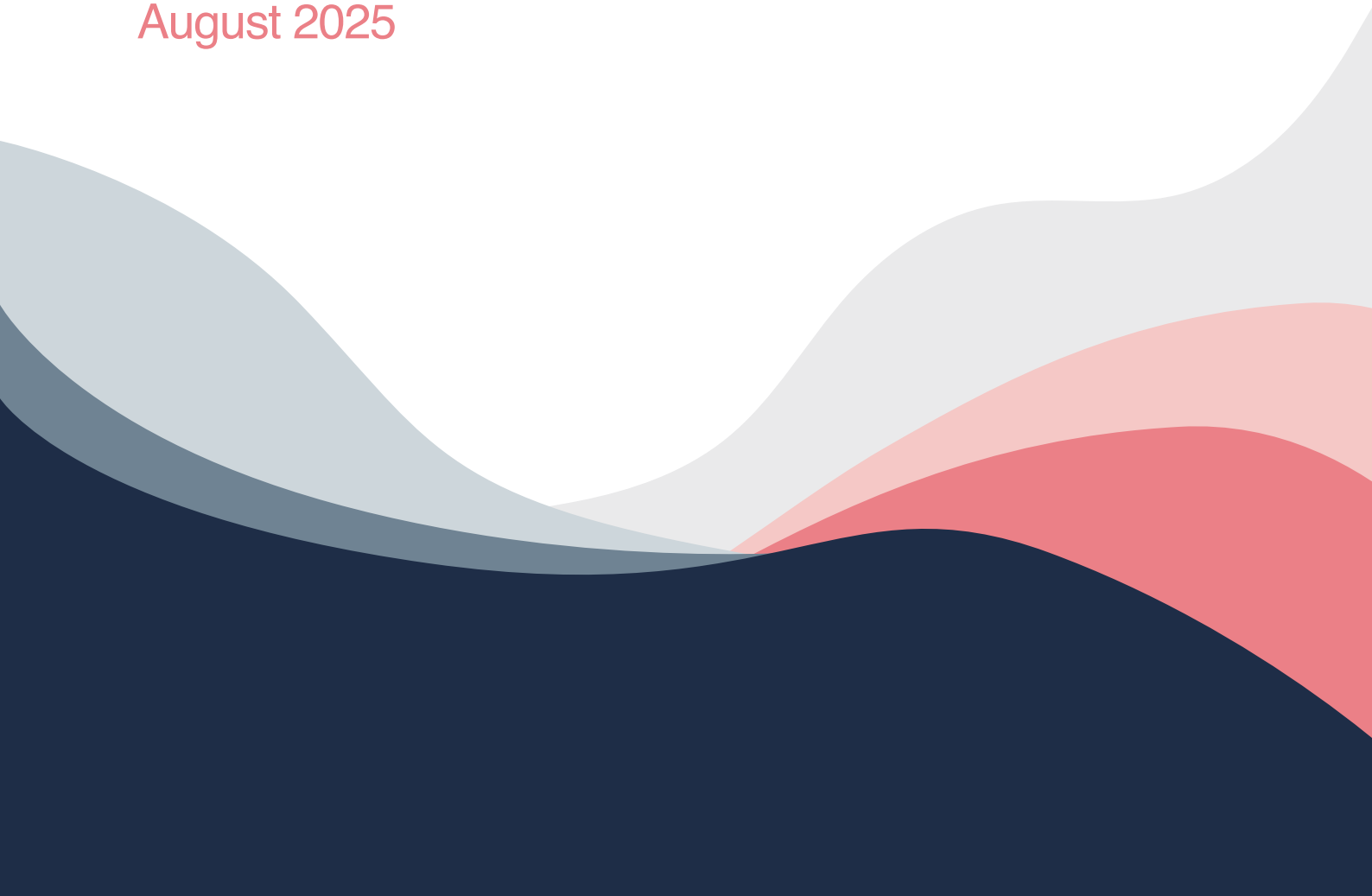
Pilot and feasibility studies: Guidance for anaesthesia investigators

August 2025



Purpose of document:

This guidance document provides an overview of what pilot and feasibility studies are, how to design and conduct them, and how they fit into the broader research landscape. It is informed by real-world examples and sector-specific considerations relevant to anaesthesia, perioperative, and critical care research in Australia and New Zealand.It is based on a presentation by Prof David Story at the 2020 ANZCA CTN virtual workshop.

Acknowledgements:

The development of the Anaesthesia Research Coordinator Network (ARCN) and ANZCA CTN toolkit is being led by the CTN office team, in collaboration with the ARCN sub-committee and the CTN executive. We gratefully acknowledge the contributions of the ANZCA CTN members, CTN office, ARCN sub-committee, and CTN executive in the creation, preparation, development, and review of this document.

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DOI

10.60115/11055/1332

Suggested citation for this document:

ANZCA Clinical Trials Network. Understanding and designing pilot and feasibility studies:*Guidance for anaesthesia investigators*. Melbourne: Australian and New Zealand College of Anaesthetists; 2025. doi.10.60115/11055/1332.

Document history:

Version	Contributors	Reviewed/Approved	Date Approved by ARCN Sub-Committee & CTN Executive	Changes
1.0	Prof David Story Paige Druce Gillian Ormond Karen Goulding	Dhiraj Bhatia Dwivedi Kasey Button Prof David A. Scott AM	1/8/2025	Creation

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Pilot and feasibility studies: Guidance for anaesthesia investigators

Based on a presentation by Professor David Story at the 2020 ANZCA CTN Workshop.

1. Introduction

Pilot and feasibility studies play an important role in strengthening the design and success of clinical trials. They are especially important for emerging researchers, honours and postgraduate students, and clinical trial networks like ANZCA CTN. These studies help clarify whether a research idea is operationally, ethically, and scientifically viable before moving on to large-scale trials that require significant investment. A well conducted pilot study will be an important component of a funding application for a future, larger clinical trial.

This guidance document provides an overview of what pilot and feasibility studies are, how to design and conduct them, and how they fit into the broader research landscape. It is informed by real-world examples and sector-specific considerations relevant to anaesthesia, perioperative and pain medicine, and critical care research in Australia and New Zealand.

2. Definitions and purpose

What is a feasibility study?

A feasibility study is a broad term for research designed to determine:

- Can we do this research?
- Should we proceed?
- How can we proceed effectively?

Feasibility studies are conducted to identify unknowns or anticipated barriers in research delivery, including access to data, patient recruitment, protocol compliance, resource availability, staff engagement, and ethical considerations.

What is a pilot study?

Pilot studies are a subset of feasibility studies. They mimic the future full-scale study on a smaller scale, including core components like:

- Randomisation
- Intervention delivery
- Outcome measurement, including unexpected outcomes
- Site and staff engagement

Key Insight: Pilot studies should not aim to test hypotheses about treatment effectiveness. Instead, they focus on the feasibility and logistics of trial delivery.

3. Why conduct pilot and feasibility studies?

Strategic reasons

- Prevent large-scale failure: Avoid wasting money and time on trials that won't work in real-world settings.
- Improve grant success: Demonstrate feasibility to funders (e.g., National Health and Medical Research Council (NHMRC), Medical Research Future Fund (MRFF),Health Research Council (HRC)).

- Strengthen trial design: Identify and refine protocols, interventions, and workflows.

Career development benefits

- Publishable output: Feasibility is an emerging research field with reputable journals.
- Valuable for degrees: Ideal for honours, Masters, and PhD students.
- Safe learning curve: Allows trial-and-error in a low-stakes format.

4. Feasibility across research types

Feasibility studies are not limited to randomised trials. They also apply to:

- Cohort and observational studies: Can we collect the required data across sites?
- Health services research: Will workflows or policies allow the intervention?
- Public health and informatics: Are data systems and software compatible and affordable? e.g. data linkages
- Preclinical/lab research: Can technical or biological methods scale appropriately?

5. Design considerations

Mixed methods approach

- Quantitative: Recruitment rates, dropouts, protocol deviations, data completion compliance.
- Qualitative: Interviews/focus groups with clinicians, patients, and coordinators about acceptability, barriers, and improvements.

Best practices

- Predefine progression criteria (e.g., recruitment target, protocol compliance).
- Avoid testing or over-interpreting the primary endpoint of the intended full trial. Data from a pilot study may however inform the expected primary event rates overall.
- Engage frontline staff early: nurses, coordinators, surgeons, Intensive Care Unit (ICU) clinicians.
- Carefully choose a diversity of sites to take part at this stage as they will provide you with input for the larger trial.

6. Example: RELIEF pilot study

RELIEF was a large multicentre trial investigating restrictive versus liberal fluid strategies during and after surgery. Prior to launching the main trial, a pilot was conducted in three hospitals.

Key elements:

- 82 patients randomised.
- Demonstrated capacity for ~2L difference in fluids administered across arms.
- Identified logistical feasibility, ethics processes, and clinician acceptability.
- Outcomes supported the feasibility of the larger RELIEF trial.

This illustrates the pilot's role in confirming that protocol fidelity and treatment separation were achievable.

7. Reporting standards: CONSORT extension for pilot studies

The CONSORT 2016 Extension for pilot and feasibility studies is the gold standard for reporting.

- 26-item checklist
- Encourages transparency, rigor, and comparability
- Includes progression criteria and reflection on unintended consequences

Use CONSORT not just to write up your study, but to design it.

8. Publishing pilot and feasibility studies

Where to publish

- Pilot and Feasibility Studies (BMC Open Access)
- Implementation Science
- BMC Medical Research Methodology
- BMJ Open (selectively)
- Less high-impact journals e.g. Anaesthesia and Intensive Care

Key points for publication

- Negative or "stop" results are publishable if methodologically sound.
- Avoid overanalysis of clinical outcomes.
- Highlight implementation insights and future study recommendations.

9. What if the pilot study shows the trial is not feasible?

This is still a meaningful outcome and should be communicated. Examples include:

- Poor protocol adherence.
- Low patient or clinician engagement.
- Recruitment bottlenecks.
- Logistical failures.

Publishing failed feasibility trials helps the sector avoid duplication and refine ideas. The lessons learned may also help in the planning of the next study, not necessarily on the same topic.

"A failed pilot study is better than a failed large trial."

10. Practical tips for researchers

- Pilot work can strengthen funding applications and ethics submissions.
- Feasibility trials are ideal for honours/Masters/PhD students.
- Timeline: 9–15 months from design to publication is realistic.
- Use small college or institutional grants (e.g., ANZCA project grants).
- Collaborate with experienced mentors and statisticians.
- Consumer engagement is becoming vital in trial design and conduct (patients/community members, research coordinators).

11. Registration and ethics

- Registration (e.g. ClinicalTrials.gov or Australia and New Zealand Clinical Trials Registry (ANZCTR)) is best practice but not always required.
- Ethics committees increasingly expect registration for transparency.
- Even qualitative or observational feasibility studies benefit from public listing.

12. Pilot versus small underpowered randomised controlled trial (RCT)

Pilot study	Small underpowered RCT
Designed to assess feasibility	Designed to assess effectiveness (poorly)
Mixed-methods and progression criteria	Underpowered analysis of clinical outcomes
Explicitly not for hypothesis testing	Risks drawing invalid conclusions
Accepted by funders and journals	Increasingly discouraged

"Stop doing small, crappy randomised trials." — Professor David Story

13. Final thoughts

Pilot and feasibility studies:

- Allow researchers to refine ideas and avoid costly missteps.
- Are critical tools for building capacity and credibility.
- Are well suited to emerging researchers seeking experience and impact.

For more guidance or support, reach out to the ANZCA Clinical Trials Network and explore:

- Pilot and Feasibility Studies journal
- The CONSORT Pilot Extension
- NHMRC/MRFF/HRC funding guidelines for feasibility research (check the individual funding round for these guidelines).

14. Contact:

ANZCA CTN Office