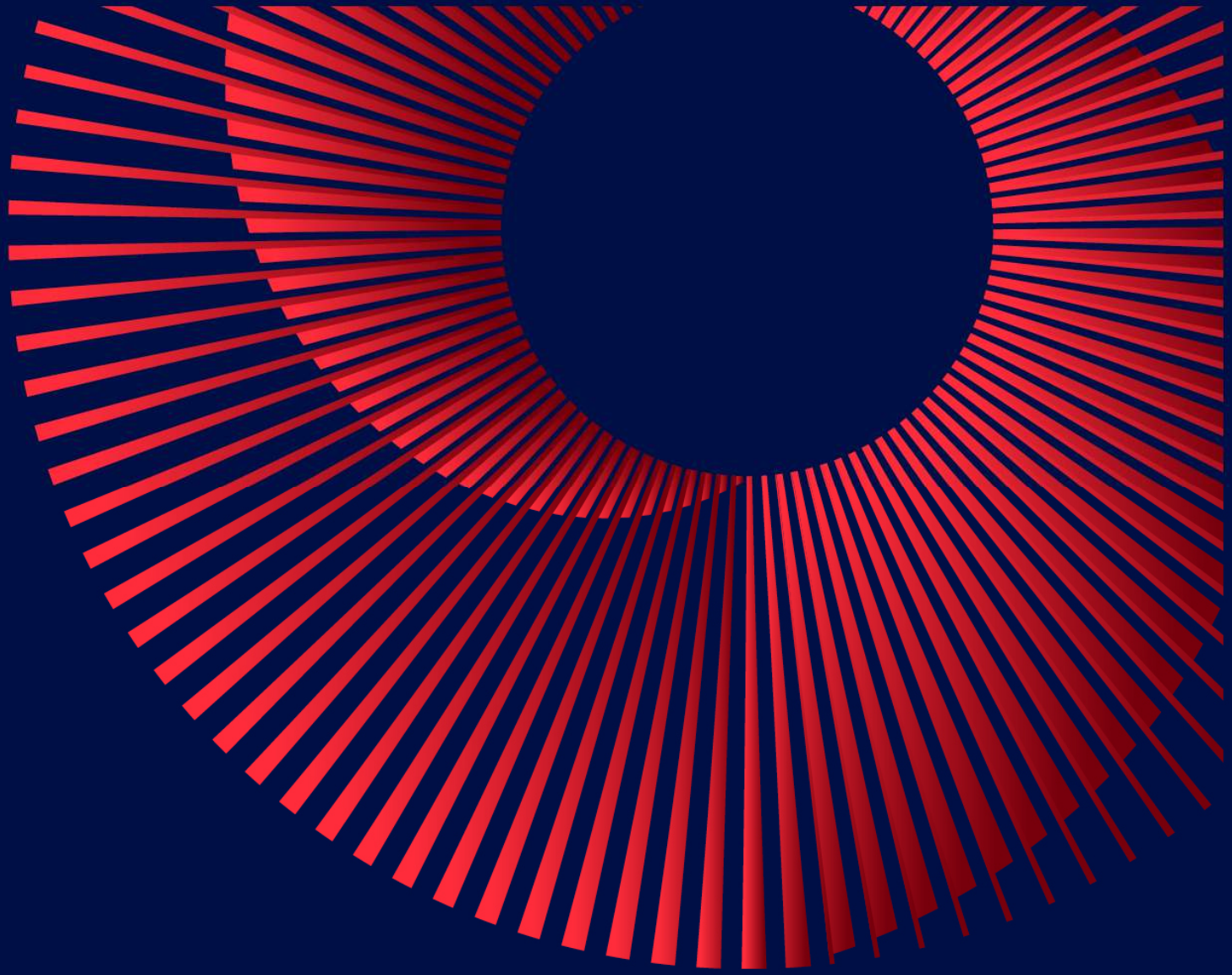
THE UNIVERSITY OF MELBOURNE

Faculty of Medicine, Dentistry and Health Sciences

MISCH *Hub*

Methods and Implementation Support for Clinical and Health Research



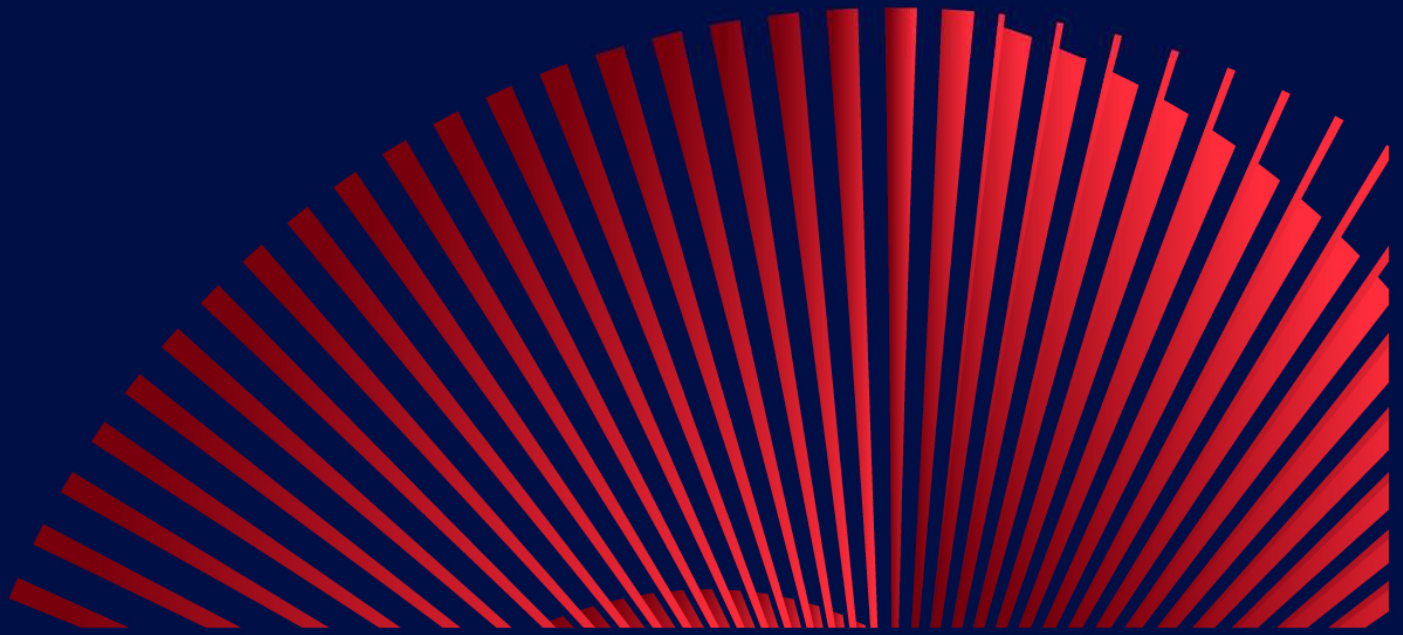
Acknowledgment of Country



Co-design and consumer involvement in clinical trials

MACH EMCR Research Design Webinar series

18 June 2025




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MISCH co-design and consumer involvement node support

- **Grant development support** – provide methodological and ethics application support and advice to ensure robust co-design and/or consumer involvement phase in research design that is fit for purpose.

- **Subscription model** – provide advice on and design project plans and information packs, design recruitment strategy and materials, plan and run co-design workshops and run consumer reference groups, analyse qualitative data and contribute to report writing. Can be multi-nodal across MISCH.

Consumer involvement in clinical trials

- Brief primer – what is co-design and consumer involvement?
- Setting the scene – why involve consumers in clinical trial research?
- The challenge: building confidence and capacity
- Two ways to incorporate consumer involvement in clinical trials
- Four principals to keep in mind
- Case study – PRE-TREAT randomised controlled trial



What is consumer involvement and co-design in health research?

- **Consumer involvement**: where individuals with lived experience of a health condition and/or their carers/families or those who represent consumers actively participate in shaping research questions, design and implementation.

- **Co-design**: a methodology that actively involves people with lived experience of a health condition and/or their carers/families, consumer groups, health professionals, researchers and other stakeholders to design health processes, services and interventions. It’s a collaborative and iterative process.

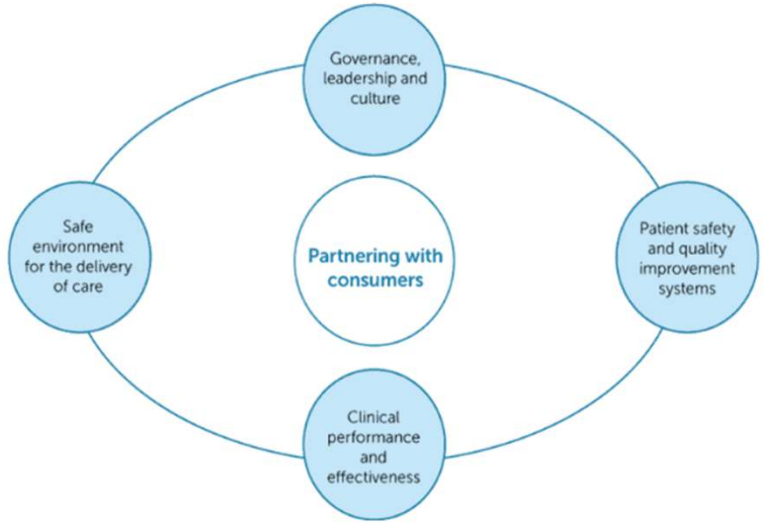
Consumer involvement in clinical trials

Australian Commission on Safety and Quality in Health Research:

- Australian Charter of Human Rights
- National Clinical Trials Governance Framework

MACH:

- National Clinical Trials Governance Framework Implementation Workbook for Partnering with Consumers



Consumer involvement in clinical trials

National Health and Medical Research Council (NHMRC)

DRAFT Statement on Consumer and Community Involvement in Health and Medical Research (2025)

"Consumers and communities bring valuable skills, perspectives, and lived experience to the research process. Their involvement adds value to all aspects; early research planning, conducting the research, translating and communicating the results, evaluation of research, and peer review. There are benefits to involving relevant consumers and communities in research, and an ethical responsibility of researchers, institutions, and funders to do so." (Principle 1 – Consumers and communities are involved in all stages, levels and types of health and medical research)

Australian Government
National Health and Medical Research Council

The challenge: building confidence and capacity for consumer involvement in clinical trials

Clinical trial teams are keen to involve consumers, but may lack:

- confidence
- time
- understanding of where to find the right people
- experience in how to manage expectations of consumers (McKenzie, et al., 2022)

This can lead to uncertainty and risks of tokenistic or superficial engagement



McKenzie et al.
Research Involvement and Engagement (2022) 8:3
https://doi.org/10.1186/s40900-022-00338-w

Research Involvement and Engagement

RESEARCH ARTICLE Open Access

A snapshot of consumer engagement in clinical trials in Australia: results of a national survey of clinical trial networks and research organisations

Anne McKenzie[1], Janelle Bowden[2], John R. Zalcberg[3,4], Karena Conroy[5,6], Julia Fallon-Ferguson[7,8], Shilpanjali Jesudason[9,10], James Ansell[11], Ania Anderst[12] and Nicola Straiton[13,14*]

Two ways to involve consumers in clinical trials

Consumer reference groups
(drawing from existing advisory or steering committees)

Across the life of the project

Help to drive the direction, review documents, provide insights and represent their communities

Co-design working groups
(drawing from existing or new networks)

Iterative workshops over months (multiple times across the life of the project)

Help to co-design documents, recruitment flyers, compliance tools

Consumer Reference & Co-design Working Groups



CONNECT EARLY

Engage consumer organisations for effective partnerships.

CLARIFY INFLUENCE

Define how consumers will impact the research process.

SUPPORT PARTICIPATION

Create an inclusive environment for all participants.

SHARE POWER

Ensure equitable involvement among all group members.

Case study – PRE-TREAT RCT (Treatment Preventing COPD) led by Prof Shyamali Dharmage - MSPGH

Background

Tasmanian Longitudinal Health Study (TAHS)

- Commenced in 1968
- Currently in 7th decade follow up testing
- Nearly 7000 of the original cohort still actively involved



Tasmanian Longitudinal Health Study

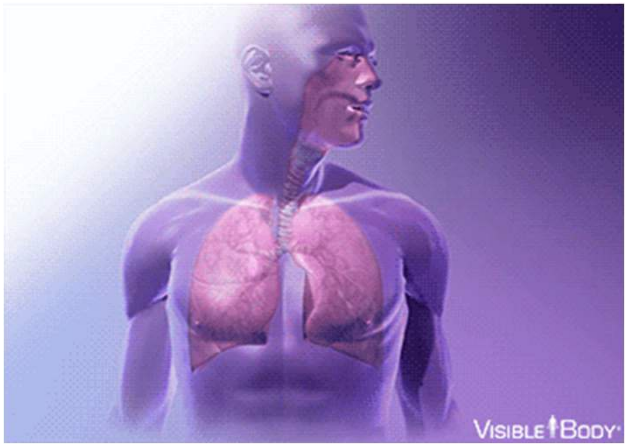
Freecall 1800 110 711

What is the PRE-TREAT RCT Trial?

This is the first study to test the Triple Therapy treatment to see if works to slow or stop COPD (Chronic Obstructive Pulmonary Disease) from developing. These medications are already used to treat people with COPD.

Triple therapy combines three medications into one inhaler:

1. **Inhaled steroids** to reduce inflammation in the lungs.
2. **Long-acting beta agonists (LABA)** to help keep the airways open.
3. **Long-acting muscarinic antagonists (LAMA)** to help the airways stay open longer.

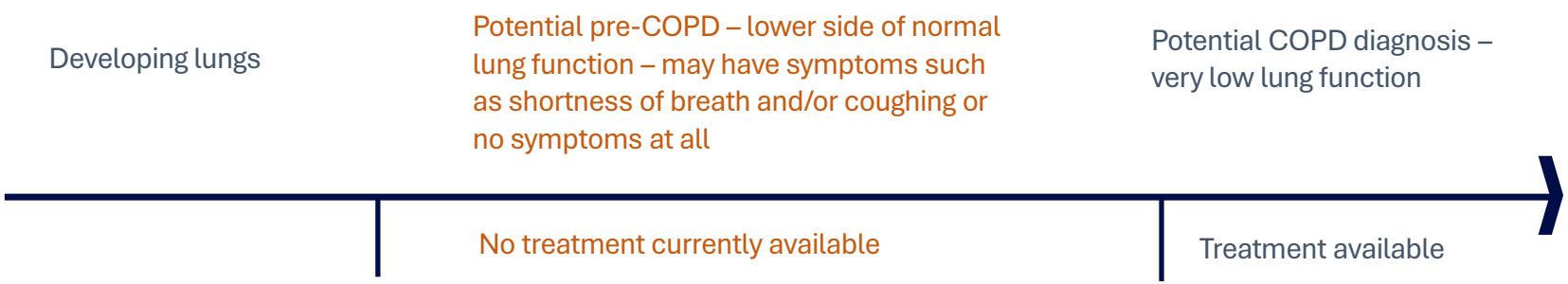


If we can prevent COPD by intervening in the early stages, we could help people avoid becoming seriously ill later in life. The goal is to protect lung health and improve quality of life for people at risk of COPD.

What is Pre-COPD?

COPD is usually diagnosed when lung function becomes very low, and by then, some lung damage is permanent.

This is why researchers are now focusing on the long period (typically many years) before the development of COPD- called pre-COPD. Pre-COPD is not a formal medical diagnosis.



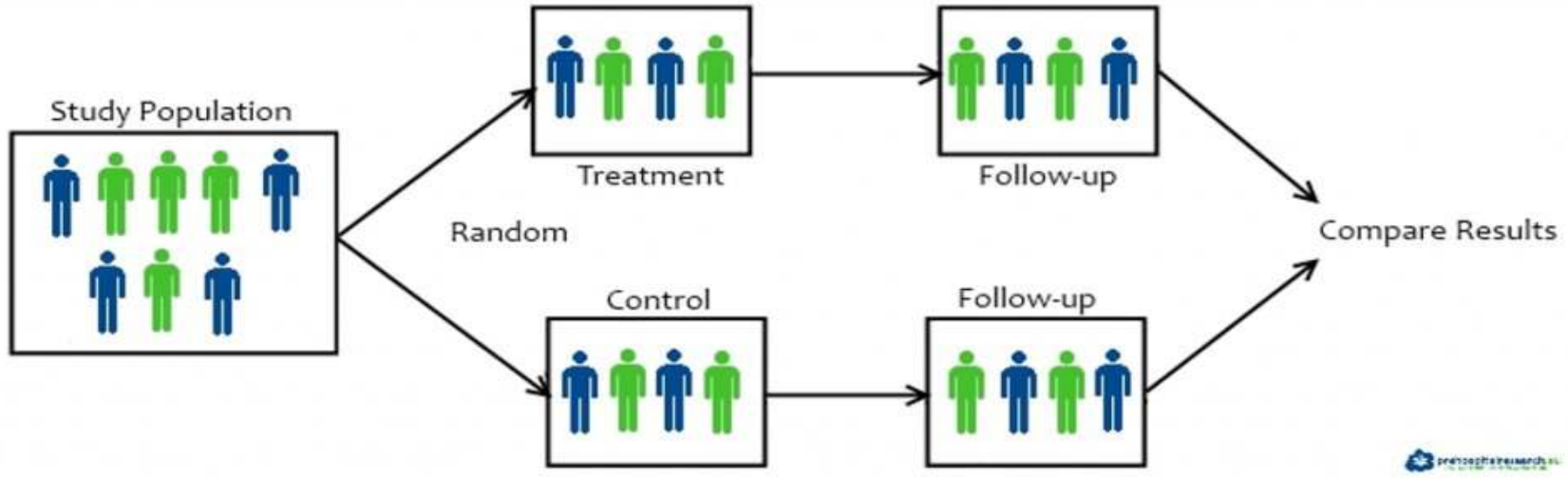
Right now, there is no treatment for pre-COPD.

PRE-TREAT RCT STUDY

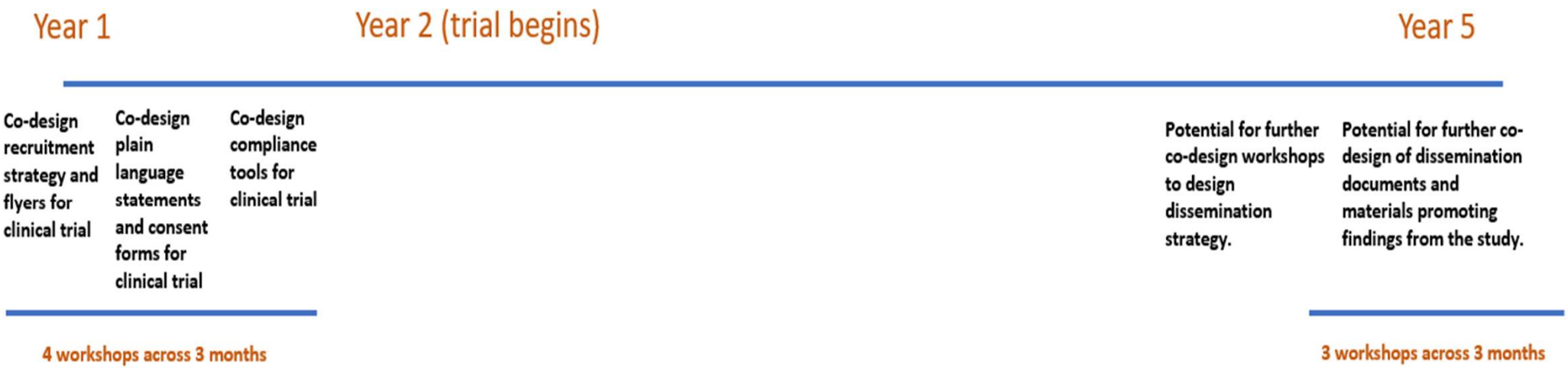
Researchers are inviting **500** participants from the **Tasmanian Longitudinal Health Study (TAHS)** who have shown some indication of lower lung function (pre-COPD) to take part in a new randomised controlled trial.

Study Goals:

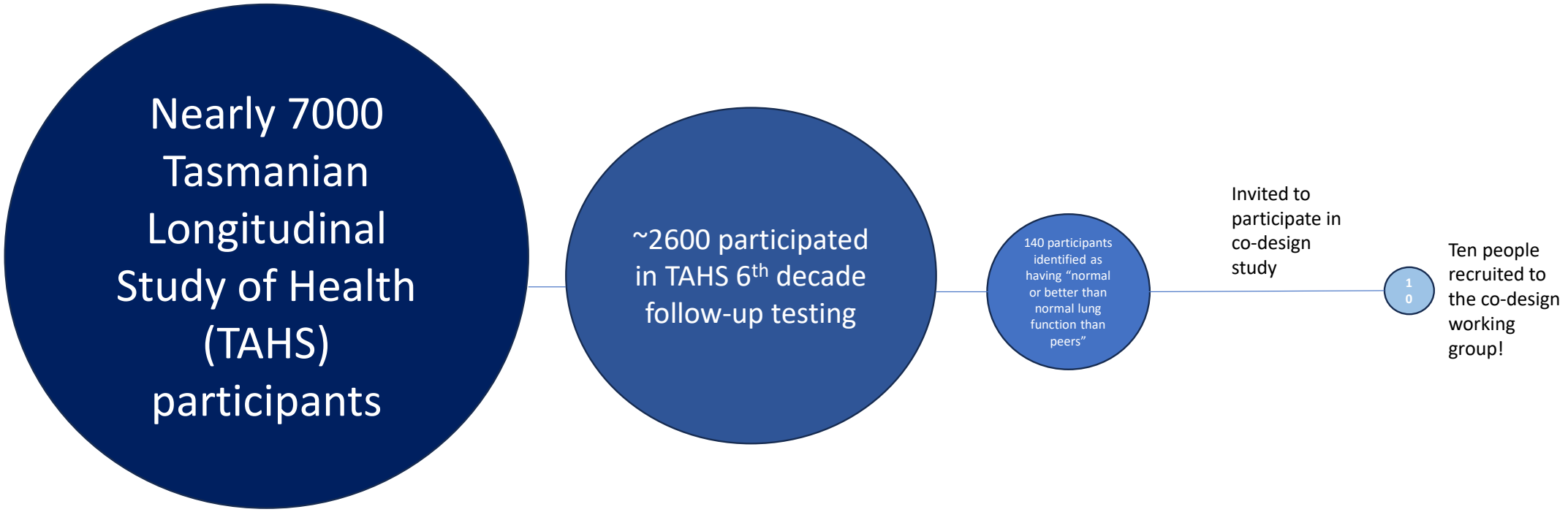
1. Test if triple therapy can help slow down lung function decline and prevent further damage.
2. Learn more about pre-COPD—how it progresses and how people respond to different treatments.



Co-design Working Group – PRE-TREAT RCT



Co-design Working Group



Co-design Working Group



Workshop 1, in-person – May 2025 – 5 attended

- Co-designed 2x recruitment flyer options for PRE-TREAT RCT
- Co-designed 1st draft of plain language statement for PRE-TREAT RCT
- Developing FAQ for RCT participants

Workshop 2, online – June 2025 – 5 attended

- Finalised PLS, recruitment flyer
- Identified barriers to adherence, provided ideas for retention strategies

Workshops 3-4, online – (July and August 2025)

- Consider inclusions for compliance diaries
- Respond to feedback from RCT research team
- Respond to additional questions from RCT research team

Community Reference Group



The group will:

- Include a consumer chair, 4 people currently living with COPD and 2 TAHS participants (supported by co-design facilitator)
- Review study materials co-designed by consumers prior to ethics application submission
- Discuss issues that arise during the RCT study
- Reflect their communities' priorities into the research
- Discuss findings as they arise
- Review dissemination strategy (to be co-designed)



Summary

- Timing
- Clarifing influence
- Supporting participation
- Sharing power

Thank you

- Website:-https://clinicalresearch.mdhs.unimelb.edu.au/
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