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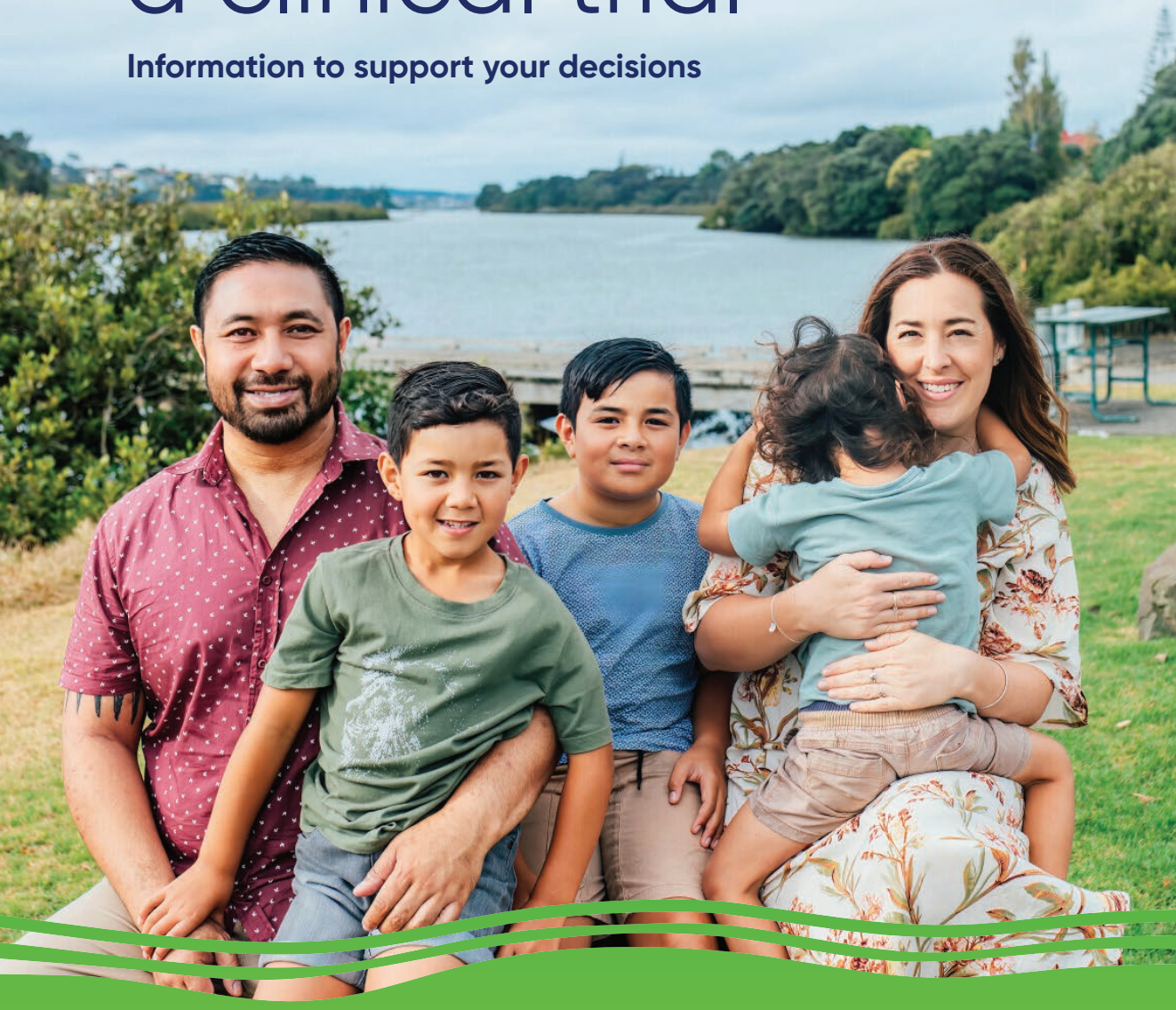
Aotearoa Clinical Trials
Te Kohinga Ora

Taking part in a clinical trial

Information to support your decisions



Your participant journey

1. Thinking about a clinical trial? Start here
2. What taking part looks like - your clinical trial journey
3. Your safety, rights, and responsibilities
4. Ready to take the next step?

www.aotearoatrials.nz

Quick-start overview

A clinical trial progresses through the following steps:

→ Step 1

First conversation

Conversation with a doctor, research nurse or coordinator. Find out about the study, ask questions. There is no pressure to take part in a trial, it is your decision.

→ Step 2

Detailed information about trial

Written information is provided so you can read it in your own time and discuss it with whānau/family or your GP.

→ Step 3

First trial visit informed consent

The study is explained again before you sign a consent form. You can withdraw at any time.

→ Step 4

First trial visit checking eligibility

This often involves checking medical history, taking bloods and a physical examination. Other tests may be required. Not everyone is eligible, if you are not eligible, the trial doctor may be able to discuss other options. We explain what will happen next, so you know what to expect.

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→ Step 5

During the trial

You will attend regular in person or phone visits, this will allow for close monitoring of your progress. Trial-related medicines, travel and parking are free. Continue attending your regular appointment with your family doctor or specialist.

→ Step 6

If you're worried

Contact us if you have concerning symptoms, change your medication, or if you have questions or concerns. We're here to support you.

→ Step 7

End of study & follow-up

You will attend a final visit for the trial. Results help improve care for future patients. Thank you for being part of research that matters.

Thinking about a clinical trial? Start here

Deciding whether to take part in a clinical trial can feel like a big step.

You might be looking for new treatment options, wanting to understand your condition better, or simply gathering information.

At Aotearoa Clinical Trials, our role is to support you. We help you understand your options, answer your questions, and give you the time you need to decide whether a clinical trial feels right for you.

In short:

- A clinical trial is a carefully monitored study of a treatment or intervention
- Taking part is always voluntary
- Your safety, wellbeing, and choices come first
- You can stop at any time
- You continue with your usual medical care

If you're not sure where to start, that's okay. This guide will walk you through the process, step by step.

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Is a clinical trial right for me?

What is a clinical trial?

A clinical trial is medical research that involves people. Trials help doctors, and researchers find out whether new medicines, devices, or treatments are safe and work as intended.

Before a clinical trial can begin:

- It must be reviewed and approved by an **Independent Ethics Committee**
- It must meet strict safety and quality standards
- The treatment/intervention has been tested, often in non-human e.g., lab trials
- Participant rights and wellbeing must be protected

Why do people choose to take part?

People take part for many reasons, including:

- Their current treatments are not helping enough
- There are no other funded treatment options available
- They want access to new or emerging therapies
- They want to take an active role in their health
- They want to help improve care for others in the future

There is no "right" reason - only what feels right for you.

Types of clinical trials

There are different kinds of clinical trials:

Interventional trials

These test a treatment, such as a medicine, medical device, or therapy, to see whether it helps a condition.

Non-interventional (observational) trials

These do not involve a new treatment. Researchers observe health information over time to better understand a condition.

Your trial team will explain exactly what type of trial you are being invited to join.

How clinical trials progress

Clinical trials happen in stages, called phases:

Phase 1
Small groups; focuses on safety and side effects.

Phase 2
More people; looks at how well the treatment works.

Phase 3
Larger trials compare the new treatment with standard care.

Phase 4
Ongoing monitoring after approval and public availability.

Each phase builds on what is already known, with safety monitored at every step.

Where can i find a clinical trial?

You can:

- Talk with your GP or specialist doctor
- Browse the Recruiting Trials webpage on our website
- Contact our team. We're happy to talk things through

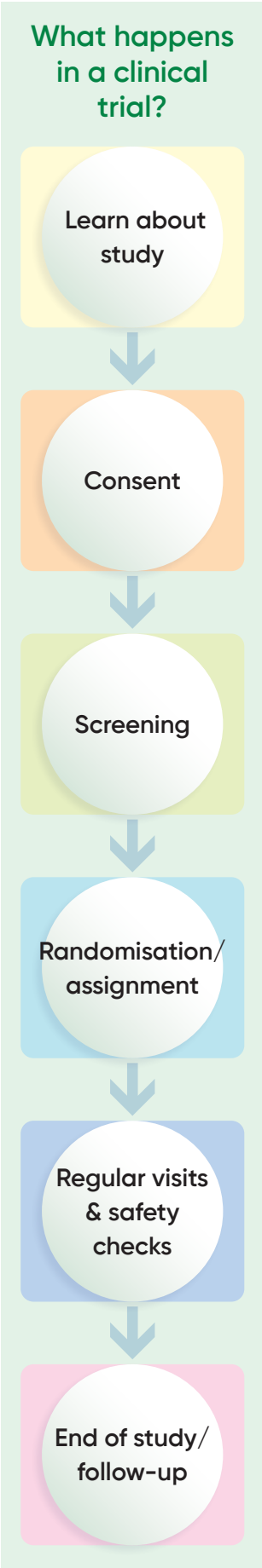
Call - 0800 Enroll (0800 367 655)

Text or call - 021 574 509

Email - participants@aotearoatrials.nz

Visit our website for more information - www.aotearoatrials.nz/participants

What taking part looks like



Your clinical trial journey, step by step

We know the unknown can feel worrying. Here's what usually happens.

Before you join

- You talk with a research doctor, nurse or coordinator
- The trial is explained in plain language
- You receive written information to read in your own time
- You can discuss taking part with your whānau/ family or GP
- There is no rush and you do not have to take part
- Not taking part will not affect your care

Joining the clinical trial

If you choose to proceed, an appointment will be made for you at one of our research sites. At his visit we will:

- Discuss the trial and ask you to sign an **Informed Consent Form**, confirming you understand what's involved
- Check that you appear to be eligible. This usually involves checking your medical history, taking bloods and a physical examination. It may also involve other tests, depending on the trial

You can only take part in **one clinical trial at a time,** for safety reasons.

Making sure the trial is right and safe for you/checking you are eligible

If you consent to take part, the research team check whether you are eligible and that the trial is safe and suitable for you. Sometimes this is called screening.

Screening may include:

- A discussion with the research doctor or nurse
- A review of your medical history
- Physical checks, blood tests, imaging scans and/or questionnaires

The team may consider:

- Your age and stage of disease
- Your health history and current medicines
- Whānau/family or genetic factors (if relevant)

Many people are screened for each trial to help ensure the safety of people taking part and the results are credible.

A few important things to know:

- Not everyone who is screened will be able to join a trial
- Being excluded from one trial does not mean you can't take part in another
- Screening is about safety, not suitability as a person

If a trial isn't the right fit, the team will explain why and talk with you about other options.

If you have questions about screening or results, please ask - we're happy to explain.

During the clinical trial

- You attend scheduled trial visits
- Your health is monitored closely
- You are given contact details so you can reach the team as required
- All trial-related medicines and certain expenses are covered
- You continue seeing your usual doctor (family doctor and/or hospital doctor) for routine care

After the clinical trial

- You attend a final visit in person or via a phone call
- The team explains what happens next
- Trial results are analysed to help improve future care
- If you have asked to, you will receive a copy of the trial results

Your safety, rights, and responsibilities

Your rights as a participant

You always have the right to:

- Ask questions at any time
- Take time to decide
- Bring whānau/family or support people to visits
- Withdraw from the trial at any stage
- Continue receiving your usual medical care
- Have your privacy protected

Your participation is always voluntary.

Your personal information is kept confidential and handled according to local privacy laws.

Your responsibilities

If you choose to take part, we ask you to:

- Attend scheduled trial visits
- Follow study instructions
- Tell the team if your health, medicines or circumstances change
- Ask questions if anything is unclear

Benefits and risks

What are the benefits?

Participants often value:

- Close monitoring and specialist doctor care
- Access to new treatments not yet widely available
- Learning more about their condition
- Feeling supported and listened to
- Helping improve care for others

What are the possible risks?

All treatments have risks. These may include:

- Side effects, some of which may be unexpected
- The treatment may not help you
- You may be placed in a comparison or placebo (no treatment) group. This varies by trial and will be discussed before you agree to take part (consent)

These risks are explained clearly before you decide, and your safety is monitored throughout the study.

Whangārei Site Manager Kayley King (left) and participant Mary

"My specialist was calm, warm, and full of knowledge. He mentioned a trial that might be opening soon. I didn't know anything about clinical trials, but I trusted him."

Between visits – if you're worried or something changes

If you're unsure what to do, start here and follow the steps below.

Emergency – get immediate help

Call **111** or go to the **Emergency Department** if:

- A symptom feels life-threatening
- Symptoms are rapidly worsening
- You feel unsafe waiting for advice

Tell them you are taking part in a clinical trial and/or show them your clinical trial card that contains details of the trial that you are taking part in. You will have been given this card when you consented to take part. Your safety comes first.

Need trial-related advice or something has changed - call or text the Trial Team

Contact the Research Nurse or Coordinator if:

- You notice new or worsening side effects
- You feel unwell and are concerned
- Something doesn't feel right
- You're unsure whether a symptom is serious
- There are any changes to your medications
- The trial team have asked you to notify them of any specific changes or symptoms
- If you are hospitalised for more than 24 hours

We are open between 8am and 4pm Monday to Friday except Public Holidays. If you are concerned about your health outside of these hours or cannot contact the Research Nurse or Coordinator, please seek alternative medical advice.

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Non-urgent – See your family Doctor/ GP for advice

Please contact your family Doctor/GP if:

- Your health concern is not related to the trial
- It affects other medications that are not part of the trial treatment, for example you need a repeat prescription for non-trial medication

Your family Doctor/GP is an important part of your healthcare. You should continue to see your family doctor/GP for all non-trial related medications and health concerns.

We need to know if:

- You start, stop, or change any medicines (including over the counter or herbal products)
- Your health changes
- You visit another doctor, urgent care clinic, or hospital
- You are admitted to hospital or receive a new diagnosis

Sharing this information helps us keep you safe and understand the study better. Even if you tell us of these changes over the phone, write any changes down and bring to your next visit to ensure that all changes to your health or medication are recorded accurately.

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Support for you and your whānau/family

Whānau/family play an important role in health and wellbeing. They are welcome to:

- Attend appointments
- Help review information
- Support decision-making
- Be part of your care journey

We are committed to providing culturally safe and respectful care for all participants.

Ready to take the next step?

Whether you're ready to join a trial, want to learn more, or are simply curious, we're here to help.

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Text or call - 021 574 509

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