What is a clinical trial?

Information for potential or new trial participants to assist in making an informed consent.

Te Kohinga Ora
Middlemore Clinical Trials

Contents

What is a clinical trial?

A clinical trial is medical research involving people.

Before a new medicine can be approved by Government regulators for testing in humans, it undergoes stringent scientific testing trials to make sure it's safety profile is known. All trials in humans must be reviewed and approved by an Independent Ethics Committee (IEC) before they commence to make sure that possible risks to patients are minimised.

There are two main categories of clinical trials.

Interventional clinical trials.

Interventional clinical trials are research studies performed in people that are aimed at testing a medical, surgical, or behavioural intervention.

They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device (for example, a pacemaker) is safe and effective in people. Often a clinical trial is used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment.

Non-Interventional clinical trials.

Non-interventional/Observational trials observe people in normal settings.

Researchers gather information, group volunteers according to broad characteristics, and compare changes over time. For example, researchers may collect data through medical exams, tests, or questionnaires about a group of older adults over time to learn more about the effects of different lifestyles on mental health. These studies may help identify new possibilities for clinical trials.

What are the four phases of clinical trials?

Clinical trials advance through four phases to test a treatment, find the appropriate dosage, and look for side effects.

Clinical trials of drugs are usually described based on their phase.
Typically regulators require Phase I, II, and III trials to be conducted to determine if the drug can be approved for use.

If, after the first three phases, researchers find a drug or other intervention to be safe and effective, the government regulator approves it for clinical use and continues to monitor its effects.

I **A Phase I trial** tests an experimental treatment on a small group of often healthy people (20 to 80) to judge a drug or device's safety and side effects.

II **A Phase II trial** uses more people (100 to 300) and the aim is to assess the effectiveness of the drug or device and whether the drug works in people who have a certain disease or condition. These trials also continue to study safety, including short-term side effects. This phase can last several years.

III **A Phase III trial** uses up to 3000 people and aims to gather more information about safety and effectiveness of the drug or device. This is done by comparing it to other drugs or devices to treat a particular condition, studying different populations and different dosages and using the drug in combination with other drugs or devices.

IV **Phase IV trial** takes place after the new drug or device has been approved by regulators for use in humans. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes, the side effects of a drug or device may not become clear until more people have taken it over a longer period of time.

Why participate in a clinical trial?

There are many reasons why people choose to join a clinical trial. Some join a trial because the treatments they have tried for their health problem did not work. Others participate because there is no treatment available for their specific health problem.

By being part of a clinical trial, participants may find out about new treatments before they are widely available. Additionally some treatments are not funded by government programs and hence the only way they are available is through a clinical trial.

People say that participating in a clinical trial is a way to play a more active role in their own health care, as they develop a greater understanding of their own disease or condition. Other people say they want to help researchers learn more about certain health problems. Whatever the motivation, when you choose to participate in a clinical trial, you become a partner in scientific discovery and your contribution can help future generations lead healthier lives by the development of newer medicines.

Major medical breakthroughs could not happen without the generosity of clinical trial participants - such as yourself.

Liver function being assessed with a state-of-the-art fibroscan machine

A spirometry machine is used to measure lung capacity

Here's what happens in a trial:

- Trial staff (e.g trial nurse co-ordinator and doctor) explain the trial in detail and gather more information about you.
- Once you have had all your questions answered and agree to participate, you sign an informed consent form.
- You are screened to make sure you qualify for the trial.
- If accepted into the trial, you are given an appointment for a baseline visit. The researchers will do a series of tests during this visit, as described in your information sheet and consent form.
- You will be assigned to a treatment group as described in your information sheet and consent form.
- You and your family members follow the trial procedures and report any issues or concerns to researchers.
- You will be asked to visit the research site at regularly scheduled times for trial related evaluations and so that the research team can collect information about effects of the intervention and your safety and well-being.
- All trial related procedures and visits included in a trial are free of charge.

You continue to see your regular doctor for usual health care throughout the trial.

What does 'informed consent' mean ?

Informed consent is the process of ensuring that participants in a clinical trial understand the risks and benefits of being involved in a particular trial. It ensures communication between participant and the clinical trial staff (usually the doctor or nurse) so that the participant understands their role, as a "subject of research" and not as a patient.

Informed consent usually involves the trial being explained in detail by the supervising doctor. The participant is then given printed material about the trial to take away and discuss with their family or family doctor so that the participant can make the best decision for themselves as to whether to take part in a clinical trial or not.

Informed consent also explains what the participant's responsibilities are should they agree to take part in a clinical trial.

Where can I find a clinical trial?

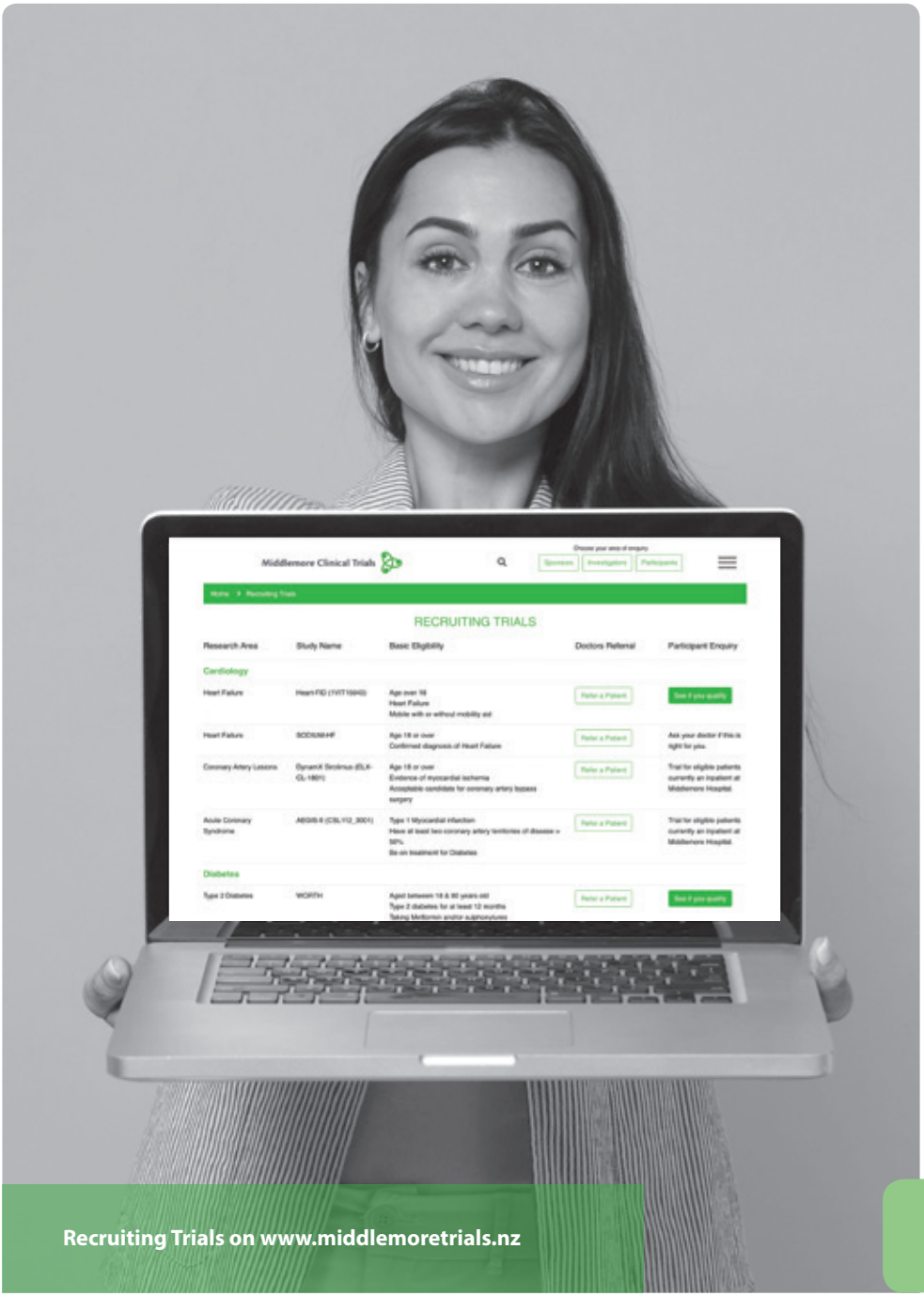
There are many ways you can get help to find a clinical trial. You can talk to your doctor or other healthcare provider. Or, you can search on our website under recruiting trials www.middlemoretrials.nz

Support groups and websites that focus on a particular condition sometimes have lists of clinical trials. Also, you may see ads for trials in your area in social media such as Facebook, the newspaper or on TV. Sometimes you may be invited by your hospital specialist, Primary Health Organisation (PHO) or family.

What is the next step after I find a clinical trial?

Once you find a trial that you might want to join, contact the clinical trial coordinator. You can usually find this contact information in the description of the trial. The first step is a screening appointment to see if you qualify to participate. This appointment will include the informed consent process which gives you a chance to ask questions about the trial.

Let your doctor know that you are thinking about joining a clinical trial. He or she may want to talk to the research team about your health to make sure the trial is safe for you and to coordinate your care while you are in the trial.



Recruiting Trials on www.middlemoretrials.nz

How do the clinical trial team decide who will participate?

After you consent, you will be screened by trial staff to see if you meet the criteria to participate in the trial or if anything would exclude you. Screening may involve both mental and physical tests.

Your age, stage of disease, sex, genetic profile, family history, your specific health problems or medications and whether or not you have a support person (if required) who can accompany you to future visits will all be considered to see if you can take part in a particular trial.

Many volunteers must be screened to find enough people for a trial. Generally, you can participate in only one trial at a time.

Different trials have different criteria, so being excluded from one trial does not necessarily mean exclusion from another.

What are the benefits of participating in a clinical trial?

- Improved access at no charge to Consultant Doctors, procedures and medicines.
- Close attention paid to your condition, including timely reviews and follow up by experienced clinical trial Doctors and Nurses.
- Access to new medications that may be helpful to your condition, but are not yet available to the market.
- Education on your condition and how you can manage or adapt your lifestyle to help your condition.
- Flexibility of visits times to try and fit in with busy lives and schedules.
- Helping others by being part of research that determines newer medicines for your condition.
- The research occurs in a controlled environment by utilising experienced research staff in a customised clinical trial unit under strict guidelines and processes.

What are the risks of participating in a clinical trial?

- You could experience unknown or unexpected side effects, so it is important you have your trial doctor and trial co-ordinators details in order to let them know If you experience any side effects.
- There may be no benefit from the experimental treatment.
- The experimental treatment may not be as effective as existing treatment.
- You are not able to choose which treatment you are on so you could receive placebo.

Adapted by MMCT from the National Institute of Health USA

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