



Understanding Clinical Trials and Research

A guide for people affected by cancer

Practical
and support
information

For information & support, call

13 11 20



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Note to reader

Always consult your doctor about matters that affect your health. This booklet is intended as a general introduction to the topic and should not be seen as a substitute for medical, legal or financial advice. You should obtain independent advice relevant to your specific situation from appropriate professionals and you may wish to discuss issues raised in this book with them.

All care is taken to ensure that the information in this booklet is accurate at the time of publication. Please note that information on cancer, including the diagnosis, treatment and prevention of cancer, is constantly being updated and revised by medical professionals and the research community. Cancer Council Australia and its members exclude all liability for any injury, loss or damage incurred by use of or reliance on the information provided in this booklet.

Cancer Council

Cancer Council is Australia's peak non-government cancer control organisation. Through the eight state and territory Cancer Councils, we provide a broad range of programs and services to help improve the quality of life of people living with cancer, their families and friends. Cancer Councils also invest heavily in research and prevention. To make a donation and help us beat cancer, visit cancer.org.au or call your local Cancer Council.



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Introduction

Cancer research is a vital part of health care. If you or someone you are caring for has been diagnosed with cancer, you might want to know about clinical trials or other cancer research that you or your family member can join.

There are many types of research about different types of cancer, including clinical trials of new treatments and population studies. Trials and research studies increase our knowledge about cancer and help find improved treatments and better outcomes for people with cancer and their families.

This booklet aims to help you make an informed decision about participating in cancer research. The first section covers general information about different types of research. The second section outlines how to get involved in a clinical trial or other research. It includes practical issues to consider and explains how you can be assured that Australian research studies are safe and reliable.

We hope this information will answer some of your questions and help you think about additional questions you may wish to ask your doctors or other health care professionals.

If you or your family have any questions, call Cancer Council **13 11 20**. We can send you more information and connect you with support services in your area. Turn to the last page of this book for more details.



**Cancer
Council
13 11 20**

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Key questions

Q: What is health research?

A: Health research refers to the many types of scientific investigations that aim to answer questions, test ideas, improve treatment options and increase knowledge about human health.

Q: Why is health research important?

A: What we know about cancer evolves over time as more and more research is done. Health research has helped make the medical treatments and health programs available today possible. These advances have contributed to the five-year survival rate from all cancers increasing from 47% to 66% in the past two decades.¹ However, the search for better methods of prevention, diagnosis and treatment for all human diseases is ongoing and requires the active participation of patients, carers and healthy people.

Q: Why participate in research?

A: The involvement of patients, carers and healthy people in research helps researchers learn more about a disease. Adults and children can participate in different ways, including:

- consenting to their medical records being accessed
- completing surveys
- having treatments that have never been given to people before or only to a small number of people
- agreeing to be examined regularly by health professionals.

Types of health research

There are three main types of health research: population research, laboratory research and clinical research. People affected by cancer mainly take part in clinical research.



Population research

This is also known as epidemiology. It studies the causes and effects of diseases in groups of people (populations). Scientists working in this field are called epidemiologists. They look for reasons that people get sick and also compare the health of different groups of people. Their findings often lead to recommendations for ways to reduce disease.

See page 9 for more information.



Laboratory research

Scientists conduct laboratory experiments with the building blocks of disease to try to understand how it works. They study cells, enzymes and DNA from humans and animals, or disease-causing agents such as chemicals, bacteria and viruses. Scientists also study and develop new drugs in the laboratory. Laboratory research is often the starting point for clinical research.

See page 11 for more information.



Clinical research

This focuses on the causes, diagnosis, treatment and prevention of illness in people. It is usually carried out in a clinical setting such as a hospital or outpatient clinic, and it often requires patient participation. It includes clinical trials that test new ways of preventing, diagnosing and treating diseases.

See page 15 for more information.

To find out more about participating in clinical trials or other types of cancer research, see pages 34–43. The *Making decisions* chapter (page 44) can help you weigh up the benefits and risks of being in a study and answer other questions you may have.

Q: Who can participate in research?

A: Both adults and children can participate, but children under the age of 18 need a parent’s or guardian’s permission. While most cancer research involves cancer patients, some studies target carers, family members, people at risk or people not diagnosed with cancer.

It is important that people of all ages and social, economic and racial backgrounds take part so the results reflect Australia’s diverse population.

Q: How many people participate in cancer research?

A: The participation rate of adults in cancer clinical trials is low worldwide. In Australia only 2–3% of adult cancer patients take part², and the rate is lower among minority groups and women. The participation rate is much higher for children – over 50% – even though there are far fewer children than adults who are diagnosed with cancer.² This has led to a great improvement in children’s survival rates because children have been able to access promising treatments, and the evidence for their effectiveness has been obtained quickly.

The number of people participating in other types of cancer research is unknown, but it may be higher than the clinical trial participation rate. This is because other research may need people during or after their treatment, there may be fewer restrictions and risks, and the time commitment is usually shorter.

Q: Is research safe?

A: Understandably, people want to know if there are any risks to them participating in a study. Researchers must follow strict guidelines to make sure studies are as safe as possible for everyone involved. This is called their duty of care.

All studies need to be approved by specially appointed research and ethics committees before they can begin. As part of this process, researchers describe risks, such as possible side effects, that they predict might occur. They must also explain how they will reduce these risks and what will be done if problems occur. For more information, see the chapter *Regulating research* on page 31.

Q: Where does research take place?

A: Research is carried out in many places, including hospitals, laboratories and universities. Sometimes you can participate from home – you might have treatment or medicines mailed to you, or you might be asked to fill in a survey or complete a telephone interview.

Q: Who funds cancer research?

A: Funding comes from many sources.

National Health and Medical Research Council (NHMRC) –

This is the Government's main funding body for medical research. NHMRC grants are awarded to researchers based on their ability to investigate important questions about human health.

Medical research institutions and clinics – These often use their own resources to support research.

Policymakers and government – The government and their advisers often require scientific information when making decisions about health programs. They sometimes provide funding for independent research on specific policy questions.

Government bodies – They offer a competitive grants program to fund research and to employ cancer trials staff.

Cancer charities – State and territory Cancer Councils and other charities receive donations from the public and grants from both public and private sectors. This funds their own research and supports research carried out by other institutions.

Private sector – Companies producing medicines and medical equipment run trials to determine safety and effectiveness before applying for licences to sell these products. Private companies may also fund research in partnership with a university or other research institution, or for goodwill (philanthropic) reasons.



Population research

Epidemiology is the study of how and why diseases occur in different groups of people (populations). It looks for patterns and trends in illness to work out why certain diseases, such as cancer, occur in some people but not in others. For example, it compares the health of people who have different lifestyles or occupations, live in different regions or come from different countries, and tries to determine the impact on health.

The key areas of epidemiology include:

Health services research – This investigates the quality of, and ease of access to, health services such as hospitals, specialists and allied health care practitioners. The aim is to find the best ways to help patients at all stages of disease and improve safety. Health services research also works out how much health care costs and can help identify where to direct funds for staffing, medical equipment and therapies.

Research into cancer causes – Researchers examine medical data, often from many hundreds or thousands of people, to understand what causes cancer and how it might be prevented. Research into the causes of cancer focuses on groups of people rather than individuals.

Modelling – This is a mathematical way of using information from the past to estimate what might happen in the future. For example, researchers use modelling to work out how many people are likely to be diagnosed with cancer in 10 years time, or how much funding will be needed to run a cancer screening program.

Types of population studies

The two most common types of population studies used in epidemiology include:

Cohort studies – These set out to answer the question, ‘What will happen to me?’ This involves identifying a large number of people, collecting information about them at the beginning of the study, either from medical records or through surveys, and then watching them over a period of time to see what happens to their health. Cohort studies are also called prospective studies.

Case control studies – These aim to answer the question, ‘why me?’ A case control study compares people who have a disease (the cases) with people who don’t have the disease but are otherwise similar (the controls). The study then looks back over a period of time to see if exposure to something in particular (e.g. at work, in the environment, lifestyle) was more likely in the group with the condition than in the group without. In some cases, the researchers may look at medical records. Case control studies are also called retrospective studies because they look back.



Laboratory research

Scientists carry out research in laboratories using the latest equipment. There are different types of laboratory research. They provide the basis for clinical research.

Basic research

Basic research looks at the body's basic building blocks – its cells and molecules – to find out how they function. This helps scientists work out why cancer starts or spreads and how it might be prevented or treated more effectively.

Basic research is sometimes called test tube research because of the equipment used in the laboratory. The main focus of basic research in cancer includes investigating:

- the role of molecules, such as enzymes or hormones, in starting or stopping cancer
- the role of genes in cancer
- new drugs and treatments.

Before treatments are trialled in humans, basic researchers need to show that they are likely to be safe, effective and not likely to cause life-threatening side effects. At first they test new drugs in cells in the laboratory. The cells are from samples of living tissue (a cell culture).

If the treatment has the desired outcome in the cell culture, it will be tested on animals. This gives scientists more understanding of how the treatment works, problems it might cause, and whether it might be useful in humans.

Animal research

Before drugs are approved for use by people, they are tested on animals. Mice are commonly used because they have similar genes to humans, breed quickly, have a relatively short life span and are easy to look after.

Some people ask whether it is fair to test medicines on animals. There are regulations to ensure that animal testing is only carried out if there's no alternative and that it is done in the kindest and most humane way. For more information, see nhmrc.gov.au.



'In vitro' (meaning 'in glass'), refers to experiments conducted in laboratory equipment such as test tubes and dishes. This is different to an 'in vivo' experiment, which means 'in a living thing' and refers to experiments involving humans or animals.

Stem cell research

Stem cells are the first cells that are formed when a person develops. Initially they appear the same, but they divide and change to become many different cell types. These eventually form the many tissues and organs in the body.

Because stem cells can potentially change into any kind of cell, researchers are investigating them in the laboratory for their possible use in cancer therapies. To find out more, see stemcellsaustralia.edu.au.

Pharmacogenetics

Pharmacogenetics is the study of how genes affect a person's response to drugs. It is sometimes called pharmacogenomics.

This new branch of research combines pharmacology (the study of drugs) and genetics (the study of characteristics passed down from biological parents). It investigates why some people respond well to a particular drug and others do not. It also considers why some people get side effects or have serious reactions to drugs, yet others are not affected.

Pharmacogenetics may eventually help doctors to select specific treatments for individual patients based on their genes. This will also help improve drug safety as more will be known about how and why certain medications affect different people.

Tissue banking

Tissue banking (or biobanking) involves collecting and storing groups of cells (tissue) removed during a medical procedure such as an operation, biopsy or blood test. Tissue can be from different parts of the body, for example, bone marrow, organs such as the liver, or blood. A tissue sample taken for research is also called a biospecimen.

Researchers use tissue banking to study cells, cancers and treatments in the laboratory. Researchers must seek permission from a human research ethics committee (see page 32) before using human tissue.

The person will be asked to consent to donating their tissue sample. If you agree to donate tissue, samples are collected at different stages of care:

- **Collected specifically for the tissue bank** – For example, you may need an appointment for vials of blood to be taken.
- **During a test or treatment** – For example, you may be booked in for a blood test, and an extra tube of blood will be taken for the tissue bank, or you may be asked to consent before scheduled surgery for tissue to be kept.



Clinical research

Clinical research is conducted on people to better understand, diagnose, prevent and treat diseases. Participants are usually patients, but may also include former patients and people who are well.

The different areas of clinical research



Human participation

Studies require contact with patients and/or healthy volunteers. Examples include clinical trials and surveys of people using questionnaires.



Record-based studies

These access personal data without involving any face-to-face contact. An example is an examination of patients' medical records.



Clinical samples

Laboratory studies examine human material such as blood or tissue obtained during surgery, from tissue sampling (biopsy) or in a post-mortem (autopsy).



Technology development

Researchers develop or adapt technology for diagnosis and therapies.

Clinical trials

Clinical trials are an essential step from laboratory research to real improvements in health care. They are part of the final stages of the long research process. Trials show whether new approaches to prevention, screening, diagnosis and treatment work better than those currently used, and whether they are safe.

There are several types of clinical trials designed to answer different research questions.

- **Prevention trials** – evaluate whether medicines or health programs lower the risk of developing diseases such as cancer.
- **Screening trials** – look at new methods of detecting diseases before symptoms appear.
- **Diagnostic trials** – identify more accurate or less invasive ways of diagnosing a particular disease in people who have signs or symptoms.
- **Treatment trials** – test new treatments, new ways of giving existing treatments, or new combinations of treatments such as drugs, radiotherapy, surgery, nutrition, physiotherapy and complementary therapies.
- **Quality of life trials** – designed to improve the comfort and quality of life of people who have cancer.

For more information, see *Clinical trials explained* on page 19.

Behavioural research

Behavioural researchers try to understand why people behave in the way that they do. They study people's individual characteristics, lifestyles and social circumstances to see how these factors affect the risk of someone developing cancer or surviving cancer.

Researchers also look at how cancer impacts people emotionally and socially. Behavioural research does not focus on what causes cancer. This is studied in the field of epidemiology (see page 9).

If you take part in a behavioural research study, you may need to fill in questionnaires or be interviewed about your lifestyle, including your eating, drinking, smoking, communication and exercise habits.

You may also need to participate in a program aimed at positively changing these behaviours. For example, you might be offered free counselling, an exercise class or a session on improving communication skills. The aim of the programs may be to reduce cancer risk or to improve the way you cope with cancer.

Psychosocial research

One area of behavioural research is called psychosocial research. This looks at how cancer impacts people emotionally, psychologically and socially. In cancer care this is sometimes called psycho-oncology. Researchers try to understand how patients and carers cope emotionally at different stages of disease. They develop and test methods to improve people's ability to deal with various issues.

Translational research

While it can take many years for research findings to become standard health care, there is pressure to use basic research (see page 11) to improve patients' lives as fast as possible.

Translational research aims to get new treatments or medical approaches into practice quickly. It is sometimes called 'bench to bedside research' because basic research results are directly used to create new therapies and diagnostic tools.

Findings in the clinic can also influence research in the laboratory. This is called 'bed to bench-side research'. For example, hospitals and health care professionals give information to researchers to help direct research into the most useful areas.

Often one institution oversees all aspects of a translational research project, from its beginnings in the laboratory to the rollout of a clinical trial and the commercial development of a medicine.



Clinical trials explained

Clinical trials look at new ways to improve the diagnosis, treatment and management of people with cancer. If a trial proves that a test or treatment is better than existing options, it may become the new standard care for patients in the future.

The majority of cancer clinical trials test anti-cancer treatments, particularly drugs, but also include radiotherapy and surgery. Most of the information in this chapter relates to trials of treatments.

The phases of a clinical trial

Researchers spend many years developing new treatments or medicines in the laboratory before involving people. They then plan the clinical trial to progress in a series of steps called phases. There are usually four phases, and information gathered in each phase determines whether the studies can move on to the next phase. See the next page for a description of the different phases.

There are also exploratory studies, sometimes referred to as 'Phase 0 trials' or 'pilot studies'. These trials are less common, and are used to test how the body responds to an experimental drug before moving to Phase 1 trials. A small dose of the drug is given once or for a short time to a limited number of people.

To find out how to get involved in a clinical trial or another type of study, see page 34. For more information on what happens during a clinical trial, see the table on the next page.



PHASE

1

PHASE

2

PARTICIPANTS



10–40



30–300

PURPOSE

- first study in people
- tests safety of new treatment
- finds the safest dose and the best way a treatment can be given
- identifies side effects
- studies how it works with other medicines or food (interactions)

- builds on the results of Phase 1
- continues to test safety of a drug
- begins to assess how well a new treatment works on the disease

HOW IT WORKS

- participants are given a fixed dose and watched closely for side effects
- if no side effects, dose is increased in next group of participants, this continues until significant side effects appear

- focuses on one cancer type
- all participants receive the same experimental treatment
- sometimes randomised controlled trial – i.e. participants are put into separate groups and given different treatments, which are then compared to see how well they treat the disease

OTHER INFO

Patients sometimes benefit from having the new treatment but great improvements in their condition are uncommon.

People often have treatment as an outpatient, but occasionally need to stay overnight in hospital for monitoring.

PHASE

3



100s–1000s

- tests if the new treatment is better than the standard treatment
 - compares side effects, survival and quality of life
 - collects information that allows new treatments and existing treatments to be used in new ways or for different diseases
-
- uses two treatment groups – experimental and control
 - usually groups are randomised and sometimes blinded (see page 29)
 - placebo may be used for comparison
 - runs over a long period of time

New drugs go through two Phase 3 trials before they can be registered with the Australian Therapeutic Goods Administration (TGA) for use.

PHASE

4



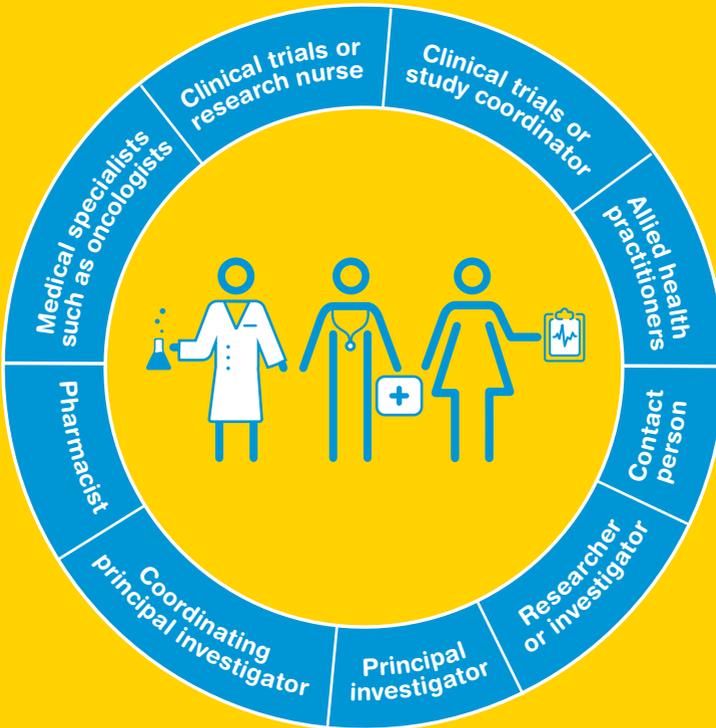
1000s

- identifies how well treatment works when used more widely
 - monitors the long-term benefits and risks
 - looks for other uses of the drug or treatment
-
- carried out after a treatment has been registered by the TGA
 - usually run by pharmaceutical companies that make the product

Not all treatments go through Phase 4 studies. They are less common than trials in the earlier phases.

Health professionals and researchers working in clinical trials

Cancer research is a large part of the health industry and offers many varied roles. If you join a study, you may have contact with some of these people:



Who works in clinical trials?

Medical specialists, such as oncologists, haematologists and surgeons

- supervise your treatment, follow-up and overall care.

Clinical trials nurse or research nurse

- coordinates recruitment by talking to potential participants, making sure they are eligible and explaining the purpose of the trial
- arranges appointments for tests, treatments or to see the specialist, and makes sure all paperwork is completed once you have agreed to join a trial
- provides emotional support
- acts as a link between the patient and the researchers or the health care team
- may also be the main contact person (see next page)
- larger clinical trials or hospitals have a dedicated clinical trials nurse, but smaller ones might not.

“ A clinical trials nurse accompanied me at every stage of the process. She explained what was happening and answered any questions I had. ” *Marg (breast cancer)*

Clinical trials or study coordinator

- is similar to a clinical trials or research nurse, but instead of nursing qualifications they have a science degree or similar.

Allied health practitioners and complementary therapists

- give treatment or advice in studies that investigate the use of non-medical treatments such as nutrition, physiotherapy, counselling, acupuncture or massage.

Pharmacist

- provides advice about medicines and monitors their effect on patients; does laboratory research.

Coordinating principal investigator

- oversees research taking place at more than one study site, e.g. at multiple hospitals.

Principal investigator

- has overall responsibility for conducting the trial at their hospital and ensuring patients are safe and the trial is properly run. This is usually a doctor with expertise in the field.

Researcher or investigator

- develops and plans studies, and obtains, analyses and publishes results. Health researchers come from backgrounds such as medicine, science, psychology, allied health, consumer advocacy or complementary therapies.

Contact person

- acts as the point of contact for all research participants if they have any queries or problems during a study. See page 38 for more information.



Planning research

Researchers plan and carry out studies in a way that ensures results are accurate and not caused by chance. This means they have to follow strict guidelines. They also have to reduce the risk of their own – or participants’ – ideas or beliefs about the research unfairly influencing (biasing) the results. This chapter describes some methods used to make sure studies are fair and reliable. Some information applies to clinical trials only.

Randomised controlled trials

Randomised controlled trials (RCT) are the best way to test if a new treatment is effective. This is because they help prevent bias. Bias occurs when the results of a trial are influenced by human choice or other factors not related to the treatment being tested.

Most Phase 3 trials and some Phase 2 trials are randomised. In an RCT participants are randomly assigned into two groups, or arms, of the study, and the results of both groups are compared.

Test or experimental group (or arm) – This is the group that is given the experimental treatment being studied.

Control group (or arm) – This group receives the current best available standard treatment for the disease.

When randomly allocated groups are compared with each other, it is possible to reliably work out which treatment is better. This is because researchers can be certain that the results are related to the treatment or chance, and not to any other factors.

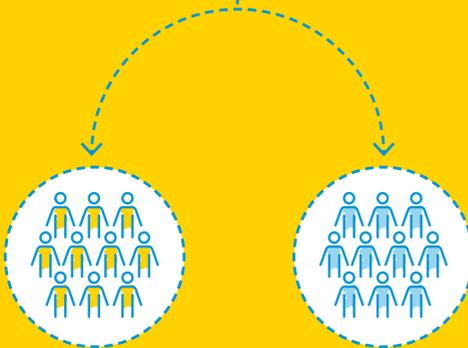
How randomisation works



Patient information is entered into a computer.



The computer gives each participant a code number. The code numbers are randomly assigned to the different treatment groups, helping to prevent bias.



The control group receives the standard treatment and the test group receives the new treatment.

Standard treatment and placebos

Standard treatment – This is the current most effective treatment or care given to people for their disease or condition. For example, standard treatment for newly diagnosed early breast cancer is surgery to remove the breast tumour, often followed by radiotherapy, hormone therapy and/or chemotherapy.

In some cases, there is no known useful medication or treatment, but patients will be monitored regularly. Regular monitoring is then the currently available best standard of care. This would be the case for women who have completed standard surgery, radiotherapy, hormone therapy and/or chemotherapy for early breast cancer.

Placebo – This is an inactive or fake treatment made to look, taste or feel like the treatment being tested, but that doesn't have any active (therapeutic) ingredients (if a medicine) or a remedial effect (if another type of treatment).

A placebo is used to compare treatments to see whether the patients' outcome is because of the actual treatment or because of other factors associated with being in the study. If the people given the experimental treatment show more improvement than those given the placebo, this provides strong evidence that it's the experimental treatment that is responsible.

Placebos are not often used in cancer treatment trials. Only trials that use a placebo together with the best standard therapy are approved. Participants will be told if a study uses a placebo, but will not be told which treatment they are receiving.



Marg's story

After I was diagnosed with breast cancer, I asked if there were any clinical trials I could go on. One was assessing how effective a pain-relieving inhaler was for women having a sentinel node biopsy, which was the procedure I needed.

I felt that the trial was low risk and I had the potential to receive some useful extra treatment. It required an overnight stay in hospital to have the biopsy and treatment, and to be monitored.

I had to fill out questionnaires about my emotional and physical wellbeing on the day of the trial and the following day. This gave me something to do and I felt that I was actively participating in my own health care.

The study was blinded and we were randomly assigned to get either the experimental treatment or a placebo. I don't think I was given the experimental drug, but it was still a positive experience to participate in the trial.

Crossover studies

A type of clinical trial in which the study participants receive each treatment in a random order. In these studies, the two arms of the trial have their assigned treatment for a period of time before swapping and having the other treatment. This enables all participants to experience all treatments, which helps confirm which is the most effective.

Crossover studies are often used when researchers feel it would be difficult to recruit participants willing to risk not receiving a promising new treatment.

Blind studies

If the participant doesn't know which arm of a study they're in, this is called a blind study. Some randomised controlled trials are called double-blind studies as neither the participant nor other members of the trial team know whether the participant is receiving the experimental treatment or the control treatment. In a double-blind trial, even the lead researchers only discover who is in each arm of the study at the end of the trial when the results are being analysed.

Blinding aims to reduce bias in the reporting of benefits and side effects. For example, if you or your doctor knew you were having standard treatment, you might feel disappointed that you didn't receive the experimental treatment and this may affect your wellbeing. However, if you or your doctor knew you were having the experimental treatment, then you might report that you're feeling better than you actually are because you want the treatment to work. If you don't know which treatment you're having, the results are less likely to be influenced by you or your doctor's thoughts.

If necessary for safety reasons, your doctor can find out what treatment you're having by contacting those running the study.

Blinding is used only when participants can't tell what treatment they're having or can't tell the difference between the two types of treatment. For example, it is hard to disguise surgery and massage, or two noticeably different control and experimental treatments.





Philipa's story

When I was diagnosed with non-Hodgkin lymphoma in 2006, the drug rituximab wasn't available for a patient's first line of treatment. However, a worldwide trial was being conducted to compare the outcomes of patients who no longer had active lymphoma after receiving rituximab.

My haematologist suggested I join this trial to get rituximab immediately, rather than wait until my other treatment options had been exhausted. I got a second opinion from another haematologist and he also recommended the trial. There was a lot of patient information to read, but my brother read it too, which was helpful.

The clinical trials nurse looked after me every time I went in for treatment. I had chemotherapy and then rituximab, and after a few months I went into remission. Then I began the experimental part of the trial.

One group of patients was given a maintenance dose of rituximab and had check-ups every three months. The control group just had check-ups every three months. I was in the control group so was observed until the cancer came back. At that point I came off the trial.

During treatment and for the check-ups, I had to have a physical examination, blood tests and an interview about my general wellbeing. It was good to be monitored so often, especially as I didn't have to pay for any of these tests. I had to travel overseas at one point, as it was a worldwide trial, and I was able to attend a clinic in the UK to have my regular three-monthly check-up.

It was worthwhile going on the trial because I was able to have the rituximab straightaway. I also felt by participating in the trial I was contributing to finding a cure for this particular cancer.



Regulating research

Research is regulated to make sure it is conducted to a high professional and scientific standard. All health professionals must follow a set of international standards for designing, conducting, recording and reporting of clinical research called Good Clinical Practice (GCP). These standards ensure that people taking part are safe, and information is collected to the highest standard. GCP is the same anywhere in the world where clinical trials are run.

In Australia, several committees examine and approve a study before it begins. These committees confirm that a study is considered scientifically worthwhile and fair (ethical).

- **Research review committee** – decides whether the study has social and scientific value, and if the way it is to be conducted will produce valid scientific results.
- **Ethics review committee** – confirms that the interests of participants are protected and that researchers will run the study in a fair, honest and neutral (impartial) way. It ensures researchers won't force people into participating, and that the risks of the research generally don't outweigh the benefits. See the next page for more details.
- **Research governance review** – checks every site where the research will take place. This review is done by a research governance officer who makes sure there are enough resources to carry out the proposed research and that the staff members involved are adequately qualified. The governance officer authorises the research to begin at each site.

The study may also be monitored by outside agencies such as pharmaceutical companies, research institutions and auditors. These bodies ensure that the research is carried out properly.

For more information on how studies are conducted fairly, see the *Planning research* chapter on page 25.

Human research ethics committee

Once research has been approved by a research review committee, the human research ethics committee (HREC) assesses the impact of the proposed research on participants, researchers and the general community. The impact is then weighed up against the benefits of conducting the research. The committee makes sure that the study will be carried out in a way that protects participants.

The committee reviews a number of aspects of the study, including:

- the qualifications of the researchers conducting the study
- the way participants are recruited
- the quality of the participant information
- how risks to participants will be minimised
- how the study might impact on the participants' quality of life.

Members of an ethics committee are always independent of the researchers. Committee members come from a variety of backgrounds, including medical, scientific, legal and religious professions, and the general community. There are usually at least eight core members covering a range of professional and personal experiences to reflect different points of view and provide balance.

National Health and Medical Research Council (NHMRC)

NHMRC's mission is to build a healthy Australia.

It does this by developing health advice for the general community and health professionals, and funding research projects ranging from basic research through to clinical, public health and health services research.

NHMRC produces guidelines outlining ethical conduct in research. Ethics committees must follow these guidelines and report to NHMRC every year. You can download the *National Statement on Ethical Conduct in Human Research (2007) (Updated March 2014)* from nhmrc.gov.au/guidelines-publications/e72.

Changes to research

Sometimes changes need to be made to the research, and these will need to be approved by the human research ethics committee.

- **Before approval** – The ethics committee may ask the research team to make changes to the proposed research before it can go ahead.
- **After approval** – Any changes that researchers want to make during the study must go through ethics approval again before the change can take place. This is called an amendment. If there are any changes to the participant information, then participants already taking part in the study may need to sign a form to show that they have been informed of the changes (amendment) and still agree to be involved.



Getting involved

This chapter explains how to find out about a study and what happens once you've decided to participate.

How to find a study

There are many ways to find out about a clinical trial or other study. Most specialists know about current studies and may recommend a suitable study to you. If your hospital has a clinical trials or research nurse, you can also ask them about any studies that might be suitable for you.

Hospital and treatment centre waiting rooms often have information about current studies. You can also search clinical trial websites or you might hear about them through patient support groups and in the general media. If there isn't a suitable study now, you can register with some organisations to be informed of studies that come up in the future. See pages 52–53 for a list of websites where you can find or register for studies.

If you find a trial you're interested in joining, ask your doctor whether they could find out more about the trial and whether they could coordinate your involvement or put you in touch with the research team.

“ My doctor suggested I take part in a study and I thought it sounded beneficial. I found the thorough disclosure of both the trial and the possible side effects reassuring. ” Piers (*chronic lymphocytic leukaemia*)

Taking part in a study

Before a trial begins, researchers develop the protocol. This detailed plan describes the study's design, reasons for the study and who can participate (the eligibility criteria).

Eligibility criteria

All clinical trials have guidelines for who can join. These are called the eligibility criteria and they outline the characteristics that must be shared by all participants to ensure that people taking part are as similar as possible.

The inclusion criteria describe the required characteristics for enrolling in a study. The exclusion criteria outline the factors that disqualify someone from participating.

Depending on the research, eligibility criteria may include:

- age or sex
- cancer type
- stage of the cancer
- symptoms or side effects experienced
- length of time since diagnosis or treatment
- previous medical history
- previous medical treatments.

The eligibility criteria also make sure people are safe while on a trial by taking into account any characteristics that might make your participation risky. For example, you may be excluded from a trial if you are pregnant, have high blood pressure, or have some other condition that significantly increases the risks of the treatment.

Informed consent

Before you join a trial, a doctor, nurse or other researcher will ask your permission. Informed consent is the legal term for the process through which participants are asked to confirm they have read and understood the purpose, risks and possible outcomes of the research before deciding whether to join.

The informed consent process includes:

- receiving written information about the study, expected side effects and possible outcomes. This is called participant information (see opposite). You can also talk to your doctors and/or clinical trials or research nurse about any aspect of the study.
- signing the informed consent form. For people under 18, a parent or guardian has to give legal consent. Signing the form is not a contract and you can withdraw at any time (see page 42).

The process of providing informed consent continues throughout a study. If the study changes or new information becomes available while you are involved, you will be given new patient information and you may need to sign an updated version of the consent form.



Sometimes you may need to consent to each aspect of a study. For example, you might agree to take part in a trial of a new surgical procedure, and then need to consent for your tissue to be collected and banked during that surgery. You might be given an extra questionnaire, which may also require you to consent again.

Participant information

Researchers must provide written information about the study to anyone thinking about getting involved. This is called participant (or patient) information.

It answers a range of questions about a study, including:

- the purpose of the study
- if it is a clinical trial, and what phase it is in
- who can participate in the study
- who is running the study (institution and researchers)
- who has approved the research
- who is funding the study
- how the study will be run and what you need to do
- whether you will need to have tests or other procedures
- how long you need to be involved for
- where you need to go for appointments, treatments or meetings
- whether your medical records need to be accessed
- whether you will be reimbursed for any related expenses
- information about possible side effects or other risks
- who to contact for further information or if you have any problems or complaints during the study (see page 38)
- information about your rights, such as keeping your records private (see page 39) and your ability to withdraw from a study.

Answers to some of these questions are provided in the informed consent document. The participant information can help people decide whether they want to enrol or continue participating in the study. You can also ask the research team any questions you have about the study.

Contact person

All studies include a contact person. You can talk to this person before you decide to participate and at any stage during the study if you have questions or concerns. The contact person is often a clinical trials nurse or study coordinator (see page 23).

You will also be given details of who to contact if you have a complaint about the study, for example, how it was run or how you were treated. This person is independent of the research team. Complaints about research are rare, but it is one of your rights as a participant to have your concerns heard if you have a problem.

Communicating with the treatment team

- Keep contact information handy if you have questions before and during the study.
- Sometimes a trial is run at a different hospital to the one where you're having treatment. This means you may have two treatment teams. If this is the case, make sure your medical information and any relevant test results are available to both treatment teams, and ask who your main contact person is. It may also help to take your own record of test results to the hospital.
- If you are in a clinical trial and develop significant problems, go to your hospital's emergency department and/or contact your hospital's oncology registrar. If you go to hospital, let your trial team know.

Privacy

Medical records are private and confidential, including those relating to your involvement in a trial or study. Health professionals directly involved in your care or study can access your personal and medical information, but only if it's necessary for their work. They can't disclose anything about you to others unless it is relevant to your health care or the study.

The participant information may mention who will and won't have access to your personal data. For example, it might state that your regular medical team won't have access to your questionnaire responses but the researchers will. You might be asked to consent to the research team accessing your existing medical records or particular test results.

Often, information collected during the study is de-identified. This means that it won't have your name on it so the results cannot be linked to you. Not even the researchers know which results belong to which individuals. When the results are published in journal articles and the studies discussed at conferences, you will not be named.

For more information about privacy issues in health care, talk to the social worker at your hospital or call Cancer Council 13 11 20.

At the end of a clinical trial or other study, all personal information is stored securely for at least 15 years before it can be destroyed. This is a legal requirement.



Being part of a clinical trial

What you need to do when you agree to join a study depends on what kind of research it is. Generally, only clinical trials require preparation or ongoing follow-up, but it depends on what the study is testing and what phase it is in.

Before the trial starts

- Discuss the trial with a member of the clinical trials team, your oncologist or other cancer specialists.
- Read the participant information (see page 37). You may want to discuss the information with family, friends or your GP.
- Ask your doctors or the clinical trials or research nurse any questions you have about the study. See pages 23–24.
- Have any medical tests, such as a CT scan and blood test, to check that the trial is suitable for you.

During the trial

- Follow the instructions you are given about the trial to help ensure that the trial results are as reliable as possible. That means going to all appointments, having the required tests, taking medicines at the specified time, and completing logs or questionnaires.
- Be prepared for more tests and visits to your doctor than you would normally have. This is to monitor your health and to see if and how the treatment is working. The research team will also ask about how you are feeling emotionally and physically.

Your participation is usually organised by one person (often a clinical trials or research nurse), but you may come into contact with different members of the research team (see pages 23–24). Your overall care will probably continue to be coordinated by your cancer specialist.

After the trial is over

Researchers may stay in contact with you for some time after the trial so they can collect long-term information on how you are doing. You will return to having the standard care and/or check-ups that are appropriate for you, depending on the stage of the cancer and what your cancer specialist recommends.

Continuing access to medications

Many people wonder whether they're able to continue receiving the experimental treatment after a trial is over.

This depends on several factors including the phase of the trial, the study results, how effective the treatment was for you, what the recommended course of treatment is, and whether the trial sponsor is prepared to continue providing the treatment.

Some people join clinical trials to access treatments that would otherwise not be available to them. It can be frustrating and disheartening to not be able to continue with the promising treatment after the study ends.

Ask your doctor or clinical trials nurse whether it's possible and advisable to continue the experimental treatment.

Withdrawing from a study

Participating in research is voluntary and you can pull out at any time. You may want to withdraw because you:

- no longer have the time or energy to commit to it
- don't feel it is helping
- are having side effects or your health is worsening
- move further away from where you are receiving treatment
- change your mind.

You will not be penalised, and you will continue to receive the type of treatment that is currently the best option for you.

Finding trial results

It can take a while to get trial results. Usually results are available in 2–5 years, but sometimes it can take 10 years or more. The results of most clinical trials will be published in medical journals and presented at conferences and scientific meetings.

If you'd like to know the results of the study you participated in, start by asking your doctor. The participation information you read at the beginning of the trial and the informed consent document you signed often say how the results will be available.

You may want to ask your doctor what the results mean. When research teams analyse trial results, they look at end points. Examples of end points are whether a cancer has shrunk (response to treatment) or how long it is before the cancer starts to grow again (duration of response).

Involving consumers in research

Sometimes people want to contribute to research but don't want to participate in a study. They may have been affected by cancer in the past – either directly or indirectly – so they want to offer their knowledge to help shape future cancer research. Researchers refer to these people as 'consumers' to distinguish them from patients or others recruited to a study.

The role of consumers in research has increased over the years. Consumers are now involved in identifying priorities for research and helping to decide what projects should be funded. They may also work directly on research studies, providing an informed consumer review.

Cancer Australia developed the *National Framework for Consumer Involvement in Cancer Control*. This includes a web-based toolkit designed

to support CEOs, managers, health professionals, researchers and policymakers in involving consumers in their work. For more details, go to **consumerinvolvement.canceraustralia.gov.au**.

Cancer Voices is a consumer advocacy organisation that operates in most states. It focuses on improving cancer treatment through active consumer participation. To learn more, visit them online at:

- Cancer Voices Australia **cancervoicesaustralia.org**
- Cancer Voices NSW **cancervoices.org.au**
- Cancer Action Victoria **canceractionvic.org.au**
- CanSpeak Queensland **canspeakqld.org.au**
- Cancer Voices SA **cancervoicessa.org.au**.

If you would like to get involved, contact Cancer Voices or call Cancer Council **13 11 20**.



Making decisions

You may have many questions when deciding whether or not to join a study, particularly if it is a clinical trial. As well as talking to your doctor and clinical trials (or research) nurse, it's recommended that you talk to your family or carer. This is because your involvement may also impact them. Ultimately, though, it's your decision to participate in research or not.

You shouldn't feel pressured to take part in research, and you should not be rushed into making any decisions that may affect your health or treatment. Ask your doctor or nurse how much time you have to think about whether or not to join a study. If you'd like to take some time to consider your participation, ask if this is likely to affect your treatment outcomes.

Weighing up the benefits and risks

- Consider what is most important to you. Some people want to be certain of which treatment they will receive, whereas others prefer the opportunity to try something new.
- Think about the possible problems of being in a study and how they might affect your wellbeing and lifestyle. Weigh them up with the possible benefits, such as a possibly longer survival time or not having to experience certain side effects. Everybody's situation is different – what is right for someone else may not be right for you.
- Most people diagnosed with cancer who decide to participate in research do so because they want to help improve outcomes for others in the future.

Frequently asked questions

Q: Will I be better off in a study?

- A:** There are many advantages of being involved in research or a clinical trial. Depending on the study, these may include:
- accessing programs, medicines or other treatments that are not available outside of the study and may be better than the current standard care for the disease
 - accessing expensive drugs that are not currently covered by the Pharmaceutical Benefits Scheme
 - seeing your treatment team, including specialists, more often
 - being motivated to take an active part in your health care
 - learning new ways to improve your lifestyle
 - improving your quality of life
 - feeling that you've tried all treatment possibilities
 - knowing you've made a valuable contribution to helping others in the future.

Joining a study doesn't always mean you will be better off than before or compared to other people in a similar situation. This is because although researchers may predict that the outcomes of their study will be positive, not everyone will respond in the way that they hope.

In a clinical trial, you may be in the control arm and not given the experimental treatment (see page 25). If this is the case, you will receive the best standard care available and be monitored more frequently and closely than usual. Either way, your doctor and the clinical trials or research nurse will discuss the possible advantages for you before you join a study.

Q: How long will a study last?

A: From start to finish, a study often takes years or even decades. However, you may only need to be involved for some of this time. It may be a one-off couple of hours, or you may need to give a bit of time every few weeks, months or years.

Some studies require people to be surveyed at regular intervals for several months or years. This allows researchers to understand the long-term effects of treatments, monitor the general health of study participants and collect data about long-term survival.

Studies have what is known as a recruitment phase. This usually occurs over a few months or years until the required number of people have agreed to take part.

Q: Can I be involved in more than one study?

A: You may be interested in joining multiple studies. Check with the contact officers of each study whether you can participate in more than one study at the same time. If you can, think about whether you'll be able to commit to all their requirements.

Q: Is participation free?

A: The costs will be paid for by the organisation that is funding or conducting the research. This will include treatment, tests and patient check-ups. Travel or out-of-pocket costs may be refunded. Ask your doctor if this is available. People who are not an Australian permanent resident or citizen will have to cover costs.

Q: Will I be paid?

A: People participating in cancer research and trials don't usually receive payment, apart from reimbursement of out-of-pocket costs if this applies to the study.

Q: Can I have other treatment if I go on a clinical trial?

A: Check whether the study will have an impact on other treatment you're having or planning to have. This includes medicines for symptoms or side effects of cancer or other conditions, or complementary therapies such as herbal or nutritional supplements or massage.

Ask your doctor if you need to stop or delay these other treatments, or whether they need to be modified (for example, changing the dose).

A second opinion

Some people like to get a second opinion about whether they should join a study, particularly if it is a clinical trial. A second opinion can confirm or clarify your doctor's recommendations and reassure you that you have thought about the different issues that might affect you.

Ask your GP for a referral to another cancer specialist, but keep in mind that you may have to wait several weeks for an appointment and it will cost you extra money. Ask your cancer specialist if it is possible to talk to another specialist on the hospital ward.



Seeking support

When you are first diagnosed with cancer you may feel that you don't have enough time or energy to think about research. For most people, their key goal will be to start treatment as soon as possible and then concentrate on getting better.

However, you may want to take part in research, or you may be invited to take part. Being involved may give you an opportunity to feel more supported during or after cancer treatment. You may also find the experience rewarding.

If you agree to participate, you may have mixed emotions during or after the study. Although people who participate in trials generally report a positive experience, you may find that the extra appointments are stressful or that dealing with a different health care team is unsettling or confusing. The treatment you're having may cause side effects, or you may worry that you're not getting the best treatment.

After the trial ends, you may be relieved because you no longer have this commitment. You may be happy with the outcome and feel ready to put the cancer behind you. However, you may feel less certain because your health won't be monitored as frequently, or you may be disappointed that the cancer has not gone into remission.



To find out more about these services and to get free copies of resources about coping with emotions during and after cancer treatment, call Cancer Council **13 11 20**.

It's important to discuss any worries with your doctor or clinical trials or research nurse. They can help you understand information about the research so that you feel reassured and positive about your involvement. Make sure you understand the aims of the research before you participate so you have realistic expectations.

Talk to someone who's been there

Coming into contact with other people who have had similar experiences to you can be beneficial. You may feel supported and relieved to know that others understand what you are going through and that you are not alone.

People often feel they can speak openly and share tips with others who have gone through a similar experience.

Types of support

There are many ways to connect with others for mutual support and to share information. This includes:

- **face-to-face support groups** – often held in community centres or hospitals
- **telephone support groups** – facilitated by trained counsellors
- **peer support programs** – match you with someone who has had a similar cancer experience, e.g. Cancer Connect
- **online forums** – such as cancerconnections.com.au.

Talk to your nurse, social worker or Cancer Council 13 11 20 about that is available in your area.



Caring for someone with cancer

You may be reading this booklet because you are caring for someone with cancer. The person you're caring for may be interested in or invited to participate in research. Depending on the type of research, it is usually recommended that carers read about the study themselves and talk it over with the person who has cancer. You can also discuss the study with the clinical trials or research nurse.

While the decision to participate lies with the person who has cancer (unless they're under 18), it's important that you, as the carer, know what impact the study might have on the participant and on you and your family. For example, it may mean you have to take extra time off work to drive the person you're caring for to appointments, or you may be worried about how the treatment will affect them. Check with the clinical trials or research nurse whether you can be reimbursed for costs associated with helping the person to participate in the study.

Being involved in research may offer the person with cancer an opportunity to have a promising new treatment or other useful supportive care options. It may be satisfying to know that their participation will help others in the future.

Weighing up these options – and just being a carer in general – can be very stressful. Try to look after yourself by giving yourself some time out and sharing your worries and concerns with a counsellor or your doctor. You can also call Carers Australia on 1800 242 636, or contact Cancer Council 13 11 20 to ask for a copy of the *Caring for Someone with Cancer* booklet.



Useful websites

Australian

National websites

- Cancer Council Australia
cancer.org.au
- healthdirect Australia
healthdirect.gov.au
- National Health and Medical Research Council
nhmrc.gov.au
- National Health and Medical Research Council Clinical Trials Centre
ctc.usyd.edu.au
- Pharmaceutical Benefits Scheme
pbs.gov.au
- Therapeutic Goods Administration
tga.gov.au

International

- ClinicalTrials.gov (US)
clinicaltrials.gov
- EU Clinical Trials Register
clinicaltrialsregister.eu
- ISRCTN registry
isrctn.com
- Macmillan Cancer Support
macmillan.org.uk
- NHS Choices – Clinical Trials and Medical Research
nhs.uk/conditions/clinical-trials/pages/introduction.aspx
- International Clinical Trials Registry Platform
apps.who.int/trialsearch
- World Health Organization
who.int/topics/clinical_trials

Clinical trial websites

To find current trials

- Australian Cancer Trials
australiancancertrials.gov.au
- Australian New Zealand Clinical Trials Registry
anzctr.org.au
- Consumer Involvement in Cancer Cooperative Trials Groups
consumerlearning.canceraustralia.gov.au
- Cancer Trials Australia
cancertrialsaustralia.com
- Cancer Council SA
cancersa.org.au/research/current-clinical-trials
- Victorian Cancer Trials Link
cancervic.org.au/trials
- Western Australia Cancer Clinical Trials Registry
cancerwa.asn.au/patients/making-decisions-about-treatment/clinical-trials/wa-clinical-trials-registry

To register for studies

- Australian Prostate Cancer Research
prostatecancerresearch.org.au/research/register-for-research
- Breast Cancer Network Australia
bcna.org.au/get-involved/participate-in-research
- Cancer Council NSW
cancercouncil.com.au/joinastudy
- Register4
register4.org.au

National Cancer Cooperative Trials Groups

- Australasian Gastro-Intestinal Trials Group
agitg.org.au
- Australasian Sarcoma Study Group
australiansarcomagroup.org
- Australasian Leukaemia & Lymphoma Group
allg.org.au
- Australasian Lung cancer Trials Group
altg.com.au
- Australia and New Zealand Breast Cancer Trials Group
anzbctg.org
- Australia and New Zealand Children's Haematology/Oncology Group
anzchog.org
- Australia and New Zealand Gynaecological Oncology Group
anzgog.org.au
- Australia and New Zealand Melanoma Trials Group
anzmtg.org
- Australia and New Zealand Urogenital & Prostate Cancer Trials Group
anzup.org.au
- Cooperative Trials Group for Neuro-Oncology
cogno.org.au
- Palliative Care Clinical Studies Collaborative
caresearch.com.au/caresearch/tabid/97/default.aspx
- Primary Care Collaborative Cancer Clinical Trials Group
pc4tg.com.au
- Psycho-Oncology Co-operative Research Group
pocog.org.au
- Trans Tasman Radiation Oncology Group
trog.com.au



Question checklist

You may find this checklist helpful when thinking about the questions you want to ask your doctor, clinical trials or research nurse, or the research contact person.

Practical questions

- What are my chances of benefiting from this research?
- What are the risks to me?
- Will I experience any side effects? How will they be treated?
- Are there any tests involved?
- Do I need to stay overnight in hospital?
- Will I need to take time off work? Will being involved affect my day-to-day life?
- Can I receive any reimbursement of out-of-pocket expenses?
- Can I still participate if I need to travel interstate or overseas?
- Who will oversee my cancer care while I'm participating?
- Can I be involved in more than one study at the same time?
- If I join this study, will I miss out on other treatment opportunities later?
- Can I still take other medication or complementary therapies while I'm involved in the trial?
- How much time do I have to think about whether or not to join this trial or study?

Study background

- What is being tested in the trial or study and why?
- How many other people will be involved in this research?
- How long does the research last? For how long do I need to be involved?
- If I take some time to decide, will delaying the treatment affect how well it works?

Legal and ethical questions

- Has the study been approved by an ethics committee?
- Can you go through the participant information with me?
- Can I have the participant information in a different language?
- Will I be covered if anything happens to me while I'm on this study?
- How will my identity be protected while I'm participating, and who will have access to my information?
- What will happen with the results of the research?
- Who can I contact if I have a problem?



Glossary

active ingredient

The compound in a medicine that has a beneficial effect on the body.

animal research

Research using animals to check the safety and effectiveness of a treatment before it is tested on humans.

arm

Group of people who receive the same treatment in a randomised trial. Most randomised trials have two arms, but some have three arms or even more.

baseline

A phase during a study when the participants are not receiving any treatments. This is usually at the beginning of a trial before treatment is started.

basic research

Scientific research carried out in a laboratory to study the tiniest components of the body, including cells, compounds and molecules. Sometimes called test tube or laboratory research.

behavioural research

Research that looks at people's behaviours and how these affect their chances of getting cancer or recovering from it.

bias

Human choices or other factors not related to the treatments being tested that might affect a study's results.

biospecimen

See tissue.

blinded trial

A trial in which participants do not

know if they are receiving the control or the experimental treatment.

blood test

A test that requires blood to be drawn through a needle so it can be examined. It assesses levels of different substances in the blood.

bone marrow

The soft, spongy material inside bones, which produces red blood cells, white blood cells and platelets.

cancer

A disease of the body's cells that starts in the genes. Damaged genes cause cells to behave abnormally, and they may grow into a lump called a tumour.

case control study

A type of study that compares people who have a particular disease (the cases) with people who are healthy (the controls) and looks back over time to see if they have anything in common, such as their history of smoking or exposure to asbestos. Also called retrospective studies.

cells

The basic building blocks of the body. A human is made of billions of cells that are adapted for different functions.

chemistry

The study of matter (such as atoms and ions) and how it changes and reacts to other matter.

clinical research

Research that focuses on people's health and medical care.

clinical trial

A research study that tests new and

better treatments to improve people's health.

cohort study

A study to determine risk factors for a disease by tracking a group of healthy people who share a similar characteristic, such as their type of work, and seeing whether they develop the disease in question. A cohort study also has a control group. Also called prospective studies.

control group

A group of patients that is compared with a group receiving the experimental treatment. In a clinical trial, the control group receives the control treatment.

controlled trial

A trial that compares two or more treatments to find out which one is more effective.

control treatment

The existing treatment that is being compared with the experimental treatment. The control is generally the best standard treatment available. In some cases, a placebo is used.

CT scan

A computerised tomography scan. This scan uses x-rays to create a picture of the inside of the body.

diagnosis

The identification and naming of a person's disease.

DNA

A tiny molecule in every cell of the body that carries instructions for how that cell behaves and functions. Also called deoxyribonucleic acid.

double-blind trial

A trial in which neither the patient nor their research team know what treatment the patient is receiving, to reduce bias.

eligibility criteria

Characteristics of the people for whom a trial is suitable.

end point

What a clinical trial is trying to measure or find out. It is important that the goals for clinical trials be clearly defined in advance. Typical end points include measurements of toxicity, response rate and survival.

epidemiology

The study of how and why diseases occur in different populations.

ethics

The study of moral values or principles, including responsible conduct and what is fair.

ethics committee

A committee that reviews the plans and other paperwork relating to a research study to make sure it is safe and ethical.

experimental treatment

The new or modified treatment that is being tested in a clinical trial.

first line treatment

The initial treatment used to target tumours.

genes

The microscopic units that determine how the body's cells grow and behave.

Genes are found in every cell of the body and are inherited from both parents.

genetic marker

A gene or DNA sequence associated with a particular characteristic.

haematologist

A doctor who specialises in studying and treating diseases of the blood, bone marrow and lymphatic system.

hypothesis

An explanation or guess based on limited evidence that serves as a starting point for research.

immunology

A branch of medicine that studies the immune system, which helps fight off disease in the body.

informed consent

A legal process by which a patient is given detailed information about a study before they agree to become involved.

investigator

Another term for a researcher.

in vitro

Laboratory experiments that are done using scientific equipment, such as test tubes and dishes.

in vivo

Experiments that are done using a living organism, such as an animal or human.

laboratory

Place where experiments are carried out and new medicines developed.

laboratory research

Research that is carried out in a laboratory.

literature review

A review of the previous research that has been done on a particular area and which relates to a current problem being investigated.

longitudinal study

A study done over a long period of time – often decades – with the participants being asked the same questions or having the same tests periodically to assess how their health changes over time.

lymphatic system

A network of tissues, capillaries, vessels, ducts and nodes that removes excess fluid from tissues, absorb fatty acids and transport fat, and produce immune cells. Includes the bone marrow, spleen, thymus and lymph nodes.

medical intervention

Medical tests, procedures or treatments that are aimed at relieving illness or injury, or curing disease.

medical oncologist

A doctor who specialises in treating cancer with chemotherapy.

medical science

An area of study focusing on maintaining health and preventing and treating disease.

molecular research

Laboratory research that focuses on discovering which genes are responsible for certain diseases and how the disease develops.

molecules

Very small particles that can join with other molecules to form larger substances. A gene is a type of molecule.

MRI scan

A magnetic resonance imaging scan. A scan that uses magnetism and radio waves to take detailed cross-sectional pictures of the body.

oncology

The study, diagnosis and treatment of cancer.

palliative care

The holistic care of people who have a life-limiting illness, their families and carers. It aims to improve quality of life by addressing physical, emotional, spiritual and practical needs. It is not just for people who are about to die, although end-of-life care is a part of palliative care.

participant information

An information sheet that explains everything a participant needs to know about the trial and treatment. Sometimes called a fact sheet.

peer review

A process in which independent experts check research to make sure it is accurate and reliable.

pharmacogenetics

A branch of pharmacology that examines both drugs and genes to see why certain people react positively or negatively to different treatments. Also called pharmacogenomics.

pharmacology

The study of drugs and how they can be used to treat diseases.

phase

A stage of a clinical trial. There are usually four phases of testing.

pilot project

A small project that is carried out to see whether a similar large-scale study is feasible.

placebo

A dummy pill, injection or other treatment that looks like the new treatment being tested but doesn't contain the active ingredient.

prevention trial

Trial that tests a new approach that researchers and doctors believe may lower the risk of getting cancer.

prospective study

Research that looks at what happens to different groups of people from the start of the study up to a point in the future.

protocol

A plan that describes all the details about a study, including its aims and methods and the reasons for conducting it.

psychosocial research

Research looking at the emotional, psychological and social effects of disease and how people can be helped through supportive care measures.

qualitative study

Research that focuses on individual responses rather than numerical data to obtain the results.

quality of life

Your comfort and satisfaction, based on how well your physical, emotional, spiritual, sexual, social and financial needs are met within the limitations of your health and personal circumstances.

quantitative study

A study that focuses on collecting numerical data and analysing the results using statistics.

radiation oncologist

A doctor who specialises in treating cancer with radiotherapy.

randomisation

A method used to prevent bias in research. A computer is used to assign patients into groups by chance, rather than the researchers or doctors choosing the groups.

randomised controlled trial (RCT)

A trial in which participants are randomly assigned to receive the experimental treatment or the standard treatment (the control).

research governance officer

The person responsible for the management and approval of applications for research at their particular location.

response

A significant decrease in the size of tumours as a result of treatment.

retrospective study

Research that looks at what has happened in the past to gain an understanding about why something is occurring in the present.

screening

An organised program to identify disease in people before any symptoms appear.

screening trial

A trial that tests the best way to find cancer, especially in its earliest stages.

side effect

Unintended effect of a drug or treatment.

single blind study

A study in which only the research team know whether patients are receiving the standard treatment or the new treatment.

stage

The extent of a cancer and whether the disease has spread from an original site to other parts of the body.

standard treatment

The best treatment known and in current use, based on the results of past research.

statistics

A type of mathematics used to collect and analyse large quantities of numerical data.

stem cell research

Research to better understand how stem cells work and how they might be used to help treat disease.

stem cells

Early-stage cells from which mature cells develop. Stem cells are found in the bone marrow.

supportive care

Care that extends beyond treating the actual cancer. It covers wider issues that occur due to cancer and includes

counselling, practical assistance, physiotherapy, occupational therapy, spiritual care and complementary therapies.

surgical oncologist

A doctor who specialises in the surgical treatment of cancer.

survival rate

The proportion of patients diagnosed with the same disease who are still alive after a particular period of time.

tissue

A collection of cells that make up a part of the body. When removed from the body, tissue is sometimes called a biospecimen.

tissue bank

A secure place where body tissue, such as blood, is frozen and stored for future research.

tissue banking

When people donate their tissue for research in the future.

toxicity

See side effect.

toxicology

The study of poisonous substances. It is a branch of pharmacology.

translational research

Research that fast-tracks results from basic research into studies that focus on a clinical situation.

treatment trial

A trial that tests a new or modified treatment.

x-ray

A type of scan that shows solid areas

in the body such as bone. It is used to diagnose different conditions.

References

1. Australian Institute of Health and Welfare, *Cancer survival and prevalence in Australia: period estimates from 1982 to 2010*. AIHW, Canberra, 2012.
2. Clinical Oncological Society of Australia, The Cancer Council Australia and the National Cancer Control Initiative, *Optimising Cancer Care in Australia*. National Cancer Control Initiative, Melbourne, 2003.

Can't find a word here?

For more cancer-related words, visit:

- cancercouncil.com.au/words
- cancervic.org.au/glossary
- cancersa.org.au/glossary



How you can help

At Cancer Council, we're dedicated to improving cancer control. As well as funding millions of dollars in cancer research every year, we advocate for the highest quality care for cancer patients and their families. We create cancer-smart communities by educating people about cancer, its prevention and early detection. We offer a range of practical and support services for people and families affected by cancer. All these programs would not be possible without community support, great and small.

Join a Cancer Council event: Join one of our community fundraising events such as Daffodil Day, Australia's Biggest Morning Tea, Relay For Life, Girls' Night In and Pink Ribbon Day, or hold your own fundraiser or become a volunteer.

Make a donation: Any gift, large or small, makes a meaningful contribution to our work in supporting people with cancer and their families now and in the future.

Buy Cancer Council sun protection products: Every purchase helps you prevent cancer and contribute financially to our goals.

Help us speak out for a cancer-smart community: We are a leading advocate for cancer prevention and improved patient services. You can help us speak out on important cancer issues and help us improve cancer awareness by living and promoting a cancer-smart lifestyle.

Join a research study: Cancer Council funds and carries out research investigating the causes, management, outcomes and impacts of different cancers. You may be able to join a study.

To find out more about how you, your family and friends can help, please call your local Cancer Council.



Cancer Council 13 11 20

Being diagnosed with cancer can be overwhelming. At Cancer Council, we understand it isn't just about the treatment or prognosis. Having cancer affects the way you live, work and think. It can also affect our most important relationships.

When disruption and change happen in our lives, talking to someone who understands can make a big difference. Cancer Council has been providing information and support to people affected by cancer for over 50 years.

Calling 13 11 20 gives you access to trustworthy information that is relevant to you. Our cancer nurses are available to answer your questions and link you to services in your area, such as transport, accommodation and home help. We can also help with other matters, such as legal and financial advice.

If you are finding it hard to navigate through the health care system, or just need someone to listen to your immediate concerns, call 13 11 20 and find out how we can support you, your family and friends.

Cancer Council services and programs vary in each area.

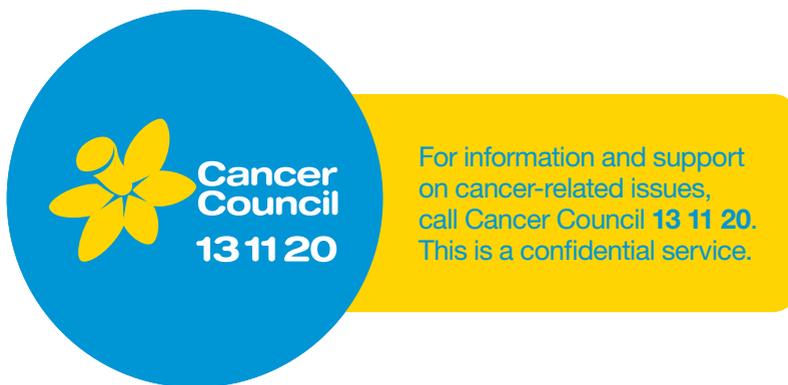
13 11 20 is charged at a local call rate throughout Australia (except from mobiles).



If you need information in a language other than English, an interpreting service is available. Call 13 14 50.



If you are deaf, or have a hearing or speech impairment, contact us through the National Relay Service.
www.relayservice.gov.au



Visit your local Cancer Council website

Cancer Council ACT
actcancer.org

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cancercouncil.com.au

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 To support Cancer Council, call your local Cancer Council or visit your local website.*