

Understanding Clinical Trials and Research

A guide for people with cancer, their families and friends



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.



Cancer Council acknowledges Traditional Custodians of Country throughout Australia and recognises the continuing connection to lands, waters and communities. We pay our respects to Aboriginal and Torres Strait Islander cultures and to Elders past, present and emerging.



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About this booklet

This booklet has been prepared to help you understand more about cancer research, particularly the research studies known as clinical trials. Cancer research has led to many advances in cancer care and continues to improve the lives of people affected by cancer.

We hope this booklet helps you make an informed decision about whether to take part in clinical trials or other types of cancer research. You can read about how to get involved in a clinical trial, what to consider before deciding to take part, and what to expect during and after the trial.

We cannot give advice about whether you should join a clinical trial. You need to discuss this with your doctors. However, this information may answer some of your questions and help you think about what to ask the clinical trials team (see page 51 for a question checklist).

This booklet does not need to be read from cover to cover – just read the parts that are useful to you. You may also like to pass this booklet to family and friends for their information.

How this booklet was developed – This information was developed with help from a range of health professionals and people who have taken part in clinical trials.



If you or your family have any questions or concerns, call **Cancer Council 13 11 20**. We can send you more information and connect you with support services in your area. You can also visit your local Cancer Council website (see back cover).



Contents

An overview of cancer research	4
Key questions	6
Why get involved in research?	6
Who can participate in research?	6
Where does research take place?	7
Who works on clinical trials?	8
Will I get better care in a clinical trial?	10
Is research safe?	11
How long do studies last?	11
Can I still have other treatments?	12
Is it free to join a study?	13
Will I be paid?	13
Can I be involved in more than one research study?	13
Clinical trials explained	14
The phases of a clinical trial	15
Randomised controlled trials	18
Non-randomised trials	22
Other types of clinical research	23
Joining a trial or study	26
Finding a trial or study	26
Deciding to take part	27
Eligibility criteria	28
Informed consent	30
Your role in the trial or study	34
Continuing the treatment	36
Withdrawing from a clinical trial	37
Finding trial results	37

Cancer research in Australia	40
Who funds cancer research?	40
Are there rules for research with people?	41
Involving consumers in research	44
Seeking support	46
Support from Cancer Council	47
Useful websites	48
Caring for someone with cancer	50
Question checklist	51
Glossary	52
How you can help	56

Key to icons

Icons are used throughout this booklet to indicate:



More information



Alert



Personal story



Tips



An overview of cancer research

Cancer research has led to the medical treatments and health programs available today. These advances have improved outcomes for people with all types of cancer over the past 20 years, with increases in both length of survival and quality of life. The search for better ways to prevent, diagnose and treat cancer is ongoing.

There are three main types of cancer research:

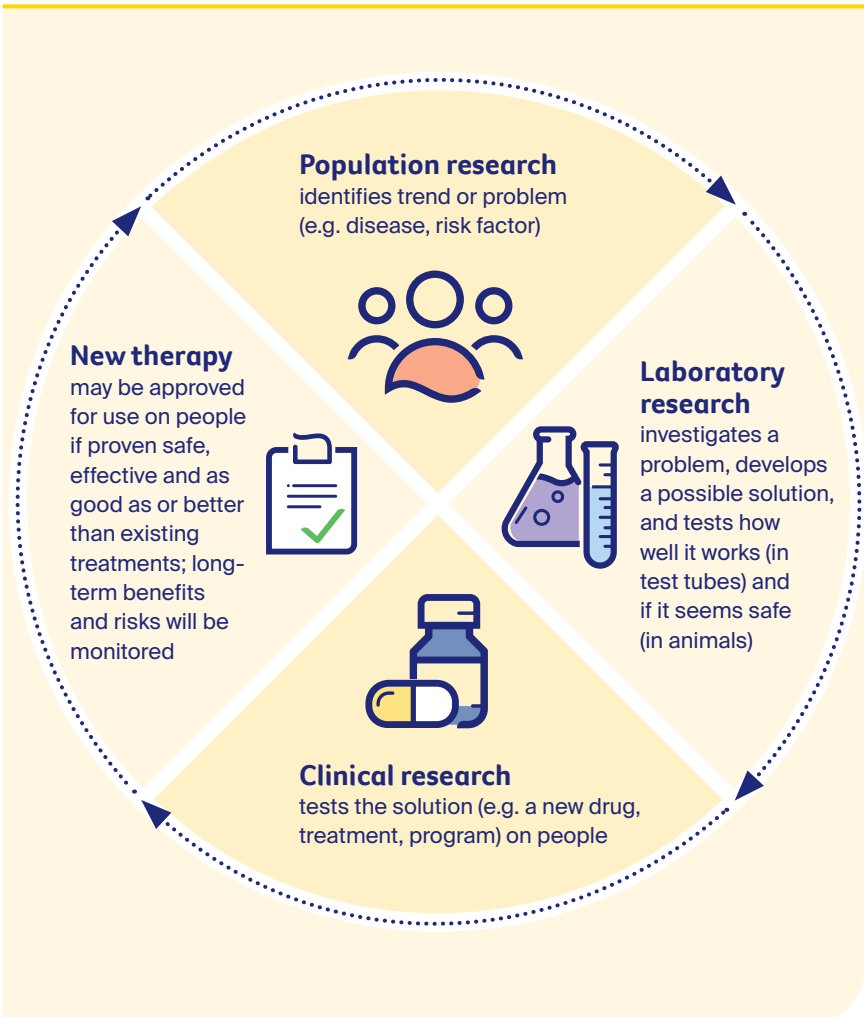
- **population research** – researchers known as epidemiologists look for patterns and trends to work out how and why cancers occur in groups of people (populations)
- **laboratory research** – scientists do experiments with the building blocks of disease, such as cells and blood, to try to understand how cancer works, and they also study and develop new drugs and treatments in the laboratory
- **clinical research** – research is done on people to better diagnose, prevent and treat cancer, often in a hospital or treatment centre.

Population research and laboratory research are often the starting point for clinical research, which may involve clinical trials.

What is a clinical trial? – A clinical trial can help show whether a new approach to prevention, screening, diagnosis or treatment works better than current methods and is safe. People volunteer to help test how well the new way works and if it causes side effects or other problems. If the new way is shown to work better than the existing method, it may become available. Some clinical trials compare existing approaches to see which one is more effective. See pages 14–25 for more information.

Cycle of research

The research process is a continuous cycle. People affected by cancer mainly take part in clinical trials, a type of clinical research. Research can lead to new and improved therapies becoming part of standard care.



Key questions

Q: Why get involved in research?

A: When cancer patients, carers and survivors, as well as people not affected by cancer, take part in research, it helps researchers learn more about cancer and ways to treat it.

Many people diagnosed with cancer who join a clinical trial or another research study do so because they want to help improve outcomes for others in the future, as well as for themselves.

Adults and children can take part in different ways, including:

- consenting to their medical records and personal information being accessed
- doing surveys and interviews
- being involved in a clinical trial
- agreeing to be examined regularly by health professionals
- allowing samples of cells or tissue taken during tests or treatment to be used for research outside of their own medical care.

Q: Who can participate in research?

A: All research studies, including clinical trials, have guidelines setting out who can take part. These are known as the eligibility criteria.

Most cancer research involves current patients, but some studies focus on cancer survivors, carers, family members, people at risk of cancer or people who have not been affected by the disease.

Anyone under the age of 18 needs permission from a parent or guardian before joining a research study.

To make sure results reflect Australia's diverse population, it is important that research involves people of all ages, genders and sexualities, as well as people from a wide range of social, economic, racial and cultural backgrounds.

To find out more about taking part in clinical trials or other types of cancer research, see pages 26–39.

Q: Where does research take place?

A: Cancer research is carried out in many places, including hospitals, treatment centres, laboratories and universities.

Sometimes you can be involved in cancer research from home. For example, you might have treatment or medicines mailed to you, or you might be asked to fill in a survey or complete a telephone or face-to-face interview.

Tele-trials for cancer

In Australia, some people are now taking part in clinical trials that use telehealth. This means that the research team use telephone or video calls to talk with patients and with local health professionals who are delivering part of the trial.

Clinical trials that use telehealth are sometimes called tele-trials. They were developed to make joining a

clinical trial easier for people in rural and remote locations, but they can make it more convenient for anyone to take part.

You can talk to your cancer specialist about whether there is a tele-trial you could join. If you are already involved in a clinical trial, you could ask if parts of it can be delivered by telehealth.

Who works on clinical trials?

A team of people work on clinical trials, and some of their roles overlap. If you decide to join a clinical trial, you may have contact with all or some of the people listed here.

Investigator

- also known as a researcher – there are usually a number of investigators/ researchers involved in a clinical trial
- develops and plans research studies, and obtains, analyses and publishes the results
- may have a background in medicine, nursing, science, psychology, allied health, consumer advocacy or complementary therapies
- the principal investigator is responsible for conducting the trial at their hospital or university, ensuring patients are safe and the trial is properly run; is usually a doctor or senior academic with expertise in the field of research
- a co-investigator works in partnership with the principal investigator in helping run the trial
- the coordinating principal investigator oversees research that is taking place at more than one study site, e.g. at two or more hospitals

Nurse or research assistant

- may be called a clinical trials nurse, a clinical research nurse or a research assistant
- coordinates finding people for the trial (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
- makes sure all necessary 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 for the trial (see pages 31–32)
- larger clinical trials or hospitals have a dedicated clinical trials nurse, but smaller ones might not

In most cases, your cancer specialist will continue to look after your overall cancer care while you are on the clinical trial.

Study coordinator	Cancer specialist	Other professionals
<ul style="list-style-type: none">• may be called a clinical research coordinator or clinical trials coordinator• may be combined with the nursing role• may have a science or nursing degree (or similar)• ensures the trial meets ethical and legal requirements• applies for grants and manages budgets• reviews the detailed plan (protocol, see page 28) for the trial and organises records	<ul style="list-style-type: none">• may be a medical oncologist, surgeon, radiation oncologist or haematologist• supervises your treatment, follow-up and overall care• usually is also the principal investigator or the coordinating principal investigator	<ul style="list-style-type: none">• a pharmacist stores and dispenses trial medicines, monitors their effect on patients and provides advice; may conduct laboratory research• allied health practitioners and complementary therapists may give advice or treatment if the study is investigating non-medical treatments such as counselling, nutrition, massage, physiotherapy and acupuncture

Q: Will I get better care in a clinical trial?

A: There are many advantages to being involved in a clinical trial or other research study. Depending on the type of research, the benefits may include:

- knowing you have made a valuable contribution to helping others in the future
- joining programs or having medicines or other treatments that are not readily available outside of the study and may be better than the current standard treatment for that disease
- getting access to expensive drugs that your specialists recommend but that are not currently subsidised by the Pharmaceutical Benefits Scheme (PBS)
- seeing your treatment team, including specialists, more often
- taking an active role in your health care
- learning new ways to improve your lifestyle
- improving or maintaining your quality of life
- feeling that you have tried all treatment possibilities.

Your doctor and the clinical trials or research nurse will discuss the possible advantages and disadvantages for you before you join a research study. Taking part in research doesn't always mean you will be better off than before or compared to other people in a similar situation. Some people may not respond in the way researchers hope and will not benefit from being involved in the research.

In some clinical trials, people are divided into two groups. Only one group receives the experimental treatment, while the other group receives the current standard treatment (see *Randomised controlled trials*, pages 18–22). You won't get to choose which treatment you have, but either way you will be monitored more frequently and closely than usual.



The Australian Government provides useful information for people who are considering joining a clinical trial – visit australianclinicaltrials.gov.au.

Q: Is research safe?

A: Understandably, people want to know if there are any risks to taking part in research. Researchers must follow strict guidelines to make sure clinical trials and other research studies are as safe as possible for everyone involved. This is called their duty of care.

Before any research involving people can begin, it must be approved by a special group known as a human research ethics committee (see page 42). As part of this process, researchers identify risks that might occur, such as possible side effects. They must also explain how they will closely monitor these risks and what will be done if problems occur. Before you agree to take part in research, you must be told about the risks, how you will be monitored for problems, and what will be done to help you if problems occur. For more information, see pages 30–32.

To reduce the risks, clinical trials are arranged in a series of steps known as phases. See pages 15–17 for information about the different phases of a clinical trial.

Q: How long do studies last?

A: From start to finish, clinical trials and other research studies may take several months or many years, but you may only need to be involved for some of this time. For example, you might just have a single appointment lasting a couple of hours, or you may go to appointments every few weeks, months or years. You may also have

to do surveys at regular times. The participant information (see page 32) will set out what you would need to do and how long you would be involved.

Studies have what is known as a recruitment phase. This involves finding people to enrol in the study. It usually occurs over a few months or years until the required number of people have agreed to take part. The study is then closed to new participants.

After the treatment stage is over, there may be a follow-up phase. People may be followed up at set intervals for months or years. This allows researchers to understand the long-term effects of treatments, monitor the general health of the participants, and collect data about long-term survival and quality of life.

Q: Can I still have other treatments?

A: Ask your doctor whether being involved in the research will affect any other treatments you're having or planning to have. These may include standard cancer treatments; medicines for managing treatment side effects or symptoms of cancer or other conditions; and complementary therapies such as herbal or nutritional supplements or massage.

Your doctor may suggest stopping or delaying some treatments, or adjusting them in some way (e.g. by changing the dose).



It is important to let the research team know about any other medicines, supplements or complementary therapies you are having, as these may interact with the treatment being tested and cause harmful side effects.

Q: Is it free to join a study?

A: Joining a clinical trial or other research study is free for Australian citizens and residents, and you should not be asked to pay to join.

The cost of trial-related treatment, tests and check-ups will be paid for by the organisation that is funding or conducting the research, sometimes called the sponsor. You will usually still have to pay for any treatments or tests you would normally pay for as part of your standard care. The participant information (see page 32) will outline any extra costs to you.

Q: Will I be paid?

A: People participating in cancer research usually don't get paid. This is because offering people money to join a clinical trial may put too much pressure on them to agree.

In some circumstances, you may be paid back for certain expenses (e.g. for travel, parking, light refreshments). These are known as out-of-pocket costs. The participant information (see page 32) will outline what expenses will be covered.

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

A: You may be interested in joining multiple clinical trials and other research studies. Check with the research team whether you can be part of more than one study at the same time. If you can, think about whether you'll be able to commit to all the requirements of the studies. With clinical trials for medicines, you can usually only join one trial at a time.



Clinical trials explained

Cancer clinical trials are research studies that use volunteers to test new ways (interventions) to diagnose, treat and manage cancer. If a trial proves that a test, treatment or other intervention is better than existing options, it may become the new standard of care for patients in the future.

A medicine or another intervention can be developed in a laboratory and tested on animals, but it is only once it has been tested on the human body that we can know it works in people. It also has to be tested on enough people to show that any benefit is not just a random effect for a single person.

A clinical trial will be designed to answer a particular type of research question.

Treatment trials – These test new treatments, new ways of giving existing treatments, or new combinations of treatments. They look at whether the treatment works and if it causes side effects. The treatments that can be tested include: medicines (chemotherapy, immunotherapy, targeted therapy and other drugs); medical devices; radiation therapy; surgical techniques; nutrition advice; physiotherapy; exercise programs; psychological therapies; and complementary therapies.

Most cancer clinical trials in Australia are treatment trials. The information in this chapter mostly relates to treatment trials.

Prevention trials – These work out whether medicines and health programs lower the risk of developing diseases such as cancer.

Screening trials – These look at new methods of detecting diseases before symptoms appear.

Diagnostic trials – These identify more accurate or easier tests for diagnosing a particular disease in people who have signs or symptoms.

Quality of life trials – These test ways to improve the comfort and quality of life of people who have cancer. They are done alongside a treatment trial.



To find out how to get involved in a clinical trial or another type of study, see pages 26–27.

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. Every phase considers whether the risks outweigh the benefits. Information gathered in each phase determines whether the study can move on to the next phase, and whether the drug or treatment is approved for use. There can be up to four phases, but not all clinical trials go through every phase. See the next two pages for a description of different phases.

“When I was diagnosed with cancer, a friend told me about the study. Getting involved was simple. Participating in cancer research is about giving to other people, and I think that’s a very valuable thing.” PHILLIPA

How clinical trial phases work

	PHASE 1 SAFETY	PHASE 2 EFFECTIVENESS
How many people take part (participants)	 <p>10-100</p>	 <p>100-300</p>
What it aims to do (purpose)	<ul style="list-style-type: none"> • first study in people • tests safety of new treatment • finds the safest dose and the best way it can be given, identifies side effects and checks how the treatment works with other medicines or food (interactions) • often includes people with different types of cancer 	<ul style="list-style-type: none"> • builds on the results of the phase 1 trial • continues to test safety of the new treatment • begins to assess how well the new treatment works on the disease
How it works	<ul style="list-style-type: none"> • participants are given a fixed dose and watched closely for side effects • the dose is often small in the first group of participants, and then gradually increased in the next groups until any side effects outweigh the potential benefits 	<ul style="list-style-type: none"> • often focuses on one type of cancer • the participants may be put into separate groups and given different treatments (randomised controlled trial, see page 18) or they may all have the same experimental treatment (non-randomised trial, see page 22)
More information	<ul style="list-style-type: none"> • may involve overnight stay in hospital for monitoring • people may benefit but often don't see big improvements 	<ul style="list-style-type: none"> • people often have treatment as an outpatient

PHASE 3 COMPARISON



100s-1000s

- tests if the new treatment is better than the best currently available treatment (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 or more treatment groups – experimental and control (see page 18)
- usually groups are randomised and sometimes blinded (see pages 19–22)
- a placebo (see page 21) may be used for comparison
- runs over a longer period of time
- some phase 3 trials help the Therapeutic Goods Administration (TGA) work out whether to approve a new drug for use in Australia

PHASE 4 FOLLOW-UP



1000s

- identifies how well the new treatment works when used more widely in the real world
- monitors the long-term benefits and risks
- looks for other uses of the treatment
- sometimes known as an expanded access study
- carried out after the treatment has been approved by the TGA
- usually run by pharmaceutical companies that make the product
- some people are able to get early access to new drugs before the cost is covered by the Pharmaceutical Benefit Scheme (PBS)
- not all treatments go through a phase 4 clinical trial
- phase 4 trials are less common than phase 1–3 trials

Randomised controlled trials

It is important for researchers to know that the results of a study are accurate and not caused by chance. This means they must follow strict guidelines. Researchers also need to make sure their own – or the participants’ – ideas or beliefs about the research don’t unfairly influence the results. There are various ways to make sure clinical trials are fair and reliable.

Many clinical trials are randomised controlled trials (RCTs). A randomised controlled trial helps prevent bias, so it is the best way to test if a new treatment works. (Bias occurs when the results of a trial are affected by human choice, expectations or other factors not related to the treatment being tested.)

Most phase 3 trials and some phase 2 trials are randomised. This means participants in the study are put into two or more groups (known as treatment arms) at random. The two groups then receive different treatments, and the results of the different groups are compared. Researchers cannot choose who goes into each group (see opposite).

Test or experimental arm – This group is given the new treatment that is being tested. Sometimes, the experimental treatment is given in addition to the current standard treatment.

Control arm – This group receives the current standard treatment for the disease or an inactive treatment known as a placebo (see pages 20–21).

When randomly allocated groups are compared with each other, it is possible to work out which treatment is better. This is because researchers can be certain that the results are related to the treatment, and not to any other factors (see also *Blinded studies*, pages 21–22).

How randomisation works

Information about everyone taking part in a clinical trial is entered into a computer.



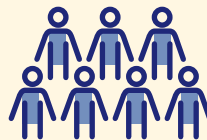
The computer gives each participant a code number.



The code numbers are randomly assigned to the different treatment arms, helping to prevent bias.



The control arm receives the standard treatment.



The test arm receives the new treatment.



Marg's story

After I was diagnosed with breast cancer, I asked if there were any clinical trials I could go on. I was told about a trial that was assessing a pain-relieving inhaler 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 a

questionnaire 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 be involved in the trial.

Standard treatment and placebos

In a randomised controlled trial, people in the control arm may receive the standard treatment or a placebo.

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

In some cases, the current standard of care is for the doctors to monitor the cancer closely with regular tests and check-ups, and only offer

treatment if the cancer progresses. This approach may be known as active surveillance or watchful waiting. For example, active surveillance is recommended for some early thyroid cancers that aren't causing any symptoms and are low risk, since the risks of treatment may outweigh the benefits in this situation.

Placebo – This is an inactive or “dummy” treatment. It is made to look, taste or feel like the treatment being tested, but it doesn't have any active (therapeutic) ingredients (if a medicine) or beneficial effect. Examples of placebos are sugar pills and saline injections.

A placebo is used to show whether any improvements are because of the actual treatment or because of other factors linked with being in the study, such as being more closely monitored or simply expecting the treatment to be helpful. If the people on the experimental treatment improve more than those on the placebo, this provides stronger evidence that it is the experimental treatment that is responsible.

Participants will be told if a study uses a placebo, but they won't be told which treatment they are having, and the research team usually don't know either. In cancer treatment trials, placebos may be used:

- together with the standard treatment – for example, one group gets the existing standard therapy plus the experimental treatment, and the other group gets the standard treatment plus a placebo
- on their own, but only when there is no existing standard treatment to compare against an experimental treatment.

Blinded studies

In a blinded study, participants don't know which arm of a study they're in. Some randomised controlled trials are called double-blind studies as neither the participant nor the research team know who is

receiving the experimental or control treatment. In a double-blind trial, the researchers only discover who is in each arm of the study at the end of the trial when the results are being analysed.

Blinding is used only when participants can't tell the difference between the two types of treatment. It is not used when the control and experimental treatment are noticeably different – for example, it would be hard to hide surgery and massage from the participant.

The aim of blinding is to reduce bias in the reporting of benefits and side effects. If you don't know which treatment you're having, the results are less likely to be influenced by your or your doctor's views. For example, if you or your doctor knew you were having the experimental treatment, you might report that you're feeling better than you actually are because you believe you are having a more effective treatment. In an emergency, your doctor can find out what treatment you're having by contacting those running the study.

Crossover studies

In crossover studies, the people in each trial arm receive that treatment for a time and may then have the opportunity to swap to the other treatment. This can mean all participants have all treatments and helps confirm which is the most effective. If the new treatment doesn't work as hoped with the first group, the second group won't cross over. You also won't cross over if you are doing well on the first treatment.

Non-randomised trials

In a single arm trial, everyone receives the same experimental treatment. This method may be used for phase 1 and phase 2 trials, or where the cancer being treated is rare and it is hard to conduct a randomised trial.

Registry trials

For most treatment trials, you will have the treatment as part of the trial. Another way researchers can compare how well different treatments work is through registry trials. A registry trial collects information from people with a particular type of cancer who are having routine treatment. It can't be used for testing new treatments, but it can answer a range of questions about existing treatments.

Your cancer treatment team may talk to you about joining a registry

trial. If you choose to join the registry, you agree to share your health information, such as your medical history, the treatments you are having and the results of tests. This information will then be compared with information from many other patients to work out which treatment approaches are the most effective.

Registry trials are a cost-effective way to run a clinical trial and they allow many more people to participate in cancer research.

Other types of clinical research

Clinical trials are not the only type of clinical research studies. You may also be invited to get involved in behavioural research or translational research.

Behavioural research

Behavioural researchers try to understand why people behave in the way that they do. They study the characteristics, lifestyles and social situations of different people to see how these factors may affect the risk of developing or surviving cancer. They then try to develop ways to prevent or change behaviours that might increase cancer risk or lower survival outcomes. Behavioural researchers also look at the emotional and social impacts of cancer on the person with cancer, as well as the impact on their family and friends.

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

You may also be able to take part in a program aimed at changing these behaviours. For example, you might be offered free counselling, an exercise class or a session on healthy eating. The aim of the programs may be to reduce cancer risk or to improve how you cope with the impacts of cancer.

Psychosocial research

One area of behavioural research is called psychosocial research. This looks at how cancer affects 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 a disease. They develop and test ways to improve people's ability to deal with the impacts of cancer.

Translational research

Translational research forms a link between laboratory and clinical research, or between clinical research and standard treatments. It aims to get new treatments or medical approaches into practice quickly. It is sometimes called “bench to bedside” research because laboratory research results are directly used to create new therapies and tests. The findings of behavioural and psychosocial research are also translated into information resources for people affected by cancer.

There can also be “bedside to bench” research – for example, hospitals, treatment centres and health professionals may collect information about how well a treatment works to help laboratory researchers work out what to study next.

Key points about clinical research

What clinical trials do

- Clinical trials test new or modified ways to prevent, screen, diagnose and treat cancer. Most cancer clinical trials look at new treatments.
- There may be up to four phases in a clinical trial to test whether the benefits outweigh the risks.

Types of clinical trials

- Randomised controlled trials test different treatments by randomly putting people into two or more separate groups (arms). These trials are the best way to prevent bias and work out which treatment is better.
- The test arm will receive the experimental treatment, and the control arm will receive the current standard treatment or a placebo.
- In a blinded study, the participant will not know whether they are receiving the experimental or the standard treatment. In a double-blind study, neither the participants nor the research team know who is getting which treatment.
- Non-randomised (single arm) trials are mostly used in phase 1 and 2 trials. All participants receive the same experimental treatment.

Other types of clinical research

- Behavioural research looks at why people act the way they do and what can be done to improve their ability to cope with cancer.
- Psychosocial research is a type of behavioural research. It looks at how cancer affects people emotionally, psychologically and socially.
- Translational research aims to get new treatments and prevention strategies into practice quickly by sharing information back and forth between researchers and hospitals, treatment centres or health professionals.



Joining a trial or study

This chapter explains how to find out about a clinical trial or other research study and what happens once you decide to participate.

Finding a trial or study

There are many ways to find out about clinical trials and other research studies. Most cancer specialists know about current studies and may recommend you join a suitable study, or you can ask them if there are any trials you can consider. If your hospital has a clinical trials or research nurse, you can also ask them about current studies. You don't have to join a study at your current treatment centre – your doctor can refer you to a suitable trial at another centre.

Hospital and treatment centre waiting rooms often have information about current studies, or you might hear about a study through patient support groups, in the general media or through social media (such as Facebook). Before providing any personal information, especially via social media, check the study with your doctors.

You can also search clinical trials websites (see pages 48–49). If there isn't a suitable study available right now, you can register through websites such as register4.org.au and www.cart-wheel.org, and they will tell you about any studies that come up in the future.

If you find a trial or study you're interested in joining, discuss it with your cancer specialist. You can ask them if you meet the eligibility criteria (see pages 28–29) and, if so, whether they could coordinate your involvement or put you in touch with the research team.

Deciding to take part

You may have many questions when deciding whether to join a clinical trial. As well as talking to your doctor and clinical trials nurse, it is a good idea to talk to people close to you, such as your family, carers or close friends. Ultimately, though, it's your decision to participate in research or not to participate.

You shouldn't feel pressured to take part in research, and you should not feel 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. You should usually be given at least a few days to consider the participant information (see page 32). If you would like to take more time to think about it, ask if it is safe to wait a bit longer before starting treatment. If you decide not to join a study, you will still receive the standard treatment for the cancer, and it won't affect your relationship with your treatment team.

Weighing up the benefits and risks

- Consider what is most important to you. Some people prefer to have standard treatment with predictable side effects, whereas others want to try something new even if the benefits are not yet proven or it may have unknown side effects.
 - Think about how the study might affect your health, wellbeing and lifestyle. What is the chance of any serious side effects? Will any parts of the study be too difficult (e.g. having to have extra tests or trips to the hospital)?
 - Weigh up these drawbacks and risks against the possible benefits, such as a possibly longer survival time or not having to experience certain side effects.
 - Remember that everyone's situation is different – what is the right decision for someone else may not be right for you.
-

“A clinical trials nurse accompanied me at every stage of the process. She explained what was happening and answered any questions I had.” MARG

Getting a second opinion

Some people like to get a second opinion about whether they should join a research study, particularly if it is a clinical trial. A second opinion can:

- confirm or clarify your doctor’s recommendations
- help you to consider all the advantages and disadvantages of being on the trial
- reassure you that you have thought about the different issues that might affect you.

If you would like to get a second opinion, ask your general practitioner (GP) for a referral to another cancer specialist, but keep in mind that you may have to wait several weeks for an appointment and you may have to pay extra.

You can also ask your cancer specialist if it is possible to talk to another specialist within the same hospital or treatment centre. Some people also like to discuss the possibility of a trial with their GP.

Eligibility criteria

Before any clinical trial or other research study begins, researchers develop the protocol for that study. This detailed plan describes the study’s design, the reasons for doing the study, and who can join (known as the eligibility criteria).

The eligibility criteria are the rules for who can take part in the research study. They outline the features that must be shared by all participants to ensure that the people taking part are similar in certain ways. This is so the results of the study will be clearly related to the treatment, not to other individual factors.

Depending on the research, the 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 treatments for the cancer
- other medical conditions.

Eligibility criteria can be broken down into:

- **inclusion criteria** – the features a person needs to have to join a research study
- **exclusion criteria** – the features that stop someone from taking part.

The eligibility criteria also help keep people safe by considering things that might make the trial too risky for them. For example, you may be excluded from a trial if you are pregnant, have high blood pressure, or have some other condition that increases the risks of the treatment.



Although there are thousands of different clinical trials occurring around the world at any one time, eligibility requirements can be very specific, and there may not be a trial suitable for your particular situation. For example, if you have metastatic cancer, the disease may have to be active or progressing for you to be eligible to join a particular trial.

Informed consent

Before becoming part of a clinical trial or other research study, all participants have to give “informed consent”. This means you will be asked to confirm you have read and understood the purpose, risks and possible outcomes of the research before deciding to join. Informed consent involves:

Written information – After talking to you about the study, members of the research team will give you a written document known as the participant information. This written information explains the purpose of the study, what is expected of you if you join, what the possible risks are, how your information will be used, and how the results will be presented (see page 32 for more details). You should read the participant information carefully and note down any questions you have for your doctors and the clinical trials or research team.

Informed consent discussion – After you have read the participant information, you can discuss the study in more detail with the clinical trials or research team. You should ask them to explain any parts of the written information that seemed unclear to you.

Agreement in writing – Once all your questions have been answered, you can then decide whether or not to join the study. If you do choose to take part, you will be asked to sign the informed consent form. This confirms that you understand the purpose of the study, what is involved, the potential risks and benefits, and you agree to participate.



For some low-risk studies, written informed consent may not be needed. For example, if you are doing a survey, just completing the survey may be taken as consent, or you may be able to say you consent over the phone.

“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}

For people under 18, a parent or guardian has to give legal consent as well. Signing the form is not a contract and you can change your mind at any time (see page 37). You will receive a copy of the consent form signed by you and the researcher.

The process of informed consent continues throughout the study. If the study changes or new information becomes available while you are involved, you will be given updated participant information. You will need to sign an updated version of the consent form if you are willing to continue.

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 also need to consent again if you are given an extra survey or interview.

Contact person

All clinical trials and other research studies have a contact person. You can talk with this person before you decide to take part 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 pages 8–9).

You will also be given details of who to contact if you have a complaint about the study (e.g. about how the study was run or how you were

treated). This person is independent of the research team and is usually a senior member of the human research ethics committee (see page 42). Complaints about research are rare, but it is your right to have your concerns heard if you have a problem.

Participant information

Researchers must provide written information about the research study to anyone thinking about joining. This is called participant (or patient) information. It answers a range of questions about the 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
- how the study will be monitored
- whether you will need to have tests, scans or other procedures
- how long you need to be involved
- where you need to go for appointments, treatments or meetings
- whether the researchers need to see your medical records
- whether you will be paid back (reimbursed) for any expenses related to the study (e.g. transport or parking costs)
- information about possible side effects or other risks
- information about possible benefits
- any restrictions on things you can do while you are on the study (e.g. treatments you can't have)
- who to contact for more information or if you have any problems or complaints during the study (see *Contact person* on previous page)
- information about your rights, such as keeping your records private (see opposite) and your ability to withdraw from a study (see page 37).

Privacy

Medical records are private and confidential, including those about your involvement in a clinical trial or any other research 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 give any information about you to others unless it is relevant to your health care or the study.

Clinical trials and other research studies collect personal data about you. The participant information may mention who will and won't have access to your personal data. For example, it might state that your regular treatment team won't see your survey responses, but the researchers will. You might be asked to consent to the research team seeing your existing medical records or particular test results.

Information collected during the study is often de-identified. In most cases, this means that your name will be removed and replaced with a unique participant number so your identity cannot be revealed unless necessary, e.g. for safety reasons. Being de-identified means when the results are published in medical journal articles or discussed at medical conferences, you will not be named.

If you have questions or concerns about your privacy in a clinical trial or other research study, talk to the clinical trials or research nurse. For general information about privacy issues in health care, talk to the social worker at your hospital.



At the end of a clinical trial, all personal information is stored in a secure place for at least 15 years before it can be destroyed. This is a legal requirement.

Your role in the trial or study

What you need to do when you agree to join a clinical trial or other research study depends on what kind of research it is. Some studies need preparation and ongoing follow-up, others involve a single visit or just a survey.

Finding out about the trial



- Your cancer specialist may suggest a trial to you, or you may find a trial through your own research (see page 26).
- Discuss the trial with a member of the clinical trials team and your cancer specialist. You may also choose to see another specialist for a second opinion.

Checking you are eligible



- Answer some questions about your medical history and have a physical examination and any required tests, such as a CT scan and blood test, to check that the trial is suitable for you. This is known as screening.
- Once the clinical trials team has these results, they will let you know if you have been accepted into the trial.

Deciding to join



- Read the participant information (see page 32). You may want to discuss the information with family, friends or your GP.
- Ask the trials team any questions you still have about the study, including questions about safety, side effects, financial issues, number of visits and timing (see page 51 for a list of suggested questions).
- If your questions have been answered and you agree to take part in the trial, sign the informed consent form (see pages 30–31).

Your participation is usually organised by one person (often a clinical trials or research nurse or research assistant), but you may come into contact with different members of the research team (see pages 8–9).

What to expect



- Expect that you may have less flexibility on the trial than you would with standard cancer care – for example, you may need to have blood tests or treatment on particular days. This may mean you need to adjust your work schedule or childcare arrangements more than you would if you were not involved in the research.
- 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.

During the trial



- Follow the instructions you are given about the trial – that means going to all appointments, having the required tests, taking medicines at precise times, and completing logs, surveys or interviews. This will help make the trial results as reliable as possible.
- Tell the research team about any side effects you are experiencing. The research team will ask about how you are feeling emotionally and physically.

After the trial



- Researchers may stay in contact with you and ask follow-up questions for some time after the trial. This will give them long-term information on how you responded to the trial.
- You may return to having the standard care and/or check-ups and tests that are appropriate for you, depending on the stage of the cancer and what your cancer specialist recommends. In certain circumstances, you may be able to keep having the trial treatment (see next page).



Communicating with the treatment team

- Keep contact details handy in case you have questions before, during or after the trial or study.
- If your clinical trials team has given you a participant card, keep this with you and show it to any other health professionals you see.
- If you join a clinical trial at a different hospital to the hospital where you started cancer treatment, you may have two treatment teams. In this 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.
- If you are in a trial and develop new or worsening symptoms, let your clinical trial and cancer care teams know immediately. If the symptoms are serious, go directly to your hospital's emergency department and/or contact the oncology registrar at the hospital. It is important to tell the hospital you're in a clinical trial and show them the participant card if you have one. If you go to hospital, let your clinical trials team know.

Continuing the treatment

Many people wonder if they can keep having the experimental treatment after a trial is over. This depends on several factors, such as the trial phase and results; how effective the treatment was for you; what the recommended course of treatment is; and whether the trial sponsor (see page 13) is prepared to continue providing the treatment.

Some people join clinical trials to get treatments that are not available anywhere else. It can be frustrating to have to stop a treatment after the study ends. When a trial shows that the experimental treatment works and has no major side effects, the treatment can sometimes be continued after the trial. Ask your doctor or clinical trials nurse.

Withdrawing from a clinical trial

Participating in research is voluntary and you can stop (withdraw) at any time. You may want to leave because you no longer have the time or energy for it; don't feel it is helping; have side effects or your health is worsening; move away from the treatment centre; or change your mind.

If you do decide to withdraw from a clinical trial, you will receive the standard treatment that is currently the best option for you. You may be asked why you are withdrawing from the trial – you do not have to give a reason, but it can help the research team understand more about the needs of participants if you do. You may also be asked if the team can still collect some information about your health. This can help them learn more, but it is your choice.

Finding trial results

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

If you'd like to know the results of the study you participated in, start by asking your doctor or clinical trials coordinator. The participant information you read at the beginning of the trial and the informed consent document you signed often say how and when the results will be available. The results are usually reported for everyone in the trial together, so you may not be able to see your individual results.

You may want to talk to your doctor about what the overall results mean. Sometimes the study results are shared with participants in an easy-to-understand document (lay summary).



Phillipa's story

When I was diagnosed with non-Hodgkin lymphoma, 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 I 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 these tests.

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.

“I got a second opinion from another haematologist.”

Key points about joining a trial or study

Deciding to take part

- There are lots of things to consider when deciding whether to join a clinical trial or another research study, such as the impact of the study on your wellbeing and lifestyle.
- You need to weigh up the benefits and risks before deciding that the study is right for you.

Joining a trial or study

- You may find out about current clinical trials and other research studies from your cancer specialist, your hospital's clinical trials nurse, clinical trials websites, and patient groups.
- You can only join a trial or study if you meet the eligibility criteria. This is because everyone in the group needs to have similar characteristics.
- You have to give informed consent to join a clinical trial. Before joining, you will be given written information about the study and will have an appointment to discuss the trial with the research team. If you decide to take part, you will need to sign a consent form.
- Talk to your doctors or the clinical trials nurse if you are thinking about joining a trial or study.

During the trial

- It is important to follow the instructions from the clinical trials team to ensure the results are valid.
- Your team will monitor your emotional and physical health.
- You can leave a trial at any time. You will continue to receive the standard treatment.
- Once the trial is over, it may take several years before the results are available.



Cancer research in Australia

Australia is an international leader in cancer research and has contributed to many of the major advances in cancer prevention, treatment and support. The involvement of people affected by cancer has been the key to much of this progress.

Before any clinical research can begin, it has to show it is scientifically worthwhile and fair to the people participating. The organisation, institution or company responsible for the overall conduct of a clinical trial is known as the trial sponsor. Their responsibilities include developing, financing and managing the trial, and ensuring the trial meets all legal, ethical and insurance requirements.

Who funds cancer research?

In 2016–18, more than \$252 million was awarded to 589 individual cancer research projects, with \$187 million (74%) of that from the Australian Government.¹ Cancer Council is the largest non-government funder of cancer research in Australia.

The funding for cancer research comes from a range of government and non-government sources:

National Health and Medical Research Council (NHMRC) – This is the Australian Government’s main funding body for medical research. The NHMRC awards grants to researchers based on their ability to investigate important questions about human health. The NHMRC also helps run the Medical Research Future Fund.

Medical Research Future Fund (MRFF) – The Australian Government set up this ongoing research fund in 2015, and it had grown to \$20 billion by 2020. The fund earns interest that can then be used to pay for important health and medical research projects.

Cancer charities – State and territory Cancer Councils and other charities receive donations from the public, as well as grants from government bodies and private companies. This funds their own cancer research and allows them to financially support cancer research carried out by other institutions.

Government bodies – Researchers can apply for grants from other national, state and territory government agencies. The grants fund the research and allow them to employ cancer trials staff.

Universities, medical research institutions and clinics – These sometimes use their own funds and staff to support research.

Private companies (industry funded) – Companies producing medicines and medical equipment run trials to check their products are safe and effective before applying for licences to sell them. Private companies may also fund research in partnership with a university or other research institution, or for goodwill (philanthropic) reasons.

Are there rules for research with people?

All research involving people must follow a set of international standards. These standards cover how the research is designed, conducted, recorded and reported. They ensure that people taking part in the research are safe, their privacy is protected, information is collected to the highest standard, and the results are reliable.

In addition, clinical trials and other clinical research must follow a set of standards called Good Clinical Practice (GCP). GCP is the same anywhere in the world where clinical research is conducted.

For links to more information about Australian guidelines for research involving people, visit australianclinicaltrials.gov.au/researchers/research-principles-and-guidelines.

How research is approved

Before a clinical trial or other research study can begin in Australia, it has to be approved by a number of committees:

Research or scientific review committee – This committee decides whether the study has social and scientific value and checks that it has been designed to produce valid scientific results.

Human research ethics committee (HREC) – This 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 to participate, and that the risks of the research generally don't outweigh the benefits.

The members of the HREC are always independent of the researchers and come from a variety of professions and the general community.

Research governance review – This is a review that checks all the locations (sites) where the research will take place. It 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 qualified. The governance officer approves the research to begin at each site.

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

Conflict of interest

A conflict of interest may arise in any research project. This means the interests of an organisation or researcher could influence the results of the research. Researchers are required to declare any possible or actual conflicts of interest. All research projects should include details of how a conflict of interest will be managed.

Changes to research

Sometimes changes need to be made to the research before or after the research is approved. The HREC may ask the research team to make changes to the proposed research before it can go ahead.

After the research has been approved, if the research team want to make any changes during the trial or study, it must go through ethics approval again before the changes can take place. If the changes are made, participants already taking part may need to sign another consent form to show that they have been told about the changes and still agree to be involved.



The Therapeutic Goods Administration (TGA) is an Australian Government department that regulates all medicines sold in Australia. The TGA must be notified of any new drug that is going to be used in a clinical trial. If the trial shows that the drug is safe and effective, the TGA may then approve it for use outside of a clinical trial. For more information about the role of the TGA, visit tga.gov.au.

Involving consumers in research

Sometimes people want to contribute to research without joining a clinical trial or other research study. They may have been affected by cancer in the past – either directly or indirectly – and want their experience 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 which projects should be funded. They may also be asked to review a draft participant information sheet or provide feedback on what a proposed study is asking of participants.

Cancer Council offers an online training course known as the Cancer Consumer Involvement in Research Training Program. This teaches people how to work with researchers. Visit cancer.org.au/online-resources/elearning/consumers-in-research-training.

Cancer Australia developed the National Framework for Consumer

Involvement in Cancer Control. This initiative includes a web-based toolkit for cancer researchers and other professionals who involve consumers in their work. For more details, go to consumerinvolvement.canceraustralia.gov.au.

The Australian Clinical Trials Alliance offers a consumer involvement toolkit as well as information about clinical trials in community languages. Visit involvementtoolkit.clinicaltrialsalliance.org.au.

Consumer advocacy organisations are available at a national level and in some states. They focus 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 Voices SA cancervoicessa.org.au
- Cancer Action Victoria canceractionvic.org.au

If you would like to get involved in research as a consumer, contact one of these organisations or call Cancer Council 13 11 20.

Key points about cancer research in Australia

How research is funded

- Australian cancer research is funded by a range of government bodies, charities and private companies.
- The main government funding body is the National Health and Medical Research Council (NHMRC).
- Cancer Council is the largest non-government funder of cancer research in Australia.

How people are protected

- The international standards for research involving people ensure that the research is worthwhile, ethical and safe and will produce reliable results.
- All research and clinical trial proposals must be approved by a research or scientific review committee, a human research ethics committee and a research governance officer.

How consumers can get involved in research

- Participating in a clinical trial or other research study is not the only way to contribute to cancer research. People who get involved in research in other ways are known as consumers.
- Consumers often help decide what research should be funded.
- To find out more about getting involved in research as a consumer, contact Cancer Council or a consumer advocacy organisation.



Seeking support

When you are first diagnosed with cancer, you may feel that you don't have enough time or energy to think about getting involved in research. For most people, their key goal will be to start treatment as soon as possible and then concentrate on getting better. Some people will be keen to take part in research or they 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 in research, you may have mixed emotions during or after the study. Although people who join clinical trials generally say it is 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 your health is not improving or you're not getting the best treatment.

After the trial ends, you may feel relieved because you no longer have this commitment. You may be happy with the outcome and feel ready to put the cancer behind you. On the other hand, you may feel worried because your health won't be monitored as frequently, or you may be disappointed if the cancer has not gone away.

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.

Support from Cancer Council

Cancer Council offers a range of services to support people affected by cancer, their families and friends. Services may vary by location.

Cancer Council 13 11 20



Our experienced health professionals will answer any questions you have about your situation and link you to local services (see inside back cover).

Information resources



Cancer Council produces booklets and fact sheets on more than 25 types of cancer, as well as treatments, emotional and practical issues, and recovery. Call 13 11 20 or visit your local Cancer Council website.

Legal and financial support



If you need advice on legal or financial issues, we can refer you to qualified professionals. These services are free for people who can't afford to pay. Financial assistance may also be available. Call Cancer Council 13 11 20 to ask if you are eligible.

Practical help



Cancer Council can help you find services or offer guidance to manage the practical impacts of cancer. This may include helping you access accommodation and transport services.

Peer support services



You might find it helpful to share your thoughts and experiences with other people affected by cancer. Cancer Council can link you with individuals or support groups by phone, in person, or online. Call 13 11 20 or visit cancerCouncil.com.au/OC.

Useful websites

You can find many useful resources online, but not all websites are reliable. These websites are good sources of support and information.

For general information: Australian websites

Cancer Council Australia	cancer.org.au
Cancer Council Online Community	cancercouncil.com.au/OC
Cancer Council podcasts	cancercouncil.com.au/podcasts
Guides to Best Cancer Care	cancer.org.au/cancercareguides
Australian Clinical Trials	australianclinicaltrials.gov.au
Cancer Australia	canceraustralia.gov.au
Consumer Involvement in Cancer Cooperative Trials Groups	consumerinvolvement.canceraustralia.gov.au
National Health and Medical Research Council (NHMRC)	nhmrc.gov.au
NHMRC Clinical Trials Centre	ctc.usyd.edu.au
Pharmaceutical Benefits Scheme (PBS)	pbs.gov.au
Services Australia (Centrelink, Medicare)	servicesaustralia.gov.au
Therapeutic Goods Administration (TGA)	tga.gov.au

International websites

Cancer Research UK	cancerresearchuk.org
ClinicalTrials.gov (US)	clinicaltrials.gov
EU Clinical Trials Register	clinicaltrialsregister.eu
International Clinical Trials Registry Platform	who.int/clinical-trials-registry-platform
ISRCTN registry	isrctn.com
NHS – Clinical Trials (UK)	www.nhs.uk/conditions/clinical-trials

To find current Australian trials

Australian Cancer Trials	australiancancertrials.gov.au
Australian New Zealand Clinical Trials Registry	anzctr.org.au
Cancer Council SA	cancersa.org.au/research/clinical-trials
Cancer Institute NSW	cancer.nsw.gov.au/cancer-trials-nsw-list
ClinTrial Refer	clintrialrefer.org.au
Victorian Cancer Trials Link	trials.cancervic.org.au
Western Australia Cancer Clinical Trials Registry	cancerwa.asn.au/professionals/wa-clinical-trials-registry

To find trials for specific cancers and treatments (Multi-site Collaborative Cancer Clinical Trials Groups)

Australasian Gastro-Intestinal Trials Group	gicancer.org.au
Australasian Leukaemia & Lymphoma Group	allg.org.au
Australian and New Zealand Urogenital and Prostate Cancer Trials Group	anzup.org.au
Australia New Zealand Gynaecological Oncology Group	anzgog.org.au
Breast Cancer Trials	breastcancertrials.org.au
Cooperative Trials Group for Neuro-Oncology	cogno.org.au
Melanoma and Skin Cancer Trials	masc.org.au
Psycho-oncology Co-operative Research Group	pocog.org.au
Thoracic Oncology Group Australasia	thoraciconcology.org.au
Trans Tasman Radiation Oncology Group	trog.com.au



Caring for someone with cancer

You may be reading this booklet because you are caring for someone with cancer who is interested in taking part in a clinical trial or another research study. It is often a good idea for carers to 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 join a study can only be made by the person with cancer (unless they're under 18), it's important to understand what impact the study might have on them, and on you and your family. For example, you may have to take extra time off work to drive the person to appointments, or you may be worried about how the treatment will affect them. If the study will mean you have extra expenses (such as parking fees), check whether you can be paid back for these.

Being involved in research may offer the person with cancer a chance to have a promising new or improved treatment or useful supportive care options. It may be satisfying to know that their participation will help others in the future. As a carer, you may also be asked to take part in research into the experience of carers, for example, by doing surveys about your wellbeing. You could read this booklet to help you decide.

Caring for someone with cancer can be stressful. Try to give yourself some time out, and share your worries and concerns with somebody neutral such as a counsellor or your doctor. To find local support services and information, contact the Carer Gateway (call 1800 422 737 or visit carergateway.gov.au) or call Cancer Council 13 11 20.

► See our *Caring for Someone with Cancer* booklet.

Question checklist

Asking questions will help you make an informed choice. You may want to include some of the questions below in your own list.

How the trial or study will affect you

- What are my chances of benefiting from this research?
 - What are the potential risks to me?
 - Will I experience any side effects? How will they be treated?
 - Are there any extra tests involved?
 - Will I need to take time off work? Will my day-to-day life be affected?
 - Can I be paid back for any out-of-pocket expenses?
 - Can I still participate if I need to travel interstate or overseas?
 - If I join this study, will I miss out on other treatment opportunities?
 - How much time do I have to think about whether to join this trial? If I take time to decide, will delaying the treatment affect how well it works?
 - Who will oversee my cancer care while I'm participating?
 - Can I still have other medicines or complementary therapies?
-

About the trial or study

- Can you go through the participant information with me?
 - Can I have the participant information in a different language?
 - 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? How long do I need to be involved?
 - Will the trial use a placebo?
 - If it is a randomised controlled trial, will I have the option to switch treatment arms if the cancer advances or I have bad side effects?
 - Who is funding the trial? Has it been approved by an ethics committee?
 - Who can I contact if I have a problem?
 - Can I leave the trial early?
-

After the trial or study

- What will happen with the research results? How will I be told about them?
 - Will I have follow-up care through the clinical trials team?
 - If I respond to the treatment, will I still be able to get it after the trial is over?
-

Glossary

allied health professional

A university-qualified professional who works with others in a health care team to support a person's medical care. Examples include psychologists, social workers, occupational therapists, physiotherapists and dietitians.

arm

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

behavioural intervention

Method of influencing a person's behaviour, e.g. to encourage them to take certain actions to improve their physical or mental health.

behavioural research

Research into how people's behaviours affect their chances of getting or recovering from cancer.

bias

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

blinded trial/study

A trial in which participants do not know if they are receiving the control or the experimental treatment.

bone marrow

The soft, spongy material inside bones. Bone marrow makes stem cells that become red blood cells, white blood cells and platelets.

cancer

Uncontrolled growth of cells that may result in abnormal blood cells or grow into a lump called a tumour. These cells may spread through the lymphatic system or bloodstream to form secondary (metastatic) tumours.

cells

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

clinical research

Research that is done on people to better diagnose, prevent and treat disease.

clinical trial

A research study that tests new approaches to prevention, screening, diagnosis or treatment, to see if they are better than current approaches.

complementary therapy

Any of a range of therapies used alongside conventional treatment to improve general health, wellbeing and quality of life.

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

diagnostic trial

A trial that identifies more accurate or easier tests for diagnosing a particular disease in people who have signs or symptoms.

double-blind trial

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

eligibility criteria

Characteristics of the people who are suitable for a particular trial.

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.

haematologist

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

informed consent

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

intervention

What is tested in a clinical trial. Examples include drugs, surgical methods, medical devices, tests and behavioural interventions.

investigator

Another term for a researcher. Can be a coordinating principal investigator (multiple sites) or a principal investigator (one site).

laboratory

Place where experiments are carried out and new medicines developed.

laboratory research

Research that is carried out in a laboratory to study tiny components of the body,

including cells, compounds and molecules. Sometimes called basic research.

longitudinal study

A study done over a long period of time – often decades – with 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 vessels, nodes and organs that removes excess fluid from tissues, absorbs fatty acids, transports fat and produces immune cells. Includes the bone marrow, spleen, thymus and lymph nodes.

medical device

A device placed in or on a person's body to help treat a disease.

medical oncologist

A doctor who specialises in treating cancer with drug therapies such as chemotherapy, targeted therapy and immunotherapy (systemic treatment).

oncology

The study, diagnosis and treatment of cancer.

participant (in a clinical trial)

Someone who has the treatment or other intervention being tested in a clinical trial. In cancer clinical trials, this will usually be the person with cancer but sometimes can be former patients, carers, family members, people at risk of cancer or people who have been affected by cancer.

participant information

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

Pharmaceutical Benefits Scheme (PBS)

A government-funded scheme that subsidises some prescription medicines.

phase

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

placebo

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

population research

Research that looks for patterns and trends to work out how and why cancers occur in groups of people (populations). It is done by researchers known as epidemiologists.

prevention trial

A 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 people from the start of the study up to a point in the future. Also called cohort studies.

protocol

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

psycho-oncology

A field of cancer care concerned with the emotional and social responses of people with cancer and their families.

psychosocial research

Research into the emotional, psychological and social effects of disease and how people can be helped by supportive care measures.

qualitative study

A study that focuses on individual responses (e.g. to a survey) rather than numerical data.

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.

quality of life trial

A trial that tests ways to improve the comfort and quality of life of people who have cancer.

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 radiation therapy.

radiation therapy (radiotherapy)

The use of targeted radiation to kill or damage cancer cells so they cannot grow, multiply or spread. The radiation is usually in the form of x-ray beams.

randomisation

A method that can help prevent bias in research. A computer puts patients into groups by chance.

randomised controlled trial (RCT)

A trial in which people are randomly put into groups to have the experimental treatment or the standard treatment (the control).

registry trial

A trial that collects information from people with a particular type of cancer who are having routine treatment.

remission

When the signs and symptoms of the cancer reduce or disappear. This may not mean that the cancer is cured.

research governance officer

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

research grant

Money that is given by an institution to fund research. The grant is usually allocated through a competitive process.

response

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

retrospective study

Research that looks at what has happened in the past to help understand something in the present. Also called case control studies.

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. Most side effects can be managed.

single-blind trial

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

sponsor (trial sponsor)

The organisation, institution or company responsible for developing, financing and managing a clinical trial, and making sure that the trial meets all legal and insurance requirements.

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.

supportive care

Care and support that aims to improve the quality of life of people living with cancer, their family and carers.

surgical oncologist

A doctor who specialises in treating cancer with surgery.

survival rate

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

telehealth

Health care appointments done by phone or video instead of face to face.

tele-trials

Clinical trials that use telehealth to involve patients and local health professionals in different locations.

tissue

A collection of cells of similar type that make up an organ or structure in the body. When removed from the body, tissue is sometimes called a biospecimen.

toxicity

See side effect.

translational research

Research that fast-tracks results from laboratory research with the aim of getting new treatments into clinical practice quickly.

treatment trial

A trial that tests a new or modified treatment.

Can't find a word here?

For more cancer-related words, visit:

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

References

1. Cancer Australia, *Cancer Research in Australia 2016 to 2018*, Cancer Australia, Surry Hills, 2016. Available from: canceraustralia.gov.au/research/grants-and-funding/cancer-research-in-australia.



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 other Pink events, 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 experienced health professionals 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.



If you need information in a language other than English, an interpreting service is available. Call 131 450.



If you are deaf, or have a hearing or speech impairment, you can contact us through the National Relay Service. communications.gov.au/accesshub/nrs

*Cancer Council services and programs vary in each area.
13 11 20 is charged at a local call rate throughout Australia (except from mobiles).*

For information & support
on cancer-related issues,
call **Cancer Council 13 11 20**

Visit your local Cancer Council website

Cancer Council ACT
actcancer.org

Cancer Council NSW
cancercouncil.com.au

Cancer Council NT
cancer.org.au/nt

Cancer Council Queensland
cancerqld.org.au

Cancer Council SA
cancersa.org.au

Cancer Council Tasmania
cancer.org.au/tas

Cancer Council Victoria
cancervic.org.au

Cancer Council WA
cancerwa.asn.au

Cancer Council Australia
cancer.org.au

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

