

Understanding Clinical Trials

A guide for people with cancer, their families and friends.



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First published November 2001

This edition September 2004

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ISBN 1 865 07 083 1

Acknowledgements

The Cancer Council NSW thanks the authors of this booklet, Dr Martin Stockler, the Director of Cancer Trials NSW, and Marie Malica, Project Manager, Cancer Trials NSW. Dr Stockler is also Senior Lecturer in Cancer Medicine and Clinical Epidemiology, University of Sydney; Co-director of Cancer Trials, NHMRC Clinical Trials Centre, University of Sydney; and Consultant Medical Oncologist, Sydney Cancer Centre, Royal Prince Alfred and Concord Repatriation General Hospitals.

We thank Sally Crossing, of Cancer Voices NSW, Mary Curtis, of the ANZ Breast Cancer Trials Group, Consumer Advocacy Panel, and Laura Jakob and Jenny Mothoneos of The Cancer Council NSW for their valuable comments.

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The Cancer Council New South Wales

The Cancer Council is the leading cancer charity in New South Wales. It plays a unique and important role in the fight against cancer through undertaking high-quality research, advocating on cancer issues, providing information and services to the public and people with cancer, and raising funds for cancer programs.

This booklet is funded through the generosity of the people of New South Wales. To make a donation to help defeat cancer, visit The Cancer Council's website at www.cancercouncil.com.au or phone 1300 780 113.

Before commencing any health treatment, always consult your doctor. This booklet is intended as a general introduction to the topic and should not be seen as a substitute for your own doctor's or health professional's advice. All care is taken to ensure that the information contained here is accurate at the time of publication.

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Introduction



If you have been diagnosed with cancer, you may want to know about clinical trials and what role they may have in your treatment. This booklet explains what clinical trials are, why they are necessary, and how they are done.

People participating in trials are helping to advance medical science and are improving the prospects for people in the future. Every trial increases our knowledge and helps the search for better results.

The aim of this booklet is to help you make informed decisions by answering the questions often asked by people considering being in a clinical trial.

You may like to pass this booklet to your family and friends for their information.

This booklet does not need to be read from cover to cover – just read the parts that are useful to you.

Some medical terms that may be unfamiliar are explained in the glossary.



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What is a clinical trial?

Clinical trials are research studies that test new and better ways of improving health in people.

They find out whether new and promising approaches to prevention, diagnosis and treatment are possible, safe and effective. Some trials look at ways of improving a person's quality of life.

In cancer, clinical trials are the final stages of a long and careful process that often starts many years earlier in the laboratory. Trials are the link between scientific discoveries made in the laboratory and making new treatments available for people with cancer.

Types of trials

Treatment trials: test new treatments and are the most common kind of clinical trial. Many types of treatment may be tested including:

- drugs, such as chemotherapy, hormones and new drugs
- radiation therapy
- surgical methods
- supportive treatments (treatment against the effects of the cancer, not against the cancer itself)
- palliative care
- ways to combine treatments
- new treatments like gene therapy, vaccines and antibodies
- counselling and psychological support
- alternative therapies.

While this booklet focuses on information about treatment trials, two other main types of clinical trials are conducted in cancer research.

Prevention trials: test new approaches – such as medicines, vitamins, minerals or other supplements – that may lower the risk of getting cancer. These trials look for the best way to prevent cancer in people who have never had it, or to prevent second new cancers in people cured of their first cancer.

Screening trials: test the best way to find cancer, especially in its earliest stages. Examples of screening include Pap smears, mammograms, x-rays and blood tests.

Why clinical trials are important

Clinical trials are the best way to improve the treatment and care of people who have cancer. Trials give us essential information about the effects of different treatments – information that doctors and patients cannot find in any other way.

Trials are how we discover if new treatments are more effective or have fewer side effects.

The results of clinical trials today will improve treatment for people who develop cancer in the future. A new treatment can only become standard treatment if it is proven to be safe and effective in a clinical trial.

Many of the most effective treatments used today are the result of clinical trials done in the past 30 years.

Clinical trials are also important because they identify risks and side effects, which must be weighed up against the possible benefits of the new treatment.

How clinical trials help people with cancer

People being treated as part of a clinical trial do better than people treated outside of a clinical trial. This is at least partly because people who go in trials are fitter and better able to comply with treatment than people who aren't in trials.

People who take part in trials get the best available treatment or treatment that may be better. They also get extra personalised care and attention from their research nurses and treating doctors. Their treatments, tests and follow-up abide by strict plans and guidelines. They also get extra information about their disease and treatment.

The benefits of being in a clinical trial are the same for people whether they are in a control group, which receives the best standard treatment, or in the experimental group, which receives the new treatment being tested.

Therefore, one of the best ways to improve the care of people with cancer is to get people into clinical trials. Despite this, less than 3% of adults diagnosed with cancer in NSW are enrolled in cancer clinical trials.

Clinical trials have been enormously successful for children. Over 80% of children with cancer are enrolled in clinical trials, compared with less than 15% 20 years ago. As enrolment in clinical trials has improved, the overall survival rate for children with cancer has increased from less than 15% to over 80% and is still climbing.

Personal insight

Andrew, 75, is taking part in an international trial of a new drug to reduce bone problems from prostate cancer. This is a double blinded trial, so neither Andrew nor his doctors know whether his monthly injections contain an active drug or placebo (dummy drug).

“When I was asked to enter this trial, I couldn’t see how I could lose out,” Andrew said. “If I’m having the placebo, at the very least I’m seeing the oncologist every four months. More importantly, I’m getting a bone scan every four months. Bone scans cost hundreds of dollars but are free in the trial.

“If I wasn’t in the trial, I wouldn’t have a bone scan every four months. But being in the trial means that if something does begin to go wrong, it will be picked up on the bone scan fairly quickly. If I have to have further treatment, it could be initiated fairly quickly, so that could conceivably be to my benefit.”

Why do people enter trials?

People enter clinical trials for the same reasons that doctors and researchers run them – in the hope that new treatments will be found that benefit people affected by cancer.

Clinical trials test treatments that aim to treat cancer better. You should have the same hope of being helped by the new treatment as you would of being helped by the best available treatment.

People in trials may also get a new treatment that is not available outside the trial.

If you choose to take part in a clinical trial, remember that all the treatments have been carefully researched and tested to make them as safe and suitable for your disease as possible.

The treatment will often have been tested in other people – ask your doctor how many people have had this treatment before. See page 34 for a checklist of questions for your doctor.

“When my doctor asked me if I wanted to go on the trial, he said it may not help me but it might help somebody else. I was quite happy to go along with that.”



How clinical trials work

Each trial tries to answer specific questions that will help find new and better ways of helping people affected by cancer.

Three questions must be answered before a new treatment can be used widely:

1. How should the new treatment be given or done?
2. Does the new treatment seem to work?
3. Is the new treatment better than the best current treatment?

A separate and different clinical trial is needed to answer each of these questions. The three kinds of trials needed to answer these questions are called phase 1, phase 2 and phase 3 clinical trials, because they need to be done in this order.

Phase 1 trials

Phase 1 trials are the first clinical studies that involve people. They are conducted after the treatment has been tested for safety in laboratory tests and in animals.

These trials test how a new treatment should be given (for example, by mouth, injected into the blood or a muscle, or some other way), how often it should be given and, if it involves medication, what dose is safe.

A phase 1 trial usually involves up to about 20 people, because only a small number of people are needed to find a safe dose. At first, a few people are given a certain dose and watched carefully for side effects.

If side effects are not a major problem, a few more people are treated at a higher dose. The dose is gradually increased to find the best dose that can be given safely.

These trials carry the greatest uncertainty because there is little experience with the treatment. They are generally only suitable for people who have already had all the known effective treatments for their cancer.

If a phase 1 trial shows the new treatment is safe, the treatment will go on to phase 2 testing.

Most people in phase 1 trials have incurable cancer. Some people take part in the hope that the treatment may extend their life or improve their quality of life. But often people go on a phase 1 trial because they want to fight their cancer and to help others.

All new drugs have to be tested in phase 1 trials, but only a small number prove to be beneficial. People who participate in phase 1 trials sometimes benefit from having the new treatment, but major improvements in their condition are uncommon.

Phase 2 trials

Phase 2 trials continue to monitor the safety of the treatment, and test how well it seems to work in more people.

These trials usually involve between 20 and 50 people who have the same kind of cancer and are given the same treatment. Throughout the study, researchers monitor the people taking part (participants). They watch for side effects and measure the effects of the treatment on their cancer, often using scans and blood tests.

Phase 2 trials are generally suitable for people who have already had treatments known to be effective for their kind of cancer. The chance of benefiting from treatment in a phase 2 trial depends on the type and stage of the cancer, and on the person's response to previous treatment.

If the treatment continues to be safe and seems effective in a significant number of people, it goes on to phase 3 testing, where it is compared with the best standard treatment.

Phase 3 trials

Phase 3 trials compare the new treatment with the current standard. The aim of phase 3 trials is to work out which treatment is best.

Having progressed successfully through phases 1 and 2, phase 3 trials test new drugs, combinations of drugs, types of surgery, ways of giving radiation therapy and other new approaches.

Participants are assigned at random to either a group that will receive the best standard treatment or the group to have the new treatment. (Randomisation is explained on page 24).

Phase 3 trials are large and often involve between hundreds and thousands of people with the same kind of problem. They are usually done at many doctors' offices, clinics and cancer centres around the country or even around the world.

Participants are given the treatment and are watched carefully for side effects, and for effects on their disease, length of life and quality of life. At the end of the study, these effects are compared – to work out which treatment is best and by how much.

Trial phases: key points

Phase 1

- the first study that involves people
- looks at how a new treatment should be given, how often and, if it involves medication, what dose is safe
- only involves a small number of people.

Phase 2

- continues to test the safety of the treatment
- assesses how well the new treatment seems to work
- involves about 50 people.

Phase 3

- compares a new treatment to the best standard treatment, to work out which is best
- assigns people at random to receive the new treatment or the best standard treatment
- usually involves between hundreds and thousands of people.

How to find a clinical trial

If you would like to take part in a clinical trial but have not been asked, you can talk to your doctor, who may be involved in a suitable trial or know of one being done elsewhere.

If not, they may be able to help you find one. Each trial is not run in every centre, so you might have to travel to a different location.

If you hear or read in the media about a clinical trial for your type of cancer, you should ask your doctor for more information. Keep in mind that the trial may be for people with other kinds of cancer, and may not be running in your State or country.

Cancer trials register

The Cancer Council and Cancer Trials NSW are planning a comprehensive website and register of all cancer clinical trials available in Australia. At this time general information about clinical trials and the first stages of the register are available on The Cancer Council website, www.cancerCouncil.com.au.

The Internet can be a useful source of information for people with cancer. Always check information you find on the Internet with your doctor. Some suggested websites are listed on page 33.

Personal insight

Rosemary, aged 59, was diagnosed with breast cancer in 2000. After having surgery aimed at curing her cancer, she was advised to have additional (adjuvant) treatment. She was offered this additional treatment as part of a randomised trial aimed at improving cure rates. Rosemary agreed, and is one of about 600 women from Australia, and more than 2,700 worldwide, taking part in this trial.

“I was really happy to be involved in the trial. Many women had been on trials before me and I had the advantage of those previous trials,” Rosemary said. “My first reaction was: ‘If I can do something to help other women along the line, I would like to do that.’”

“I realise I had a lot of personal benefit from being in the trial because I was very well taken care of. I had a lot of personalised care and I felt that I was receiving better care because I was on the trial.

“With the randomness, there was equal opportunity I would have the new drug that they were testing or the current treatment. It didn’t worry me what treatment I was on. Even if I didn’t have the new drug, I realised that I was better off.

“I would definitely be involved in a clinical trial again. I have worked in market research so I know if we are going to go forward, we have to do the research. I’m 59, I’ve had a good life, and I want to give something back.”

How trials change cancer treatment

It normally takes several years before the results of a trial are known. During this time, researchers follow up what happens to people in the trial, calculate and interpret results, and prepare reports.

The results are usually first presented at a meeting of the researchers involved in the trial. The next step is to present the results to a meeting of cancer researchers not involved in the trial where there is more scrutiny and debate.

A report is then prepared and submitted to a medical journal. The report is peer-reviewed – this means that independent experts in the field provide criticisms, questions and suggestions. If the researchers are able to answer these satisfactorily, the medical journal accepts the report and it is published.

When a study is published in a medical journal, it allows many doctors to consider the study, to debate the issues and consider whether they should change the way they treat cancer.

When the treatment is proven to be better, based on the available medical evidence, clear recommendations can be made about the treatment, such as who should have it, in what dose and for how long.

Comparing results

To work out whether accepted cancer treatment should change, all trials looking at the same question have to be compared to reach an overall conclusion.

For example, a 1998 review of chemotherapy for early breast cancer included 18,000 women in 47 randomised trials who were followed for more than 10 years. All the information from these trials proved beyond doubt that chemotherapy reduced recurrence and improved survival rates in women with early breast cancer.

Trials that have changed treatment

Chemotherapy for cancer of the testis

A recent Australian trial of chemotherapy aimed at curing men with cancer of the testis compared different ways to give three drugs. One arm of the trial used four treatment cycles of chemotherapy and took 12 weeks to complete.

The other arm used three cycles of chemotherapy given in higher doses and took nine weeks. When the trial began, both combinations were being used in Australia.

The trial was stopped in April 2001 when it became clear that the nine-week treatment using higher doses was more effective than the 12-week treatment, and that it caused fewer side effects. It is now the standard treatment.

Improved outcomes from breast cancer

Recent results show that death rates from breast cancer have dropped by 30% over the past 20 years. This is probably due to a combination of better treatment – with tamoxifen and chemotherapy – and screening with mammography, which has picked up many cancers early.

Each of these advances occurred because of clinical trials. In the case of tamoxifen, the benefits of its use in early breast cancer have been established by 55 randomised trials involving 37,000 women, and the benefits of chemotherapy have been established by 47 trials involving 18,000 women.

Quality of life

Trials not only measure the effect of a new treatment on cancer, but also its wider impact on a person's life. In phase 3 trials, researchers often ask participants to fill out questionnaires to measure the impact of a treatment on their quality of life. The questionnaires ask people how they feel and how they are able to carry out everyday tasks. The effects are compared with those of other treatments.

Personal insight

In May 2004, Margery, 79, agreed to enrol in one of the many trials that Cancer Trials NSW supports.

The trial looks at an antidepressant's effect on symptoms, survival time and general wellbeing for patients with advanced cancer. While the main aim of this trial is to help people feel better, the investigators are also interested in whether helping people cope better with their illness or treatment might also help them live longer.

Margery said: "When I was asked to take part in the clinical trial it also seemed a good way to partly repay the medical profession for the excellent treatment I have always been given and in a small way to help other cancer sufferers.

"Then, when I joined the trial I suddenly found I had very ready access to a whole new group of people (ie, the nursing staff involved in the study).

"The practical help I am receiving and the feeling of being cared for by such a dedicated group of professionals has been of huge benefit to me personally. I have no hesitation in recommending others to take part in a clinical trial if they are able."



Risks and side effects in trials

Many medical treatments have side effects. The risks of side effects in clinical trials are more uncertain because less is known about the new treatments being tested. This is one of the important reasons for clinical trials – to identify risks and side effects, which must be weighed up against the possible benefits of the new treatment.

In a trial, a person may experience none, some or all of the side effects, which may be mild, moderate or severe. There is also the risk of a previously unknown side effect occurring.

Some clinical trials try to find treatments that are as effective as existing treatments but have fewer side effects. Other trials test treatments for reducing side effects, for example, drugs to reduce nausea caused by chemotherapy.

Making decisions about treatment can be hard for everyone. All treatments have risks and side effects, whether they are used in routine practice or in a clinical trial. There are many things to consider.

Cancer is a life-threatening illness that causes its own symptoms. The unavoidable risks of the cancer need to be weighed against the risks and benefits of any treatments.

Talk to your doctor about the risks and side effects of being in a clinical trial. You should be given comprehensive information to read and discuss before deciding whether to take part in a clinical trial. There are some questions on page 34 that will help you talk things over with your doctors.



Is a trial suitable for you?

Your doctor may suggest that you enter a clinical trial. This would only be after you have been carefully assessed and the trial is believed to be suitable for you. If the trial is not suitable, the best treatment currently available will be offered.

If you want to consider taking part, your doctor must explain the trial to you and make sure you understand it completely. Your treating doctor should answer any questions you have about the trial.

If you are unsure, ask your doctor if there is someone else you can talk to about the trial. You can also seek a second opinion about the trial and other options.

You should only agree to participate in a trial when you understand all you need to know about it.

Information about the trial

You are entitled to make your own decisions about medical treatments or procedures, and doctors should give you all the information you need to make those decisions.

Doctors follow guidelines to make sure they provide all the information you need. If you are considering a trial, you should be given a participant information sheet – or fact sheet – about the trial. This should explain everything you need to know about the trial and treatment.

Your doctor should help you understand the trial, without trying to persuade you either way. In turn, you should be open and honest in telling your doctor about your health and information needs.

Trial checklist

Your doctor should give you the following information:

- your diagnosis – details of the type of cancer you have
- options for investigating, diagnosing and treating your illness
- recommendations for investigating, diagnosing and treating your illness
- uncertainties about your illness and its outcome with or without treatment
- possible benefits with the available and proposed treatments
- any risks that are likely to influence your decisions
- where and how the treatment will be done
- where and how follow-up will be done
- time and costs involved.

What is informed decision-making?

Informed decision-making is required by law and is an essential part of being in a clinical trial. It means you should only be enrolled in a clinical trial after you understand the trial fully and have given your consent in writing.

You should be given a full explanation of the treatment proposed for you in the trial. You will then be able to discuss this with your doctor or nurse. This should enable you to decide whether you wish to participate in the trial.

If you choose to participate, you will be asked to sign an informed consent form before entering the trial. A copy of this form will be given to you for your records. This is a standard part of every clinical trial.

The informed consent form will provide the following information:

- the aim of your treatment
- what the treatments are, and how they are given
- possible alternative treatments
- risks and benefits of each treatment
- any information you need to decide whether or not to take part
- your rights as a participant in the trial
- contact people.

Ensuring safety in clinical trials

Clinical trials are carefully designed to minimise the risks to participants. New treatments must be carefully tested in test tubes and animals before they can be tested in humans. Participants in clinical trials are checked regularly and carefully to make sure side effects are found and treated quickly.

The medical profession formally reviews clinical trials. This is called peer review, and it is carried out by an ethics committee and other bodies. Before a trial can begin in a hospital, the ethics committee must judge it to be safe and ethical before approving it.

The ethics committee makes sure people participating in the trial have their rights and interests protected. They ensure people in the trial are offered the best available treatment, and that no beneficial treatments are denied.

Before entering a trial, you must be informed of exactly what is involved in the study, what side effects to expect and, as much as possible, what uncertainties you may face.



How clinical trials are done

Your role in a clinical trial

In a clinical trial, you will face a new world of medical terms and procedures. Some people associate fears of experimentation with clinical trials. There can also be fears of the unknown. Understanding what is involved can ease some of your anxieties.

If you participate in a clinical trial, you will be watched closely and detailed records will be kept. You may receive more examinations and tests than are usually given. Although these tests can be inconvenient, they provide extra information about your progress and the effects of treatment.

You may also be asked to answer questions about how you are feeling – the quality-of-life questionnaires discussed on page 17. These additional tests and observations can have their own risks, benefits and inconveniences.

Always remember that the choice to join the trial is yours and you can withdraw at any time. Withdrawal will not affect your future care, and you will return to receiving the standard treatment for your type of cancer.

During the trial, if it is clear that a treatment is not in your best interest – for example, if it is not working or if you have severe side effects – you or your doctor can stop the treatment at any time.

Trial protocol

Researchers studying cancer treatments follow strict guidelines. First they must write a plan of the clinical trial. This is called a protocol. Before the trial can begin, the protocol must be reviewed and approved by the ethics committee at each place the trial will be done.

Everyone doing the trial must follow the protocol, which describes:

- reasons behind the trial
- how participants will be selected
- how the treatments will be given
- what tests will be done
- how participants will be monitored
- how the trial will be analysed and reported.

The protocol also describes how the trial may need to be modified if new information becomes available.

Randomised controlled trials

A controlled trial compares a new treatment with the current best standard treatment (the control). In a randomised controlled trial, some people receive the new treatment while others receive the standard treatment.

A computer randomly assigns people to each group. All treatments tested in a randomised trial are considered likely to be at least as good as the best standard treatment, and possibly better.

The information collected during a randomised trial is carefully analysed to work out which treatment is most effective and has the fewest side effects. The results are closely monitored during the trial. If it becomes clear that one treatment is better than another, the trial is stopped immediately.

What is randomisation?

If you take part in a randomised trial, you will receive one of the treatments being compared in the trial.

Your treatment will be chosen using a process called randomisation, which is usually done by a computer. This means your treatment will be selected at random (like drawing a card from a pack). This is done so each group has a similar mix of people – to ensure the people getting each treatment can be compared without bias. Neither you nor your doctor can choose which treatment you will receive.

Blinding and placebos

If you are involved in a trial of a new drug, you and your doctor might not be told which treatment group you are in. This is known as blinding, and is used to eliminate bias from a trial.

For example, if people know they are taking the new treatment, they might expect it to work and report positive reactions because they want to believe they are getting better. This can make the trial results look better than they really are.

Blinding is done by making the medicines look the same so that they cannot be told apart. Sometimes this involves placebo (dummy) tablets or injections that look the same as the experimental treatment but don't contain the active ingredient.

In double blind trials, neither you nor your doctor knows which treatment you are getting. You must be told if the trial you are considering is blinded or if some people will receive a placebo.

Supportive care

For some types of cancer, there is no proven effective anti-cancer treatment. In this situation, the standard approach is supportive care. This means treatment against the effects of the cancer, not against the cancer itself.

Studies of new treatments in this situation are often done by giving everyone the best supportive care and assigning half the people to get the new treatment as well. People in trials are never denied treatment that is known to be beneficial.

How much does it cost and who pays?

Clinical trials are usually funded by research funding organisations, such as The Cancer Council and the National Health and Medical Research Council, or by companies that produce the treatments being tested, like drug companies and device manufacturers.

Taking part in a trial will not cost you more money than not taking part. Some of the tests and treatments involved in a trial are part of standard care. The cost of any extra tests or treatments that are not part of standard care are covered by the trial organisers.

Participation in trials generally means extra work for doctors, nurses and other medical staff. In many cases, the research group or company running the trial provides funds to help pay for some or all of these extra costs.

Cancer trials take time and money. Research funding is limited and competition for funds is fierce. Fewer than one in four research proposals get funding and many trials are not adequately funded.

Expensive drugs and trials

Participation in cancer trials gives patients early access to promising new treatments.

In Australia, the Government subsidises the cost of expensive treatments, but only after they have been tried, tested and proven to be better than existing treatments.

Until that time, promising new treatments may only be available to people participating in trials. Sometimes the treatments are available outside of a trial, but are difficult to obtain and must be paid for by the patient.

Cancer trials in NSW

The Cancer Council NSW is a major supporter of cancer trials in this State.

In 2001, The Cancer Council established Cancer Trials NSW, a collaborative initiative to support and promote cancer clinical trials research in NSW.

Cancer Trials NSW aims to:

- Improve the lives of people affected by cancer, by working in partnership with consumers, health professionals and the wider community to increase participation in cancer clinical trials and research throughout NSW.
- Select, promote and support a portfolio of cancer clinical trials research that best addresses important questions for people affected by cancer throughout NSW.

The program achieves these aims by selecting the trials that are most worthy of support and providing hospitals across NSW with funds to employ nurses to help support participation in these clinical trials.

For more information about Cancer Trials NSW, go to www.cancercouncil.com.au or call the Cancer Helpline on 13 11 20.





Seeking support

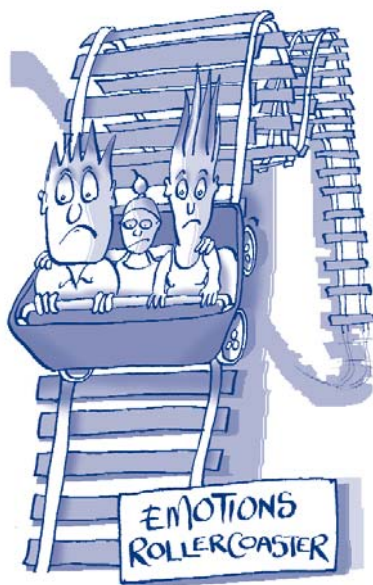
When you are first diagnosed with cancer, it is normal to experience a range of extreme emotions, such as fear, sadness, depression, anger or frustration. It will help to talk about your feelings with your partner, family members and friends or, if you prefer, talk to a hospital counsellor, social worker, psychologist, your religious or spiritual adviser, or a support group.

You may find that your friends and family don't know what to say to you. They may have difficulty with their feelings as well. You may feel able to approach your friends directly and tell them what you need.

You may prefer to ask a close family member or a friend to talk with other people for you.

Some people may feel so uncomfortable that they avoid you. They may expect you to 'lead the way' and tell them what you need.

This can be very difficult to handle and can make you feel lonely. The Cancer Council's booklet *Emotions and Cancer* may help at this critical time. Ring 13 11 20 for a copy.



Practical and financial help

A serious illness often causes practical and financial difficulties. You don't need to face these alone.

Many services are available to help:

- Financial assistance, through benefits and pensions, can help pay for the cost of prescription medicines and for travel to medical appointments.
- Home nursing care is available through community nursing services, or through the local palliative care service.
- Meals on Wheels, home care services and aids and appliances can make life easier.

Contact the hospital social worker, occupational therapist or physiotherapist, or the Cancer Helpline for information.

The Cancer Helpline

The Cancer Helpline is a service of The Cancer Council NSW. It is a telephone information and support service for people affected by cancer. It is a confidential service where you can talk about your concerns and needs with specialist cancer nurses. The nurses can send you written information and put you in touch with appropriate services in your own area.

You can call the Cancer Helpline on 13 11 20, Monday to Friday, 9am to 5pm, for the cost of a local call. The teletypewriter (TTY) number for deaf or hearing-impaired people is (02) 9334 1865.

As well as English, the Helpline is offered in the following languages:

Cantonese and Mandarin	1300 300 935
Greek	1300 301 449
Italian	1300 301 431
Arabic	1300 301 625

To access the Cancer Helpline in languages not on this list, call the Translating and Interpreting Service on 13 14 50.

Caring for someone with cancer

Looking after someone with cancer can be very stressful, particularly when it is someone you care about. Try to look after yourself during this time. Give yourself some time out, and share your worries and concerns with someone.

You may have to make many decisions. You will probably have to attend many appointments with doctors, support services and hospitals. Many people have found it helpful to take another member of the family or a close friend with them.

There are a variety of support services, such as home help, Meals on Wheels and visiting nurses that can help you cope with treatment at home. Call the Cancer Helpline to find out about the services in your area.

The Carers Association offers support and information for carers. Call 1800 242 636.



Information on the Internet

The Internet can be a useful source of information, although not all websites are reliable. The websites listed below are good sources of reliable information. However, The Cancer Council is not responsible for their content.

General cancer websites

The Cancer Council NSW www.cancercouncil.com.au

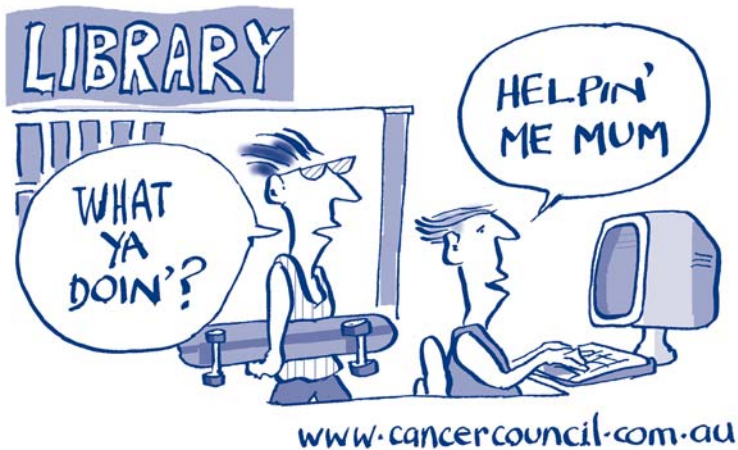
The Cancer Council Australia www.cancer.org.au

CancerBACUP www.cancerbacup.org.uk

National Cancer Institute ... www.cancer.gov/cancer_information

American Cancer Society www.cancer.org

Canadian Cancer Society www.cancer.ca



Clinical trials websites

National Health and
Medical Research Council
Clinical Trials Centre www.ctc.usyd.edu.au

Database of Cancer Research
in Australia (CARA) .. www.ludwig.edu.au/cara2/index2.html

US National
Cancer Institute www.cancer.gov/search/clinical_trials

US Coalition of National
Cancer Co-operative Groups www.cancertrialshelp.org

US National Institutes of Health
and National Library of Medicine <http://clinicaltrials.gov>

Database of trials
featuring a 'MetaRegister' of
randomised clinical trials www.controlled-trials.com

Medical Research Council UK,
Clinical Trials Unit www.ctu.mrc.ac.uk/ukcccr/home.asp



Information checklist

You may find the following checklist helpful when thinking about questions to ask the clinical trials team.

The answers, which will vary according to your situation and the trial you are considering, should help you decide whether or not to take part, and help you make an informed decision. There is space on these pages to write down the answers.

1 What is the purpose of the trial?

2 Who is running the trial?

3 How long has the trial been running?

4 How many other people are on the trial?

5 How long will the trial last?

6 What tests are involved?

7 What do I have to do?

8 Who can I contact if any problems arise?

9 What is likely to happen to my condition with or without this treatment?

10 How could the trial affect my daily life?

11 How much of my time will the trial take?

12 What costs are involved in the trial?

13 Where will the treatment take place? For example, will it be in a clinic?

14 Will I have to be hospitalised?

15 What are the possible side effects?

16 How will the treatment affect me emotionally?

17 How will the treatment affect me physically?

18 Is the information collected about me confidential?

19 What happens if I change my mind about participating in the trial?

Glossary



active ingredient

The drug being tested.

adjuvant therapy

Treatment that is added to increase the effectiveness of a primary treatment. In cancer, adjuvant treatment often refers to chemotherapy, hormonal or radiation therapy after surgery, which is aimed at killing any remaining cancer cells.

advanced cancer

Cancer that has metastasised (spread to a part of the body away from the original cancer) and is more difficult to treat.

antibody

Part of the body's immune system. Antibodies are proteins made by the blood in response to an invader (antigen) in the body. They help protect against viruses, bacteria and other foreign substances.

baseline

At the beginning of the trial, before treatment is started.

bias

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

blinded trial

A trial in which participants do not know which treatment they are getting.

cancer

A general term for abnormal cell growth and its uncontrolled spread.

chemotherapy

The use of special (cytotoxic) drugs to treat cancer by killing cancer cells or slowing their growth.

clinical trial

A research study that tests new and better ways of improving health in people.

control treatment

The existing treatment that is being compared with the experimental treatment. The control is generally the best standard treatment available.

controlled trial

A controlled trial compares two or more treatments to discover which is best.

diagnosis

The identification and naming of a person's disease.

double blind trial

A trial in which neither the patient nor their doctor knows what treatment the patient is receiving, to reduce bias.

eligibility criteria

Characteristics of the people for whom the trial is suitable.

ethics committee

A hospital committee that reviews the plan for a clinical trial to ensure it is safe and ethical.

experimental treatment

The new treatment being tested in the trial.

fact sheet

An information sheet for people in a trial that should explain everything they need to know about the trial and its treatment. Also known as a participant or subject information sheet.

gene therapy

Treatment aimed at correcting or interfering with a genetic abnormality causing cancer.

hormone

A substance that has a specific effect on the way the body works. Hormones, which are made by glands, help to regulate and co-ordinate growth, metabolism and reproduction.

hormone therapy

Medical treatment using hormones.

informed consent form

The form a person signs to show that they understand the information they have been given about a trial and that they agree to take part.

informed decision-making (informed consent)

A process in which a patient makes a decision – about a clinical trial or treatment – after being given information that they fully understand and give their consent in writing.

investigator

A researcher in a clinical trial.

medical oncologist

A doctor who specialises in treating cancer with drugs.

meta-analysis

A process in which the results of a number of clinical trials assessing the same questions are summarised, compared and combined.

metastasis

Also known as a secondary cancer. A cancer that has spread from another part of the body.

oncologist

A doctor who specialises in the study and treatment of cancer.

oncology

The branch of medicine concerned with the study and treatment of cancer.

palliative treatment

Support and treatment directed against the effects of the cancer, not against the cancer itself.

participant information sheet

An information sheet that explains everything a participant needs to know about the trial and treatment. Also known as a fact sheet.

peer review

A process in which independent experts check something. For example, ethics committees include peer review by getting independent experts to check all clinical trials before they can go ahead. Medical journals also have a peer review process, in which experts check articles before they are accepted for publication.

placebo

A dummy pill or injection, which looks like the new treatment being tested but contains no active ingredient.

prevention trial

Trials that test new approaches that doctors believe may lower the risk of getting cancer.

primary cancer

The original cancer. Cells from the primary cancer may break away and be carried to other parts of the body, where secondary cancers may form.

protocol

An action plan that describes what will be done in the study and why.

quality of life

How a person is feeling and doing. Quality of life is often affected by cancer and its treatments.

radiation oncologist

A doctor who specialises in radiotherapy to treat cancer.

radiotherapy

The use of radiation, usually x-rays or gamma rays, to kill cancer cells or injure them so they cannot grow and multiply. Radiotherapy treatment can also harm normal cells, but they are able to repair themselves.

randomisation

A method used to prevent bias in research. A computer will be used to put patients into groups by chance, rather than the doctor choosing.

randomised controlled trial

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

screening

An organised program to identify disease, such as cancer, before symptoms appear.

screening trial

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

secondary cancer

Also called a metastasis. A tumour that has spread from the original site to another part of the body.

side effect

Unintended effects of a drug or 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, based on results of past research.

supportive treatment

Treatment directed against the effects of the cancer, not against the cancer itself.

surgical oncologist

A doctor who specialises in the surgical treatment of cancer.

treatment trial

A trial that tests a new treatment.

tumour

A new or abnormal growth of tissue on or in the body.



Cancer Council stores, NSW

Bondi

Shop 5042
Westfield Bondi Junction
Oxford Street
Bondi Junction NSW 1355
Ph: (02) 9369 4199
Fax: (02) 9369 3199

Chatswood

Shop 442, Level 4
Westfield Shoppingtown
Victoria Avenue
Chatswood NSW 2057
Ph: (02) 9413 2046
Fax: (02) 9413 2051

Hornsby

Shop 3010
Westfield Shoppingtown
Pacific Highway
Hornsby NSW 2077
Ph: (02) 9987 0662
Fax: (02) 9987 1778

Kotara

Shop 106
Westfield Kotara
Cnr Park Avenue and
Northcott Drive
Kotara NSW 2289
Ph: (02) 4965 5171
Fax: (02) 4952 2604

Miranda

Shop 3076, Upper Level
Westfield Shoppingtown
The Kingsway
Miranda NSW 2228
Ph: (02) 9525 9209
Fax: (02) 9525 9593

Shellharbour

Shop 228
Shellharbour Square
Lake Entrance Road
Blackbutt NSW 2529
Ph: (02) 4297 4777
Fax: (02) 4295 1744

Sydney – City

Shop C35
Westfield Centrepoint
Castlereagh Street entrance
Sydney NSW 2000
Ph: (02) 9223 9430
Fax: (02) 9223 9437

Warringah Mall

Shop 349, Level 1
Warringah Mall
Cnr Condamine Street and
Old Pittwater Road
Brookvale NSW 2100
Ph: (02) 9939 2668
Fax: (02) 9939 2208

Regional offices



Central Coast Region

127 Erina Street
Gosford NSW 2250
Ph: (02) 4325 5444
Fax: (02) 4325 5688

Far North Coast Region

120 Tamar Street
Ballina NSW 2478
Ph: (02) 6681 1933
Fax: (02) 6681 1936

Hunter Region

22 Lambton Road
Broadmeadow NSW 2292
Ph: (02) 4961 0988
Fax: (02) 4961 0955

Mid North Coast Region

121 High Street
Coffs Harbour NSW 2450
Ph: (02) 6651 5732
Fax: (02) 6652 1530

North West Region

Shop 2
218 Peel Street
Tamworth NSW 2340
Ph: (02) 6766 1164
Fax: (02) 6766 7053

South West Region

40 Morrow Street
Wagga Wagga NSW 2650
Ph: (02) 6921 7760
Fax: (02) 6921 3680

Southern Region

1 Lowden Square
Wollongong NSW 2500
Ph: (02) 4225 3660
Fax: (02) 4225 1700

Sydney Metropolitan Region and Head Office

153 Dowling Street
Woolloomooloo NSW 2011
(PO Box 572
Kings Cross NSW 1340)
Ph: (02) 9334 1900
Fax: (02) 9334 1739

Western Sydney Region

43 Hunter Street
Parramatta NSW 2150
Ph: (02) 9687 1399
Fax: (02) 9687 1118

Western Region

84 Byng Street
Orange NSW 2800
Ph: (02) 6361 1333
Fax: (02) 6361 1863

Cancer Helpline 13 11 20

For support and information on cancer and cancer-related issues, call the Cancer Helpline. This is a free and confidential service.

Cancer Helpline	13 11 20 (cost of a local call)
TTY	(02) 9334 1865 for deaf and hearing-impaired
Cantonese and Mandarin	1300 300 935
Greek	1300 301 449
Italian	1300 301 431
Arabic	1300 301 625

For further information and details please visit our website:

www.cancercouncil.com.au



*Building a
Cancer Smart
Community*