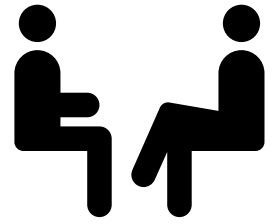


# A guide to prostate cancer clinical trials




## In this fact sheet:

- What is a clinical trial?
- Why are trials done?
- What are trials looking into at the moment?
- What happens in a clinical trial?
- Should I take part in a trial?
- What does taking part in a trial involve?
- How can I find out about prostate cancer trials?
- Where can I get support?
- Questions to ask your doctor or nurse
- More information
- About us


This fact sheet is for men with prostate cancer who want to find out more about taking part in a clinical trial – a type of medical research. Trials are done for all types of illnesses, but in this fact sheet we only look at clinical trials for prostate cancer. Your partner, family or friends might also find this information helpful.


Each hospital will do things slightly differently. Use this fact sheet as a general guide and ask your doctor or nurse for more information about clinical trials. You can also call our

 Specialist Nurses, in confidence, on 0800 074 8383, or chat to them online.

## Symbols

These symbols appear in this fact sheet to guide you to more information:

 Speak to our Specialist Nurses

 Read our publications

## What is a clinical trial?

A clinical trial is a type of medical research. It aims to find new and improved ways of preventing, diagnosing, treating and managing illnesses.

Clinical trials often test new medicines, medical procedures or medical equipment. Some trials also look at the way an illness or treatment makes people feel, or the effect on their relationships or daily life.

## Why are trials done?

Clinical trials aim to answer questions, usually about a treatment or a procedure. The following are common questions.

- Is it safe?
- Does it cause side effects?
- What is the best dose to use?
- Does it work?
- Does it work better than existing treatments?
- How does it affect quality of life?

## What are trials looking into at the moment?

Clinical trials for prostate cancer look at many different things, including the following.

- **Prevention** – whether medicines, vitamins, diet or physical activity can reduce a man's risk of prostate cancer.
- **Screening** – the benefits and risks of a national screening programme, where lots of men would be tested for prostate cancer. Read more about the pros and cons of screening in our booklet, **Understanding the PSA test: A guide for men concerned about prostate cancer**.
- **Diagnosis** – trying out new tests or scans to improve the diagnosis of prostate cancer. For example, developing better tests to find out whether a man has prostate cancer or how quickly it grows and spreads outside the prostate.
- **Treatment** – testing new treatments or new ways of using existing treatments.
- **Quality of life** – looking at how prostate cancer or its treatment could affect you in your daily life. For example, a trial might look at the side effects of treatment and ways to manage them.
- **Counselling and complementary therapies** – looking at ways to help men deal with the effects of prostate cancer.
- **Genetics and lifestyle studies** – looking at whether certain genes or lifestyles (like smoking or exercise) can affect a man's risk of getting prostate cancer, or whether they affect the growth of the cancer.

Treatments for prostate cancer are an important area of research at the moment. For example, there are trials looking at:

- different doses of radiotherapy and ways of giving it
- developing techniques for surgery (radical prostatectomy), such as robotic surgery

- newer treatments that only treat the areas of the prostate where there is cancer, such as focal cryotherapy
- combining treatments such as hormone therapy and radiotherapy
- developing new treatments for advanced prostate cancer that is no longer responding to other treatments
- whether the order that treatments are given in makes a difference
- how a man's genes might affect his risk of getting prostate cancer, or his response to treatment
- why a treatment that works for one man might not work so well for another.

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## What happens in a clinical trial?

### Types of clinical trials

There are different ways of gathering evidence in cancer research. There are two main types of trials – observational studies and intervention studies.

In an **observational study**, researchers collect information about you that might tell them more about the risk of getting cancer, or the effects of cancer or its treatment. For example, they might select a large group of people and take blood samples, or ask them to answer questions about their lifestyle and diet at the start of the study. Then many years later, the researchers would look at whether or not the people developed cancer. They would then be able to see if there were any differences between the people who developed cancer and those who didn't.

In an **intervention study**, researchers give a group of people a treatment or test to see how well it works. One type of intervention study is called a randomised controlled trial – this is normally used to test new drugs (see below).

Trials called phase 1, 2, 3 and 4 trials, described next, are intervention studies.

### The different phases in clinical trials

Trials that look at treatments usually take place in four stages, called phases. If a phase is successful, the trial moves on to the next phase.

- **Phase 1** finds out about safety and side effects, and if the treatment could work well in humans. If it's a drug trial, the research team will begin to work out the best dose to use.
- **Phase 2** looks at how well a treatment works, and collects more information about safety, side effects, and the best dose to use.
- **Phase 3** tests a new treatment against a placebo or the standard treatment, if there is one. And researchers continue to look at safety and side effects.
- **Phase 4** takes place after a new treatment is in use. Researchers collect information about long-term risks and benefits.

Phase 1 and 2 trials include small numbers of people, anywhere between about 10 and a few hundred. They usually take place at specialist centres. Phase 3 and 4 trials usually involve many more people, sometimes thousands, and usually take place at your local hospital.

### Randomisation

Everyone taking part in a randomised trial is put into different groups at random. Nobody chooses who goes in which group and it's usually decided by computer.

There are usually two groups in a randomised trial, but some have more. One group has the new treatment. The other, called the control group, has the standard treatment or a placebo (see below). The research team can then compare results from the two groups.

You don't get to choose whether you get the new treatment or the standard treatment.

One reason that trials are randomised is so that the research team can't choose who goes into which group based on what they know about their patients. For example, they might put people who they thought were either healthier or more unwell into a particular group, which could make the results of the trial unreliable.

Almost all phase 3 trials and some phase 2 trials are randomised.



## Making the decision about going on a randomised trial, where I may not have got the treatment I was hoping for, was hard. In the end I decided that I wanted to take the chance.

*A personal experience*

### Placebo

A placebo is a dummy treatment. For example, it can be a pill that looks the same as the drug being tested, but just contains an ingredient that won't have any effect, like sugar. People can sometimes feel better when they have a placebo because they think they are having a real treatment. This is known as the 'placebo effect'.

Comparing a group of people taking a new treatment with a group taking a placebo can show if the new treatment is really working. A truly effective drug will work better than the placebo.

Whether you decide to take part in a trial or not, you should receive the best care and support available. Wherever there is a standard treatment or standard of care available, new treatments are tested against this. So even if you don't get the new treatment, you will still have the best available treatment.

### Blinded trials

In a blinded trial, you won't know whether you are getting the trial treatment, or the standard treatment or placebo. They will all look the same. Trials need to be 'blind' because just knowing that you are getting a new treatment can affect how you respond to it, and make the results unreliable.

Often the researchers who give you your treatment are also 'blinded', meaning they don't know which treatment you're getting either – so they can't be influenced by what they know. This is called 'double blinding'.

If you decide to take part in a clinical trial, the research team must tell you whether it is randomised, if they are using a placebo and if it's a blinded trial.

### Safety

Before any trial begins there is a long and thorough process to make sure it's as safe as possible. There are many stages of research before a drug is tested in people. And when it's ready to be tested in people, experts design the trial very carefully to make sure it's safe. You'll have checks and tests before the trial starts (see page 6) to make sure you're suitable for the trial and it's safe for you to take part. Once the trial begins you'll be monitored closely so that any problems are spotted early and can be dealt with.

For more information about how trials are run, visit [www.cancerresearchuk.org](http://www.cancerresearchuk.org)

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## Should I take part in a trial?

Taking part in a clinical trial is a personal decision. Without clinical trials and research studies we wouldn't have the treatments we have now. Thousands of people volunteer every year to take part in trials. But you have to decide if it's right for you.



**Before I decided to take part I wanted to learn all about it. I knew the research team wanted me to know the benefits of the trial, but I wanted to know about the disadvantages as well.**

A personal experience

If you find a trial that could be suitable for you, find out as much as you can about it (see page 5). Each trial is different, but these are some of the possible advantages and disadvantages.

### Advantages

- You might be able to have newer and more effective treatments that aren't available outside the trial.
- You may have more regular check-ups, tests and support from doctors and nurses than usual – some men find this very reassuring.
- You will be helping to improve future cancer treatment for others.
- You may feel you're doing something positive about your health and taking an active role in your treatment and recovery.

### Disadvantages

- There could be check-ups for many months or years afterwards, with questionnaires, tests or scans. Some men also find that having lots of tests makes them worry more about their cancer.
- As with all medicines, clinical trial drugs may have side effects. Talk to the research team about the possible side effects, and how common they are.
- You might not know about all the possible side effects before the trial starts – the research team might not know about them all yet.
- If the trial is randomised (see page 3) you won't be able to choose which treatment you have.
- If the trial is blinded (see page 3), you won't know which treatment you are getting.
- The new treatment may not be any better than the existing treatment.
- The new treatment might not help you, even if it helps others.

On page 8 we've suggested some questions to ask your medical team. The answers may help you decide if taking part in a trial is right for you.



**For me, the benefits of being on the trial were that the oncologist had more time to talk me through what was happening, and I was able to have regular scans to check my progress.**

*A personal experience*

## What does taking part in a trial involve?

There are differences between trials depending on the type of trial and what the trial is looking at. If you decide to take part in a trial, the research team should give you information about what it involves.

For each trial, researchers need to find people who fit very specific criteria. For example, they might need men with a certain PSA level, or men with cancer at a particular stage. They might also consider other things, such as how fit you are.

This means that before the trial, you'll probably need to have checks and tests to see if you're suitable (see page 6).

During the trial you'll usually go to a hospital to have your treatment, as well as tests or scans. You'll have regular check-ups as part of the trial. You might have your usual hospital checks as well.

You won't be paid for taking part in a trial, but it's sometimes possible to claim back what you spend on things like travel. Ask your research team what they will pay for.



**Other than the regular trips to the hospital for radiotherapy there was no problem with the treatment and staff were kind and friendly.**


*A personal experience*

## Getting information and giving your consent

Before you start on a clinical trial, the research team has to get your consent. This means signing a form to say that you understand what the trial involves and that you agree to take part.

Before you agree to take part, the research team should explain the trial to you in detail. They should give you written information and talk you through everything. They should answer your questions and give you time to think it over before you agree to sign the consent form.

Make sure you find out everything you can about the trial so that you have all the information you need to make a decision that's right for you. And don't feel that you have to make a quick decision.

You might want to discuss the trial with someone else before you decide – maybe your partner, family, GP, hospital doctor or nurse. Or you can  call our Specialist Nurses. They'll be happy to discuss the trial with you.

Before you sign the consent form, ask yourself these things.

- Am I comfortable with the tests that need to be done during the trial – and with how often they will happen?
- Can I get to the hospital easily for the tests and treatment? Some people having cancer treatment find travelling long distances very tiring.

- Do I clearly understand the possible side effects and risks of having the treatment, and that there might be unexpected side effects?

If you decide to go ahead, the research team should also tell you who to contact if you have any questions during the trial.



**The research team explained all the risks in great detail. At first this felt a bit like unnecessary information, but I was glad they were thorough and told me everything.**

A personal experience



**The trial I was involved in meant I had to travel a long way for treatment. So I made sure I planned a route where I could get a seat on the train, in case I felt tired.**

A personal experience

### **Checks and tests before the trial**

Once you've given your consent, you'll have some tests and checks to make sure you're suitable for the trial. The research team will ask about your medical and treatment history, and any symptoms you have. You'll also have a physical examination and you might have blood tests, scans and other tests. This is to find out more about your prostate cancer and any other health problems you might have. In some trials, men with certain other health problems won't be able to take part.

### **Can I leave the trial?**

You can leave the trial at any time without giving a reason. But if you're happy to give a reason, it could help the research team to improve their trials in the future.

If you leave a trial, you will still have treatment for your cancer. You'll be offered the standard treatments for your stage of cancer. Health professionals won't treat you differently because you've left a trial.

### **What will happen to my personal information?**

Your personal information should be stored securely and kept confidential. The research team might use a code so you can't be identified by name. They will let you know how any information they collect during the trial will be used.

Normally your GP will be told that you're taking part in a clinical trial. The research team will tell you what information they will give to your GP. If your GP, or other health professionals who aren't involved in the trial, prescribe you any treatment or medicines – not just for prostate cancer – ask them to contact the research team to make sure it won't affect the trial.

### **What happens when the trial finishes**

The research team should tell you what will happen with the results of the research. For example, whether they will be published in a medical journal, and if you can see them. You won't be identified in any report or publication without your permission.

If the trial is successful, you might want to keep having the treatment after it ends. This is sometimes possible, but not always. Ask the research team about this before the trial starts. If a new treatment works well, the research team might stop the trial early so that everyone on the trial can be offered it, not just those in the treatment group.

They might also stop the trial early if the new treatment doesn't work well or causes too many side effects.

## Why can trials take so long?

Sometimes you might hear about a new treatment years before it actually becomes available. Developing a new treatment can take a long time. How long depends on lots of things, such as the type of treatment, how many patients are needed on the trial and the aim of the trial.

## How can I find out about prostate cancer trials?

To find out about current clinical trials for men with prostate cancer you can:

- ask your doctor or nurse if there are any local or national trials that may be suitable for you
- search Cancer Research UK's list of clinical trials in the UK – this only shows some of the current trials
- call our Specialist Nurses for the most up-to-date information on clinical trials.

If you find a trial you're interested in, show the details to your doctor or nurse. They can help you decide if it's likely to be suitable for you.

## Where can I get support?

Deciding whether to take part in a clinical trial can be difficult. You might want to ask questions or raise concerns before, during or after a trial. When a trial ends you might also feel you need some support.

### Who can help?

#### Your medical team

It could be useful to speak to your nurse, doctor, GP or anyone else in your medical team. They can explain your diagnosis, treatment and side effects, listen to your concerns, and put you in touch with others who can help.

#### Trained counsellors


Many hospitals have counsellors or psychologists who specialise in helping people with cancer – ask your doctor or nurse at the hospital to refer you.

## Local support groups

At local support groups, men get together to share their experiences of living with prostate cancer. Some groups have been set up by local health professionals, others by men with prostate cancer themselves.

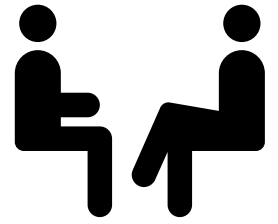
## Prostate Cancer UK services

We have a range of services to help you deal with problems caused by prostate cancer or its treatments:

-  **our Specialist Nurses** who can answer any of your questions in confidence
- **one-to-one support service**, where you can speak to someone who's been there
- **online community**, a free forum to talk about what's on your mind
- **our fatigue support** telephone service delivered by our Specialist Nurses to help with extreme tiredness.

 Speak to our Specialist Nurses on 0800 074 8383 or visit [prostatecanceruk.org/get-support](https://prostatecanceruk.org/get-support)

# Questions to ask your doctor or nurse



You may find it helpful to keep a note of any questions you have to take to your next appointment.

Are there any clinical trials for prostate cancer that I could take part in?

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What will the trial aim to find out?

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What are the possible benefits and risks of taking part in the trial, including any possible side effects?

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What extra tests will I have if I take part in the trial?

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How long will the trial last?

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How soon could I start the trial?

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Will I need to travel to another hospital?

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Will my travel or other expenses be paid?

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What happens if something goes wrong when I'm on the trial? Am I covered by insurance?

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What support can I get during and after the trial?

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Who should I contact if I have questions while I'm on the trial?

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If the trial is successful, will I be able to keep having the treatment after it ends?

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## More information

### Cancer Research UK

[www.cancerresearchuk.org](http://www.cancerresearchuk.org)

Telephone: 0808 800 4040

Patient information from Cancer Research UK. Includes information on some clinical trials and advice on finding a trial.

### Healthtalk.org

[www.healthtalk.org](http://www.healthtalk.org)

Watch, listen to and read personal experiences of men with prostate cancer and other health problems.

### Macmillan Cancer Support

[www.macmillan.org.uk](http://www.macmillan.org.uk)

Telephone: 0808 808 0000

Practical, financial and emotional support for people with cancer, their family and friends. Includes information about clinical trials and lists websites where you can search for them.

### NHS

[www.nhs.uk](http://www.nhs.uk)

Information about conditions, treatments and lifestyle. Support for carers and a directory of health services in England. Includes a database of clinical trials.

### UK Clinical Trials Gateway

[www.ukctg.nihr.ac.uk](http://www.ukctg.nihr.ac.uk)

Information about clinical trials in the UK. Includes a database of clinical trials that are currently recruiting and information on how to contact the trial team.

## About us

Prostate Cancer UK has a simple ambition: to stop men dying from prostate cancer – by driving improvements in prevention, diagnosis, treatment and support.



This fact sheet is part of the Tool Kit. You can order more Tool Kit fact sheets, including an **A to Z of medical words**, which explains some of the words and phrases used in this fact sheet.

Download and order our fact sheets and booklets from our website at **[prostatecanceruk.org/publications](http://prostatecanceruk.org/publications)** or call us on **0800 074 8383**.

At Prostate Cancer UK, we take great care to provide up-to-date, unbiased and accurate facts about prostate cancer. We hope these will add to the medical advice you have had and help you to make decisions. Our services are not intended to replace advice from your doctor.

References to sources of information used in the production of this fact sheet are available at **[prostatecanceruk.org](http://prostatecanceruk.org)**

**This publication was written and edited by** our Health Information team.

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- Susan Asterling, Urology Research Nurse, Sunderland Royal Hospital
- Vincent Gnanapragasam, University Lecturer in Uro-oncology and Honorary Consultant Urological Surgeon, University of Cambridge
- Linda Welsh, Prostate Specialist Radiographer and Clinical Research Radiographer, Torbay Hospital
- Rhoda Molife, Medical Oncologist in Phase I Trials, The Royal Marsden NHS Foundation Trust
- Our Specialist Nurses
- Our Volunteers.

### Tell us what you think

If you have any comments about our publications, you can email:

**[literature@prostatecanceruk.org](mailto:literature@prostatecanceruk.org)**



**Speak to our  
Specialist Nurses**

**0800 074 8383\***

**prostatecanceruk.org**

### Donate today – help others like you

Did you find this information useful? Would you like to help others in your situation access the facts they need? Every year, 40,000 men face a prostate cancer diagnosis. Thanks to our generous supporters, we offer information free to all who need it. If you would like to help us continue this service, please consider making a donation. Your gift could fund the following services:

- £10 could buy a Tool Kit – a set of fact sheets, tailored to the needs of each man with vital information on diagnosis, treatment and lifestyle.
- £25 could give a man diagnosed with a prostate problem unlimited time to talk over treatment options with one of our Specialist Nurses.

To make a donation of any amount, please call us on **0800 082 1616**, visit **prostatecanceruk.org/donate** or text **PROSTATE** to **70004**<sup>†</sup>.

There are many other ways to support us. For more details please visit **prostatecanceruk.org/get-involved**

<sup>†</sup> You can donate up to £10 via SMS and we will receive 100% of your donation. Texts are charged at your standard rate. For full terms and conditions and more information, please visit [prostatecanceruk.org/terms](http://prostatecanceruk.org/terms)



**f** Like us on Facebook: **Prostate Cancer UK**

**t** Follow us on Twitter: **@ProstateUK**

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**Call our Specialist Nurses from Monday to Friday 9am - 6pm, Wednesday 10am - 8pm**

\* Calls are recorded for training purposes only.  
Confidentiality is maintained between callers and Prostate Cancer UK.

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