

GUIDE TO CLINICAL TRIALS



What is a clinical trial?

Clinical trials are medical research studies that involve people. They aim to find new and improved ways to **treat, manage, prevent** and **diagnose** conditions such as Parkinson's.

Clinical trials are the best way to find out whether a new treatment:

- is safe
- is beneficial to people with Parkinson's
- is more effective than current treatments
- can improve quality of life for people with Parkinson's

During a clinical trial new treatments are tested in a way that is controlled to minimise risk to participants and so their effect can be carefully monitored.

How can clinical trials help people affected by Parkinson's?

Clinical trials can help people with Parkinson's in lots of ways. Some of the benefits include:

- broadening our understanding of Parkinson's so that we can treat people with Parkinson's more effectively
- giving people with Parkinson's the opportunity to become involved in research which uses the most up-to-date treatments and devices
- helping to improve the quality of life for people with Parkinson's
- improving treatment for future generations of people with Parkinson's
- ultimately driving us closer to a cure

"When the opportunity came to participate in a research trial that seemed particularly interesting I just jumped at the chance."

What is the government's policy on research and clinical trials?

In the recently updated NHS Constitution, the NHS has committed itself to offering patients opportunities to take part in research relevant to them. The constitution sets out rights to which patients, public and staff are entitled, and the pledges which the NHS is committed to achieve. As part of this the NHS have pledged to - 'inform you of research studies in which you may be eligible to participate.'

Read the NHS Constitution here –
www.nhs.uk/constitution

Will my information be kept confidential?

All your information will be kept confidential unless you give permission for it to be shared.

The NHS has committed to anonymising patient records before they are used for research purposes. This will protect your privacy and confidentiality while also enabling the NHS to use information collected or generated during the course of providing care to improve care, treatment and services for everyone. You have the right to know how your information is being used and request that your confidential information is not used beyond your own care and treatment.



What are the phases of clinical trials?

Clinical trials take place in a number of phases, each which has a specific purpose.

Phase 1 – This phase tests for safety and side effects usually involving a very small number of people (10-80).

Phase 2 – This phase begins to test how beneficial a treatment is and involves a larger group of participants (100-300).

Phase 3 – During phase 3 researchers test the treatment in a much larger group of people (1,000 - 3,000) continuing to assess the safety and benefits to people with Parkinson's. Researchers will also compare the new treatment with treatments already available.

Phase 4 – This phase continues to monitor the safety of the treatment once it is on the market and being used by people with Parkinson's.

How are clinical trials designed and regulated?

There are lots of people involved in the design of a clinical trial including doctors, nurses, physiotherapists and other health professionals. The research team put together a trial protocol or plan that must be reviewed and approved by an ethics committee and NHS Research Governance Groups before the trial can begin.

NHS Research Governance Groups are made up of experts in the field who review the study protocol and offer independent advice on the quality of the research.

The **ethics committee**, an independent group of doctors, nurses and members of the public, are vital for ensuring participants are protected. They make sure people's rights, dignity, safety and wellbeing are maintained throughout the trial.

What are the benefits and risks of taking part in a clinical trial?

Trials are carefully designed to minimise the risk to people taking part. However, as with any new treatment, there will always be an element of risk involved. Before any new treatment can be tested in people it is rigorously tested in animal models. Only when there is strong evidence that it is safe and effective for people can it be taken forward into clinical trials.

If you take part in a trial you will be monitored closely during and after the study to support you and help make sure all is well.

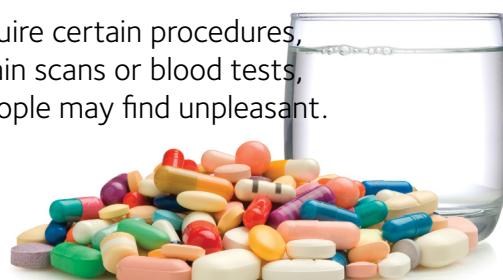
To help you decide whether you want to take part in clinical trials, we've listed the main risks and benefits.

Benefits

- People who take part in a clinical trial may have access to newer and perhaps more effective treatments otherwise unavailable to people with Parkinson's.
- Some people find taking part a positive experience and feel they are taking an active part in their health care.
- During trials people often have more regular check-ups, tests and support from doctors and nurses.
- Taking part could also benefit future generations by helping to find more effective treatments and drive us closer to a cure.

Risks

- You may experience side effects.
- As with most treatments, there is a chance that it may not help you with your Parkinson's.
- Some people find being regularly monitored may make them more anxious about their Parkinson's.
- Some trials require regular visits to the research team and can be a big commitment.
- Some trials require certain procedures, for example brain scans or blood tests, which some people may find unpleasant.



What happens in a clinical trial?

If you decide to take part in a clinical trial you will be given full details of what will be involved and the chance to discuss this with the researcher to ensure you fully understand the process. Before the trial begins you will be screened to see if you are suitable and then need to give your consent.



Screening – Depending on what the trial is investigating, the research team will be looking for people who fit specific criteria – called inclusion and exclusion criteria – that ensure you are suitable for the trial.

Screening usually involves answering questions about your Parkinson's, your medication, treatment history and checking details such as your age and when you were diagnosed. It's possible you may need to have blood tests, scans or other tests as well. If you fit the team's criteria you will then be invited to take part in the trial.



Consent – The research team running the trial must have your permission to enter you into the trial. You will be asked to sign a form to show you understand what is involved in taking part and that you are willing to take part. Before you do so the research team should talk you through in detail what is involved and answer any questions you have.

Questions to ask before signing up

Before you take part in a trial it's vital you fully understand what is involved and what the risks and benefits may be.

Here are some questions you may want to ask the research team.

- What is the aim of the project?
- What are the risks and benefits of taking part in this trial?
- Can you talk me through exactly what is involved?
- Will I receive the treatment or is there a possibility I may receive a placebo (dummy version with no active ingredients)?
- How much of my time is needed and how many visits will I have to make to the hospital?
- How long will the trial last?
- How will I find out the results?
- Who can I contact if I have a problem?
- What will happen once the trial has finished?
- Will you cover the cost of my travel expenses?

Before you sign the consent, we always suggest you discuss the information with your GP or specialist and your family.

"Initially my family was worried. My wife hid it well but I think she was quite nervous because it is quite major surgery. But they were all really supportive and that's been so important, I couldn't have done it without them."

Taking part in a clinical trial

If you are selected by the research team and are happy to give your consent, you will be able to take part in the trial.

Clinical trials can vary hugely depending on what the team are investigating, so it's very hard to say exactly what will happen. However most trials will ask you to complete questionnaires and undergo tests. You will also probably have to visit the research team regularly to have treatment.

"It is quite an intensive study and it is a big commitment, but I believe the trial is worth it and that it's going to make a difference for somebody, if not me then I hope for people with Parkinson's in the future."

What happens after a clinical trial?

Trials can last for several years so it can take a long time for the results to be known. Once completed, the results will be available to all those who took part.

It's vital researchers also share their findings with other researchers and health professionals, no matter what the outcome. This makes sure future research is based on the latest information. Parkinson's UK is supporting the 'All Trials' campaign that is fighting to ensure the results of all trials both past and present are published.

Treatments used in trials may not be made available immediately or at all after the end of the trial, in which case you will go back to having the treatment currently available.

Why do some trials take several years?

It's often frustrating when we hear about successful trials in the media, but it's several years before a new treatment is available to people with Parkinson's.

Developing a new treatment, ensuring it is safe and has genuine benefits for people with Parkinson's can take a long time and will need a large number of people to be tested over a period of time. Unfortunately this does mean that developing new treatments for conditions such as Parkinson's can take up to 15 years.

How can I find out about clinical trials taking place?



Speak to your specialist – You should be receiving information about research from your GP or health professional. If you aren't, don't be afraid to ask them about research opportunities. The more patients ask

about research, the more NHS staff will be encouraged to get engaged with research.

The government wants to encourage patients to talk to their doctors about clinical research and keep research at the top of the NHS agenda. The 'Ok to ask' campaign provides information and support on how you can do this. www.nihr.ac.uk/awareness/Pages/OKtoask2014.aspx



Visit our website – We keep a list of Parkinson's research projects including clinical trials around the UK which are looking for participants on our website. You can browse the list to find studies in your area. parkinsons.org.uk/researchstudies

Join our Research Support Network – Our network brings people affected by Parkinson's together to help find a cure and better treatments for the condition. People who join the network receive frequent emails from us highlighting opportunities to support research, including trials that need participants, research events and many more. parkinsons.org.uk/researchsupportnetwork

Databases and register

- UK Clinical Trials Gateway** – has been developed to inform people of clinical trials that they may be eligible to take part in based in the UK. www.ukctg.nihr.ac.uk
- NIHR Clinical Research Network** – for people living in **England**, the NIHR Clinical Research Network is the government-funded network that supports clinical research into all conditions including Parkinson's. The Clinical Research Networks are organised in different regions and some regions have their own registers of people who are interested in participating in research. www.crn.nihr.ac.uk
- NEURODEM Cymru** – for those living in **Wales**, NEURODEM is the government funded network supporting clinical research, established by the Wales Office for Research & Development in health and social care. NEURODEM also has a register for those who want to be updated about trials taking place locally. www.neurodemcymru.org
- SHARE** – for people living in **Scotland**, SHARE is the new government initiative and register for those interested in taking part in clinical research. www.registerforshare.org

- **Fox Trial Finder** – This is a web-based clinical trial matching tool that works globally, developed by the Michael J. Fox Foundation. To use Fox Trial Finder you'll need to create an account with some information about yourself – such as your postcode, date of birth and a brief medical history – and the trial finder will find studies to match.
foxtrialfinder.michaeljfox.org

Other way to get involved in research

Taking part in a clinical trial is a very personal decision and there is no right or wrong opinion. There are lots of other ways to get involved in research which carry less risk and often are less of a commitment.

"There are loads of different studies that you can participate in and whatever your attitude to risk there is probably one for you."

Although we highlight clinical trials to our supporters through the Research Support Network, we also share other opportunities which are vital to helping us improve life for people with Parkinson's and drive us closer to a cure. These can include:

- taking part in an observational study which can include completing questionnaires or giving a fluid sample (blood, urine etc)
- taking part in a focus group
- reviewing participant documentation
- helping a researcher to shape a new study

parkinsons.org.uk/researchsupportnetwork

"There are many studies that are observational and that carry no significant risk. Some of these require nothing more than carefully completing a few questionnaires and perhaps being examined by an extra doctor or two. These can add significantly to the knowledge of the condition and its treatment."

We are always encouraging researchers to involve people with Parkinson's at every stage of their research to make sure the research is relevant and meaningful to people living with the condition.

Key terms explained

Many researchers use scientific terms to talk about their work. Here's a quick guide to the most common and what they mean.

Placebo effect – is the belief that a treatment will work. The placebo effect is very strong and can significantly affect the results of a trial.

Placebo – a 'dummy' or inactive version of a treatment that has no effect and is designed to appear the same as the active treatment. By comparing people's responses to a placebo and an active drug researchers can establish if the drug is having a real benefit.

Controlled trials – designed to compare different treatments. Often a standard treatment or placebo is compared to a new treatment.

Single blind trials – during blind trials participants are not told whether they are in the treatment or placebo group to minimise the placebo effect.

Double blind trials – during double blind trials both the participants and the researchers are not told whether they are in the treatment or placebo group to minimise the placebo effect, but also so there is no bias when the data is analysed.



Randomisation – many trials are randomised. Usually randomised trials use a computer system to allocate people at random to a treatment or placebo group.

Inclusion criteria – participant must fit the inclusion criteria to take part in a trial.

Exclusion criteria – if a participant fits any of the exclusion criteria they will not be eligible to take part in the trial.

Control group – this is a group of people in the trial who are often given a placebo or may not be given any treatment at all. Control groups are vital so researchers can compare people who are taking an active treatment against those who are not.

More information

Visit us at **parkinsons.org.uk/research**
or call us on **020 7963 9313**

Read our policy statement on clinical trials at
parkinsons.org.uk/clinicaltrialspolicy

**We're the Parkinson's support
and research charity. Help us
find a cure and improve life for
everyone affected by Parkinson's.**

Parkinson's UK

215 Vauxhall Bridge Road, London SW1V 1EJ
Free* confidential helpline **0808 800 0303**.
parkinsons.org.uk

*Calls are free from UK landlines and most mobile networks.