Clinical trials in Parkinson's disease

Questions to ask when considering taking part

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People who are thinking about joining a clinical trial or who are already taking part, have the right to ask the research team any questions they may have about the study.

You may not be sure of what questions to ask.

The questions below have been collated from working with people with Parkinson's who have taken part in trials and with their support network. It may be useful for patients, potential study volunteers, and their family members or friends to use these as a checklist. The checklist can be used to assess your understanding of the participant information material you have been given about the trial, or as discussion points to raise with those who support you, or the research team. The research team will include doctors, nurses, study coordinators and other people who are involved in the conduct of a trial.

This document is provided as a checklist, but for each section there is also a brief explanation for why this might be relevant to you and/or the study you are being asked to take part in. These are suggested questions, but there may be others you can think of that are more specific to the study you are thinking of taking part in. We have provided space for you to add your own questions as you think of them or to make notes. This is designed to go alongside any documents you receive from the research team.

We have defined some key terms here:

Placebo	An inactive or 'dummy' substance or other intervention that looks the same as, and is given the same way as, an active drug or treatment being tested.
Treatment arm	A group of people that receive a particular study treatment. There may be different treatment groups in a trial, including group(s) that receive no treatment or who have a placebo.
Blinding	This describes a situation where you and/ or the researchers running the trial do not know if you are receiving the treatment or are in the placebo/ control group.
Screening	An evaluation before you are accepted into the trial to determine if you fit the criteria.
Assessments	A range of activities from questionnaires to physical tasks completed by yourself or with a researcher
Off medication	A period of time when your Parkinson's medication isn't working effectively or you deliberately haven't taken medication for several hours.
Brain imaging	There are different methods used for taking pictures of your brain which require you to lie still inside a scanner.

1 Ask about the purpose of the study and the people involved in running it

Some studies may relate to other research studies that have been carried out before and their results may have been published in academic journals. You may not be able to access these, but the team should be able to tell you what has been found previously and how that has affected the study you are considering getting involved in.

Some trials involve new drugs not given to people before, others are investigating if it is possible to 'repurpose' drugs that have been used previously for other conditions (one example is a diabetes drug that is widely used and has now been tested to see if it can help slow Parkinson's disease). If the drug is already in use, a lot is known about its safety. These trials are still very important to do because it is necessary to know how the drug will work in people with Parkinson's; the dose of the drug may need to be changed, or it might affect certain age groups in different ways.

Some trials (not all) involve a placebo or control. A placebo is a 'dummy' medicine or treatment, and for other trials that do not involve a medicine, it is more appropriate to use a 'control' group who do not receive the intervention being tested (ie the exercise programme, app etc). In some cases, the control group is 'standard care' which means that you will continue to receive treatment for your Parkinson's in the same way you would if you were not involved in the trial. If you are in the placebo/ control group you will not have the treatment, but you will still undertake all of the assessments. You may or may not know which treatment group you are in depending on the design of the study.

Some studies will offer you the chance to get the intervention (treatment or exercise for example) at the end of the study, OR as part of the study but delayed compared to the main study group.

You may or may not want other people to know you are taking part, the decision to tell anyone outside of the trial team should be yours but your family doctor may be informed. You may want your regular doctor to know about the trial so that they can support your care afterwards.

There are different phrases (patient contributors, public patient involvement) used to describe the process through which people living with Parkinson's can advise on the way a trial is designed. You may want to know how the study has involved people with Parkinson's and what impact that had. Finding out how and when they have been involved may help you understand the trial and give you confidence that your needs are understood.

If it helps you to make a decision about whether to take part, you are able to ask the trial team and their previous experiences of running trials.

You may want to understand their motivations for being involved in running the trial, they should declare any to you.

1	What is the main purpose of this study? *What are the specific research aims and why are they important?*	○ ○
2	What is known about the study treatment and are any study results published?	○
3	Does the study involve a treatment that is already on the market/ licensed?	○
4	Does the study involve a placebo or control group?	○
5	If I am in the placebo or control group of the study, will I be offered the treatment or intervention at the end or anytime during the study?	○
6	Can anyone find out whether I'm participating in the clinical trial? *Will my usual/ family doctor be told that I am on the trial?*	○ ○
7	Have People with Parkinson's been involved in the clinical trial design?	○
8	What are the credentials and research experience of the physician/doctor and study staff?	○
9	Have other studies been conducted at this site? Are all the patients recruited here or are they being recruited to other sites?	○
10	Does the doctor/investigator leading the trial have any financial or special interest in the clinical study?	○
11	What is the planned duration of the study? When do you hope to complete recruiting to the study?	○
12	What procedures are in place for telling me if my trial is halted or terminated early?	○
13	What procedures are in place for telling me if there is any new information about the treatment being tested?	○
14	How and when will participants be advised on what steps to take if the study is stopped?	○

2 Ask about consent and screening

Screening is the process undertaken to determine whether you meet the criteria for the trial. If you do not meet these criteria you are not able to take part. It is important to open and honest in the screening process as these criteria can often be for your own safety.

You will go through a process of providing informed consent. This means someone should be explaining the study to you in depth, which may take place on more than one occasion. It may also involve videos, reading material and the opportunity to ask any questions and to read and understand the information given to you. You should understand what this means to you, what you have committed to and what the process is.

Sometimes changes occur through the course of the study, knowing how they will communicate these to you is important. You may decide to stop taking part in the study, or withdraw your data, for any reason. You have the right to do this at any time with no consequence for you, so ensure you understand how this can happen.

1	What is involved in the screening process and how will I be supported?	○
2	What are the implications of signing informed consent?	○
3	What is the procedure of signing informed consent?	○
4	How will participants be informed of changes in this study? Will there be a new consent form to sign?	○
5	Can participants withdraw from the study at any time?	○
6	Can participants withdraw from some parts, but not all of the study?	○
7	What is the procedure for withdrawal from the study?	○
8	If People with Parkinson's stop participating, will they face any penalties or be denied future treatment?	○

3 Ask about the treatment you may receive on the trial

When a control or placebo is offered, participants will be randomised to one group or arm, or the other. Many drug trials are 'blinded' which means you and/or the researchers do not know which group you are in. If the trial is blinded, it is likely that you will not be told which group you are in until the trial is complete. You should try not to think about which group you are in.

Treatments are administered in different ways and understanding how you will take the medicine and any special conditions associated with it may be relevant to you, for example is it a large pill you need to swallow, or an injection? The team should be able to give you an idea of what side effects to anticipate, this may depend on how new the drug is so you should know how to contact them if something unexpected happens.

1	Are there different treatments in the study (known as arms)?	○
	How will I be allocated to the arm of the study?	○
	Will there be a control or placebo arm?	○
2	When will I know if I have had the control or placebo?	○
3	How will the treatment be given to me and for how long?	○
4	What are the possible side effects of the treatment?	○
5	What happens if I can't tolerate the side effects?	○
6	What is the procedure for reporting side effects?	○

4 Ask about what will happen to you during the trial

You may have been in studies or trials previously and while there will likely be similarities, all trials are different and may have unique aspects. Being confident you know what to expect from each part of the trial may help you feel more reassured or get the support you need.

Many studies require you to do several different types of assessments which will take more or less of your time and may be done on different days. Understanding this time commitment may be key for you.

Very often in drug trials it is important to conduct the tests both on your medication and in 'off' which means that you would not take your medication overnight and would do the assessments without your medication. This enables the researchers to see what effect the drug might have on your symptoms. This can be a worry for some people and their support partners, and not everyone experiences 'off' in the same way.

Some assessments involve trying to measure what is happening in your brain by taking 'pictures' of it in a process known as imaging. There are different ways to image the brain, some involve magnets (MRI) or X rays (CT) and other involve a very small amount of radioactive drug which is injected in to you (PET). Some may require you to be scanned off your medication, but others do not require this. Knowing how the different assessments may impact your life and how long for, will be important for you and your support network.

1 **What will I be asked to do as a participant?**

- What type of assessments will there be?
- What time of day will the assessments be?
- How long will it take to complete the assessments?
- Will I be able to complete them all in one day?
- How many times/ days will I be assessed on?
- Where will the assessments be?
- What paperwork will I have to complete?

2 **Will I have assessments without my medication?**

- What can I expect when completing 'off-medication' assessments?
- How long will I be off medication for and who will give me my medication at the end of the assessment?
- What should my care-partners expect when I complete off-medication assessments?
- Will there be any support provided before my medication works again?

3 Will I have my brain imaged, will that be on or off my medication?

4 What, if any, medical procedures will I have within the trial?

5 How long is the study going to last?

6 Will I have to change my current drug routine?

5 Ask about your care

Your regular neurologist and/or general practitioner may be informed that you are taking part in the study but the information they receive may be limited.

It is very useful to know how they will be informed and what information they will be given. It will be important to understand how your Parkinson's will be managed through the trial (if you need changes to your medication, if you get a new symptom or change). Your involvement in a trial may stop at any time and when this happens you will revert back to your normal care.

1	Who will provide medical care in the event of any complications during the trial?	○
2	Will I be able to see my own doctor during the trial?	○
3	How will the study staff work with my Doctor to keep them informed about my care?	○
4	Can my regular medication be changed if I need it and who will do it?	○
5	What will happen to my medical care if I stop participating in the study?	○
6	If the treatment works for me, can I keep using it after the study?	○
7	What procedures are in place in the event that, due to the progression of Parkinson's, participants are no longer able to make decisions with regard their participation in this study?	○
8	If participants leave the trial before it is over due to health problems resulting from being in the study, will treatment be available to them?	○

6 Ask about costs

Costs will vary depending on the project and your commitment. It will also depend on the health system in your country.

As a minimum your costs for taking part should be covered.

1. Do I have to pay for any part of the study? ○

2. **Some questions if you live in a country where your health is covered by insurance:**

   Will participants have to pay for any part of the clinical study, such as tests to determine eligibility, or the study drug itself? ○

   Which costs are likely to be covered by health insurance? Are there any costs that are not covered by my health insurance? ○

   In the case of a drug trial or trial for a new treatment, will insurance / the institution's insurance cover participants in the case of an adverse reaction or there is a problem (called an adverse event) and will long term care be offered? What alternative treatment will be offered? ○

   Who can help answer any questions from insurance companies or health plan? Who can participants contact at the trial centre and at my insurance company if there is a problem? ○

3. Is there any reimbursement for travel costs, childcare or other out of pocket expenses? ○

4. How and when will these costs be reimbursed? ○

7 Ask about your data and privacy

Through the course of a study data about you and your Parkinson's will be collected for you as an individual and then grouped with other people getting the same treatment as you.

If, how and when you may receive information collected about you will vary depending on how long it takes to recruit enough participants and the length of the trial, as well as time to process the data. Know what to expect and ask if they are getting your consent to stay in contact with you to allow you to receive this kind of information.

1. How is my data going to be used and protected? ○
2. Will I be asked if you can use my data to contact me in the future about my results or a future trial? ○
3. Will the trial outcomes be shared with me, and when do you anticipate I will receive them? ○
   Will they be made available to the public? ○
4. Will the trial outcomes be shared with anyone else? ○
5. Will my individual data/results be shared with me? ○

8 Ask about support and information during and after the study

Individual trials differ in length and you may not know at the start what you might need later on as the study progresses.

At the end of a study your own doctor continues to be responsible with your usual medical care. These questions may help you understand how you will be communicated with and how information is shared throughout and after the study is completed.

1	How will I be informed if the trial stops prematurely?	○
2	Will there be any practical support during the trial (e.g. organisation or reimbursement of travel/accommodation costs, if applicable)?	○
3	Will there be any psychological support/advice available during the trial?	○
4	Will I be able to communicate directly with the research team during the trial? And if so, how?	○
5	Will I receive any follow-up care after the study has ended?	○
6	Will I be told if this study leads to further trials or treatments?	○
7	How will I be informed if any side effects/benefits or risks that may emerge after my participation had ended?	○
8	Will being on this trial exclude me from involvement from other future trials?	○
9	Can I provide feedback during or after the trial?	○

You may find it useful to take some time to ask yourself AND your support network these questions before making a final decision on whether to participate.

1. What will I have to give up to be involved in this trial?
2. Do I have support to take part in this trial?
3. Have you talked about whether your taking part will impact on your support network?
4. How do they feel about the trial?
5. Do you feel prepared to see yourself ‘off’ medication if this is part of the trial assessment?
6. Do you think your support network is prepared to see you ‘off’ medication?
7. Are you happy with the answers to the above questions?
8. Is your support network happy with the answers?

My questions and notes

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Please contact the LEARN study team if you have any queries, questions or suggestions to improve this document on **Learnstudy@cardiff.ac.uk**