




# Assessments in 'clinically defined off'

*What does it mean, why are they needed  
and what can you expect?*



## **This document has been produced with People living with Parkinson's who have taken part in assessments 'off' their medication whilst taking part in a clinical trial.**

**This has been collated into guidance on what to expect and suggestions for making the experience more manageable. You may wish to discuss this with the research team.**

### **What are assessments in 'clinically defined off'?**

During clinical trials studying Parkinson's disease you may be asked to undertake a range of assessments of your physical symptoms and/or scans of your brain. In most cases you will take your medication as normal for these assessments but for some trials you may be asked to come in 'off' your medication. 'Clinically defined off' is a medical term for when you have not taken your medication for at least 12 hours. 'Off assessments' are the tests that take place during this 'off medication' phase. You may need to withdraw from medication for longer periods of time depending on the trial, although this is less common.

### **Why do I need to be in 'off' on a trial?**

Undertaking assessments in 'clinically defined off' provides additional invaluable information about how your Parkinson's disease is progressing and helps researchers understand whether the intervention you are testing is helping your symptoms, or slowing the progression of your Parkinson's.

### **What is it like being 'off' medication?**

Everyone has a unique experience of their Parkinson's and in the same way, each person will experience 'clinically defined off' differently. Some people find it an interesting experience, being able to see for themselves how beneficial their medications are for them and how their disease is progressing. They also find it relatively straightforward to manage during this time. Some patients find that the first experience of 'off' can be a shock, as you see how much your Parkinson's has progressed. Patients report feeling more vulnerable during this time and everyday activities may be harder. It can also be distressing to anyone who is accompanying you to provide support.

You may have experienced periods of 'off' yourself already, however, since this will be a longer period without your medication it may be more severe.

### **How does this work in a clinical trial environment?**

If you are doing assessments that measure your ability to move and walk, you may be asked to do the assessment in 'off' and then repeat it after taking your medication in 'on'. If you are having a brain PET scan you would normally only do this once during an assessment session and you will be told beforehand if it needs to be 'on' or 'off' your medication (see video/leaflet on brain scans for more information).

*Being prepared for this may help with the experience and please be reassured that your medication should take effect within a few hours of taking it again.*

*You can expect to return to your normal medication routine immediately. There should be no long-lasting effects from the time 'off' but you may experience some disruption to your normal routine over the next 24h as your normal medication stabilises.*

# Tips for assessments in 'clinically defined off'

**Tips (from people who have tried it) for making the experience of assessments in 'clinically defined off' more manageable.**

## *Medication*

- Discuss with the research team when you should take your last dose of medication, this may mean missing your last dose before bedtime. If you have a patch for medication, ask if and when this should be removed. Confirm what time your assessment or scan is expected to be and time your last dose of medication accordingly if you can.
- Ensure that you know when you will be able to take your Parkinson's medication after the assessment is finished and who will have it for you/where it is and that water is available.
- Discuss whether medication (muscle relaxants/sedatives) may be available to you to ease any discomfort during 'off'. Have they been prescribed and who will be able to provide them?
- If you are taking a dopamine agonist, discuss with the clinical team the risks of side effects, known as Dopamine Agonist Withdrawal Syndrome (DAWS).

## *Before the day*

- Consider having someone with you who can assist you in getting ready in the morning/can look after your medication on the day.
- Prepare yourself (and your support partner) mentally by discussing how you think you might feel before and after. Share your concerns if you have any.
- Some people find sleeping through brain scans when 'off' medication makes it easier, either naturally if they can or with the help of a light sedative prescribed for them. If you think you may need one discuss with the clinical team in advance.
- You may be able to listen to music during a brain scan which may help you relax, find out if you can bring your own music/playlist, or prepare one just in case.
- A yoga mat can be useful if you suffer from painful cramping/dystonia, as a place to lie down whilst waiting for the brain scanner/assessments. You may want to take one with you if you have one.



## *On the day*

- Make sure your accommodation overnight is very close to the assessment venue or imaging centre, you may find any length of journey uncomfortable when 'off'.
- Lay out clothes the night before whilst you are still 'on' as you will be much slower in the morning.
- Eat the right breakfast: Avoid a high protein breakfast (e.g. eggs/meat), protein may limit the way in which your medication reaches your brain and slow the effects of your medication when you do take it. You may need to discuss this with a support partner or the hotel if you are staying away from home the night before the assessment.
- Ensure transport is arranged to the assessment venue and that it is 'door-to-door'.
- Depending on the stage of disease you are at, you may find it easier to have a wheelchair available the first time you go 'off', it may not be needed but better to have it there and not need it. You may need to request this from the research team.



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