

Participant Information Sheet

ON TIME: Investigating the impact of missed or delayed Parkinson's medication while in hospital

(Version 2, 07 Sept 2022)

Get it on time: Parkinson's medication management while in hospital

Here is some information about the study. You can access the survey at the bottom of this page if you are completing online. If you are completing the survey on paper, you will receive hard copies.

1. Invitation to research

We would like to invite you to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like more information. Contact details can be found at the end of this form.

2. Brief summary and aim of the research

Medications prescribed for Parkinson's disease must be taken on time, and medication schedules are particular to an individual, based on their symptoms. When people with Parkinson's attend hospital, they may not be given the opportunity to manage their own medication, even when they are able to. Sometimes, this has led to missed or delayed medication, leading to negative health outcomes and unnecessarily extended stays in hospital.

We want to understand the impact of this for people with Parkinson's both during and after their hospital visit.

3. Who is eligible for the study?

This project aims to recruit people who are living with Parkinson's Disease who have recently stayed, are currently in, or will stay in the near future in hospital for more than 12 hours for any reason.

4. Do I have to take part?

It is up to you to decide. We will describe the study in this information sheet, following which we will ask for your consent to take part in the study on the next page. You are free to withdraw from the survey at any time by exiting the form. If you wish to withdraw from the study during the 6-month follow-up period, you can contact the chief investigator, Dr Nicola



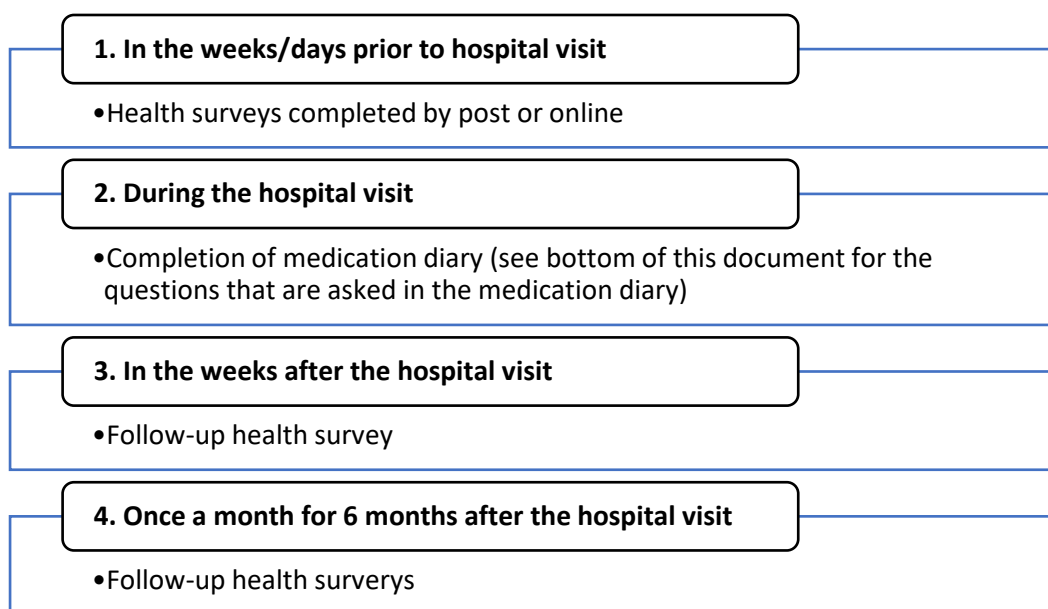
Ray, via email at n.ray@mmu.ac.uk. A reminder of these details will also be given in the monthly email invitations for the follow-up diaries (see below). Please note that neither your medical care or your legal rights will be affected by your choice to take part (or not) in this study. They will also not be affected if you chose to take part and then later decided to withdraw before the study was completed.

5. What will I be asked to do?

The study involves taking a survey about your health and completing a medication diary to describe your access to medication while in hospital. The medication diary will record whether or not you received medication doses on time during your hospital stay. The diary is only for research and is not intended as a means to alert clinical staff that your medication has been delayed. If you do experience delays to your medication, please let staff on the ward know that you need to take your Parkinson's medication on time. A copy of the diary is provided at the bottom of this form so that you can get a feel for the questions that would be asked.

The health survey can be completed online, or we can send the materials to your home for you to complete.

If your hospital visit has not yet happened, the first survey will be carried out before your hospital visit. A second survey will be completed after your hospital stay, and monthly follow-up surveys will then be carried out for 6 months. Each survey is expected to take between 30-40 minutes to complete. Please see the flow chart below for an illustration of the study timeline:



Alternatively, if you are already in hospital, or have already returned home, you will still be able to participate by filling out the medication diary retrospectively (i.e. by recalling as much detail as possible about your access to medication while in hospital).

1. In the weeks/days after hospital visit

- Health survey about your health prior to your hospital visit completed by post or online
- Medication diary (for as much as you can remember about your medication while in hospital)
- Health survey about your health since leaving hospital

4. Once a month for 6 months after the hospital visit

- Follow-up health surveys

If you agree to participate, you'll follow a link to the online surveys. You can also request to receive the surveys by post (via the telephone or email details provided below). The survey will include questions on your health, whether you have experienced falls, and symptoms related to Parkinson's Disease.

At the end of the initial survey, you will be asked to provide an email address that we can use to contact you for follow-up responses. As part of this follow-up, you will be emailed a link every month (for 6 months) to a similar survey to ask about your recovery. Again, we can provide the follow up surveys by post if this is preferred and return postage for all surveys will be paid.

6. Are there any risks if I participate?

Due to the online nature of the study, the only potential risks are eye fatigue due to the prolonged use of a computer screen or discomfort due to the sensitive content of some of the questionnaires. In order to minimise fatigue, you may complete the survey in multiple sittings by using the 'Save and Continue' button on the form, which allows you to return to your answers (however, this must be done within seven days of starting the survey).

If you experience any discomfort as a result of the mental health topics discussed in the survey and wish to seek support, we will direct you to available support resources in the debrief at the end of the survey. Additionally, please remember that you can withdraw from the survey at any point by exiting the form.

7. Are there any advantages if I participate?

Although there is no direct benefit to you if you take part in this study, we hope that the information we get from this study may help us to understand more about how medication



mismangement impacts people affected by Parkinson's, which may help inform future interventions.

8. What will happen with the data I provide?

We will need to use information from you for this research project.

This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data for 2 years so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

8.1. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. To facilitate this, once the study is complete, we will make anonymous data collected for the project available for other researchers by uploading it to an online data repository (such as the open science framework)

8.2. Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- Via the leaflet at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to our Data Protection Managers at legal@mmu.ac.uk
- by ringing us on 0161 247 2566

9. What will happen with the results of the research study?



The results of the study will be published in academic journals, presented at scientific conferences, and will be disseminated in an accessible format on or website and at participant-friendly events organized by the research teams.

10. Who has reviewed the research project?

The London - Harrow Research Ethics has reviews this research and approved the study procedure and documents. In addition, the research team and our clinical partners have reviewed the project to ensure the data we collect can be used to answer questions about how your experience in hospital has impacted your recovery after you return home.

11. Who do I contact if I have concerns about this study or I wish to complain?

If you have any concerns regarding the personal data collected from you, our Data Protection Officer can be contacted using the legal@mmu.ac.uk e-mail address, by calling 0161 247 3331 or in writing to: Data Protection Officer, Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH. You also have a right to lodge a complaint in respect of the processing of your personal data with the Information Commissioner's Office as the supervisory authority. Please see:

<https://ico.org.uk/global/contact-us/>

If you have concerns regarding the general running of the study people contact the study lead: Dr Nicola ray, n.ray@mmu.ac.uk, or the ethics team at Manchester Metropolitan University, ethics@mmu.ac.uk

Medication diary

Date:

1) Were you given the opportunity to administer your own medication today?

Yes/No

Please try to complete the following as best you can, and feel free to ask a family member or carer to help.

Medication schedule	Delayed (yes/no)	Missed (yes/no)	How confident are you (see scale below)
Time	Yes/no (if yes: by how long:)		
Time	Yes/no (if yes: by how long:)		
Time	Yes/no (if yes: by how long:)		
Time	Yes/no (if yes: by how long:)		
Time	Yes/no (if yes: by how long:)		
Time	Yes/no (if yes: by how long:)		
Time	Yes/no (if yes: by how long:)		
Time	Yes/no (if yes: by how long:)		

How confident are you about remembering when and if you received your Parkinson's medication today?

Not at all confident	A little confident	Somewhat confident	Mostly confident	Very confident	A family member/carer has helped to confirm
0	1	2	3	4	5