Participant Information Sheet

(Randomised Controlled Trial)

Name of Lead Researchers: Prof. Anette Schrag & Prof Kate Walters
Name of Site Principal investigator: [Add name here]

We would like to invite you to take part in our research study. Before you decide whether you want to take part, it is important that you understand why the study is being done and what participating in the study entails. One of our team will go through this information sheet with you, to help you decide whether you would like to take part or not and answer any questions you may have. We'd suggest this should take about 45 minutes. Please read the following information carefully and please feel free to talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear and do take time to decide whether you wish to take part.

Part 1

1. **What is the purpose of the study?**
   This study aims to improve the health and well-being of people with Parkinson's by testing the effectiveness of the '*Live Well with Parkinson's'* Toolkit compared to usual care in a clinical trial. The toolkit is available online and in paper and aims to help increase the active involvement of people with Parkinson's in the management of their care, including how to keep healthy and independent, where to access resources and how to manage their Parkinson's. The toolkit is facilitated by a 'Supporter' who will offer up to six one-to-one sessions with the participants in which they will be directed to relevant information and advice on symptoms that may be bothering them as well as identifying what living well means to them and what steps they can take to achieve this. It is hoped that the *Live Well with Parkinson's* toolkit will reduce disability and hospital admissions and improve day-to-day living and quality of life. This study will test if the toolkit works in this and also whether it is cost-effective to be used in the NHS. If successful, this toolkit could then be used across the NHS to be available to help as many people as is possible.

2. **Why have I been invited?**
   We are inviting people who are [registered at [GP name] /who are under the care of [Hospital name] (enter/delete as appropriate)] who have a diagnosis or possible diagnosis of Parkinson's in their medical records and are living at home. We are inviting up to 338 people to take part in this stage of the study.

3. **Do I have to take part?**
   No, participating in this study is voluntary. If you prefer not to take part in the study, this will not influence the current care you receive from doctors, nurses, or any other healthcare professionals. If you agree to

take part, we will then ask you to sign a consent form. If you agree to take part but then change your mind you can withdraw from the study at any time without giving a reason. This would not affect the standard of care you receive.

4. What will I have to do if I take part?

Consent

- Before taking part in the study a member of the research team will discuss the study in detail with you and give you time to ask any more questions that you may have. If you're eligible to take part in the study, you will then be asked to sign a consent form to confirm that you are happy to take part.

Assessments

- Taking part in the study will involve meeting with the research team on three separate occasions throughout a year to complete some outcome assessments. We would like to complete these assessments at the start, 6 months later and 12 months later.
- The assessments are split into two stages:

  The first stage is a questionnaire booklet about your health, well-being, and about your home circumstances. This take around 15 minutes to complete and can be done with the researcher or on your own via post or online.

  The second stage involves a physical assessment as well as answering some questions and about your memory and the impact of Parkinson's on your daily life. This will be led by one of the study team's qualified researchers who will always provide you with clear instructions and takes up to an hour and 30 minutes Breaks are given as necessary.
- It is important for the study that you try to complete all the follow-up visits.
- The assessments should take approximately one to one and a half hours, and you can take refreshment breaks as you need to. The assessments will take place at the study site or remotely using telephone and videoconferencing (e.g., via Zoom).

  One assessment (known as the motor components of the Unified Parkinson's Disease Rating Scale) will be video-recorded so we can check the researcher is administering and assessing correctly. The recording will be saved on secure UCL data safe haven systems and deleted from the recording device.

Optional assessments

In addition to the main study's assessments, we will invite you to take part in two optional assessments not directly related to this study.

Activity monitor

- Activity monitors track how often people are active and the level of activity intensity as well as sleep length and quality. You will be asked to wear the activity monitor on your wrist and/or trunk for 7 continuous days without taking it off, if this is comfortable. The device is waterproof and can be worn in the shower and bath. The devices do not collect or use GPS data. The device will not provide you will feedback. This will allow us to collect potentially more accurate data on motor symptoms of Parkinson's. Please see image on the right for an example of an activity monitor.

Saliva sample

- You will also be asked to donate a saliva sample for genetic analysis for use in future research in Parkinson's only. This will be used for analysis of genetic variation underlying Parkinson's. The sample will be stored and used in ongoing and future Parkinson's projects by the sub-

study investigators and their teams. Samples may be shared on a collaborative basis with other researchers investigating Parkinson's in the UK and abroad. The laboratory will process, store, and dispose of blood samples in accordance with all applicable legal and regulatory requirements, including the Human Tissue Act, 2004. Some information about you (age, sex, age at onset of PD, race, family history) linked to your study number, will be provided to the genetic sub-study team. At the end of the study, information collected during the study (for example clinical rating scales) will be combined with data from the genetics sub-study to help with future genetics analysis. Please note that we will not feed back results on genetic analysis to individuals.

Both additional assessments are optional and do not impact whether you can take part in the main study.

Intervention: Live Well with Parkinson's Toolkit

- This study is a randomised control trial. This is a method where participants are put into groups and each group is given a different treatment and the results are compared to see if one is better. To try to make sure the groups are the same to start with, each person with Parkinson's is put into a group by chance (randomly). Therefore, half the people taking part will be allocated by chance to a group where they will be given access to the *Live Well with Parkinson's* toolkit and supporter sessions. This is in addition to their usual care (for example hospital outpatients' appointments, seeing a GP or Parkinson's specialist nurse etc), which will continue as normal. The other half will be allocated to a group that continues to receive their usual care as normal but will not be able to access the *Live Well with Parkinson's* toolkit.
- The Live Well with Parkinson's toolkit is available in paper and online format. It includes a range of information pages related to Parkinson's with links to additional resources, a section to review any symptoms you may be experiencing, a tracker for medication, symptoms or activities, as well as a personalised section for you to input information about you.
- If you are allocated to receive the *Live Well with Parkinson's* toolkit, we will also arrange for up to six sessions one-to-one with a 'Live Well with Parkinson's' supporter. This is a trained health or social care professional who will help you to get the best use from the toolkit. During these sessions you will work with them to navigate the toolkit and identify information and advice that is relevant to you. This might include information on symptoms you are experiencing, and what you could do to address these. You can also use tools such as a tracker (e.g., of medication, symptoms, or activities). The supporter will help you to identify possible well-being priorities for living well with Parkinson's and planning how this can be achieved. You may take breaks throughout the sessions as frequently as you need.
- As part of the trial, we would like to audio-record the supporter sessions to ensure they are delivered as expected.
- If you have a relative, friend or carer who helps you on a regular basis, the research team, with your permission, would like to ask them to complete a couple of questionnaires about their needs. They can also attend any sessions with you if you wish and you can give them access to the toolkit. You can still take part in the study even if you do not have a relative, friend or carer willing to take part.
- We are asking approximately 25 people who use the Live Well with Parkinson's toolkit to complete an interview after six months to explore what they liked and disliked about the toolkit and sessions. This is voluntary and you do not have to take part in this if asked. You will be given a separate information sheet about this at the time if you are invited to take part.

5. Expenses and payments

If you agree to take part in the study you will be offered a £20.00 high street shopping voucher as a thank you for your time for the first assessment, and £10 for each of the two further shorter assessments that you

complete (£40 in total for completing all three assessments). We will also reimburse any travel expenses you may have.

6. What are the alternatives for diagnosis or treatment?

We will not be changing your medications. The treatment you usually receive for your Parkinson's will remain the same as it would if you were not taking part in the study.

7. What are the possible disadvantages and risks of taking part?

There are minimal disadvantages in taking part in the study, but it will require a commitment of your time and you may find taking part is tiring. If you become distressed at any point during the study, you can take breaks or stop completely. The researcher will work with you to ensure you get ongoing support (e.g., from your GP).

8. What are the side effects of any treatment received when taking part?

This study does not involve taking any medications or any changes to your usual treatment.

9. What are the possible benefits of taking part?

If you are in the group that is allocated to receive the *'Live Well with Parkinson's'* toolkit, you will receive a comprehensive guide to support living well with Parkinson's and up to six sessions with a supporter to help you work through this. If found to be effective, it is hoped that the *Live Well with Parkinson's Toolkit* will improve quality of life, reduce disability and unnecessary hospital admissions; and help health care professionals in the delivery of the best care. If it is cost-effective in improving care and quality of life, we hope that it could then be commissioned so that it is available to other people with Parkinson's across the NHS. It may also be used as a model approach to develop similar toolkits to help people live with other long-term health conditions.

10. What happens when the research study stops?

The study will not affect your usual Parkinson's treatment and therefore, when the study is completed you will continue with your usual treatment. We will be able to share the results of the study with you and we hope the toolkit will be adopted by the NHS.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

11. What will happen if I don't want to carry on with the study?

You can withdraw from any aspects of the study at any time without giving a reason and without affecting the standard of care you receive. If you withdraw consent for research use of genomic or phenotypic data at any time, your data will be removed from the data platform, but it may not be possible to retrieve data already used for research use.

12. What if I lose capacity or go into a care home during the study?

If you go into a care home during the course of the study you will still be able to continue in the study if you have capacity to do so. As you are unlikely to be able to engage and benefit from the study if you lose capacity, you will be withdrawn from the study. All data collected up until that point will be retained unless otherwise requested.

13. What if there is a problem?

Every care will be taken during this study to ensure that your well-being is not compromised. If however you or your relatives have any concerns about any aspect of the way you have been approached or

treated by members of staff during this study you can speak to a member of the research team who will do their best to answer any questions. Their contact details are at the end of this information sheet.
If you remain unhappy and wish to complain formally, you can do this by contacting the confidential patient advice and liaison service (PALS). PALS was set up to support patients, their families and visitors who need advice or have problems and concerns. [The patient advice and liaison service for the Royal Free Hospital is in the hospital's main reception. The service is open from 10am to 4pm, Monday to Friday, except Wednesday, when the service is open from 10.30am to 4pm.

Tel: 020 7472 6446/6447; (020 7472 6445 - 24-hour answer phone)
Fax: 020 7472 6463
SMS: 447860023323 (Deaf and hearing-impaired patients only)
Email: rf.pals@nhs.net]

In the unlikely event that something does go wrong, and you are harmed during the research due to someone's negligence then you may have grounds for a legal action for compensation against [Hospital Site], but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

14. Will my taking part in this study be kept confidential?

Royal Free London NHS Foundation Trust is the sponsor of this study and is based in the United Kingdom. We will be using information from you/ and your medical records to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Royal Free London NHS Foundation Trust will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting study members listed at the end of this information sheet and/or Royal Free London NHS Foundation Trust's Data Protection Officer: rf-tr.rfldpo@nhs.net

Royal Free London NHS Foundation Trust will use your name, NHS number and contact details to contact you about the research study and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Royal Free London NHS Foundation Trust, Clinical Trials Unit and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Local sites will pass these details to Royal Free London NHS Foundation Trust along with the information collected from you and your medical records. The only people in Royal Free London NHS Foundation Trust who will have access to information that identifies you will be the people who need to contact you to complete the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

15. Will my GP be informed of my involvement?

With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study. At the end of the study, with your permission, we will send a summary of your involvement in the study including what progress you made, if any.

16. What will happen to the results of the research study?

The scientific results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the participants involved in the study will be identified in any report or publication. Should you wish to see the results, or the publication, please sign the relevant section of the consent form.

17. Who is organising and funding the research?

Royal Free London NHS Foundation Trust is the sponsor for the study and the study is funded from a grant from the National Institute of Health Research (NIHR). None of the doctors or researchers who are working on this study are being paid for including participants in the study, and there are no conflicts of interest.

18. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by _____Research Ethics Committee.

19. Further Information and contact details

You are encouraged to ask any questions you wish, before, during or after the study. If you have any questions about the study, please speak to a member of the research team who will be able to provide you with up to date information. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Trial Manager:	Megan Armstrong	megan.armstrong1@nhs.net
Research Assistants:	Tasmin Rookes	t.rookes@nhs.net
	TBC	TBC

Study email address: rf.livewellparkinsons@nhs.net

Alternatively if you or your relatives have any questions about research or Parkinson's you may wish to contact one of the following organisations that are independent of the hospital at which you are being seen: Parkinson's UK's website www.parkinsons.org.uk, the NIHR website www.peopleinresearch.org or www.invo.org.uk

Thank you for taking the time to read this information sheet and for considering taking part in this study. You can have more time to think this over if you are at all unsure. If you decide you would like to take part then please read and sign the consent form provided by the research team. You will be given a copy of this information sheet and the signed consent form to keep. A copy of the consent form will be filed in your patient notes, and one will be filed with the study site files.

Chief Investigators

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