# Participant Information Sheet

# Evaluating the feasibility of a samba percussion intervention for people with Parkinson's Disease

## Introduction

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. This should take about 30 minutes. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. The second part will give you more detailed information about the conduct of the study.

Please do ask if anything is unclear.

### Why are we doing this research?

Interventions that include physical activity (exercise, physiotherapy, dancing) or repetitive beats to music, known as rhythmic auditory stimulation, are thought to help with the symptoms that people with Parkinson's Disease (PD) experience. Community-based activities have also shown to be beneficial. SParky Samba is a community-based samba percussion activity. It has been designed for people with PD by people with PD with the support of a samba band leader. We want to see if SParky Samba has any health and wellbeing benefits for people with PD. The first step in this is to test the practicalities of investigating SParky Samba in a trial setting. This information will be used to design a bigger clinical trial of SParky Samba in the future to see if SParky Samba has any health benefits for people with PD. For this study we will compare people who take part in SParky Samba for 12 weeks with people who have not. This will include measuring movement, falls and quality of life in people before and after the 12 weeks.

### Why have I been invited to take part?

You have been invited to take part as we understand that have a PD diagnosis and may live near one of the existing SParky Samba groups.

### What will taking part involve?

If you decide to take part in the research, we will send you a link to the study database (by email) where you can confirm that you are eligible to take part (are living with PD and have not previously taken part in a SParky Samba group) and provide your consent to participate. When this is complete you will be asked to complete some on-line questionnaires about you and your PD. You can do these using a computer, smart phone

or tablet. If you would like a researcher to provide telephone support to complete these tests, that can be arranged for you. You will also need to do some simple tests to measure movement and thinking at your local hospital. The outcome of these tests will not prevent you from taking part in the research.

Once the tests are complete you will be selected at random by a computer to attend either the SParky Samba Group or be part of the control group. We will send you an email to tell you which group you are in within two weeks of completing the initial tests.

If you are allocated to the SParky Samba group, we will ask you to attend as many of these sessions as possible within a 12 week period. Ideally, we would like you to attend 6 sessions on consecutive weeks and at least 8 sessions in total, but the more you attend the better. We will ask you to record the number of sessions you attend and their dates. The SParky Samba groups take place once per week.

There will be no cost associated with attending SParky Samba sessions for the duration of the research. We will also support your attendance at SParky Samba sessions by covering the cost your travel. We can choose how we do this- either we can arrange travel for you, or you can submit a reimbursement claim to the trial team for any travel costs you have.

After the 12 weeks, you will need to complete the movement and thinking tests at your local hospital again. We will also ask you to repeat the on-line questionnaires.

Once you have completed your participation in the study you are able to keep attending the SParky Samba group if you want to.

To see what happens at a standard SParky Samba session please use this link or the QR code below to watch the promotional video.

If you are allocated to be in the control group, we would like you to continue your usual activities for 12 weeks. After the 12 weeks is complete, you will be asked to repeat the movement and thinking tests and on-line questionnaires. You will also be able to join the local SParky Samba group so that you have the option of experiencing the activity. You do not have to do this if you do not want to.

The table below describes what will happen at each stage of the trial, where it will happen and how long for. You will receive some assessments at your local hospital at the start of the study and after you have finished the 12-week research period. These assessments are described below and we can provide you with further details about these before you take part if you wish also.

Once you have completed the below, we may ask you to take part in a semi-structured interview to ask about your views on the trial and what it was like to take part. This is very helpful information for knowing how to conduct similar research in the future.

If you chose to take part in an on-line interview, the interview will be video recorded and securely stored on Cardiff University password protected servers and will only be accessible to researchers working on the study. If you choose to do the interview in person, the interview will be audio-recorded using an encrypted recording device. Audio recordings will be transferred to password protected servers at Cardiff University as soon as possible.

Interviews will be transcribed for analysis, which may involve the use of external company. Any company used needs to be approved by Cardiff University and agree to confidentiality terms. Video and audio files will be deleted once all data analyses have been completed.

In total, you be involved in the research for a maximum period of 16 weeks.

| Visit | What Will Happen? | Where? | How long? |
|---|---|---|---|
| Baseline Assessment (Visit 1, Week 0) | Movement tests<br>Thinking test<br>Questionnaires | Local hospital <localise to site><br>On-line (at home) | 45 minutes<br><br>20 minutes |
| Intervention Period (Week 1-12) | Attendance at Sparky Samba group or continue activities as usual | <add local details> | 1 hr per week |
| Follow-up Assessment Visit 2, Week 12) | Movement tests<br>Thinking test<br>Questionnaires | Local hospital <localise to site><br>On-line (at home) | 45 minutes<br><br>20 minutes |
| Optional Week 12-16 | Semi-structured interview | On-line or at a location of your choosing | Up to 1 hr |

## What are the possible benefits of taking part?

Many people who have engaged with SParky Samba have found it beneficial for them. However, we do not know if taking part in SParky Samba will have any specific benefits (health or otherwise) for you. An initial qualitative evaluation that the people with PD

attending SParky Samba feel several benefits in their movement, health and wellbeing from participating in the group. There is a possibility that taking part in the study will help you learn more about your condition and ways to manage your symptoms. You may also benefit from the social interaction with other people with PD. In taking part you will be contributing to research to learn more about what activities help people with PD and why. Many people also find contributing to research rewarding.

## What are the possible disadvantages and risks of taking part?

There is minimal risk from taking part in the SParky Samba activity. The activity is designed to accommodate people with PD and current group members have not experienced any problems with taking part.

## What will happen if I decide I don't want to continue?

If you decide you no longer wish to continue on the trial, you can stop at any stage. You do not have to give a reason for this and it will not affect how you are treated.

If you stop the study, we won't collect any more data from you. The information we have collected before you decided to stop the study will be still used as part of our analysis unless you specifically request that we do not. You won't be able to be identified by this information.

If we have collected any information that could potentially identify you such as your name, address, phone number or email address, you can request that we destroy this within 28 days of you telling us that you no longer want to continue in the study however we will delete this information as standard at the end of the trial.

## Will I be paid to take part?

No, we will not pay you to take part in the research. However, we will reimburse your travel costs for attending study visits and SParky Samba sessions. If you are allocated to take part in the control group, we will support travel costs for you to attend a SParky Samba session after you have completed taking part in the research. If you choose to get travel costs reimbursed by the trial, we will need to share your personal data (including bank details) with people in the finance department at Cardiff University.

## How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your name and contact details (including email address and telephone number). 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.

Cardiff University is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Only using a code number to identify your data (i.e data will not be stored using your name or other identifying information
- Storing electronic data within secure, password protected systems only
- Not storing your personal information on paper.

We may share data about you with other researchers, including those outside the UK for research related purposes including understanding non-drug interventions for PD.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- research organisations (such as universities)
- charitable foundations who engage in PD research

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says

## How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data 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.

We will keep your study data for the maximum period of time required by Cardiff University's data retention policies (15 years). The study data will then be fully anonymised and securely archived or destroyed.

## 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
- you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

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

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- by asking one of the research team
- by viewing the Cardiff University Data Protection Policy and Privacy Notices: https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection
- by contacting the Cardiff University Data Protection Officer by email: inforequest@cardiff.ac.uk or in writing to: Compliance and Risk, University Secretary's Office, Cardiff University, 42 Park Place, Cathays, Cardiff, CF10 3BB.

## What will happen to the results of the trial?

The results of this trial will be written up as research articles, they may also be presented at conferences. All data will be merged, and you will not be identifiable from the results. Results will be communicated to patient, clinical and academic spaces for people with PD and their healthcare professionals and to help build knowledge on non-drug interventions. Summaries of results will be made available to people who participated in the trial and/or their families on the CTR website (https://www.cardiff.ac.uk/centre-for-

trials-research) and also sent directly to you as a study participant. We will work with people with PD and dedicated PD groups to share the results of the trial in infographic and media forms.

## How have patients and the public been involved?

SParky Samba was the idea of and has been developed by someone living with PD. We have talked to people living with PD and those currently attending SParky Samba to help design the trial, choose what we measure and to produce all the documents. They will also help us summarise the results for participants and spread the news of the results to the PD community. People living with PD continue to be included within the research group, overseeing the conduct and progress of the whole study.

## Who is organising and funding the research?

This research is funded by the Jacques and Gloria Gossweiler Foundation. The study is being coordinated by the Centre for Trials Research at Cardiff University. The Chief Investigators for the study are Dr Cheney Drew and Dr Katy Hamana from Cardiff University.

## Who has reviewed the trial?

This trial has been reviewed by an independent group of people, called a Research Ethics Committee (The North of Scotland Research Ethics Committee 2 [Ref: 25/NS/0037]) They ensure the safety, rights, well-being, and dignity of trial participants.

## Contact Information

If you experience any problems while taking part in the trial, or you would like any further information about the trial, please do not hesitate to contact the trial team at the email address below.

SParky Samba Trial Team Email: SParkySamba@cardiff.ac.uk

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of the trial, the normal NHS mechanisms are available to you <add name of NHS organisation address for complaints>.

If you would like an independent point of contact to discuss any aspect of this study you can contact Rachel McNamara, Director of the Brain, Health and Mental Wellbeing Division at the Centre for Trials Research on: McNamara@cardiff.ac.uk

We will not contact your GP while you are taking part in the trial, but you are welcome to let them know that you are taking part.

Thank you for taking the time to read this information sheet and your consideration to take part in this trial.