.

EVALUATING THE FEASIBILITY OF A SAMBA INTERVENTION

FOR PEOPLE WITH PARKINSON'S DISEASE

PROTOCOL

V1.0 20TH MARCH 2025

Sponsor:	Cardiff University, Joint Research Office Lakeside Building, 2nd Floor, University Hospital Wales, Heath Park Cardiff, CF14 4XW
Sponsor ref:	SPON2008-25
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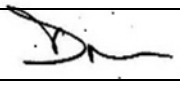
Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the relevant trial regulations, GCP guidelines, and CTR's SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

Trial Sponsor: Cardiff University			
Name	**Position**	**Signature**	**Date**
Natalie Richards	Research Integrity and Governance Officer	Please see email dated 20th March 2025	20th March 2025
CTR Director: Rachel McNamara			
Name	**Signature**	**Date**	
Rachel McNamara	Please see email dated 21st March 2025	21st March 2025	
Chief Investigator:			
Cheney Drew		24th March 2025	
Name	**Signature**	**Date**	

General Information

This protocol describes the SParky Samba clinical trial and provides information about the procedures for entering participants into the trial. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other patients. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial. Problems relating to the trial should be referred, in the first instance, to CTR

Contact Details – Co-Investigators

Co-Chief Investigators	
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Trial Co-ordination:

The SParky Samba trial is being coordinated by the Centre for Trials Research (CTR), Cardiff University, a Clinical Research Collaboration (UKCRC) registered trials unit.

This protocol has been developed by the SParky Samba Trial Management Group (TMG)

For **all queries** please contact the SParky Samba team through the main trial email address.

Any clinical queries will be directed through the Trial Manager to either the Chief Investigators or Co-Investigators

Main Trial Email:	SparkySamba@cardiff.ac.uk
Trial Administrator:	Lorraine Williams
Trial Manager:	Rebecca Hamilton/ Adam Williams/ Elinor Coulman
Senior Trial Manager:	n/a
Data Manager:	Nigel Kirby
Trial Statistician:	Philip Pallmann
Director:	Rachel McNamara
Safety Officer	N/A

Randomisations:

Randomisation
To randomise a participant you will need to access the study REDCap database https://redcap.ctr.cardiff.ac.uk/redcap/redcap_v13.7.5/

Clinical queries:

Clinical queries
SparkySamba@cardiff.ac.uk All clinical queries will be directed to the most appropriate clinical person.

Serious Adverse Events:

SAE reporting
Where the adverse event meets one of the serious categories, an SAE form should be completed by the responsible clinician and submitted to the trial team (SparkySamba@cardiff.ac.uk) within 24 hours of becoming aware of the event (See section 13.0 for more details).

Table of Contents

Glossary of Abbreviations

AE	Adverse Event
AR	Adverse Reaction
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
CTR	Centre for Trials Research
CV	Curriculum Vitae
DREFAQ	Dresden Falls Questionnaire
FoG	Freezing of Gait
GCP	Good Clinical Practice
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
MoCA	Montreal Cognitive Assessment
NHS	National Health Service
OxPAQ	Oxford Participation and Activities Questionnaire
PD	Parkinson's disease
PDQ-8	Parkinson's Disease Questionnaire 8
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PROMS	Patient Reported Outcome Measures
QA	Quality Assurance
QC	Quality control
QoL	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TIDieR	Template for Intervention Description and Replication
TM	Trial Manager
TMF	Trial Master File

TMG	Trial Management Group
TSC	Trial Steering Committee
TUG	Timed Up and Go
UPDRS	Unified PD Rating Scale

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No.	Protocol version no.	Date issued	Summary of changes made since previous version

2 Synopsis

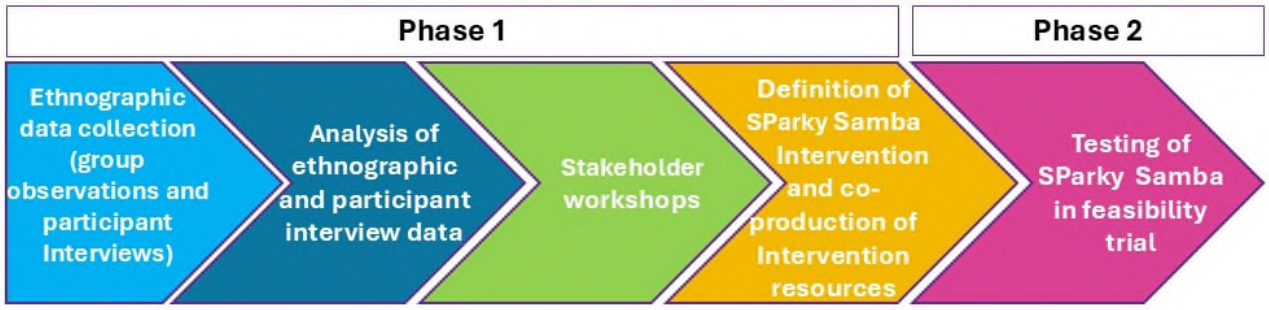
Short title	Evaluating the feasibility of a samba percussion intervention for people with Parkinson's disease (PD)
Acronym	SParky Samba
Funder and ref.	Jacques and Gloria Gossweiler Foundation
Trial design	Feasibility Randomised Controlled Trial (RCT)
Trial participants	Patients with Parkinson's disease (PD)
Planned sample size	Feasibility RCT, n = 60 (30 in intervention group, 30 in activity as usual)
Planned number of sites	4
Inclusion criteria	• People diagnosed with PD • Age 18 or older • Able to provide consent to take part
Exclusion criteria	• Has already taken part in a SParky Samba group
Intervention duration	12 weeks
Planned trial period	Planned recruitment time from April 2025 – February 2026
Primary objectives	• Determine feasibility of testing the SParky Samba intervention in a feasibility RCT.
Secondary objectives	• Explore the effect of the SParky Samba intervention as compared to activities as usual across function and wellbeing of people with PD.
Primary outcomes	• Feasibility of participant recruitment and retention and intervention adherence according to pre-specified criteria.
Secondary outcomes	• Unified PD Rating Scale (UPDRS) • Freezing of Gait Questionnaire (FoG) • Dresden Falls Questionnaire (DREFAQ) • MiniBEST Test • Montreal Cognitive Assessment (MoCA)

	• PD Questionnaire 8 (PDQ-8) • Oxford Participation and Activities Questionnaire (OxPAQ). • Lorig Self Efficacy Scale • Physical Activity Scale for the Elderly (PASE)
Intervention	SParky Samba group activity; weekly sessions lasting between 1 hour for 12 weeks.

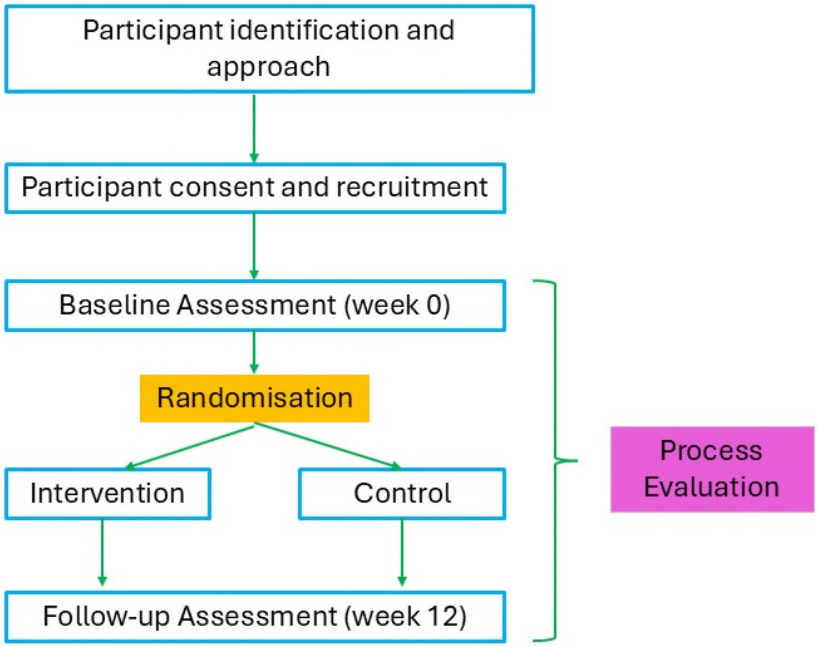
3 Trial Summary & Schema

3.1 Sparky Samba Study Overview

Phase 1 was conducted separately. This protocol is for Phase 2 of the study



3.2 Participant Flow Diagram



3.3 Trial Lay Summary

Parkinson's disease (PD) affects areas of the brain that are important for regulating many vital functions including movement, thinking, mood, sleep and pain. Symptoms progress over time, reducing independence, wellbeing and quality of life (QoL). Treatments are available that reduce some symptoms, but no proven treatment can slow or stop the decline. Treatments include medication and surgery, or lifestyle changes, commonly known as non-drug interventions. People with PD have highlighted the need for more interventions to help combat the movement problems and other symptoms they experience.

Interventions that include physical activity (exercise, physiotherapy, dancing) or repetitive beats to music, known as rhythmic auditory stimulation, have been shown to help with PD symptoms. Largely these have been delivered and tested in clinical settings. We know that community-based interventions can have positive health benefits. It has been suggested that providing interventions in the community, rather than in clinical settings, will help people with PD stay engaged with the intervention to achieve maximum and sustainable potential health benefit.

SParky Samba Trial

Our research team has been working with a group that has developed a new community-based samba percussion activity (SParky Samba). This has been designed for people with PD by people with PD, with the support of a samba band leader. An initial qualitative evaluation has shown that the people with PD attending SParky Samba experience several benefits in their movement, health and wellbeing from participating in the group. We want to perform an evaluation of SParky Samba to see if it has potential to help improve health outcomes and wellbeing in people with PD.

Firstly, to understand what the key parts of SParky Samba are, we have undertaken a series of observations of the SParky Samba group and interviews with group members. We have used this information to define SParky Samba as an intervention so that it can be delivered to new groups of people with PD.

Now we want to undertake a feasibility trial of the SParky Samba intervention in people with PD at different community SParky Samba groups in Wales. We will recruit 60 participants to take part in the trial. A computer programme will randomly determine whether they should either attend a SParky Samba group or a be part of an activity as usual (control) group for 12 weeks. We will measure movement, thinking and wellbeing at the beginning and end of the 12 weeks. We will also record how many people are willing to join and then stay in the trial. This will provide important information that

will help us design a bigger clinical trial to see if the SParky Samba intervention definitely affects the health and wellbeing of people with PD.

4 Background

Parkinson's disease (PD) is the second most common neurodegenerative disorder after Alzheimer's disease, that causes cell loss in the brain largely due to the abnormal aggregation of the alpha-synuclein protein. In PD, atrophy of dopaminergic cells in the substantia nigra leads to progressive decline of motor function alongside changes in cognition, sleep, mood and other non-motor symptoms. There are no disease modifying therapies, with treatment options primarily supporting motor-symptom management, and often with significant side effects that worsen other PD symptoms. Stakeholder research prioritisation exercises demonstrate the need for developing non-pharmacological interventions that may aid both motor and cognitive functions (1,2) and allow tailoring for disease stage (3).

Common non-pharmacological interventions shown to have both motor and non-motor benefits for people with PD include physical activity in the form of targeted exercise (4,5) or other forms of movement such as dancing (6) or music-based movement therapy(7) as well as neurological music therapy in the form of rhythmic auditory stimulation (RAS) (8). RAS can be achieved through activities such as walking to a rhythmic beat or drumming and similar forms of music-based therapy, which have shown promising effects on gait and mobility in people with PD (9–11). The majority of these interventions have been trialled in clinical settings, but it is recognised that community-based activities promoting healthy behaviours in people with PD are likely to have greater long-term impacts (12–14) due to their enhanced accessibility and effects of social cohesion.

SParky Samba Initiative

A recently established PD specific samba percussion group 'SParky Samba' is a patient initiative led; designed by people with PD for people with PD and supported by a samba percussion tutor. This group activity combines RAS activities with social stimulation. Awareness of SParky Samba has gained momentum amongst people with PD who have indicated a need for more similar groups in other local communities. An initial qualitative evaluation of SParky Samba, conducted by our group (unpublished data) has highlighted its potential utility as a community-based activity for people with PD to improve social connectedness, wellbeing, physical activity participation and cognition. As indicated by our trial research partner, people with PD like therapeutic activities and lifestyle interventions that they

themselves, can control. Patient-led research is essential to develop interventions that have a better chance of successfully translating into practice because they are inherently acceptable, meaningful and relevant to those they have been developed for (15–17).

We have conducted an ethnographic study of the existing SParky Samba group in Cardiff, with follow-up stakeholder workshops in order to: 1) identify core intervention components (duration, exercises, movements) in preparation for intervention delivery; 2) refine intervention components, and determine intervention flexibility and how this may be adapted for individuals; 3) describe and specify the resulting intervention in detail according to the TIDieR framework (18); 4) create a logic model and identify a 'theory of change' regarding intervention mechanisms (how it may work), including the core elements of the music-based rhythms and pieces in terms of tempo, complexity, syncopation, use of beaters as metronomes which may affect mechanisms of change. This could be facilitating movement and impacting mood and reward, summarising inputs and resources, implementation strategies, outcomes, impact and context.

4.1 Rationale for Current Trial/Justification of Treatment Options

SParky Samba has achieved support from the PD community (individuals, the UK's leading PD charity PDUK) and arts-based funders, but it warrants further investigation for its potential health benefits. The SParky Samba intervention will be compared to an activities as usual control group. This will help to differentiate between the community and social potential benefits of standard social activities versus the specifics of the SParky Samba intervention and potential benefits of RAS.

Research Aim: Evaluation the feasibility of SParky Samba in a small-scale randomised controlled trial (RCT) as the next step towards a full effectiveness evaluation of SParky Samba.

5 Trial Objectives/Endpoints & Outcome Measures

5.1 Primary Objectives

- Determine feasibility of testing the SParky Samba intervention in a feasibility RCT.

5.2 Secondary Objectives

- Explore the effect of the SParky Samba intervention as compared to an active social control across function and wellbeing of people with PD.

5.3 Primary Outcome Measure

Feasibility of participant recruitment and retention and intervention adherence according to pre-specified criteria

Variable		Progression Criteria		
		Red	Amber	Green
Recruitment	No. approached willing to participate (number consented/ number approached)	<5%	5-19%	≥20%
	No. recruited	< 24 in total	25-44	45-60
Retention	No of participants completing primary end point	<50%	51-89%	≥90%
Adherence	% Participants adherent to the intervention (as defined in section 11.1)	<50%	51-79%	≥80%
Data Completeness	% Participants completing at least 90% of available baseline measures	<70%	71-94%	≥95%
	% Participants completing at least 90% of follow up measures	<50%	51-74%	≥75%

5.4 Secondary Outcomes Measures

- Unified PD Rating Scale (UPDRS) (19),
- Freezing of Gait (FOG) Questionnaire (20)
- Dresden Fall Questionnaire (DREFAQ) (21)
- MiniBEST Test (22)
- Montreal Cognitive Assessment (MoCA) short from [Espresso] (23)
- PD Questionnaire 8 (PDQ-8) (24)
- Oxford Participation and Activities Questionnaire (OxPAQ) (25,26)

- Lorig Self Efficacy Scale (26,27)
- Physical Activity Scale for the Elderly (PASE)(28)

6 Trial Design & Setting

This will be a parallel group feasibility RCT of the SParky Samba intervention compared to an activity as usual control group. A recruitment target of 60 people with PD will be randomised 1:1 to intervention or activity as usual. Participants will be recruited from a combination of specialist movement disorder clinics, via the PD specialist nurse network, social media advertising and advertising through local PD focused organisations such as Parkinson's UK Cymru. The SParky Samba intervention will be delivered across three principal community sites in Wales (Cardiff, Llandudno and Fishguard) with possible additional sites in Carmarthen and Chepstow, dependent on external funding. Outcomes will be assessed at baseline (prior to randomisation) and at the end of the 12 week intervention delivery period. Those randomised to the activity as usual group will be able to access SParky Samba after the completion of the 12 week follow-up assessments.

6.1 Risk Assessment

A Trial Risk Assessment has been completed to identify the potential hazards associated with the trial and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to human subjects
- How high the risk is compared to standard practice
- How the risk will be minimised/managed

This trial has been categorised as low risk, where the level of risk is comparable to the risk of standard medical care. A copy of the trial risk assessment may be requested from the Trial Manager. The trial risk assessment is used to determine the intensity and focus of monitoring activity (see section 22.1).

7 Site & Investigator Selection

This trial will be carried out at participating sites within Wales local to existing SParky Samba groups.

Before any site can begin recruitment a Principal Investigator (PI) at each site must be identified. The following documents must be in place and copies sent to the SParky Samba Trial email account (see contact details on page 4):

- The confirmation of Capability &Capacity from the site's R&D Department following sharing of local information pack
- Favourable opinion of host care organisation/PI from Main Ethics committee
- A signed Trial Agreement
- Current Curriculum Vitae (CV) and GCP training certificate of the PI
- Completed Site Delegation Log
- Full contact details for all host care organisation personnel involved, indicating preferred contact
- A copy of the most recent approved version of the Participant Information Sheet(s) and Consent Form(s) on host care organisation headed paper
- A copy of the most recent Consent Form(s) on host care organisation headed paper
- Returned copy of the Self-Evident Correction Log signed by the PI.

Upon receipt of all the above documents, the Trial Manager (TM) will send written confirmation to the PI/lead Research Nurse detailing that the centre is now ready to recruit participants into the trial. This letter/email must be filed in each site's Site File. Along with the written confirmation, the site should receive anything relating to trial intervention and a trial pack holding all the documents required to recruit into the Trial.

Occasionally during the trial, amendments may be made to the trial documentation listed above. The CTR will issue the site with the latest version of the documents as soon as they become available. It is the responsibility of the CTR to ensure that they obtain local R&D approval for the new documents.

Site initiation will be by attendance at a teleconference meeting online.

8 Participant Selection

Participants are eligible for the trial if they meet all of the following inclusion criteria and none of the exclusion criteria. All queries about participant eligibility should be directed to the TM before randomisation/registration.

8.1 Inclusion Criteria

- People diagnosed with PD.
- Age 18 or older
- Able to provide consent to take part

8.2 Exclusion Criteria

Have already taken part, or are an active member in a SParky Samba group

9 Recruitment, Screening & Registration

9.1 Participant Identification

Participants will be identified in a range of secondary care provisions and movement clinics that cater for people diagnosed with PD, which include neurology and care of the elderly. Clinical staff (consultants, nurses and PD specialist nurses) will identify potential participants for recruitment alongside social media and advertising through local PD focussed organisations such as Parkinson's UK Cymru. Participants may also self-refer by contacting the trial team on the advertised e-mail address.

9.2 Screening Logs

A screening log of all ineligible and eligible but not consented and/or not approached individuals will be kept at each site so that any biases from differential recruitment can be detected. When at site, logs may contain identifiable information but this **must** be redacted prior to being sent to the CTR. The screening log should be sent to the SParky Samba Trial email every month (see section 16 for further detail on data monitoring/quality assurance).

9.3 Recruitment Rates

A total of 60 participants will be recruited at an expected rate of 6 per month (2 participants per site per month).

9.4 Informed Consent

The participant's informed consent must be obtained using the electronic trial Consent Form (eCF), which follows the PIS. The participant should be given sufficient time after the initial invitation to participate before being asked to sign the eCF. Informed consent must be obtained prior to the participant undergoing trial activities. Consent may be facilitated by trial trained healthcare research delivery workforce staff at the SParky Samba activated sites.

The REDCap e-consent module will be used for e-consent in Sparky Samba. A pdf copy of the consent form will be sent to the participant by email for their records.

Please note, only when informed consent has been obtained from the participant via REDCap and they have been registered into the trial can they be considered a trial participant.

The right of the participant to refuse to participate in the trial without giving reason must be respected. Similarly, the participant must remain free to withdraw at any time from the protocol intervention without giving reasons and without prejudicing his/her further treatment.

9.5 Registration & Randomisation

9.5.1 Registration

Participants will be added to the REDCap database to be able to complete their consent and their baseline assessments. When they have completed these assessments, they will then be randomised. Participants must be randomised within 2 weeks of their registration.

9.5.2 Randomisation

Participants will be randomised to the intervention or activity as usual in a 1:1 ratio, stratified by disease burden (Hoen and Yahr stage). The randomisation system will be designed, tested and

implemented via a REDCap database hosted by the CTR. Dummy randomisations will be completed via the database to ensure that the groups balance ahead of live randomisations. Full details of the randomisation procedure will be specified in a separate randomisation plan.

10 Withdrawal & Lost to Follow-up

10.1 Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the trial at any time. The participants care will not be affected at any time by declining to participate or withdrawing from the trial.

If a participant initially consents but subsequently withdraws from the trial, clear distinction must be made as to what aspect of the trial the participant is withdrawing from including:

- Withdrawal from intervention
- Partial withdrawal from further data collection (e.g. questionnaires, clinical assessments, process evaluation)
- Complete withdrawal from further data collection

Participants will not be able to request deletion of any of the data that they have provided which links with any of the trial outcomes. However, if they have provided any personally identifiable data (e.g. name, email address) then as part of the withdrawal process, they can request that the CTR delete this type of information that they hold from their databases.

The withdrawal of participant consent shall not affect the trial activities already carried out and the use of data collected prior to participant withdrawal. The use of the data collected prior to withdrawal of consent is based on informed consent before its withdrawal.

In all instances participants who consent and subsequently withdraw should complete a withdrawal form (see Withdrawal Form in trial pack) or the withdrawal form should be completed on the participant's behalf by the researcher/PI based on information provided by the participant. This withdrawal form should be sent to the SParky Samba Trial email and any queries relating to potential withdrawal of a participant should be forwarded to the SParky Samba Trial email.

10.2 Lost to follow up

Participants who are absent for more than 3 consecutive weeks from intervention sessions will be contacted by the research team to provide assistance or determine of a participant wants to withdraw. If participants are uncontactable after three attempts (three each phone call and/or email) and they continue to be absent from the intervention sessions no further action will be taken. They will not be regarded as lot to follow up until they fail to complete the 12 week follow up assessment (see below).

Participants not completing follow-up assessments on-line, or who do not attend clinic for follow-up assessments will be contacted by the research team in an attempt to ensure follow-up is completed, this may include providing telephone support to complete patient reported outcomes. If the person does not respond after three contact attempts (three each phone call and/or email), then they will be regarded as lost to follow-up.

11 Trial Intervention

11.1 SParky Samba Intervention

SParky Samba is a samba-based rhythm/ drumming intervention delivered within the community for people with PD. The setting is determined by local availability of facilities, which are chosen by SParky Samba leaders based on their geographic location and accessibility for group members.

The group is facilitated by either a local Samba musician, or a regular member of the group who has been trained by the musician to deliver SParky Samba sessions. The group size is usually around 8-15 participants but there is no minimum or maximum number of participants required for any given session.

In their first session participants will be offered a choice of instrument that is suitable for their range of motion. This could range across tamborims, Snare drums (Caixa), Agogo bells, Surdos, Ganzás / Chocalho (shakers), Cuíca, Timbal, Pandeiro, and the Repinique.

During each session, participants will be instructed to follow a sequence of rhythms, as guided by the facilitator. Each rhythm is broken down into smaller sections with sub-groups (grouped by instrument) concentrating on their own section before coming together. The band leader often carries a Repinique, as well as using Apitos (whistle) to signal breaks to participants.

Each session will last approximately 60 minutes with time either side for the set-up and break down of instruments and seating.

Participants will be asked to attend as many sessions as possible, ideally weekly over a period of 12 weeks following randomisation. Participants will be encouraged to attend at least 6 consecutive sessions and a minimum of 8 in total (completion of 8 sessions in total will be regarded as adherent to the intervention). The costs of participant travel to attend Sparky Samba sessions will be reimbursed. Alternatively, travel arrangements will be made upfront on behalf of the participant if they prefer.

The PPI Group have been involved in the co-production of patient facing materials and the intervention definition through a series of stakeholder workshops that have informed phase 2 of the trial. The trial team will continue to work with the PPI Group throughout the trial in co-production of documents for publication and an Intervention Manual.

11.2 Intervention Comparator

Participants randomised to the activity as usual control group will be asked to continue with their normal activities and attend any social or support groups they would normally attend over the 12 weeks. Following completion of the 12-week follow-up assessment they will be offered the opportunity to join their local SParky Samba group.

11.3 Adherence

Participants will be emailed a link to the REDCap database each week following the session to complete a self-report attendance checklist.

Group facilitators will also be asked to complete a checklist following each session during the recruitment and intervention delivery period.

12 Trial Procedures

Recruitment and follow-up:

Participants will be identified at clinical sites or via social networks/ word of mouth and eligible participants will be approached and provided with trial information prior to giving informed consent. Participants will be assessed at baseline and at 12 weeks post randomisation following intervention delivery. The intervention delivery period will commence at randomisation (to occur within 2 weeks of baseline assessment) and will last for a period of 12 weeks. With the addition of the process evaluation (see below), participants are expected to be in the trial for no longer than 16 weeks.

Data collection/assessments and blinding

Outcome data will be collected through a combination of patient reported measures completed directly within the database and in person assessments conducted by research staff at site. If a participant choses, they will be able to complete the patient reported outcomes on paper copies if they prefer (see data management section 16.2). participants may be supported with on-line or paper completion at the hospital research visit by the trial research staff, or at home by one of the core trial team members via telephone. Due to the nature of the intervention and the pragmatic design of the trial, researchers collecting assessment data will not be blind to the allocation of participants. In an effort to reduce bias of rating the UPDRS, this assessment will be videoed by the assessor at site and rated independently by an expert blinded to allocation. The measures included in SParky Samba do not form part of routine care, although PD specific measures such as UPDRS and Hoen and Yahr may be used by clinicians ad-hoc as part of their routine assessment of participants at clinic appointments.

Intervention (and intervention comparator) adherence data will be provided through participant self-report and self-report from SParky Samba group facilitators.

Process Evaluation:

The process evaluation will utilise qualitative data (semi-structured interviews with intervention staff) and quantitative data (structured reflections by members of the research team delivering the intervention and a purpose developed fidelity questionnaire as well as data on completed visits) to assess fidelity (whether the intervention has been delivered as intended and as a measure of quality assurance), and the key mechanisms of change. Participants and their support partners will be asked to complete a structured questionnaire that focusses on their views of the trial and of the intervention. We will also attempt to contact any participants who drop out of the intervention to ascertain reasons for discontinuing. A more detailed protocol for the process evaluation will be maintained separately in Document 'SParky Samba Feasibility RCT Process Evaluation'.

12.1 Assessments

Table 2. SParky Samba Outcome Assessments

Construct	Measure	Time to complete	Time points
Motor	**UPDRS III:** We will use section III of the Unified Parkinsons Disease Rating Scale to assess global motor function in participants	15 min	Baseline and 12 weeks
	Freezing of Gait questionnaire (FOG): this is a patient self report measure designed to assess the severity of gait freeing in people with PD.	5 min	Baseline and 12 weeks
	Dresden Falls Questionnaire– this is a patient report questionnaire designed to assess the risk and severity of falls, a common symptom in people with PD.	5 min	Baseline and 12 weeks
	MiniBEST Test in this assessment participants are assessed across dynamic balance, functional ability and gait.	15 minutes	Baseline and 12 weeks
	Physical Activity in the Elderly (PASE) questionnaire this questionnaire is designed to capture the level of physical activity across a range of usual activities over the past 7 days.	5 min	Baseline and 12 weeks
Cognitive	**Montreal Cognitive Assessment (MoCA)** – we will use the truncated on-line version of the MoCA, known as Expresso, to assess cognitive function in participants. This is well validated for assessing cognitive function in people with PD	6 minutes	Baseline and 12 weeks
Quality of Life	**Parkinson's Disease Quality of Life Questionnaire [8 items] – PDQ-8;** This is a self-completion participant reported outcome designed to address aspects of functioning and well-being for those affected by Parkinson's disease. The PDQ-8 asks one question from each of the domains of the longer PDQ-39; activities of daily living, attention and working memory, communication, depression, quality of life and social relationships.	5 minutes	Baseline and 12 weeks
Self Efficacy	**Oxford Participant and Activities Questionnaire (OxPaq)–** this is a validated self-report questionnaire designed to assess the degree of activity and participation of those with chronic conditions taking part in community based interventions	5 minutes	Baseline and 12 weeks
	The Lorig Self Efficacy (scale will be utilised to measure self-efficacy related to exercise (exercise sub-scale only)	5 minutes	Baseline and 12 weeks

Figure 3. Schedule of enrolment, interventions and assessments

Procedures	Visits (insert visit numbers as appropriate)

	Baseline Visit (week 0)		**Intervention Delivery (Day 0 – Day 84)**	**Follow Up Visit (week 12 ± 5 days)**	
	At home (Day -3; ± 2 days)	**At hospital (Day 0)**		**At home (Day 85 ±5 days)**	**At hospital Day 88 ±2 days)**
Informed consent	x				
Demographics	x				
Medications		x			
Hoen and Yahr staging		x			
Randomisation		x			
Delivery of intervention			x		
Intervention Adherence			x	x	
UPDRS		x			x
FoG	x			x	
MiniBEST		x			x
DREFAQ	x			x	
MoCA [Espresso]		x			x
PDQ-8	x			x	
OxPAQ	x			x	
Lorig	x			x	
PASE	x			x	
Adverse event assessments			x	x	x

Process Evaluation questionnaire				x	

12.2 Follow-up

No follow up of patients after their 12-week assessment will take place.

The follow-up period will be 12 weeks in line with completion of the primary endpoint. There will be a four week window beyond this timepoint to allow for the completion of measures relating to the process evaluation.

13 Safety Reporting

The PI is responsible for ensuring that all site staff involved in this trial are familiar with the content of this section.

All Serious Adverse Events (SAEs) that meet requirements of an SAE must be reported immediately (and within 24 hours of knowledge of the event) by the PI at the participating site to the CTR Trial team unless the SAE is specified as not requiring immediate reporting (see section 13.2).

13.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant or clinical trial participant administered an intervention which are not necessarily caused by or related to that product
Serious Adverse Event (SAE)	Any adverse event that - • Results in death • Is life-threatening* • Required hospitalisation or prolongation of existing hospitalisation** • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly or birth defect

	• Other medically important condition***
Serious Adverse Reactions (SARs)	Any SAE occurring in a clinical trial participant for which there is a reasonable possibility that it is related to the intervention.
Suspected Unexpected Serious Adverse Reactions (SUSARs)	A SAR, the nature and severity of which is not consistent with the Reference Safety Information (RSI) for the intervention.

***Note:** The term 'life-threatening' in the definition of serious refers to an event in which the trial participant was at risk of death at the time of the event or it is suspected that used or continued used of the product would result in the subjects death; it does not refer to an event which hypothetically might have caused death if it were more severe.

**** Note:** Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.

***** Note:** other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

13.2 Trial Specific SAE Reporting Requirements

For this low risk trial there will be no additional SAE reporting requirements to those detailed above. However, all falls, regardless of severity should be reported as an expected adverse event. Falls should be reported within 7 days of the event using the specific form on the REDCap database, but noting that the event does not constitute a serious event.

These should be completed in the participant's notes and on the relevant CRF pages and forwarded to the CTR in the normal timeframes for CRFs.

Participants should be encouraged to email the trial team if they experience any adverse events to the trial email address listed below and this will be recorded by the trial team.

13.3 Causality

Causal relationship will be assessed for the intervention and procedures:

Intervention: SParky Samba intervention

The PI (or another delegated medically qualified doctor from the trial team) will assess each SAE to determine the causal relationship and the Chief Investigator (CI) (or another appropriately qualified member of the Trial Management Group (TMG)) can also provide this assessment where necessary:

Relationship	**Description**	**Reasonable possibility that the SAE may have been caused by the intervention?**
Unrelated	There is no evidence of any causal relationship with the intervention	No
Unlikely	There is little evidence to suggest there is a causal relationship with the intervention (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).	No
Possible	There is some evidence to suggest a causal relationship with the intervention (e.g. because the event occurs within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).	Yes
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	Yes
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	Yes

The causality assessment given by the PI (or delegate) cannot be downgraded by the CI (or delegate), and in the case of disagreement both opinions will be provided.

13.4 Expectedness

The CI (or another delegated appropriately qualified individual) will assess each SAE to perform the assessment of expectedness.

SAEs which add significant information on specificity or severity of a known, already documented adverse event constitute unexpected events. For example, an event more specific or more severe than that described in the protocol is considered unexpected. All AE and SAE reporting relating to falls should be reported as expected unless the person reporting judges that the specific incident is an unforeseen consequence of participating in the intervention.

13.5 Reporting Procedures

13.5.1 Participating Site Responsibilities

The PI (or delegated appropriately qualified doctor from the trial team) should sign and date the SAE CRF to acknowledge that he/she has performed the seriousness and causality assessments. Investigators should also report SAEs to their own health boards or trust in accordance with local practice.

A completed SAE form for all events requiring immediate reporting should be submitted via email to the CTR within 24 hours of knowledge of the event. A separate form must be used to report each event, irrespective of whether or not the events had the same date of onset.

The participant will be identified only by trial number, age at time of adverse event or partial date of birth (mm/yy) and initials. The participant's name should not be used on any correspondence.

It is also required that sites respond to and clarify any queries raised on any reported SAEs and report any additional information as and when it becomes available through to the resolution of the event. Additionally, the CTR may request additional information relating to any SAEs and the site should provide as much information as is available to them in order to resolve these queries.

Serious Adverse Event (SAE) email address:

SparkySamba@Cardiff.ac.uk

Serious adverse events should be reported from time of signature of informed consent, throughout the intervention delivery period up to, and including the outcome assessment visit at 12 weeks.

An SAE form is not considered as complete unless the following details are provided:

- Full participant trial number
- An Adverse Event
- A completed assessment of the seriousness, and causality as performed by the PI (or another appropriately medically qualified doctor registered on the delegation log).

If any of these details are missing, the site will be contacted and the information must be provided by the site to the CTR within 24 hours.

All other AEs should be reported on the CRF following the CRF procedure described in Section 16.

13.5.2 The CTR Responsibilities

Following the initial report, all SAEs should be followed up to resolution wherever possible, and further information may be requested by the CTR. For follow-up information, sites to update the initial copy of the SAE form and put a single line through the old information and new information added.

The CTR should continue reporting SAEs until the participant has completed the 12 week follow-up assessment.

Once an SAE is received at the CTR, it will be evaluated by staff at the CTR and sent to the CI (or their delegate) for an assessment of expectedness.

Only reports of related and unexpected SAEs should be submitted to the REC. These should be sent within 15 days of the CI becoming aware of the event.

13.7 Urgent Safety Measures

An Urgent Safety Measure (USM) is an action that the Sponsor, Co-CIs or Site PI may carry out in order to protect the participants of a trial against any immediate hazard to their health or safety. Any USM relating to this trial must be notified to the REC immediately by telephone, and in any event within three days in writing, that such a measure has been taken. USMs reported to the CTR will be handled according to CTR processes.

14 Statistical Considerations

14.1 Randomisation

Participants will be randomised to the intervention or control in a 1:1 ratio, stratified by disease burden (Hoen and Yahr stage). Randomisation will be completed within study REDCap database. Full details of the randomisation procedure will be specified in a separate randomisation plan.

14.2 Blinding

Owing to the nature of the intervention under investigation, this study will remain unblinded.

14.3 Sample Size

As a feasibility study, this has not been powered to detect effects in clinical outcome measures. The recruitment target of 60 has been selected in line with guidance for sample sizes in feasibility studies for 30 participants per group (29). This sample size will allow estimation of recruitment, retention and adherence rates with a 95% binomial confidence interval of no more than plus or minus 13 percentage points irrespective of the point estimate.

14.4 Missing, Unused & Spurious Data

Details will be provided in the Statistical Analysis Plan (SAP).

14.5 Procedures for Reporting Deviation(s) from the Original SAP

These will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

14.6 Termination of the Trial

This is a low risk feasibility study thus no early stopping rules will be specified.

14.7 Inclusion in Analysis

All eligible participants will be included in the assessment of feasibility. All participants providing secondary outcome data will be included in those analyses.

15 Analysis

15.1 Main Analysis

Key demographic data will be summarised using descriptive statistics. For feasibility outcomes, recruitment will be assessed as the percentage of eligible people who provide consent to participate in the trial; retention as the percentage of participants recruited who complete the 12-week follow-up assessment; adherence as the percentage of recommended intervention or social control sessions completed. Feasibility criteria will be assessed according to a traffic light system with green (proceed to full effectiveness RCT) if all criteria listed in section 5.3 are in the green zone; amber (requiring adjustment before proceeding to full RCT) if all criteria are either in the amber or green zone; and red (do not progress to full RCT unless major changes are implemented) if at least one criterion is in the red zone. For secondary outcome measures we will calculate descriptive summaries such as mean and standard deviation, and 95% confidence intervals of participants' percentage changes from baseline to 12-week follow-up. This will provide estimates of effect size and variability of drumming-induced changes for use in power calculations for a future RCT.

15.1.1 Sub-group & Interim Analysis

Exploratory sub-group analyses may be specified in the SAP. No interim analyses are planned.

15.2 Process Evaluation Analysis

Semi-structured interviews will be audio-recorded, transcribed and analysed thematically. All quantitative data will be summarised using frequency based data.

16 Data Management

Source Data is defined as *"All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents."* There is only one set of source data at any time for any data element.

Source data will be the online versions of the Case Report Forms (CRFs) / Consent form. The preferred option of data collection will be that participants complete the Case Report forms on the REDCap database. However, we will provide paper copies of the CRF forms from the REDCap database to be completed if the participant wishes to complete via this method. Consent will be taken via the e-consent module on REDCap. This will return the consent form to the participant via email.

Access to the database for CTR and the sites will be via username and password and restricted to appropriately trained personnel only.

The database will be housed on local servers managed by Cardiff University staff in accordance with all appropriate legislation.

Identifiable data will be encrypted and stored separately from non-identifiable data. This data will only be made available to those who require it and as part of database testing we will ensure that this data cannot be exported.

Wherever possible, data will be validated at point of entry, thereby reducing the opportunity for missing or unexpected data. All changes made to the data following initial data entry will be recorded and visible via an audit log within the database.

The planning, development, testing and maintenance of the database will be performed in line with CTR SOPs, as will all aspects of the data management function. A data management plan will be developed to outline the details of how data will be collected, transferred stored and accessed by the team.

Trial data			*Source Data*					
	eCRF	*Participant medical notes*	*Screening Log*	*Withdrawal form*	*Electronic System*	*SAE form*	*Motor examination video*	*MS Teams or Audio Recording*
Consent					*x*			
Concurrent Medications		*x*						
Adverse events		*x*				*x*		
Feasibility outcomes	*x*		x	x	*x*			
Outcome Data	*x*							
Adherence Data					*x*			
UPDRS	*x*						*x*	
Process evaluation Questionnaire					*x*			
Process evaluation interview								*x*

16.1 Data Collection

Data will primarily be collected online; however, participants will have an option to complete the data collection with a member of the research team if they don't wish to independently complete it online. Participants will also be offered a phone or video call from a researcher to aid completion of data collection online.

16.2 Completion of Case Report Forms (CRFs)

16.2.1 Electronic CRFs

Participants will be asked to complete CRFS and questionnaire data using an online system. The system will be developed by the CTR and tested prior to going live. The participant can either complete these when at a session or they can be emailed directly to them to complete.

This is a secure encrypted system accessed by an institutional password and complies with the General Data Protection Regulation 2018.

https://redcap.ctr.cardiff.ac.uk/redcap/redcap_v13.7.5/

A user password will be supplied to site staff upon completion of all processes required prior to opening. There access will be restricted to just data collection forms that they need to view, enter and edit.

A detailed data management plan will be developed.

16.2.2 Paper CRFs

We recognise that some aprticipants may struggle to complete questionnaires directly on-line. In addition to the option of facilitatory support from research staff at site, we will also give aprticipants the option of completing PROMs on paper. They can do this as their research visit (aided by research staff if necessary) or at home. If paper versions of the PROMS are completed at site, data will be entered into the REDCap database by local research staff on the trial delegation log. If they request paper versions to be completed at home, these will be sent by CTR trial staff, complete with a stamped addressed envelope for returning completed CRFs to CTR.

17 Protocol/GCP Non-Compliance

The PI should report any non-compliance to the trial protocol or the conditions and principles of GCP to the CTR in writing as soon as they become aware of it.

18 End of Trial Definition

The end of the trial is defined as the date of final data capture to meet the trial endpoints. In this case end of trial is defined as when the last participant has completed their Follow-up interview for the process evaluation- typically by 16 weeks post randomisation.

Sponsor must notify the REC of the end of a clinical trial within 90 days of its completion or within 15 days if the trial is terminated early.

19 Archiving

The TMF and TSF containing essential documents will be archived at an approved external storage facility for a minimum of 15 years. The CTR will archive the TMF and TSFs on behalf of the Sponsor. The Principal Investigator is responsible for archival of the ISF at site on approval from Sponsor. Essential documents pertaining to the trial shall not be destroyed without permission from the Sponsor.

20 Regulatory Considerations

20.1 Ethical &Governance Approval

This protocol has approval from a Research Ethics Committee (REC) that is legally "recognised" by the UK Ethics Committee Authority for review and approval.

This trial protocol has been submitted through the relevant permission system for global governance review in Wales as the lead nation for the trial to the Health Regulatory Authority (HRA).

Approval will be obtained from the host care organisation who will consider local governance requirements and site feasibility. The Research Governance approval of the host care organisation must be obtained before recruitment of participants within that host care organisation.

Participants will not be offered any incentives to join the trial, however all travel costs will be covered for them to attend assessment and intervention sessions.

20.2 Data Protection

The CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016.

This includes collection of postcode, telephone number and email address to enable contact of participants for follow up and assessment of geographic spread of participants.

20.3 Indemnity

- Non-negligent harm: This trial is an academic, investigator-led and designed trial, coordinated by the CTR. The CI, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a clinical trial and they cannot offer any indemnity. The Association of the British Pharmaceutical Industry (ABPI) guidelines will not apply.
- Negligent harm: Where studies are carried out in a hospital, the hospital continues to have a duty of care to a participant being treated within the hospital, whether or not the participant is participating in this trial. Cardiff University does not accept liability for any breach in the other hospital's duty of care, or any negligence on the part of employees of hospitals. This applies whether the hospital is an NHS Trust or not. The Sponsor shall indemnify the site against claims arising from the negligent acts and/or omissions of the Sponsor or its employees in connection with the Clinical Trial (including the design of the Protocol to the extent that the Protocol was designed solely by the Sponsor and the Site has adhered to the approved version of the Protocol) save to the extent that any such claim is the result of negligence on the part of the Site or its employees.

All participants will be recruited at NHS sites and therefore the NHS indemnity scheme/NHS professional indemnity will apply with respect to claims arising from harm to participants at site management organisations.

20.4 Trial Sponsorship

Cardiff University will act as Sponsor for trial and the CTR are responsible for coordination of the trial. Delegated responsibilities will be assigned to staff members at the sites taking part in this trial.

20.5 Funding

The trial has been awarded funding from the Jacques and Gloria Gossweiler Foundation as part of their Research Grants in the field of Neurology. The trial team will report regular updates to the funder including an end of trial report.

21 Trial Management

21.1 Trial Management Group (TMG)

The TMG is responsible for management of the trial from different perspectives required provided by members (trialists, qualitative researchers, clinicians, research partners). TMG meetings will occur monthly to discuss ongoing aspects of the trial. TMG members will be required to sign up to the remit and conditions as set out in the TMG Charter.

21.2 Trial Steering Committee (TSC)

TSC members will be required to sign up to the remit and conditions as set out in the TSC Charter. The TSC will meet at the beginning of the trial opening, mid way through recruitment and close to the trial closing. The TSC will be given a full report of updated trial activities, milestones and observations prior to the TSC meetings which will be used to provide guidance to the TMG for the ongoing nature of the trial.

22 Quality Control & Assurance

22.1 Monitoring

The trial risk assessment has been used to determine the intensity and focus of monitoring activity in the SParky Samba trial. Low monitoring levels will be employed and are fully documented in the trial monitoring plan.

Investigators should agree to allow trial related monitoring, including audits and regulatory inspections, by providing direct access to source data/documents if required. Participant consent for this will be obtained.

Findings generated from monitoring at TMG and TSC meetings will be shared with the Sponsor, CI, PI and local R&D offices.

22.2 Audits & Inspections

The trial is participant to inspection by HRA as the regulatory body. The trial may also be participant to inspection and audit by Cardiff University Joint Research Office under their remit as Sponsor.

24 Publication Policy

All publications and presentations relating to the trial will be authorised by the TMG and the funders will be informed. A record of all publications including presentations and conference abstracts will be kept in a central location and made available to the trial team.

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