ISRCTN11861663 https://doi.org/10.1186/ISRCTN11861663

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

Submission date
22/04/2025

Recruitment status
Recruiting

Registration date
20/06/2025

Overall study status
Ongoing

Last Edited
20/06/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Parkinson's disease (PD) affects parts of the brain that control movement, thinking, mood, and sleep. Over time, symptoms can get worse and affect a person's independence and quality of life. While treatments can help manage symptoms, there is currently no cure or proven way to slow the disease down. People with PD have said they want more support for movement and other symptoms. Research shows that physical activity and music with a steady beat can help. SParky Samba is a fun, community-based samba drumming activity created by and for people with PD. Early feedback suggests it may help with movement, health, and wellbeing. This study will test whether it's possible to run a larger trial in the future by first checking how well this smaller trial works.

Who can participate?
Anyone with a diagnosis of Parkinson's disease who has never taken part in a SParky Samba group before.

What does the study involve?
If you take part, you'll be randomly placed into one of two groups:
One group will join a local SParky Samba session once a week for 12 weeks.
The other group will continue with their usual activities for 12 weeks.

Before and after the 12 weeks, all participants will complete tests to measure movement, thinking, and wellbeing. These include both in-person assessments and questionnaires that can be done at home.

What are the possible benefits and risks of participating?
Taking part may help improve movement, mood, and overall wellbeing. It's also a chance to try a new, enjoyable group activity. There are no major risks, but as with any physical activity, there may be mild tiredness or discomfort. You'll be supported throughout the study.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
June 2024 to May 2026.

Who is funding the study?
Jacques and Gloria Gossweiler Foundation (Switzerland)

Who is the main contact?
SparkySamba@cardiff.ac.uk

Study website
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/sparky-samba

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
349733

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 67853

Study information

Scientific Title
Evaluating the feasibility of a samba percussion intervention for people with Parkinson’s disease

Acronym

SParky Samba

Study objectives
It is possible to conduct an RCT of the SParky Samba intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/04/2025, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 1224558458; gram.nosres@nhs.scot), ref: 25/NS/0037

Study design
Randomized; Interventional; Design type: Treatment, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
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 Parkinson’s disease (PD) will be randomised 1:1 to either the intervention or control group.

Participants will be recruited from a combination of specialist movement disorder clinics, the PD specialist nurse network, social media advertising, and local PD-focused organisations such as Parkinson’s UK Cymru.

Interested participants will be provided with the Participant Information Sheet and consent materials, which they can complete online at home or during their initial study visit.

Participants will be asked to attend their local hospital for a baseline assessment lasting approximately one hour. This will include:

A videoed motor assessment for evaluating the Unified Parkinson's Disease Rating Scale (UPDRS) Part III
The miniBEST test
The truncated online version of the Montreal Cognitive Assessment, known as Expresso
Participants will also complete several patient-reported outcome measures at baseline, including:

Freezing of Gait Questionnaire
Dresden Falls Questionnaire
Parkinson's Disease Quality of Life Questionnaire (PDQ-8)
Lorig Self-Efficacy Scale
Oxford Participation and Activities Questionnaire
Physical Activity Scale for the Elderly
These questionnaires can be completed online at home or during the baseline hospital visit and are expected to take no more than 45 minutes. Participants may receive support from a researcher either in person or via telephone.

Following completion of baseline measures, participants will be randomised to either the SParky Samba intervention or the activity-as-usual control group.

Participants in the SParky Samba group will attend weekly sessions (approximately one hour each) for 12 weeks. The intervention will be delivered at three community sites in Wales: Cardiff, Llandudno, and Fishguard.

Participants in the activity-as-usual group will continue their usual activities for the same 12-week period.

After the 12-week intervention period, all participants will complete follow-up assessments, which will mirror the baseline assessments. These will include both in-person assessments and patient-reported outcomes, which can be completed at home.

Following the completion of follow-up assessments, participants in the activity-as-usual group will be supported to attend their local SParky Samba group.

Finally, arrangements will be made for the process evaluation phase of the study. This will consist of brief semi-structured interviews and a short questionnaire focusing on participants' views of the trial and their experiences with the intervention or usual activities.

Intervention Type
Behavioural

Primary outcome measure
Primary feasibility outcomes:
1. Recruitment (measured by total no. participants recruited and No. approached willing to participate [number consented/ number approached])
2. Retention (No of participants completing primary end point)
3. Intervention adherence (% Participants adherent to the intervention)
4. Data completeness (% Participants completing at least 90% of available baseline measures and % Participants completing at least 90% of follow up measures)

Secondary outcome measures

Assessed at baseline and 12 week follow up:
1. Unified Parkinson’s Disease Rating Scale (UPDRS)
2. Freezing of Gait (FOG) Questionnaire
3. Dresden Fall Questionnaire (DREFAQ)
4. MiniBEST Test
5. Montreal Cognitive Assessment (MoCA) – short form [Espresso]
6. Parkinson’s Disease Questionnaire-8 (PDQ-8)
7. Oxford Participation and Activities Questionnaire (OxPAQ)
8. Lorig Self-Efficacy Scale
9. Physical Activity Scale for the Elderly (PASE)

Overall study start date
01/06/2024

Completion date
30/05/2026

Eligibility

Key inclusion criteria
Inclusion criteria have been made deliberately broad to make the trial as inclusive as possible. These are:
1. People diagnosed with Parkinson's disease
2. Aged 18 years or older
3. Able to provide consent to take part

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
Exclusion criteria have also been limited so as not to exclude people who may want to take part from doing so. The only exclusion criterion the researchers stipulate is:
1. Has already taken part in a SParky Samba group

Date of first enrolment
01/05/2025

Date of final enrolment
27/02/2026

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Centre for Trials Research - Cardiff University
7th Floor Neuadd Meirionnydd
Cardiff
United Kingdom
CF14 4YS

Study participating centre
Hywel Dda University Lhb
Corporate Offices, Ystwyth Building
Hafan Derwen
St Davids Park, Jobswell Road
Carmarthen
United Kingdom
SA31 3BB

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
Betsi Cadwaladr University Lhb
Executive Offices, Ysbyty Gwynedd
Penrhosgarnedd
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Sponsor information

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Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Jacques und Gloria Gossweiler-Stiftung

Alternative Name(s)
Jacques and Gloria Gossweiler Foundation, Fondation Jacques und Gloria Gossweiler, Jacques & Gloria Gossweiler Foundation, Jacques und Gloria Gossweiler Stiftung, JGGF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/05/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available on reasonable request. Requests can be made via CTR@cardiff.ac.uk, please see https://www.cardiff.ac.uk/centre-for-trials-research/collaborate-with-us/data-requests for details on how to apply. All requests will be assessed individually for compliance with original participant consent and data anonymisation in accordance with CTR standard operating procedure.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	20/03/2025	13/05/2025	No	No