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**PARTICIPANT INFORMATION SHEET**

**PD-Ballet: Effectiveness of ballet dancing on motor and non-motor symptoms of Parkinson’s disease: a hybrid type 2 effectiveness-implementation trial**

We would like to invite you to take part in this research project, being conducted to investigate the effects of arts intervention and specifically ballet training on the symptoms of Parkinson’s. This trial is being conducted at King’s College Hospital. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and ask if anything is unclear or if you would like more information.

**Aims of the research**

Physical activity is increasingly advocated as an additional intervention for People with Parkinson’s (PwP). Recent literature shows that exercise-based interventions have a positive impact on physical capacities and functional capacities and quality of life for PwP. Studies in the last 10 years have shown some forms of dance to be beneficial for mobility, balance, and psychosocial health in Parkinson’s.

English National Ballet has been running *Dance for Parkinson’s* programme for the most part of the past decade, proving it very popular and attractive to PwP. However, to date, no studies have explored the effectiveness of the programme clinically and in a systematic way.

This is a world first, largest study utilising dance as an intervention for Parkinson’s. We will aim to explore both the short-term and the long-term effects of dance training on the motor and non-motor symptoms, quality of life and brain function in people with Parkinson’s.

**Why we are asking for your help**

It is of great importance to understand what kind of clinical effect exercise such as ballet has on your body. The outcome of this study will help us understand which symptoms specifically can be addressed by this additional therapy and whether it is effective at improving the quality of life for PwP. We will also investigate whether this form of an additional therapy is deliverable within the NHS clinical care pathways and to what extent it can be used for clinical management of Parkinson’s. In addition, we will look at whether any changes to your symptoms or quality of life, introduced by the ballet training, have an effect on your spouse or carer.

Also, we will be able to investigate what changes take place immediately after the intervention and in the long term. To date, no other evidence exists on the way ballet training affects Parkinson’s symptomatology and therefore it is essential that we start investigating this topic, as the importance of exercise in Parkinson’s is still largely under recognised.

**Why have I been asked?**

We are approaching all people with Parkinson’s who attend our outpatient clinics.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and we will ask you to sign the informed consent form at the end of this document. You are free to withdraw your participation at any time and without giving a reason. A decision to withdraw at any time will not affect your standard clinical care.

**What will happen to me if I take part?**

You will be given this information sheet at your routine appointment and you will be free to contact the study researcher who can answer any further questions that you may have about this study.

This study involves three visits to the Clinical Research Facility (CRF) at King’s College Hospital in South-East London, Denmark Hill campus: one before you start your intervention, one just after you finish and one 3 to 6 months after completing the intervention. We will give you full information to make sure you can easily find us. If you are unable to travel to the CRF, you will be presented with the option for the visits to be conducted digitally.

At the first study visit, we will determine your eligibility for this study. We will ask you questions about your medical health and history. Once deemed eligible, at the baseline (pre-intervention) visit, you will have a range of clinical assessments, much like the ones you would routinely complete as part of your Parkinson’s follow up. Each session should take no longer than 90 minutes.

You will return to see the study researcher at the end of the intervention to undergo the same set of assessments. You will also be asked to return once more at 3 to 6 months after you finish the intervention to undergo another set of assessments. Some of the assessments can be completed online by yourself. If you wish to use this option, the study team will provide you with a link for the completion of the assessments.

The active intervention (ballet training) will be conducted either at the local dance studio in London or remotely via a secure online platform, with one session per week, for 12 sessions over 13 weeks (you will have a one-week break after Week 6). The study team will inform you of the exact dates and times for each session. Each ballet session will last for approximately 60 minutes, with a “Tea and Biscuits” time the end of the session. The sessions will be led by English National Ballet dancers who are experts at delivering this programme. Your carer is welcome to attend the sessions with you. There is no need for you to have any previous knowledge of this form of exercising, as the dance leaders will ensure that you will be comfortable following all the moves. You do not need any special clothes or footwear; just make sure you are wearing something comfortable that you are able to move freely in.

*How will the remote sessions be conducted?*

Prior to declaring your eligibility, the Study Team will ask that you complete a risk assessment and will connect with you digitally to assess the space in which you plan to carry out the dancing. Once the risk is assessed and you are allocated to one of the two study conditions, the Study team will inform you how to connect to the weekly sessions. You will need a working computer/laptop/tablet with internet connection, a camera and a microphone.

**Are travel expenses reimbursed?**

We value you as a potential participant, however we are unable to offer any reimbursement. Travel expenses both to the dance studio and King’s College Hospital CRF cannot be reimbursed. In the event where the dance sessions are delivered wholly digitally, the only travel expenses incurred would be from travelling for assessments at three time points to King’s College Hospital. If you cannot afford such travel, or are unable to do so for any reason (e.g. COVID-19), please inform the study team so that they can make arrangements for the assessments to be conducted digitally (via an online platform).

**What does it mean that the study is randomised?**

The study is called “randomised” because the participants will be randomly divided into two groups: some will be doing the ballet training, and some will be “monitored”, which means that they will not have to attend the dance sessions. The allocation to both groups is random and done by a computer so that there are no researcher bias. If you are allocated to the “monitoring” group, you will be offered to attend the social “Tea and Biscuits” sessions taking place after the ballet dancing sessions. You will also receive an invitation to take part in a set of 12 sessions at the end of the study, so you will not be missing out on the ballet sessions; it may just take longer before you get to do them.

**What will I have to do?**

If you decide to take part in this study, your eligibility will be determined by the study team who will perform a number of assessments. You will then be asked to do the following:

* You must be willing and able to attend scheduled assessment visits described above.
* You must also be able to attend the ballet training sessions and keep track of any sessions that you may miss.
* The researcher will ask you to wear an objective wearable sensor called Parkinson KinetiGraph watch (PKG Watch) for 6 days around your assessment time so that we can get an idea of your motor symptoms (slowness or excessive movement) in an objective manner and in your natural setting as we know that sometimes your time with the clinicians is not fully representative of what your symptoms are like on a daily basis. Parkinson KinetiGraph is a clinically validated tool, which looks like a smart watch. It is worn on a wrist of your most affected side for six days (day and night) and returned for analysis. The PKG watch is also water-resistant so you can wear it in the shower or whilst having a bath. Should you have any troubles with it, you will be given a number to contact for technical support. If at any point you will find wearing it uncomfortable, you can stop and let the Study Team know.

It is also important that you tell our clinical staff about any other medication you are taking before and during the study. You will be asked to take a pregnancy test if you are of childbearing age.

**What are the risks for you of taking part in this study?**

*Risks associated with the study procedures*

All study assessments are being used routinely in studies looking at the symptoms of Parkinson’s disease and none of them are invasive. If, at any point, you feel that the study assessments are too bothersome, you can inform the study team. You are free to withdraw your participation at any point.

*Risks associated with ballet dancing sessions*

English National Ballet’s delivery team is experienced delivering dance for people living with Parkinson’s and will take all necessary care to ensure your safety in the sessions. There is a small risk associated with the movements performed during the sessions, especially related to balance. The sessions will be tailored to your motor capacities and although we will make sure any potential risks are minimal, we will be asking that you take the class at your own pace with due care and if you need assistance, staff [we will have artists, staff and volunteers] will be there to help.

**What are the possible benefits of taking part?**

The study will inform the current knowledge on the effects of ballet-based interventions in Parkinson’s Disease and your taking part may be of benefit to the parkinsonian symptoms that you are experiencing.

**Will my taking part in the study be kept confidential?**

Yes, all personal information about you is regarded as strictly confidential; all the information about you including your samples (personal data) will be coded; you will not be identifiable in any research outcomes or publications.

By signing this form, you consent to the Research Team, the Sponsor (King’s College London and King’s College Hospital NHS Foundation Trust), regulatory authorities and Ethics Committee collecting and processing your personal data, including the following: your date of birth, your sex, your race or ethnic origin, personal data on your physical or mental health or condition and any other personal data obtained during your participation in the study or as a result of any follow-up assessments.

Also, we would like your permission to tell your GP that you are taking part in the study. You may still take part in the study, if you do not wish us to contact your GP.

**What will happen to the results of the research study?**

It is expected that the results of the study will be published in medical journals after the study has been completed but you will not be identified in any report or publication. The results will also be discussed in patient group meetings, international meetings on Parkinson’s. You will be able to request a copy of the results from the Study Team.

**What happens if I become incapacitated during the study?**

If you become incapacitated during the study, you must inform the study team and your further eligibility will be re-assessed. We will keep the information you have already provided, and it will be used in the results of the study.

**Who is organising and funding the research?**

This study is supported and funded by the Wellcome Trust.

**Who has looked at the research?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Wales 7 Research Ethics Committee.

**How we will use your data?**

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

This information will include your name, address, date of birth and any relevant medical history. People will use this information to do the research or to check your records to make sure that the research is being done properly.

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

We will keep all information about you safe and secure. Some of your information will be sent to the Global Kinetics Corporation, who will be responsible for arranging delivery of the wearable sensor (PKG watch) that you will be asked to wear as part of the study. They must follow our rules about keeping your information safe.

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.

*What are your choices about how your information is used?*

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
* Where can you find out more about how your information is used?

You can find out more about how we use your information:

* on the Health Research Authority website www.hra.nhs.uk/information-about-patients/
* in a leaflet called: HowWeWillUseYourData KCH V1 (21-11-19) – available from the study team
* at our website https://www.kch.nhs.uk/about/corporate/data-protection
* by emailing our Data Protection Officer on kch-tr.dpo@nhs.net

**Thank you**

Thank you for considering taking part and taking the time to read this information sheet.

If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.

**Contact for Further Information/Queries/Complaints**

Should you want further information about the study or if you have any queries, concerns or complaints please contact:

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| Professor K Ray Chaudhuri Neurology Department King’s College HospitalTel: 0203 299 8336 Email: ray.chaudhuri@nhs.net aleksandra.podlewska@nhs.net**Direct number to the study team: 0203 299 7189** | King’s Patient Advice and Liaison Service (PALS)Hambleden Wing, King’s College Hospital Tel: 020 3299 3601Email: kch-tr.pals@nhs.net(Service is available 09:00 -17:00 Monday to Friday) |

If you decide to take part in this study, you will be given a copy of this information sheet and a signed consent form to keep.

Thank you for taking the time to read this information sheet.

****Participant Initials:
Participant Identification Number:

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 **INFORMED CONSENT FORM**

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|  | Please initial |
| 1. I confirm that I have read the Participant Information Sheet dated 01MAR2022 (version 4.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
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| 1. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. The information that I have provided during the study, including all samples, could still be used as described in the information sheet for the study.
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| 1. I understand that relevant sections of my medical notes and data collected during the study may be looked at by running the study or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
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| 1. I agree that my anonymised personal data, including data relating to my physical or mental health or condition, and race or ethnic origin, may be transferred and used as described in the information sheet for the study.
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| 1. I agree to my General Practitioner being informed of my participation in the study. I agree to my General Practitioner being involved in the study, including any necessary exchange of information about me between my GP and the research team.
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| 1. I agree to be contacted in the future by the researchers involved who would like to invite me to participate in follow up projects of a similar nature.
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| 1. I understand that my consent form showing my name and signature will be sent to the Sponsor for archiving on completion of the study. (This will be kept in a NHS secure site)
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| 1. I agree to provide the study team with telephone number and email address for them to provide me with the necessary study material, including links to online platforms through which study-related activities might be performed.
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| 1. I agree to take part in this study.
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| 1. I would like to be informed of the results of the study. *Please circle* YES NO
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Name of Participant Date Signature

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Name of Researcher Date Signature