SUPPLEMENTAL MATERIAL FILES

Supplemental material 1. Copy of participant consent form.
IRAS ID: 333484

Participant Identification Number for this trial:

CONSENT FORM

Title of Project: 'The use of the CUE1+ device in people with Parkinson's disease and related disorders.'

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet dated ……., Version……. for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from Queen Mary University of London, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
5. I agree to my General Practitioner being informed of my participation in the study. ☐
6. I agree to my General Practitioner being involved in the study, including any necessary exchange of information about me between my General Practitioner and the research team. ☐
7. I understand that my data will be securely stored in Wolfson Institute of Population Health, Queen Mary University of London, Charterhouse Square Campus, Charterhouse Square, EC1M 6BQ, London and in accordance with the data protections guidelines of the Queen Mary University of London for 25 years in pseudonymised form. ☐
8. I understand that the information held and maintained by the research team at Queen Mary University of London may be used to help contact me or provide information about my health status. ☐

Azoidou V, *et al. BMJ Open* 2025; 15:e096051. doi: 10.1136/bmjopen-2024-096051

9. I understand that I can access the information I have provided and request destruction of that information at any time prior to open-source publication. I understand that following open-source publication, I will not be able to request withdrawal of the information I have provided. ☐

10. I understand that the researchers will not identify me in any publications and other study outputs using personal information obtained from this study. ☐

11. I understand I will have to wear a wrist band watch named Parkinson's KinetiGraph (produced by Global Kinetics Pty Ltd) which will track my movement symptoms. ☐

12. I understand that the information I have submitted will be published as a report and I wish to receive a copy of it **(Optional).** ☐

13. I agree to be contacted in the future by the Queen Mary University of London researchers would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature or others including human tissue samples, imaging investigations, and/or video recordings **(Optional).** ☐

14. I agree to be video recorded by the researchers during movement assessments (optional). ☐

15. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person seeking consent	Date	Signature

Supplemental material 2. Information to participants on using their device.

10 STEPS ON USING YOUR CUE1+ DEVICE
Step 1: Unbox Your CUE1+ Device Inside the box, you will find: The CUE1+ device A charging dock Adhesive patches An instruction manual A USB charging cable
Step 2: Charge Your CUE1+ Before Using Plug the small end of the USB cable into the charging dock and the large end into a USB port. Place the CUE1+ device onto the dock, making sure the gold contacts align with the pins on the dock. While charging, the light-ring will turn amber. Once fully charged, the light will turn green. Charge the device completely before your first use.
Step 3: Turn On Your CUE1+ Press the large central button once to turn the device on. Press the button again to turn it off. In this study, we are testing which setting of the CUE1+ works best. So, one group will use the device with vibrations, and the other group will use it without vibrations. We cannot choose which group you will be in for the next three months, but do not worry—once the trial is over, everyone will get a chance to try all the settings of the CUE1+. For now, when you turn on the device, it may or may not vibrate. If it does vibrate, it means the device is active. If it does not vibrate, a blue light will briefly flash to show the

device is on. Just remember, whether the device vibrates or shows a blue light depends on which group you are in, but both mean the device is working.
Step 4: Check If Your Device Is Working If you are in the study group that your CUE1+ vibrates, you will feel it when it is turned on. If you are in the study group that your CUE1+ does not vibrate, you will see a blue light briefly when pressing the button. To turn off the device, in either group, press the button again. If it vibrates, it will stop vibrating. If it does not vibrate, the blue light will flash again briefly to show it is off.
Step 5: Contact for Questions or Problems **For general questions about appointments, tracking symptoms, or completing questionnaires,** email Dr. Viktoria Azoidou at v.azoidou@qmul.ac.uk. **For questions about your CUE1+ vibration or settings,** email Dr. Cristina Simonet at c.simonet@qmul.ac.uk. Please **DO NOT** contact Dr. Azoidou about the vibration or settings, as she needs to remain unaware of which group you have been allocated to during the study.
Step 6: Wearing the Adhesive Patch Clean and dry the middle of your chest (your sternum). Peel the backing from the adhesive patch and place it on your chest. Press it firmly to ensure it sticks properly. The adhesive patch will last around 14 days, but if it irritates your skin, remove it immediately. If you have issues with the adhesive, contact Dr. Azoidou at v.azoidou@qmul.ac.uk
Step 7: Removing the Device

Gently hold the adhesive in place while pulling the device off your chest. The adhesive will stay attached to your skin.
Step 8: Getting More Adhesive Patches If you only have one adhesive patch left and your next appointment is not soon, email Dr. Azoidou at v.azoidou@qmul.ac.uk to request more patches.
Step 9: Using the Device Daily Use the CUE1+ device every day for 8 hours, no matter in which study group you are, starting in the morning with your first Parkinson's medication dose. Charge the device overnight so it is ready for use the next day. Dr. Azoidou will tell you when to start using it, which is typically one week after your baseline assessment.
Step 10: Questions About Your Device Settings **If you have concerns about the settings or vibration,** contact Dr. Cristina Simonet at c.simonet@qmul.ac.uk. **Please DO NOT discuss vibration or settings with Dr. Azoidou**, as she should remain unaware of this throughout the study.
Thank You for Participating! We appreciate your involvement in the CUE1+ study! If you need any help, feel free to reach out, and we will support you throughout the process.

Supplemental material 3. Participant clinical diary.

Participant's diary

This study will last about 3 months, or around 13 weeks, for each participant. You will receive a copy of this questionnaire at weeks 0 and 13 during the assessment sessions. We kindly ask that you fill it out each time. If you do not wish to complete it during the assessment sessions, you can complete it on your own or with the help of a caregiver, family member, friend, doctor, or nurse—whatever works best for you, at home, in your own time.

The diary helps us understand how your Parkinson's symptoms including incidence of **'near' falls** and **falls** change throughout the study. It also helps us see how you respond to and how safe it is to use the CUE1+ device and adhesive patches during the study. Filling out the diary should take about 20 minutes. Please return the completed diary to the research team.

In this questionnaire, a fall is defined as an event which results in you unintentionally coming to rest on the ground or other lower-level A **'near' fall** is referred to a situation where a person almost loses their balance and is at risk of falling but manages to catch themselves before actually hitting the ground. It's like a stumble or a close call, where they might wobble or trip but avoid a full fall. These incidents are common in people with Parkinson's due to issues with balance, muscle stiffness, or freezing of gait. **Balance problem** or otherwise known as **postural instability** refers to the inability to stay balanced, whether you are standing still or moving.

Participant's ID:

Date:

Time:

Who completed the questionnaire for you?

I completed the questionnaire myself	☐
Someone else completed the questionnaire for me	☐

Section 1: How severe?

Please rate how bad your symptoms are, on average, using a scale from 0 to 4. A 0 means you do not have the symptom at all, and a 4 means the symptom is very severe.

1. Tremor:

0-absent	1-mild	2-moderate	3-severe	4-very severe
☐	☐	☐	☐	☐

2. Stiffness and rigidity:

0-absent	1-mild	2-moderate	3-severe	4-very severe
☐	☐	☐	☐	☐

3. Slowness of movement:

0-absent	1-mild	2-moderate	3-severe	4-very severe
☐	☐	☐	☐	☐

4. Freezing such as during walking or turning:

0-absent	1-mild	2-moderate	3-severe	4-very severe
☐	☐	☐	☐	☐

5. Postural unsteadiness:

0-absent	1-mild	2-moderate	3-severe	4-very severe
☐	☐	☐	☐	☐

6. Random, spontaneous movements (also known as dyskinesia) that happen without your will:

0-absent	1-mild	2-moderate	3-severe	4-very severe
☐	☐	☐	☐	☐

7. Light-headedness upon standing:

0-absent	1-mild	2-moderate	3-severe	4-very severe
☐	☐	☐	☐	☐

8. Dizziness with head or body movements:

0-absent	1-mild	2-moderate	3-severe	4-very severe
☐	☐	☐	☐	☐

Section 2: How frequent?

Please rate how often you experience the following on a scale of 0 to 4, where 0 means you never experience it and 4 means you experience it almost all the time.

1. Dizziness with head or body movements:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

2. Sleep difficulties:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

3. Mood swings:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

4. Anxiety, feeling tense:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

5. Depression, feeling low:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

6. Light-headedness upon standing:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

7. Pain:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

8. Fatigue, feeling tired:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

9. Leg weakness:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

10. Hand grip weakness of the most affected hand:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

11. Cognitive difficulties such as memory, attention, concentration, calculation problems:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

12. 'Near' falls:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

13. 'Falls':

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

14. Injuries occurring from 'near' falls:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

15. Injuries occurring from falls:

0-not at all	1-monthly	2-weekly	3-daily	4-all the time
☐	☐	☐	☐	☐

Section 3. 'Near' falls and falls.

This section is about any times you almost fell or fell, and how these experiences affected you in the **last three months.**

Questions on 'near' falls:

1. In the **last three months**, how many times can you recall experiencing a '**near' fall**?

Total number of 'near' falls	**----------**
☐ I did not experience a 'near' fall.	**Please skip the questions 2-9 below and proceed to questions related to falls**

2. In the last three months, where did you almost fall? Please check below if it happened indoors or outdoors. Also, write down how many times you nearly fell in each place.

Environment

Environment	(please tick the box)	Total number of 'near' falls
Indoor	☐	----------
Outdoor	☐	----------

3. In the last three months, please let us know about up to five times when you almost fell inside. For each one, tell us where it happened.

☐ **I did not experience an indoor 'near' fall.**	**Please proceed to question 5**

Indoor environment-'Near' fall	1	2	3	4	5
Bedroom	☐	☐	☐	☐	☐
Kitchen	☐	☐	☐	☐	☐
Bathroom/ toilet / shower	☐	☐	☐	☐	☐
Living /dining room	☐	☐	☐	☐	☐
Corridor/ hall / doorway	☐	☐	☐	☐	☐
Garage	☐	☐	☐	☐	☐
Stairs inside the house	☐	☐	☐	☐	☐
Someone's else home	☐	☐	☐	☐	☐
Other indoor environment (e.g., restaurant, shopping centre, train station etc)	☐	☐	☐	☐	☐
Events (e.g., theatre, cinema, conference etc)					
I cannot remember	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

If other, please indicate here	----------

4. In the last three months, can you tell us what indoor activity you were doing during your last five times when you almost fell?

Indoor activity-'Near' fall	1	2	3	4	5
Turning over in bed	☐	☐	☐	☐	☐
Dressing/ washing myself	☐	☐	☐	☐	☐
Getting out or in bed	☐	☐	☐	☐	☐
Sitting or standing from a chair/ sofa/toilet	☐	☐	☐	☐	☐
Getting out of or in the shower/ car	☐	☐	☐	☐	☐
Climbing stairs/ using escalators	☐	☐	☐	☐	☐
Carrying/ lifting objects	☐	☐	☐	☐	☐
Reaching out	☐	☐	☐	☐	☐

Turning around	☐	☐	☐	☐	☐
Walk through a narrow door/ corridor/ lift	☐	☐	☐	☐	☐
Pulling/ pushing objects	☐	☐	☐	☐	☐
Exercising/ dancing / rushing/ running	☐	☐	☐	☐	☐
I cannot remember	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

If other, please indicate here ----------

5. In the last three months, please tell us about up to five times when you almost fell while outside. For each time, describe where it happened.

☐ I did not experience an outdoor 'near' fall. **Please proceed to question 7**

Outdoor environment	**1**	**2**	**3**	**4**	**5**
Outdoor stairs/ escalators	☐	☐	☐	☐	☐
Garden/ yard	☐	☐	☐	☐	☐
Park/ countryside/ mountain/ beach/ farm	☐	☐	☐	☐	☐
Pavement / road/ footpath	☐	☐	☐	☐	☐
At traffic lights	☐	☐	☐	☐	☐
Public transport (e.g., train, bus, boat etc)	☐	☐	☐	☐	☐
Parking area	☐	☐	☐	☐	☐
Concert / play/ exhibition / live event	☐	☐	☐	☐	☐
Public areas such as sport courts, fields	☐	☐	☐	☐	☐
I cannot remember	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

If other, please indicate here ----------

6. In the last three months, please list up to five times when you almost fell outdoors. For each time, tell us what you were doing at the time.

Outdoor activity	**1**	**2**	**3**	**4**	**5**
Gardening/ cleaning road or yard	☐	☐	☐	☐	☐
Exercising/ dancing/ running/ cycling etc	☐	☐	☐	☐	☐
Putting out rubbish/ bins	☐	☐	☐	☐	☐
Turning/ looking over my shoulder	☐	☐	☐	☐	☐
Walking and carrying/ lifting objects	☐	☐	☐	☐	☐

Standing or getting off/on public transport	☐	☐	☐	☐	☐
Climbing outdoor stairs/ escalators	☐	☐	☐	☐	☐
I was pushed/ pulled in public	☐	☐	☐	☐	☐
Crossing the road at traffic lights	☐	☐	☐	☐	☐
Rushing to reach (e.g., someone/ bus etc)	☐	☐	☐	☐	☐
Talking to someone/ replying on the phone	☐	☐	☐	☐	☐
I cannot remember	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

If other, please indicate here **----------**

7. In the last three months, have you had any close calls where you almost fell, either indoors or outdoors? If so, did any of these close calls lead to you getting hurt, like bruises, strains, cuts, or anything similar?

☐ **Yes**	☐ **No (Please proceed to question 9)**

8. In the last three months, how many times have you almost fallen and ended up getting injured? Please check whether these injuries happened indoors or outdoors and tell us the total number of times you were injured from a **'near'** fall.

Environment	**Environment (please tick the box)**	**Total number of 'near' falls**
Indoor	☐	----------
Outdoor	☐	----------

9. Think about all the times you almost fell in the last three months, whether it was indoors or outdoors and whether you got hurt or not. On a scale from 0 to 10 (where 0 means it didn't impact you at all and 10 means it had the biggest impact possible), how would you rate the overall effect these **'near'** falls had on you? Please tick the box that best represents your score.

Impact on your	**How much?**										
Balance confidence	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Independence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Activities of daily living	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ability to socialise	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Overall quality of life	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fear of falling	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Being embarrassed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Feeling frustrated	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Mood (e.g., feeling low)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Questions on falls:

1. In the **last three months**, how many times can you recall experiencing a **fall**?

Total number of falls	**----------**
☐ I did not experience a fall	**Please skip the questions 2-9 in this section and proceed to questions in Section 4**

2. In the past three months, where have you had falls? Please check if they happened indoors or outdoors. Also, let us know how many falls you had in each type of environment.

Environment	**Environment (please tick the box)**	**Total number of falls**
Indoor	☐	----------
Outdoor	☐	----------

3. In the past three months, for up to five falls you've had indoors, can you tell me where each of these falls happened?

☐ I did not experience a fall in an indoor environment	**Please proceed to question 5**

Indoor environment	**Fall 1**	**Fall 2**	**Fall 3**	**Fall 4**	**Fall 5**
Bedroom	☐	☐	☐	☐	☐
Kitchen	☐	☐	☐	☐	☐
Bathroom/ toilet / shower	☐	☐	☐	☐	☐
Living /dining room	☐	☐	☐	☐	☐
Corridor/ hall / doorway	☐	☐	☐	☐	☐
Garage	☐	☐	☐	☐	☐
Stairs inside the house	☐	☐	☐	☐	☐
Someone's else home	☐	☐	☐	☐	☐
Other indoor environment (e.g., restaurant, shopping centre, train station etc)	☐	☐	☐	☐	☐
Events (e.g., theatre, cinema, conference etc)					

I cannot remember	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

If other, please indicate here ----------

4. In the past three months, can you tell me what you were doing indoors during your last five falls?

Indoor activity	**Fall 1**	**Fall 2**	**Fall 3**	**Fall 4**	**Fall 5**
Turning over in bed	☐	☐	☐	☐	☐
Dressing/ washing myself	☐	☐	☐	☐	☐
Getting out or in bed	☐	☐	☐	☐	☐
Sitting or standing from a chair/ sofa/toilet	☐	☐	☐	☐	☐
Getting out of or in the shower/ car	☐	☐	☐	☐	☐
Climbing stairs/ using escalators	☐	☐	☐	☐	☐
Carrying/ lifting objects	☐	☐	☐	☐	☐
Reaching out	☐	☐	☐	☐	☐
Turning around	☐	☐	☐	☐	☐
Walk through a narrow door/ corridor/ lift	☐	☐	☐	☐	☐
Pulling/ pushing objects	☐	☐	☐	☐	☐
Exercising/ dancing / rushing/ running	☐	☐	☐	☐	☐
I cannot remember	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

If other, please indicate here ----------

5. In the past three months, for each of your most recent five falls that happened outside, please tell us where each fall took place.

☐ **I did not experience a fall in an outdoor environment** **Please proceed to question 7**

Outdoor environment	**Fall 1**	**Fall 2**	**Fall 3**	**Fall 4**	**Fall 5**
Outdoor stairs/ escalators	☐	☐	☐	☐	☐
Garden/ yard	☐	☐	☐	☐	☐
Park/ countryside/ mountain/ beach/ farm	☐	☐	☐	☐	☐
Pavement / road/ footpath	☐	☐	☐	☐	☐
At traffic lights	☐	☐	☐	☐	☐
Public transport (e.g., train, bus, boat etc)	☐	☐	☐	☐	☐
Parking area	☐	☐	☐	☐	☐

Concert / play/ exhibition / live event	☐	☐	☐	☐	☐
Public areas such as sport courts, fields	☐	☐	☐	☐	☐
I cannot remember	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

If other, please indicate here ----------

6. In the last three months, please tell us what you were doing outside when you fell. You can mention up to five different times when this happened.

Outdoor activity	**Fall 1**	**Fall 2**	**Fall 3**	**Fall 4**	**Fall 5**
Gardening/ cleaning road or yard	☐	☐	☐	☐	☐
Exercising/ dancing/ running/ cycling etc	☐	☐	☐	☐	☐
Putting out rubbish/ bins	☐	☐	☐	☐	☐
Turning/ looking over my shoulder	☐	☐	☐	☐	☐
Walking and carrying/ lifting objects	☐	☐	☐	☐	☐
Standing or getting off/on public transport	☐	☐	☐	☐	☐
Climbing outdoor stairs/ escalators	☐	☐	☐	☐	☐
I was pushed/ pulled in public	☐	☐	☐	☐	☐
Crossing the road at traffic lights	☐	☐	☐	☐	☐
Rushing to reach (e.g., someone/ bus etc)	☐	☐	☐	☐	☐
Talking to someone/ replying on the phone	☐	☐	☐	☐	☐
I cannot remember	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

If other, please indicate here ----------

7. In the last three months, have any of the times you have fallen, whether indoors or outdoors, caused you to get hurt (like bruises, strains, cuts, etc.)?

☐ **Yes**	☐ **No (Please proceed to question 9)**

8. In the past three months, how many of the falls you've had have caused an injury? Please check if the fall happened inside or outside and write down the total number of falls that caused injuries.

Environment	**Environment (please tick the box)**	**Total number of falls**
Indoor	☐	----------
Outdoor	☐	

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9. Think about all the falls you have had in the last three months, whether they were inside or outside, and whether or not they caused injuries. On a scale from 0 to 10, where 0 means the falls had no impact at all and 10 means they had the biggest impact possible, please mark how much of an impact the falls had on you.

Impact on your	**How much?**										
Balance confidence	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Independence	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Activities of daily living	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ability to socialise	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Overall quality of life	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fear of falling	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Being embarrassed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Feeling frustrated	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Mood (e.g., feeling low)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Section 4. Questions on your experience with the CUE1 device (only complete in the end of the trial)

The questions below are on **your experience with using the CUE1+ device** over the **past three months**. Please answer the questions below only if you used the CUE1+ device during the study.

1. How many hours a day have you been using the CUE1+ over the past three months?

	Not at all	1 - 3 hours	4 - 6 hours			7 - 9 hours	10 - 12 hours	12 + hours
.	☐	☐	☐			☐	☐	☐

2. Could you turn the CUE1+ on and off?

	Yes	No
.	☐	☐

3. On average, how many hours a day did you need to charge your CUE1+ to use it over the last three months?

	Not at all	1 - 3 hours	4 - 6 hours			7 - 9 hours	10 - 12 hours	12 + hours
.	☐	☐	☐			☐	☐	☐

4. Did you have any issues with your CUE1+ device in the past three months?

	Yes	No
.	☐	☐

If you did have issues, please describe what happened here.

---

5. Did you have any skin irritation, redness, itchiness, or sensitivity from the adhesive patch in the past three months?

	Yes	No
.	☐	☐

If you did experience any issues, please describe what happened and rate the severity on a scale from 0 to 10, where 0 means not at all severe and 10 means extremely severe.

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

6. Did you have any problems with attaching or removing the adhesive patch in the past three months?

	Yes	No
.	☐	☐

If you did have problems, please describe what happened.

---

7. Did you have any side effects while using the CUE1+ device in the past three months?

	Yes	No
.	☐	☐

If yes, what side effects did you experience? Please also rate the severity from 0 to 10, where 0 means not at all severe and 10 means extremely severe.

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

8. Overall, how comfortable was the CUE1+ to use in the past three months?

	not at all	slightly	moderately	very	extremely
.	☐	☐	☐	☐	☐

If you found it not comfortable or only slightly comfortable, please provide more details below.

---

9. On average, how comfortable was it to listen to or feel the vibrations from the CUE1+ in the past three months?

	not at all	slightly	moderately	very	extremely
.	☐	☐	☐	☐	☐

If you found it not comfortable or only slightly comfortable, please provide more details below.

---

10. On average, how comfortable was the adhesive patches to use in the past three months?

	not at all	slightly	moderately	very	extremely
.	☐	☐	☐	☐	☐

If you found them not comfortable or only slightly comfortable, please provide more details below.

---

11. On average, how easy was it to use the CUE1+ device in the past three months? Please think about how long it took to charge the device, how easy it was to apply and remove it from your body, if the device felt stable when you were using it, and whether you could apply or remove it on your own or needed help from others.

	not at all	slightly	moderately	very	extremely
.	☐	☐	☐	☐	☐

If you found it not easy or only slightly easy, please provide more details below.

---

12. On average, how easy was it for you to apply the adhesive patch on your skin in the past three months? Please think about how long it took and whether you could do it by yourself or needed help from others.

	not at all	slightly	moderately	very	extremely
.	☐	☐	☐	☐	☐

If you found it not easy or only slightly easy, please provide more details below.

---

13. On average, how easy was it for you to remove the adhesive patch from your skin? Please think about how long it took and whether you could do it by yourself or needed help from others.

	not at all	slightly	moderately	very	extremely
.	☐	☐	☐	☐	☐

If you found it not easy or only slightly easy, please provide more details below.

---

14. Did you notice any symptoms that improved in the last three months because of using the CUE1+ device? Please list up to THREE SYMPTOMS that you think have improved (if any) and rate the improvement from 0 to 10, where 0 means no improvement at all and 10 means extreme improvement or that the symptom is completely gone.

a).....

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

b).....

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

c).....

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

15. Is there any activity in your daily life that was easier to do in the last three months because of using the CUE1+ device? Please list up to THREE ACTIVITIES and rate each one from 0 to 10, where 0 means it was not easy at all and 10 means it was extremely easy or had no problems performing the activity.

a).....

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

b).....

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

c).....

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

16. Is there any activity in your daily life that you usually rely on others for but were able to do independently (partially or completely) in the last three months because of using the CUE1+ device? Please list up to THREE ACTIVITIES and rate your level of independence for each one from 0 to 10, where 0 means not independent at all and 10 means fully independent (doing the activity without help)

a).....

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

b).....

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

c).....

	0	1	2	3	4	5	6	7	8	9	10

.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

17. On average, how severe was your fear of falling during the hours you used the CUE1+ device in the last three months?

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

18. On average, how severe was your fear of falling during the hours when you were not using the CUE1+ device in the last three months?

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

19. Overall, how much do you think that your symptoms can improve with the CUE1+ intervention?

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

20. On average, how much do you think your symptoms have been improving with the CUE1+ intervention?

	0	1	2	3	4	5	6	7	8	9	10
.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Thank you for completing the participant diary every three months. If you have any questions or concerns about using your CUE1+ device or the adhesive at any time, please feel free to contact Dr. Viktoria Azoidou at v.azoidou@qmul.ac.uk.

Supplemental material 4. Description of motor and non-motor outcomes.

Outcome	Outcome subcategories	Description	Scoring	Reference
Movement Disorder Society sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS)	Part I	Evaluates non-motor experiences of daily living through 13 questions, divided into Part IA (investigator-assessed) and Part IB (patient self-administered but	Each MDS-UPDRS item is rated on a scale from 0 (normal) to 4 (severe), reflecting the impact of PD symptoms, with higher scores indicating greater	Goetz et al.[16]

		reviewable by the rater).	severity. Part I: Non-Motor Experiences of Daily Living Score Range: 0-52 Part II: Motor Experiences of Daily Living Score Range: 0-52 Part III: Motor Examination Score Range: 0-108 Part IV: Motor Complications Score Range: 0-28	
	Part II	Addresses motor experiences of daily living with 13 self-administered questions, reviewable by the rater.		
	Part III	Involves a motor examination with 33 scores based on 18 questions, completed by the rater following specific instruction.		
	Part IV	Covers motor complications with 6 questions, integrating patient information and rater observations.		
Functional Gait Assessment (FGA)	Not applicable	A 10-item test evaluating complex gait tasks like walking with head turns, walking and turning and climbing stairs.	It scores between 0 and 3 per item, with a maximum of 30 points, where higher scores indicate better performance.	Wrisley et al.[17]
Timed Up and Go (TUG) test	Not applicable	Assesses mobility, balance, walking ability, and fall risks.	The mean time in patients with Parkinson's has been reported between 10.3-14.8 seconds.	Podsiadho et al.[18]

Bradykinesia Akinesia Incoordination test (BRAIN) tap test	(a) Kinesia score, (KS) (b) Akinesia time (AT) (c) Incoordination score (IS)	Assesses upper limb motor function and has been validated in patients with Parkinson's and controls. Participants use the index finger of a single hand to alternately strike the 'S' and ';' keys on a standard computer keyboard, as fast and accurately as possible. The test is repeated for the other hand.	Kinetic parameters: (a) KS: the number of key taps in 30 seconds (s)- higher scores indicate better performance. (b) AT: the mean dwell time on each key in milliseconds (ms). (c) IS: the variance of the time interval in milliseconds between keystrokes. For AT, and IS lower scores indicate better performance.	Giovannoni et al.[20] Noyce et al.[21] Hasan et al.[22]
Digital Finger Tapping (DFT) test	(a) Kinesia score, (KS) (b) Akinesia time (AT) (c) Incoordination score (IS)	The DFT test consists of a 20-second single key tapping test. Participants are instructed to repeatedly tap the down arrow key with their left index finger, as fast as possible for 20 s, whilst simultaneously depressing the left arrow key with their left middle finger. The same task is then repeated for the right hand. These instructions stabilise the wrist and forearm, isolating movement to the index finger metacarpal joint, thereby giving a true measurement of distal finger movement. This movement is also similar to the MDS-	Kinetic parameters: (a) KS: is a measure of speed (number of keystrokes typed in 20 seconds- higher scores indicate better performance. (b) AT: is a measure of akinesia (average dwell time (ms) that keys are depressed), and (c) IS: measures the rhythm (variance (ms2) of travelling time between keystrokes). For AT, and IS lower scores indicate better	Akram et al.[23]

		UPDRS finger tapping task where patients are asked to tap their index finger and thumb repeatedly.	performance.	
(Data points from Parkinson's KinetiGraph): Median bradykinesia score (BKS) Median dyskinesia score (DKS) Fluctuation dyskinesia score (FDS) The percent (%) with tremor (PTT) % Time immobile (PTI) Steps (average per day) % Time in sleep Uninterrupted sleep duration (median in minutes) % Sleep quality	n/a	The PKG system includes a wrist-worn data logger, algorithms that generate data every two minutes, and graphs and scores to present the data in a clinically useful format. The logger, a 35g smartwatch, is worn on the most affected wrist. It features a rechargeable battery, a 3-axis iMEMS accelerometer (ADXL345), and records 11-bit digital acceleration (±4g) at 50 samples per second, with data stored on flash memory.	a) Median BKS: 50th percentile is considered for scoring. Mild BKS is considered > 25 AND < 39.3 while severe BKS >39.3 AND <80. b) Median DKS: 50th percentile is considered for scoring. Mild DKS is considered > 9 AND <47.2 while severe DKS >47.2 No dyskinesia or bradykinesia is present when scores are <9 for DKS AND <25 for BKS. c) FDS: This is based on the scores of DKS and BKS as above. Target interpretation is between 7.5 - 13.0. d) % PTT: Percent time per day spent with tremor. No Tremor 0 - 0.5% Inconclusive 0.6% - 1% Tremor present > 1%. e) % PTI: The percent time the patient was immobile	Odin et al.[11] Khodarakami et al.[12]

			(2minute BKS > 80) during the recording from times between 11pm and 6am. Not clinically significant < 5%. Suggestive of excessive daytime sleepiness > 10%. f) Steps (average per day): Steps per day, averaged over the 7 days in the PKG session during 6am – 11pm each day. g) % Time in sleep: Sleep period determined by immobility (BKS > 80) in 14-minute intervals through night hours. h) Uninterrupted sleep duration: The median length of periods of sustained sleep between 11pm and 6am. Higher values represent longer median periods of sustained sleep. This score is based on being inactive (BKS 40-80). i) % Sleep	

			quality: An indication the quality of the patient's sleep during the recording times between 11pm and 6am. The percentage is calculated as the time spent very immobile (BKS > 110) relative to the time of immobility (BKS > 80). Higher values will represent percentage of time spent in higher stages of sleep (e.g., N3 or REM) during period of immobility (sleep).	
Activity-specific Balance Scale (ABC)	Not applicable	A 16-item questionnaire which assesses self-perceived balance confidence in daily activities.	Scores range from 0-100. Cut-off score of 69%. Are predictive of recurrent falls. (sensitivity: 93%, specificity: 69%)	Mak & Pang et al.[24]
Pittsburgh Sleep Quality Index (PSQI)	Not applicable	Includes seven component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medication, and daytime dysfunction.	Scores range from 0-21 with a higher total score indicating worse sleep quality. In distinguishing good and poor sleepers, a global PSQI score > 5 yields sensitivity of 89.6% and specificity of 86.5%.	Buysse et al.[25]
Hospital Anxiety and Depression Scale (HADS)	HADS-Anxiety component (HADS-A) HADS-Depression component (HADS-D)	Consists of 14 items, divided into two 7 item subscales: HADS-A: items reflect a state of generalised anxiety; HADS-D: focus on the concept of anhedonia.	The total score is out of 42, (21 per subscale). Higher scores indicate greater levels of anxiety or depression. The total HADS score may be regarded as a global	Roberts et al.[26]

			measure of psychological distress.	
Fatigue Severity Scale (FSS)	Not applicable	Is a 9-item scale which measures the severity of fatigue and its effect on a person's activities and lifestyle in patients with a variety of disorders, including those with Parkinson's diagnosis.	The items are scored on a 7-point scale with 1 = strongly disagree and 7= strongly agree. The minimum score = 9 and maximum score possible = 63. Higher the score = greater fatigue severity.	Hagell et al.[27]
Parkinson's Disease Questionnaire-39 (PDQ-39)	Mobility Activities of Daily Living (ADL) Emotional Wellbeing Stigma Social Support Cognition Communication Bodily Discomfort	A 39-item self-report questionnaire, which assesses how often patients with Parkinson's experience difficulties across the 8 quality of life dimensions and impact of PD on specific dimensions of functioning and well-being.	Dimension score is the sum of scores of each item in the dimension divided by the maximum possible score of all the items in the dimension, multiplied by 100. Lower scores reflect better quality of life.	Jenkinson et al.[28]

Supplemental material 5. Participant's satisfaction form.

Participant satisfaction form

Study title: 'Non-Invasive Device to Alleviate Symptoms in People Living with Parkinson's: Study Protocol for a Multi-Centre Phase II Double-Blind Randomised Controlled Trial.'

Now that you completed your intervention, we would like you to take a bit of time to answer a few questions. Your feedback is important to us as this will help to gain a better understanding of your experience with using your CUE1+ device in this trial. This form will take less than 5 minutes to complete.

Please select ONLY ONE option for each of the questions below.

	not at all	slightly	moderately	very	extremely
How helpful did you find the CUE1+ device in relation to your symptoms?	☐	☐	☐	☐	☐
How satisfied were you with using the CUE1+ device?	☐	☐	☐	☐	☐
If you get the option, how likely are you to continue using the CUE1+ device?	☐	☐	☐	☐	☐
How easy was it for you to use the CUE1+ device on the recommended body position (e.g., sternum)?	☐	☐	☐	☐	☐
How easy was it for you to use the adhesive patches provided with the CUE1+ device on the recommended body position (e.g., sternum)?	☐	☐	☐	☐	☐
How likely are you to recommend the CUE1+ device to other people with	☐	☐	☐	☐	☐

Parkinson's disease and/or related disorder who experience similar symptoms to yours?					

Thank you for completing the participant's satisfaction form.