ISRCTN59284050 https://doi.org/10.1186/ISRCTN59284050

A wearable device for people with Parkinson's disease to help with drooling and other symptoms of Parkinson's

Submission date
16/11/2021

Recruitment status
No longer recruiting

Registration date
04/05/2022

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Drooling is a common symptom of Parkinson's disease, experienced in up to 70% of people with Parkinson's (PwP). Drooling can be a major problem in PwP due to decreased automatic swallowing, particularly when people are multi-tasking and concentrating on other things such as watching television. When automatic swallows don't occur, saliva pools in the mouth leading to drooling which can be very embarrassing and restricts the social life of PwP. Current treatments decrease the production of saliva, which need to be repeated on a 3-monthly basis. Such treatments are problematic as saliva is essential for good oral health. Impaired reduction of loss of saliva through drooling exposes individuals to a range of negative health and psychosocial issues. NICE therefore recommend non-invasive treatment options such as behavioural cueing methods. A wearable wrist device using haptic (touch based) cueing was not only an effective treatment method to increase swallowing but also a socially acceptable solution for PwP. However, the device had limited functionality and was not suitable for all day use for example, participants were required to wear it for 1 hour per day and had to manually start/stop the cueing as needed; this made it less desirable as an everyday solution. Further work is needed in a larger sample size and to understand the real-world behaviours and usage of the intervention to understand the longer-term effects. We will deploy an application (App) on a smartwatch designed to work with a smartphone. The smartwatch is a discrete and comfortable wearing device that can be worn on the wrist – referred to as Cue Band. We will recruit 3000 PwP to wear the device throughout our 6-week evaluation. Participants will be asked to wear the device 24/7 during this time, giving us a greater understanding of the effectiveness and acceptability of the technology within real-world use. We will explore the application of CUE Band to deliver haptic cueing in an interventional study for 300 PwP experiencing drooling.

Who can participate?
Any person living with Parkinson's disease who self-identifies as having an issue with drooling.

What does the study involve?
Participants are being asked to take part in an eight-week cueing method intervention study. This will involve being asked to take part in two different methods that will provide cueing (a

vibration) for swallowing. Participants are being asked to wear a discrete and comfortable device that can be worn on the wrist, referred to as Cue Band and use a Smartphone app, only. We would like participants to take part in the cueing methods for 6-weeks, 24 hourly. To do so, they will be asked to download an Apps on their smartphone device that will allow them to access the software used for the cueing methods. Once downloaded, they will be randomly allocated to receive either the Cue Band method for cueing or the Smartphone method for Cueing. Participants will complete the first cueing method for the first 3-weeks, followed by a two-week wash out period where no intervention will be received, following this the participant will receive the alternative cueing method for the following 3-weeks. The Cue Band will be posted out to participants for free and will be theirs to keep.

Following the 8-week intervention, participants will be asked to stop using the cueing methods for a period of 3-weeks prior to further assessment. This part of the study is optional and participants can carry on using their preferred cueing method if they would prefer to.

Once participants have finished the intervention, they can set up their preferred prompting method for example, the Cue Band or Smartphone only, or they can disable and remove the mobile applications if they no longer wish to use them.

As part of the assessments, participants will be asked to complete questionnaires and maintain a daily diary. Some of the participants will be invited to take part in a semi-structured interview.

What are the possible benefits and risks of participating?
There are no perceived risks of participating, however, we envisage possible benefits of the study include the use of the device as a cueing method for swallowing.

Where is the study run from?
Northumbria University, Northumbria Healthcare NHS Foundation Trust and North Cumbria Integrated Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to January 2024

Who is funding the study?
Parkinson's UK

Who is the main contact?
Professor Richard Walker, Richard.Walker@nhct.nhs.uk

Study website
https://cue.band/

Contact information

Type(s)
Scientific

Contact name
Prof Richard Walker

ORCID ID

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305798

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 305798, CPMS 51528

Study information

Scientific Title
A wearable device for cueing for the management of drooling, and monitoring of symptoms, in people with Parkinson's disease

Acronym
Cue Band

Study objectives
Drooling is a common symptom of Parkinson's disease, experienced in up to 70% of people with Parkinson's (PwP). Drooling can be a major problem in PwP due to decreased automatic swallowing, particularly when people are multi-tasking and concentrating on other thing's such as watching television. When automatic swallows don't occur, saliva pools in the mouth leading to drooling which can be very embarrassing and restricts the social life of PwP. Current treatments decrease the production of saliva, which need to be repeated on a 3-monthly basis. Such treatments are problematic as saliva is essential for good oral health. Impaired reduction of loss of saliva through drooling exposes individuals to a range of negative health and psychosocial issues. NICE therefore recommend non-invasive treatment options such as behavioural cueing methods. A wearable wrist device using haptic cueing was not only an effective treatment method to increase swallowing but also a socially acceptable solution for PwP. However, the device had limited functionality and was not suitable for all day use for example, participants were required to wear it for 1 hour per day and had to manually start/stop the cueing as needed; this made it less desirable as an everyday solution. Further work is needed in a larger sample size and to understand the real-world behaviours and usage of the

intervention to understand the longer-term effects. We will deploy an application (App) on a smartwatch designed to work with a smartphone. The smartwatch is a discrete and comfortable wearing device that can be worn on the wrist – referred to as Cue Band. We will recruit 3000 PwP to wear the device throughout our 6-week evaluation. Participants will be asked to wear the device 24/7 during this time, giving us a greater understanding of the effectiveness and acceptability of the technology within real-world use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/01/2022, Newcastle North Tyneside 1 REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048139; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: none provided

Study design
Multicentre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format - to request a participant information sheet please contact lorelle.dismore@northumbria-healthcare.nhs.uk

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

Interventions
The first phase of the project involves developing 3000 wearable devices that will be published in a mobile app using iOS and Android. As part of this phase of the project, we have received ethical approval from Northumbria University to recruit 3000 participants. Participants will be recruited from Parkinson's UK and Special Interest Group on Parkinson's and Technology (SIGPAT) research networks and mailing lists. We will advertise the study through the networks as well as advertising through a project website. Participants will be required to register their interest in taking part in the research via the project website. Participants will self-identify as having difficulties with drooling and swallowing and will be required to own an iOS or Android smartphone device that supports the App in order to communicate with the wrist-worn device. During registration, participants will be provided with information about the research and they will agree to be contacted about the intervention study. Following registration, the researcher will send out instructions to download the app and will post a free Cue Band device that participants can keep and continue to use beyond the research study.

During the developmental phase, we will allocate 300 persons with Parkinson's disease (PwP) out of the 3000 into receiving the intervention. This will include Group A (150 PwP) and Group B (PwP). Group C will include the 2700 remaining participants. Group A and Group B will also include PwP under the care of the Parkinson's Team at Northumbria Healthcare NHS Foundation Trust (NHCFT) and North Cumbria Integrated Care Trust (NCIC). Patients attending a clinical appointment will be invited to take part in the intervention and will be randomly allocated to Group A or Group B. All participants included in the intervention phase will be asked to complete a screening questionnaire for presence of a drooling problem.

Group C (2700 participants) will only provide anonymous usage data including cueing schedule, physical activity and sleep behaviours, they will also have the option to provide feedback and suggestions through the mobile app.

Group A and Group B will take part in an eight-week cueing method intervention study and will be asked to complete informed consent. The participants in Group A and Group B will be consented into the study using a flexible approach to consent including consent obtained via the App, face-to-face, postal or witnessed consent.

Following consent and prior to the start of the intervention, participants will be asked to complete a two-week daily diary using the mobile App. They will be asked to report their drooling severity using a chart and other self-reporting.

The intervention involves the use of the Cue Band wearable device or the use of a smartphone only. Participants will be randomly allocated to the Cue Band device or use of the smartphone only. They will be asked to use the intervention allocated for a period of three weeks. After the three weeks, they will take part in a two-week wash out period. Following this participants will receive the alternative intervention for three weeks. Following the eight-week intervention, participants have the option to continue using the Cue Band device or smartphone or they will be asked to voluntarily opt into Groups D and E. Groups D and E will include a sub-sample of participants who agree to stop using the cueing methods for 3 weeks.

During the intervention (groups A and B), participants will be required to maintain a daily diary using the mobile App (6-weeks in total). This will include reporting on their swallowing severity, frequency and duration, as well as providing additional comments or reflections on their experiences prior to that date. For those participants who volunteer to discontinue using the cueing methods post-intervention, they will not be required to maintain a daily diary, however they will be asked to complete the questionnaires.

Following the intervention, participants will be asked to complete a questionnaire about their experiences and preferences regarding both interfaces (Cue Band wearable device or smartphone only). Participants will be allowed to retain the Cue Band wearable device beyond our evaluation; we will disable any data sharing with the research team. As part of the debrief phase, we will assist the participants in setting up their preferred prompting method (Cue Band wearable device or smartphone only), or disable and remove the mobile applications if they no longer wish to use them.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cue Band

Primary outcome measure
Drooling frequency and severity measured using the ROMP-Saliva scale at baseline (pre-intervention) and following the first cueing method and second cueing method.

Secondary outcome measures
1. Frequency, severity, and duration of drooling on the visual analogue scales, UPDRS 2.2 subset for saliva, NMSQ and PDQ-8 (measured daily in the app).
2. Acceptability of the device for use in day to day life (daily dairies and interviews).

Participants will be asked to maintain a daily diary using the tools provided through our mobile app. They will self-report on their swallowing severity, frequency and duration using visual analogue scales, placing a cross on a 100-millimetre (mm) line, (0 mm being no problem) and (100 mm being as bad as can be); as well as provide any additional comments or reflections on their experiences that day. Prior to receiving the interventions, participants will complete a two-week baseline during our on boarding phase, whereby they complete the daily diary (drooling severity chart) and self-reporting without any intervention.

Overall study start date
01/10/2021

Completion date
01/01/2024

Eligibility

Key inclusion criteria
1. PwP experiencing symptoms of oropharyngeal dysphagia or self-reporting as having difficulties with drooling and swallowing.
2. PwP that own an iOS or Android smartphone device (to support the research engagement). Their smartphone must support Bluetooth BLE 4.0+ to communicate with the band (relatively standard in smartphones for 4-5 years).
3. PwP willing and able to provide consent to participate.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3300

Key exclusion criteria

Participants with insufficient cognitive function and manual dexterity with/without assistance from carers.

Date of first enrolment
28/03/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare NHS Foundation Trust
Rake Lane
Tyne & Wear
United Kingdom
NE29 8NH

Study participating centre
North Cumbria Integrated Care NHS Foundation Trust
Newtown Rd
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
North Tyneside General Hospital
Rake Lane

North Shields
England
United Kingdom
NE29 8NH
+44 (0)191 293 4087
ResearchAndDevelopment@nhct.nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Charity

Funder Name
Parkinson's UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings will be presented at local and national conferences as well as peer reviewed journals.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/02/2023	02/10/2023	Yes	No