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# Drooling in Parkinson's disease: a case for divided attention

**Submission date**
17/12/2015

**Recruitment status**
No longer recruiting

**Registration date**
01/02/2016

**Overall study status**
Completed

**Last Edited**
24/05/2018

**Condition category**
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a chronic condition where nerve cells in a small part of the brain called the substantia nigra become damaged and die. The nerve cells in this region send signals that controls the muscles of the body. Dopamine is the main neurotransmitter (a chemical that sends signals from one nerve cell to the next) produced by these nerve cells. As more of these cells die, the amount of dopamine produced also falls. Over time, the lack of nerve cells and low levels of dopamine affects how well the person affected can control their muscles. The most common symptoms of the condition are slowness of movement, muscle stiffness and shaking (tremors). Studies have shown that many people with PD also experience drooling. This has a real impact on their quality of life. Drooling happens because PD makes it more difficult for people to swallow saliva properly. It happens most often when people are busy doing another task. Studies have looked at controlling saliva with medicine and retraining the swallow with prompt badges and watches. However, within every study there is a group of people who find that drooling continues despite these interventions (treatments). There are also people who only drool when they are concentrating on something else. Patients often state that treatments dry their mouths too much and they only drool at particular times. Furthermore, drooling appears to be very personal affecting each person differently. This study will look at whether drooling is affected by how much attention people with PD pay to managing their saliva. Does drooling in PD increase when attention is divided? This is important because understanding why drooling varies will help in developing more flexible treatments that can help manage a distressing and embarrassing symptom of PD. This study builds on research projects that have looked at why people with PD drool and how medicines and therapy helps. It aims to fill the gap in knowledge about why drooling is so variable because at present there seems to be a missing link.

Who can participate?
Adult patients with PD that have said that they have problems with drooling.

What does the study involve?
Participants are visited by a researcher at their home to help them understand the study and are given a week to decide whether they want to take part. If they give their consent to take part, they have an assessment to find out more about their drooling and also their memory, attention

and problem solving skills. They are then asked to complete the tasks for the study, which takes about an hour and a half. First of all, the researcher records the sounds of the participant swallowing using a swallow detection device for 30 minutes while sitting in a chair. The swallow detection device is a small microphone headset which is worn in the ear and is connected to a small recording device. Software in the recording device allows identification of swallowing sounds, which can then be counted and compared. After this, the participants are given a set of listening tasks to do. They have to make decisions about how whether words they see on a screen are related to a sentence they have just heard by pressing a button to say “yes” or “no”. Their swallowing is monitored using the swallow detection device throughout the test. Both steps of the task is videoed to make sure that the researchers capture everything that happens. At the end of the study, participants may be asked to attend a feedback session to tell them of the results and thank them for their participation.

What are the possible benefits and risks of participating?
The risks to participants should be low. There will be no physical risk to the patient, but they may develop problems concentrating and become tired during the experiment. Attempts will be made to prevent these with comfort breaks. While there will be no direct benefit to the subjects, if cognition and attention is a factor in drooling further larger studies will be needed, which may lead to the development of treatments for people who experience drooling.

Where is the study run from?
Northumbria Healthcare NHS Foundation Trust Parkinson's Disease Services and South Tyneside NHS Foundation Trust Speech and Language Therapy Service (UK)

When is the study starting and how long is it expected to run for?
October 2015 to August 2016

Who is funding the study?
Parkinson’s UK

Who is the main contact?
Ms Hannah Reynolds

# Contact information

### Type(s)
Scientific

### Contact name
Ms Hannah Reynolds

### Contact details
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
Protocol version 5

# Study information

### Scientific Title
Is drooling in Parkinson’s disease affected by divided attention? A cross-sectional study

### Study objectives
There will be a significant negative impact on the efficiency and frequency of saliva swallows and a consequent effect on severity of drooling in a dual task model involving a concurrent cognitively demanding task which requires divided attention.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Newcastle and North Tyneside 2, 25/09/2015, ref: 15/NE/0257

### Study design
Cross-sectional study

### Primary study design
Observational

### Secondary study design
Cross sectional study

### Study setting(s)
Hospital

### Study type(s)
Other

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

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

### Interventions

Baseline condition: 30 minute observation of saliva swallows at rest in a chair. To avoid unintentionally priming the client to monitor their saliva swallows no spoken reference to saliva swallowing will be made. They will be told the baseline phase is to observe them at rest using the microphone and video in preparation for the experiment.

Dual task condition: Design based on Brodsky 2007/12 which used a lexical decision task that had enough cognitive demand to impact on anticipatory stages of swallowing. The task designed for the current study requires participants to decide whether a word they see on screen could be associated or not with a sentence they just heard (e.g. they hear: He picked up the spade. The word they might see could be: garden; card; space). They then have to press a button for yes if related or a button for no if unrelated. The response item will be presented after 250 ms and for 3000 ms or until the person responds. There will be a 250ms interval before the next item is presented. This timing was chosen because it is shown to involve the attentional system in lexical decision making rather than a shorter interval which leads to automatic responses. Items are grouped in 4 blocks and take 30 minutes in total to complete.

### Intervention Type
Other

### Primary outcome measure
1. Frequency of saliva swallows, using a swallow detection device. This is a small microphone headset which is worn in the ear and is connected to a small recording device. Software in the recording device allows identification of swallowing sounds, which can then be counted and compared.
2. Observed drooling with and without cognitive load

All subjects will complete a 30 minute baseline assessment for drooling at rest and then then another 30 minute assessment whilst completing a series of cognitive tasks involving reading, listening and decision making.

### Secondary outcome measures
Self report of drooling, measured using the Unified Parkinson's disease rating scale questionnaire

### Overall study start date
01/10/2015

### Completion date
31/08/2016

## Eligibility

### Key inclusion criteria
1. Patients under the care of the Northumbria Parkinson's Disease Services or South Tyneside Speech and Language Therapy Service with a diagnosis of Idiopathic Parkinson's Disease
2. Have a self reported problem with daytime drooling on the Unified Parkinson’s Disease Rating scale subset 2.6 saliva question (Movement Disorder Society 2008)
3. Able to participate in the tasks in the proposed study protocol
4. Giving fully informed consent

### Participant type(s)

Patient

**Age group**
Adult

**Sex**
Both

**Target number of participants**
20

**Key exclusion criteria**
1. Patient unable, for cognitive or physical reasons, to comply with the project protocol
2. Patient has had botulinum toxin therapy or surgery on their saliva glands

**Date of first enrolment**
01/10/2015

**Date of final enrolment**
01/06/2016

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Northumbria Healthcare NHS Foundation Trust Parkinson's Disease Services**
Rake Lane
North Shields
United Kingdom
NE29 8NH

**Study participating centre**
**South Tyneside NHS Foundation Trust Speech and Language Therapy Service**
South Shields
United Kingdom
NE33 4JP

# Sponsor information

### Organisation
Northumbria Healthcare NHS Foundation Trust

### Sponsor details
North Tyneside General Hospital
Rake Lane
North Shields
England
United Kingdom
NE29 8NH

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/01gfeyd95

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Northumbria Healthcare NHS Foundation Trust

## Results and Publications

### Publication and dissemination plan
1. Peer reviewed journal
2. Presentation to participants
3. Feedback sheets to participants
4. Presentations at Royal College of Speech and Language Therapy and Parkinson's UK research conference

### Intention to publish date
01/04/2017

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Stored in repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

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|---|---|---|---|---|---|
| Results article | results | 01/12/2018 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |