# Improving Parkinson's related overactive bladder

Submission date 15/05/2017	<b>Recruitment status</b> No longer recruiting	
Registration date 15/05/2017	<b>Overall study status</b> Completed	[_] [X]
Last Edited 17/02/2020	<b>Condition category</b> 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 long-term medical condition which is caused by the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). Seven out of ten people with PD report having to pass urine frequently or with little warning, often resulting in urinary incontinence. Urinary symptoms are associated with poorer quality of life and admission to long-term care. Medications used to treat urinary symptoms in the general population are untested in people with PD. These medications have widespread effects beyond the bladder. There is growing concern that PD makes people particularly vulnerable to the adverse effects of these medications on the brain, increasing patients' risk of falls, confusion and dementia. Finding alternative evidence based treatments for urinary symptoms has been designated a research priority by people with PD. The aim of this study is to look at the effectiveness of a new bladder-training program for people with PD.

## Who can participate?

Adults with PD who are suffering from urinary symptoms.

# What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a 30 minute appointment where they are given advice about bladder and bowel care. Those in the second group also receive the conservative advice, with the addition of attending a one hour appointment where they learn about bladder training and urge suppression techniques. Participants in the intervention group will also be taught pelvic floor exercises. A personalised training schedule will be developed for participants to practice, and participants are followed up by phone every two weeks. After 12 weeks, the groups are then compared to see if bladder training is better than conventional treatment for urinary problems in Parkinson's.

What are the possible benefits and risks of participating? Participants who receive the program may benefit from an improvement to their bladder symptoms. There are no notable risks involved with participating.

Where is the study run from? Clinical Ageing Research Unit, Newcastle upon Tyne (UK)

When is the study starting and how long is it expected to run for? April 2016 to April 2018

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Dr Claire McDonald Claire.mcdonald@ncl.ac.uk

# **Contact information**

**Type(s)** Scientific

**Contact name** Dr Claire McDonald

ORCID ID http://orcid.org/0000-0002-7592-9952

# **Contact details**

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# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 34260

# Study information

# Scientific Title

Improving Parkinson's Related OVEractive bladder

# Acronym

IMPROVE

# **Study objectives**

The aim of this study is to evaluate whether bladder training in combination with pelvic floor exercises improve troublesome bladder symptoms in Parkinson's disease is better than conservative measures alone.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Northeast Tyne and Wear South Research Ethics Committee, 18/04/2017, ref: 17/NE/0095

## Study design

Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Physical, Rehabilitation

# Primary study design

Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

# Study type(s)

Treatment

# Participant information sheet

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

# Health condition(s) or problem(s) studied

Specialty: Dementias and neurodegeneration, Primary sub-specialty: Parkinson's Disease; UKCRC code/ Disease: Neurological/ Other degenerative diseases of the nervous system

## Interventions

Participants will be randomised in 1:1 (stratified by sex) to one of two groups.

Control group: Participants attend a single 30 minute appointment to receive standard conservative advice regarding bladder and bowel care (including hydration, management of constipation and containment products).

Intervention group: In addition to attending a 30 minute appointment to receive standard conservative advice, participants will have a 1 hour appointment to explain bladder training and urge suppression techniques. Participants in the intervention group will also be taught pelvic

floor exercises. A personalised training schedule will be developed for patients in the intervention group. This will be supported by written information and a training DVD. They will receive a phone call from trained health care professional every 2 weeks to discuss their progress. After assessing participants progress over the phone a new set of training targets will be agreed.

The intervention last 12 weeks. Both groups will be asked to complete a bladder diary at 12 weeks and attend clinic to complete clinical examination and questionnaire pack.

At 20 weeks both groups will be asked to complete a final set of questionnaires to assess is and effect is sustained after the intensive follow-up phase.

## Intervention Type

Behavioural

## Primary outcome measure

1. Number of urgency episodes on 3 day bladder diary from baseline to 12 weeks 2. Global measure of improvement (much improved, a little improved, no change, worse much worse) is measured by visual analogue scale at 12 weeks

All primary and secondary measures will be repeated 20 week to see if improvements are sustained once the intervention is completed.

## Secondary outcome measures

- 1. Patient perception of bladder control is measured using baseline at 12 weeks
- 2. Number of incontinence episodes is measured using bladder diary baseline at 12 weeks
- 3. Number of micturition during day is measured using bladder diary baseline at 12 weeks
- 4. Number of nocturnal voids is measured using bladder diary baseline at 12 weeks
- 5. Average volume voided per micturition is measured using bladder diary baseline at 12 weeks
- 6. Maximum postural drop on standing is measured using bladder diary baseline at 12 weeks
- 7. bladder symptoms are measured using the ICIQ-OAB score at baseline and 12 weeks
- 8. Patient quality of life is measured using the ICIQ-OAB\_QOL and PDQ 39 questionnaires at baseline and 12 weeks
- Patient satisfaction with bladder control is measured using a visual analogue scale (VAS) at ...
   Non-motor symptom score is measured using PDUKNon-motor symptom score at baseline and 12 weeks
- 11. Carer quality of life is measured using the OAB-fim and PDQ carer questionnaire at baseline and 12 weeks

All primary and secondary measures will be repeated 20 week to see if improvements are sustained once the intervention is completed.

# Overall study start date

01/04/2016

Completion date 04/04/2018

# Eligibility

Key inclusion criteria

1. Idiopathic Parkinson's disease

2. Urinary symptoms defined as one or more of the following:

2.1. Urinary frequency (need to pass urine 7 or more times during the day)

2.2. Urgency: A sudden compelling desire to pass urine which is difficult to defer accessed

2.3. Urge incontinence : involuntary leakage of urine accompanied by/ or immediately preceded by urgency

2.4. Mixed urinary incontinence: involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing. Where clinically urge incontinence is the major component

2.5. Over active bladder: urgency combined with frequency or nocturia (need to pass urine one or more times a night)

# Participant type(s)

Patient

## Age group

Adult

# Sex

Both

# Target number of participants

Planned Sample Size: 144; UK Sample Size: 144

# Total final enrolment

38

# Key exclusion criteria

1. Dementia such that they cannot follow training program or a Montreal Cognitive Assessment Score <24

- 2. Indwelling catheter
- 3. Renal failure requiring dialysis
- 4. Congestive cardiac failure requiring diuretic therapy
- 5. Current urinary tract infection confirmed by on microscopy
- 6. Completed bladder training in the last 12 months
- 7. Known prostate cancer or clinical evidence of this conditions
- 8. Uncontrolled bladder outlet obstruction / BPH
- 9. Pelvic organ prolapse past the vaginal introits
- 10. Known bladder malignancy or persistent haematuria on dipstick
- 11. Urinary retention >200ml on post void bladder scan
- 12. Previous Urogynecological Surgery for incontinence
- 12. Poorly controlled diabetes

# Date of first enrolment

11/05/2017

# Date of final enrolment 14/09/2017

Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre Clinical Ageing Research Unit** Campus for Ageing and Vitality Newcastle upon Tyne United Kingdom NE4 5PL

# Sponsor information

**Organisation** Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details Freeman Hospital, Freeman Road High Heaton NEWCASTLE-UPON-TYNE England United Kingdom NE7 7DN +44 191 282 5959 Andrew.Johnston@nuth.nhs.uk

**Sponsor type** Hospital/treatment centre

Website

http://www.newcastle-hospitals.org.uk/about-us/research-and-newcastle-hospitals.aspx

ROR

https://ror.org/05p40t847

# Funder(s)

**Funder type** Government

**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

Planned publication of data in high impact peer reviewed journals and at scientific meetings.

Intention to publish date

30/06/2018

# Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Other

## Study outputs

Output type	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>		31/03/2020	17/02/2020	Yes	No
HRA research summary			28/06/2023	Νο	No