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Improving Parkinson's related overactive bladder

Submission date
15/05/2017

Recruitment status
No longer recruiting

Registration date
15/05/2017

Overall study status
Completed

Last Edited
17/02/2020

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 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
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Contact information

Type(s)
Scientific

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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
9. Patient satisfaction with bladder control is measured using a visual analogue scale (VAS) at …
10. 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
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NE4 5PL

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Freeman Hospital, Freeman Road
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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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/03/2020	17/02/2020	Yes	No
HRA research summary			28/06/2023	No	No