

Lower urinary tract symptoms in Parkinson's disease effectiveness of pelvic floor muscle exercises and electrical stimulation

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Objective: To study the effectiveness of pelvic physical therapy and ES in patients with PD suffering from LUTS. Which are the most effective parameters for ES. Intervention: Intervention: 8 treatment sessions of 30 minutes pelvic physical therapy...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON53472

Source

ToetsingOnline

Brief title

LIPPE study

Condition

- Movement disorders (incl parkinsonism)
- Urinary tract signs and symptoms

Synonym

overactive bladder

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Koninklijk Nederlands Genootschap fysiotherapie en de Hersenstichting

Intervention

Keyword: electrical stimulation, lower urinary tract symptoms, Parkinson disease, physical therapy

Outcome measures

Primary outcome

The effect of pelvic physical therapy with ES will be estimated by evaluating LUTS symptoms at 12 weeks (T1), based on the IPSS score (men and women) at T1 in the 3 study arms.

Secondary outcome

Demographic: age, sex, obstetric history, constipation, level of completed education, year of diagnosis PD, bloodpressure and diabetes

Secondary outcome IPSS: measure at T2 (short term effect) -T3 (long term effect)

Secondary outcomes at T0, 12 weeks (T1), 24 weeks (T2), and one year (T3)

- International Consultation on Incontinence Questionnaire-Urinary Incontinence

Short form (ICIQ-UI SF),

- International Consultation on Incontinence Questionnaire-Lower Urinary Tract

Symptoms quality of Life (ICIQ-LUTSqol), evaluating QoL in LUTS,

particular reference to social effects.

- International Consultation on Incontinence Questionnaire-Overactive

Bladder, evaluating quality of Life of urgency incontinence

Other secondary outcomes (T0) and 12 weeks (T1)

- 24 hour bladder diary T0-T1

- Global Perceived Effect (GPE), to quantify the patient's perceived improvement or deterioration over time. (T1)

- Changes in EMG signals after pelvic physical therapy intervention of PFM during rest, maximum voluntary contractions (MVC) and endurance contractions (EC). T0-T1

Study description

Background summary

In the Netherlands, 63.500 people suffer from Parkinson's Disease(PD). PD is predominantly a movement disorder. In addition, PD is associated with non-motor and autonomic symptoms. Over 75% of PD patients, experience lower urinary tract symptoms (LUTS), one of the most common autonomic symptoms. LUTS consists of urgency, frequency and nocturia with or without urinary incontinence(UI). More than 60% of PD patients experience nocturia. LUTS have a negative impact on Quality of Life(QoL), increases the risk of falls, are a barrier to exercise and reduce social activities. Therefore, this potentially increases healthcare related costs.

Treatment options for LUTS in the general population are conservative therapy and medication, botox in the bladder muscle and neuromodulation (kind of pacemaker, providing electrical stimulation on the nerve to reduce urge).

In people with Parkinson's disease, medications do not work as well and produce more side effects such as dry mouth and difficulty defecating.

Conservative therapy consists of e.g. behavioral advice, bladder training provided by a pelvic physical therapist(PPT), and, electrical stimulation(ES).

Two small studies show that pelvic physical therapy has a positive effect.

Knowledge of the effectiveness of conservative treatment options for LUTS in PD is limited. Although ES is used effectively in patients with LUTS, it has not yet been studied in PD patients. ES has hardly any side effects, but there is

uncertainty about optimal ES parameters.

Pelvic physical therapy with electrical stimulation can be promising treatment option for LUTS in Parkinson's disease

Study objective

Objective: To study the effectiveness of pelvic physical therapy and ES in patients with PD suffering from LUTS. Which are the most effective parameters for ES.

Intervention:

Intervention: 8 treatment sessions of 30 minutes pelvic physical therapy over a 12 week period. The intervention consists of bladder- and behavioural advice, pelvic floor muscle exercises (PFME), urge suppression techniques, biofeedback and ES with an intra anal or intra vaginal probe. The group is divided into 3 groups. Group 1: ES with phase duration 200µs/20hz, group 2: ES with 1000µs/8hz and, group 3: (control group) receiving ES 200µs/100Hz,(2 sec active stimulation 20 sec no stimulation) sham ES.

Study design

Randomized control trial , single blind

Intervention

Pelvic physical therapy

All patients: bladder training , toilet behavioral, biofeedback assisted pelvic floor muscle exercises

Randomization in three groups:

group 1 : electrical stimulation, pulse duration 1000 microsec /8 Hz for 20 min

group 2: electrical stimulation, pulse duration 200 microsec e/20 Hz for 20 min

group 3: electrical stimulation, (2 sec active stimulation 20 sec no stimulation) pulse duration 200 microsec /100Hz sham for 20 min

All groups 8 treatment sessions

Study burden and risks

-Very low risks

-Burden :

Online questionnaires : total 59 questionnaires at T0-T1-T2-T3 (four times,

about 15 minutes)

bladder diary, before and after pelvic physical therapy, T0-T1

2 visits to a research pelvic physical therapist , 30-45 min each visit

8 treatment sessions , pelvic physical therapy, 30 min per treatment session,
one a week, (8 treatment sessions in 10 weeks)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Parkinson*s disease

- >= 18 years of age

- Self-reported LUTS
- Patients taking (stable) for at least three months medications such as alpha-blocker medicines could be included at the discretion of the PI.
- Stable Parkinson's medication for at least three months
- Able and willing to independently read and fill in online questionnaires in the Dutch language, sufficient understanding of Dutch language
- Able to independently visit a pelvic physical therapy practice

Exclusion criteria

- Patients with other neurological diseases
- Surgery in the pelvic region in the last year
- Cancer or cancer treatment in the pelvic region
- Pregnancy
- Current urinary tract infection
- Pure stress-urinary incontinence without urgency, frequency, nocturia
- Botox, PTNS or pelvic physical therapy in the last year
- Sacral neuromodulator
- Pacemaker and Implantable cardioverter defibrillator (ICD)
- Deep Brain stimulation (DBS)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	25-09-2023

Enrollment:	150
Type:	Actual

Ethics review

Approved WMO	
Date:	02-06-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	08-01-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83019.058.22