ISRCTN13500331 https://doi.org/10.1186/ISRCTN13500331

Evaluation of a new technology for the treatment of bladder leakage in women

Submission date
10/05/2017

Recruitment status
No longer recruiting

Registration date
16/05/2017

Overall study status
Completed

Last Edited
21/04/2022

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Urinary incontinence (bladder leakage) affects as many as one in three women and can have a considerable impact on quality of life. It can cause the leakage of urine during activities such as physical activity, coughing, or sneezing, which is known as urinary stress incontinence. Some feel the need to urinate urgently, frequently or are woken up multiple times during the night to use the toilet. Femeda, a UK-based company, and scientists at the University of Manchester have developed a disposable device called Pelviva that inserts into the vagina like a tampon and creates a stimulation signal to contract the pelvic floor muscles. A previous study demonstrated the effectiveness of the Pelviva device for the treatment of urinary incontinence in women. The trial showed that Pelviva is a successful device for the treatment of urinary incontinence when combined with unsupervised pelvic floor muscle exercise and produces better results than unsupervised pelvic floor muscle exercise alone. Furthermore, there are no apparent adverse incidents associated with using the device. The device is generally easy and comfortable to use and enables women to manage their incontinence in the privacy of their own home. The Pelviva device has undergone further development and modification since the previous studies. The aim of this study is to compare the quality of life and other incontinence associated outcomes between women receiving routine GP prescribed care and those who use the Pelviva device.

Who can participate?
Women aged 18 to 65 who have GP determined urinary incontinence.

What does the study involve?
Women are randomly allocated to one of two groups. Those in the first group receive regular care for their urinary incontinence symptoms. Those in the second group receive a Pelviva device. They are asked to use this for three months about every other day. After this they are asked to continuing using the device for three more months about once every five days. Participants are followed at the beginning and the end of the study to evaluate their quality of life, as well as their urinary incontinence symptoms.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their symptoms. There are no notable risks with participating.

Where is the study run from?
Bodey Medical Centre (UK)

When is the study starting and how long is it expected to run for?
November 2016 to June 2020 (updated 21/04/2022, previously: April 2022; updated 14/05/2020, previously: August 2019 to October 2019; updated 16/04/2019, previously: September 2018 to February 2022)

Who is funding the study?
Femeda Ltd. (UK)

Who is the main contact?
Dr Jane Garnett (Public) (jane.garnett@manchester.ac.uk)
Professor Jackie Oldham (Scientific)

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT04059653

Secondary identifying numbers
Evaluation of a new technology for treatment of bladder leakage v1.0

Study information

Scientific Title
Primary care evaluation of a novel disposable neuromuscular electrical stimulation treatment for female urinary incontinence: a randomised controlled trial

Acronym
PELVIVA

Study objectives
The aim of this study is to compare the quality of life and other incontinence associated outcomes between women receiving routine GP prescribed care for urinary incontinence compared with those prescribed the neuromuscular stimulation device (Pelviva device).

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West – Greater Manchester South Research Ethics Committee, 08/08/2017, 17/NW/0395

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Female urinary incontinence

Interventions
Participants are randomly allocated to either the control group or to the intervention group:

Control group (standard best practice care):
Participants continue routine standard treatment for their incontinence including any medication that has already been prescribed via their GP as normal. Routine treatment adheres to best practice standards as outlined in NICE Clinical Guidelines 171 (2013) where appropriate. Routine treatment may include pelvic floor exercises explained by the practitioner, weighted exercise cones, pelvic toner devices, vaginal insert devices (i.e. Contiform), pelvic floor physiotherapy, bladder re-training (continence service) and/or medication (which could include anticholinergics or mirabegron.

Participants who complete the study are offered vouchers for a 3-month course of Pelviva.

Intervention group (Pelviva group):
Participants are supplied at their first visit with one 15-day pack of single use disposable Pelviva devices to use for the initial month (at an average rate of one every other day) of a three month course of treatment. The next three months is the maintenance phase where participants continue using Pelviva at a dose of 6 devices per month (on average using one every five days)

The Pelviva device has been designed to be soft and comfortable to wear, intuitive to use and capable of delivering effective stimulation to the pelvic floor muscles. The device is manufactured from reversibly compressible foam and is inserted like a tampon into the vagina and removed using a pull cord. Subsequent devices are posted to the patient's home address in plain packaging. The stimulation programme is delivered using a duty cycle of 10 seconds stimulation followed by 10 seconds rest that runs for a period of 30 minutes. The Pelviva devices are pre-programmed to automatically gradually ramp-up the intensity of stimulation over a 24 second period to reach a therapeutic level and switch off automatically after 30 minutes. All devices are programmed to supply the same level of stimulation namely the average intensity that is considered comfortable and capable of producing a contraction of the pelvic floor muscles. During the 10 second ''on time'' the device delivers a patent protected 10 repeats of a short high intensity burst of 50 Hz stimulation immediately preceded by a doublet (125 Hz), superimposed on continuous low frequency 2 Hz stimulation.

All participants are followed up 12, 24 and 36 months after the main trial to assess their quality of life and incontinence symptoms.

Intervention Type
Device

Primary outcome measure
Quality of Life is measured using the International Consultation on Incontinence Questionnaire—Urinary Incontinence (ICIQ-UI) at baseline, month one and a half, three, six, 12, 24 and 36.

Secondary outcome measures
1. Sexual function is measured using the International Urogynecological Association (IUGA) Pelvic Organ Prolapse/ Urinary Incontinence Sexual Questionnaire (PISQ-IR) at baseline, mid point (one and a half months) and at the end of the trial (three months)
2. Patient Global Assessment of Severity at baseline, mid point (one and a half months) and at

the end of the trial (three months)
3. Patient Global Assessment of Improvement at the end of the trial (three months)
4. Bladder leakage is measured using a 1 hour provocative pad weight test at baseline and at the end of the trial (three months)
5. Episodes of incontinence is measured using a regular diary record during the 3 month trial and then at 12 and 24 months
6. Treatment usage and usability (pelvic floor exercises, vaginal cones, drug intervention) are measured using a regular diary record during the 3 month trial
7. Health economics are measured using EQ-5D and a diary of expenditure on incontinence products at baseline and month three, as well as month six, 12, 24 and 36

Overall study start date
01/11/2016

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Women
2. Aged between 18 and 65
3. GP determined urinary incontinence

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
330

Total final enrolment
86

Key exclusion criteria
Current exclusion criteria as of 01/09/2017:
1. Abnormal abdominal mass
2. Clinical history of urinary retention problems
3. Severe atrophic vaginitis, vaginal infection, vaginal lesion, severe urogenital prolapse at the level of the vaginal introitus or any other pathology of the vagina or labia
4. Pregnancy or given birth within the last three months
5. Implanted pacemaker

6. Recent pelvic surgery (within the last 12 months)
7. Recent haemorrhage, haematoma and/or tissue damage to the vagina
8. Undergoing any active therapy or review appointments for pelvic malignancy
9. Current urinary tract infection confirmed by urinary dip stick test on initial visit (can be included following a subsequent clear urinary dipstick test)
10. Manual dexterity insufficient to place the Pelviva device in the vagina
11. Presence of a severe neurological conditions such as Multiple Sclerosis, Motor Neuron Disease or Parkinson's Disease
12. Anticholinergic and/or device treatment in the preceding 4 weeks
13. Multiple co-morbidities to the extent that the activities involved in the pad test (i.e. stair climbing) cannot be completed
14. Insufficient cognitive ability to provide informed consent and/or participate in the study
15. Unwillingness to participate in the study

Previous exclusion criteria:
1. Abnormal abdominal mass
2. Problems with urinary retention
3. Severe atrophic vaginitis, vaginal infection, vaginal lesion, severe urogenital prolapse at the level of the vaginal introitus or any other pathology of the vagina or labia
4. Pregnancy or given birth within the last three months
5. Implanted pacemaker
6. Recent pelvic surgery (within the last 12 months)
7. Recent haemorrhage, haematoma and/or tissue damage to the vagina
8. Previous or current active treatment for pelvic malignancy
9. Current urinary tract infection confirmed by urinary dip stick test on initial visit
10. Manual dexterity insufficient to place the Pelviva device in the vagina
11. Presence of a severe neurological conditions such as Multiple Sclerosis, Motor Neuron Disease or Parkinson's Disease
12. No anticholinergic and/or device treatment in the preceding 4 weeks
13. Multiple co-morbidities to the extent that the activities involved in the pad test (i.e. stair climbing) cannot be completed
14. Unwillingness to participate in the study

Date of first enrolment
06/01/2020

Date of final enrolment
27/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barlow Medical Centre
28 Ladybarn Lane

Fallowfield
Manchester
United Kingdom
M14 6WP

Study participating centre
South Manchester GP Federation
Bourchart Medical Centre
62 Whitchurch Road
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United Kingdom
M20 1EB

Sponsor information

Organisation
University of Manchester

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Sponsor type
University/education

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ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Industry

Funder Name
Femeda Ltd.

Results and Publications

Publication and dissemination plan
Participants will be sent a summary of trial findings once data has been analysed and has been submitted for publication.

Intention to publish date
30/04/2024

Individual participant data (IPD) sharing plan
The current 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?
Results article		20/08/2021	20/04/2022	Yes	No
HRA research summary			28/06/2023	No	No