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A package to support the management of urinary leakage in older women

Submission date
04/09/2019

Recruitment status
No longer recruiting

Registration date
11/09/2019

Overall study status
Completed

Last Edited
18/06/2020

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Urinary incontinence (UI) is a distressing condition that limits people's quality of life and places a heavy financial burden on health and social care services. Behavioural treatments are recommended as a first-line treatment worldwide. A multifaceted evidence-based self-management package was developed following the Medical Research Council (MRC) framework for developing and evaluating complex interventions. This study aims to evaluate the feasibility and acceptability and provide preliminary outcomes of the effectiveness of the intervention in older women living with UI.

Who can participate?
Women aged 55 or over living with a symptom of urine leakage who are able to read and speak the English Language will be eligible to take part. However, individuals suffering from UI caused by neurological diseases affecting the brain and spinal cord, or are cognitive impaired will be excluded.

What does the study involve?
A total of 50 women are randomly allocated to two groups: a 3-month course of self-management package with an opportunity to request a single support session, or a control group who receive the package at 3 months. Participants are asked to complete a set of questionnaires at baseline and 3-month follow-up. At 3 months a smaller number of participants who have been given the package are invited to have an individual interview talking about their experiences of using the package.

What are the possible benefits and risks of participating?
The information from this study is unlikely to benefit participants directly, but the researchers will share a summary of the results. Taking part will give participants the opportunity to practise some self-management skills and receive relevant information included in the package. It will also give the opportunity for their views and experiences to be heard and the information may help refine the self-management package, which may support older women with UI in the future. The researchers do not anticipate any risks. Participants may find talking about their experiences touches upon personal topics around incontinence and related issues. They do not have to answer any questions they do not wish to and they may pause or stop the interview at

any time. The interviewer has a background in medicine and experience in dealing with distressed patients and will advise participants to see their general practitioner if necessary.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
April 2016 to August 2019

Who is funding the study?
Leeds Benevolent Society for Single Ladies (LBSSL) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title
An evidence-based self-management package for urinary incontinence in older women: a mixed methods feasibility study

Study objectives
Urinary incontinence (UI) is a distressing condition that limits people’s quality of life and places a heavy financial burden on health and social care services. Although several options are available for treating and managing UI, behavioural treatments are recommended as a first-line treatment worldwide.
A multifaceted intervention involving a trial of behavioural strategies has been considered to be more effective than a single component for the management of UI in older women. Self-management for chronic conditions is a multidimensional construct and defined as an intervention designed to develop individuals’ knowledge, skills or psychological and social resources and their ability to manage their health condition and consequences, through education, training and support. However, evidence for self-management programmes incorporating multifaceted behavioural treatments for use in UI among older women is currently limited.
An evidence-based self-management package has been co-developed with older women with UI and health professionals providing treatment and care. However, the feasibility and acceptability of using this package to self-manage women's UI remained unknown.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/10/2018, School of Healthcare Research Ethics Committee at the University of Leeds (The Secretariat, University of Leeds, Leeds, LS2 9JT, UK; Tel: +44 (0)113 3431642; Email: FMHUniEthics@leeds.ac.uk), ref: HREC 18-001

Study design
Mixed-methods approach comprising a two-arm RCT with a nested qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

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
Urinary incontinence

Interventions
Eligible women will be randomised using a 1:1 ratio to either the intervention or control group. The randomisation procedure will be performed by a web-based randomisation service (https://sealedenvelope.com/).

The intervention group receive a 3-month course of self-management package with an opportunity to request a single support session
The control group do not receive the self-management package or the support session. However, they are informed that they will receive the package only at the end of this study (at three months).

The experimental intervention was the self-management package, co-developed with older women living with UI, health professionals and lay members. The aim of the package was to provide information and practical skills for women to self-manage their UI and other symptoms. Following elements were included: recognition and awareness, getting the support you need, understanding the cause, learning to manage your UI, developing a self-management plan and how can you find out more. Descriptions of self-management techniques such as PFME, bladder training and lifestyle interventions were also provided. The researcher with medical background acted as a facilitator and delivered the intervention in person straight after the completion of baseline data collection. A self-management brochure was also distributed. The intervention group were also informed that they could request a single one-hour support session with the researcher on how to use the package and/or addressing questions or concerns that they may have.

Both groups will be assessed at the start of the study and 3 months later. Measures will include generic and disease-specific quality of life, UI severity, self-efficacy and psychological health status. Some participants will be interviewed to facilitate the understanding of how the package might work and further explore facilitators and barriers to acceptance of the self-management package.

Findings will inform the design of the larger trial, provide information about the feasibility of offering self-management package to older women with UI, and produce preliminary outcomes about its effectiveness. Findings will be shared with women and professionals and with service commissioners.

Intervention Type
Behavioural

Primary outcome measure
1. Generic quality of life is measured using EQ-5D-5L at baseline and 3-month follow up
2. Disease-specific quality of life is measured using King’s Health Questionnaire at baseline and 3-month follow up
3. UI severity is measured using international consultation on incontinence questionnaire short form at baseline and 3-month follow up
4. Self-efficacy is measured using the geriatric self-efficacy index for urinary incontinence at

baseline and 3-month follow up
5. Psychological health is measured using hospital anxiety and depression scale at baseline and 3-month follow up
6. Subjective improvement is measured using Global Impression: Improvement at 3-month follow up for the intervention group only

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2016

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Women aged 55 or over
2. Self reported symptom of any involuntary leakage of urine
3. Be able to read and understand English

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
UK sample size: 50

Total final enrolment
50

Key exclusion criteria
1. Aged under 55 years
2. No symptoms of urine leakage
3. UI caused by neurological diseases affecting the brain and spinal cord
4. Cognitive impaired

Date of first enrolment
01/04/2019

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Older People's Forum
Suite C24
Joseph’s Well
Hanover Walk
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Sponsor information

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University of Leeds

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Sponsor type
University/education

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ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Leeds Benevolent Society for Single Ladies (LBSSL)

Results and Publications

Publication and dissemination plan
To be published by the end of 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the researchers are not allowed to share any research data with anyone outside the direct research team.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/04/2020	18/06/2020	Yes	No