ISRCTN11669964 https://doi.org/10.1186/ISRCTN11669964

TreatIng urinary symptoms in men in primary healthcare using non-pharmacological and non-surgical interventions

Submission date
12/03/2018

Recruitment status
No longer recruiting

Registration date
12/04/2018

Overall study status
Completed

Last Edited
06/05/2025

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Lower Urinary Tract Symptoms (LUTS) refer to problems with storing urine, such as increased urinary daytime frequency, urgency, having to pass urine overnight, slow stream while passing urine, or dribbling afterwards. Half of men over 40 experience at least one LUTS, which can have a significant impact on their daily lives. The aim of this study is to test whether personalised advice based on a nurse's assessment of men's urinary symptoms improves symptom control.

Who can participate?
Men aged 18 years and over with current bothersome LUTS

What does the study involve?
Participating GP practices are randomly allocated to provide either usual care or personalised care. Men in the personalised care group are offered non-drug therapy, based on an assessment by a nurse. The nurse educates the patient on LUTS, teaches him the appropriate treatments and provides written information. Ongoing support is offered to help men adhere to the treatments. Treatment advice may include advice on drinks, pelvic muscle exercises, bladder training and techniques to reduce urinary dribbling. The aim is to find out whether personalised standard treatment achieves better symptom relief than usual care by comparing the change in symptoms between the two groups after a year.

What are the possible benefits and risks of participating?
If they are in the personalised booklet group, they will receive a booklet to keep with personalised information and advice on their symptoms. If they are in the usual care group, they will have access to the booklet at the end of the study. Their symptoms may improve and bother them less. Even if they do not feel any improvement, their taking part will help us to understand what advice and information will help improve LUTS in other men, without having surgery or drugs to help their symptoms. We do not anticipate any disadvantages in taking part. However, we do not know how much their symptoms will improve, whichever group they are in. Therefore,

their symptoms may not improve as much as they would like. They will need to spend time completing questionnaires, and if they are in the personalised advice group they will be asked to spend time following the advice given.

Where is the study run from?
1. University of Bristol (UK)
2. University of Southampton (UK)
3. At least 24 GP practices from Bristol and Southampton (UK)

When is the study starting and how long is it expected to run for?
November 2017 to January 2021

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

Who is the main contact?
Dr Jo Worthington
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Study website
https://www.journalslibrary.nihr.ac.uk/programmes/hta/169003/#/

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
CPMS 37405

Study information

Scientific Title
TReatIng Urinary symptoms in Men in Primary Healthcare using non-pharmacological and non-surgical interventions

Acronym
TRIUMPH v1.0

Study objectives
Lower Urinary Tract Symptoms (LUTS) refer to problems with storing urine, such as increased urinary day-time frequency, urgency, having to pass urine overnight, slow stream while passing urine, or dribbling afterwards. Half of men over 40 experience at least one LUTS, which can have a significant impact on their daily lives.

The TRIUMPH (TReating Urinary symptoms in Men in Primary Healthcare) study will test whether personalised advice based on a nurse's assessment of men's urinary symptoms achieves improved symptom control over usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Preston Research Ethics Committee, 12/04/2018, ref: 18/NW/0135

Study design
Randomized; Both; Design type: Treatment, Education or Self-Management, Qualitative

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Lower urinary tract symptoms

Interventions
GP practices are randomised to deliver either usual care or personalised care. Men in the personalised care group will be offered non-drug therapy, based on an assessment by a nurse. The nurse will educate the patient on LUTS, teach him the appropriate treatment(s) and provide written information. Ongoing support will be offered to help men adhere to the treatments. Treatment advice may include advice on drinks, pelvic muscle exercises, bladder training and techniques to reduce urinary dribbling.

The primary outcome is to find out if personalised standard treatment achieves better symptom relief overall than usual care, by comparing the change in a prostate symptom score (IPSS) between the two groups after a year. The treatment phase is 12 weeks, and follow up is at 6 and 12 months after consent. Each patient will be in the study for 12 months.

Intervention Type
Other

Primary outcome measure
Lower urinary tract symptoms assessed using the IPSS score; Timepoint(s): 12 months after consent

Secondary outcome measures
1. LUT-specific QoL, assessed using IPSS QoL at 6 and 12 months
2. Symptoms scores at 6 months (IPSS overall score) and 6 and 12 months (ICIQ-UI-SF)
3. Cost-effectiveness analyses from an NHS perspective. The EQ-5D-5L will be used to calculate QALYs at 12 months
4. Number of adverse events (e.g. infection, urinary retention) at 12 months
5. Number of GP consultations at 12 months
6. Number of referrals to secondary care at 12 months
7. Overall quality of life measured by the EQ-5D-5L at 12 months
8. A qualitative element of the research study will evaluate patient experiences of intervention throughout the trial

Overall study start date
01/11/2017

Completion date
31/01/2021

Eligibility

Key inclusion criteria
Adult men (aged ≥18 years) with bothersome LUTS

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Planned Sample Size: 840; UK Sample Size: 840

Total final enrolment
1076

Key exclusion criteria
1. Lack of capacity to consent
2. Unable to pass urine without a catheter (indwelling or intermittent catheterisation)
3. Relevant neurological disease including referral to neurology
4. Undergoing urological testing for LUTS
5. Currently being treated for prostate or bladder cancer
6. Previous prostate surgery
7. Unable to complete assessments in English
8. Poorly-controlled diabetes mellitus
9. Recently referred or currently under urology review
10. Visible haematuria
11. Hypercalcaemia
Eligibility will be checked by the patient's own GP as part of the screening process

Date of first enrolment
01/05/2018

Date of final enrolment
01/08/2019

Locations

Countries of recruitment
England

United Kingdom

Uruguay

Study participating centre

University of Bristol
United Kingdom
BS8 1TH

Study participating centre
University of Southampton
United Kingdom
SO17 1BJ

Study participating centre
At least 24 GP practices from Bristol and Southampton
Uruguay
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Sponsor information

Organisation
University of Bristol

Sponsor details
Research and Enterprise Development
3rd Floor, Senate House
Tyndall Avenue
Bristol
England
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/90/03

Results and Publications

Publication and dissemination plan

Protocol can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/169003/#/. Planned publication of the results in a high-impact peer reviewed journal.

Intention to publish date

31/01/2022

Individual participant data (IPD) sharing plan

The 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?
Protocol article		02/09/2019	08/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		15/11/2023	16/11/2023	Yes	No
Results article	Costs and QALYs results	30/01/2024	09/02/2024	Yes	No
Results article		01/03/2024	06/05/2025	Yes	No