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Primary care management of lower urinary tract symptoms in men

Submission date
11/09/2017

Recruitment status
No longer recruiting

Registration date
09/10/2017

Overall study status
Completed

Last Edited
03/02/2025

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
More than 10% of older men experience the need to pass urine more frequently than usual and often find their sleep interrupted by having to go to the toilet during the night. Some will find that their urine flow rate has become slower, and some will experience loss of bladder control. Such problems are distressing for men, affect their work and social life, and are a common reason why men visit a general practitioner (GP) with over 60,000 attendances yearly across the UK. They firstly need reassurance that they are not suffering from cancer or any other sinister medical condition. GPs follow established procedures when considering signs of cancer or these more serious conditions, but they have no easily available assessment tools to identify other more common causes of lower urinary tract symptoms (LUTS), or to advise men about the best treatment options for symptom relief. Because of this, men have to be referred to hospital based urology specialists for tests and diagnosis. The aim of this study is to investigate the accuracy of a new decision aid for use by GPs to diagnose the cause of LUTS in men and to assist decisions in determining appropriate person centred treatment. The aim of the main PriMUS study is to create a practical and accurate 'decision aid' to help GPs find out the most likely cause of patients' lower urinary tract symptoms (LUTS). The GP will then use the decision aid so that they and the patient can choose the best treatment option together. Follow-up is to be conducted at approximately 3-6 months, collating the treatment and management decisions made as a result of these procedures.

Who can participate?
Men aged 16 and older who have a lower urinary tract symptoms.

What does the study involve?
All participants receive the same procedures; including index tests (standard care according to NICE guidance) and a reference test (completed at secondary care level if patient referred to urology). The results of the simple tests with results of urodynamics and identify which simple tests give best prediction of the urodynamic result.

What are the possible benefits and risks of participating?
Participants may benefit from having a very thorough investigation of their urinary symptoms within a few weeks of seeing their GP. This includes an urodynamics test, which is the gold

standard test for determining the cause of urinary symptoms and usually takes place once a patient has been referred to hospital. Symptoms might therefore be suitably managed in a shorter timeframe than usual, as a patient's GP will have all the information they need to make an accurate diagnosis. Patient's will receive a high street shopping voucher to a maximum value of £30, to cover any travel expenses incurred whilst taking part in the study. There are potential risks with undergoing the urodynamics test. After the test patient's may experience a mild stinging sensation when they pass urine for a few hours, or in some cases up to a day or so, but these symptoms usually improve quickly. They may also pass a little blood with the urine the first time they pass water. About 5% (five in a hundred) of patients who have this test get a bladder infection (cystitis) afterwards. If this happens the stinging will get worse and they may feel more unwell. If this occurs they should see their GP as soon as possible, and will probably be treated with a course of antibiotics. There is a small risk, (less than one in a hundred) of urine retention (inability to pass water) following the urodynamics test in men with difficulty emptying their bladders, although this rarely occurs. If patients are at all worried they should see their GP as soon as possible.

Where is the study run from?
This study is being run by Cardiff University (UK) and takes place in GP practices across England and Wales recruited from three main research hubs (Newcastle, Bristol and Wales).

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

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

Who is the main contact?
Janine Bates, batesmj@cf.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Janine Bates

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03520673

Secondary identifying numbers
CPMS 36076

Study information

Scientific Title
Primary care management of lower urinary tract symptoms in men: Development and validation of a diagnostic and decision-making aid

Acronym
PriMUS

Study objectives
Current study hypothesis as of 12/03/2018:
The aim of the PriMUS study is to create a 'Clinical Decision Support Tool' to help GPs find out the most likely cause of patients' urinary symptoms, so that together they can choose the best management. It is believed that this will have many benefits such as getting to the right treatment sooner, avoiding unnecessary hospital visits, and getting those who need to be treated by a specialist there more quickly.

Original study hypothesis:
The aims of the PriMUS study is to create a 'decision aid' to help GPs find out the most likely cause of patients' urinary symptoms, so that together they can choose the best management. It is believed that this will have many benefits such as getting to the right treatment sooner, avoiding unnecessary hospital visits, and getting those who need to be treated by a specialist there more quickly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval statement as of 12/03/2018:
Wales REC 6, 20/06/2017, ref: 17/WA/0155

Original ethics approval statement:
Wales REC 3, 20/06/2017, ref: 17/WA/0155

Study design
Non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

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
Lower urinary tract symptoms

Interventions
All patients receive the same treatment. They receive simple index tests, outlining NICE clinical guidance, and all receive the reference test urodynamics. The purpose of the study is to compare the results of all the index tests, with the results of urodynamics, to see whether the index tests can provide an accurate diagnosis and management decision for LUTS. GPs are sent the results of all the index tests and a recommendation for a management decision, to follow up the patient as appropriate. The participants' medical records are reviewed approximately 3-6 months after, to collate the management decision made by the GP.

Intervention Type
Other

Primary outcome measure
Sensitivity and specificity of the diagnoses of detrusor overactivity, bladder outlet obstruction and detrusor underactivity estimated by the decision aid (using invasive urodynamics as the gold standard reference test).

Secondary outcome measures
1. Construction of a patient management algorithm to guide initial treatment for men with LUTS
2. Construction of a prototype online decision aid for use in primary care
3. Qualitative analysis of patients and clinicians views on the use of a LUTS decision aid in the primary care setting
4. Percentage change in referral rates to secondary care for men with LUTS
5. Estimation of costs / savings of implementation of the primary care LUTS decision aid both from a population and individual patient perspective

Overall study start date
01/05/2016

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Men
2. Aged 16 years and over
3. Present to their GP with a main complaint of one or more lower urinary tract symptoms
4. Able and willing to give informed consent for participation in study
5. Able and willing to undergo all index tests and reference test, and complete study documentation

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Male

Target number of participants
Planned Sample Size: 880; UK Sample Size: 880

Key exclusion criteria
Current exclusion criteria as of 12/03/2018
1. Neurological disease or injury affecting lower urinary tract function
2. LUTS considered secondary to current or past invasive treatment or radiotherapy for pelvic disease
3. Contraindications to urodynamics e.g. heart valve or joint replacement surgery within the last 3 months, immunocompromised/immunosuppressed.
4. Indwelling urinary catheter or intermittent self-catheterisation
5. Initial assessment suggests that clinical findings are suggestive of possible:
5.1. prostate or bladder cancer*
5.2. recurrent or persistent symptomatic UTI**
5.3. retention, e.g. palpable bladder after voiding renal impairment
6. Unable to consent in English or Welsh where a suitable translator is not available

Original exclusion criteria
1. Neurological disease or injury affecting lower urinary tract function
2. Past or current invasive treatment for LUT malignancy
3. Initial assessment suggests that clinical findings are suggestive of possible:
3.1. Prostate or bladder cancer*
3.2. Recurrent or persistent symptomatic UTI**
4. Unable to consent in English or Welsh where a suitable translator is not available

*According to standard NHS cancer pathways. If deemed unlikely, then eligible for study participation.
**If UTI successfully treated but LUTS remain, then eligible for study.

Date of first enrolment
19/02/2018

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Vauxhall Surgery
Vauxhall Ln
Chepstow
United Kingdom
NP16 5PZ

Study participating centre
Bellevue Surgery
Bellevue Terrace,
Newport
United Kingdom
NP20 2WQ

Study participating centre
North Celynen Practice
Ashfield Rd
Newbridge
Newport
United Kingdom
NP11 4RA

Study participating centre
Greenmeadow Surgerydge
Greenmeadow Way
Cwmbran
United Kingdom
NP44 3XQ

Study participating centre
Malpas Brook Health Centre
107 Malpas Rd
Newport
United Kingdom
NP20 5PJ

Study participating centre
St Davids Clinic
Belle Vue Terrace
Newport
United Kingdom
NP20 2LB

Study participating centre
Nantgarw Road Medical Centre
4 Beddau Way
CaerphillyK
United Kingdom
CF83 2AX

Study participating centre
St Paul's Clinic
Palmyra Place
Newport
United Kingdom
NP20 4EJ

Study participating centre
Clifton Surgery
151-155 Newport Rd
Cardiff
United Kingdom
CF24 1AG

Study participating centre
The Practice of Health
31 Barry Road
Barry
United Kingdom
CF63 1BA

Study participating centre
Stanwell Surgery
Stanwell Road
Penarth
Vale of Glamorgan
United Kingdom
CF64 3XE

Study participating centre
Llan Healthcare
Llan Healthcare
Maelfe
Llanedeyrn
Cardiff
United Kingdom
CF28 9PN

Study participating centre
Llandaff and Pentyrch Surgery
19a High Street
Llandaff
Cardiff
United Kingdom
CF5 2DY

Study participating centre
Ely Bridge Surgery
23 Mill Road
Ely
Cardiff
United Kingdom
CF5 4AD

Study participating centre
Roath House Surgery
100 Pen-Y-Lan Rd
Cardiff
United Kingdom
CF23 5RH

Study participating centre
Llandaff North Medical Centre
99 Station Rd
Cardiff
United Kingdom
CF14 2FD

Study participating centre
Whitchurch Village Practice
Park Road Surgery
Park Road
Whitchurch
Cardiff
United Kingdom
CF14 7EZ

Study participating centre
Rumney Primary Care Centre
Barmouth Road
Rumney
Cardiff
United Kingdom
CF3 3LG

Study participating centre
Llwyncelyn/Hollybush Practice
Park Road
Whitchurch
Cardiff
United Kingdom
CF14 7EZ

Study participating centre
Ashgrove Surgery
Morgan Street
Pontypridd
United Kingdom
CF37 2DR

Study participating centre
Cynon Vale Medical Practice
8 Cardiff Road
Mountain Ash
United Kingdom
CF45 4EY

Study participating centre
Cwm Gwyrdd Medical Centre
High Street
Gilfach Goch
United Kingdom
CF39 8TJ

Study participating centre
Penygraig Surgery
George Street
Penygraig
Tonypandy
United Kingdom
CF40 1QN

Study participating centre
Keir Hardie Health Park Practice 3
Aberdare Rd
Merthyr Tydfil
United Kingdom
CF48 1AZ

Study participating centre
The Foundry Town Clinic
74 Monk Street
Aberdare
United Kingdom
CF44 7PA

Study participating centre
Oaklands Surgery
13 Oakland St
Bedlinog
Treharris

United Kingdom
CF46 6TE

Study participating centre
St John's Medical Practice
Mid Glamorgan
High St
Aberdare
United Kingdom
CF44 7DD

Study participating centre
Pont Newydd Medical Centre
Aber-Rhondda Rd
Porth
United Kingdom
CF39 0LD

Study participating centre
St Andrews Surgery
De Winton Street
Tonypandy
Rhondda Cynon Taff
United Kingdom
CF40 2QZ

Study participating centre
Swarland Avenue Surgery
2 Swarland Avenue
Benton
Newcastle upon Tyne
United Kingdom
NE7 7TD

Study participating centre
Redburn Park HC
15 Station Road
Percy Main
North Shields
United Kingdom
NE29 6HT

Study participating centre
49 MA Surgery
49 Marine Avenue
Whitley Bay
United Kingdom
NE26 1NA

Study participating centre
Park Rd MP
93 Park Rd
Wallsend
United Kingdom
NE28 7LP

Study participating centre
West Farm Surgery
31 West Farm Avenue
Longbenton
Newcastle upon Tyne
United Kingdom
NE12 8LS

Study participating centre
Cheviot MG
2 Padgepool Pl
Wooler
United Kingdom
NE71 6BL

Study participating centre
Alnwick Medical Group
Consulting Rooms
Infirmary Drive
Alnwick
United Kingdom
NE66 2NR

Study participating centre

Well Close Surgery
Well Close Square
Berwick-upon-Tweed
United Kingdom
TD15 1LL

Study participating centre
Belford Surgery
Croft Field
Belford
United Kingdom
NE70 7ER

Study participating centre
Glendale MG
Cheviot Primary Care Centre
Padgepool Place
Wooler
United Kingdom
NE71 6BL

Study participating centre
Union Brae Surgery
Tweedmouth
Berwick-upon-Tweed
United Kingdom
TD15 2HB

Study participating centre
Coquet Medical Group
Broomhill Health Centre
Hadston Road
South Broomhill
Morpeth
United Kingdom
NE65 9SF

Study participating centre
Corbridge Surgery
Newcastle Rd
Corbridge

United Kingdom
NE45 5LG

Study participating centre
Burn Brae Surgery
Hexham Primary Care Centre
Corbridge Road
Hexham
United Kingdom
NE46 1QJ

Study participating centre
Branch End Surgery
Stocksfield
United Kingdom
NE43 7LL

Study participating centre
Humshaugh & Wark Surgery
1 E Lea
Humshaugh
Hexham
United Kingdom
NE46 4BU

Study participating centre
White Medical Group
Ponteland Primary Care Centre
Meadowfield
Ponteland
Newcastle upon Tyne
United Kingdom
NE20 9SD

Study participating centre
Bellingham Practice
Bellingham
Hexham
United Kingdom
NE48 2HE

Study participating centre
Sele Medical Practice
Hexham Primary Care Centre
Corbridge Road
Hexham
United Kingdom
NE46 1QJ

Study participating centre
Village Medical Group
Dudley Ln
Cramlington
United Kingdom
NE23 6US

Study participating centre
Netherfield House
Station Rd
Seghill
Cramlington
United Kingdom
NE23 7SE

Study participating centre
Kingswood Healthcentre
Alma Road
Kingswood
Bristol
United Kingdom
BS15 4EJ

Study participating centre
Cadbury Heath Health Centre
Parkwall Road
Cadbury Heath
Bristol
United Kingdom
BS30 8HS

Study participating centre
Hanham Health
Whittucks Road
Hanham
Bristol
United Kingdom
BS15 3HY

Study participating centre
Close Farm Surgery
47 Victoria Road
North Common
Bristol
United Kingdom
BS30 5JZ

Study participating centre
Westbury on Trym Surgery
Westbury Hill
Westbury On Trym
Bristol
United Kingdom
BS9 3AA

Study participating centre
Greenway Community Practice
Graystoke Avenue
Southmead
Bristol
United Kingdom
BS10 6AF

Study participating centre
Fallodan Way Medical Practice
13 Fallodon Way
Henleaze
Bristol
United Kingdom
BS9 4HT

Study participating centre

Monks Park Surgery
24 Monks Park Avenue
Horfield BS7 0UE
Bristol
United Kingdom
BS7 0UE

Study participating centre
Tyntesfield Medical Group (Backwell Surgery, Brockway Surgery, Long Ashton Surgery, Tower House Medical Centre)
Brockway Medical Centre
8 Brockway
Nailsea
Bristol
United Kingdom
BS48 1BZ

Study participating centre
Heart of Bath Medical Partnership
Oldfield Surgery
45 Upper Oldfield Park
Bath
United Kingdom
BA2 3HT

Study participating centre
West Walk Surgery
21 West Walk
Yate
Bristol
United Kingdom
BS37 4AX

Study participating centre
Courtside Surgery
Kennedy Way
Yate
Bristol
United Kingdom
BS37 4DQ

Study participating centre
Frome Valley Surgery
2 Court Rd
Frampton Cotterell
Winterbourne
Bristol
United Kingdom
BS36 2DE

Sponsor information

Organisation
Cardiff University

Sponsor details
Research and Innovation Services
McKenzie House
30-36 Newport Road
Cardiff
Wales
United Kingdom
CF24 0DE
+44 29 2087 9277
FalconerHE@cardiff.ac.uk

Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/04/2021

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	protocol	30/06/2020	02/07/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/01/2025	03/02/2025	Yes	No