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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

### Contact details
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CF14 4YS
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batesmj@cf.ac.uk

# Additional identifiers

### ClinicalTrials.gov (NCT)
NCT03520673

### Central Portfolio Management System (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

### Primary study design
Interventional

### Study design
Non-randomized

### Study type(s)
Treatment

### 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(s)
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).

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
16 Years

### Sex
Male

### 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
United Kingdom

England

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

**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

**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? |
|---|---|---|---|---|---|
| Results article | | 01/01/2025 | 03/02/2025 | Yes | No |
| Protocol article | protocol | 30/06/2020 | 02/07/2020 | Yes | No |

| | | | |
|---|---|---|---|
| HRA research summary | 28/06/2023 | No | No |