

Urodynamics for Prostate Surgery Trial; Randomised Evaluation of Assessment Methods (UPSTREAM) for diagnosis and management of bladder outlet obstruction in men



Research questions

UPSTREAM aims to address two key questions: 1) Is a care pathway excluding invasive urodynamics no worse for men in terms of symptom outcome than one in which it is included? and 2) Does the inclusion of invasive urodynamics reduce the rate of bladder outlet surgery?

The Trial

UPSTREAM (ISRCTN56164274) aims to randomise 800 participants. Adult men (≥ 18 years) with bothersome voiding lower urinary tract symptoms (LUTS) and suspected bladder outlet obstruction for whom surgeons would potentially offer surgery, and who are willing and able to give informed consent would be considered for trial entry. Men are ineligible if they: are in urinary retention; have a relevant neurological disease; are undergoing treatment for prostate or bladder cancer; have had prior prostate surgery; and/or are considered medically unfit for surgery. Participants will be randomised to one of two assessment pathways, that is either: a) usual care (non-urodynamics, control); or b) usual care plus urodynamics assessment (intervention). Usual care typically consists of at least: medical history review; physical examination; urinary frequency volume chart; and measurement of urinary flow rate with post-void residual volume measurement by ultrasound. After diagnostic assessments all men will see their surgeon to decide on whether to proceed to surgical treatment. The treatment decision is between the urologist and the patient and there are no treatment 'requirements' imposed by the trial. All men will complete trial-specific follow-ups at six, 12 and 18 months (post-randomisation); the primary outcome being International Prostate Symptom Score (IPSS) 18 months

post-randomisation. All men who underwent surgery for their bothersome LUTS will also be followed-up four months post-surgery (Figure 1).

Progress and future timelines

Funding for UPSTREAM started in April 2014 and it opened for recruitment in late-September 2014. By early June 2015, 153 participants had been randomised from 17 centres, with another one open for recruitment. We anticipate a few more centres joining the trial in coming months. Planned recruitment end is 31 March 2016, followed by an 18-month follow-up phase. Planned completion date is March 2018.

How you can help

UPSTREAM is, to our knowledge, the first pragmatic randomised controlled trial (RCT) to address these research questions, and other secondary outcomes, including cost effectiveness (see trial website for details). Results will inform patients, clinicians and policy makers about whether urodynamics should be more widely used for the assessment of men with bothersome LUTS who are seeking further treatment, such as surgery.

If you are interested in being involved or require further information, please contact the trial team (see below).

Contact details

- Chief investigator, Marcus Drake, marcus.drake@bui.ac.uk
- Trial manager, Amanda Lewis, amanda.lewis@bristol.ac.uk

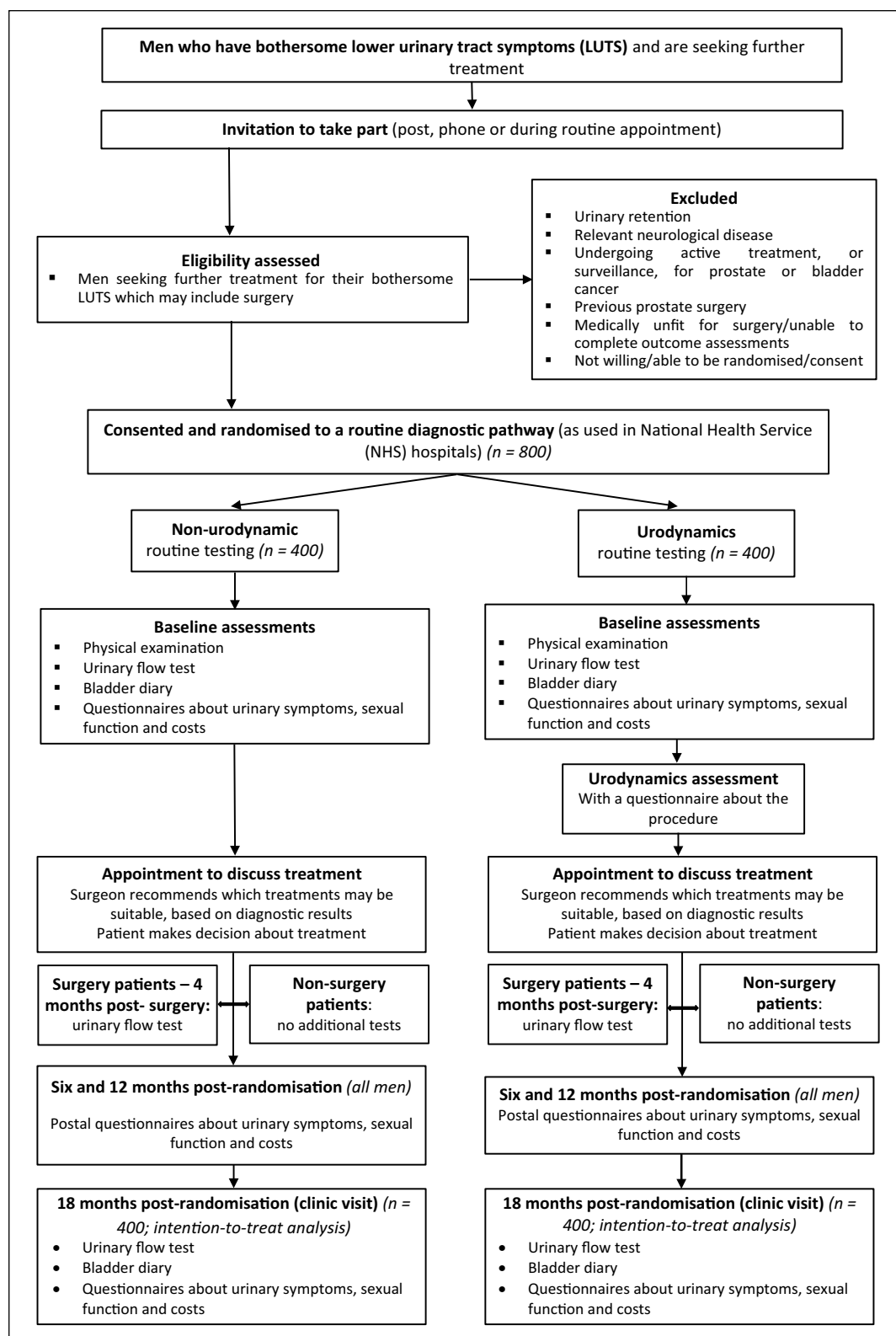


Figure 1. UPSTREAM study flow chart.

- Trial website, <http://www.bristol.ac.uk/social-community-medicine/projects/upstream/>
- National Institute for Health Research (NIHR) portfolio, <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=17461>

Conflicting interests

None Declared.

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Ethical approval

South Central - Oxford B, 14/SC/0237.

Guarantor

Marcus Drake.

Contributorship

Article written by Amanda Lewis (UPSTREAM Trial Manager) and reviewed by John McGrath, Rob Pickard, and Marcus Drake. Full listing of trial co-investigators include:

- Marcus Drake, Senior Lecturer in Urology; University of Bristol and Bristol Urological Institute.

- Peter Blair, Reader in Medical Statistics, BRTC
- Cathryn Glazener, Professor of Health Services Research, University of Aberdeen
- Robert Pickard, Professor of Urology, University of Newcastle
- Athene Lane, Co-Director of BRTC, University of Bristol
- Paul Abrams, Professor of Urology, North Bristol NHS Trust
- Jeremy Horwood, Qualitative Research Fellow, BRTC
- Gordon Taylor, Former Dean of Education (retd.), University of Plymouth
- Sian Noble, Senior Lecturer in Health Economics, University of Bristol,
- John McGrath, Consultant Surgeon, Royal Devon and Exeter NHS Foundation Trust
- Christopher Chapple, Consultant in Urology, Sheffield Teaching Hospitals NHS Trust

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