INVESTIGATE-I (INVasive Evaluation before Surgical Treatment of Incontinence Gives Added Therapeutic Effect?): a mixed-methods study to assess the feasibility of a future randomised controlled trial of invasive urodynamic testing prior to surgery for stress urinary incontinence in women

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Declared competing interests of authors: The authors have no current personal financial interests; the following non-financial interests are declared: Dr Hilton was a member of the National Institute for Health and Care Excellence (NICE) Interventional Procedures Advisory Committee (2002–7); a member of the National Institute for Health Research (NIHR) Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) Health Technology Assessment (HTA) Therapeutic Procedures Panel (2007–8) and the NETSCC-HTA Clinical Evaluations and Trials Prioritisation Group (2008–10); chair of the NICE development group for clinical guideline on urinary incontinence in women (2004–7); and a member of the James Lind Alliance Working Partnership on research priorities on urinary incontinence (2007–9). These last two groups identified the research question underlying this report as an important area for further research. Dr Lucas currently chairs the European Association of Urology Guidelines panel on Urinary Incontinence which has produced guidance on the use of urodynamics in clinical practice based on existing evidence. Professor McColl is a member of the NIHR Journals Library Editorial Group although she was not involved in the editorial processes for this report.

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Plain English summary

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When a woman consults about urinary incontinence, the doctor will ask about her symptoms, conduct a physical examination and may use some simple tests such as urine samples, scans and recording of toilet habits. He or she may also recommend tests that involve passing a thin tube into the bladder to measure its activity. Described as 'invasive urodynamic tests', these are intended to help the doctor select the best treatment.

However, although invasive tests are usually used before surgery, there is little evidence to prove that they really help. The tests take time to do, can cause discomfort and some women may develop cystitis afterwards. Therefore, a large research study is needed to find out whether treatment chosen after invasive tests is more or less successful than treatment after just the simpler tests.

To help plan the research and ensure best use of NHS research funds, surveys and a small rehearsal of the proposed study were conducted. These found that many surgeons treating incontinence currently carry out invasive tests routinely and many would be willing to ask their patients to take part in the research. Women themselves also appeared to be willing to take part. Interviews with some women and doctors helped the researchers understand what they felt about the tests and the research.

The study rehearsal was too small to produce strong conclusions about whether or not invasive tests lead to more effective treatment but it did support the need for the larger study, and confirmed that such a study can be conducted.
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**This report**

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