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Trial participation as a strategy to avoid overdiagnosis

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IUT in diagnosis of urinary incontinence

- Options for reaching a diagnosis
- Invasive and non-invasive options
- Invasive come with potential costs



Uncertainty about use of IUT

- Appropriate position in diagnostic pathway not clear
- Yet often considered ‘normal care’ in practice

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Doing diagnosis: Whether and how clinicians use a diagnostic tool of uncertain clinical utility



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INVESTIGATE-I

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RESEARCH

Open Access



A mixed methods study to assess the feasibility of a randomised controlled trial of invasive urodynamic testing versus clinical assessment and non-invasive tests prior to surgery for stress urinary incontinence in women: the INVESTIGATE-I study

Paul Hilton^{1*}, Natalie Armstrong², Catherine Brennan³, Denise Howell⁴, Jing Shen⁴, Andrew Bryant⁴, Douglas G. Tincello², Malcolm G. Lucas⁵, Brian S. Buckley⁶, Christopher R. Chapple⁷, Tara Homer⁴, Luke Vale⁴, Elaine McColl^{3,4} and on behalf of the INVESTIGATE studies group

Methods

- Qualitative interviews
- Purposive sample of 29 trial participants
- Analysis based on constant comparative method



Awareness of invasive urodynamic testing,
and a wish to avoid it

- *I had spoken to other people who had had the same operation as I was going to have and they had told me that the worst part about the operation, apart from being in hospital and having the operation and the discomfort afterwards, was having the tests beforehand and they said it just felt like there was a lot of discomfort and, you know, it's just not a very nice experience. (Interviewee 08, basic clinical assessment)*

Avoidance as a primary motivator for participation

- *What really worried me was having all the bladder tests beforehand because I felt quite stressed about things like that and I was told there was a chance if I entered the trial I might still have to have them but there was a chance I might not have to have them, which was quite a good incentive. (Interviewee 05, basic clinical assessment)*

Reactions to trial allocation

- *We were laughing and I said oh I am bound to be picked to do it [IUT] because (laughs) it's one of them things you think, God I hope I am not picked to do it and then they go oh yes you have been picked to do it. (Interviewee 07, urodynamics)*

The potential to avoid invasive testing outside of the trial context

- *WHAT WAS YOUR FIRST REACTION WHEN YOU WERE TOLD ABOUT THE TRIAL FIRST OF ALL?*
- *Probably to not take part, because I promised myself I'd never take part in any trials. I'd previously been involved in a trial when I was pregnant with my first child and it didn't affect the delivery but we were at a different hospital than we would've chosen had we not been part of that trial and I had a very traumatic delivery which caused the incontinence, and it was quite. . .caused quite a lot of damage, well my child had brain injuries as a result, and so I was quite. . .I promised myself I'd never get involved in a trial again [. . .] but the big carrot was potentially not having the bladder function tests. (Interviewee 05, basic clinical assessment)*

Discussion

- Previously undeclared preferences surfaced
- No apparent discussion of these with health professionals
- Trial participation is probably not the optimal mechanism to achieve desired end

Original Research Paper

Trial participation as avoidance strategy: a qualitative study

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Issue



Health Expectations
Early View (Online Version of Record published before inclusion in an issue)

