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A randomised controlled cluster trial to evaluate an electronic system for assessing pelvic floor symptomatology in women

Submission date 30/09/2004	**Recruitment status** No longer recruiting
Registration date 30/09/2004	**Overall study status** Completed
Last Edited 13/09/2017	**Condition category** Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0059132289

Study information

Scientific Title
A randomised controlled cluster trial to evaluate an electronic system for assessing pelvic floor symptomatology in women

Study objectives
We aim to evaluate the impact of a new electronic pelvic floor symptoms assessment questionnaire (e-PAQ) on the diagnosis and management of pelvic floor disorders, compared with traditional clinical interviewing. We propose to evaluate this system in a randomised, controlled cluster trial in the areas of pelvic floor medicine in which it is likely to be employed; community continence clinics (physiotherapists and continence nurses) and in secondary care (urologists, gynaecologists and colorectal surgeons). The study will focus on detection rates of symptoms, the patient's perspective of the clinical episode and subsequent referral rates and prescribing patterns.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Pelvic floor symptoms

Interventions
A randomised controlled cluster trial of a new electronic pelvic floor symptoms assessment questionnaire (e-PAQ), compared with traditional clinical interviewing for the diagnosis and management of pelvic floor disorders

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Added 28/01/10:
1. Factor analysis
2. Reliability
3. Validity
4. Patient satisfaction
5. Completion times
6. System costs

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/10/2005

Eligibility

Key inclusion criteria
Sheffield patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/12/2003

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
STH NHS Trust
Sheffield
United Kingdom
S10 2SF

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sheffield Teaching Hospitals NHS Foundation Trust (NHS R&D Support Funding)

Funder Name
Urogynaecology research fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2006		Yes	No
Results article	results	01/10/2008		Yes	No