

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/09/2017	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

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 measure

Added 28/01/10:

1. Factor analysis
2. Reliability
3. Validity
4. Patient satisfaction
5. Completion times
6. System costs

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2003

Completion date

01/10/2005

Eligibility**Key inclusion criteria**

Sheffield patients

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Target recruitment: 1500

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

England

United Kingdom

Study participating centre

STH NHS Trust

Sheffield

United Kingdom

S10 2SF

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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

Funder Name

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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