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Stage 3 Pilot Study: a decision tool to improve the management of urinary incontinence in women in the community

Submission date	Recruitment status	[X] Prospectively registered
18/03/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/07/2017	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9940

Study information

Scientific Title
Stage 3 Pilot Study: a decision tool to improve the management of urinary incontinence in women in the community

Study objectives
The overall aim of the project is to develop a decision tool for the management of urinary incontinence in women in the community that can be used by health care professionals based in primary and community care settings (GPs, practice and community nurses). The decision tool has been developed with input from clinicians through a series of focus groups and is being tested for validity and reliability. The aim of the current pilot study is the implementation of the decision tool in practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/H1307/1

Study design
Both; Interventional; Design type: Diagnosis, Process of Care, Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Renal and Urogenital; Subtopic: Not Assigned, Renal and Urogenital (all Subtopics); Disease: All Diseases, Urogenital

Interventions
We seek to recruit at least 60 health care professionals from each of the two study sites and as many patients as present with symptoms of UI during the course of the pilot study.

Use of the decision tool: The decision tool has been developed to imrove the management of urinary incontinence in women in the community.

Follow Up Length: 4 month(s); Study Entry : Other; Details: Patients will not be randomised. It is the health care professionals who will be randomised.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Amelioration of symptoms of urinary incontinence; Timepoint(s): Baseline, 1 months, 4 months

Secondary outcome measures
Not provided at the time of registration

Overall study start date
01/04/2011

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Healthcare professionals: Any healthcare professional who works in a community/primary care setting whose role involves assessment and management of urinary incontinence in women in the community. Health care professionals will be working within two primary care trusts where NHS permissions will be sought for the study to proceed
2. Patients: Women who are over 18 years of age, not pregnant and have symptoms of urinary incontinence are eligible to be invited into the study.; Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Key exclusion criteria
1. Health care professionals who were involved in the intial development of the decision tool
2. Patients who are under 18 years of age

3. Patients who are pregnant
4. Patients who are unable to give informed consent

Date of first enrolment
01/04/2011

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of York (UK)

Sponsor details
Department of Health Sciences
York Trials Unit
Area 4
Sebohm Rowntree Building, Heslington
York
England
United Kingdom
YO10 5DD

Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit Programme (ref: grant codes: PB-PG-1207-15081)

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