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Evaluation of services for urinary dysfunction

Submission date	Recruitment status	[_] Prospectively registered
25/10/2000	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/09/2007	Urological and Genital Diseases	

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
G9410491

Study information

Scientific Title

Study objectives
The objective of the phase I trial is to compare a new Continence Nurse Practitioner (CNP) led service with existing service provision for individuals with incontinence and lower urinary tract symptoms in terms of symptom severity, associated factors, impact and economic implications. Treatment in the nursing service lasts eight weeks. The new nursing service delivers a package of evidence based interventions for the provision of continence care which are protocol driven.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Urinary dysfunction

Interventions
1. Existing service provision: general practitioners and primary health care team
2. Nurse led service provision: new service instituting evidence based assessment and interventions provided by specially trained nurses

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
An independent interview is carried out 13 weeks and 26 weeks after randomisation in both arms of the trial . This measures symptom severity, associated factors, impact (social and psychological) and economic aspects of the condition.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/1996

Completion date
31/03/2002

Eligibility

Key inclusion criteria
Urinary dysfunction measured on a postal questionnaire (incontinence, nocturia, frequent voiding, urinary urgency)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
6000

Key exclusion criteria
1. Pregnancy
2. Malignancy
3. Fistula
4. Those already in receipt of treatment

Date of first enrolment
01/06/1996

Date of final enrolment
31/03/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Epidemiology and Public Health
Leicester
United Kingdom
LE1 2TP

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/08/2002		Yes	No