

Evaluation of services for urinary dysfunction

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/09/2007	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

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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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clinical.trial@headoffice.mrc.ac.uk

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