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Randomised controlled trial and cost-effectiveness evaluation of an interactive video system to promote shared decision making in general practice

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
24/08/2007

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

Contact name
Dr Elizabeth Murray

Contact details
Primary Care and Population Sciences
University College London
Holborn Union Building
Archway Campus
London
United Kingdom
N19 3EU
+44 (0)20 7288 3091
elizabeth.murray@pcps.ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PSI04-13

Study information

Scientific Title

Study objectives
To determine whether a decision aid on benign prostatic hypertrophy influences decision making, health outcomes, and resource use.

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)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Urological and genital diseases: Other urological and genital disease

Interventions
Patients with clinical diagnosis of benign prostatic hypertrophy were referred into the study by their General Practitioner (GP). The intervention group received an information package consisting of a session with an evidence based interactive video disc plus printout plus booklet; the control group received normal care only. Data were collected at baseline, three months and nine months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patients' and general practitioners' perceptions of who made the decision, decisional conflict scores, treatment choice and prostatectomy rate, American Urological Association symptom scale, costs, anxiety, utility, and general health status.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1996

Completion date
31/12/1999

Eligibility

Key inclusion criteria
1. Men attending participating general practices with a clinical diagnosis of benign prostatic hypertrophy and sufficient command of English to consult without an interpreter
2. Any clinical suggestion of carcinoma of the prostate
3. Chronic retention of urine
4. Recent urinary tract infection
5. Recent acute urinary retention
6. History of prostate surgery
7. Severe visual or hearing impairment, such that the patient could not use the decision aid
8. Severe learning difficulties or mental illness, such that the patient might not be competent to reach an informed decision

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
112

Key exclusion criteria
1. Any clinical suggestion of carcinoma of the prostate
2. Chronic retention of urine
3. Recent urinary tract infection
4. Recent acute urinary retention
5. History of prostate surgery
6. Severe visual or hearing impairment, such that the patient could not use the decision aid

7. Severe learning difficulties or mental illness, such that the patient might not be competent to reach an informed decision

Date of first enrolment
01/01/1996

Date of final enrolment
31/12/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care and Population Sciences
London
United Kingdom
N19 3EU

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Primary and Secondary Care Interface National Research and Development Programme (UK)

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		01/09/2001		Yes	No