

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

Prospectively registered

Protocol

Registration date
23/01/2004

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
24/08/2007

Condition category
Urological and Genital Diseases

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

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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