

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

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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