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A randomised controlled trial of the effects of a web based Prostate Specific Antigen decision explorer, Prosdex

Submission date 21/03/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/04/2007	**Overall study status** Completed	
Last Edited 15/12/2011	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RCUC062 C6475/A7490

Study information

Scientific Title

Acronym
PROSDEX

Study objectives
To evaluate the effects on men of a web-based Prostate Specific Antigen (PSA) decision-aid, Prosdex. The objectives are to assess the effect of Prosdex on:
1. Knowledge of PSA and prostate cancer-related issues
2. Attitudes to testing
3. Decision conflict
4. Anxiety
5. Intention to undergo PSA testing
6. Uptake of PSA testing

In addition, a mathematical simulation model of the effects of Prosdex on subsequent resource use and health outcomes will be developed. The null hypothesis, based on the principal outcome, knowledge, is that Prosdex would not have an effect on knowledge of PSA and prostate cancer-related issues.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the South East Wales Research Ethics Committee, Panel D on the 8th January 2007 (ref: 06/WSE04/138).

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
PSA decision aids, prostate cancer

Interventions
A web-based PSA decision aid, Prosdex: it will require a password for access and will generate the online questionnaire.

Intervention group:
Group one: Men in intervention group one will be asked to log onto and view the website, either in their own homes or in another setting of their choice.
Group two: The second intervention group will receive a paper document comprising the text of the website. This enables evaluation of the Prosdex features (e.g. video clips and the structured decision support) that go beyond the mere presentation of the text content.

Control group:
Group three: In the first control group, men, after inserting their password, will be asked to complete the online questionnaire without viewing Prosdex.
Group four: The second control group will not initially be given the details of the study website.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Knowledge of PSA and prostate cancer-related issues: this will be assessed using a set of knowledge questions, used in an earlier evaluation of a brief paper-based leaflet about PSA testing, which showed an ability to discriminate between intervention and control groups.

The primary outcome, knowledge, will be measured immediately after the intervention: that is, men will be directed, automatically, from the Prosdex website to the online questionnaire. Men in the second intervention group and the first control group will also be asked at T0 to log onto the online questionnaire.

Key secondary outcome(s))
The secondary outcome measures will be measured immediately after the intervention: that is, men will be directed, automatically, from the Prosdex website to the online questionnaire.

1. Attitudes to testing: this will use a 12-item scale developed and used in the same evaluation of a brief paper-based leaflet about PSA testing
2. Decision conflict: this scale measures patients confidence or uncertainty (conflict) about whether they feel their choice is the best for them personally. It has acceptable validity and reliability (internal consistency alpha coefficients range from 0.78 - 0.89; test-retest reliability coefficients exceed 0.80). Given the nature of the decision about having a PSA test, with a high degree of uncertainty likely to affect decision making, it is important to use this, the most widely used outcome measure in decision aid studies
3. Anxiety: This will be assessed using the short form Spielberger questionnaire for state anxiety, validated and shown to be responsive in our earlier studies of shared decision making and risk communication
4. Intention to undergo PSA testing: this will be assessed using a single item question, with Likert-like response scale, which has also been used in our earlier evaluation of a brief paper-based leaflet about PSA testing
5. Uptake of the PSA test: measured six months after the intervention

In addition, based on these results, a mathematical simulation model of the effects of Prosdex on subsequent resource use and health outcomes will also be developed. Secondary outcomes one to four, in addition to the primary outcome, knowledge, will be gathered from the online questionnaire.

After the six month PSA testing, all the men will be asked to to complete the online questionnaire again.

Completion date
01/06/2008

Eligibility

Key inclusion criteria
Men between ages of 50 and 75

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Previous PSA test or prostate cancer
2. Inability to access internet
3. Men who are known to be unable to read English
4. Serious uncontrolled medical conditions or concurrent medical illness likely to compromise life expectancy
5. Severe mental illness or dementia

Date of first enrolment
01/10/2007

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of Primary Care and Public Health
Cardiff
United Kingdom
CF14 4YS

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK) (ref: C6475)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	1. results	26/05/2010		Yes	No
Results article	results	06/08/2010		Yes	No