

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

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| Submission date 21/03/2007 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/04/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 15/12/2011 | Condition category Cancer | <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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/10/2007

Completion date

01/06/2008

Eligibility

Key inclusion criteria

Men between ages of 50 and 75

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

600

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)

Sponsor details

Research and Commercial Division

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30 - 36 Newport Road

Cardiff

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DaviesKP2@cf.ac.uk

Sponsor type

University/education

Website

<http://www.cardiff.ac.uk/index.html>

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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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 | 1. results | 26/05/2010 | | Yes | No |
| Results article | results | 06/08/2010 | | Yes | No |