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# A decision explorer for women deciding about breast cancer treatments

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 29/04/2010 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 29/04/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 25/02/2019 | 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**
4261

## Study information

**Scientific Title**
A decision explorer for women deciding about breast cancer treatments: BresDex trial

**Acronym**
BresDex

## Study objectives
Women who have breast cancer often have a choice of operations, the most common include either mastectomy or breast conservation surgery followed by radiotherapy. Women faced with such choices need clear, accurate information about what the treatments involve and how they differ. They also need to be able to think about how they feel about these options, so they can make a choice that is best for them. Equivalent survival data have led to an assumed view that women, if offered a choice, would choose to have breast conservation surgery. However, studies reveal national and international variation in surgical practice in this area. Our research highlights the importance of addressing treatment expectations and preferences of both patients and professionals.

Experience in other areas demonstrate patient decision support tools (aids) can be useful where difficult decisions exist. At present, such tools are not available for the UK context. These tools help people make informed choices, consistent with their views and values, and support them to the extent they need. Such tools are an important extension of the information giving that is currently available, but does not replace the vital contact between patient and professionals. We propose to develop, validate, field test, and evaluate the impact of an interactive decision explorer in helping UK women make decisions about treatment after they have been told they have early breast cancer.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
MREC for Wales approved on the 5th February 2007 (ref: 07/MRE09/3)

## Study design
Non-randomised interventional and observational trial

## Primary study design
Observational

## Study type(s)

## Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

## Interventions
Internet bases decision aid/explorer called BresDex. BresDex is designed to support women diagnosed with early breast cancer who do not have to have a mastectomy, but instead have the option of a wide local excision. This support is to be provided as an adjunct to the help and support women currently receive from their clincial teams.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
Online quantitative study which looks at how patients use BresDex

### Key secondary outcome(s))
A qualitative study exploring patients reactions to BresDex while facing this decision.

### Completion date
31/03/2010

## Eligibility

### Key inclusion criteria
Patient needs assessment:
1. Women diagnosed as having early breast cancer within 3 to 6 months of their 1st therapeutic treatment
2. Given an option of either breast conservation surgery or mastectomy

Professional needs assessment:
Data will be collected from a purposive sample of NHS based individuals recruited to represent a number of multidisciplinary breast teams and their constituent members; breast surgeons, breast care nurses, breast oncologists, opinion leaders with expertise in the surgical, oncological and psycho-oncological perspectives of breast cancer management including a representative of the Association of Breast Surgeons at the British Association of Surgical Oncology (BASO).
Inclusion criteria:
1. Willingness to be interviewed about this area of clinical practice
2. Experience of directly dealing with women facing treatment decisions for early breast cancer

Prototype development:
1. Women (any age) diagnosed as having early breast cancer (stage 1)
2. Given an option of either breast conservation surgery or mastectomy
3. Within 3 to 6 months of their first therapeutic treatment

External key informants including the health care professionals identified and consented in Step 3 and those nominated by the Study Management Group who agree to provide formative advice will also be consulted during the prototype development. These key informants must show a willingness to participate in the development and evaluation of a prototype of the decision explorer.

Evaluation of completed decision explorer:
1. Women (any age) diagnosed as having early breast cancer (stage 1 and 2)
2. Surgical treatment options

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
Patient needs assessment:
1. Women beyond 6 months of their initial therapeutic treatment who have chosen to undergo either breast conservation surgery or mastectomy
2. Women recently diagnosed with breast cancer who were not given surgical treatment options
3. Any conditions or illness that preclude the completion of a semi-structured interview about the issue of breast cancer, i.e. mental illness such as severe anxiety or depression likely to be exacerbated by discussing the diagnosis
4. Any conditions precluding the ability to give informed consent to participate in the study

Professional needs assessment:
1. For the sample of NHS-based multidisciplinary team members, health care professionals who are not permanent specialist members of specialist multidisciplinary breast team
2. Individuals not routinely involved in discussing treatment options with patients newly diagnosed with breast cancer

Prototype development:
1. Women beyond 6 months of their initial therapeutic treatment who have chosen to undergo either breast conservation surgery or mastectomy
2. Women recently diagnosed with breast cancer who were not given surgical treatment options
3. Any conditions or illness that preclude the completion of a semi-structured interview about the issue of breast cancer, i.e. mental illness such as severe anxiety or depression likely to be exacerbated by discussing the diagnosis
4. Any conditions precluding the ability to give informed consent to participate in the study

Evaluation of completed decision explorer:
1. Women beyond their initial therapeutic surgical treatment who have chosen to undergo either breast conservation surgery or mastectomy
2. Women recently diagnosed with breast cancer who were not given surgical treatment options
3. Any conditions or illness that preclude the completion of a semi-structured interview about the consideration of treatment choices for early breast cancer, i.e. mental illness such as severe anxiety or depression likely to be exacerbated by discussing the diagnosis
4. Conditions precluding the ability to give informed consent to participate in the study
5. Health care professionals who are not involved in the care and therefore the recruitment of patients asked to use the decision explorer in this step

### Date of first enrolment
03/12/2007

### Date of final enrolment
31/03/2010

## Locations

### Countries of recruitment
United Kingdom

Wales

**Study participating centre**
**Department of Primary Care and Public Health**
Cardiff
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# Sponsor information

**Organisation**
Cardiff University (UK)

**ROR**
https://ror.org/03kk7td41

# Funder(s)

**Funder type**
Charity

**Funder Name**
Cancer Research UK (CRUK) (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 | results | 01/08/2012 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |