

A decision explorer for women deciding about breast cancer treatments

Submission date 29/04/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/04/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/02/2019	Condition category Cancer	☐ 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

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)

Primary study design

Observational

Study design

Non-randomised interventional and observational trial

Study type(s)

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions

Internet based 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 clinical 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
United Kingdom
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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