ISRCTN18709765 https://doi.org/10.1186/ISRCTN18709765

A decision explorer for women deciding about breast cancer treatments

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Stephanie Sivell

Contact details
Department of Primary Care and Public Health
Centre for Health Sciences Research
3rd Floor, Neuadd Meirionnydd, Heath Park
Cardiff
United Kingdom
CF14 4XN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Online quantitative study which looks at how patients use BresDex

Secondary outcome measures
A qualitative study exploring patients reactions to BresDex while facing this decision.

Overall study start date
03/12/2007

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

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 148

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
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Division
7th Floor, 30 - 36 Newport Road
Cardiff
Wales
United Kingdom
CF24 0DE

Sponsor type
University/education

Website
http://www.cardiff.ac.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, 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	results	01/08/2012		Yes	No