The Process Evaluation of the Bridging the Age Gap in Breast Cancer decision support intervention cluster randomised trial.

Maria Burton
Kate Lifford, Lynda Wyld, Fiona Armitage, Karen Collins, Malcolm Reed,
Kate Brain, Adrian Edwards,
on behalf of the Age Gap Team
Trial Design

Cohort Study
53 sites

22 Intervention Sites
Usual Care + access to DESI(s)

25 Usual Care Sites
Continuation of usual practice

Primary Outcome - Quality of Life

- Spielberger State-Trait Anxiety Inventory (STAI)
- Decision Regret Scale (DRS)
- CollaboRATE
- The Brief Illness Perception Questionnaire (BIPQ)
- Brief COPE

Treatment Decision support Consultation

Process Evaluation

Discussing Treatment Options
Development of On-line Decision Aid

Registry (Section 7)
- Retrospective data
- 10 year follow up

Cohort Study (Section 9)
- Prospective data
- 2 year follow up

Health Economic Modelling (sections 8)
- Local Control
- Overall survival
- Disease specific survival
- Quality of life

Health Economic Modelling (sections 10)
- Age
- Comorbidity
- Frailty
- Disease Biology
- Cognitive ability
- Independence
- Treatment type
- Treatment related side effects

Web Based Clinician Decision Aid for PET versus Surgery choice (section 11)
Web Based Clinician Decision Aid for adjuvant chemotherapy (section 11)
Overview of Development of Booklet and Brief Decision Aid

Qualitative interviews

Systematic literature review

Published evidence

Views of older women

Expert view

Scientific reference group

Quantitative questionnaires

Evidence summary for DSI characteristics

Media type and format for DSI

Information content for decision making

DSI construction and field testing

Multi-centre cluster RCT
What is a Process Evaluation?

- Process evaluations aim to explain how complex interventions work.

- MRC guideline suggest examining:
  - Fidelity *whether the intervention was delivered as intended*
  - Adaptation *alterations made to the intervention in order to achieve a better contextual fit.*
  - Reach *whether the intended audience comes into contact with the intervention, an how.*
  - Dose *the quantity of intervention implemented*
  - Participants response to intervention *how participants interact with the intervention*
Process Evaluation - Aims

The process evaluation will help us to understand the trial results; why there was or was not an effect of the decision support intervention(s) (DESI)

Aims
1. To assess DESI usage, usefulness and acceptability, and to consider facilitators and barriers to everyday clinical use

2. To compare the levels of shared decision making and information provision in the two trial allocation groups
Process Evaluation Methods

Mixed-methods: interviews, questionnaires and audio-recording of consultations

16 sites (8 usual care, 8 intervention)
- Random selection, stratified by trial arm & recruitment rate

Audio-recording of consultations (chemotherapy decision only)
Patient questionnaires
Clinician interviews (intervention arm only)
Patient interviews
Staff Trained in DESI usage

<table>
<thead>
<tr>
<th>Category</th>
<th>All Intervention sites (220 N=229)</th>
<th>PE sites (8) N=91</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgeons/physicians</td>
<td>57</td>
<td>21</td>
</tr>
<tr>
<td>Admin</td>
<td>17</td>
<td>12</td>
</tr>
<tr>
<td>Clinical nurses</td>
<td>53</td>
<td>19</td>
</tr>
<tr>
<td>Research nurses</td>
<td>53</td>
<td>14</td>
</tr>
<tr>
<td>Oncology medics</td>
<td>15</td>
<td>6</td>
</tr>
<tr>
<td>Trials staff</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>Imaging staff</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Miscellaneous*</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>229</strong></td>
<td><strong>91</strong></td>
</tr>
</tbody>
</table>
PE Recruitment

8 intervention sites

PET or surgery
target 15-20
23 interviews

Chemotherapy
target 15-20
11 interviews

8 usual care sites

PET or surgery
target 15-20
23 interviews

Chemotherapy
target 15-20
15 interviews

1 consultation
audio-recorded

7 consultations audio-recorded
(4 from one site, and 2 from two other sites)

Questionnaires:
20 CollaboRate
31 Discussing Treatment Options
Patient Interview Findings

- **Treatment choice and decision making**
  - Not all offered choice - but most aware of treatment options
  - Most felt supported and were given time
  - Satisfaction level with DM was high
  - Chemo - some women felt they had 'no choice' but to accept
  - Some rejected prior to consultation - some then changed to accept
  - Patients were keen to have reassurance the decision was 'correct'

- **Use & usefulness of information**
  - Received large amounts of information
  - Helped to understand the treatment options & process
  - Verbal info more impactful - with written support
  - Written often read - some shared with family
  - DESI (PvS & Chemo) not always confidently identified. Booklet most often used
  - Rare for all elements of DESI to be used together
Patient Interview Findings

• Impact of information

  • Difficult to split the impact of verbal and written information

  • 3 primary uses of information
    • allowed active involvement in decision making
    • provided reassurance the correct decision was made
    • it allowed understanding of the process and details of treatment enabling them to cope with the decision
HCP Interview Findings

• 6 surgeons, 1 nurse practitioner, 1 oncologist
• Online tool - well liked
  • prior to consultation, helped in discussion with patients / supported decision-making
  • provided objectivity to thinking - evidenced based
  • personalised sheet useful or 'a bit harsh'
• Impact of tool use:

  "I’m biased in the way that I think that you know people should be offered surgery [...]... the tool swayed me on the other area and also the patients so, it has changed in my practice."

  "I’ve been quite surprised how much benefit they do get out of surgery and so that’s altered the perception on a number of patients"
Possible barriers to implementation

• Training - ? reached the staff who were best placed to use DESIs
• Numerous staff changes
• Difference in understanding what constitutes choice
• Seen as a research study and not integrated as part of usual practice
Limitations of Process Evaluation

- Self selection of interviewees - may not recruit the frailer patients
- Low numbers of questionnaires
- Low representation of HCPs giving feedback
Summary

• Where the DESIs have been implemented they have been valued by both staff and patients.
• The number of 'hits' on the on-line tool indicates a lot of interest from sites.
• Further integration of the findings is required to understand the factors that affected implementation of the DESIs.
Acknowledgements

All participants, site staff and PPI members for their most important input.

Funding

The Bridging the Age Gap in Breast Cancer Study has been funded by the National Institute for Health Research (NIHR) under the Programme Grants for Applied Research programme (RP-PG-1209-10071). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.