

Efficient development and usability testing of decision support interventions for older women with breast cancer

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1 **ORIGINAL RESEARCH**

2 **Title:** Efficient development and usability testing of decision support interventions for older
3 women with breast cancer.

4 **Short running header:** Breast cancer decision support intervention development and testing.

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5

Accepted manuscript

1 **Abstract**

2 Around a third of breast cancers diagnosed each year in the UK are in women aged 70 years
3 and older. However, there are currently no decision support interventions for older women
4 who have a choice between primary endocrine therapy and surgery followed by adjuvant
5 endocrine therapy (surgery+endocrine therapy), or who can choose whether or not to have
6 chemotherapy following surgery. There is also little evidence-based guidance specifically on
7 the management of these older patients. A large UK cohort study is currently underway to
8 address this lack of evidence and to develop two decision support interventions (DESI) to
9 facilitate shared decision-making with older women about breast cancer treatments. Here we
10 present the development and initial testing of these two DESIs.

11 An initial prototype DESI was developed for the choice of primary endocrine therapy or
12 surgery+endocrine therapy. Semi-structured interviews with healthy volunteers and patients
13 explored DESI acceptability, usability and utility. A framework approach was used for analysis.
14 A second DESI for the choice of having chemotherapy or not was subsequently developed
15 based on more focused development and testing.

16 Participants (n=22, aged 75-94 years, 64% healthy volunteers, 36% patients) found the primary
17 endocrine therapy/surgery+endocrine therapy DESI acceptable, and contributed to improved
18 wording and illustrations to address misunderstandings. The chemotherapy DESI (tested with
19 14 participants, aged 70-87 years, 57% healthy volunteers, 43% patients) was mostly
20 understandable, however suggestions for re-wording sections were made. Most participants
21 considered the DESIs helpful, but highlighted the importance of complementary discussions
22 with clinicians.

23 It was possible to use a template DESI to efficiently create a second prototype for a different
24 treatment option (chemotherapy). Both DESIs were acceptable and considered helpful to

1 support/augment consultations. Development of acceptable additional DESIs for similar target
2 populations using simplified methods may be an efficient way to develop future DESIs. Further
3 research is needed to test the effectiveness of the DESIs.

4 **Keywords:** patient decision aids; decision support; shared decision-making; breast cancer;
5 older patients.

6

Accepted manuscript

1 Introduction

2 Each year about a third of all new invasive breast cancer diagnoses in the UK are in women
3 aged 70 or above.¹ Several patient decision aids exist to support women with breast cancer
4 when making treatment decisions.² However, to date none has been developed for older
5 women with oestrogen receptor positive breast cancer who have a choice between primary
6 endocrine therapy and surgery followed by adjuvant endocrine therapy (surgery+endocrine
7 therapy), or for older women with high recurrence risk breast cancers (eg HER2 positive,
8 oestrogen receptor negative, node positive) who can choose whether or not to have
9 chemotherapy following surgery. The current absence of decision support may, in part, reflect
10 heterogeneous research and practice in managing breast cancer in older women. ³⁻⁶

11 Research is needed to guide clinicians (this term is used to include all healthcare professionals)
12 and patients about appropriate treatment for older women with oestrogen receptor positive
13 breast cancer and for older women with breast cancer with high recurrence risk. Surgery is the
14 recommended treatment for breast cancer for those who are fit enough, that is unless
15 precluded due to comorbidities.^{7,8} However, the benefits of surgery vary in older women
16 because life expectancy varies; there are some women for whom primary endocrine therapy
17 may be as effective as surgery if they have a reduced life expectancy.⁹ For older women (70
18 plus), randomised trials have shown that while overall survival is not significantly different,
19 primary endocrine therapy is less effective for local control⁹ and survival outcomes may be
20 inferior on long term follow up¹⁰. The decision for older women is therefore preference
21 sensitive. There is evidence of benefit of chemotherapy following surgery for older women
22 with high risk breast cancer.^{7,11} However, the trial evidence to underpin this is weak relative to
23 other age groups, side-effects are more common in older women,¹² and the benefits of

1 chemotherapy are less marked than in younger women. Consequently, rates of adjuvant
2 chemotherapy use are highly variable across the UK in this older population.¹³

3 The Bridging the Age Gap in Breast Cancer programme (National Institute for Health Research
4 Programme Grants for Applied Research programme RP-PG-1209-10071, ISRCTN 46099296/
5 32447¹⁴) aims to provide guidance to clinicians about management and to provide decision
6 support for patients. As part of this programme of work, decision support interventions (DESIs)
7 for two treatment choices (primary endocrine therapy or surgery+endocrine therapy and
8 adjuvant chemotherapy or no chemotherapy) were developed. DESIs are tools that aim to
9 support shared decision-making between clinicians and patients. The DESIs developed as part
10 of this study each included a brief decision aid to be used within a consultation (a table of
11 frequently asked questions with the answers for each treatment option), along with a booklet
12 for patients that provided detailed information and a values clarification exercise (see methods
13 for more details) for use at home, with family or friends if desired. Guidelines from the
14 International Patient Decision Aid Standards (IPDAS)¹⁵ were consulted for advice on areas such
15 as how to best present probabilities. An online algorithm to predict individual survival
16 outcomes under each treatment option has also been developed (similar to Adjuvant! Online¹⁶
17 and PREDICT¹⁷), for clinicians to use alongside the DESIs in clinical practice, which permits
18 some tailoring of outcomes for the different options according to disease stage and type, age
19 and fitness. Development and usability testing of the brief decision aids and booklets are the
20 focus of the present study.

21 Although it has been assumed that older cancer patients have stronger preferences for taking
22 passive roles (doctor-centred or paternalistic decision-making) in the decision-making process
23 than younger patients,¹⁸⁻²⁰ recent evidence suggests that many older cancer patients do want
24 to be involved in treatment decisions,²⁰ including women with breast cancer.²¹⁻²⁴ Preferences

1 for decision-making style vary amongst older women with breast cancer treatment
2 decisions.^{22,23} In a questionnaire survey of women aged 75 years and over who had previously
3 had a choice of primary endocrine therapy or surgery+endocrine therapy, preferences for
4 patient-centred or doctor-centred decision-making were fairly even (39% and 38%
5 respectively) with slightly fewer preferring shared decision-making (24%).²² Most women
6 discussing chemotherapy were found to prefer to be involved in decision-making.²³ DESIs
7 improve knowledge, accuracy of risk perception and participation in decision-making as well as
8 decreasing aspects of decisional conflict in decision-making in older samples.²⁵ They may
9 therefore be particularly useful for clinicians and older women.

10 When developing DESIs it is important to use a transparent and systematic approach.¹⁵ This
11 includes an initial needs assessment and collating and summarising the clinical evidence.¹⁵
12 Another integral part of DESI development is usability testing, before finalising it for
13 effectiveness testing and implementation.²⁶ This consists not only of checking the DESI for
14 clarity and understanding but also for its perceived usefulness by the target population and
15 potential implementation barriers and facilitators. Field testing with patients facing the
16 decision and their clinicians involved in shared decision-making about the decision has been
17 included as a criterion of decision aid quality in the IPDAS instrument (IPDASi).^{26,27} The aims of
18 the present study were to (1) develop two DESIs (primary endocrine
19 therapy/surgery+endocrine therapy and chemotherapy) for older women with breast cancer
20 treatment choices, with a more focused development and testing stage for the second DESI
21 and (2) test the DESIs for usability, acceptability and utility amongst older participants.

1 **Methods**

2 **Prototype development**

3 Approval for healthy volunteer involvement in the study was obtained from Cardiff University
4 School of Medicine Research Ethics Committee (reference 13/72) and Brighton and Sussex
5 Medical School Research Governance and Ethics Committee (reference 15/111/HAR). Approval
6 of the study protocol for patient involvement was obtained from the National Research Ethics
7 Service London - Surrey Borders committee (reference 12/LO/1722) and the appropriate
8 National Health Service Trust Research and Development Departments.

9 **Primary endocrine therapy/surgery+endocrine therapy DESI**

10

INSERT FIGURE 1 ABOUT HERE

11 A schematic representation of DESI development is shown in Figure 1. The prototype DESI
12 (brief decision aid plus booklet) was initially based upon literature reviews and analyses of
13 previous patient interviews conducted by members the group^{9,10,18,21,24} and was developed
14 using an iterative process. Literature reviews were conducted of the clinical evidence and
15 patient informational needs and preferences. Existing breast cancer treatment decision aids
16 were also reviewed. Data from patient interviews^{21,24} and a focus group with healthy female
17 volunteers in the same age group (not reported here) were collected and a summary of all the
18 collated evidence was produced. The Coping in Deliberation (CODE) framework²⁸ was the
19 theoretical basis for the DESI.²⁴ The CODE framework highlights that cognitions, emotions and
20 coping are important in healthcare decisions throughout the deliberation process.²⁸ The DESI
21 therefore addressed cognitive and emotional processes throughout deliberation as well as
22 coping resources. The CODE framework was previously adapted for the decision about primary
23 endocrine therapy or surgery+endocrine therapy in older women²⁴ and this was included
24 within the overall evidence summary which guided the content of the DESI. An expert

1 reference group consisting of 15 experts in the field (plus a chair from the study management
2 group) reviewed the clinical evidence summary in detail (they also had the opportunity to
3 comment on a draft prototype and the overall evidence summary). The overall summary was
4 used as a basis for the DESI content. Guidelines from the Plain English Campaign²⁹ were
5 followed and editorial suggestions to improve the readability of the DESI were received from
6 the Plain English Campaign²⁹ before testing with patients (the final brief decision aid and
7 booklet had 'Crystal Marks' for clarity from the Plain English Campaign²⁹). Feedback from
8 healthcare professionals (n=3) who used the DESI during testing with patients was used to
9 improve the DESI (not reported here). An outline of the DESI content is shown in Figure 2.

10 **INSERT FIGURE 2 ABOUT HERE**

11 **Chemotherapy DESI**

12 A similar but more focused method was used to develop the prototype chemotherapy DESI.
13 Content was based on analysis of patient interviews²³ and a review of the published clinical
14 evidence about chemotherapy use in older women by a small group of experts. The format
15 and style (and some of the wording/headings/questions where appropriate) of this DESI were
16 based on the primary endocrine therapy/surgery+endocrine therapy DESI due to similarity
17 between the patient populations. An outline of the chemotherapy DESI content is shown in
18 Figure 3.

19 **INSERT FIGURE 3 ABOUT HERE**

20 **Usability testing**

21 Following initial development, both prototype DESIs (both brief decision aid and booklet for
22 each decision) were tested for usability, acceptability and utility using semi-structured
23 interviews (supplementary file 1). To minimise burden among women diagnosed with breast

1 cancer, preliminary testing was first conducted among healthy volunteers aged 70 years and
2 over (75 years and over for the primary endocrine therapy/surgery+endocrine therapy DESI).
3 This was followed by testing with patients who had made a breast cancer treatment decision
4 in the last 12 months, before finally testing the DESI (primary endocrine
5 therapy/surgery+endocrine therapy DESI only) with those currently facing the treatment
6 decision. Modifications to the DESIs were made between the two phases based on the results
7 and further changes to the primary endocrine therapy/surgery+endocrine therapy DESI were
8 made following patient feedback.

9 **Sample recruitment**

10 *Volunteers*

11 Female volunteers were recruited from a number of sources including breast cancer charities
12 and local community groups (eg older persons' groups in churches and community centres).
13 Emails and phone calls were made to various organisations and in some cases the researchers
14 visited groups and either gave a presentation or had an informal discussion about the study. A
15 snowball sampling method was used. Invitation packs (including invitation letter, information
16 sheet, consent form and pre-paid envelope) were given to anyone interested.

17 *Patients*

18 Patients were recruited via four UK breast units: Cardiff, Doncaster, Sheffield and
19 Southampton. They were identified from other strands of the Bridging the Age Gap in Breast
20 Cancer programme (having completed a form to register their interest) or from clinic records
21 and multi-disciplinary team meetings. Some patients who had already registered interest in
22 the study were sent an invitation pack directly. Others were invited by a research nurse and/or
23 their clinician.

1 **Procedure**

2 Completed consent forms were returned to the researcher, who then contacted the
3 participants to answer any further questions about the study and arrange an interview.
4 Participants were sent the relevant DESI along with a letter confirming their interview
5 appointment. Semi-structured interviews were conducted at a place convenient to the
6 participant (most in their home, one in a church and six by telephone, and were audio-
7 recorded if participants consented to this). Participants who used the DESI when they faced
8 the decision of primary endocrine therapy or surgery+endocrine therapy and chose surgery
9 were interviewed before surgery. The interview guide included the following topics:
10 understanding of the content, layout, usefulness and potential improvements of the DESI.

11 **Data analysis**

12 Sections relevant to data analysis were transcribed. A framework³⁰ approach was used to
13 analyse the data. This included the following stages a) familiarisation of the data (both
14 listening to the recordings and reading transcripts), b) coding of the data (see Table 1), c)
15 charting the data by each code, d) reviewing and summarising each of the charted codes for
16 the groups of participants. Data were initially coded by KL and 20% was double coded by HH or
17 MB. Following discussions about discrepancies, all transcripts were re-coded (KL). NVivo
18 qualitative data analysis Software³¹ version 11 was used to manage the data.

19 **INSERT TABLE 1 ABOUT HERE**

1 **Results**

2 **Sample characteristics**

3 **Primary endocrine therapy vs Surgery+endocrine therapy DESI**

4 Interviews were completed with 22 women: 14 were healthy volunteers; four were patients
5 who had faced the decision in the last 12 months, and four were currently facing the decision
6 when they first received the DESI. Women were aged between 75 and 94 years (median 82.5
7 years). Volunteers were from South Wales (n=9) and South West England (n=5). Patients were
8 from South Wales (n=3), Wessex (n=3), and Yorkshire and the Humber (n=2). Of the eight
9 patients, four were having primary endocrine therapy and four were due to have (currently
10 facing the decision) or had undergone (previously faced the decision) surgery. Transcripts from
11 21 participants were analysed. One participant chose not to be recorded, therefore
12 interviewer's notes were analysed.

13 **Chemotherapy DESI**

14 Interviews were completed with 14 women: eight were healthy volunteers and six were
15 patients who had faced the decision in the last 12 months. Participants' ages ranged from 70
16 to 87 years (median 74 years). Healthy volunteers from South Wales (n=3), South West
17 England (n=1) and South England (n=4) were recruited and interviewed. Of the six patients, all
18 of whom were from Yorkshire and the Humber, five had had chemotherapy and one had not.

19 **DESI Feedback**

20 Results from the main analyses are presented in three sections below: primary endocrine
21 therapy/surgery+endocrine therapy DESI content, chemotherapy DESI content and DESI
22 use/implementation (covering both DESIs). Sample quotes to demonstrate the findings are
23 presented in Table 2 and referred to in the text in parentheses. Each quote is followed by a

1 description of the participant characteristics as follows: DESI viewed, which element they are
2 referring to and which part of the testing they were involved with (see Table 1 footnote for
3 details).

4 **INSERT TABLE 1 ABOUT HERE**

5 **Primary endocrine therapy/surgery+endocrine therapy DESI content**

6 Generally, the feedback was positive about the primary endocrine therapy/surgery+endocrine
7 therapy DESI. Both the brief decision aid and booklet were understood and mostly clear (A).
8 The brief decision aid was described as the “headlines” and the booklet containing more
9 detailed back up information. Women thought the DESI covered the information patients
10 would want and most women thought the amount of information was appropriate. Some of
11 the healthy volunteers felt the booklet was quite long, but none said the amount should be
12 reduced; rather, it was comprehensive. A mixture of views was given by volunteers about the
13 size of the booklet, some liking the A4 size (user testing paper version) and others liking the
14 idea of an A5 booklet. The graphic design version of the booklet received generally positive
15 feedback from patients in terms of colour, size (A5 was standard and a large print A4 version
16 was also available) and layout. The diagrams and pictures had mixed reviews in terms of both
17 understanding and helpfulness (some thought redundant). A diagram showing lymph nodes
18 was misinterpreted as cancer by one patient (who had previously faced the decision) and was
19 thought quite frightening by two other patients, so was changed during field testing (before
20 testing with patients currently facing the decision) (B). This new version of the diagram was
21 understood. Natural frequencies in the text were understood by most volunteers, although
22 two found them confusing. Pictograms were added in the field testing versions of the booklet
23 and most, but not all, patients were positive about these.

1 Some information lacked clarity and/or caused confusion to the volunteers. Examples include,
2 the information on recurrence not being comparable and for some the values clarification
3 exercise - which included a table with each treatment option listed at the top of each column
4 where participants could enter their preferences for that treatment (see Figure 4 for final
5 version) - needed more explanation (C). These were reviewed by the development team and
6 changes made to the DESI as appropriate before field testing. Similarly, volunteers suggested
7 improvements such as re-wording sentences, emphasising particular pieces of information and
8 adding details which were amended as seen appropriate (D). A number of questions were
9 raised. Some questions raised by volunteers could be addressed within the DESI, others would
10 be asked of a clinician. Patients asked general questions as well as requested clarifications and
11 made suggestions for improvements (E).

12 **INSERT FIGURE 4 ABOUT HERE**

13 **Chemotherapy/no chemotherapy DESI content**

14 The feedback on the chemotherapy DESI was also positive overall. Most women thought that it
15 was understandable and included the things that patients would want to know. However some
16 healthy volunteers acknowledged that some people might need help going through it and one
17 woman found the page about secondary breast cancer and what increases the risk of the
18 cancer spreading (page 5) particularly confusing (F). Despite changes, a few things were not
19 understood by patients, with one not understanding about having trastuzumab and another
20 struggling to understand the increased benefit of trastuzumab (but another woman felt that it
21 clarified some people have trastuzumab alongside chemotherapy). One woman did not seem
22 to understand the increase in benefit that chemotherapy offers; she interpreted the increase
23 as the chance of survival (G).

1 Most liked the layout, describing it as well set out and they liked the photographs (H).
2 However, one woman commented that there were no women from ethnic minorities. The lack
3 of ethnic minority photographs was deliberate because there are currently very few ethnic
4 minority women in the 70 years and over age group in the UK³², although this will change in the
5 future as cohorts age. Some women felt the booklet was a bit repetitive but others felt that
6 the repetition was appropriate and that all the information needed to be included, hence no
7 changes were made. Patients thought the amount of information was about right. Some
8 improvements were suggested by healthy volunteers (eg emphasising that not everyone will
9 experience the side-effects) and patients (eg supplying the information in different languages),
10 however few patients thought that any improvements were needed (I).

11 **DESI use/ implementation**

12 The DESIs were generally thought to be helpful. Women mentioned it being a good basis for
13 questions (eg as a prompt or reminder) and primary endocrine therapy/surgery+endocrine
14 therapy patients talked about reading the information multiple times and finding it useful to
15 be able to do this (K). Many healthy volunteers thought that it would be useful to take the DESI
16 home to read, refer back to and discuss with friends/family with a further discussion with
17 clinicians afterwards. Some mentioned that the information would be too much to take in at
18 the diagnostic consultation or when initially hearing about treatments. They highlighted the
19 importance of discussions with and advice from clinicians and expressed the view that some
20 patients might need additional help with processing the information (L).

21 Many patients (previously facing the decision) thought that it could be helpful for others
22 (including family members) (M). One found it very useful to confirm her chemotherapy
23 decision, another felt she had learned more from the primary endocrine
24 therapy/surgery+endocrine therapy brief decision aid than she had at diagnosis and another

1 found receiving the information as part of the study useful (N). Two patients however, felt the
2 chemotherapy DESI was not for them (one preferring discussions with clinicians). Two patients
3 found some of the information about treatment benefits and survival changes in the
4 chemotherapy DESI upsetting and frightening (for one, possibly due to some misunderstanding
5 of what the natural frequencies were) (G). Two patients who were currently facing the primary
6 endocrine therapy/surgery+endocrine therapy decision thought the DESI had helped to
7 reinforce their initial decision leaning or to make the decision. Only one patient currently
8 facing the decision (primary endocrine therapy/surgery+endocrine therapy) wrote in the
9 values clarification exercise or “My questions” sections (O). The others felt no need to use it as
10 they had already made their decision or spoken with their clinician (J).

11 **Discussion**

12 Two DESIs for older women with breast cancer treatment choices were developed based on
13 the best available published evidence and feedback from healthy volunteers and patients. A
14 detailed and iterative process was used to develop the primary endocrine
15 therapy/surgery+endocrine therapy DESI, both in terms of the initial prototype development
16 (reviews of literature, theory based, new data collected and Plain English Campaign²⁹
17 involvement) and usability testing (with healthy volunteers and patients). It was possible to
18 use the primary endocrine therapy/surgery+endocrine therapy DESI as a template upon which
19 to base the chemotherapy DESI, hence a more efficient development and testing process was
20 used for this second DESI. General feedback about language, colours, format and size of the
21 DESIs was transferable from one to the other. Feedback from participants about the DESIs
22 included many positive comments, but areas of confusion were noted and possible changes
23 were suggested. Potential amendments to the DESIs were discussed amongst the development
24 team and changes made where appropriate (eg in the case where a diagram had been

1 misinterpreted). While the DESIs were thought to be useful (for self or others), some patients
2 preferred not to use the values clarification exercise as they had already spoken with their
3 clinicians or made their decision. However, this section was retained in the DESIs, as helping
4 patients consider and discuss their values and preferences about the options is a key element
5 of decision support.¹⁵ Furthermore, the importance of discussions with clinicians was
6 highlighted by women, and was reflected by the inclusion of signposting to this in the DESIs.

7 To our knowledge, no DESIs currently exist for older women making these two breast cancer
8 treatment choices. The DESIs are currently being trialled within the Bridging the Age Gap in
9 Breast Cancer study as part of an intervention (which includes the booklets, brief decision aids
10 and an online algorithm to predict survival under different treatment options) to primarily
11 assess their effects on quality of life¹⁴. Other measures of decision support are also being
12 evaluated in the trial (eg shared decision-making, decision regret, knowledge¹⁴). Another
13 strength of this study is the detailed and systematic process used to develop the initial DESI,
14 following IPDAS¹⁵ guidelines, and use of the first DESI as a template to develop the second
15 DESI. The advantages of being able to develop a DESI more efficiently are important. Using a
16 more efficient development method could save resources, both in terms of burden to
17 participants (which may be particularly relevant in this older and sometimes frailer population)
18 and in terms of developers' time and funds. That a sample of older women was recruited to
19 the present study, including some much older people (four participants 90 years or older), is a
20 further strength. Previously, difficulties in recruiting older women have been described,
21 though these were within the context of clinical trials (and due to protocol restrictions and
22 clinician reservation about treatments) rather than studies in general.³³

23 We recognise the limitations of our development study. Firstly, the two groups of women
24 likely to be eligible for the respective treatment options are different; those with a choice of

1 primary endocrine therapy or surgery+endocrine therapy are likely to be frailer and older than
2 those with a choice about chemotherapy. Older women may have different preferences for
3 information style. Burton and colleagues²² found an inverse association between preference
4 for written information and age even within a sample of older breast cancer patients (75 years
5 and over) offered a choice of primary endocrine therapy or surgery+endocrine therapy.
6 Preferences elicited for the first DESI (which were based on women aged 75 years and over)
7 may therefore not be completely transferable to the chemotherapy DESI. Secondly, due to
8 time constraints of the programme of work, patients currently facing the decision about
9 chemotherapy were not included in the sample. Lastly, while the DESIs are based on the best
10 clinical evidence available at the time, new survival outcome data for this older population are
11 being collected as part of the Bridging the Age Gap in Breast Cancer study (ISRCTN46099296/
12 32447¹⁴). Not only will the DESIs therefore need updating when this is available, they will also
13 need updating if new treatment options become available in the future.

14 Participants highlighted the need for interaction with clinicians, and the importance of
15 clinicians' shared decision-making skills and attitudes has recently been highlighted.³⁴ Skills
16 development for shared decision-making along with guidance on using the DESIs remains
17 crucial for successful implementation in clinical practice.

18 Further research is needed in a larger sample to test the effectiveness of the DESIs in
19 improving shared decision-making for older women with breast cancer treatment choices
20 (currently being done in the Bridging the Age Gap in Breast Cancer study, ISRCTN 32447¹⁴). If
21 they are effective, this will show that where patient populations are similar, DESIs for different
22 treatment decisions can be developed based on the template of another DESI and on
23 information already obtained from the patient population, and then implemented. Resources
24 saved (both time and funds) during the initial prototype and testing phases of development

1 could then be directed towards supporting shared decision-making skills for clinicians and
2 updating DESIs with new clinical evidence.

3 **Conclusions**

4 Two DESIs for older women with breast cancer have been successfully developed for two
5 different treatment choices (primary endocrine therapy/surgery+endocrine therapy and
6 chemotherapy/no chemotherapy). Using an iterative process of feedback and improvements,
7 the DESIs were found to be acceptable and usable by patients. Having developed one DESI
8 using a detailed and systematic process, it was possible to develop the second DESI for a
9 different treatment choice more efficiently using information already captured for the initial
10 DESI. Before developing the DESIs, there were none (to our knowledge) available for this group
11 of older women having to make these particular treatment choices. With policy makers keen
12 to promote shared decision-making and enhance patient centred care, development of DESIs
13 which inform patients about treatments and enable them to be involved in treatment
14 decisions is vital. An efficient process to develop these is therefore beneficial.

15 **Abbreviations**

16 DESI: decision support intervention

17 IPDAS: International Patient Decision Aid Standards

18 Surgery+endocrine therapy: surgery plus adjuvant endocrine therapy

19 **Ethics approval and informed consent**

20 Approval for healthy volunteer involvement in the study was obtained from Cardiff University
21 School of Medicine Research Ethics Committee (reference 13/72) and Brighton and Sussex
22 Medical School Research Governance and Ethics Committee (reference 15/111/HAR). Sheffield

1 Hallam University provided approval based on Cardiff University approval and the University of
2 Sheffield Research Ethics Committee deemed that duplicate ethical approval from them was
3 not required. Approval of the study protocol for patient involvement was obtained from the
4 National Research Ethics Service London - Surrey Borders committee (reference 12/LO/1722)
5 and the appropriate National Health Service Trust Research and Development Departments.
6 All participants completed a consent form for their participation in the study.

7 **Consent for publication**

8 Participants gave consent for words said during the interviews to be used anonymously, in the
9 presentation of the research. All personal identifiers have been removed or disguised so the
10 person(s) described are not identifiable and cannot be identified through the details of the
11 story.

12 **Data availability**

13 The datasets used and analysed during the current study are available from the corresponding
14 author on reasonable request.

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18 The views expressed are those of the authors and not necessarily those of the NHS, the NIHR
19 or the Department of Health.

20 **Competing interests**

21 The authors declare that they have no competing interests.

1 **Authors' contributions**

2 KJL: design of the study, acquisition, analysis and interpretation of data, drafting and final of
3 approval the article, accountable for the work.

4 AE: conception and design of the study, acquisition, analysis and interpretation of data,
5 drafting and final approval of the article, accountable for the work.

6 MB: design of the study, acquisition, analysis and interpretation of data, reviewing and final
7 approval of the article, accountable for the work.

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24 for the work.

1 KBr: conception and design of the study, acquisition, analysis and interpretation of data,
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15

1 **Legends**

2 **Figure 1. Schematic representation of the primary endocrine therapy/surgery+endocrine**
3 **therapy DESI development process.**

4 **Figure 2. primary endocrine therapy/surgery+endocrine therapy DESI content.**

5 **Figure 3. Chemotherapy DESI content.**

6 **Figure 4. Values clarification exercise in primary endocrine therapy/surgery+endocrine**
7 **therapy booklet.**

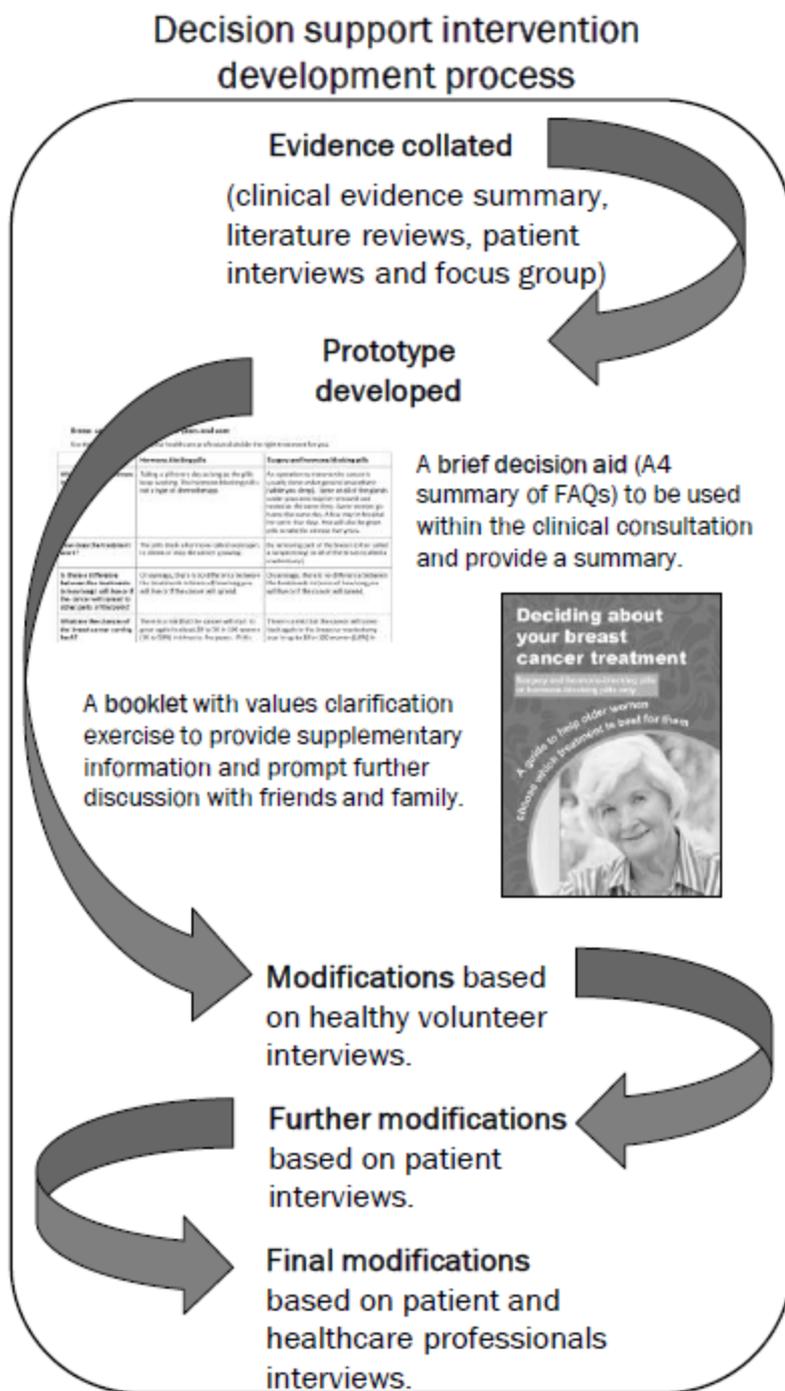
8 **Table 1. Interview transcript coding framework**

9 **Table 2. Example quotes for the main findings**

10

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1 Figure 1.



2

3

1 **Figure 2.**

Booklet sections

Welcome

About breast cancer

Breast cancer in older women

Types of breast cancer

Your experiences of cancer and cancer treatment

Choice of breast cancer treatment

What can be done to treat my breast cancer?

Do I have a choice?

How can I decide?

Options at a glance (brief DA)

Surgery and hormone-blocking pills

Will I have to go to sleep if I have surgery?

What are the different types of surgery?

How long will I stay in hospital after surgery?

How will I manage at home after the operation?

Will I need to go for check-ups at the hospital?

What are the side effects of surgery?

How will surgery affect my normal daily activities?

What treatment might I need after surgery?

What are the chances of the breast cancer coming back after surgery?

How might I feel about surgery and hormone-blocking pills?

Hormone-blocking pills only

Will the cancer be removed?

How long do I have to take the pills for?

What are the chances of the pills working?

Will I need to go for check-ups at the hospital?

What are the side effects of the pills?

What effect may other medication have on the hormone-blocking pills?

What are the chances of the breast cancer starting to grow again?

What happens if the cancer starts growing again?

How might I feel about taking hormone-blocking pills?

How might I feel about having breast cancer?

My decision

Discussing my decision and going ahead with treatment

Can I change my mind?

Can I stay well without treatment?

How can I find out more about my options?

My questions

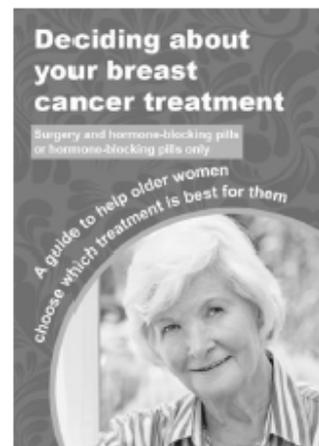
Weighing up my options

Deciding what I feel is the best choice for me

My choice

What happens next?

Evidence



Brief decision aid frequently asked questions

What does the treatment involve?

How does the treatment work?

Is there a difference between the treatments in how long I will live or if the cancer will spread to other parts of the body?

What are the chances of the breast cancer coming back?

Will anything else happen at the start of treatment?

Can I carry on with my normal activities?

Will I have to go for hospital check-ups?

What are the risks of side effects of treatment?

2

3

1 **Figure 3.**

Booklet sections

Welcome

About breast cancer

Choice of breast cancer treatment after surgery

What are the options for treatment after surgery to remove breast cancer?

Do I have a choice?

How can I decide?

Options at a glance (brief DA)

About chemotherapy

What is chemotherapy?

How is chemotherapy given?

What are the benefits of chemotherapy?

What are the side effects of chemotherapy?

About Herceptin

What is Herceptin treatment?

What are the benefits of Herceptin?

What are the side-effects of Herceptin?

What other treatments might I need?

Hormone-blocking pills

Radiotherapy

What are the chances of the breast cancer coming back?

How might I feel about having breast cancer and about whether or not to have chemotherapy?

My decision

Discussing my decision and going ahead with treatment

Can I change my mind?

How can I find out more about my options?

My questions

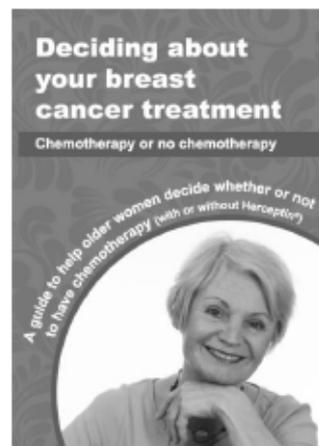
Weighing up my options

Deciding what I feel is the best choice for me

My choice

What happens next?

Evidence



Brief decision aid frequently asked questions

What does the treatment involve?

How does the treatment work?

Is there a difference between the options in how long I will live?

What are the chances of the breast cancer coming back?

What are the side effects of treatment?

Can I carry on with my normal activities?

Will I have to go for hospital check-ups?

2

3

Accept

1 Figure 4.

My questions

You might find it helpful to write down any questions you have about your treatment options. You can draw one page number and write it down. Or, the inside cover of this booklet about them. There is a space to note them down.

My questions

Weighting an option

There is a table to help you think about what is important to you about the treatment options. You can use the table to list the things that make you want to have one treatment or the other. You can also put stars (★) next to the things that are the most important to you.

Here is an example.

I think I would like hormone therapy only because...	I think I would like surgery and hormone therapy only because...
I don't want hormone therapy...	I want to avoid having regular hospital check-ups.
I don't want surgery or hormone therapy for the rest of my life.	I don't want to be in hospital.

Your list

There is a table for you to list the things that matter most to you. You may find it helpful to fill it in yourself. It is **not** meant to be filled in for you. You might like to fill it in with someone or you may prefer to continue to talk to your doctor and write about your treatment options.

I think I would like hormone therapy only because...	I think I would like surgery and hormone therapy only because...

Deciding what I feel is the best choice for me

To help you decide, you may want to use the table below. There are two options in the table you chose to draw from. Choosing pills only or surgery and hormone therapy pills. You might feel that the option with the most reasons is best for you.

do

You may feel there is one most important reason that leads you to choose either surgery and hormone therapy pills or hormone therapy pills only. You may want to write down that most important reason.

My choice

I feel the best treatment for me would be:

Remember, you can discuss your treatment options again with your doctor or nurse at the breast clinic at your next appointment, or you can phone them to make an appointment.

What happens next?

Now that you have thought about what you feel is the best treatment choice for you, you can't choose to discuss this with a member of the team. They will make plans with you about what happens next. If you decide to have a treatment plan in place, you can still contact your breast care team to discuss your options and discuss. But you may need to phone them to arrange this.

My decision
What happens next?

2

3

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1 **Table 1. Interview transcript coding framework**

Primary code	Secondary code
Brief DA	Layout /ease of use (usability)
	Useful content (usability)
	Understanding (accessibility)
	Information amount
	Questions
	Improvements
Booklet	Layout /ease of use (usability)
	Useful content (usability)
	Understanding (accessibility)
	Information amount
	Questions
	Values clarification exercise
	Other sections
	Improvements
Implementation	Usefulness (utility)
	Practicalities
	Usage ¹
Other	Personal experiences ²
	Cancer diagnosis ^{2,3}
	Decision ²
	Follow up care ^{2,3}
	Question ²
	Reference ²
	Miscellaneous ²
	General comment on DESI

2 ¹patients facing the decision only

3 ²text in grey shows codes not used for presented analysis

4 ³patients only.

5

1 Table 2. Example quotes for the main findings

Primary code	Secondary code	Example quotes	Text reference
Primary endocrine therapy/surgery +endocrine therapy brief decision aid & booklet		<i>...it was really in layman's terms, you didn't have to know anything about medicine or medical matters, it was all put down to you in a very, you know, very straightforward way... DESI-S-Bo-SFT</i>	A
	Understanding	<i>[Referring to diagram of cancer lump and lymph nodes] It's all over the flaming place isn't it? Look at that, lymph node, gee by gum, yes that is pretty bad that. [...] It grows away from the cancer doesn't it, going to the nodes and into your arm? [...] That makes it look as if it's where the cancer is. DESI-S-Bo-SFT</i>	B
		<i>[Referring to the chances of the breast cancer coming back]... its 20 in 100 women after 1 to 3 years in the hormone blocking. 10 in 100 – 10% over the lifetime time so if a person wanted to know what would be my risks of getting it in the first few years of either treatment – if it's possible to answer that...DESI-S-Br-SUT</i>	C
	Improvements	<i>...is there a difference in how long I will live – does that mean if you don't have treatment? [...] no difference to what? [...] that's not very clear. [...] there has to be an 'if' in it somewhere. Interviewer : yes so if – is there a difference in how long I will live if I take the tablets or if I [...] have the surgery and the tablets. P: yes DESI-S-Br-SUT</i>	D
		<i>'Usually women notice the swelling because their arm feels heavier or rings and clothes seem' [...] Your clothes seem tighter, I wouldn't have thought, your sleeves might (seem) tighter, but not all your clothes, surely. DESI-S-Bo-SFT</i>	E
Chemotherapy brief decision aid & booklet	Understanding	<i>... I found page 5 in the booklet thoroughly confusing... because I felt it came in very early in the booklet and it, for a person, an older person to try to take in all that information, I found more confusing than... DESI-C-Bo-CUT</i>	F
		<i>I found the numbers, the ratio of the numbers of me living longer...or even surviving...seemed very small... [...] it's been scare...a bit scare...it's been frightening...reading, reading what your chances are...[...]it looks as though I've got like a 1 in a 5 chance... DESI-C-Bo-CFT</i>	G
	Layout	<i>...it was nice to have photographs in and I thought they were perfectly alright. And 1 or 2 of them were quite nice, there's a nice one on page 19, I was just looking at it now. You feel as if the nurse and the patient are very much on the same wave length that's very nice and I think anything like that is, that's particularly good. DESI-C-Bo-CUT</i>	H

	Improvements	<i>I mean the other thing is you probably would have to have it in, in different languages wouldn't you? DESI-C-CFT</i>	I
Primary endocrine therapy/surgery +endocrine therapy booklet	Values clarification exercise	<i>I didn't (look at) this page to be honest. I suppose it's because I'd spoken to [name], that probably did that you see. DESI-S-Bo-SFT</i>	J
		<i>...they can go home and look through the booklet, they can write down what they want to ask you because I think like when you go to the doctor you need to write down what you want to say because when you get there you've forgotten all what you wanted to say to them. DESI-S-Bo-SUT</i>	K
Implementation	Usefulness	Interviewer: How do you think women might find this if they did have breast cancer, when they were thinking about their decisions and treatments options? <i>P: I think they would probably find it helpful but they'd need to have, it's not helpful just on its own, it needs to have someone that you're able to discuss it with. DESI-C-Bo-CUT</i>	L
		<i>I wish, when they diagnosed me and everything, I wish I'd had a book like this to read. DESI-S-Bo-SFT</i>	M
		<i>'Is there an option, difference between the options in how long I will' and I thought if I don't have chemo I might die if it hasn't all gone and reading that I thought well I have done the right thing, I've had chemo and if there's anything there its, it's made me decide...if I hadn't have had it...[...]...I would have chosen to have it...[separate quote] ... it help me cope because I knew I'd do, done right thing. DESI-C-CFT</i>	N
	Usage¹	<i>My daughter wrote in it for me, things I had to remember to ask. [...] I had to remember to ask them when I went before I decided. We sat and we discussed it. DESI-S-Bo-SFT</i>	O

1 ¹Patients facing the decision only

2 DESI-S, Primary endocrine therapy/surgery+endocrine therapy DESI; DESI-C, chemotherapy DESI; Bo, booklet; Br, brief decision aid; SUT, Primary
3 endocrine therapy/surgery+ endocrine therapy user testing (healthy volunteers); CUT, chemotherapy user testing (healthy volunteers); SFT, Primary
4 endocrine therapy/surgery+ endocrine therapy field testing (patients); CFT, chemotherapy field testing (patients).

5
6

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1 **Supplementary file 1**

2

3 **Interview guide**

- 4
- What do you think about the brief decision aid / booklet?
- 5
- Is the brief decision aid / booklet easy to use and understand?
- 6
- What do you think about the questions listed on the left (brief decision aid only)?
- 7
- What do you think about the different sections of the booklet (booklet only)?
- 8
- Are there areas in the brief decision aid / booklet that need changing?
- 9
- Healthy volunteers: How useful do you think it could be for women who have a
- 10
- decision to make about treatment? Patients: How useful do you think it was/ could
- 11
- have been when making your decision about treatment?
- 12
- Do you have any suggestions for improvement?
- 13
- Any other comments?
- 14

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