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Decision aids for female BRCA mutation carriers: a scoping review

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ABSTRACT

Objectives Women who inherit a pathogenic *BRCA1* or *BRCA2* mutation are at substantially higher risk of developing breast and ovarian cancer than average. Several cancer risk management strategies exist to address this increased risk. Decisions about which strategies to choose are complex, personal and multifactorial for these women. Decision aids (DAs) are tools that assist patients in making health-related decisions. The aim of this scoping review was to map evidence relating to the development and testing of patient DAs for cancer unaffected *BRCA* mutation carriers.

Design Scoping review conducted according to the Joanna Briggs Institute's (JBI's) scoping review methodological framework.

Data sources MEDLINE, EMBASE, CINAHL, Web of Science. No restrictions applied for language or publication date. A manual search was also performed.

Eligibility criteria for selecting studies Studies on DAs for cancer risk management designed for or applicable to women with a pathogenic *BRCA1* or *BRCA2* mutation who are unaffected by breast or ovarian cancer.

Data extraction and synthesis Data were extracted using a form based on the JBI instrument for extracting details of studies' characteristics and results. Data extraction was performed independently by two reviewers. Extracted data were tabulated.

Results 32 evidence sources relating to development or testing of 21 DAs were included. Four DAs were developed exclusively for cancer unaffected BRCA mutation carriers. Of these, two covered all guideline recommended risk management strategies for this population though only one of these was readily available publicly in its full version. All studies investigating DA effectiveness reported a positive effect of the DA under investigation on at least one of the outcomes evaluated, however only six DAs were tested in randomised controlled trials.

Conclusion This scoping review has mapped the landscape of the literature relating to developing and testing, DAs applicable to cancer unaffected *BRCA* mutation carriers.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study has provided a comprehensive mapping of the literature relating to the features and efficacy testing of existing decision aids for BRCA mutation carriers without a personal history of cancer.
⇒ This scoping review was conducted according to the Joanna Briggs Institute's scoping review methodological framework and was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews checklist.
⇒ Decision aids included in this review were identified by searching four databases, reference lists and the internet, however, it is possible that other relevant decision aids may exist elsewhere in the grey literature.
⇒ A formal independent quality appraisal of included evidence sources was not conducted, however, quality appraisals conducted by authors of included studies were summarised where applicable.

INTRODUCTION

Background

BRCA1 and *BRCA2* are tumour suppressor genes that play an important role in the repair of DNA damage. Women who inherit a pathogenic mutation in the *BRCA1* or *BRCA2* genes are at substantially higher risk of developing breast and ovarian cancer over their lifetime than the average woman. Estimates for lifetime breast cancer risk vary between studies and differ according to mutation location and family history but have been reported to be in the region of 45%–85% for female *BRCA1* mutation carriers and 27%–84% for female *BRCA2* carriers to age 70 overall.[1–13] Furthermore, some studies have reported that *BRCA* mutation carriers born in recent decades, have a substantially higher risk of developing breast cancer than those in earlier birth cohorts.[7 14–16]

Cumulative ovarian cancer risk to age 80 was estimated to be 44% for *BRCA1* mutation carriers and 17% for *BRCA2* mutations carriers in a study using data from a prospective cohort.[1] This represents a significant risk compared with a population average of≤2%.[17]

Following a positive genetic test, women diagnosed as *BRCA* gene mutation carriers may be followed up in high-risk programmes for monitoring and management. Management strategies in this setting are aimed at

early detection and/or prevention of the disease. Early detection strategies aim to diagnose breast cancer at an early stage to improve clinical outcomes; these include radiologic surveillance at regular intervals by mammography and MRI. Radiological screening techniques have not been proven to be effective in detecting ovarian cancer at an early stage. Prevention strategies aim to reduce a woman's risk of developing breast or ovarian cancer by means of prophylactic surgery (including risk-reducing bilateral mastectomy and/or bilateral salpingo-oophorectomy (BSO)) or risk-reducing medication (chemoprevention) with drugs such as tamoxifen, anastrozole or raloxifene to reduce breast cancer risk.[18]

For BRCA mutation carriers, decisions about which risk management strategies to choose are complex, personal and multifactorial. Each option has associated risks and anticipated outcomes, which women need to understand to make an informed decision regarding which interventions to choose. Decision aids (DAs) in various formats, have been developed internationally to support decision-making for *BRCA* mutation carriers. Such tools require sophisticated design to effectively support decision-making, communicate risk, and clarify patients' values and preferences.[19] DAs for BRCA mutation carriers have not yet been widely incorporated into routine clinical practice.

Rationale

In order to better understand the features of existing DAs for this population and to reveal which of these DAs may be appropriate for various populations of *BRCA* mutation carriers a scoping review of existing DAs designed to support decision-making around risk management for female BRCA mutation carriers was conducted.

The overarching goal of this scoping review was to explore the breadth of the literature in this field and to map evidence relevant to cancer risk-management DAs for female *BRCA* mutation carriers without a personal history of cancer. This information may be beneficial for designing new DAs or adapting existing DAs to support decision-making in terms of cancer risk management for female BRCA mutation carriers.

A scoping review can be used to identify, map and discuss certain characteristics in papers or studies.[20] The aim of this review is to summarise the key characteristics (content, features and efficacy) of patient DAs for female BRCA mutation carriers who are as yet cancer unaffected. A scoping review approach can provide a broad overview of the landscape of the literature and is, therefore the most appropriate design for this evidence synthesis.[21]

Review question

The question that this scoping review aimed to answer is:

What are the characteristics of patient DAs that have been developed to support risk-management decision-making in cancer unaffected female BRCA mutation carriers?

Objectives

The objectives of this scoping review were:

- To identify and summarise the key features of patient DAs that have been developed for or are applicable to cancer unaffected female BRCA mutation carriers to support decision-making in terms of choosing which cancer risk management options to opt for.
- To map the evidence related to testing of these DAs.

METHODS

This scoping review was conducted according to the Joanna Briggs Institute's (JBI's) scoping review methodological framework.[20] In addition, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews checklist was used for guidance.[22] The published protocol for this scoping review is available here.[23]

Inclusion criteria

Types of participants

This review considered studies on DAs for cancer risk management designed for or applicable to women with a pathogenic *BRCA1* or *BRCA2* mutation who are unaffected by breast or ovarian cancer.

Concept

The concept of interest in this scoping review is patient DAs for female BRCA mutation carriers to support decision-making around cancer risk-management options.

In the absence of a universally accepted definition for 'decision aid' we included DAs that were (1) described as such by their developers and/or (2) included in the Ottawa Hospital Research Institute's patient DAs inventory[24] and/or that in the author's judgement could be considered a DA based on the DA definition provided by the International Patient Decision Aids Standards (IPDAS) Collaboration.[25]

Context

The context of this review is decision-making supports for female BRCA mutation carriers without a personal history of breast or ovarian cancer. Sources of evidence on cancer risk management patient DAs for BRCA mutation carriers pertaining to any contextual setting were eligible for inclusion.

Types of evidence sources

Included

(1) Studies that describe the development and/or testing of a patient DA suitable for cancer unaffected female BRCA mutation carriers to support decision-making in terms of choosing which cancer risk management options to opt for; (2) standalone DAs applicable to this population (ie, those that are available publicly but whose development has not necessarily been reported in a journal article); and (3) systematic reviews of the above-mentioned evidence sources.

Excluded

This review did not include case reports, non-systematic reviews, protocols, letters, posters or conference abstracts. Studies that described patient DAs aimed solely at BRCA mutation carriers with a personal history of breast or ovarian cancer were excluded. Patient DAs that focused on interventions that do not manage or reduce cancer risk (such as genetic testing, breast reconstruction or hormone replacement therapy) were also excluded.

Search strategy

A three-step search strategy was used. First, an initial limited search of the databases MEDLINE (Ovid) and EMBASE was conducted. This initial search was followed by an analysis of the text words contained in the title and abstract of retrieved papers, and of the index terms used to describe the articles. A second search using identified keywords and index terms was then be undertaken across all included databases (MEDLINE, EMBASE, CINAHL, Web of Science) (online supplemental appendix 1). Databases were searched from inception to 6 October 2020. No restrictions were applied for language or publication date. The reference lists of reports and articles selected for inclusion in the review were also searched for additional sources. Finally, a manual search of the internet using Google Scholar and The Ottawa Hospital Research Institute Decision Aid Library Inventory (decisionaid.ohri.ca) was conducted on 9 March 2022.

Evidence source selection

Search results were uploaded to EndNote X8 (Clarivate Analytics, PA, USA) and duplicate records were removed. Retrieved studies were initially screened for inclusion by title and abstract by two review authors independently using the web-based Covidence screening tool (Veritas Health Innovation, Melbourne, Australia). Disagreements were resolved by discussion. Full-text papers and reports were retrieved for potentially relevant studies. For these studies, Covidence software was again used to assess and document studies for inclusion and exclusion according to the inclusion criteria. Studies for inclusion were selected independently by two review authors. Disagreements were resolved by discussion. In cases of no consensus, final resolution was achieved by involving a third review author as arbiter.

Data extraction

Data were extracted from included articles and other evidence sources using a data extraction form developed by the reviewers, pilot tested and modified in an iterative process to produce the final version (online supplemental appendix 2). The design of this instrument is based on the JBI instrument for extracting details of the studies characteristics and results. Data extraction was performed independently by two reviewers. Disagreements between the reviewers were resolved through discussion. Extracted data were tabulated.

Patient and public involvement

Patients and public were not formally involved in the development of this scoping review protocol; however, the research questions were informed by the author team's extensive clinical experience working with BRCA mutation carriers.

Deviations from the protocol

The data extraction template was amended from that published with the protocol to include additional fields to capture pertinent data identified during pilot testing (online supplemental appendix 2).

RESULTS

Evidence source inclusion

A total of 1007 articles were retrieved through database searching. An additional 1647 records were identified through searching other sources including reference lists of included studies (n=5), the Patient Decision Aids Inventory maintained by The Ottawa Hospital Research Institute (n=12) and a manual internet search of Google Scholar performed on 9 March 2022 (n=1630). Following exclusion of duplicates and irrelevant records; 32 studies/evidence sources were included in the scoping review. The screening and selection process is depicted in figure 1.[26]

Of the included articles/evidence sources; 15 solely described DA development or presented a developed DA,[27–41] 10 reported testing of a previously developed DA(s)[42–51] and 6 articles reported both development and testing of a DA.[52–57] In addition, one systematic review of DAs developed for the population of interest was included.[58]

Within the above-mentioned evidence sources, 21 DAs that met the inclusion criteria were identified. However, of these, there appeared to be some overlap between two pairs of DAs; those reported in Tiller *et al*[55] and C. f. G. E. N. Health[31] with the latter DA based on work reported in the former and those reported by van Roosmalen *et al*[56 57] whereby the later study incorporated the former DA as part of a wider decision-making intervention. There may also be some overlap between the DAs described by van Roosmalen *et al*[56 57] and Unic *et al*[41] that were developed by the same author teams, though the extent of overlap is difficult to gauge as the full DAs are not publicly available.

Review findings

Characteristics of included evidence sources

An overview of the included evidence sources is shown in online supplemental tables 1 and 2.

Target populations

Of the 21 included DAs; 8 were developed exclusively for known BRCA mutation carriers.[27 28 30 40 52–54 57] A further DA was aimed at women undergoing genetic testing for germline BRCA 1/2 mutations but whose genetic test results were not necessarily known.[56] 11 DAs were targeted at mixed groups of women at increased risk of developing

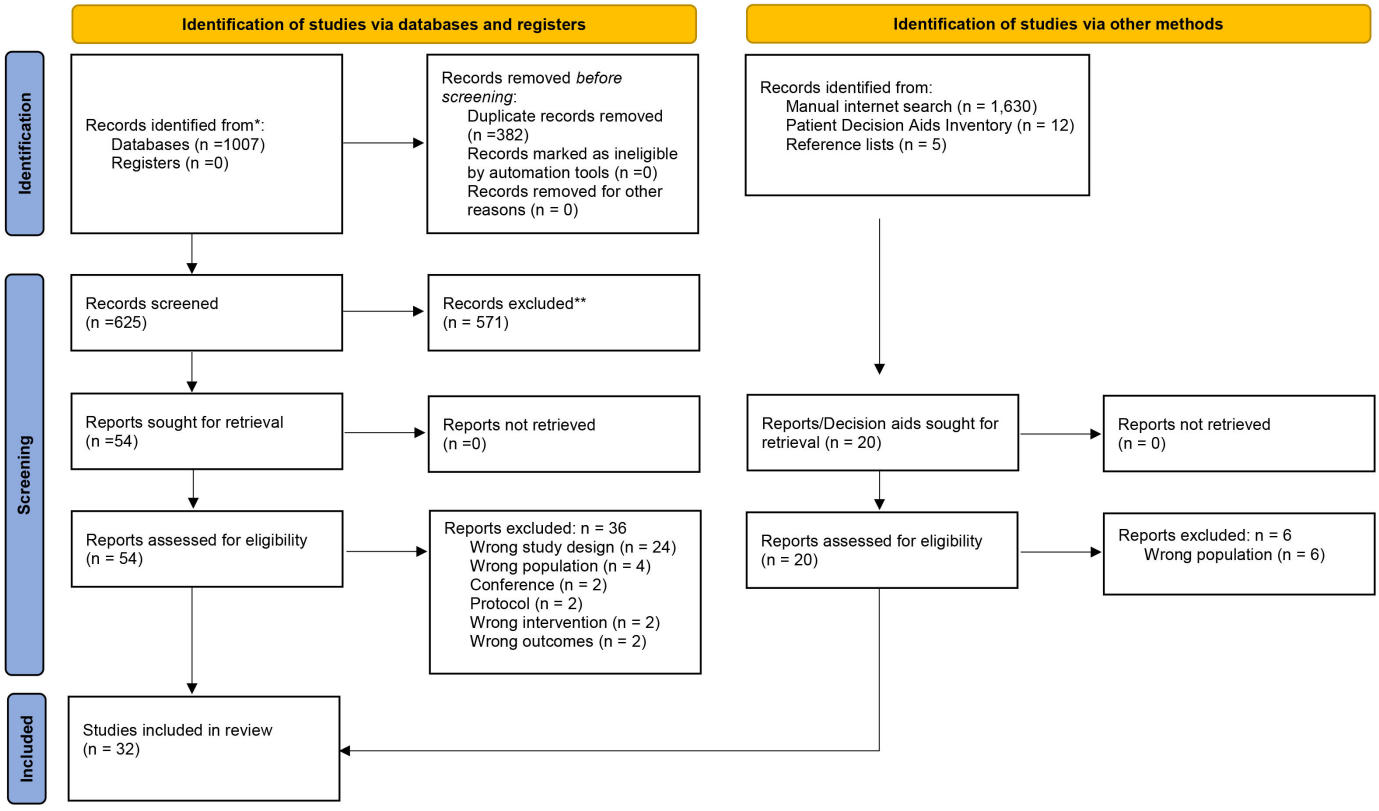

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram detailing search results and evidence source selection and inclusion process. Adapted from Page *et al*.[26]

breast or ovarian cancer.[31–39 41 55] In addition, one DA was aimed at women across the spectrum of breast cancer risk including those with a known BRCA mutation.[29] Five of the identified DAs were targeted specifically at women without a personal history of breast or ovarian cancer 'previvors'.[28 40 41 53 54] Three DAs were targeted at those unaffected by breast cancer (but not necessarily unaffected by ovarian cancer)[29 37 38] and six DAs were aimed at women unaffected by ovarian cancer (but not necessarily unaffected by breast cancer).[30 31 35 39 52 55] Five DAs were targeted at women either affected or unaffected by breast cancer.[27 32 36 56 57] For two DAs the target population in terms of cancer affected status was not reported or unclear.[33 34]

DA development methods

The IPDAS include 'a systematic development process' as a quality criterion for patient DAs.[59] DA development methods were reported (fully or partially) for 15 of the included DAs. Methodology used during DA development process varied but frequently involved a review of the literature and/or clinical guidelines in the field,[27 28 30 37–40 52–55] a needs assessment with targeted end users,[27 29 30 40 53–55 55] prototype development,[27 29 30 39 40 53–55] acceptability and usability testing followed by refinement based on end user and/or clinician feedback.[27 30 39 41 53 54] In the case of DAs that incorporated a cancer risk estimate calculator or algorithm, modelling approaches such as Markov or Monte Carlo modelling were used.[28 52] In one case, existing risk prediction models were incorporated into the DA.[29] The DA development process was often overseen by a steering committee or working group.[29 30 37 38 40 53–55]

Risk management options addressed

An overview of the risk management options addressed in each DA is shown in online supplemental table 1 and depicted in figure 2. Five DAs included both breast and ovarian cancer risk management options.[28 40 53 56 57] 10 DAs focused on breast cancer risk management options.[27 29 32 33 36–38 41 52 54] Many of these also briefly mentioned ovarian cancer risk management options[27 36 54] and several included BSO but focused on this intervention from a breast cancer risk management rather than an ovarian cancer risk management perspective.[29 33 52] Five DAs addressed ovarian cancer risk management options only.[30 31 34 39 55] Eight DAs included[27 29 33 52–54] or focused solely[37 38] on chemoprevention (risk reducing medication). Of these one DA was targeted exclusively at premenopausal[37] and one DA exclusively at postmenopausal women[38] based on the different risk-reducing medications recommended for each of these groups. A further two DAs mentioned chemoprevention briefly, however this option was not a focus of these DAs.[32 36]

Presentation of risks and benefits

The IPDAS quality criteria framework for patient DAs outlines several quality criteria for presenting probabilities

Decision Aid	Developed exclusively for *BRCA* mutation carriers	Developed exclusively for BC & OC unaffected women 'previvors'	Risk management options addressed					Full DA readily available publicly
			Surveillance/Screening		RRM	BSO	Chemoprevention (for BC)	
			Breast	Ovarian				
Kaufman 2003	✓	×	✓	✓**	✓	✓**	✓	×*
Armstrong 2005	✓	×	✓	×	✓	✓***	✓	×*
Jabaley 2020	✓	✓	✓	✓	✓	✓	✓	✓
Kurian 2012	✓	✓	✓	×	✓	✓	×	✓
Collins 2016	×	?	✓	×	✓	✓***	✓	✓
Harmsen 2018	✓	?	×	×	×	✓	×	✓
Centre for Genetics Education, NSW Health (2012 update) Breast	×	?	✓**	×	✓	×	✓**	✓
Centre for Genetics Education NSW Health (2017) Ovarian	×	?	×	×	×	✓	×	✓
Healthwise staff a (2020 update) Breast	×	?	✓	×	✓	✓***	✓	✓
Healthwise staff b (2020 update) Ovarian	×	?	×	✓**	×	✓	×	✓
Mayo Clinic Staff (2020 update) Ovarian	×	?	×	✓**	✓**	✓	×	✓
Mayo Clinic Staff (2021 update) Breast	×	×	✓**	×	✓	✓**	✓**	✓
Metcalfe 2007	✓	✓	✓	×	✓	✓	✓	×*
NICE 2017 (Pre-menopausal)	×	?	×	×	×	×	✓	✓
NICE 2017 (Post-menopausal)	×	?	×	×	×	×	✓	✓
TILLER 2003	×	?	×	✓	×	✓	×	×*
VANROOSMALEN BJC 2004a	✓#	×	✓	✓	✓	✓	×	×*
VANROOSMALEN JCO 2004b	✓	×	✓	✓	✓	✓	×	×*
Witt 2014	×	?	×	×	×	✓	×	×*
Kautz-Freimuth 2021	✓	✓	✓	×	✓	✓	×	×*
Unic 1998	×	✓	✓	×	✓	×	×	×*

Figure 2 Overview of target populations and risk management options addressed in each decision aid (DA). *May be made available through contacting authors but not readily accessible in public domain. **Option mentioned but not a main focus of DA. *** BSO included as a BC risk management option in DA. #Women being tested for a BRCA mutation but not necessarily confirmed BRCA mutation carriers. BC, breast cancer; BSO, bilateral salpingo-oophrectomy; RRM, risk-reducing mastectomy.

of outcomes including the use of multiple methods to view probabilities (words, numbers, visual diagrams).[59] Among the DAs reviewed here, where included, various approaches were used to present baseline cancer risks and cancer risk reductions associated with the different options. Commonly, a text description of risks (and risk reductions) was included,[27 29–39 41 53–56] often with a visual presentation by means of bar charts,[27 28 53 57] pie charts,[30] shaded icon arrays[29 30 33 37–39 54] or other graphical presentations.[29 31 52] Other benefits and harms (or side-effects) of the various options were typically portrayed using text descriptions[27 29–41 53–56] and in some cases photographs and videos.[41 56]

Values clarification approaches

According to the IPDAS patient DA quality criteria framework, DAs should include 'methods for clarifying and expressing patients' values' to enable patients to consider what matters most to them.[59] 13 of 21 DAs included an activity that enabled end users to work through their values and feelings in relation to the risk management options presented. Various values clarification approaches were used such as rating or scoring statements or attributes relating to the benefits and harms of the risk management option(s) in question based on how important they are to the user.[27 30 33 34 37–39 53–55] Several DAs included a space for users to write additional thoughts or concerns that they have.[30 33 34 37–40 53 54] In some cases, users are asked to rank statements in order of importance in an attempt to clarify which values matter most to them.[30] In some cases, more complex approaches to values clarification were used such as time trade-off methods[41 57] or model-based approaches.[27]

DA recommendation for which option(s) the patient should choose

The majority of included DAs did not provide a recommendation for which option(s) the patient should choose. One DA provided a recommendation for which option the patient should choose based on their answers to values clarification statements by stating that 'If you mainly 'agree' with these three statements, removal of the fallopian tubes and ovaries is the best option for you. If you mainly 'disagree' with these three statements, initial removal of the fallopian tubes and removal of the ovaries at a later date is the best option for you'.[30] In addition, one DA implies, but does not explicitly recommend, which option the patient should choose by indicating that during the 'decision task' activity, the highest preference score indicates the risk management option that is most consistent with the values and preferences the woman entered in the decision task.[27]

DA formats and availability

The most common format of the DAs was paper-based, typically in the form of a booklet or brochure (online supplemental table 1). Some of these booklets were provided with an accompanying videotape containing informational material.[41 56] Other paper-based formats included pdf formats available online or binders containing printed material.[52] The second most common DA format was web-based. Web-based DAs were usually interactive to some degree with some web-based DAs enabling a large degree of individualisation particularly in terms of presenting personalised cancer risk estimates based on user inputted data.[28 29] Some web-based DAs were also available as printable pdf versions.[33 34] One DA was in the format of a CD-ROM.[27] Only 12 DAs[28–38 53] were available in full in the public domain without requirement to contact the developers for access (figure 2).

Year of DA development or update

The identified DAs span a time period of greater than 20 years in terms of their year of development or last update. More than half of the included DAs (n=12), however, were developed and/or updated in the past 10 years[29–31 33–40 53] with six of these developed/updated in the past 5 years.[33–36 40 53] For several DAs the date of last update was not readily apparent. For DAs whose development was reported in journal articles, the development year was recorded as the year of article publication unless a more recent update was available publicly in which case the later year was reported (online supplemental table 1). For publicly available DAs (whose development was not necessarily reported in journal articles), the development/update year was recorded as year of update or last review stated on the DA when this was reported (online supplemental table 1).

Intended moment(s) of use of DAs

In the majority of cases, DAs were intended to be self-administered by patients at home.[27 30–34 37 38 40 41 52 54–56] Five DAs were designed to be used collaboratively with a clinician.[28 29 37 38 53] For five DAs, developers specified that the DA was intended to be used by the patient at home in addition to a consultation with a healthcare professional.[27 30 40 41 54] One DA included a shared decision-making intervention that was interview administered by a researcher.[57] For three DAs the intended moment of use of the DA was unclear or not explicitly reported though these appeared to be suitable for self-administration by patients at home.[35 36 39]

Patient and public involvement

There was some degree of patient and public involvement (PPI) in development of the majority (14 of 21) of included DAs (online supplemental table 1). PPI commonly entailed a needs assessment with target end users of the DA by means of focus groups or interviews.[27 29 30 39 40 53–55] Target end user representatives frequently contributed to DA development through reviewing the DA prototype and/or subsequent DA versions and providing feedback to facilitate DA refinement.[27 29 30 40 53] In some cases, DA development was led by a steering group containing patient representatives.[37 38 55] In some cases, patients and their families featured in the DA informational material through featuring on videos or providing quotes about

their personal experiences.[27 41 56] For the remaining DAs PPI was either not reported[28 33–36 52 57] or where PPI was reported, the nature of patient involvement was not specified.[31 32]

Adherence to quality criteria

In this scoping review, a formal quality appraisal of included DAs was not performed as per guidance on conducting scoping reviews.[20] However, a recent full systematic review on this topic evaluated the quality of DAs for preventive treatment alternatives for BRCA 1/2 mutation carriers. In this review, the authors reported that only 9 of the 20 DAs included in their review (19 of which are included in the current scoping review) met fundamental quality criteria of the IPDAS Collaboration (IPDASi V.4.0).[58]

Testing and effectiveness of DAs

The IPDAS recommend that patient DAs are field tested with users (patients and practitioners) to evaluate whether the DA is acceptable, balanced in terms of information and is understood by those with limited reading skills. This framework also recommends DA efficacy testing in terms of determining whether the DA improves the match between the chosen option and the features that matter most to the informed patient.[59]

11 of the 21 included DAs had been tested for efficacy in 15 primary studies. Study designs included seven randomised controlled trials (RCTs), one non-RCT, two single group pretest/post-test studies, four pilot studies. One study that compared responsiveness of several instruments used to evaluate DA effectiveness, using two DAs for BRCA mutation carriers, was also included, however this study did not report results in terms of effectiveness of these two DAs themselves.[49] In addition, one systematic review synthesised evidence on effectiveness of four of the included DAs.[43] Outcomes evaluated typically included decision related outcomes and/or information related outcomes. In some cases, outcomes on actual preventive choice and other health related outcomes were evaluated. Pilot studies commonly evaluated DAs in terms of usability, feasibility or acceptability. A description of individual effectiveness studies and their findings is shown in online supplemental table 2. All of the included studies reported a positive effect of the DA under investigation on at least one of the outcomes evaluated. However, negative effects of DAs were also found at some time points. For example, Hooker *et al* reported increased distress among DA users compared with the control group at 1-month postrandomisation.[42] Indeed, timing appears to be relevant with some studies reporting differential effects of DAs on outcomes in the short term versus longer term.[42 48 57]

The included systematic review reported that BRCA mutation carriers using a DA had less decisional conflict, were more likely to reach a decision and were more satisfied with their decision, however, the authors noted that overall risk of bias was high or serious in all but one of the studies evaluated.[58]

DISCUSSION

This scoping review has mapped evidence relevant to cancer risk-management DAs that are applicable to female BRCA mutation carriers without a personal history of cancer. Specifically, we have identified and described the features of cancer risk-management DAs for this population and reported on the efficacy testing of these DAs where this has been conducted.

Two other systematic reviews on this topic have been published by Krassuski *et al*[43 58] as well as a further study that incorporated a survey of existing DAs.[40]

Krassuski *et al* conducted a structural analysis and quality assessment of DAs for BRCA mutation carriers (with or without breast/ovarian cancer) and examined their applicability to the German context.[58] In this study they identified 20 patient DAs of which nine met fundamental IPDAS quality criteria. The authors reported that some DAs differed markedly in content from the recommendations of German guidelines.

Krassuski *et al* conducted a systematic review of effectiveness of DAs for BRCA mutation carriers (with or without breast/ovarian cancer) that have been tested in randomised control trials or pretest and post-test studies. This study reported that DAs significantly improved decision related outcomes in female BRCA mutation carriers, though the authors noted bias concerns regarding most of the included studies.[43]

Kautz-Freimuth *et al* incorporated a review of existing DAs for BRCA mutation carriers as part of their development process for new DAs targeted towards German BRCA mutation carriers. Seven DAs were included in this review and an overview of the structural elements and basic medical contents of these DAs was provided. The authors concluded that due to various limitations related to content of the DAs; none were transferable to the German setting.[40]

Our scoping review differs from these articles in a number of ways. The population of interest for our study was BRCA mutation carriers without a personal history of breast or ovarian cancer often termed ‘previvors’. As such, DAs developed solely for cancer affected women were excluded from this review. In addition, as a scoping review we took a broader approach in terms of included evidence sources by combining a synthesis of features of existing DAs that can be used by cancer unaffected BRCA mutation carriers, the efficacy testing of these DAs and systematic reviews of same. As such, we believe that this work is a useful resource for clinicians and researchers which maps current evidence relating to features and efficacy of existing DAs for cancer unaffected BRCA mutation carriers in a single paper.

The findings described here therefore build on, complement and include those reported by Krassuski and colleagues.[40 43 58]

Our findings demonstrate that only four DAs have been developed exclusively for known BRCA mutation carriers without a personal history of cancer 'previvors'.[28 40 53 54] Considering the unique issues that these women face in relation to their high cancer risk and decision-making about their risk management, DAs designed exclusively for this group may be more appropriate.

Furthermore, of the DAs designed exclusively for cancer unaffected BRCA mutation carriers, only two included the full range of guideline[18] recommended breast and ovarian cancer risk management strategies[53 54] and only one of these is readily available publicly in its full version.[53]

The included DAs span a period of >20 years in terms of their date of development or last update. It is likely that time since development/update may have impacted content and features of DAs. For example, DAs developed recently were more likely to be web-based with four of the six DAs developed in the last 5 years having a web-based format. Furthermore, the evidence base in the BRCA field is continuously evolving. It is noteworthy that content included in some DAs is not in line with current evidence. For example, current evidence does not support screening for ovarian cancer as a valid risk management option for BRCA mutation carriers, therefore, DAs that include this as a risk management option[53 55–57] may no longer be appropriate for use in their current version.

In addition, breast cancer risk reduction was listed as a benefit of BSO in eight DAs.[29 33–36 39 53 54] Due to the conflicting evidence in relation to this[60–62] it may be inappropriate to include breast cancer risk reduction as a benefit of BSO for BRCA1 mutation carriers in DAs presently.

Thus, currently there is no DA publicly available that has been designed exclusively for cancer unaffected BRCA mutation carriers, that includes all breast and ovarian risk management strategies recommended for this population together with a values clarification activity and that aligns with current best evidence in the field.

In terms of effectiveness of the existing DAs for BRCA mutation carriers; the included studies all reported a positive effect of the DA in question on at least one decision related or information related outcome. However, only six DAs were tested in an RCT, and bias concerns have been raised in relation to most of these RCTs.[43] In addition, various instruments were used to assess outcomes in the DA effectiveness studies, some of which were validated and others not. Furthermore, it is possible that publication bias may have contributed to an over-representation of positive findings on DA effectiveness in the literature. Publication bias was not formally evaluated in this scoping review. Thus, while the reported effectiveness of these DAs in improving various decision and information related outcomes is promising; further high-quality studies using validated instruments are required to clarify the influence of DAs on these outcomes.

Limitations of this review

This scoping review has several limitations. As the intention of this study was to map the landscape of the evidence on development and testing of DAs applicable to cancer unaffected BRCA mutation carriers we took an inclusive approach to eligibility of evidence sources for inclusion. In the absence of a universally accepted definition for 'decision aid' we included DAs that were described as such by their developers and/or included in the Ottawa Hospital Research Institute's patient DAs inventory and/or that in the author's judgement could be considered a DA based on the DA definition provided by the IPDAS Collaboration.[59] In addition, DAs included in this review were identified by searching databases, reference lists and the internet. It is possible that other relevant DAs may exist elsewhere in the grey literature. Several of the included DAs were not readily accessible as full versions in the public domain; as such, details of their features and content were derived from the articles describing their development rather that the full DA version. This may have resulted in some DA features being omitted in this report. Finally, as a scoping review a formal quality appraisal of included evidence sources was not conducted thus the evidence on DA quality and the quality of studies testing DA effectiveness reported here was drawn from reports by other authors[43 58] rather than an independent appraisal.

Conclusions

Implications for research or practice

The features of existing DAs and evidence relating to their efficacy testing reported here and by others will serve as a useful basis for identifying which DAs are suitable for various populations of BRCA mutation carriers and will assist in the development of new DAs for this population.

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Appendix 1: Search strategies

1A: Decision Aids

Medline (OVID)

1. Decision Support Techniques/
2. (Decision adj3 (support* OR aid* OR navigation OR patient* OR tool*)).ti,ab.
3. or/1-2
4. Genes, BRCA1/
5. BRCA1 Protein/
6. Genes, BRCA2/
7. BRCA2 Protein/
8. (BRCA* or brca* or hereditary breast ovarian cancer syndrome or hereditary breast ovarian cancer syndrome or HBOC).mp.
9. ((BRCA* or brca*) adj5 (carrier* or tumor* or tumour* or gene* or suppress* or protein* or mutat* or alter* or damage* or inherit* or heredit*)).mp.
10. or/4-9
11. 3 AND 10

EMBASE

1. 'decision support system'/exp
2. (Decision NEAR/3 (support* OR aid* OR navigation OR patient* OR tool*)):ti,ab
3. #1 OR #2
4. 'breast cancer'/exp AND ('mutation'/de OR 'gene mutation'/exp OR 'germline mutation'/exp)
5. 'tumor suppressor gene'/exp
6. 'BRCA1 protein'/exp
7. 'BRCA2 protein'/exp
8. (BRCA* or brca*):ti,ab
9. ((BRCA* or brca*) NEAR/5 (carrier* or tumor* or tumour* or gene* or suppress* or protein* or mutat* or alter* or damage* or inherit* or heredit*)):ti,ab
10. #4 OR #5 OR #6 OR #7 OR #8 OR #9
11. #3 AND #10

CINAHL

1. (MH "Decision Support Techniques") OR (MH "Decision Making, Patient")
2. TI (Decision N2 (support* OR aid* OR navigation OR patient* OR tool*)) OR AB (Decision N2 (support* OR aid* OR navigation OR patient* OR tool*))
3. S1 OR S2
4. (MH "Genes, BRCA")
5. TI ("brca1") OR AB ("brca1")
6. TI ("brca protein") OR AB ("brca protein")
7. TI ("brca2") OR AB ("brca2")
8. TI ("BRCA* OR brca*") OR AB ("BRCA* OR brca*")
9. TI ((BRCA* or brca*) N5 (carrier* or tumor* or tumour* or gene* or supress* or protein* or mutat* or alter* or damage* or inherit* or heredit*)) OR AB ((BRCA* or brca*) N5 (carrier*

or tumor* or tumour* or gene* or supress* or protein* or mutat* or alter* or damage* or inherit* or heredit*))

10. S4 OR S5 OR S6 OR S7 OR S8 OR S9
11. S3 AND S10

Web of Science

TS =((Decision NEAR/3 (support* OR aid* OR navigation OR patient* OR tool*)) AND ((BRCA* or brca*) OR ((BRCA* or brca*) NEAR/4 (carrier* or tumor* or tumour* or gene* or suppress* or protein* or mutat* or alter* or damage* or inherit* or heredit*))))

Appendix II: Data Extraction Template

Extracted by:

Date:

Evidence source Details and Characteristics	
Author	
Year	
Title	
Country	
Aims/Purpose	
Target population or Study population and sample size	
Concept	
Context or Setting	
Methodology	
Details/Results extracted from source of evidence (in relation to the concept of not the scoping review)	
Risk management options addressed in decision aid	
Format of decision aid (paper, web-based etc.)	
Presentation of risks and benefits in decision aid	
Included specific advantages & disadvantages of each option	
Are there separate sections for BRCA1 & BRCA2 mutation carriers?	
Does the decision aid facilitate users to work through their values & how they feel about the different options? How?	
Disclaimer(s) provided? If yes provide details	
Patient & Public Involvement (PPI) in decision aid development	
Other features of decision aid	
Efficacy of decision aid on decision related outcomes (if applicable)	

Does the DA provide a recommendation for which option(s) the patient should choose?	
Intended moment(s) of use of DA eg. Self-administered by patient or interview administered by clinician during routine consultation	
Author reported strengths & weaknesses of DA	
Author correspondence: (Details of correspondence with study authors for additional information or clarification of queries)	
Additional Notes	
References: (Additional relevant articles cited in reference list of article)	

Developer& Year#	Country	Title	Target Population	DA designed exclusively for BRCA mutation carriers?	Risk management options addressed in decision aid	Format of decision aid	Decision aid Language	Presentation of risks and benefits in DA	Separate sections for BRCA1 & BRCA2 mutation carriers?	Decision aid facilitates users to work through their values?	Patient & Public Involvement (PPI) in decision aid development?	Efficacy of decision aid on decision related & other relevant outcomes reported ?	DA provides recommendation for which option(s) the patient should choose?	Intended moment(s) of use of DA
Armstrong 2005	USA	Individualized Survival Curves Improve Satisfaction with Cancer Risk Management Decisions in Women With BRCA1/2 Mutations	BRCA1 & BRCA2 mutation carriers without OC or metastatic BC & significant residual BC or OC risk	Yes	**Breast:** Screening Prophylactic mastectomy; Chemoprevention (tamoxifen, raloxifene) **Ovarian:** Prophylactic oophorectomy;	Paper Binder containing survival & cancer incidence curves printed on translucent paper	English	Graphic presentation of cancer risks and risk reductions with the various options by means of individualized overall survival curves, and individualized breast cancer incidence curves for alternative management options and combinat	Risk estimates are individualised therefore it is likely that BRCA 1/2 status is taken into account.	Not reported	Not reported	Yes See table 2	No	Mainly self-administered By patient.

								ions of options.						
Centre for Genetics Education NSW Health (2017)	Australia	Surgery to Reduce the Risk of Ovarian Cancer Information for Women at Increased Risk	women at increased risk of ovarian cancer	No	**Ovarian:** RR-BSO (main focus)	Paper booklet	English	Graph showing baseline OC risk at various ages according to family hx of OC, BRCA or Lynch syndrome status Text description of risks & benefits	No	No	Unclear	Unclear *? An earlier version of this DA appears to have been tested in Tiller 2006*	No	Self-administered by patient
Centre for Genetics Education, NSW Health (2012 update)	Australia	Information for Women considering Preventive Mastectomy because of a strong family history of breast cancer	Women with a strong family hx of breast cancer who may be considering preventive mastectomy.	No	**Breast:** Risk-reducing mastectomy (main focus) Following options addressed briefly: Lifestyle behaviours Screening/surveillance (mammography, MRI, ultrasound)	Paper booklet	English	Text description of risks and benefits	No	No	Yes	Not reported	No	Self-administered by patient

					Chemoprevention (anastrozole)									
Collins 2016	Australia	iPrevent®: a tailored, web-based, decision support tool for breast cancer risk assessment and management.	All women (including women at increased BC risk and known BRCA mutation carriers) Age 18-70yrs Without BC Without RRM Without mutation in cancer gene other than BRCA1/2 Without 'half' relatives with BC, OC, prostate or pancreatic cancer	No	**Breast:** Screening (mammography, MRI) Risk-reducing Medication (tamoxifen raloxifene, anastrazole, exemestane) risk-reducing mastectomy premenopausal risk-reducing salpingo-oophorectomy Lifestyle Modification	Web-based	English	Breast cancer risks & risk reductions presented as words, percentages, a visual scale or pictogram and graphs risk management options appear are, tailored to the woman's risk category and her input data	Yes (indirectly) BRCA 1 or BRCA2 status inputted by user & risk estimates tailored accordingly	No	Yes	Reported in Lo 2018 (see table 2)	No	To be used collaboratively by healthcare providers and women
Harmsen 2018	The Netherlands	A patient decision aid for risk-reducing surgery in premenopausal BRCA1/2	*BRCA1/2* mutation carriers who participate in a preference trial that compares	Yes	**Ovarian:** Risk-reducing salpingo-ophrectomy	Paper booklet	Dutch with English translation available	Shaded icon arrays to indicate % risk) and pie charts	Yes	Yes	Yes	No Testing of final DA not reported	Yes	To be used in addition to face-to-face consultation

		mutation carriers: Development process and pilot testing	RRSO with salpingectomy and delayed oophorectomy Pre-menopausal, age 25-45 yrs, completed childbearing, not currently being treated for malignancy		Risk-reducing salpingectomy			were used for risk communication. Text description of benefits & risks						
Healthwise staff a (2020 update) **DA reviewed and content assessed as current 2023**	USA	Breast Cancer: What Should I Do if I'm at High Risk?	Women at high risk for breast cancer	No	**Breast:** Screening/surveillance RRM BSO Chemoprevention	Web-based (with option to print as pdf)	English	BC risks depicted using shaded icon arrays Text description of benefits & risks DA allows users to compare benefits and risks of 2 options side by side by selecting the options they want to	No	Yes	Not reported	Not reported	No	Self-administered by patient

								compare from a dropdown list						
Healthwise staff b (2020 update) **DA reviewed and content assessed as current 2023**	USA	Ovarian Cancer: Should I Have My Ovaries Removed to Prevent Ovarian Cancer?	Women who at high risk of ovarian cancer	No	**Ovarian:** BSO Screening	Web-based (with option to print as pdf)	English	Test Description of baseline OC risks for women with 1 or 2 first degree relatives with OC and for BRCA mutation carriers Text description of benefits and risks of BSO DA allows users to compare the benefits and risks of the 2 options (BSO, no surgery) side by side	No	Yes	Not reported	Not reported	No	Self-administered by patient

Jabaley 2020	USA	Development and Testing of a Decision Aid for Unaffected Women with a BRCA1 or BRCA2 Mutation	BRCA 1/2 mutation carriers without a personal history of breast or ovarian cancer 'previvors'	Yes	**Breast:** Surveillance /Screening ((Breast self-exam, Clinical breast exam, , MRI, Mammography) Prophylactic Mastectomy Chemoprevention (tamoxifen, raloxifene) **Ovarian:** Screening (TVU, CA125) Prophylactic Oophorectomy OCP	Paper/ electronic pdf	English	Bar charts depicting cancer risks Text description & tables showing risks & benefits	No but cancer risks and recommended ages for ovarian risk management options reported separately for BRCA1 & BRCA2 mutation carriers.	Yes	Yes	Yes (information related outcomes only)- see table 2.	No	Intended to be Initially initiated by clinicians (designed with the possibility of being initiated by patients).
Kaufman 2003	USA	Development of an Interactive Decision Aid for Female BRCA1/BRCA2 Carriers	BRCA1 & BRCA2 mutation carriers	Yes	**Breast:** Screening (Breast self-exam, Clinical breast exam, Mammography) Chemoprevention (tamoxifen, raloxifene)	CD-Rom	English	Text description of risks & benefits Risks portrayed using bar charts (eg. depicting cumulative BC risk	Yes	Yes	Yes	Yes Reported in Schwartz 2009 & Hooker 2011 (see table 2)	Partly During the 'decision task' activity, the highest preference score indicates the risk manage	Self-administered by patient to be used in addition to comprehensive genetic counselling sessions

					Prophylactic mastectomy **Ovarian:** ***not main focus*** Screening (CA-125, transvaginal ultrasound) Oral contraceptives Prophyactic oophrectomy			to age 50 and age 70)					ment option that is most consisten t with the values and preferen ces the woman entered in the decision task	
Kautz-Freimuth 2021 DA (A) 'Previvors'	Germany	Development of decision aids for female BRCA1 and BRCA2 mutation carriers in Germany to support preference-sensitive decision-making	BRCA1/2 mutation carriers (in Germany) without a history of cancer (previvors)	Yes	Intensive breast cancer screening Risk-reducing bilateral mastectomy: Risk-reducing salpingo-oophrectomy	Paper brochure & electronic pdf version	German	Reported only briefly Average risks of breast cancer and ovarian cancer each subdivided into BRCA1 and BRCA2 mutations Lifetime, age and time-related	Yes	Yes	Yes	No	No	To be used in post-test genetic counselling and given to women to take home

								(10 year) risks Personal risk of breast cancer and ovarian cancer Effect of RRM on risk of developing breast cancer Effect of BSO on risk of developing ovarian cancer & survival *-unclear if test descriptions, graphic depictions or both were used* pros/cons, overview table of each intervention						

Krassuski 2021	Germany	Decision Aids for Preventive Treatment Alternatives for BRCA1/2 Mutation Carriers: a Systematic Review	Decision aids applicable to BRCA mutation carriers	NA	Various- see individual included studies	Various- see individual included studies	Various- see individual included studies	Various- see individual included studies	see individual included studies	see individual included studies	see individual included studies	Not Reported	see individual included studies	see individual included studies
Kurian 2012	USA	Online Tool to Guide Decisions for BRCA1/2 Mutation Carriers	female *BRCA1/2* mutation carriers unaffected by cancer Age 25-69 yrs Who have NOT undergone breast screening, risk-reducing breast or ovarian surgery and have NOT taken risk-reducing medication.	Yes	**Breast:** Screening (mammogram, MRI, both) Prophylactic mastectomy (at various ages). **Breast & Ovarian:** Prophylactic oophrectomy (at various ages).	Web-based	English	Outcomes shown in decision aid are shown as bar charts & % probability of each outcome.	Yes	No	Not reported	Reported in Schackmann 2013 (see table 2)	No	Designed for joint use by cancer unaffected women with BRCA mutations and their health care providers.
Mayo Clinic Staff (2020 update)	USA	Prophylactic oophorectomy: Preventing cancer by surgically removing your ovaries.	women at high risk of ovarian cancer (including BRCA mutation carriers & those with Lynch syndrome)	No	**Breast & Ovarian:** BSO (main focus) Screening for OC, RRM and OCP mentioned briefly as alternatives	Web-based	English	Text description of risks and benefits	No	No	Not reported	Not reported	No	Appears self-administered

Mayo Clinic Staff (2021 update)	USA	Preventive (prophylactic) mastectomy: Surgery to reduce breast cancer risk	Women at high risk of breast cancer (both cancer unaffected & cancer affected)	No	RRM (bilateral & contralateral) - *main focus* Following options also mentioned briefly: Chemoprevention Breast cancer screening BSO Healthy lifestyle	Web-based	English	Text description of risks & benefits	No	No	Not reported	Not reported	No	Appears self-administered
Metcalfe 2007	Canada	Development and testing of a decision aid for breast cancer prevention for women with a BRCA1 or BRCA2 mutation.	BRCA 1/2 mutation carriers unaffected by BC or OC	Yes	Preventive Mastectomy Preventive salpingo-oophrectomy before age 50Tamoxifen for 5 years Breast screening	Paper booklet	English	Probabilistic information on likelihood of benefits and risks of each option depicted using text & shaded icon arrays	Not Reported	Yes	Yes	Yes Use of the decision aid decreased decisional conflict, increased knowledge levels & decreased uncertainty about each option Efficacy tested further in RCT reported in Metcalfe 2017 (see table 2)	No	Self-administered designed to be used in addition to standard genetic counselling

NICE 2017 (Pre-menopausal)	UK	Taking tamoxifen to reduce the chance of developing breast cancer Decision aid for premenopausal women at high risk	Pre-menopausalwomen at high risk of breast cancer BC unaffected	No	Risk-reducing medication (Tamoxifen for 5 years)	Paper (pdf)	English	Yes Risks and benefits of each option displayed in tabular form & using shaded icon arrays.	No	Yes	Yes	Not reported	No	Intended to be used in conjunction with healthcare professionals within secondary care or specialist genetic clinics, who have expertise in familial breast cancer.
NICE 2017 (Post-menopausal)	UK	Taking a medicine to reduce the chance of developing breast cancer Decision aid for postmenopausal women at high risk	Post-menopausalwomen at high risk of breast cancer BC unaffected	No	Risk-reducing medication: Anastrozole for 5 years Raloxifene for 5 years Tamoxifen for 5 years	Paper (pdf)	English	Yes Risks and benefits of each option displayed in tabular form & using shaded icon arrays.	No	Yes	Yes	Not reported	No	Intended to be used in conjunction with healthcare professionals within secondary care or specialist genetic clinics, who have expertise in familial breast cancer.
TILLER 2003 (updated 2008)	Australia	A decision aid for women at increased risk for ovarian cancer.	Women at increased risk of ovarian cancer	No	Watchful waiting Screening Use of OCP	Paper booklet with separate values clarificati	English	Text description of benefits & risks	Not reported	Yes	Yes	Yes Pilot testing of the DA with at-risk women	Not reported	Self-administered

Overlaps with Centre for Genetics Education NSW Health (2017) DA					Prophylactic oophorectomy	on exercise		Numerical information on risk reduction of different options provided as % reduction of risk				attending a familial cancer clinic demonstrated women reported that the decision aid had increased their knowledge, led to more accurate expectations of benefits and risks, assisted them in arriving at a decision, and reduced their decisional conflict and uncertainty Efficacy tested further in RCT reported in Tiller 2006 (see table 2)		
Unic 1998	The Netherlands	Assessment of the Time-trade off Values for Prophylactic	Healthy women suspected or known to have a	No	Prophylactic mastectomy Breast cancer screening	Paper brochure & videotape	Unclear	Text description & some risks &	Not reported	Yes	Yes	Yes (see table 2) Reported in Stalmeier	No* **Advice based on women's*	DA informational material viewed and

		Mastectomy of Women with a Suspected Genetic Predisposition to Breast Cancer	genetic predisposition to breast cancer			(provided as part of a Shared Decision Making Program (SDMP))		benefits explained through interviews in the video[$] [$] *full details not reported in article.*				1999 (see table 2)	*preferences subsequently given by clinicians as part of the wider SDMP*	read at home- provided as part of a Shared Decision Making Program (SDMP)
VANROOSMALEN BJC 2004a	The Netherlands	Randomised trial of a decision aid and its timing for women being tested for a BRCA1/2 mutation.	Women undergoing testing for a BRCA1/2 mutation	No (Designed for women undergoing genetic testing therefore participants are not necessarily aware of their BRCA status at the time of use)	Breast cancer screening Prophylactic mastectomy Ovarian cancer screening Prophylactic oophorectomy	Paper brochure and video	Dutch	Yes Text description of benefits & risks of each option in qualitative terms & where possible in quantitative terms Video portrayed consequences of the options through interviews with BRCA mutation carriers	No	Not reported	Yes	Yes (see table 2) Additional efficacy testing reported in VANROOSMALEN JCO 2004b (see table 2)	No	brochure and video to be viewed at home. DA is considered suitable for use either before or after a genetic test result.

								Photographs showed results of prophylactic mastectomy						
VANROOSMALEN JCO 2004b	The Netherlands	Randomized Trial of a Shared Decision-Making Intervention Consisting of Trade-Offs and Individualized Treatment Information for BRCA1/2 Mutation Carriers.	BRCA 1/2 mutation carriers (both BC or OC affected or unaffected) without distant metastasis, had not undergone both RRM & RR-BSO	Yes	**Breast:** Breast Cancer screening Prpphylactic mastectomy **Ovarian:** Ovarian cancer screening Prophylactic oophrectomy	Face to face and telephone TTO interviews.	Dutch	individualized treatment information was shared with the women using two bar charts, one for life expectancy (LE) and one for quality-adjusted life expectancy (QALE). The bar charts presented the treatment options relative to each other	Unclear	Yes	Not reported	Yes (see table 2)	Unclear	Interview administered by a research assistant Subsequent to use (at home) of an informational DA

Witt 2014 (Cardiff University)	UK	Ovdex The Oophorectomy Decision Explorer v5	Women at increased risk of ovarian cancer	No	BSO (main focus) OCP & lifestyle behaviours briefly mentioned	Web-based booklet	English	OC risks & complication s/side effects of BSO displayed using shaded icon arrays and text description Benefits and risks of the 2 options (BSO, no surgery) compared side by side in a table	Unclear mentions that information can be personalised by answering 3 questions on linked website (no longer in use)	Yes	Yes	Not reported	No	Self-administered by patient? Unclear

Author & Year	Decision aid evaluated	Country	Study design	Participants & sample size	Did any participants have a personal history of breast or ovarian cancer?	Intervention	Comparator	Outcomes evaluated	Outcome assessment methods	Main Results
Armstrong 2005	Armstrong 2005	USA	Double-blind randomised controlled trial	Women with BRCA1/2 mutations (n = 32) Women were excluded if they did not have significant residual breast or ovarian cancer risk (ie, they had already undergone both bilateral oophorectomy and bilateral mastectomy). women were excluded if they had ovarian cancer or metastatic breast cancer.	Yes 48% of participants had been diagnosed with breast cancer before undergoing BRCA testing	one-on-one meeting with research study coordinator that included a structured review of an educational booklet containing information about the cancer risks associated with BRCA1/2 mutations and the alternative management options PLUS Individualised decision support system (DSS) printouts n = 13	one-on-one meeting with research study coordinator that included a structured review of an educational booklet containing information about the cancer risks associated with BRCA1/2 mutations and the alternative management options n = 14	*Primary outcome:* decision satisfaction. *Secondary outcomes*: perceptions of cancer risk, anxiety & depression, and behaviour & behavioural intentions.	*Decision satisfaction* measured with 12-item scale that combined items from the Decisional Conflict Scale with the Satisfaction With Decision Scale. *Perceptions of cancer risk* measured using the same survey items as the baseline assessment. *Anxiety* measured with the Intrusion Subscale of the RIES and the Hopkins Symptom Checklist *Management decisions* assessed by asking participants to select the decision that best matched their current situation.	27 women completed a 6-week follow-up. Women in the intervention arm reported significantly higher decision satisfaction at follow-up than women in the control arm ($p < .0005$). The effect of the DSS was greater among women with low cancer anxiety at baseline than women with high cancer anxiety at baseline ($P = .01$ for interaction). DSS did not significantly alter cancer anxiety at follow-up, perceptions of cancer risk given alternative management strategies, or management decisions.

Hooker 2011	Kaufman 2003	USA	Randomized controlled trial nested within a larger observational study assessing the outcomes of BRCA1/2 testing. Longitudinal	Female BRCA1/2 mutation carriers (aged 21–75 years) who had not had prior bilateral mastectomy and did not have metastatic breast or ovarian cancer n = 214	Yes 37% were affected with breast cancer and 10% with ovarian cancer (mean time since diagnosis of either cancer = 7.7 years)	Usual care plus decision aid (DA) (n = 100)	Usual care (UC) (n = 114)	General distress Cancer-specific distress Genetic testing–specific distress Management intentions & behaviours at 1-, 6-, and 12-months post-randomization.	*General distress*: 12-item Brief Symptom Inventory (BSI) instrument (Likert scale) *Cancer-specific distress:* 15-item Impact of Event Scale (IES) instrument (Likert-style) *Genetic testing distress:* 25-item scale Multidimensional Impact of Cancer Risk Assessment Questionnaire (MICRA) *Management decision*: asked participants, "Have you made a final decision about how to manage your risk for breast cancer?" & asked participants whether they had obtained a risk-reducing mastectomy since previous assessment	Of the 100 DA participants included in study, 36 (36%) reported that they did not use the DA. Analyses to evaluate the impact of the DA among individuals who reported using it (n = 64). **DA users analysis:** Identified different distress trajectories in the DA and the UC groups cancer-specific and genetic testing–specific distress adjusted for baseline levels were greater among the DA group at 1 month post-randomization (P = 0.009 and 0.04, respectively) individuals in the DA group who viewed the DA reported significantly lower genetic testing–specific distress 12 months post-randomization than did the UC group (P = 0.03) DA use was not associated with general distress.

Jabaley 2020 24 3	Jabaley 2020	USA	Piliot study using surveys to assess DA for organization, clarity, usefulness, comprehensiveness, ease of understanding, and relevance to the cancer risk management decision-making process	Convenience sample of unaffected BRCA mutation carriers (n = 15) and healthcare professionals (n = 8)	No	Prototype DA	NA	Rate DA for: Organization, clarity, usefulness, comprehensiveness, ease of understanding relevance to the cancer risk management decision-making process of previvors.	Surveys containing 11 Likert scale items	Mean scores were 3 or higher on Likert scales of 1–4 (high) for each of the 11 items. Most end users reported that the decision aid increased their knowledge and was useful in sharing information with family members.
Krassuski 2019	Systematic review of multiple DAs	Germany	Systematic review	Included original studies evaluating effectiveness of DA for known BRCA mutation carriers aged 18 to 75 Six studies included: *Armstrong 2005* RCT-PARALLEL GROUP *Schwartz 2009* RCT-PARALLEL GROUP	Yes	DA (see individual studies)	Various (see individual studies)	Decision related outcomes Information related outcomes Actual preventive choice Health outcomes	Various instruments (see individual studies)	Female BRCA mutation carriers using a DA had less decisional conflict, were more likely to reach a decision and were more satisfied with their decision

				Hooker 2011 RCT-PARALLEL GROUP *Metcalfe 2017* RCT-PARALLEL GROUP *VanRoosmalen 2004* -RCT CROSS-OVER TRIAL *Metcalfe 2007* -One group pretest-posttest study.						
Lo et al (2018)	iPrevent (Collins 2016)	Australia	Pilot study to assess usability & acceptability of iPrevent DA	Stage 1: Pilot test (n=10 patients with prior risk assessment attending a Breast and Ovarian Cancer Risk Management Clinic) Stage 2: Patients & clinicians from a mix of hospital & primary care settings (n=20	No	Stage 1: Patients used iPrevent under the supervision of a research assistant & were emailed resulting report Stage 2: Clinicians were first familiarized with iPrevent using hypothetical paper-based cases and then actor	BC worry, anxiety, risk perception & knowledge pre- and 2 weeks post-iPrevent.	Usability BC worry anxiety risk perception knowledge	*Usability:* 10 item (Likert scale) System Usability Scale (SUS) *Acceptability:* 9 item acceptability questionnaire *BC worry:* 3 item Lerman BC worry scale *Anxiety:* 6 item State-Trait Anxiety Inventory Risk perception: single item asks patients to rate their BC risk	Usability rated above average (SUS score >68) for 68% clinicians and 76% patients. Amount of information provided by iPrevent was reported as "about right" by 89% clinicians and 89% patients 95% clinicians and 97% patients would recommend iPrevent to others, 53% clinicians and 27% patients found it too long.

				clinicians & n = 33 patients) Patients and clinicians were not selected according to their level of BC risk or prior experience with BC risk assessment. Only 16% (n = 7) of included patients were at high risk of BC		scenarios; subsequently, they used iPrevent with their patients Patients provided a printout of their iPrevent output via email.			category: "average," "somewhat increased," or "substantially increased" *Knowledge*: 16 item survey assessing knowledge regarding BC (11 items), risk-reducing medication (3 items), and risk-reducing mastectomy (2 items)	Exploratory analyses suggested that iPrevent could improve risk perception, decrease frequency of BC worry, and enhance BC prevention knowledge without changing state anxiety.
Metcalfe 2007	Metcalfe 2007	Canada	Pre-test/post-test pilot study	BRCA 1/2 mutation carriers who had not yet made their BC prevention decision n =21 women completed pre-test questionnaire and n = 20 completed post-test questionnaire.	No	Decision aid	Outcomes Pre-test versus post-test	*Primary outcome*: decisional conflict *Other outcomes:* knowledge of BC prevention options, psychological distress, choice predisposition & acceptability. Outcomes measured at two time points (prior to using DA & within 4 weeks after using DA).	*Decisional conflict*: 16 item Decisional Conflict Scale *Knowledge*: bespoke knowledge questionnaire *Choice predisposition*: choice predisposition tool *Cancer-specific distress*: 15 item Impact of Event Scale (IES)	Use of the decision aid decreased decisional conflict to levels suggestive of implementation of a decision. In addition, knowledge levels increased and choice predisposition changed with fewer women being uncertain about each option.

									Acceptability: questionnaire using open- and closed-ended questions	
Metcalfe 2017	Metcalfe 2007	Canada	Randomised controlled trial	BRCA 1/2 mutation carries age 25-60 years with no previous cancer diagnosis or risk -reducing surgery or tamoxifen use. 150 participants recruited (intervention group n = 76, control group n = 74)	No	Decision aid + usual care	Usual care	*Primary outcome*: decisional conflict *Secondary outcomes:* cancer-related distress, knowledge & choice disposition.	*Decisional conflict*: 16 item Decisional Conflict Scale *Cancer-specific distress*: 15 item Impact of Event Scale (IES) *Knowledge*: 13 item bespoke knowledge questionnaire *Choice predisposition*: choice predisposition tool	Cancer-related distress scores significantly lower in intervention group compared with the control group at 6 months (P = 0.01) and at 12 months postrandomization (P = 0.05). Decisional conflict (*primary outcome*) scores declined over time for both groups and at no time were there statistical differences between the two groups.
Schackman n 2013	Kurian 2012	USA	Feasibility & usability pilot study	BRCA1/2 mutation carriers (n = 40) & clinicians involved in their care (n = 16) Women with BRCA1/2 had not undergone PM, but	Not reported	Decision aid	None	Usability of DA Satisfaction with DA Clinical relevance	*Usability*: 10-item System Usability Scale (SUS) *Satisfaction & contribution to clinical care:* 8 item Center for Healthcare Evaluation Provider Satisfaction Questionnaire (CHCE-PSQ).	Most patients and clinicians rated the decision tool highly on usability scale (82.5 & 85 respectively out of a possible 100 points), Most patients and clinicians stated that the tool could improve patient–physician encounters, Most patients and clinicians expressed high

				those with prior PO were eligible.					Modified CHCE-PSQ used for patients.	overall satisfaction (4.28 & 4.38 respectively out of a possible 100 points, on a scale of 1–5).
Schwartz 2009	Kaufman 2003	USA	Randomised controlled trial nested within observational study evaluating outcomes of BRCA1/2 testing	Female BRCA1/ BRCA2 mutation carriers aged 21–75 (n =214) Who had not had prior bilateral mastectomy, and did not have metastatic BC or OC randomised to Usual Care (UC; n=114) or Usual Care plus Decision Aid (DA; n=100) arms.	Yes 37% affected with BC and 10% with OC (mean time since diagnosis = 7.7 years)	DA + usual care	Usual care	Decisional conflict Decisional satisfaction Final management decision Receipt of risk reducing mastectomy at 1-, 6-, and 12-months post randomisation.	*Decisional Conflict:* 16 item Decisional-Conflict Scale (DCS) *Decision Satisfaction:* 6-item Satisfaction With Decision Scale (SWD) *Management Decision:* Participants asked 'Have you made a final decision about how to manage your risk for breast cancer?' Y/N Participants also asked whether they had obtained an RRM since the previous assessment.	DA effective among carriers who were initially undecided about BC risk management Within this group, DA led to an increased likelihood of reaching a management decision (OR=3.09, 95% CI=1.62, 5.90; p< .001), decreased decisional conflict (B=−.46, z=−3.1, p<.002), and increased satisfaction (B=.27, z=3.1, p=0.002) compared to UC. Among carriers who had already made a management decision by time of randomization, DA had no benefit relative to UC.
Stalmeier 1999	Unic 1998	The Netherlands	one-group pretest-posttest study	Women with a family hx of BC (mixture of known BRCA mutation carriers, non-carriers & untested)	No	DA (Shared Decision Making Program (SDMP)).	Outcomes compared in participants pre & post intervention	Decision uncertainty, decision burden, subjective knowledge, risk comprehension breast cancer concern, desire to participate in the program,	*Decision uncertainty:* single item bespoke survey *Decision burden:* single item bespoke survey	Decision uncertainty (effect size d = 0.37) and decision burden (d= 0.41) were reduced by the SDMP. Subjective knowledge and risk comprehension were improved. The women were satisfied with the SDMP and

				n = 54				satisfaction, program acceptability, Intention to act upon SDMP emotional reaction to program information	*Subjective knowledge:* 2 item bespoke survey *Risk comprehension:* 4 item bespoke survey *Breast cancer concern:* 4 item bespoke survey *Desire to participate in the program:* 4 item bespoke survey *Satisfaction:* 7 item bespoke survey *Program acceptability:* 4 item bespoke survey *Emotional reaction to program information:* 4 item bespoke survey	found its rationale acceptable. Women who had strong emotional reactions to the information benefited less from the SDMP, whereas women with strong desires to participate in the decision benefited more.
Stalmeier 2009	van Roosmalen 2004 a&b	The Netherlands	Study to compare the responsiveness of several instruments used to evaluate DA's	Participants from Van Roosmalen 2004 a & b (see above)	Yes	Two decision aids: DA1: (reported in Van Roosmalen 2004 a) DA2: (SDMI) reported in (reported in	Compared responsiveness of various DA evaluation measures in 2 DAs	Responsiveness (effect sizes) of various instruments	Effect sizes calculated according to equation reported on p106 of article	Three factors were identified related to Information, Well-being and Decision Making. Within each factor, single item measures were as responsive as multi-item measures.

						Van Roosmalen 2004 a)				Four single items, 'the amount of information received for decision making,' 'strength of preference,' 'I weighed the pros and cons,' and 'General Health,' were adequately responsive to the decision aids.
Steenbeek 2021	Harmsen 2018	The Netherlands	Non-randomised controlled trial	Premenopausal BRCA 1/2 mutation carriers (n= 585) taking part in a dutch preference trial (the TUBA study)	Yes 14% had history of breast cancer None affected by ovarian cancer.	Usual care + DA (n = 282)	Usual care (UC) (n = 283)	Actual choice, Feasibility Knowledge, cancer worry, Decisional conflict, Decisional regret Self-estimated influence on decision	Validated questionnaires including: Self-estimated ovarian cancer risk, Cancer Worry Scale & a Decisional Conflict Scale Decisional regret scale DA arm received additional questions on feasibility & self-estimated influence of the DA.	Users of the decision aid reported increased knowledge about the options and increased insight in personal values. Knowledge on cancer risk, decisional conflict, decisional regret and cancer worry were similar in both arms. Significantly more women in DA arm chose novel surgical strategy.
Tiller 2003	Tiller 2003	Australia	Pilot testing of DA	Women at increased risk of ovarian cancer attending a familial cancer clinic	Not reported	DA	Not reported	Not reported	Not reported	Women reported that the decision aid had increased their knowledge, led to more accurate expectations of benefits and risks, assisted them in arriving at a decision, and reduced their decisional conflict and uncertainty

Tiller 2006	Tiller 2003	Australia	Randomised Controlled Trial	Women (age ≥ 30 years) with a family history of breast and/or ovarian cancer or of hereditary nonpolyposis colorectal cancer (n = 131) With no hx of OC or BSO.	OC = No BC = Yes	DA	General educational pamphlet	Decisional conflict knowledge about ovarian cancer risk management options Psychological adjustment At baseline, 2 weeks & 6 months post intervention	*Knowledge of Ovarian Cancer Risk Management Options*: 10 item true-false questionnaire *Decisional conflict:* modified Decisional Conflict Scale (DCS) *Psychological adjustment*: 7 item intrusion subscale Impact of Event Scale (IES) 6 item short form State-Trait Anxiety Inventory (STAI) Hospital Anxiety and Depression Scale (HADS)	Two weeks postintervention, the intervention group demonstrated a significant decrease in decisional conflict compared to the control group (t = 2.4, P < 0.025) and a trend for a greater increase in knowledge about risk management options (t = 2.1, P = 0.037). No significant differences were found 6 months post-intervention. No significant differences between groups were observed for any of the psychological outcomes.
Van Roosmalen BJC 2004a	VAN ROOSMALEN BJC 2004a	The Netherlands	Randomised controlled trial	Women undergoing testing for a BRCA1/2 mutation n= 368 DA group (n = 184), Control	Yes	DA+ usual care	Usual care	Strength of treatment preference Decision uncertainty Preference for decision-making Subjective knowledge	*Strength of treatment preference*: 4-point Likert scale questionnaire *Decision uncertainty:* 3 items related to	DA had no impact on decision uncertainty, Women randomised to the DA more frequently considered prophylactic surgery,

				group (n = 184) Women excluded if: diagnosed with distant metastases, had undergone both BM & BSO, or had been treated with chemotherapy, radiotherapy, or surgery for BC OR OC < 1 month before blood sampling. *Sub group:* To evaluate the impact of timing, mutation carriers who had received the DA before the test result (n = 47) were compared to mutation carriers who received the DA after the test result (n = 42)				Amount of received information Satisfaction with quality of information Risk perception	the uncertainty subscale of the Decisional Conflict Scale *Preference for decision-making:* 2 decision-making items from the Problem-Solving Decision-Making Scale (PSDM) *Subjective knowledge:* Questionnaire, items rated on 10 point scale. *Amount of received information:* rated on 7 point scale *Satisfaction with quality of information:* 13-item questionnaire. Items rated on on a 6-point scale *Risk perception: 8 cancer risk items rated from 0-100%*	DA group felt better informed & showed more accurate risk perceptions. Timing of the DA (before versus after genetic test result) had no effect on any of the outcomes

VanRoosmalen JCO 2004b	VANROOSMALEN JCO 2004b	The Netherlands	Randomised controlled trial	Female BRCA 1/2 mutation carriers (n = 88) Intervention group (n = 44) Control group (n = 44) Women excluded if: diagnosed with distant metastases, had undergone both BM & BSO, or had been treated with chemotherapy, radiotherapy, or surgery for BC OR OC < 1 month before blood sampling.	Yes	Shared Decision Making Intervention (SDMI) + usual care All participants had previously received DA described in VAN ROOSMALEN BJC 2004a	Usual care All participants had previously received DA described in VAN ROOSMALEN BJC 2004a	Strength of treatment preference, Decision uncertainty, Perceived participation in decision making, Weighing treatment choice Perceived preference of the specialists, Support and advice from specialists. Well-being Treatment choice	*Strength of treatment preference:* survey, preference for options rated on 4 point likert scale *Decision uncertainty:* 3 items related to the uncertainty subscale of the Decisional Conflict Scale *Perceived participation in decision making:* 2 decision-making items from the Problem-Solving Decision-Making scale, rated on 5 point scale *Weighing treatment choice:* single item survey rated on 5 point scale. *Perceived preference of the specialists:* Women were asked whether they felt that the specialists held a treatment preference (Y/N) and, if so, its	In the short term, 3 months after the test result, the SDMI had no effect. In the long term, 9 months after the test result, the SDMI group reported less intrusive thoughts about cancer in the family & better general health. SDMI group reported a stronger treatment preference and more strongly agreed to having weighed the pros and cons for the breast treatment. Beneficial effects of SDMI found only in cancer unaffected participants.

									strength (strong/weak) *Support and advice from specialists:* Women asked whether they had wanted more support & advice from their specialists regarding their treatment choice, rated on 7 point scale *Well-being:* anxiety (state anxiety subscale of the Spielberger State-Trait Anxiety Inventory), Depression (Center for Epidemiologic Studies Depression Scale) intrusive and avoidance thoughts about cancer in the family (intrusion and avoidance subscale from the Impact of Event Scale). women rated their general health during the	

									last week on an 11-point scale *Treatment choice:* Survey, women indicated their intended treatment choice for the breasts and/or ovaries Women answered the question, "How suitable do you find prophylactic mastectomy for yourself?" by rating on a 10-point scale Data on the actually performed treatment also collected by questionnaire.	