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.	