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Effectiveness of Decision Aids for Women Considering Breast Cancer Surgery:
A Systematic Review and Meta-Analysis

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Effectiveness of Decision Aids for Women Considering Breast Cancer Surgery: A Systematic Review and Meta-Analysis

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Background

Breast Cancer
In 2018, it is estimated that 2,088,849 (11.6%) new cases of breast cancer were identified worldwide (Bray, Ferlay, Soerjomataram, Siegel, Torre, & Jemal, 2018). The number of women with breast cancer has been increasing in the developed countries, as well as in the developing world because of increasing life expectancy, urbanization, and adopting Western-type lifestyles (Yip et al., 2008).

The typical care of breast cancer is surgery. While adjuvant therapies, such as chemotherapy and radiotherapy, reduce the risks of disease recurrence,
breast cancer surgery remains as one of the most sensitive decisions related to a variety of patients’ preferences for women with early breast cancer (Stacey, Samant, & Bennett, 2008). Furthermore, each treatment option is significantly different and carries different risks. Older patients have to make a decision about their surgery or other treatments in consideration of their frailty and comorbidities (Collins et al., 2017).

**Body Image for Women With Breast Cancer**

Generally, breasts are one of the important body parts that helps to establish body image for women. In that regard, body image is affected due to breast alterations such as removal of the entire breast. For the patients who lose physical symmetry, there is an obvious change physically, and that has a negative impact especially for women with high expectations for physical beauty (Turk & Yilmaz, 2018). Because one of the treatment methods is mastectomy, there are a variety of impacts on women because it often lowers of self-estimation and threatens one’s image of femininity (Sheppard & Ely, 2008). The number of women with breast cancer who were disturbed by their body image was 15 to 30% (Anagnostopoulos & Myrgianni, 2009; Lyngholm, Christiansen, Damsgaard, & Overgaard, 2013; Rooney Michelle, 2007) Therefore, it is important to consider that their body image may change at any cancer stage and at any age (Angarita, Elmi, Zhang, & Hong, 2018).
Decision Aids Defined

According to the International Patient Decision Aids Standards (IPDAS) Collaboration (Elwyn et al., 2006; Joseph-Williams et al., 2014), decision aids (DAs) consist of tools backed by evidence, which are provided to people to support decision making for health care choices. DAs are intended to improve the quality of the user's decision. There are several reasons why decision aids are important for patients (Stacey et al., 2017):

(a) Helping patient in decision-making that needs to be considered

(b) To provide the best choice depending on the benefits, harms, probabilities, and scientific uncertainties by the evidence

(c) Helping patient for informing and consideration about the values-sensitive nature of the decision and to clarify, either implicitly or explicitly, the value of carrying out the benefits and harms to them

DAs are the decision support interventions, which have been developed to support patients in order to clarify their preferences and values using evidence-based information about their treatment benefits or harms, and the other options. Recently, patient centered care has become recognized as important in providing patient care, and DAs contribute to patient centered care philosophy. Shared decision making has also becoming important in providing oncology care (Politi, Studts, & Hayslip, 2012).
Background of DAs

Why are DAs currently important for practitioners and patient? There are some reasons why the DAs trend is growing in the clinical.

Evidence-based medicine (EBM) was altered in order to assimilate excellent evidence of research with clinical experiences, clinical practice, and patient values (Strauss, 2011). In the post-1990s era, EBM was a principle medical paradigm (Bae, 2015). Mainly, EBM focused on determining the best research evidence which related to clinical problems, or decision and applying the evidence for the issue resolution (Haynes, Devereaux, & Guyatt, 2002).

However, some medical decisions are not certain about the evidence on outcome, or the options have different advantages and disadvantages in terms of each patient’s value (Eddy, 1999; Kassirer, 1994). Therefore, practice guidelines recommended that practitioners should consider involving patients in order to cope with difficulties for decision of treatment, and patients need to accurately understand their options of outcomes with consideration of their preferences (Grady et al., 1992).

Haynes, Devereaux, and Guyatt (2002) reported about a model, which included individual patient preferences. This model consisted of three components which were: (a) “research evidence, (b) clinical state and circumstances, and (c) patients’ preferences and actions”, because even if their preference is treatment, a patient’s preference might be opposite of their clinician’s suggestion (Haynes, 2001). Some randomized clinical trials failed to
evaluate of clinical effectiveness in spite of producing the highest quality
evidence (Bae, 2015). As a result, patient-centered care has gained momentum
as a crucial factor in delivering higher quality care (Mead & Bower, 2000).

Patient-centered care (PCC) was defined as care provision in order to
achieved healthcare discussions and decisions involving patient’s values,
needs, and desires (Mead & Bower, 2000). Shared decision making is one of
the consultation models that involved patient engagement and activation using
decision aids. Therefore, DAs is one of the tools as part of shared decision aids
(Coulter, 1999; Elwyn et al., 2006).

**Effectiveness of DAs**

Patient DAs have been explored for a variety of health conditions
including breast cancer (Nicholas, Butow, Tsson, & Boyle, 2016; O'Brien et al.,
2009; Stacey et al., 2017). For instance, O'Brien et al. (2009) reported that
cancer-related decision aids improved patient knowledge compared to usual
practice and did not increase anxiety in terms of cancer screening (O'Brien et
al., 2009). Recent reviews reported that DAs supported patients with uncertain
individual values for reducing decisional conflict and increasing knowledge
about treatment options better than usual care (Stacey et al., 2017). It has been
known that it is important to provide patients with decision-making support tools
such as online support or printed materials (Stacey et al., 2017).
Women With Breast Cancer and DAs

Regarding of DAs for women with breast cancer, age range as well as breast cancer stages should be considered when providing decision-making tools, because breast cancer outcomes in younger women have been improving steadily since screening and therapies are improving. Not only young women, but also older women with breast cancer may receive surgery for their breast cancer, even though the outcome ratio is no higher than in younger patients (Collins et al., 2017).

Angarita, Elmi, and Zhang (2018) reported about factors that affect the DAs process of older woman with breast cancer treatment such as relating the impact of body image and improvement of acknowledging and addressing personal and family factors (Angarita et al., 2018). However, they did not report what kind of DA tools for older women with breast cancer were effective.

Some studies found that there were DAs tool for women with breast cancer that significantly increased knowledge and decreased decision-conflict. Dhage et al. (2013) reported that women with breast cancer were satisfied with the contents of computer-based animations as DAs (Dhage et al., 2013). Another tool is the ‘A Patchwork of Life’, a computer DAs focusing on values clarification for women with lower literacy and novice computer skills (Jibaja - Weiss et al., 2006). The patient’s treatment preferences became clearer, and details of their treatment options as well (Jibaja - Weiss et al., 2006). A decision
board significantly improved satisfaction regarding information, decision-making process, and knowledge (Whelan et al., 1999).

Nicholas, Butow, and Tesson (2016) reported in a systematic review about the effect of DAs for overall care for early stage of breast cancer treatment: chemotherapy, radiotherapy, and surgery (Nicholas et al., 2016). However, each of the treatments was significantly different and had different risks (Collins et al., 2017), therefore, DAs should be addressed in terms of each treatment. In addition, a previous systematic review only focused on the early stage of breast cancer (Nicholas et al., 2016).

For the above reasons, DAs are important interventions for patients with breast cancer. However, it is not at all obvious what kind of DAs tools are effective for considering surgery of breast cancer surgery in any stages and ages.

**the Aim of This Review**

The aim of this systematic review was to determine the effectiveness of DAs tools for women considering breast cancer surgery in any stages of breast cancer and any age above 18 years. Only surgery treatment was considered.
Methods

Searching Strategy

The researcher included all published studies, which used individual or cluster randomized controlled trial (RCT) design evaluating Decision Aids (DA) with women considering breast cancer surgery.

The researcher included studies that met all the PIS criteria as follows:

Population:
(a) Women with breast cancer who were faced with the decision about their surgery
(b) Women above 18 years old with any stage of breast cancer who use a support tool which assists in making a decision about treatment, especially, breast conserving surgery

This review did not specify the stages of breast cancer. According to the National Cancer Institution (https://www.cancer.gov/publications/dictionaries/cancer-terms/def/early-stage-breast-cancer), early stage of breast cancer stating:

“Breast cancer that has not spread beyond the breast or the axillary lymph nodes. This includes ductal carcinoma in situ and stage I, stage II A, stage II B, and stage III A breast cancer.”
Intervention:

(a) DAs tools such as decision technologies, apps and other methods of supporting DAs about their surgery

Study design:

Individual and cluster randomized control trials (RCTs) were included. Quasi randomized controlled trials were excluded. The researcher included conference abstract in this review.

This systematic review was conducted by the Cochrane Handbook for Systematic Reviews (Higgins & Green, 2011). Furthermore, this systematic review followed Prepared Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement for reporting of systematic reviews and meta-analyses (Moher, Liberati, Tetzlaff, & Altman, 2009). The search was not restricted by publication status, to reduce the publication bias. The search used the following databases: Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, PubMed, CINAHL, and PsycINFO. The researcher searched papers published by October 31, 2018. No language restrictions were included in the search strategy. Search categories used were as follows: decision aids and other decision support tools; breast cancer with surgery. The researcher proceeded with the search by collaborating with a librarian. The following keywords were used:
**Comparison**

Comparison that was usual care or any control defined by trialist about DAs tools, the context was any setting.

**Outcomes**

Primary outcome, which the patient reported outcome measure results with decision aid support tools.

1. Knowledge of their surgery (any measurements)

2. Decisional conflict (measurement: Decision Conflict Scale (DCS) or other measurements)

3. Acceptability (any measurements)
For patient value clarification, it is important for the patients to clarify in terms of factor of uncertainty (Stacey et al., 2017), therefore, I decided decisional conflict as one of the primary outcomes.

Secondary outcome, appraisal outcomes associated with decision-making tools. Measures including:

1. Satisfaction with the choice of their DAs (any measurements)
2. Mental anxiety (depression: any measurements, emotional distress: any measurement)
3. Patients’ quality of life (QOL) (any measurement)

**Study Selection**

After removing duplicates, the title and abstracts of studies identified through database searches were independently screened by two reviewers (YK and HS). Next, two reviewers (YK and HS) independently assessed the full texts for eligibility. When there was a disagreement, the researchers discussed the reasons and worked to find a consensus.

**Assessment of Risk of Bias in Included Studies**

Risk of bias was assessed using the Cochrane Risk of Bias Tool for randomized controlled trials (Higgins & Green, 2011). The seven domains of bias were assessed: sequence generation, allocation concealment, blinding of participants and personal, blinding of outcome assessment, incomplete
outcome data, selective outcome reports, and other bias such as bias because the problems lacked information in the data table. The researcher rated the risk of bias in each domain as either “low risk”, “unclear risk”, “high risk”, and provided an explanation for each rating. The studies were judged with inadequate randomization and lack of blinding as “high risk of bias”.

The researcher used Grading of Recommendations Assessment, Development and Evaluation (GRADE) to summarize all the results for the primary outcomes as follows: (a) knowledge of their surgery, (b) satisfaction with the choice of their DAs, and (c) acceptability, and rate the certainty of evidence (Andrews et al., 2013). Using GRADE, the certainty of evidence for risk prediction models was assessed by five factors of decreased certainty: study limitations, inconsistency, indirectness, imprecision, and publication bias. The researcher rated each primary outcome using four ratings: high, moderate, low, and very low. The researcher presented a summary of these in a ‘summary of findings’ table (Higgins & Green, 2011).

Data Extraction

Extraction of data included the following: study designs, settings, sample size, source of participants (e.g. Women with breast cancer surgery, over 18 years old, country), outcome(s) definitions, outcomes, interventions, comparisons, completeness of data (missing data, losses to follow-up), candidate predictors, model development, model performance, model
evaluation (e.g. development and test data set), model interpretation. These data were extracted using excel format and if the data were available for synthesis, the researcher conducted a meta-analysis. When the results were not appropriate for meta-analyses, the researcher used a synthesis for the results in a narrative format. In case of available for calculation, the researcher conducted missing standard deviations (SD) from other reported data.

**Measures of Treatment Effect, Sensitivity Analyses, and Assessment of Heterogeneity**

The treatment effect for each dichotomous outcome was showed as a risk ratio (RR) with 95% confidence intervals (CI). The treatment effect for each continuous outcome was expressed as a mean difference (MD) with 95% CI. In case of continuous outcomes that were measured with different scales, the treatment effect was showed as a standardized mean difference (SMD) with 95% CI.

At first, the researcher analyzed all data using a fixed-effects model, but when heterogeneity was high, the researcher analyzed the data with a random-effects model. Heterogeneity was assessed using $I^2$ statistics. When the researcher found heterogeneity ($I^2$ statistics ≥ 60), the researcher would conducted a subgroup analysis of studies which used the patient decision aid tools and the reasons when the researcher corrected the date about heterogeneity.
The researcher considered potential subgroups as: patient’s age (under 65 vs over 65), cancer stage (stage 0 vs stage I to II, III to IV, metastasis), and marital status (married vs unmarried), when the data was collected. The researcher planned a sensitivity analysis to clarify the effect of the studies by excluding studies with high risk of bias regarding attrition bias. The researcher performed analyses using Review Manager 5.3 (Cochrane Collaboration, 2014).

Results

Summary of the Search Result

In total, the researcher identified 6,777 reports, and one trial was retrieved by hand search. After exclusions, this review included 10 trials from 13 reports. Figure 1 displays the review process and trial selection.

The reasons for exclusions were as follows: the study design was not a randomized control trial (n = 13), the intervention format was not enough for the decision aids (n = 21), population was inappropriate (n = 21), and the study was not published due to protocol or clinical trial (n = 7). Included studies were from the following five countries: USA (n = 5), Canada (n = 2), Ireland (n = 1), Japan (n = 1), and China (n = 1). The studies’ participants were all women considering breast cancer surgery. In terms of stages, there was no clarity about stage details in these included trials, just “early stage” or “stage I or II” were reported. Eight trials were focused on the early stage of breast cancer (Goel,
Sawka, Thiel, Gort, & O'Connor, 2001; Hawley et al., 2018; Jibaja-Weiss et al., 2011; Katz, Griggs, Janz, & Hawley, 2012; W.W. Lam et al., 2013; Osaka & Nakayama, 2017; Galper, 2002; Whelan et al., 2004). Several trials were not clearly focused on early stage of breast cancer: one trial was stage 0 to III (Tucholka et al., 2018), and the other reported unspecific stages of patients who had been undergoing surgery for breast cancer (Foley et al., 2016).

Nine reports were about individual randomized control trials, and one was a cluster randomized control trial. Overall, 1,883 participants were included in this study. Table 1 presents the characteristic of the included trials.

**Decision Aids Format and Comparisons**

Five trials were Web-based intervention as DAs. The contents were self-administered, home based, informed about their surgery such as advantages and disadvantage, and treatment options (Foley et al., 2016; Hawley et al., 2018; Jibaja-Weiss et al., 2011; Katz, Griggs, Janz, & Hawley, 2012; Tucholka et al., 2018).

Tucholka et al. (2018) used a format that was web-based information prior to the surgical consultation. Jibaja-Weiss et al. (2011) provided a format which, had user-friendly contents in order to be usable for lower literate and multi-ethnic women as decision aids. For instance, they provided navigational instructions using voice-over narration, and on-screen text. Hawley et al. (2018) format was an interactive and tailored “iCanDecide” Web site, including patient
activation modules with testimonials involving tailor-made age, race, and the timing of surgical consults (Hawley et al., 2018). Katz, Griggs, and Janz (2012) tested a web-based tool with interactive preference clarification exercise.

Foley et al. (2016) was using an application, with tailored information related to the individual patient preference, therefore, only information was related in terms of the type of operation for each patient.

The four included trial interventions had multicomponent, of which two kinds of intervention were performed. Lam et al. (2013) used a booklet and initial consultation. Another one used the decision board and surgical consultation (Whelan et al., 2004). A third provided patient narratives combined with a standard information booklet (Osaka & Nakayama, 2017). Galper et al. (2002) used educational intervention, which consisted of a scripted review of treatment benefits and risks by a health educator and printed text for reviewing at home (Galper et al., 2002). The others decision aids formats were audiotape workbook (Goel, Sawka, Thiel, Gort, & O’Connor, 2001). Overall, there were provided with information and knowledge about surgery, advantages/disadvantaged, and a variety of treatment options.

Usual Care

American Cancer Society provides detailed information on “How will I be given information for informed consent?” in the following website:

(https://www.cancer.org/treatment/finding-and-paying-for-
The patient is given informed consent by counseling using material information by practitioners.

Generally, the patient needs an informed consent each time they receive a treatment such as one each for surgery, chemotherapy, or radiation. Basically, patient choose their treatment after the informed consent, and they recognize their treatment benefits and risks. In this review, the researcher determined usual care was that which related to informed consent such as individual consultation or only treatment booklet, which does not support their decision proses.

Outcome

Primary outcome 1: Knowledge of their surgery.

Eight trials assessed the effects of DAs on knowledge of their surgery. Seven trials measured questionnaire scores based on the content of DAs (Goel et al., 2001; Jibaja-Weiss et al., 2011; Katz et al., 2012; Lam et al., 2013; S. Galper, 2002; Tucholka et al., 2018; Whelan et al., 2004).

Two trial reported only dichotomies for assessing knowledge of their surgery so that the data could not be synthesis in a meta-analysis (Hawley et al., 2018; Tucholka et al., 2018) However, Hawley et al. (2018) reported a significant difference between the arms on the knowledge of their surgery (DA-60.7% vs UC-42.5%, p<.001).
Galper et al. (2002) reported the DA as the educational intervention and UC as the standard discussion. The intervention arm increased knowledge score more than usual care and reported the median of 11.5 correct answers on an 18-item survey compared to 9.5, respectively ($p = 0.003$).

**Primary outcome 2: Decisional conflict.**

Five trials measured decisional conflict using the Decisional Conflict Scale (DCS) (Goel et al., 2001; Jibaja-Weiss et al., 2011; Lam et al., 2013; Osaka & Nakayama, 2017; Whelan et al., 2004). The DCS is a 16-item self-report questionnaire and using a five-point Likert scale, which measures patient uncertainty about treatment decision (O'Connor, 1995). There are components contributing to uncertainty such as believing oneself to be uninformed and having unclear values. Two studies used the DCS (O'Connor, 1995) and the other studies used a modified version for their subjects (Lam et al., 2013; Osaka & Nakayama, 2017). For instance, Jibaja-Weiss et al. (2011) used the low-literacy version of DCS, which includes four subscales, and a questionnaire format with three response options: "yes", "no", or "unsure". The other studies assessed decisional conflict with DCS, which was modified in Japan and China (Lam et al., 2013; Osaka & Nakayama, 2017).
Primary outcome 3: Acceptability.

Four trials assessed related to acceptability by comparing DAs to usual care and assessed using point of view for acceptability in each study (Goel et al., 2001; Lam et al., 2013; Tucholka et al., 2018; Whelan et al., 2004).

Lam et al. (2013) reported that there were significantly fewer decision regrets four months after surgery “DA (take-home booklet)” and initial consultation compared with usual care (Mean ± SD, 18.8 vs 24.4, ± 15.8 vs ± 18.9; 95% CI [0.95, 10.84]; p = 0.026).

Secondary outcome 1: Satisfaction with the choice of their DAs.

Six trials conducted an assessment for effectiveness concerning satisfaction of their DAs.

One trial evaluated satisfaction of their DAs using the Satisfaction with Decision Scale (Jibaja-Weiss et al., 2011). The scale was reliable (Cronbach’s alpha = 0.86), the six-item scale measures patients’ satisfaction with health care decisions, and it was adapted for decision making of breast cancer treatment (Jibaja-Weiss et al., 2011). Katz et al. (2012) used a 12-item measurement each with a 5-point Likert scale from strongly agree to strongly disagree. Foley et al. (2016) assessed the information using the Satisfaction Questionnaire, which evaluated patient satisfaction for receiving the information. Two trials used the effective decision-making subscale of the decisional conflict scale for assessing patient satisfaction with decision making (Osaka & Nakayama, 2017;
Whelan et al., 2004). Lam et al. (2013) and Lam et al. (2014) were the same trials, and they were assessed by satisfaction of their DAs using treatment decision-making difficulties.

Three trials did not qualify for the meta-analysis because one trial did not report the standard deviations (Katz et al., 2012), the second report used dichotomous data (S. Galper, 2002), and the third trial reported using only the score measurement (Osaka & Nakayama, 2017).

Galper, et al. (2002) reported that no effectiveness for increased satisfaction with the decision-making process in education and consultation versus usual care ($n = 60$, 96% and 92% respectively, $p = .61$). Osaka et al. (2017) also evaluated satisfaction with decision making, but there was not significant different between DAs with patient narratives and usual care ($MD = 0.83$, 95% CI [-6.68, 5.02], $p = .98$) (Osaka & Nakayama, 2017).

Katz et al. (2012) reported about the item, “I am satisfied with my surgical treatment decision”, and there were no differences between DAs arm and usual care ($Mean = 1.44$ vs $1.65$; $MD = -0.21$; $n = 100$).

In terms of decision process, Lam (2014) reported effectiveness for patients’ satisfaction with the decisional process in take-home booklet and initial consolation as intervention ($Mean ± SD; 17.5 ± 6.3$ vs $19.1 ± 6.4$, $p = 0.016$).
Secondary Outcome 2: Mental anxiety.

Three trials evaluated DAs compared to usual care on effectiveness for mental anxiety, anxiety and depression (Foley et al., 2016; Lam et al., 2013; Whelan et al., 2004). These trials were synthesized for meta-analysis.

Secondary outcome 3: Patients’ quality of life.

No trials reported outcome for patient’s quality of life (QOL).

Risk of Bias in Included Studies

As shown Figure 2 and Figure 3, most trials were rated high risk of bias due to lacking blinding for participants and personnel and outcome assessment because the intervention was obviously different compared with usual care. Furthermore, assessing of the outcomes were evaluated via self-report so that might have affected the measurement answers under failure of blinding of participants. It would be challenging in these types of intervention studies to achieve blinding of these two domains. Most reports conferred low or unclear risk of bias in terms of selection bias and attribution bias. The researcher assessed most reports as unclear risk of bias for reporting bias because the protocol was unavailable. In these included studies, most accomplished a low risk of bias rating for other potential sources of bias because there were no claims about fraudulent activity or some other problem in the studies.
**Effectiveness of the Included Trials**

**Primary outcome 1: Knowledge of their surgery.**

For the five trials in the meta-analysis, DAs were more effective than usual care for improving knowledge of their surgery \((SMD 0.30, 95\% CI [0.10, 0.51]); participants = 737; studies = 5; \(I^2 = 48\%\); *moderate certainty of the evidence*; Fig. 4).

Web-based DAs were also significant improvement compared to usual care in knowledge of their surgery \((SMD 0.42, 95\% CI [0.13, 0.72]); participants = 186; studies = 2; \(I^2 = 60\%\); Fig. 5).

The type of multicomponent DAs also showed statistical significantly differences for improving knowledge of their surgery compared to usual care \((SMD 0.27, 95\% CI [0.08, 0.46]); participants = 426; studies = 2; \(I^2 = 73\%\); Fig. 6).

**Primary outcome 2: Decisional Conflict.**

In this meta-analysis, the researcher found statistical significance for the effectiveness in reducing decisional conflict using DAs. Overall, there were statistically significant improvement in total decisional conflict scores in DAs versus usual care. The total SMD for decisional conflict comparing DAs versus usual care was \(-0.36 (95\% CI [-0.51, -0.22]); participants = 743; studies = 5; \(I^2 = 0\%\); *moderate certainty of the evidence*; Fig. 7) Three trials with DAs type of multicomponent, also had statistical significance for decreasing decision conflict
compared with usual care \((SMD -0.36, 95\% \ CI [-0.53, -0.19]; \text{participants} = 539; \text{studies} = 3; I^2 = 0\%; \text{Fig. 8})\)

**Primary outcome 3: Acceptability.**

As Figure 9 shows, there were no significant differences in DAs versus usual care in terms of acceptability \((RR 0.96, 95\% \ CI [0.86, 1.07]; \text{participants} = 530; \text{studies} = 3; I^2 = 66\%; \text{very low certainty of the evidence}; \text{Fig. 9})\).

**Secondary outcome 1: Satisfaction with the choice of their DAs.**

Of four trials, there were not statistically significant differences in DAs versus usual care in terms of satisfaction of their DAs \((SMD 0.01, 95\% \ CI [-0.27, 0.30]; \text{participants} = 519; \text{studies} = 4; I^2 = 57\%; \text{low certainty of the evidence}; \text{Fig. 10})\).

From the data in Figure 11, two studies compared Web-based DAs versus usual care as for the outcome of satisfaction of their DAs. For the patients, no effectiveness for satisfaction of their DAs were found in Web-based DAs versus usual care \((SMD 0.03, 95\% \ CI [-0.34, 0.39]; \text{participants} = 120; \text{studies} = 2; I^2 = 0\%; \text{Fig. 11})\).

As for the multicomponent DAs, there were also not statistically significant differences compared to usual care \((SMD 0.01, 95\% \ CI [-0.50, 0.53]; \text{participants} = 399; \text{studies} = 2; I^2 = 85\%; \text{Fig. 12})\).
Secondary outcome 2: Mental anxiety.

For Anxiety, there was no effect for decreased mental anxiety using DAs (SMD 0.16, 95% CI [-0.04, 0.36]; participants = 402; studies = 3; I² = 0%; Fig. 13). For depression, there were no significantly statistical differences found for DAs versus usual care for decreasing depression (SMD 0.25, 95% CI [-0.05, 0.54]; participants = 402; studies = 3; I² = 46%; Fig. 14)

Sensitivity Analysis

The researcher explored the potential bias arising from including studies of high risk of bias for attrition bias, which resulted in exclusion of two trials for sensitivity analysis in terms of knowledge of their surgery (SMD 0.39, 95% CI [0.05, 0.73]; participants = 502; studies =3; I² = 70%; Fig. 15) and exclusion of one report for sensitivity analysis in terms of acceptability of their DAs (RR 0.96, 95% CI [0.77, 1.21]; participants = 423; studies = 2; I² = 83%; Fig.16). Finally, one trial was excluded for sensitivity analysis for decisional conflict in DAs versus usual care, (SMD -0.39, 95% CI [-0.55, -0.23]; participants = 620; studies =4; I² = 0%; Fig. 17). Overall, the results were not changed compared to the previous meta-analysis.
**Heterogeneity**

Most studies did not report subgroup characteristic such as married statue or stage of breast cancer. Therefore, the researcher could not conduct subgroup analysis.

**Certainty of evidence**

In this review, there was moderate certainty of the evidence that suggests DAs when compared to usual care for improving knowledge of their surgery. It was downgraded (-1) in terms of risk of bias due to lack of blinding in the outcome assessment; selection bias was unclear in one trial, and attrition bias was high risk in one trial. For the outcome about decisional conflict, there was moderate certainty of the evidence because of insufficiencies risk of bias. The outcome of acceptability had very low certainty of the evidence because of: lacking risk of bias, inconsistency, and imprecision (Table 2).

**Discussion**

**Summary of Results**

**New findings and uniqueness of this review.**

This systematic review included 10 trials comparing patient decision aids to usual care. The knowledge of respondents' surgery increased using DAs, and DAs decreased decisional conflict in this meta-analysis.
This is the first meta-analyses to be performed on four outcomes in women considering breast cancer surgery: decisional conflict, acceptability, satisfaction of their DAs, and mental anxiety. The researcher found new evidence as a result of meta-analysis in terms of DAs versus usual care in which decisional conflict was reduced for the women considering breast cancer surgery using DAs (fig. 12). The same literature as another author’s systematic review included four trials, however, for this systematic review six trials were newly added. This review did not specify about stages of breast cancer but focused on breast cancer surgery treatment.

The researcher clarified three categories of DAs tool: web-based intervention, multicomponent intervention, and video-tape intervention in this review. Moreover, there was an evaluation for the outcomes in each of the category using meta-analysis.

In DAs versus usual care, there were statistically significant differences between arms in knowledge and decisional conflict. Comparing Web-based DAs and usual care, there were similar result as DAs, which was statistically different in knowledge. However, there were differences in satisfaction of their DAs using web-based DAs. When comparing multicomponent to usual care, statistically significant differences appeared for knowledge and decisional conflict in the intervention arms. There were no statistically significant differences in satisfaction of DAs, acceptability, and mental anxiety in the meta-
analysis. The researcher found that there was no outcome which related to patient’s QOL in breast cancer patient considering surgery.

**Certainty of the evidence.**

There was moderate certainty of the evidence for improving knowledge of their surgery by DAs when compared to usual care.

The researcher used the ‘rule of the thumb’ for interpreting the $SMD$ results: small $SMD$: 0.2, medium $SMD$: 0.5, and large $SMD$: 0.8 (Cohen, 1988). Thus, the researcher followed the rule for evaluating of $SMD$ in terms of each primary outcome.

Moderate certainty of the evidence was found for knowledge of their surgery, as DAs versus usual care showed $SMD$ 0.30, 95% CI 0.10 to 0.51; participants = 737; studies = 5; $I^2 = 48\%$. The researcher evaluated the $SMD$ as a small effect size so that the result showed DAs was probably effective to increase knowledge of their surgery. For the knowledge of their surgery, web-based DAs versus usual care were: $SMD$ 0.42, 95% CI 0.13 to 0.72; participants = 186; studies = 2; $I^2 = 60\%$. Therefore, the $SMD$ was a middle effect size. Regarding the multicomponent DAs versus usual care, the $SMD$ was 0.27 so that the effect size was evaluated as small.

The outcome for decisional conflict was a moderate certainty of the evidence. The outcome of acceptability was very low certainty of the evidence in this systematic review.
In terms of evaluation for SMD for decisional conflict, the comparison of DAs versus usual care (SMD 95% CI [-0.51, -0.22]; participants = 743; studies = 5; $\chi^2 = 0\%$; *moderate certainty of the evidence*), and multicomponent versus usual care (SMD -0.36, 95% CI [-0.53, -0.19]; participants = 539; studies = 3; $\chi^2 = 0\%$) showed small effect size.

Agreements and Disagreements With Other Studies or Reviews

Other systematic review.

Nicholas et al. (2016) also reported in the systematic review that decision aids were effectively for improving knowledge and decreasing decisional conflict rather than usual care. Nicholas et al. (2016) conducted a systematic review for the women with early breast cancer decision making about their treatment. They evaluated that using a decision aids led to being more knowledgeable about treatment options such as surgery, chemotherapy, radiotherapy, and reconstruction (Nicholas et al., 2016). They reported that the decision aids for early breast cancer that decreased decisional conflict were acceptable to patients (Nicholas et al., 2016). They did not conduct a meta-analysis so that outcomes were reported narratively (Nicholas et al., 2016). Furthermore, their population was not only considering surgery, but also considering other treatments in early breast cancer (Nicholas et al., 2016).

Waljee, Rogers, and Alderman (2007) also conducted a systematic review for breast cancer considering surgery and performed a meta-analysis of the effect of DAs intervention on patient knowledge in three trials, and the effect to the
choice of their surgery techniques. Their study selection criteria was stage I or II breast cancer and considering breast conserving surgery or mastectomy using DAs as an intervention.

**In this review's finding and the uniqueness.**

As opposed to the other review, in this review six additional trials were newly added compared with previous author’s systematic review. This was the first-time a meta-analysis was conducted in terms of the four new outcomes: decisional conflict, acceptability, satisfaction of their DAs, and mental anxiety in the subjects of women considering breast cancer surgery at any stage. In this review, two trials of Waljee’s review were also included because one of them was not only focused on surgery treatment.

Moreover, this review followed the gold standard method of using Cochrane Handbook for Systematic Reviews (Higgins & Green, 2011). Therefore, each study was evaluated for certainly of evidence using GRADE (Andrews et al., 2013).

**Clarify DAs tool.**

The researcher clarified DAs tool based on the included studies’ interventions design, and the researcher found the intervention formats, which would be good for patients as user friendly, in order to easily understand about their treatment. Au et al. (2001) reported about the DAs content, which patients’
preferred for understandable and visualized formats such as using graphic over textual and CD-based formats (Au et al., 2011).

Following this review result, it would be important to make individual tailored intervention formats. For example, Hawley et al. (2018) used an interactive and tailored ‘iCanDecide’ Web site as intervention, and the intervention arms had higher quality decision making than control arms \( (OR, 2.00; 95\% CI, [1.37, 2.92]; p = 0.0004) \) (Hawley et al., 2018). Furthermore, the intervention arms tend to feel that the ‘iCanDecide’ Web site was helpful to make decision for their treatment \( (79.2\% \text{ vs } 67.0\%; p = 0.039) \), and the intervention arms were likely to see their physician more than control arms \( (31.2\% \text{ vs } 20.9\%; p = 0.12) \) (Hawley et al., 2018).

In this review, the researcher categorized four trials as multicomponent intervention. Multicomponent interventions consisted of behavioral, delivery, or implementation factors in addition to medications (Chakraborty, Collins, Strecher, & Murphy, 2009). Multicomponent interventions have been increasing in many health domains such as AIDS, depression, drug abuse, and gerontology (Allore, Tinettia, Gill, & Peduzzi, 2005; Golin et al., 2006; Riggs, Elfenbaum, & Pentz, 2006; Williams Jr et al., 2007)

In this review, most of interventions were intake texted material and consultation in order to achieve an individual tailored DA. Whelan et al. (2004) assessed the satisfaction of their DAs, which was evaluated as patients tended
The framework and the guideline for DAs tools.

Regarding of DAs tools that followed a framework, there were two reports based on IPDAS (Joseph-Williams et al., 2014), and one reports based on the Ottawa Decision Support Framework (Institute, 2014; O'Connor et al., 1998). Whelan et al. (2004) describes a decision board that was formed based on a systematic review of randomized trials based on well know prognostic factors for women with breast cancer and their surgeons regarding informational needs for decision making (Whelan et al., 2004). Another used published guidelines for early stage breast cancer as a framework (Goel et al., 2001; McCready et al., 2005). Tucholka et al. (2018) used a decision aid based on collaboration of the Informed Medical Decisions Foundation and Health Dialog (Ollila, Neuman, Sartor, Carey, & Klauber-Demore, 2005; Potosky, Riley, Lubitz, Mentnech, & Kessler, 1993; Tucholka et al., 2018).

Some guidelines for breast cancer decision making recommended using DAs. For instance, European Society for Medical Oncology (ESMO) suggested that clinical practices should provide process and comprehend the information in viewpoints such as: give information on diagnosis and treatment choice repeatedly (both verbally and in writing) in a comprehensive and easily understandable form and use of reliable, patient-centered websites or similar sources of information (Cardoso et al., 2019).
In Japan, the Japanese Breast Cancer Society also published a guideline about clinical practice for breast cancer in order to accomplish SDM (Society, 2018). However, there was no mention about how to accomplish SDM and DAs. Therefore, this review might be an important answer in terms of tools for reaching these guideline recommendations.

**Evaluation of the Outcomes**

**Knowledge of their surgery and decisional conflict.**

The researcher also found DAs effectiveness of knowledge for reducing decisional conflict, which means that usual care would not be enough. It must be tailored in way for patients they can use when they are faced with decisions about sensitive decisions.

Not only patients who had more than college education, but also patients who had low educational levels increased their knowledge about their surgery by receiving DAs. It was adequate for patients even though no statistical difference was found using mobile application based on individual tailored information versus usual care (Foley et al., 2016). The patient needs to know more information about treatment benefits/harms and must comprehend the treatment options before they can adequately decide about their surgery.

Additionally, DAs support patients by reducing conflict about their treatment choice, and they would be clearer about their concordance compared to usual care. It would not enough for patients to be helpful using usual care in their treatment decision processes.
**Acceptability.**

In this review, the meta-analysis could not show effectiveness for acceptability using DAs (Fig. 9).

Goel, Carol, and O’Connor (2001) assessed the acceptability using a questionnaire “It was the right decision”, which was part of decisional regret questionnaire, and there were no significantly differences between DAs, audiotape workbook and usual care, pamphlet (92.06%: 95.45%, \( p = 0.931 \)) (Goel et al., 2001). However, Whelan et al. (2004) reported effectiveness with DAs for acceptability using the question, “to strongly prefer the treatment they choose” (83%: 72%, \( p = 0.05 \)) (Whelan et al., 2004). Tucholka et al. (2018) reported that concordance was statistically different between arms (DAs 85% vs standard websites 96%, \( p = 0.04 \)) (Tucholka et al., 2018).

The above results might show that increasing knowledge of their surgery was relative to increasing acceptability. According to Ottawa Patient Decision Aids Acceptability ([https://decisionaid.ohri.ca/eval_accept.html](https://decisionaid.ohri.ca/eval_accept.html)) acceptability is related to ratings regarding the understandable component of the decision aids such as enough information, length, and balance of information about treatment options. It might be that greater contents in DAs using multicomponent contents rather than one content intervention increases acceptability.
Satisfaction of their DAs.

In terms of satisfaction of their decisions, two trials used the measurement which was called Satisfaction with Decision scale (SWD scale). Holmes-Rovner et al. (1996) developed the SWD scale. The SWD scale score related low levels of decisional conflict which was based on DCS, and higher confidence in the decision (Holmes-Rovner et al., 1996). It tapped into the influence of behavioral outcomes of the decision making. Despite the effectiveness in terms of decisional conflict, three studies did not evaluate satisfaction with the choice of their DAs (Jibaja-Weiss et al., 2011; Lam et al., 2013; Osaka & Nakayama, 2017). Therefore, the researcher cannot report a high connection between satisfaction of their DAs and decisional conflict in this review. The majority of included studies which DAs affected decisional conflict reported no significant differences between arms in term of satisfaction of DAs. The researcher hypothesize that patients might have been seeking satisfaction of their DAs process, not only the contents of the DAs tool but also more complex ingredients such as relationship with their practices, and accessibility of the care (Authorities, England, & Wales, 1993; Smith, 2000).

No effectiveness was found in term of satisfaction of DAs in the meta-analysis between DAs arm and usual care arm because satisfaction measurement is sensitive, and DAs format mainly consist of comparing treatment benefit and harms. Therefore, it would be quite challenging to evaluate satisfaction of their DAs. The researcher could say that using usual care would be high quality for satisfaction with their decision processes.
Basically, people may tend to think psychologically that their choice is matched with their comfortable satisfaction once their decisions are made. (Gruppen, Margolin, Wisdom, & Grum, 1994).

However, Whelan et al. (2004) reported that decision aids intervention groups tend to make clear choices about their treatment options with matching between surgeon suggestions, and they were more likely to receive the treatment they chose (Mean 4.50 vs 4.32; MD 0.215; SE 0.110; p = .05) (Whelan et al., 2004). Whelan et al. (2004) used the decision board which was developed to support surgeons in communicating the different surgery options for women with breast cancer and permitting women to express a preference for treatment following consultation (Whelan et al., 2004). Furthermore, they reported significant differences between arms about decisional conflict as well (Whelan et al., 2004). Using both interventions of decision board and followed by consultation affected patient satisfaction with DAs and decisional conflict. It would be shown that it is important for the DAs process by improving physician-patient communication. However, some physicians recognized that they have not had enough skills about supporting decision making in their usual patient care due to lack of training (Politi, Studts, & Hayslip, 2012).

For future research, I hypothesize that evaluation of DAs training for physician and nursing staff and then be mandatory, especially DAs could be matched with clinical practice.
Mental anxiety.

For mental anxiety, the researcher could not evaluate the effectiveness of DAs in a meta-analysis. However, some studies reported that DAs intervention arms shown significantly lower anxiety scores for women considering birthing options after caesarean and considering treatment options of menorrhagia (Frost, Shaw, Montgomery, & Murphy, 2009; Protheroe, Bower, Chew-Graham, Peters, & Fahey, 2007). There were different population comparing this review, but it would show the potential benefit for mental anxiety using DAs for patients facing sensitive decisions (Frost et al., 2009; Protheroe et al., 2007).

As DAs contents in primary care setting, multicomponent might be effective for reducing mental anxiety. Despite the fact that the population was different from this review, some RCT and systematic reviews reported that multifaceted interventions improved patient outcomes and the care process was enhanced (Gilbody, Whitty, Grimshaw, & Thomas, 2003; Von Korff & Goldberg, 2001).

In these included studies, there was a lack of sample size. There might be a different result if studies can involve enough participation in the future research.
Strengths and Limitations

The quality of evidences.

Firstly, most of the trials were high risk of bias for the blinding of participants and personnel and outcome assessment because the intervention was different compared to usual care. Moreover, the outcome was assessed using self-report, therefore, it might be affected participant's answer due to failed blinding of participant. However, it was quite challenging to blind these two domains in this review’s intervention.

Characteristics of participants.

Secondly, most subjects in the included studies were Caucasian with high educational levels, which might be limit the generalizability to other populations and those less educated. Coulter and Collins (2011) reported that people using SDM are educated and empowered while seeking their needs, while disadvantaged people are marginalized (Coulter & Collins, 2011). Another study mentioned disadvantage people who have low literacy, poor-self-efficacy and a higher disease burden tend to be at higher risk of marginalization and worse health outcomes (Durand et al., 2014). Research investigating DAs in the future should more focus on people who have low educational levels, socio-cultural marginalization and poverty such as developing countries.
The outcome for the patient’s QOL.

Furthermore, the researcher could not evaluate the outcome of patient’s QOL. For breast cancer patients, especially early breast cancer stages should have addressed improving their QOL because the treatment sometimes affects to their body image depending on the surgery such as breast conserving therapy (BCT) or mastectomy (MT), and others might suggest MT due to including unexpected radiotherapy (Molenaar et al., 2001). Molenaar et al. (2001) reported positive effects of DAs found generic QOL and breast cancer specific QOL (Molenaar et al., 2001). They clarified significant differences between the arms after three-months and nine-month surgery follow-up (Molenaar et al., 2001). Intervention arms were more likely to be in better general health condition and physical function likewise decreasing pain or arm symptoms.

Thus, there was little known about the relationship between DAs and patient’s QOL so that it will be necessary to evaluate it in a future study.

The outcome of satisfaction of their DAs.

For the people centered care, it is important for patients to address DAs effect on satisfaction of their treatment choice as well as support to their treatment choice (Constand, 2014; Mead & Bower, 2000; Stewart et al., 2003). I hypotheses that it is a deep relationship between patients and health care provide that supports their satisfaction with their DAs. There should be a focus
also on how to provide DAs, which not only focus on DAs tools but also on people centered care.

**How DAs become established in clinical practice.**

As part of routine clinical practice, it is important for practices to address skill and knowledge using DAs, and it would expand to the high quality of shared decision making (Herrmann, Hall, Zdenkowski, & Sanson-Fisher, 2019). However, in terms of clinical practice, it is not mandatory to use DAs in spite of the positive outcome evidence (Elwyn, 2013).

One could anticipate barriers for using DAs in the clinical routine care (Politi, Studts, & Hayslip, 2012). For instance, Herrmann et al. (2019) found one of the reasons for the barriers involved in the clinical routine care was methodological issues such as standardization of outcomes and outcome measures, checkup for circumstantial factors in order to replicate in clinical practice (Herrmann et al., 2019). Lloyd, Joseph-Williams, and Elwyn (2013) reported that many barriers of SDM were the lack of skills, inadequate clinical systems and inappropriate context to the clinical systems, and lack of decision support (Lloyd, 2013).

Another reason may that it is difficult for patients to speak up about their preferences in front of physicians. Berru et al. (2017) noted that one of the reasons for the barriers involved in the clinical routine care was 'hostage bargaining syndrome' which means their behavior was influenced by their perception of being caught in the power differential between themselves and
their practitioner. Being afraid to speak-up about their preferences they negotiated their health decisions out of fear and anxiety (Berry, Danaher, Beckham, Awdish, & Mate, 2017; Herrmann et al., 2019).

For the future research, it is important to address the DAs tools in order to have adequate application in clinical practice and improve communication between practitioners and patients. It would be particularly supportive to evaluate patients’ QOL to achieve DAs tailored to each patient, and to develop the framework of DAs in order to be replicated in clinical practice. Furthermore, the DAs contents should be based on patients’ preferences using the same measurement for accurate outcome evaluation.

**Conclusions**

This systematic review is the first to conduct a meta-analysis in terms of decisions conflict, acceptability, client satisfaction with DAs, and mental anxiety in women considering breast cancer surgery. The researcher found that DAs were effective for increasing knowledge of their surgery and decreasing decisional conflict for women considering breast cancer surgery. There were no statistical differences in satisfaction of DAs, for acceptability, and mental anxiety. For future research, the outcome of patient’s QOL should be considered. It is also important for practitioners to improve their skill and knowledge for using DAs as part of routine care.
Abbreviations

DAs: Decision aids; QOL: Quality of life; IPDAS: the International Patient Decision Aids Standards; AJCC: American Joint Committee on Cancer; OR: Odds ratio

Acknowledgements

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Authors’ Contributions

YK and EO designed the study. YK and HS conducted study screening, risk of bias, and data extraction. YK contributed to data interpretation and led the writing. All authors commented on successive drafts and approved the final manuscript.

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Availability of Data and Materials

The data generated and analyzed during this study are available on application to the corresponding author.
Ethics Approval and Consent to Participate

Not applicable.

Consent for Publication

Not applicable.

Competing Interests

The authors declare that they have no competing interests.
Figures and Tables

Figure 1. PRISMA 2009 Flow Diagram
Figure 2. Risk of bias summary, review authors' judgements about each risk of bias item for each included study.
Figure 3. Risk of bias graph, review authors’ judgements about each risk of bias item presented as percentages across all included studies.
Figure 4. Knowledge of their surgery, DAs vs usual care
<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>web-based DAs</th>
<th>usual care</th>
<th>Std. Mean Difference</th>
<th>Std. Mean Difference</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
<td>Total</td>
</tr>
<tr>
<td>Katz, 2012</td>
<td>3</td>
<td>1.6533</td>
<td>55</td>
<td>2.81</td>
<td>1.6533</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>95</strong></td>
<td><strong>91</strong></td>
<td><strong>100.0%</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 2.51, df = 1 (P = 0.11); I² = 60%
Test for overall effect: Z = 2.85 (P = 0.004)

**Figure 5.** Knowledge of their surgery, Web-based DAs vs usual care
<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>DAs</th>
<th>usual care</th>
<th>Std. Mean Difference</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
</tr>
<tr>
<td>Larn, 2013</td>
<td>6.1</td>
<td>2.1</td>
<td>113</td>
<td>5.9</td>
</tr>
<tr>
<td>Whelan, 2004</td>
<td>56.9</td>
<td>17.3666</td>
<td>94</td>
<td>56.7</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>207</td>
<td>219</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 3.68, df= 1 (P = 0.06); I² = 73%
Test for overall effect: Z = 2.76 (P = 0.006)

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Figure 6. Knowledge of their surgery, multicomponent DAs vs usual care
Figure 7. Decisional conflict, DAs vs usual care

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean DAs</th>
<th>SD DAs</th>
<th>Total DAs</th>
<th>Mean usual care</th>
<th>SD usual care</th>
<th>Total usual care</th>
<th>Weight</th>
<th>Std. Mean Difference IV, Random, 95% CI</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goel, 2001</td>
<td>1.98</td>
<td>0.52</td>
<td>78</td>
<td>2.08</td>
<td>0.48</td>
<td>45</td>
<td>15.8%</td>
<td>-0.20 [-0.57, 0.17]</td>
<td></td>
</tr>
<tr>
<td>Jiboja-Weiss, 2011</td>
<td>16.38</td>
<td>9.7801</td>
<td>43</td>
<td>22.41</td>
<td>9.7801</td>
<td>38</td>
<td>10.7%</td>
<td>-0.61 [-1.06, -0.16]</td>
<td></td>
</tr>
<tr>
<td>Lam, 2013</td>
<td>15.8</td>
<td>15.5</td>
<td>113</td>
<td>19.9</td>
<td>15.3</td>
<td>112</td>
<td>31.0%</td>
<td>-0.26 [-0.52, 0.01]</td>
<td></td>
</tr>
<tr>
<td>Osaka, 2017</td>
<td>26.9</td>
<td>12</td>
<td>58</td>
<td>32.7</td>
<td>14.4</td>
<td>55</td>
<td>15.3%</td>
<td>-0.44 [-0.81, -0.06]</td>
<td></td>
</tr>
<tr>
<td>Whelan, 2004</td>
<td>1.4</td>
<td>0.4969</td>
<td>94</td>
<td>1.62</td>
<td>0.4969</td>
<td>107</td>
<td>27.2%</td>
<td>-0.44 [-0.72, -0.16]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>386</strong></td>
<td></td>
<td><strong>357</strong></td>
<td><strong>100.0%</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>-0.36 [-0.51, -0.22]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.00; Chi² = 3.01, df = 4 (P = 0.56); I² = 0%
Test for overall effect Z = 4.87 (P < 0.00001)

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias
Figure 8. Decisional conflict, multicomponent DAs vs usual care
Figure 9. Acceptability, DAs vs usual care
Figure 10. Satisfaction of their DAs, DAs vs usual care
Figure 11. Satisfaction of their DAs, Web-based DAs vs usual care

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Heterogeneity: Tau^2 = 0.00; Chi^2 = 0.15, df = 1 (P = 0.70); I^2 = 0%
Test for overall effect: Z = 0.14 (P = 0.89)
Figure 12. Satisfaction of their DAs, Multicomponent DAs vs usual care
Figure 13. Anxiety, DAs vs usual care

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>DA</th>
<th>SD</th>
<th>Total</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>Std. Mean Difference</th>
<th>IV, Fixed, 95% CI</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fother, 2016</td>
<td>4</td>
<td>4.5946</td>
<td>13</td>
<td>2</td>
<td>4.5946</td>
<td>26</td>
<td>8.6%</td>
<td>0.43</td>
<td>[-0.25, 1.10]</td>
<td></td>
</tr>
<tr>
<td>Lam, 2013</td>
<td>2.2</td>
<td>3.2</td>
<td>91</td>
<td>2.1</td>
<td>3.1</td>
<td>88</td>
<td>45.5%</td>
<td>0.03</td>
<td>[-0.26, 0.32]</td>
<td></td>
</tr>
<tr>
<td>Whelan, 2004</td>
<td>39.3</td>
<td>1.6792</td>
<td>82</td>
<td>38.9</td>
<td>1.6792</td>
<td>102</td>
<td>45.3%</td>
<td>0.24</td>
<td>[-0.05, 0.53]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>186</td>
<td>216</td>
<td>100.0%</td>
<td>186</td>
<td>216</td>
<td>100.0%</td>
<td></td>
<td>0.16</td>
<td>[-0.04, 0.36]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Ch² = 1.61, df = 2 (P = 0.45); I² = 0%
Test for overall effect: Z = 1.59 (P = 0.11)

Risk of bias legend:
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias
<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>DAs</th>
<th>usual care</th>
<th>Std. Mean Difference</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Foley, 2016</td>
<td>2</td>
<td>1.3468</td>
<td>13</td>
<td>0.5</td>
</tr>
<tr>
<td>Lam, 2013</td>
<td>2.1</td>
<td>3.3</td>
<td>91</td>
<td>1.9</td>
</tr>
<tr>
<td>Whelan, 2004</td>
<td>15.1</td>
<td>3.7782</td>
<td>62</td>
<td>14.2</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td></td>
<td>186</td>
<td>62</td>
<td>14.2</td>
</tr>
</tbody>
</table>

Heterogeneity: $\tau^2 = 0.03; \chi^2 = 3.63, df = 2 (P = 0.16); I^2 = 46\%

Test for overall effect: $Z = 1.65 (P = 0.10)$

**Risk of bias legend**
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

**Figure 14.** Depression DAs vs usual care
Table 1. Sensitivity analysis for knowledge of their surgery

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>Std. Mean Difference IV, Random, 95% CI</th>
<th>Std. Mean Difference IV, Random, 95% CI</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grijalba-Weiss, 2011</td>
<td>9.6</td>
<td>3.8</td>
<td>40</td>
<td>6.3</td>
<td>3.8</td>
<td>36</td>
<td>25.6%</td>
<td>0.72 [0.25, 1.18]</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Lam, 2013</td>
<td>6.1</td>
<td>2.1</td>
<td>113</td>
<td>5.3</td>
<td>2.1</td>
<td>112</td>
<td>37.3%</td>
<td>0.09 [-0.17, 0.36]</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Whelan, 2004</td>
<td>16.9</td>
<td>17.3</td>
<td>94</td>
<td>30.7</td>
<td>17.3</td>
<td>107</td>
<td>36.9%</td>
<td>0.47 [0.19, 0.75]</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>247</td>
<td>255</td>
<td>100.0%</td>
<td>39 [0.05, 0.73]</td>
<td>-</td>
<td></td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Heterogeneity: $\tau^2 = 0.08; \chi^2 = 5.72, df = 2 (P = 0.03); I^2 = 70\%$

Test for overall effect: $Z = 2.24 (P = 0.03)$

Risk of bias legend:
- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Figure 15. Sensitivity analysis for knowledge of their surgery
Figure 16. Sensitivity analysis for acceptability
<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean DA</th>
<th>SD DA</th>
<th>Total DA</th>
<th>Mean UC</th>
<th>SD UC</th>
<th>Total UC</th>
<th>Weight</th>
<th>Std. Mean Difference</th>
<th>IV, Fixed, 95% CI</th>
<th>Risk of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jacoby-Weiss, 2011</td>
<td>15.36</td>
<td>9.7001</td>
<td>43</td>
<td>22.41</td>
<td>9.7001</td>
<td>38</td>
<td>12.7%</td>
<td>-0.61</td>
<td>-1.06, -0.16</td>
<td></td>
</tr>
<tr>
<td>Lam, 2013</td>
<td>15.6</td>
<td>15.5</td>
<td>113</td>
<td>19.9</td>
<td>15.3</td>
<td>112</td>
<td>36.8%</td>
<td>-0.26</td>
<td>-0.52, 0.01</td>
<td></td>
</tr>
<tr>
<td>Osaka, 2017</td>
<td>25.9</td>
<td>12</td>
<td>58</td>
<td>32.7</td>
<td>14.3</td>
<td>55</td>
<td>18.2%</td>
<td>-0.44</td>
<td>-0.81, -0.08</td>
<td></td>
</tr>
<tr>
<td>Whelan, 2004</td>
<td>1.4</td>
<td>0.4060</td>
<td>94</td>
<td>1.62</td>
<td>0.4060</td>
<td>107</td>
<td>32.3%</td>
<td>-0.44</td>
<td>-0.72, -0.16</td>
<td></td>
</tr>
</tbody>
</table>

Total (95% CI) 308 312 100.0% -0.39 [-0.55, -0.23]

Heterogeneity: $\chi^2 = 2.11, \text{df} = 3 (P = 0.55); I^2 = 0$
Test for overall effect: $Z = 4.85 (P < 0.00001)$

**Risk of bias legend**

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

---

**Figure 17.** Sensitivity for decisional conflict DAs vs usual care
<table>
<thead>
<tr>
<th>Setting</th>
<th>Outcome time point</th>
<th>Intervention</th>
<th>Control</th>
<th>Participants</th>
<th>The number of participants</th>
<th>Stage of Subjects</th>
<th>Framework</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web-based</td>
<td>Tools</td>
<td>Design</td>
<td>Delivery</td>
<td>Control</td>
<td>Participants</td>
<td>Web-based</td>
<td>Tools</td>
</tr>
<tr>
<td>Tucholka, 2018</td>
<td>U.S</td>
<td>After receiving the web-based material but before meeting their surgeon</td>
<td>Web-based platform</td>
<td>Converted to a web-based platform based on user feedback requesting flexibility in mode of delivery.</td>
<td>Intervention was provided before the surgical consultation</td>
<td>The standard websites supported by non-profit organizations</td>
<td>Patients were eligible if they were female, had newly diagnosed stage 0-III breast cancer, were 18 years or older, and were considering breast surgery within our breast program.</td>
</tr>
<tr>
<td>Tucholka, 2017</td>
<td>U.S</td>
<td>- Pre-decision</td>
<td>A computerized, multimedia, interactive patient decision aid (CPIDA)</td>
<td>&quot;(1) didactic soap opera episodes that were seamlessly linked to (2) interactive learning modules (ILMs) to enhance the content of the episodes.&quot;</td>
<td>- Intervention was provided after informed by their physician and explanation on how using the tools to the participant because most of them were novice about computer.</td>
<td>- usual care: education booklet</td>
<td>- Multi-ethnic, low-literacy women who received medical care at two urban public hospitals, no medical insurance, female patients who visited one of the two breast pathology clinics, who were diagnosed with early stage breast cancer (I-IIIA)</td>
</tr>
<tr>
<td>Jibaja-Weiss, 2011</td>
<td>U.S</td>
<td>- Mailed 4 weeks after enrollment - Mailed 9 months later</td>
<td>An interactive and tailored iCanDecide Web site</td>
<td>- Knowledge building key content areas: survival outcomes, risk of local recurrence, radiation, recovery from surgery, need for additional surgery, genetic testing, reconstruction, and bilateral mastectomy</td>
<td>- Flexible approach to enrollment which patients could use before or after their first surgical consultation</td>
<td>The static iCanDecide Web site</td>
<td>- Women with a new diagnosis of early stage (I to II) breast cancer between the ages of 21 and 84 years who had not yet received surgical treatment and who did not have a contraindication for either mastectomy or breast conservation therapy</td>
</tr>
<tr>
<td>Web-based</td>
<td>Tools</td>
<td>Design</td>
<td>Delivery</td>
<td>Control</td>
<td>Participants</td>
<td>The number of participants</td>
<td>Stage of Subjects</td>
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</tr>
<tr>
<td>Katz, 2012</td>
<td>U.S</td>
<td>NA</td>
<td>Using website prior answering survey</td>
<td>- Website with an interactive preference clarification exercise that was developed by health communication experts, clinicians, and breast cancer patient</td>
<td>-before completing a survey</td>
<td>Answering survey prior using website</td>
<td>Newly diagnosed early stage breast cancer patients</td>
</tr>
<tr>
<td>Foley, 2016</td>
<td>Ireland</td>
<td>Mobile application based on individual tailored information</td>
<td>-Website with an interactive preference clarification exercise that was developed by health communication experts, clinicians, and breast cancer patient</td>
<td>-before completing a survey</td>
<td>Answering survey prior using website</td>
<td>Newly diagnosed early stage breast cancer patients</td>
<td>N/A</td>
</tr>
<tr>
<td>Multicomponent: education&amp;usual care</td>
<td>Tools</td>
<td>Design</td>
<td>Delivery</td>
<td>Control</td>
<td>Participants</td>
<td>The number of participants</td>
<td>Stage of Subjects</td>
</tr>
<tr>
<td>Galper, 2002</td>
<td>U.S</td>
<td>Mobile application based on individual tailored information</td>
<td>-Website with an interactive preference clarification exercise that was developed by health communication experts, clinicians, and breast cancer patient</td>
<td>-before completing a survey</td>
<td>Answering survey prior using website</td>
<td>Newly diagnosed early stage breast cancer patients</td>
<td>N/A</td>
</tr>
<tr>
<td>Tools</td>
<td>Design</td>
<td>Delibery</td>
<td>Control</td>
<td>Participants</td>
<td>The number of participants</td>
<td>Stage of Subjects</td>
<td>Framework</td>
</tr>
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<td>------------</td>
</tr>
<tr>
<td>Lam, 2013 (2) Lam, 2014</td>
<td>Hong Kong, China</td>
<td>DA/take-home booklet &amp; initial consultation</td>
<td>&quot;Four components: one, information about the main differences among the available treatment options, including outcome probabilities (additional surgery, subsequent adjuvant therapy, and cancer recurrence) associated with each choice; two, a review of positive (benefits) and negative features (adverse effects and disadvantages) of the available treatment options; three, a personal worksheet format facilitating values clarification; and four, structured guidance resulting in either current surgical preference or unresolved decision outcomes and suggested next steps&quot;</td>
<td>- For home use as a postconsultation adjunct for treatment-decision support - The consultation which the surgeon disclosed the diagnosis and the treatment options with patient</td>
<td>- Cantonese or Mandarin speaking Chinese women - Considering breast cancer surgery for early-stage with no prior cancer history</td>
<td>N=276</td>
<td>Early-stage</td>
</tr>
<tr>
<td>Whelan, 2004</td>
<td>Canada</td>
<td>Use the decision board in their surgical consultation</td>
<td>- Consisted of four subtitles: &quot;Treatment Choice,&quot; &quot;Side Effects,&quot; &quot;Results of Treatment Choice for the Breast,&quot; and &quot;Results of Treatment Choice for Survival&quot; - Provided three separated cards for information about background: breast cancer, the propose of the intervention tools, details of breast reconstruction, and questions for the patient reflection</td>
<td>- Provided by their surgeon - &quot;Each panel is read by the patient and the surgeon.&quot;</td>
<td>- Women with clinical stage I or II Breast cancer newly diagnosed either by cytology or histological examination who and not received definitive surgical treatment - Mean age: intervention arm: 58.2, control arm: 58.1</td>
<td>N=171</td>
<td>Stage I or II</td>
</tr>
<tr>
<td>Osaka, 2016</td>
<td>Japan</td>
<td>DAs with patient narratives</td>
<td>- Intervention was provided pre-consultation for surgical treatment selection - Patients were also provided a standard information booklet.</td>
<td>Only the standard information booklet</td>
<td>- Japanese women newly diagnosed with early-stage breast cancer, older than 20 years, with no cancer history and scheduled for breast surgery as initial treatment - Mean age: DA with patient narratives: 50.2, control arm: 48.6</td>
<td>N=210</td>
<td>Early stage</td>
</tr>
<tr>
<td>Audio tape workbook</td>
<td>Tools</td>
<td>Design</td>
<td>Delivery</td>
<td>Control</td>
<td>Participants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
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<td>--------</td>
<td>----------</td>
<td>---------</td>
<td>-------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Goel, 2001</td>
<td>- Canada</td>
<td>- time 1: the enrollment questionnaire</td>
<td>- An audiotope workbook</td>
<td>- Three steps: &quot;First, the woman is asked to review the advantages and disadvantages of each procedure. Second, she considers the value of each of the advantages and disadvantages. In the third step, she examines her worksheet to identify which procedure she is leaning toward.&quot;</td>
<td>- pathological confirmation of newly diagnosed stage I or II breast cancer, suitability for either mastectomy or breast conservation therapy - No prior history of cancer - Ability to give consent and complete the study questionnaire - Mean age: intervention arm: 57.4, control arm: 57.59</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N=136</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Stage I or II</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Based on a published guideline of breast cancer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Table 2: Certainty of evidence

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge of their surgery</td>
<td>SMD 0.3 higher (0.1 higher to 0.51 higher)</td>
<td>-</td>
<td>737 (5 RCTs)</td>
<td>★★★★☆☆☆</td>
<td>MODERATE ²</td>
</tr>
<tr>
<td>Decision conflict</td>
<td>SMD 0.36 lower (0.51 lower to 0.22 lower)</td>
<td>-</td>
<td>743 (5 RCTs)</td>
<td>★★★★☆☆☆</td>
<td>MODERATE ²</td>
</tr>
</tbody>
</table>

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

Cf: Confidence interval. SMD: Standardized mean difference. RR: Risk ratio

**GRADE**

- **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect.
- **Moderate certainty:** We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- **Low certainty:** Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
- **Very low certainty:** We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of the effect.

### Explanations

- a. Blinding of outcome assessment was high risk of bias
- b. Heterogeneity was over 60%
- c. 95% CI overlaps non-significant line