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The impact of decision aids in patients with colorectal cancer: a systematic review

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The impact of decision aids in patients with colorectal cancer: a systematic review

Short Running Head: Colorectal Cancer Decision Aids

Main Category: Colorectal Cancer

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Competing interests:

M-A D was involved in developing Option Grid decision aids. She receives consulting income from EBSCO Health and may receive royalties in the future. She is also a consultant for ACCESS Community Health Network. GE has been a consultant to Emmi Solutions, which develops patient decision support tools; National Quality Forum on certification of decision support tools; Washington State Health Department on certification of decision support tools; PatientWisdom; SciMentum, Amsterdam and Access Community Health Network, Chicago. He has edited/published books that provide royalties on sales by the publishers: the books include SDM (Oxford University Press) and Groups (Radcliffe Press). He also initiated and leads the Option Grid patient decision aids collaborative, which produces and publishes patient knowledge tools in the form of comparison tables (http://optiongrid.org) and has part ownership of the registered trademark. He owns a copyright in CollaboRATE, IntegRATE and Observer OPTION measures of SDM and care integration. These measures are freely available for use. None of these interests have affected this work.

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All authors have substantial contributions to the conception or design of the work (SJI, HAJ, GE, MAD, PS), the acquisition, analysis, or interpretation of data for the work (JLG, PM, HAJ, SJI), drafting the work or revising it critically for important intellectual content including final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (JLG, PM, PS, HAJ, MAD, GE, SJI).

Data sharing statement:

There is no additional data from this systematic review.

ABSTRACT

Objective: Our aim was to conduct a systematic review of patient decision aids use for colorectal cancer treatment.

Design: Systematic review

Data Sources: Sources included Embase, Medline, Web of Science, CINAHL, and the Cochrane Library from inception to April 11, 2018.

Study Selection: We reviewed randomized controlled trials, cohort studies, or case series. Study inclusion was determined by four independent reviewers.

Interventions: Studies were included that evaluated patient decision aids for patients diagnosed with colorectal cancer undergoing treatment decisions.

Main Outcome Measures: All outcome measures related to patient decision aid use were included.

Results: Out of 1950 studies identified, three met our inclusion criteria: one randomized controlled trial, one pre-post and one mixed-method study. The studies had different key aims, different patient populations, and considered different treatment decisions. Nevertheless, in each study, the use of patient decision aids did lead to increases in patient knowledge and satisfaction.

Conclusion: Few studies have considered the use of patient decision aids for patients facing difficult decisions in colorectal cancer treatment. Given the existence of many decisions where patient preference should play a critical role, the field could benefit from further work.

Trial Registration:

We published our study protocol in PROSPERO (registration # CRD42018095153).

ARTICLE SUMMARY

- What is the available evidence on the use of patient decision aids for patients undergoing colorectal cancer treatment?

Strengths and Limitations of this Study

- A broad search strategy as well as a firm adherence to systematic review methodology make this the most comprehensive review on decision aids in colorectal cancer treatment.
- Available data on this topic is limited by the diversity of study outcomes, and the quality of the studies included.

INTRODUCTION

Treatment decisions for colorectal cancer, particularly rectal cancer, are complex, multimodal, with significant variability and controversy. For example, patients diagnosed with rectal cancer often have to decide between two equally efficacious, but lifestyle altering, surgical options: bowel reconnection (LAR) versus permanent colostomy (APR). These preference-sensitive decisions can be overwhelming to patients and their families. Studies clearly indicate that many cancer patients prefer to be actively and collaboratively involved in disease-related decisions.[1-4] As these decisions can be challenging for patients, often occurring at an emotional time, decision aids have been developed to provide evidence-based information on treatment options and help patients clarify and communicate the personal values they associate with different options for cancer treatment.[5]

Decision aids are evidence-based tools designed to help patients make informed choices by providing information on the pros, cons, risks, probabilities, and scientific uncertainty of available options prior to making a decision.[6,7] Decision aids can be used when there are multiple reasonable options, when no single option has a clear advantage over the others in terms of health outcomes, or when each option has benefits and harms that patients value differently.[8] By allowing patients to clarify and communicate the personal values they associate with different treatment options, decision aids can improve the match between personal values and treatment choice.[9,10] Studies have demonstrated that decision aids increase patient knowledge, reduce decisional conflict, help patients make appropriate decisions, and can have a positive effect on patient-clinician communication.[11]

Decision aids have been successful in helping patients make complex treatment decisions in breast, prostate, and lung cancer.[12-14] However, decision aids research within colorectal cancer has been focused around screening as opposed to treatment.[10] We aimed to systematically evaluate the current evidence on decision aids for colorectal cancer treatment.

METHODS

Design

We conducted a systematic review, guided by the PRISMA guidelines, of studies that used a colorectal cancer treatment patient decision aid as the intervention. Prior to beginning our search, we published our study protocol in PROSPERO (registration # CRD42018095153)

Inclusion and exclusion criteria

We used the population, intervention, comparison, outcome, and study design (PICOS) criteria to determine eligibility. To be included, studies had to be randomized controlled trials (RCTs), nonrandomized control trials, retrospective or prospective cohort studies, or case series. Any purely qualitative studies or case reports were excluded. Our population was defined as patients diagnosed with colorectal cancer undergoing treatment. Study participants needed to use patient decision aids (PDA) which we defined as interventions or tools that were designed to inform patients about treatment options and to facilitate patient participation in decision making.[5] The decision aids could be in any format. Our control group will be standard counseling, non-decision aids, or no control group if applicable. We included all primary and secondary outcomes.

Search Strategy

With assistance from our medical librarian (HJ), we developed an electronic search strategy for the following databases: Embase, Medline, Web of Science, CINAHL, and the Cochrane Library from inception to April 11, 2018. We identified articles that assessed decision aids in patients with colorectal cancer, employing text words and database-specific subject headings (e.g. MeSH,) such as “colon cancer,” “rectal cancer,” “decision aids,” and “decision making.” Please see appendix 1 for complete search strategy used in Medline (PubMed). For the purposes of the search, we did not impose any restrictions on language, publication type, or publication date. In addition, we performed a citation search using the 'cited by' option on Google Scholar and 'related searches' on PubMed. We manually checked references for all articles identified as meeting our eligibility requirements for added sensitivity. See Appendix 1 for search terms used for each database.

Screening

We used Rayyan to help facilitate the screening process.[15] The articles were listed alphabetically so that two reviewers (SI, HJ), blinded to each other, could independently review the first half and two additional similarly blinded reviewers (JG, PM) could independently review the second half. During this initial screen only the titles and abstracts were reviewed. Disagreements about inclusion were resolved by (JG) for the first half of the articles, and (SI) for the second half of the articles. After completing the initial screening, two reviewers (SI, JG) reviewed the full text of the remaining articles. Any disagreements about eligibility at this time were resolved by a third reviewer (PM).

Data extraction

For randomized control trials:

The data extraction sheet, piloted prior to use, included the following information: study author, publication year, publication type, country, study aims, description of participants (age, gender, education levels, etc.), intervention (what type of DA, when implemented, timing etc.), control group, primary outcome, and secondary outcome.

For non-randomized studies:

The data extraction sheet for non-randomized studies was identical to that for the RCT but excluded any information about a control group.

Risk of bias

For randomized control trials:

The risk of bias was assessed by two independent reviewers (SI, JG) using the Cochrane Collaborations Risk of Bias Tool.[16] This tool is used to evaluate RCTs in 7 domains to judge whether each domain is of high, low, or unclear risk of bias. Disagreements were discussed and if unable to be resolved were assessed by a third reviewer (PM).

For non-randomized studies:

To assess the quality of the non-randomized studies the Downs and Black Checklist was used by two independent reviewers (SI, JG).[17] This tool is used to assess quality in nonrandomized studies by evaluating 5 domains by assigning "yes" or "no" to 27 questions. The questions are then assigned points and a score out of 30, the highest quality score, is obtained. This assessment tool was chosen as it has been utilized previously for pre-post and/or mixed methods studies.[18,19] In cases of disagreement, a third reviewer (PM) settled the risk of bias score.

RESULTS

Study Characteristics

A total of 2937 studies (Appendix 2 provides a summary of the search results) were initially identified. After removing duplicates and screening titles and abstracts, 32 articles were left for full review. After applying our inclusion and exclusion criteria there were three studies[20-22] included in our final analysis, see Figure 1. This included one randomized controlled trial, one pre-post study, and one mixed methods study. Descriptive characteristics for the three included studies are shown in Table 1.

Table 1: Descriptive characteristics of three reviewed studies

Study	Study Design	Study Population	Number of Patients (n)	Age (Gender)	Intervention	DA (content and type)	Primary objective	Outcome	Quality*
Leighl et al 2011 (Australia, Canada)	RCT	Metastatic colorectal cancer patients considering chemotherapy	Control 100, Intervention 107	Median-Control: 62.5 (62%m, 38%f) Intervention: 61 (54%m, 46%f)	Standard oncology consult vs oncology consult + DA	Chemotherapy types vs no chemotherapy, paper booklet, take-home booklet with audiotape or CD	Evaluate the impact of the DA on patient understanding of the prognostic and treatment information and satisfaction with decision making	Intervention arm with improved understanding 1-2 weeks post consultation (+16% vs +5%, P <.001)	N/A
Wu et al 2016 (Canada)	Before and after study	Rectal cancer patients with lesion maximum 10cm from anal verge	36	Mean: 61.9 ± 9.7 (69%m, 31%f)	Surgical consult with DA	Risks and benefits of LAR vs APR, paper booklet, online version to review	Patient decisional conflict	Mean decisional conflict scores improved after using the decision aid (2% change after using DA (p=0.0001)	Low (score 13)
Miles et al 2017 (UK)	Mixed methods (before and after study, interviews)	Stage II colorectal cancer patients post surgery prior to adjuvant chemotherapy	13	Median: 67 (33%m, 66%f)	Oncology consult with DA	Patients personal risk of recurrence with and without chemo, Computer based DA	Patient perceived usefulness and acceptability of the DA	Patients perceived the decision aid as helping them communicate with their doctor and make a decision (PrepDM 1-5, mean 4.28)	Low (score 8)

* Assessed using the Downs and Black Checklist

Risk of bias

Randomized controlled trial

There was a low risk of selection, detection, or attrition bias, with a moderate risk of performance bias found due to inability to blind participants. Reporting bias was felt to be low-moderate because the study was performed in two locations but the data was not reported separately. Please see Appendix 3 for further details to support judgements.

Non-randomized studies

Both of the non-randomized studies had low scores on the Downs and Black Checklist. The scores were 8 and 13 out of 30, which is associated with poorer quality. In addition, both studies have a significant risk of selection bias, due to lack of control group or randomization.

Study specific results

Study 1[20]:

The randomized controlled trial took place in Australia and Canada and included a total of 207 patients, 100 in the control group and 107 in the intervention group. All patients carried a diagnosis of metastatic colorectal cancer and were meeting with an oncologist for the first time regarding chemotherapy options. The control group received consultation alone, while the intervention group received consultation plus a decision aid. The decision aid consisted of a paper booklet reviewed during the initial visit on chemotherapy options, as well as a take home booklet and audiotape. The decision aid in this study had been pilot tested and altered based on patient feedback.[23] Patients completed a series of different questionnaires prior to randomization and at multiple intervals after the initial consultation. The primary objective of the study was to evaluate patient understanding and satisfaction with the decision made. The intervention group had an improved understanding of chemotherapy options 1-2 weeks post-consultation when compared to the control group ($p<0.001$). Patient satisfaction was found to be high and the decisional conflict score was similar in both groups. As a secondary outcome, the Canadian patient population was found to be more apt to make a treatment decision immediately after consultation (86% v 42%, $p< 0.001$), but had a higher decisional conflict scores (38 v 34, $P<0.002$) when compared to the Australian population.

Study 2[21]:

This pre-post study took place in Canada and UK. They included a total of 36 patients who were diagnosed with rectal cancer. The study introduced their decision aid during or after consultation with a surgeon. The decision aid consisted of a paper booklet on the topic of LAR vs APR and sent participants home with a link to an online decision aid. Patients completed questionnaires following initial surgical consultation and after reviewing the decision aid. The primary outcome was decisional conflict. Secondary outcomes included knowledge, choice, and acceptability of the decision aid. Mean decisional conflict scores were improved by 24.2% ($p=0.0001$) after the use of the decision aid. Patient knowledge also increased 37% ($p<0.0001$). The decision aid had variable impact on choice. In terms of acceptability, 85% of participants felt the decision aid had good/excellent information about options and 97% would recommend it to others.

Study 3[22]:

This mixed method study took place in Canada and UK. A total of 13 patients diagnosed with stage II colorectal cancer post-surgery prior to chemotherapy were included. They introduced their decision aid during the patient's consultation with an oncologist. The decision aid consisted of a computer-based DA on chemotherapy options and participants were sent home with reference material. Study patients completed a post-intervention questionnaire as well as participated in semi-structured interviews. The primary outcome was patient-perceived usefulness of the decision aid assessed on the Preparation for Decision Making Scale. The decision aid scored a favorable 4.28 out of five on the Preparation for Decision Making Scale. Themes that emerged from the semi-structured interviews were: it was unclear for patients whether chemotherapy would benefit them, patient understood that the aim of chemotherapy was

to prevent cancer from coming back, and that patients' understanding of recurrence risk improved with graphical representation. Eleven of 12 patients participating ultimately declined chemotherapy.

DISCUSSION

Our review indicates that decision aids for patients with colorectal cancer can be effective at improving knowledge about the patient's clinical situation, facilitate shared decision making, and can be well received by patients. In addition, each study had similar implementation strategies such as introducing the decision aid during or after a clinical encounter and providing patient's with reference material to take home. However, our review found only three articles, including two low quality studies, to evaluate decision aids in this vulnerable patient population. Thus, although the current literature supports the use of decision aids for treatment decisions in cancer populations, there is not enough literature to make statistical conclusions about patients with colorectal cancer specifically.

Strengths of this review include our engagement with a medical librarian (HJ) in order to fully review the available literature, and our adherence to the guidelines on how to appropriately conduct a systematic review. Potential limitations of our review include possible omission of studies, although unlikely given our search strategy. A second limitation is the inability to draw statistical conclusions from the studies included due to the variety of study designs and outcomes.

This is the first systematic review that has evaluated decision aid use for treatment decisions in patients diagnosed with colorectal cancer. This review identified that the current literature evaluating decision aids for colorectal cancer treatment is sparse and of low quality. In addition, the quality of the decision aids used within these studies is unclear. This gap in the literature is especially noticeable when compared to decision aids developed for treatment of other common cancers such as breast, lung, and prostate. Given a similar complexity and variety of treatment options available for colorectal cancer, particularly rectal cancer, it is unknown why there is such a paucity of literature on the use of decision aids in this population. Possible causes include a focus on colorectal cancer screening decision aids only, lack of penetrance of decision aid benefits to colorectal cancer practitioners, and/or possible stigma associated with bowel diseases that causes investigators less likely to pursue the topic.

The lack of quality evidence on the utility of decision aids in colorectal cancer treatment is one of the factors that preclude their use in clinical situations. Future studies should focus on understanding the needs of patients diagnosed with colorectal cancer and their clinicians. Once an appropriate needs assessment is performed, high quality decision aids should be created that meet the International Patient Decision Aid Standards (IPDAS).[24] These decision aids should then be tested in context in order to ensure appropriate implementation and utility. Since patients diagnosed with rectal cancer often face particularly complex surgical treatment decisions, this may be a subpopulation that would particularly benefit from decision aid use. Future studies should confirm that decision aids for colorectal cancer treatment improve knowledge, increase facilitated decision making, and are associated with increased patient satisfaction.

CONCLUSIONS

There has been limited research on decision aids in colorectal cancer treatment, even with an increased emphasis on shared decision making in healthcare decisions. We identified only three studies, two of which are low quality, which makes it difficult to make any definitive conclusions about existing decision aids for patients diagnosed with colorectal cancer. However, there is some indication that these tools are associated with positive outcomes in this population such as increased knowledge and patient satisfaction. Future studies should be done to further evaluate decision aids for treatment decisions for patients with colorectal cancer in order to support and encourage their use in this vulnerable population.

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FIGURE AND TABLE LEGEND

Figure 1: Summary of the review process

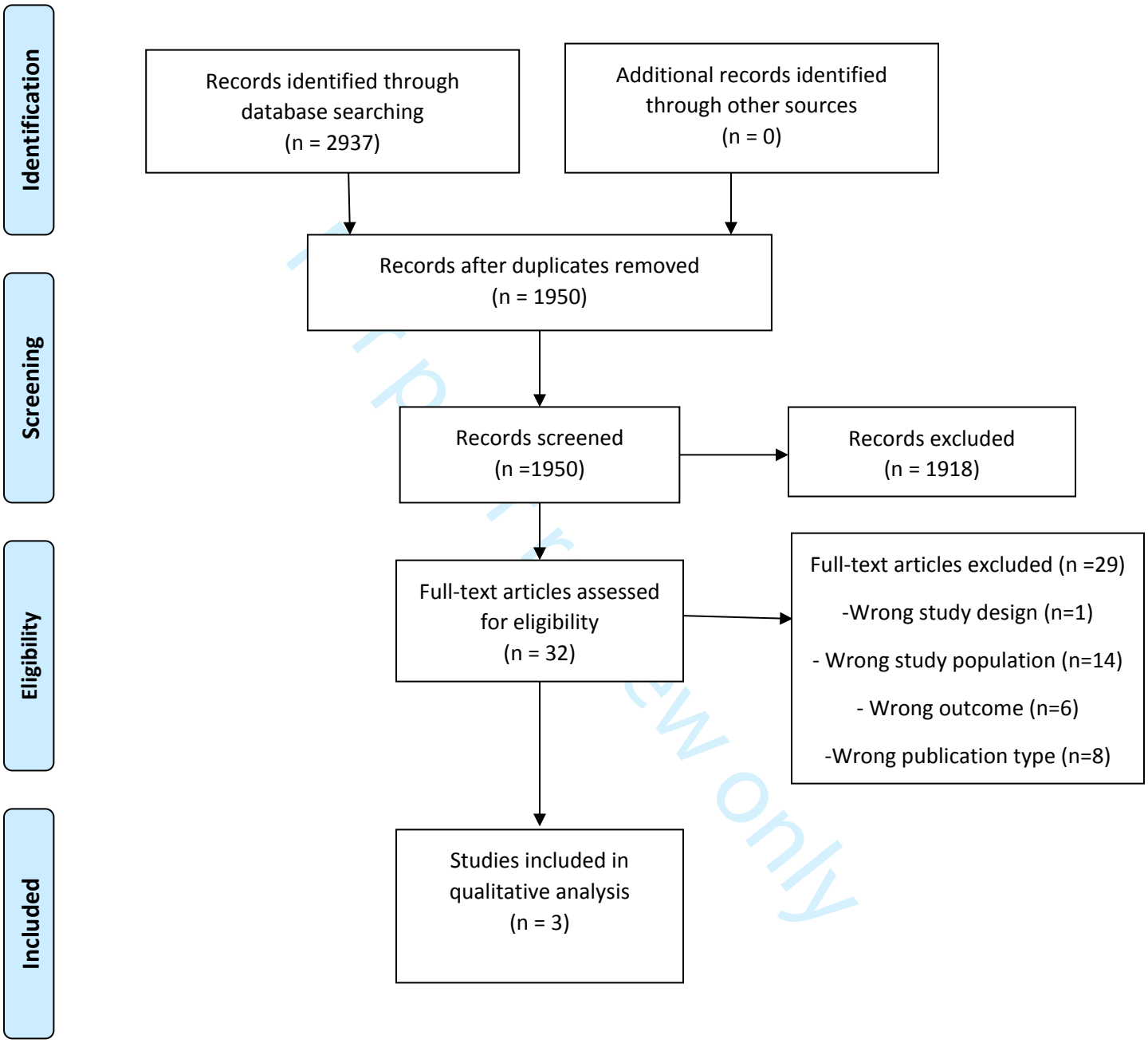
Table 1: Descriptive characteristics of three reviewed studies

Appendix 1: Search strategies

Appendix 2: Summary of search results

Appendix 3: Cochrane Collaborations Risk of Bias Tool

Figure 1: Summary of the review process



APPENDIX 1

Search strategies

PubMed (Medline)

History

Download history Clear history

Search	Add to builder	Query	Items found	Time
#7	Add	Search **(#3 AND #6)**	964	10:34:18
#6	Add	Search **(#4 OR #5)**	229794	10:34:11
#5	Add	Search **((Rectal[tiab] OR rectum[tiab] OR colon[tiab] OR colorectal[tiab]]) AND (cancer*[tiab] OR neoplasm*[tiab] OR malignanc*[tiab] OR Tumor*[tiab]))**	197997	10:34:02
#4	Add	Search **((Colorectal neoplasms[mesh:noexp] OR Rectal Neoplasms[mesh:noexp])) OR (((Rectum[mesh]OR colon[mesh]) AND (neoplasms[mesh])))**	126428	10:33:58
#3	Add	Search **(#1 OR #2)**	66696	10:32:48
#2	Add	Search **(((Decision Making[mesh] OR Decision support techniques[mesh] OR Decision making[tiab] OR Decision support[tiab]))) AND ((Patient preference[mesh] OR Patient-Centered Care[mesh] OR Patient Participation[Mesh] OR Professional-Patient Relations[mesh] OR Professional-Family Relations[mesh] OR Patient participation[tiab] OR Patient engagement[tiab] OR Patient involvement[tiab] OR Client participation[tiab] OR Client engagement[tiab] OR Client involvement[tiab] OR Patient relation*[tiab] OR Patient preference*[tiab] OR Patient centered[tiab] OR Patient centred[tiab]))**	24186	10:32:41
#1	Add	Search **((Decision[tiab] AND (aid*[tiab] OR tool*[tiab] OR box*[tiab])) OR Option grid*[tiab] OR Issue card*[tiab] OR Drug fact box*[tiab] OR Shared decision*[tiab] OR Informed decision*[tiab] OR Informed choice*[tiab] OR Collaborative decision*[tiab] OR Decision support intervention*[tiab] OR Decision Support Systems, Clinical[mesh])**	47589	10:32:11

CINAHL

Select / deselect all | Search with AND | Search with OR | Delete Searches

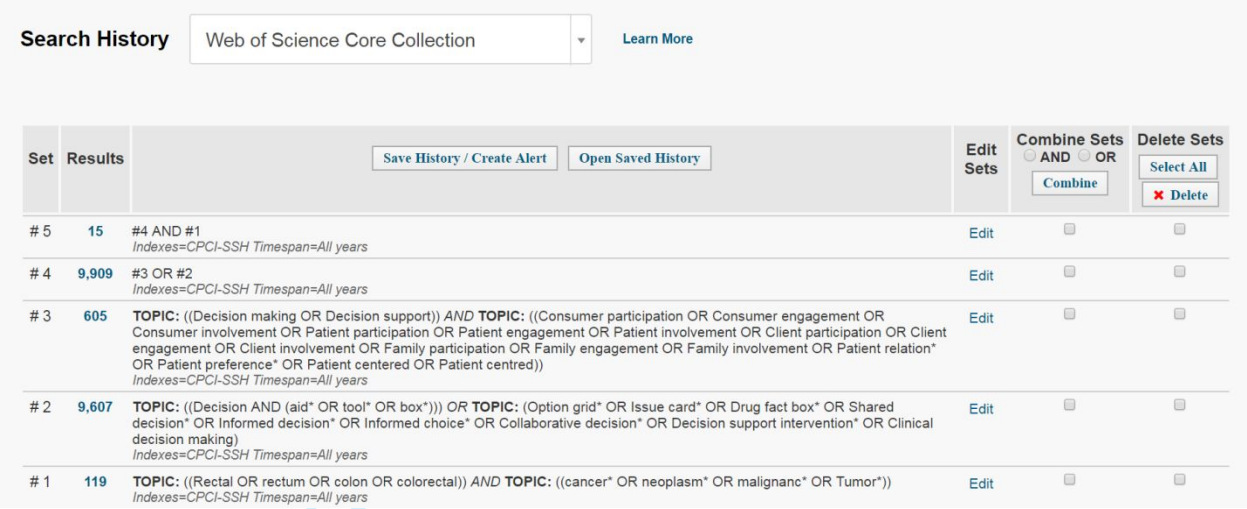
	Search ID#	Search Terms	Search Options	Actions
☐	S16	S8 AND S15	Search modes - Find all my search terms	View Results (488)
☐	S15	S11 OR S14	Search modes - Find all my search terms	View Results (58,816)
☐	S14	S12 AND S13	Search modes - Find all my search terms	View Results (19,044)
☐	S13	MH (patient-centered care and outcomes) OR MH Professional-Family Relations OR MH Professional-Patient Relations OR MH Consumer Participation OR (Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)	Search modes - Find all my search terms	View Results (222,187)
☐	S12	MH Decision Making OR MH Decision Support Techniques+ OR MH Decision Making, Family OR (Decision making OR Decision support)	Search modes - Find all my search terms	View Results (93,583)
☐	S11	(Decision AND (aid* OR tool* OR box*)) OR (Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention*) OR MH Decision Making, Clinical	Search modes - Find all my search terms	View Results (48,134)
☐	S10	(MH "Patient Centered Care")	Search modes - Find all my search terms	View Results (17,878)
☐	S9	(MH "Decision Support Techniques+") OR (MH "Decision Making, Clinical") OR (MH "Decision Making, Family")	Search modes - Find all my search terms	View Results (26,932)
☐	S8	S6 OR S7	Search modes - Find all my search terms	View Results (18,745)
☐	S7	(Rectal OR rectum OR colon OR colorectal[mesh]) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*)	Search modes - Find all my search terms	View Results (8,578)
☐	S6	S1 OR S2 OR S5	Search modes - Find all my search terms	View Results (13,557)
☐	S5	S3 AND S4	Search modes - Find all my search terms	View Results (49)
☐	S4	(MH "Rectum") OR (MH "Colon+")	Search modes - Find all my search terms	View Results (3,481)
☐	S3	(MH "Neoplasms")	Search modes - Find all my search terms	View Results (42,133)
☐	S2	(MH "colorectal Neoplasms")	Search modes - Find all my search terms	View Results (11,835)
☐	S1	(MH "Rectal Neoplasms")	Search modes - Find all my search terms	View Results (1,760)

Embase

1. exp clinical decision support system/
2. decision.ti. or decision.ab.
3. aid*.ti. or aid*.ab.
4. tool*.ti. or tool*.ab.
5. box*.ti. or box*.ab.
6. 3 or 4 or 5
7. 2 and 6
8. "Option Grid*".ti. or "Option Grid*".ab.
9. "Issue Card*".ti. or "Issue Card*".ab.
10. "Drug fact box*".ti. or "Drug fact box*".ab.
11. "Shared Decision*".ti. or "Shared Decision*".ab.
12. "Informed Decision*".ti. or "Informed Decision*".ab.
13. "Informed Choice*".ti. or "Informed Choice*".ab.
14. "Collaborative decision*".ti. or "Collaborative decision*".ab.
15. "Decision support intervention*".ti. or "Decision support intervention*".ab.
16. 1 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17. exp decision making/
18. exp decision support system/
19. "decision making".ti. or "decision making".ab.
20. "decision support".ti. or "decision support".ab.
21. 17 or 18 or 19 or 20
22. exp patient preference/
23. "patient-centered care".ti. or "patient-centered care".ab.
24. exp patient participation/
25. exp professional-patient relationship/
26. "professional-family relation*".ti. or "professional-family relation*".ab.
27. "patient participation".ti. or "patient participation".ab.
28. "patient engagement".ti. or "patient engagement".ab.
29. "patient involvement".ti. or "patient involvement".ab.
30. "client participation".ti. or "client participation".ab.
31. "client engagement".ti. or "client engagement".ab.

32. "client involvement".ti. or "client involvement".ab.
33. "patient relation*".ti. or "patient relation*".ab.
34. "patient preference*".ti. or "patient preference*".ab.
35. "patient centered".ti. or "patient centered".ab.
36. "patient centred".ti. or "patient centred".ab.
37. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38. 21 and 37
39. 16 or 38
40. colorectal tumor/
41. rectum tumor/
42. exp rectum/
43. exp colon/
44. exp neoplasm/
45. 40 or 41 or 42 or 43
46. 44 and 45
47. rectal.ti. or rectal.ab.
48. rectum.ti. or rectum.ab.
49. colon.ti. or colon.ab.
50. colorectal.ti. or colorectal.ab.
51. 47 or 48 or 49 or 50
52. cancer*.ti. or cancer*.ab.
53. neoplasm*.ti. or neoplasm*.ab.
54. malignanc*.ti. or malignanc*.ab.
55. tumor*.ti. or tumor*.ab.
56. 52 or 53 or 54 or 55
57. 51 and 56
58. 39 and 57

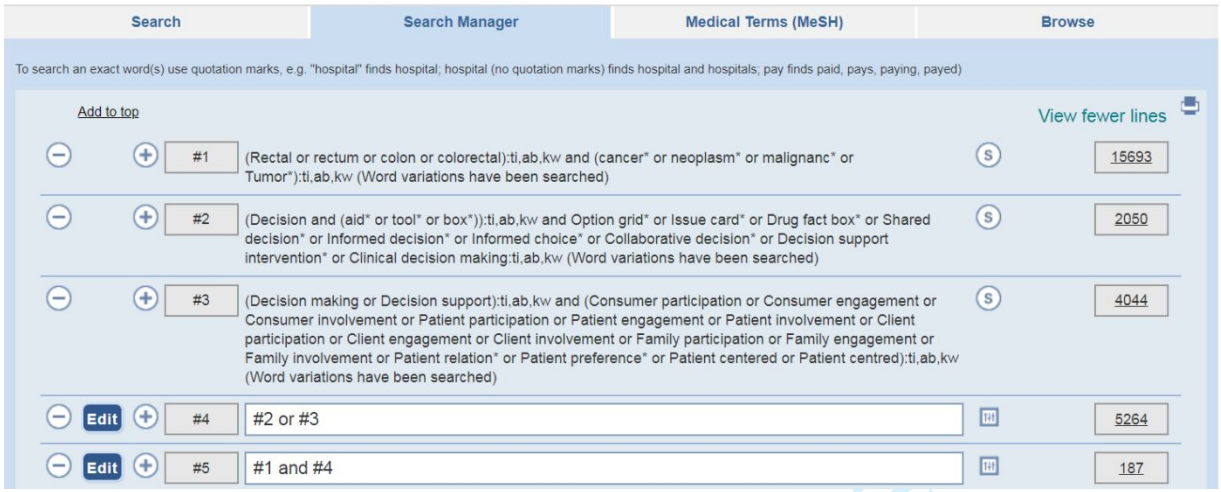
Web of Science



Search History | Web of Science Core Collection | Learn More

Set	Results	Save History / Create Alert / Open Saved History	Edit Sets	Combine Sets (AND / OR) Combine	Delete Sets Select All / Delete
# 5	15	#4 AND #1 *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 4	9,909	#3 OR #2 *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 3	605	**TOPIC:** ((Decision making OR Decision support)) *AND* **TOPIC:** ((Consumer participation OR Consumer engagement OR Consumer involvement OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Family participation OR Family engagement OR Family involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)) *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 2	9,607	**TOPIC:** ((Decision AND (aid* OR tool* OR box*))) *OR* **TOPIC:** (Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR Clinical decision making) *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 1	119	**TOPIC:** ((Rectal OR rectum OR colon OR colorectal)) *AND* **TOPIC:** ((cancer* OR neoplasm* OR malignanc* OR Tumor*)) *Indexes=CPCI-SSH Timespan=All years*	Edit		

Cochrane Library



Search | Search Manager | Medical Terms (MeSH) | Browse

To search an exact word(s) use quotation marks, e.g. "hospital" finds hospital; hospital (no quotation marks) finds hospital and hospitals; pay finds paid, pays, paying, payed)

Add to top | View fewer lines

#1	(Rectal or rectum or colon or colorectal):ti,ab,kw and (cancer* or neoplasm* or malignanc* or Tumor*):ti,ab,kw (Word variations have been searched)	15693
#2	(Decision and (aid* or tool* or box*)):ti,ab,kw and Option grid* or Issue card* or Drug fact box* or Shared decision* or Informed decision* or Informed choice* or Collaborative decision* or Decision support intervention* or Clinical decision making:ti,ab,kw (Word variations have been searched)	2050
#3	(Decision making or Decision support):ti,ab,kw and (Consumer participation or Consumer engagement or Consumer involvement or Patient participation or Patient engagement or Patient involvement or Client participation or Client engagement or Client involvement or Family participation or Family engagement or Family involvement or Patient relation* or Patient preference* or Patient centered or Patient centred):ti,ab,kw (Word variations have been searched)	4044
Edit #4	#2 or #3	5264
Edit #5	#1 and #4	187

APPENDIX 2

Summary of search results

Database	Platform	Years covered	Date conducted	# results
Medline	PubMed	1946-current	April 11, 2018	964
CINAHL	EBSCO	1981- current	April 11, 2018	488
Embase	Embase.com	1974-current	April 11, 2018	1,283
Web of Science (Core Collection)	WOS	1900-current	April 11, 2018	15
Cochrane Library	Wiley	CDSR : Issue 4 of 12, April 2018 CCRCT : Issue 3 of 12, March 2018 CMR: Issue 3 of 4, July 2012	April 11, 2018	187
Total				2,937
Total with Duplicates Removed				1,950

APPENDIX 3

Cochrane Collaborations Risk of Bias Tool

Leighl et al, 2011		
Domain	**Support for judgement**	**Authors' judgement**
Selection bias		
Random sequence generation	"Eligible consenting patients with advanced colorectal cancer who were seeing a medical oncologist for an initial consultation regarding first line chemotherapy were randomly assigned…" "randomization lists stratified by the consulting oncologist were computer generated…" Comment: No statistically significant differences in the intervention and control group except English as first language in intervention arm (see table 2)	**Low**
Allocation concealment	"randomization lists…were computer generated and the code was concealed in a sealed envelope until the time of random assignment" "…oncologists and patients were actively informed of the randomization arm only when patients received the DA."	**Low**
Performance bias		
Blinding of participants and personnel	"Although not blinded, oncologists and patients were actively informed of the randomization arm only when patients received the DA." "Those receiving the DA were counselled not to share it with others in the waiting room to avoid contamination of the standard arm." "…five consultations were audiotaped before study commencement as a baseline for comparison with consultations in the standard arm. Oncologists were to be provided with feedback in the event of marked deviation during the course of the trial, but no deviation occurred" "Oncologists were trained to use the DA during the consultation…"	**Moderate**
Detection bias		
Blinding of outcome assessment	Comment: The study does not specify whether or not the outcomes assessment was done in a blinded fashion	**Low**
Attrition bias		
Incomplete outcome data	Comment: 18 patients declined to participate initially and a total of 32 patients were lost to follow up in control, and 33 were lost to follow up in intervention with similar amounts between groups at similar intervals Comment: All patients who participated in at least one survey were included in the analysis Comment: All the outcome assessments are linked together with the surveys, no significant difference in data collection for outcomes	**Low**
Reporting bias		
Selective reporting	Comment: All outcome measures appear to be addressed within the results and discussion Comment: the researchers did not mention how many of the patients were from Canada or Australia but do mention some statistically significant differences in readiness to make a treatment decision and consultation satisfaction scores	**Low/ Moderate**
Other bias		
Other sources of bias	Comment: Insufficient information to judge	**Unclear**

Reporting checklist for systematic review and meta-analysis.

Based on the PRISMA guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA reporting guidelines, and cite them as:

Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

		Reporting Item	Page Number
	#1	Identify the report as a systematic review, meta-analysis, or both.	1
Structured summary	#2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis	3

		methods; results; limitations; conclusions and implications of key findings; systematic review registration number	
Rationale	#3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	#4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
Protocol and registration	#5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address) and, if available, provide registration information including the registration number.	5
Eligibility criteria	#6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rational	6
Information sources	#7	Describe all information sources in the search (e.g., databases with dates of coverage, contact with study authors to identify additional studies) and date last searched.	6
Search	#8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	#9	State the process for selecting studies (i.e., for screening, for determining eligibility, for inclusion in the systematic review, and, if applicable, for inclusion in the meta-analysis).	6-7

Data collection process	#10	Describe the method of data extraction from reports (e.g., piloted forms, independently by two reviewers) and any processes for obtaining and confirming data from investigators.	7
Data items	#11	List and define all variables for which data were sought (e.g., PICOS, funding sources), and any assumptions and simplifications made.	7
Risk of bias in individual studies	#12	Describe methods used for assessing risk of bias in individual studies (including specification of whether this was done at the study or outcome level, or both), and how this information is to be used in any data synthesis.	7-8
Summary measures	#13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Planned methods of analyis	#14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	NA
Risk of bias across studies	#15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	#16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA

Study selection	#17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	#18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.	8
Risk of bias within studies	#19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	9-10
Results of individual studies	#20	For all outcomes considered (benefits and harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	10-12
Synthesis of results	#21	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency.	NA
Risk of bias across studies	#22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	#23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
Summary of Evidence	#24	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers	12

Limitations	#25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	12
Conclusions	#26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13
Funding	#27	Describe sources of funding or other support (e.g., supply of data) for the systematic review; role of funders for the systematic review.	2

BMJ Open

The impact of decision aids in patients with colorectal cancer: a systematic review

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-028379.R1
Article Type:	Original research
Date Submitted by the Author:	30-Jul-2019
Complete List of Authors:	Goldwag, Jenaya; Dartmouth Hitchcock Medical Center, Department of Surgery; Geisel School of Medicine Marsicovetere, Priscilla; Franklin Pierce University, Master of Physician Assistant Studies Program; Geisel School of Medicine Scalia, Peter; Dartmouth College, The Dartmouth Institute for Health Policy and Clinical Practice Johnson, Heather; Geisel School of Medicine; Dartmouth College Durand, Marie-Anne; The Dartmouth Institute for Health Policy & Clinical Practice, Elwyn, Glyn; Dartmouth College; The Dartmouth Institute for Health Policy & Clinical Practice Ivatury, Srinivas; Dartmouth Hitchcock Medical Center, Department of Surgery; Dartmouth Hitchcock Medical Center, Department of Surgery
Primary Subject Heading:	Oncology
Secondary Subject Heading:	Patient-centred medicine, Gastroenterology and hepatology
Keywords:	Gastrointestinal tumours < ONCOLOGY, Colorectal surgery < SURGERY, Gastrointestinal tumours < GASTROENTEROLOGY

The impact of decision aids in patients with colorectal cancer: a systematic review

Short Running Head: Colorectal Cancer Decision Aids

Main Category: Colorectal Cancer

Key words: Colon Cancer, Rectal Cancer, Decision Aids, Decision making

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Competing interests:

M-A D was involved in developing Option Grid decision aids. She receives consulting income from EBSCO Health and may receive royalties in the future. She is also a consultant for ACCESS Community Health Network. GE has been a consultant to Emmi Solutions, which develops patient decision support tools; National Quality Forum on certification of decision support tools; Washington State Health Department on certification of decision support tools; PatientWisdom; SciMentum, Amsterdam and Access Community Health Network, Chicago. He has edited/published books that provide royalties on sales by the publishers: the books include SDM (Oxford University Press) and Groups (Radcliffe Press). He also initiated and leads the Option Grid patient decision aids collaborative, which produces and publishes patient knowledge tools in the form of comparison tables (http://optiongrid.org) and has part ownership of the registered trademark. He owns a copyright in CollaboRATE, IntegRATE and Observer OPTION measures of SDM and care integration. These measures are freely available for use. None of these interests have affected this work.

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Author Contributions:

All authors have substantial contributions to the conception or design of the work (SJI, HAJ, GE, MAD, PS), the acquisition, analysis, or interpretation of data for the work (JLG, PM, HAJ, SJI), drafting the work or revising it critically for important intellectual content including final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (JLG, PM, PS, HAJ, MAD, GE, SJI).

Data sharing statement:

There is no additional data from this systematic review.

ABSTRACT

Objectives: Our aim was to conduct a systematic review of the literature to determine the impact of patient decision aids (PDA) on patients facing treatment decisions for colorectal cancer.

Design: Systematic review

Data Sources: Sources included Embase, Medline, Web of Science, CINAHL, and the Cochrane Library from inception to June, 20, 2019.

Eligibility Criteria: We included randomized controlled trials, cohort studies, mixed methods, and case series in which a PDA for colorectal cancer treatment was used. Qualitative studies were excluded from our review.

Data Extraction and synthesis: Following execution of the search strategy by a medical librarian**,** two blinded independent reviewers identified articles for inclusion. Two blinded reviewers were also responsible for data extraction, risk of bias, and study quality assessments. Any conflict in article inclusion or extraction was resolved by discussion.

Results: Out of 3773 articles identified, three met our inclusion criteria: one randomized controlled trial, one before-and-after study, and one mixed-method study. In these studies, the use of a PDA for colorectal cancer treatment was associated with increased patient knowledge, satisfaction, and preparation for making a decision. On quality assessment, two of three studies were judged to be of low quality.

Conclusion: A paucity of evidence exists on the effect of PDA for colorectal cancer treatment with existing evidence being largely of low quality. Further investigation is required to determine the effect of

decision aids for colorectal cancer treatment as well as reasons for the lack of PDA development and implementation in this area.

Trial Registration:

We published our study protocol in PROSPERO (registration # CRD42018095153).

ARTICLE SUMMARY

Strengths and Limitations of this Study

- A broad search strategy as well as a firm adherence to systematic review methodology make this a comprehensive review on decision aids used for colorectal cancer treatment.
- A risk of bias tool and/or a quality assessment tool was used to assess randomized controlled trials or nonrandomized trials respectively.
- Including a broad number of outcomes in the inclusion criteria limits the ability to make discrete conclusions.
- There were not enough articles identified to perform a meta-analysis.

INTRODUCTION

Treatment decisions for colorectal cancer can be complex and multimodal, with significant variability and controversy. Patients diagnosed with colorectal cancer have many options for treatment including chemotherapy, surgery, and radiation therapy depending on their cancer stage, medical history, and preferences. For some clinical situations, such as stage II colon cancer, there is significant variability between options, including surgery alone vs surgery and chemotherapy, as well as the choice of chemotherapy.[1,2] In addition, patients diagnosed with rectal cancer often have to decide between two equally efficacious, but lifestyle altering, surgical

options: bowel reconnection with low anterior resection (LAR) versus permanent colostomy with abdominal perineal resection (APR). Further, additional factors exist for many patients increasing decision complexity including the presence or absence of additional colon polyps, concomitant cancers, and genetic predisposition. These preference-sensitive decisions can be overwhelming to patients and their families and there can be substantial variation in treatment preferences.[3,4]

In general, many cancer patients prefer to be actively and collaboratively involved in disease-related decisions.[5-8] As these decisions can be challenging for patients, often occurring at an emotional time, patient decision aids (PDA) have been developed to provide evidence-based information on treatment options and help patients clarify and communicate the personal values they associate with different options for treatment.[9,10] PDA are evidence-based tools designed to help patients make informed choices by providing information on the pros, cons, risks, probabilities, and scientific uncertainty of available options prior to making a decision.[11,12] PDA can be used when there are multiple reasonable options, when no single option has a clear advantage over the others in terms of health outcomes, or when each option has benefits and harms that patients value differently.[11] PDA have been shown to increase patient knowledge, reduce decisional conflict, help patients make appropriate decisions, and can have a positive effect on patient-clinician communication.[11]

PDA have been successful in helping patients make treatment decisions in breast, prostate, and lung cancer - other cancer types with similar treatment complexity to colorectal

cancer. The impact of PDA in the treatment of colorectal cancer, however, is unclear.[13-15] Most PDA research regarding colorectal cancer has focused on screening options for prevention as opposed to treatment decisions after diagnosis.[16] As patients diagnosed with colorectal cancer must also make complex preference sensitive decisions about treatment, we aimed to systematically evaluate the effect of PDA on outcomes associated with colorectal cancer treatment and clinical practice.

METHODS

Protocol and Registration

We conducted a systematic review, reported in this review using the PRISMA guidelines, of studies that used a colorectal cancer treatment patient decision aid as the intervention. Prior to beginning our search, we published our study protocol in PROSPERO (registration # CRD42018095153)

Patient and Public Involvement Statement

The study was performed in hopes to broaden knowledge about PDA for treatment decisions in colorectal cancer care. No patients participated in design or production of this systematic review. In particular, no patients were involved in the development of the research question or outcomes measures, recruitment or conduct, or other aspects of the review.

Eligibility Criteria

We used the Population, Intervention, Comparison, Outcome, and Study design (PICOS) criteria to determine eligibility. To be included, studies had to be randomized controlled trials (RCTs), nonrandomized controlled trials (NRCT), retrospective or prospective cohort studies, mixed

methods, or case series. Any purely qualitative studies or case reports were excluded. Our population did not contain any age restrictions, and included patients diagnosed with colon or rectal cancer needing to decide between two or more management options for treatment. The intervention is a PDA which is a tool designed to inform patients about treatment options and to facilitate patient participation in decision making.[12] The decision aids could be in any format and used at any time or location, before, during, or after a clinical encounter. The control group would be standard counseling, non-decision aids, or no control group if applicable. We included all study-specified primary and secondary outcomes that related to patients use of the decision aid such as, knowledge gained from PDA, usability of PDA, patient satisfaction of PDA etc. We excluded articles focusing on decision aids or risk calculators that were used only by physicians to guide management of colorectal cancer treatment or implementation of decision aids.

Information Sources and Search

With assistance from our medical librarian (HJ), we developed an electronic search strategy for the following databases: Embase, Medline, Web of Science, CINAHL, and the Cochrane Library from inception to June 17, 2019 (please see Appendix 1 for a summary of the search results). We also looked at conference proceedings from the American Society of Colorectal Surgery annual meeting 2010-2019. We identified articles that assessed decision aids in patients with colorectal cancer, employing text words and database-specific subject headings (e.g. MeSH,) such as “colon cancer,” “rectal cancer,” “decision aids,” and “decision making”. For the purposes of the search, we did not impose any restrictions on language, publication type, or publication date. In addition, we performed a citation search using the 'cited by' option on Google Scholar and 'related searches' on PubMed. We manually checked references for all articles identified as

meeting our eligibility requirements for added sensitivity. See Appendix 2 for search terms used for each database.

Study Selection

We used Rayyan, a systematic review web application, to help facilitate the screening process.[17] The articles were listed alphabetically so that two reviewers (SI, HJ), blinded to each other's results, could independently review articles with first author last names between A-L and two additional similarly blinded reviewers (JG, PM) could independently review articles with first author last names between M-Z. During this initial screening, titles and abstracts were reviewed. Disagreements about inclusion were resolved by discussion by the involved reviewers. If necessary, a third reviewer either (JG or SI) also contributed to the discussion. After completing the initial screening, two reviewers (SI, JG) reviewed the full text of the remaining articles. Any conflicts about eligibility at this time were also resolved by discussion.

Data Collection Process

For randomized controlled trials:

The data extraction sheet, piloted prior to use, included the following information: study author, publication year, publication type, country, study aims, description of participants (age, gender, education levels, etc.), intervention (what type of DA, when implemented, timing etc.), control group, primary outcome, and secondary outcome if applicable. Two reviewers independently extracted the data from the included articles. Disagreements were resolved by discussion.

For non-randomized studies:

The data extraction sheet and data extraction methods for non-randomized studies was identical to that for the RCT.

Risk of Bias (RCT) and Quality Assessment (NRCT)

Risk of bias for RCTs:

The risk of bias was assessed by two independent reviewers (SI, JG) using the Cochrane Collaborations Risk of Bias Tool.[18] This tool is used to evaluate RCTs in 7 domains to judge whether each domain is of high, low, or unclear risk of bias. Disagreements were resolved by discussion.

Quality assessment for NRCTs:

The Downs and Black Checklist was used by two independent reviewers (SI, JG) to assess the quality of the non-randomized studies.[19] The reviewer assesses five domains (reporting, external validity, bias, confounding, power) by assigning a "yes" or "no" to 27 questions. The answer determines if a point(s) is awarded for that particular question. The highest possible score is 30 with a higher score associated with a higher quality study. This assessment tool was chosen as it has been utilized previously for pre-post and/or mixed methods studies.[20,21] Disagreements were resolved by discussion.

RESULTS

Study Characteristics

A total of 5,594 articles were initially identified with 3773 left to review after duplicates were removed. After screening titles and abstracts, 36 articles were left for full review. After assessing the full articles there were three studies [22-24] included in our final analysis, see Figure 1.

This included one randomized controlled trial, one before-and-after study, and one mixed methods study. Characteristics for the three included studies are shown in Table 1.

Table 1: Characteristics of three reviewed studies

Study	Study Design	Study Population	Number of Patients (n)	Age (Gender)	Intervention	DA (content and type)	Primary objective	Outcome	Quality*
Leighl et al 2011 (Australia, Canada)	RCT	Metastatic colorectal cancer patients considering chemotherapy	Control 100, Intervention 107	Median-Control: 63 (62%m, 38%f) Interventi on: 61 (54%m, 46%f)	Standard oncology consult vs oncology consult + DA	Chemotherapy types vs no chemotherapy, paper booklet, take-home booklet with audiotape or CD	Evaluate the impact of the DA on patient understanding of the prognostic and treatment information and satisfaction with decision making	Intervention arm with improved understanding 1-2 weeks post consultation (+16% vs +5%, P <.001)	N/A**
Wu et al 2016 (Canada)	Before and after study	Rectal cancer patients with lesion maximum 10cm from anal verge	36	Mean: 62 ± 10 (69%m, 31%f)	Surgical consult with DA	Risks and benefits of LAR vs APR, paper booklet, online version to review	Patient decisional conflict	Mean decisional conflict scores improved after using the decision aid (2% change after using DA (P <.001)	Low (score 13)
Miles et al 2017 (UK)	Mixed methods (before and after study, interview s)	Stage II colorectal cancer patients post surgery prior to adjuvant chemotherapy	13	Median: 67 (33%m, 66%f)	Oncology consult with DA	Patients personal risk of recurrence with and without chemo, Computer based DA	Patient perceived usefulness and acceptability of the DA	Patients perceived the decision aid as helping them communicate with their doctor and make a decision (PrepDM 1-5, mean 4)	Low (score 8)

* NRCTs assessed using the Downs and Black Checklist

** RCT did not have a quality assessment rather a risk of bias was performed, (Appendix 3)

Risk of Bias and Quality Assessment

Risk of bias: Randomized controlled trial

There was a low risk of selection, detection, or attrition bias, with a moderate risk of performance bias found due to inability to blind participants. Reporting bias was felt to be low-

moderate because the study was performed in two locations and reported in aggregate. Please see Appendix 3 for further details to support judgements.

Quality Assessment: Non-randomized studies

According to the Downs and Black Checklist, both non-randomized studies were considered to be low quality. The before-and-after study scored 13 out of 30, and the mixed methods study scored 8 out of 30. In addition, both studies have a significant risk of bias and confounding, due to lack of control group or randomization.

Study specific results

Study 1: Leighl, et al. [22] (Australia, Canada)

This randomized controlled trial took place in Australia and Canada and included a total of 207 patients, 100 in the control group and 107 in the intervention group. All patients carried a diagnosis of metastatic colorectal cancer and were meeting with an oncologist for the first time to discuss and decide between chemotherapy options. The control group received consultation alone, while the intervention group received consultation plus a decision aid. The decision aid consisted of a paper booklet reviewed during the initial visit on chemotherapy options, as well as a take home booklet and audiotape. The decision aid in this study had been pilot tested and altered based on patient feedback.[25] Patients completed a series of different questionnaires prior to randomization and at multiple intervals after the initial consultation. The primary objective of the study was to evaluate patient understanding, via a modified Fiset[26] and Brundage[27]

questionnaire, and satisfaction with the decision made via the 'satisfaction with decision scale'[28]. Secondary outcomes included decisional conflict, which evaluated patients' uncertainty with the decision and factors contributing to that uncertainty, assessed via the 'decisional conflict scale'[29], and readiness to make a decision immediately after consultation. The intervention group had an improved understanding of chemotherapy options 1-2 weeks post-consultation when compared to the control group ($p<0.001$), although this is of unclear clinical significance. Patient satisfaction was found to be high and the decisional conflict score was similar in both groups. The Canadian patient population was found to be more likely to feel ready to make a treatment decision immediately after consultation (86% v 42%, $p< 0.001$), but had a higher decisional conflict scores (38 v 34, $P<0.002$) when compared to the Australian population.

Study 2: Wu, et al.[23] *(Canada)*

This before-and-after study took place in Canada and UK. They included a total of 36 patients who were diagnosed with rectal cancer. The study introduced their decision aid during or after consultation with a surgeon to aid in deciding between two surgical options. The decision aid consisted of a paper booklet on the topic of LAR vs APR and sent participants home with a link to an online decision aid. Patients completed questionnaires following initial surgical consultation and after reviewing the decision aid. The primary outcome was decisional conflict. Secondary outcomes included knowledge, choice preference, and acceptability of the decision aid. Mean decisional conflict scores were improved by 24.2% ($p=0.0001$) after the use of the decision aid. Patient knowledge also increased 37% ($p<0.0001$). The decision aid had variable impact on choice preference, with some patients changing their preference between LAR, APR, and neutral after using the DA, with no statistically significant trend toward neutral or either

surgical option. In terms of acceptability, 85% of participants felt the decision aid had good/excellent information about options and 97% would recommend it to others.

Study 3: Miles, et al [24] (United Kingdom)

This mixed method study took place in Canada and UK. A total of 13 patients diagnosed with stage II colorectal cancer post-surgery prior to chemotherapy were included. They introduced their decision aid during the patient's consultation with an oncologist to help decide which, if any, chemotherapy was right for the patient. The decision aid consisted of a computer-based DA on chemotherapy options and participants were sent home with reference material. Study patients completed a post-intervention questionnaire as well as participated in semi-structured interviews. The results of the interviews are not included in this analysis as qualitative research was excluded from this review. The primary outcome was patient-perceived usefulness of the decision aid assessed on the Preparation for Decision Making Scale. The decision aid scored a favorable 4.28 out of five on the Preparation for Decision Making Scale[30]. Eleven of 12 patients participating ultimately declined chemotherapy.

DISCUSSION

Our systematic review found limited evidence on the use of PDAs for patients facing treatment decisions for colorectal cancer. We found three articles, two of which were low quality, which evaluated PDA for the treatment of colorectal cancer. These studies found that PDAs improved patient knowledge, facilitated shared decision making, and were well-accepted by patients. However, the results of these studies must be interpreted with caution given the low quality of two of the three articles. Although these studies supported the use of PDAs in this population,

there is insufficient evidence to draw definitive conclusions on the impact of PDAs in the treatment of colorectal cancer given the paucity of studies.

Strengths of this review include our engagement with a medical librarian (HJ) in order to fully review the available literature, and our adherence to the guidelines on how to appropriately conduct and report a systematic review. Potential limitations of our methods include possible omission of studies, although unlikely given our search strategy. Another limitation is the inability to perform subgroup analysis due to the small number of articles identified which are of low quality and have low numbers of participants. There are also limitations to interpretation to the data, such as the heterogeneity of patent participants, as well as the low quality of the two non-randomized controlled trials. The risk of bias and confounding in these studies make it difficult to delineate clear effects from the target interventions.

This review determined that the current literature evaluating decision aids for colorectal cancer treatment is sparse and of low quality. In addition, the quality of the decision aids themselves is unclear. This gap in the literature is especially noticeable when compared to decision aids developed for treatment of other common cancers such as breast, lung, and prostate.[13-15] Given a similar complexity and variety of treatment options available for colorectal cancer, particularly stage II colon cancer or rectal cancer, it is unknown why there is such a paucity of literature on the use of decision aids in this population. It is possible that an emphasis in preventative care has shifted the research towards colorectal cancer screening since screening rates are lower than other common cancers.[16,31] Other possible causes include lack of provider

comfort and understanding of decision aid benefits, and or stigma associated with bowel diseases that may cause investigators less likely to pursue the topic.

Although the evidence in this review to support the use of PDAs for those with colorectal cancer treatment is suboptimal, a recent Cochrane systematic review with over 100 randomized controlled trials shows that these interventions improve patient outcomes.[11] PDAs increase knowledge of the treatment options, risk perception, preparedness to make a decision, and can facilitate patient-centered care.[11] Patients diagnosed with colorectal cancer want to be more involved in the decision-making process and have information needs that are not currently being addressed.[32-34] In addition, this population has different levels of engagement in the decision making process and has expressed that many treatment decisions, such as chemotherapy and surgical choice, are preference sensitive.[3,4,35] The need to improve healthcare delivery, and the desire for patients to be involved in the preference-sensitive decision regarding treatment, indicates that PDAs would be beneficial for patients diagnosed with colorectal cancer. Future studies, ideally RCTs, should focus on high quality PDAs to see if they can truly improve knowledge, increase facilitated decision making, and are associated with increased patient satisfaction.

CONCLUSIONS

There has been limited research on PDAs for patients facing treatment decisions for colorectal cancer. We identified only three studies, two of which are low quality, constituting insufficient evidence to make any definitive conclusions on PDA for the treatment of colorectal cancer.

There is some indication that these tools are associated with positive outcomes in this population such as increased knowledge and patient satisfaction. Future studies should develop tools that are usable and acceptable to both patients and clinicians, and evaluate these tools for effectiveness in improving decision making for patients facing treatment decisions for colorectal cancer.

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FIGURE AND TABLE LEGEND

Figure 1: Summary of the review process

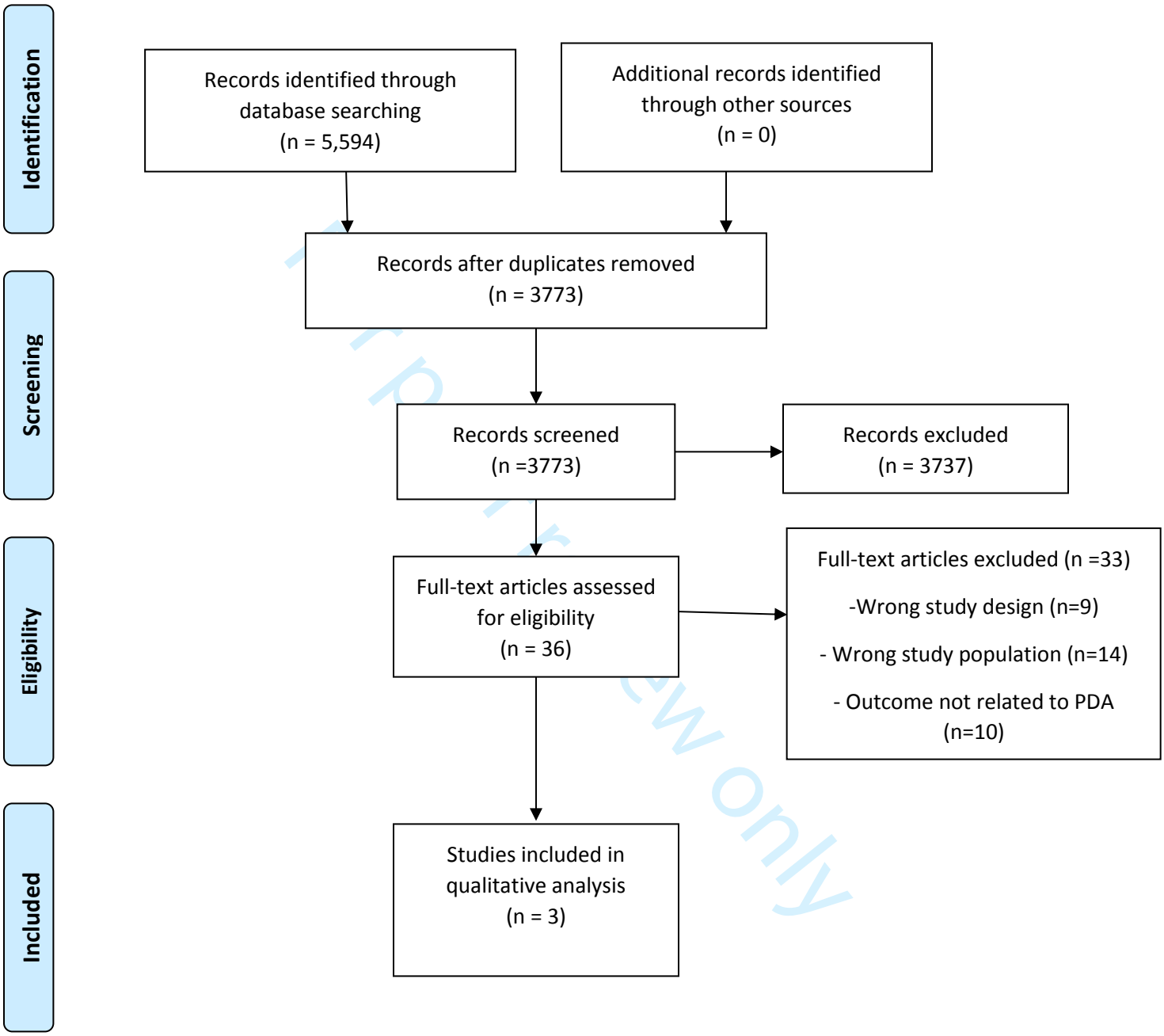
Table 1: Characteristics of three reviewed studies

Appendix 1: Summary of search results

Appendix 2: Search strategies

Appendix 3: Cochrane Collaborations Risk of Bias Tool

Figure 1: Summary of the review process



APPENDIX 1

Summary of search results

Database	Platform	Years covered	Date conducted	# results
Medline	PubMed	1946-current	April 11, 2018	964
		April 11,2018-current	June 17, 2019	156
CINAHL	EBSCO	1981- current	April 11, 2018	626
		April 11,2018 - current	June 17, 2019	127
Embase	Embase.com	1974-current	April 11, 2018	1,283
		2018- current	June 17, 2019	226
Web of Science (Core Collection)	WOS	1900-current	April 11, 2018	15
Web of Science SCI-EXPANDED SSCI A&HCI CPCI-S CPCI-SSH ESCI	Clarivate Analytics	1900-current	June 17, 2019	1642
Cochrane Library	Wiley	CDSR : Issue 4 of 12, April 2018 CCRCT : Issue 3 of 12, March 2018 CMR: Issue 3 of 4, July 2012	April 11, 2018	187
Cochrane	Wiley	April 2018-present Reviews & Trials: Issue 6 of 12, June 2019	6/20/2019	368 (excluding 2 editorials)
American Society of Colorectal Surgery annual meeting	Conference proceedings	2010-current	2019	0
Total				5,594
Total with Duplicates Removed				3773

APPENDIX 2

Search strategies

Since we updated the review from April 2018 to include articles up to June 2019 the new search strategies (updated dates) are listed below the original search.

PubMed (Medline)

History

Download history Clear history

Search	Add to builder	Query	Items found	Time
#7	Add	Search **(#3 AND #6)**	964	10:34:18
#6	Add	Search **(#4 OR #5)**	229794	10:34:11
#5	Add	Search **((Rectal[tiab] OR rectum[tiab] OR colon[tiab] OR colorectal[tiab]]) AND (cancer*[tiab] OR neoplasm*[tiab] OR malignanc*[tiab] OR Tumor*[tiab]))**	197997	10:34:02
#4	Add	Search **((Colorectal neoplasms[mesh:noexp] OR Rectal Neoplasms[mesh:noexp])) OR (((Rectum[mesh]OR colon[mesh]) AND (neoplasms[mesh])))**	126428	10:33:58
#3	Add	Search **(#1 OR #2)**	66696	10:32:48
#2	Add	Search **(((Decision Making[mesh] OR Decision support techniques[mesh] OR Decision making[tiab] OR Decision support[tiab]))) AND ((Patient preference[mesh] OR Patient-Centered Care[mesh] OR Patient Participation[Mesh] OR Professional-Patient Relations[mesh] OR Professional-Family Relations[mesh] OR Patient participation[tiab] OR Patient engagement[tiab] OR Patient involvement[tiab] OR Client participation[tiab] OR Client engagement[tiab] OR Client involvement[tiab] OR Patient relation*[tiab] OR Patient preference*[tiab] OR Patient centered[tiab] OR Patient centred[tiab]))**	24186	10:32:41
#1	Add	Search **((Decision[tiab] AND (aid*[tiab] OR tool*[tiab] OR box*[tiab])) OR Option grid*[tiab] OR Issue card*[tiab] OR Drug fact box*[tiab] OR Shared decision*[tiab] OR Informed decision*[tiab] OR Informed choice*[tiab] OR Collaborative decision*[tiab] OR Decision support intervention*[tiab]) OR Decision Support Systems, Clinical[mesh])**	47589	10:32:11

Search	Add to builder	Query	Items found	Time
#8	Add	Search **(#3 AND #6)** Sort by: **PublicationDate** Filters: **Publication date from 2018/04/11**	156	15:35:48
#7	Add	Search **(#3 AND #6)** Sort by: **Best Match**	1117	15:29:04
#6	Add	Search **(#4 OR #5)**	247839	15:28:48
#5	Add	Search **((Rectal[tiab] OR rectum[tiab] OR colon[tiab] OR colorectal[tiab])) AND (cancer*[tiab] OR neoplasm*[tiab] OR malignanc*[tiab] OR Tumor*[tiab]))**	214907	15:28:15
#4	Add	Search **(Colorectal neoplasms[mesh:noexp] OR Rectal Neoplasms[mesh:noexp] OR ((Rectum[mesh]OR colon[mesh]) AND neoplasms[mesh]))**	135037	15:27:56
#3	Add	Search **(#1 OR #2)**	75025	15:26:20
#2	Add	Search **((Decision Making[mesh] OR Decision support techniques[mesh] OR Decision making[tiab] OR Decision support[tiab]) AND (Patient preference[mesh] OR Patient-Centered Care[mesh] OR Patient Participation[Mesh] OR Professional-Patient Relations[mesh] OR Professional-Family Relations[mesh] OR Patient participation[tiab] OR Patient engagement[tiab] OR Patient involvement[tiab] OR Client participation[tiab] OR Client engagement[tiab] OR Client involvement[tiab] OR Patient relation*[tiab] OR Patient preference*[tiab] OR Patient centered[tiab] OR Patient centred[tiab]))**	26356	15:26:10
#1	Add	Search **((Decision[tiab] AND (aid*[tiab] OR tool*[tiab] OR box*[tiab])) OR Option grid*[tiab] OR Issue card*[tiab] OR Drug fact box*[tiab] OR Shared decision*[tiab] OR Informed decision*[tiab] OR Informed choice*[tiab] OR Collaborative decision*[tiab] OR Decision support intervention*[tiab] OR Decision Support Systems, Clinical[mesh])**	54629	15:25:56

CINAHL

Select / deselect all | Search with AND | Search with OR | Delete Searches

Search ID#	Search Terms	Search Options	Actions
S16	S8 AND S15	**Search modes** - Find all my search terms	View Results (488)
S15	S11 OR S14	**Search modes** - Find all my search terms	View Results (58,816)
S14	S12 AND S13	**Search modes** - Find all my search terms	View Results (19,044)
S13	MH (patient-centered care and outcomes) OR MH Professional-Family Relations OR MH Professional-Patient Relations OR MH Consumer Participation OR (Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)	**Search modes** - Find all my search terms	View Results (222,187)
S12	MH Decision Making OR MH Decision Support Techniques+ OR MH Decision Making, Family OR (Decision making OR Decision support)	**Search modes** - Find all my search terms	View Results (93,583)
S11	(Decision AND (aid* OR tool* OR box*)) OR (Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention*) OR MH Decision Making, Clinical	**Search modes** - Find all my search terms	View Results (48,134)
S10	(MH "Patient Centered Care")	**Search modes** - Find all my search terms	View Results (17,878)
S9	(MH "Decision Support Techniques+") OR (MH "Decision Making, Clinical") OR (MH "Decision Making, Family")	**Search modes** - Find all my search terms	View Results (26,932)
S8	S6 OR S7	**Search modes** - Find all my search terms	View Results (18,745)
S7	(Rectal OR rectum OR colon OR colorectal[mesh]) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*)	**Search modes** - Find all my search terms	View Results (8,578)
S6	S1 OR S2 OR S5	**Search modes** - Find all my search terms	View Results (13,557)
S5	S3 AND S4	**Search modes** - Find all my search terms	View Results (49)
S4	(MH "Rectum") OR (MH "Colon+")	**Search modes** - Find all my search terms	View Results (3,481)
S3	(MH "Neoplasms")	**Search modes** - Find all my search terms	View Results (42,133)
S2	(MH "colorectal Neoplasms")	**Search modes** - Find all my search terms	View Results (11,835)
S1	(MH "Rectal Neoplasms")	**Search modes** - Find all my search terms	View Results (1,760)

#	Query	Limiters/Expanders	Last Run Via	Results
S4	S1 AND S2	Limiters - Published Date: 20180101-20191231 Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	127
S3	S1 AND S2	Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	849
S2	((MH "Rectal Neoplasms") OR (MH "colorectal neoplasms) OR (MH "Neoplasms") AND ((MH "Rectum") OR (MH "Colon+"))) OR ((Rectal OR rectum OR colon OR colorectal) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*))	Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	43,468
S1	((Decision AND (aid* OR tool* OR box*)) OR Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR MH "Decision Making, Clinical") OR (((MH "Decision Making" OR MH "Decision Support Techniques+" OR MH "Decision Making, Family" Decision making OR Decision support) AND (MH "Patient Centered Care" OR MH Consumer Participation OR MH "Professional-Patient Relations" OR MH "Professional-Family Relations" OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)))	Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	81,370

Embase

1. exp clinical decision support system/
2. decision.ti. or decision.ab.
3. aid*.ti. or aid*.ab.
4. tool*.ti. or tool*.ab.
5. box*.ti. or box*.ab.
6. 3 or 4 or 5
7. 2 and 6
8. "Option Grid*".ti. or "Option Grid*".ab.
9. "Issue Card*".ti. or "Issue Card*".ab.
10. "Drug fact box*".ti. or "Drug fact box*".ab.
11. "Shared Decision*".ti. or "Shared Decision*".ab.
12. "Informed Decision*".ti. or "Informed Decision*".ab.
13. "Informed Choice*".ti. or "Informed Choice*".ab.
14. "Collaborative decision*".ti. or "Collaborative decision*".ab.
15. "Decision support intervention*".ti. or "Decision support intervention*".ab.
16. 1 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17. exp decision making/
18. exp decision support system/
19. "decision making".ti. or "decision making".ab.
20. "decision support".ti. or "decision support".ab.

21. 17 or 18 or 19 or 20
22. exp patient preference/
23. "patient-centered care".ti. or "patient-centered care".ab.
24. exp patient participation/
25. exp professional-patient relationship/
26. "professional-family relation*".ti. or "professional-family relation*".ab.
27. "patient participation".ti. or "patient participation".ab.
28. "patient engagement".ti. or "patient engagement".ab.
29. "patient involvement".ti. or "patient involvement".ab.
30. "client participation".ti. or "client participation".ab.
31. "client engagement".ti. or "client engagement".ab.
32. "client involvement".ti. or "client involvement".ab.
33. "patient relation*".ti. or "patient relation*".ab.
34. "patient preference*".ti. or "patient preference*".ab.
35. "patient centered".ti. or "patient centered".ab.
36. "patient centred".ti. or "patient centred".ab.
37. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38. 21 and 37
39. 16 or 38
40. colorectal tumor/
41. rectum tumor/

42. exp rectum/
43. exp colon/
44. exp neoplasm/
45. 40 or 41 or 42 or 43
46. 44 and 45
47. rectal.ti. or rectal.ab.
48. rectum.ti. or rectum.ab.
49. colon.ti. or colon.ab.
50. colorectal.ti. or colorectal.ab.
51. 47 or 48 or 49 or 50
52. cancer*.ti. or cancer*.ab.
53. neoplasm*.ti. or neoplasm*.ab.
54. malignanc*.ti. or malignanc*.ab.
55. tumor*.ti. or tumor*.ab.
56. 52 or 53 or 54 or 55
57. 51 and 56
58. 39 and 57

Web of Science

Search History Web of Science Core Collection Learn More

Set	Results	Save History / Create Alert / Open Saved History	Edit Sets	Combine Sets (AND / OR) Combine	Delete Sets Select All / Delete
# 5	15	#4 AND #1 *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 4	9,909	#3 OR #2 *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 3	605	**TOPIC:** ((Decision making OR Decision support)) *AND* **TOPIC:** ((Consumer participation OR Consumer engagement OR Consumer involvement OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Family participation OR Family engagement OR Family involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)) *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 2	9,607	**TOPIC:** ((Decision AND (aid* OR tool* OR box*))) *OR* **TOPIC:** (Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR Clinical decision making) *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 1	119	**TOPIC:** ((Rectal OR rectum OR colon OR colorectal)) *AND* **TOPIC:** ((cancer* OR neoplasm* OR malignanc* OR Tumor*)) *Indexes=CPCI-SSH Timespan=All years*	Edit		

Set	Results	Save History / Create Alert	Open Saved History
# 6	206	#4 AND #3 **Refined by: PUBLICATION YEARS:** (2019 OR 2018) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 5	1,642	#4 AND #3 *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 4	171,310	**TOPIC:** ((Rectal OR rectum OR colon OR colorectal[mesh]) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*)) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 3	302,548	#2 OR #1 *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 2	37,041	**TOPIC:** ((Decision making OR Decision support) AND (Consumer participation OR Consumer engagement OR Consumer involvement OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Family participation OR Family engagement OR Family involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient-centred)) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 1	288,995	**TOPIC:** ((Decision AND (aid* OR tool* OR box*)) OR Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR Clinical decision making) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	

Cochrane Library

Search | Search Manager | Medical Terms (MeSH) | Browse

To search an exact word(s) use quotation marks, e.g. "hospital" finds hospital; hospital (no quotation marks) finds hospital and hospitals; pay finds paid, pays, paying, payed)

Add to top View fewer lines

#1	(Rectal or rectum or colon or colorectal):ti,ab,kw and (cancer* or neoplasm* or malignanc* or Tumor*):ti,ab,kw (Word variations have been searched)	S	15693
#2	(Decision and (aid* or tool* or box*)):ti,ab,kw and Option grid* or Issue card* or Drug fact box* or Shared decision* or Informed decision* or Informed choice* or Collaborative decision* or Decision support intervention* or Clinical decision making:ti,ab,kw (Word variations have been searched)	S	2050
#3	(Decision making or Decision support):ti,ab,kw and (Consumer participation or Consumer engagement or Consumer involvement or Patient participation or Patient engagement or Patient involvement or Client participation or Client engagement or Client involvement or Family participation or Family engagement or Family involvement or Patient relation* or Patient preference* or Patient centered or Patient centred):ti,ab,kw (Word variations have been searched)	S	4044
Edit #4	#2 or #3		5264
Edit #5	#1 and #4		187

#1	((Rectal OR rectum OR colon OR colorectal) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*)):ti,ab,kw	S	Limits	21483
#2	((Decision AND (aid* OR tool* OR box*)) OR Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR Clinical decision making):ti,ab,kw	S	Limits	16454
#3	((Decision making OR Decision support) AND (Consumer participation OR Consumer engagement OR Consumer involvement OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Family participation OR Family engagement OR Family involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)):ti,ab,kw	S	Limits	3186
#4	#2 OR #3		Limits	16777
#5	#1 AND #4		Limits	229

with Cochrane Library publication date from Apr 2018 to Dec 2019

APPENDIX 3

Cochrane Collaborations Risk of Bias Tool

Leighl et al, 2011		
Domain	**Support for judgement**	**Authors' judgement**
Selection bias		
Random sequence generation	"Eligible consenting patients with advanced colorectal cancer who were seeing a medical oncologist for an initial consultation regarding first line chemotherapy were randomly assigned…" "randomization lists stratified by the consulting oncologist were computer generated…" Comment: No statistically significant differences in the intervention and control group except English as first language in intervention arm (see table 2)	**Low**
Allocation concealment	"randomization lists…were computer generated and the code was concealed in a sealed envelope until the time of random assignment" "…oncologists and patients were actively informed of the randomization arm only when patients received the DA."	**Low**
Performance bias		
Blinding of participants and personnel	"Although not blinded, oncologists and patients were actively informed of the randomization arm only when patients received the DA." "Those receiving the DA were counselled not to share it with others in the waiting room to avoid contamination of the standard arm." "…five consultations were audiotaped before study commencement as a baseline for comparison with consultations in the standard arm. Oncologists were to be provided with feedback in the event of marked deviation during the course of the trial, but no deviation occurred" "Oncologists were trained to use the DA during the consultation…"	**Moderate**
Detection bias		
Blinding of outcome assessment	Comment: The study does not specify whether or not the outcomes assessment was done in a blinded fashion	**Low**
Attrition bias		
Incomplete outcome data	Comment: 18 patients declined to participate initially and a total of 32 patients were lost to follow up in control, and 33 were lost to follow up in intervention with similar amounts between groups at similar intervals Comment: All patients who participated in at least one survey were included in the analysis Comment: All the outcome assessments are linked together with the surveys, no significant difference in data collection for outcomes	**Low**
Reporting bias		
Selective reporting	Comment: All outcome measures appear to be addressed within the results and discussion Comment: the researchers did not mention how many of the patients were from Canada or Australia but do mention some statistically significant differences in readiness to make a treatment decision and consultation satisfaction scores	**Low/ Moderate**
Other bias		
Other sources of bias	Comment: Insufficient information to judge	**Unclear**

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7-8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	7-8
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	NA

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9-10
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	11-13
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	10-11
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	11-13
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15-16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	2

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

BMJ Open

The impact of decision aids in patients with colorectal cancer: a systematic review

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Manuscript ID	bmjopen-2018-028379.R2
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Date Submitted by the Author:	16-Aug-2019
Complete List of Authors:	Goldwag, Jenaya; Dartmouth Hitchcock Medical Center, Department of Surgery; Geisel School of Medicine Marsicovetere, Priscilla; Franklin Pierce University, Master of Physician Assistant Studies Program; Geisel School of Medicine Scalia, Peter; Dartmouth College, The Dartmouth Institute for Health Policy and Clinical Practice Johnson, Heather; Geisel School of Medicine; Dartmouth College Durand, Marie-Anne; The Dartmouth Institute for Health Policy & Clinical Practice, Elwyn, Glyn; Dartmouth College; The Dartmouth Institute for Health Policy & Clinical Practice Ivatury, Srinivas; Dartmouth Hitchcock Medical Center, Department of Surgery; Dartmouth Hitchcock Medical Center, Department of Surgery
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Keywords:	Gastrointestinal tumours < ONCOLOGY, Colorectal surgery < SURGERY, Gastrointestinal tumours < GASTROENTEROLOGY

The impact of decision aids in patients with colorectal cancer: a systematic review

Short Running Head: Colorectal Cancer Decision Aids

Main Category: Colorectal Cancer

Key words: Colon Cancer, Rectal Cancer, Decision Aids, Decision making

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Competing interests:

M-A D was involved in developing Option Grid decision aids. She receives consulting income from EBSCO Health and may receive royalties in the future. She is also a consultant for ACCESS Community Health Network. GE has edited and published books that provide royalties on sales by the publishers: the books include Shared Decision Making (Oxford University Press) and Groups (Radcliffe Press).He has in the past provided consultancy for organizations, including: 1) Emmi Solutions LLC who developed patient decision support tools; 2) National Quality Forum on the certification of decision support tools; 3) Washington State Health Department on the certification of decision support tools; 4) SciMentum LLC, Amsterdam (workshops for shared decision making). He is the Founder and Director of &think LLC which owns the registered trademark for Option Grids TM patient decision aids. Founder and Director of SHARPNETWORK LLC, a provider of training for shared decision making. He provides advice in the domain of shared decision making and patient decision aids to: 1) Access Community Health Network, Chicago (Federally Qualified Medical Centers); 2) EBSCO Health Option Grids TM patient decision aids; 3) Bind Insurance, 4) PatientWisdom Inc; 5) abridge AI Inc.GE academic interests are focused on shared decision making and coproduction. He owns copyright in measures of shared decision making and care integration, namely collaboRATE, integRATE, consideRATE, coopeRATE, toleRATE, Observer OPTION-5 and Observer OPTION-12.

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Author Contributions:

All authors have substantial contributions to the conception or design of the work (SJI, HAJ, GE, MAD, PS), the acquisition, analysis, or interpretation of data for the work (JLG, PM, HAJ, SJI), drafting the work or revising it critically for important intellectual content including final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (JLG, PM, PS, HAJ, MAD, GE, SJI).

Data sharing statement:

There is no additional data from this systematic review.

ABSTRACT

Objectives: Our aim was to conduct a systematic review of the literature to determine the impact of patient decision aids (PDA) on patients facing treatment decisions for colorectal cancer.

Design: Systematic review

Data Sources: Sources included Embase, Medline, Web of Science, CINAHL, and the Cochrane Library from inception to June, 20, 2019.

Eligibility Criteria: We included randomized controlled trials, cohort studies, mixed methods, and case series in which a PDA for colorectal cancer treatment was used. Qualitative studies were excluded from our review.

Data Extraction and synthesis: Following execution of the search strategy by a medical librarian**,** two blinded independent reviewers identified articles for inclusion. Two blinded reviewers were also responsible for data extraction, risk of bias, and study quality assessments. Any conflict in article inclusion or extraction was resolved by discussion.

Results: Out of 3773 articles identified, three met our inclusion criteria: one randomized controlled trial, one before-and-after study, and one mixed-method study. In these studies, the use of a PDA for colorectal cancer treatment was associated with increased patient knowledge, satisfaction, and preparation for making a decision. On quality assessment, two of three studies were judged to be of low quality.

Conclusion: A paucity of evidence exists on the effect of PDA for colorectal cancer treatment with existing evidence being largely of low quality. Further investigation is required to determine the effect of decision aids for colorectal cancer treatment as well as reasons for the lack of PDA development and implementation in this area.

Trial Registration:

We published our study protocol in PROSPERO (registration # CRD42018095153).

ARTICLE SUMMARY

Strengths and Limitations of this Study

- A broad search strategy as well as a firm adherence to systematic review methodology make this a comprehensive review on decision aids used for colorectal cancer treatment.
- A risk of bias tool and/or a quality assessment tool was used to assess randomized controlled trials or nonrandomized trials respectively.
- Including a broad number of outcomes in the inclusion criteria limits the ability to make discrete conclusions.
- There were not enough articles identified to perform a meta-analysis.

INTRODUCTION

Treatment decisions for colorectal cancer can be complex and multimodal, with significant variability and controversy. Patients diagnosed with colorectal cancer have many options for treatment including chemotherapy, surgery, and radiation therapy depending on their cancer stage, medical history, and preferences. For some clinical situations, such as stage II colon cancer, there is significant variability between options, including surgery alone vs surgery and chemotherapy, as well as the choice of chemotherapy.[1,2] In addition, patients diagnosed with rectal cancer often have to decide between two equally efficacious, but lifestyle altering, surgical options: bowel reconnection with low anterior resection (LAR) versus permanent colostomy with abdominal perineal resection (APR). Further, additional factors exist for many patients

increasing decision complexity including the presence or absence of additional colon polyps, concomitant cancers, and genetic predisposition. These preference-sensitive decisions can be overwhelming to patients and their families and there can be substantial variation in treatment preferences.[3,4]

In general, many cancer patients prefer to be actively and collaboratively involved in disease-related decisions.[5-8] As these decisions can be challenging for patients, often occurring at an emotional time, patient decision aids (PDA) have been developed to provide evidence-based information on treatment options and help patients clarify and communicate the personal values they associate with different options for treatment.[9,10] PDA are evidence-based tools designed to help patients make informed choices by providing information on the pros, cons, risks, probabilities, and scientific uncertainty of available options prior to making a decision.[11,12] PDA can be used when there are multiple reasonable options, when no single option has a clear advantage over the others in terms of health outcomes, or when each option has benefits and harms that patients value differently.[13] PDA have been shown to increase patient knowledge, reduce decisional conflict, help patients make appropriate decisions, and can have a positive effect on patient-clinician communication.[13]

PDA have been successful in helping patients make treatment decisions in breast, prostate, and lung cancer - other cancer types with similar treatment complexity to colorectal cancer. [14-16] The impact of PDA in the treatment of colorectal cancer, however, is unclear. Most PDA research regarding colorectal cancer has focused on screening options for prevention as

opposed to treatment decisions after diagnosis.[17] As patients diagnosed with colorectal cancer must also make complex preference sensitive decisions about treatment, we aimed to systematically evaluate the effect of PDA on outcomes associated with colorectal cancer treatment and clinical practice.

METHODS

Protocol and Registration

We conducted a systematic review, reported in this review using the PRISMA guidelines, of studies that used a colorectal cancer treatment patient decision aid as the intervention. Prior to beginning our search, we published our study protocol in PROSPERO (registration # CRD42018095153)

Patient and Public Involvement Statement

The study was performed in hopes to broaden knowledge about PDA for treatment decisions in colorectal cancer care. No patients participated in design or production of this systematic review. In particular, no patients were involved in the development of the research question or outcomes measures, recruitment or conduct, or other aspects of the review.

Eligibility Criteria

We used the Population, Intervention, Comparison, Outcome, and Study design (PICOS) criteria to determine eligibility. To be included, studies had to be randomized controlled trials (RCTs), nonrandomized controlled trials (NRCT), retrospective or prospective cohort studies, mixed methods, or case series. Any purely qualitative studies or case reports were excluded. Our population did not contain any age restrictions, and included patients diagnosed with colon or

rectal cancer needing to decide between two or more management options for treatment. The intervention is a PDA which is a tool designed to inform patients about treatment options and to facilitate patient participation in decision making.[11,12] The decision aids could be in any format and used at any time or location, before, during, or after a clinical encounter. The control group would be standard counseling, non-decision aids, or no control group if applicable. We included all study-specified primary and secondary outcomes that related to patients use of the decision aid such as, knowledge gained from PDA, usability of PDA, patient satisfaction of PDA etc. We excluded articles focusing on decision aids or risk calculators that were used only by physicians to guide management of colorectal cancer treatment or implementation of decision aids.

Information Sources and Search

With assistance from our medical librarian (HJ), we developed an electronic search strategy for the following databases: Embase, Medline, Web of Science, CINAHL, and the Cochrane Library from inception to June 17, 2019 (please see Appendix 1 for a summary of the search results). We also looked at conference proceedings from the American Society of Colorectal Surgery annual meeting 2010-2019. We identified articles that assessed decision aids in patients with colorectal cancer, employing text words and database-specific subject headings (e.g. MeSH,) such as "colon cancer," "rectal cancer," "decision aids," and "decision making". For the purposes of the search, we did not impose any restrictions on language, publication type, or publication date. In addition, we performed a citation search using the 'cited by' option on Google Scholar and 'related searches' on PubMed. We manually checked references for all articles identified as meeting our eligibility requirements for added sensitivity. See Appendix 2 for search terms used for each database.

Study Selection

We used Rayyan, a systematic review web application, to help facilitate the screening process.[18] The articles were listed alphabetically so that two reviewers (SI, HJ), blinded to each other's results, could independently review articles with first author last names between A-L and two additional similarly blinded reviewers (JG, PM) could independently review articles with first author last names between M-Z. During this initial screening, titles and abstracts were reviewed. Disagreements about inclusion were resolved by discussion by the involved reviewers. If necessary, a third reviewer either (JG or SI) also contributed to the discussion. After completing the initial screening, two reviewers (SI, JG) reviewed the full text of the remaining articles. Any conflicts about eligibility at this time were also resolved by discussion.

Data Collection Process

For randomized controlled trials:

The data extraction sheet, piloted prior to use, included the following information: study author, publication year, publication type, country, study aims, description of participants (age, gender, education levels, etc.), intervention (what type of DA, when implemented, timing etc.), control group, primary outcome, and secondary outcome if applicable. Two reviewers independently extracted the data from the included articles. Disagreements were resolved by discussion.

For non-randomized studies:

The data extraction sheet and data extraction methods for non-randomized studies was identical to that for the RCT.

Risk of Bias (RCT) and Quality Assessment (NRCT)

Risk of bias for RCTs:

The risk of bias was assessed by two independent reviewers (SI, JG) using the Cochrane Collaborations Risk of Bias Tool.[19] This tool is used to evaluate RCTs in 7 domains to judge whether each domain is of high, low, or unclear risk of bias. Disagreements were resolved by discussion.

Quality assessment for NRCTs:

The Downs and Black Checklist was used by two independent reviewers (SI, JG) to assess the quality of the non-randomized studies.[20] The reviewer assesses five domains (reporting, external validity, bias, confounding, power) by assigning a "yes" or "no" to 27 questions. The answer determines if a point(s) is awarded for that particular question. The highest possible score is 30 with a higher score associated with a higher quality study. This assessment tool was chosen as it has been utilized previously for pre-post and/or mixed methods studies.[21,22] Disagreements were resolved by discussion.

RESULTS

Study Characteristics

A total of 5,594 articles were initially identified with 3773 left to review after duplicates were removed. After screening titles and abstracts, 36 articles were left for full review. After assessing the full articles there were three studies [23-25] included in our final analysis, see Figure 1. This included one randomized controlled trial, one before-and-after study, and one mixed methods study. Characteristics for the three included studies are shown in Table 1.

Table 1: Characteristics of three reviewed studies

Study	Study Design	Study Population	Number of Patients (n)	Age (Gender)	Intervention	DA (content and type)	Primary objective	Outcome	Quality*
Leighl et al 2011 (Australia, Canada)	RCT	Metastatic colorectal cancer patients considering chemotherapy	Control 100, Intervention 107	Median-Control: 63 (62%m, 38%f) Intervention: 61 (54%m, 46%f)	Standard oncology consult vs oncology consult + DA	Chemotherapy types vs no chemotherapy, paper booklet, take-home booklet with audiotape or CD	Evaluate the impact of the DA on patient understanding of the prognostic and treatment information and satisfaction with decision making	Intervention arm with improved understanding 1-2 weeks post consultation (+16% vs +5%, P <.001)	N/A**
Wu et al 2016 (Canada)	Before and after study	Rectal cancer patients with lesion maximum 10cm from anal verge	36	Mean: 62 ± 10 (69%m, 31%f)	Surgical consult with DA	Risks and benefits of LAR vs APR, paper booklet, online version to review	Patient decisional conflict	Mean decisional conflict scores improved after using the decision aid (2% change after using DA (P <.001)	Low (score 13)
Miles et al 2017 (UK)	Mixed methods (before and after study, interviews)	Stage II colorectal cancer patients post surgery prior to adjuvant chemotherapy	13	Median: 67 (33%m, 66%f)	Oncology consult with DA	Patients personal risk of recurrence with and without chemo, Computer based DA	Patient perceived usefulness and acceptability of the DA	Patients perceived the decision aid as helping them communicate with their doctor and make a decision (PrepDM 1-5, mean 4)	Low (score 8)

* NRCTs assessed using the Downs and Black Checklist

** RCT did not have a quality assessment rather a risk of bias was performed, (Appendix 3)

Risk of Bias and Quality Assessment

Risk of bias: Randomized controlled trial

There was a low risk of selection, detection, or attrition bias, with a moderate risk of performance bias found due to inability to blind participants. Reporting bias was felt to be low-moderate because the study was performed in two locations and reported in aggregate. Please see Appendix 3 for further details to support judgements.

Quality Assessment: Non-randomized studies

According to the Downs and Black Checklist, both non-randomized studies were considered to be low quality. The before-and-after study scored 13 out of 30, and the mixed methods study scored 8 out of 30. In addition, both studies have a significant risk of bias and confounding, due to lack of control group or randomization.

Study specific results

Study 1: Leighl, et al. [23] (Australia, Canada)

This randomized controlled trial took place in Australia and Canada and included a total of 207 patients, 100 in the control group and 107 in the intervention group. All patients carried a diagnosis of metastatic colorectal cancer and were meeting with an oncologist for the first time to discuss and decide between chemotherapy options. The control group received consultation alone, while the intervention group received consultation plus a decision aid. The decision aid consisted of a paper booklet reviewed during the initial visit on chemotherapy options, as well as a take home booklet and audiotape. The decision aid in this study had been pilot tested and altered based on patient feedback.[26] Patients completed a series of different questionnaires prior to randomization and at multiple intervals after the initial consultation. The primary objective of the study was to evaluate patient understanding, via a modified Fiset[27] and Brundage[28] questionnaire, and satisfaction with the decision made via the 'satisfaction with decision scale'[29]. Secondary outcomes included decisional conflict, which evaluated patients' uncertainty with the decision and factors contributing to that uncertainty, assessed via the 'decisional conflict scale'[30], and readiness to make a decision immediately after consultation. The intervention group had an

improved understanding of chemotherapy options 1-2 weeks post-consultation when compared to the control group (p<0.001), although this is of unclear clinical significance. Patient satisfaction was found to be high and the decisional conflict score was similar in both groups. The Canadian patient population was found to be more likely to feel ready to make a treatment decision immediately after consultation (86% v 42%, p< 0.001), but had a higher decisional conflict scores (38 v 34, P<0.002) when compared to the Australian population.

Study 2: Wu, et al. [24] *(Canada)*

This before-and-after study took place in Canada and UK. They included a total of 36 patients who were diagnosed with rectal cancer. The study introduced their decision aid during or after consultation with a surgeon to aid in deciding between two surgical options. The decision aid consisted of a paper booklet on the topic of LAR vs APR and sent participants home with a link to an online decision aid. Patients completed questionnaires following initial surgical consultation and after reviewing the decision aid. The primary outcome was decisional conflict. Secondary outcomes included knowledge, choice preference, and acceptability of the decision aid. Mean decisional conflict scores were improved by 24.2% (p=0.0001) after the use of the decision aid. Patient knowledge also increased 37% (p<0.0001). The decision aid had variable impact on choice preference, with some patients changing their preference between LAR, APR, and neutral after using the DA, with no statistically significant trend toward neutral or either surgical option. In terms of acceptability, 85% of participants felt the decision aid had good/excellent information about options and 97% would recommend it to others.

Study 3: Miles, et al [25] *(United Kingdom)*

This mixed method study took place in Canada and UK. A total of 13 patients diagnosed with stage II colorectal cancer post-surgery prior to chemotherapy were included. They introduced their decision aid during the patient's consultation with an oncologist to help decide which, if any, chemotherapy was right for the patient. The decision aid consisted of a computer-based DA on chemotherapy options and participants were sent home with reference material. Study patients completed a post-intervention questionnaire as well as participated in semi-structured interviews. The results of the interviews are not included in this analysis as qualitative research was excluded from this review. The primary outcome was patient-perceived usefulness of the decision aid assessed on the Preparation for Decision Making Scale. The decision aid scored a favorable 4.28 out of five on the Preparation for Decision Making Scale[31]. Eleven of 12 patients participating ultimately declined chemotherapy.

DISCUSSION

Our systematic review found limited evidence on the use of PDAs for patients facing treatment decisions for colorectal cancer. We found three articles, two of which were low quality, which evaluated PDA for the treatment of colorectal cancer. These studies found that PDAs improved patient knowledge, facilitated shared decision making, and were well-accepted by patients. However, the results of these studies must be interpreted with caution given the low quality of two of the three articles. Although these studies supported the use of PDAs in this population, there is insufficient evidence to draw definitive conclusions on the impact of PDAs in the treatment of colorectal cancer given the paucity of studies.

Strengths of this review include our engagement with a medical librarian (HJ) in order to fully review the available literature, and our adherence to the guidelines on how to appropriately conduct and report a systematic review. Potential limitations of our methods include possible omission of studies, although unlikely given our search strategy. Another limitation is the inability to perform subgroup analysis due to the small number of articles identified which are of low quality and have low numbers of participants. There are also limitations to interpretation to the data, such as the heterogeneity of patent participants, as well as the low quality of the two non-randomized controlled trials. The risk of bias and confounding in these studies make it difficult to delineate clear effects from the target interventions.

This review determined that the current literature evaluating decision aids for colorectal cancer treatment is sparse and of low quality. In addition, the quality of the decision aids themselves is unclear. This gap in the literature is especially noticeable when compared to decision aids developed for treatment of other common cancers such as breast, lung, and prostate.[14-16] Given a similar complexity and variety of treatment options available for colorectal cancer, particularly stage II colon cancer or rectal cancer, it is unknown why there is such a paucity of literature on the use of decision aids in this population. It is possible that an emphasis in preventative care has shifted the research towards colorectal cancer screening since screening rates are lower than other common cancers.[17,32] Other possible causes include lack of provider comfort and understanding of decision aid benefits, and or stigma associated with bowel diseases that may cause investigators less likely to pursue the topic.

Although the evidence in this review to support the use of PDAs for those with colorectal cancer treatment is suboptimal, a recent Cochrane systematic review with over 100 randomized controlled trials shows that these interventions improve patient outcomes.[13] PDAs increase knowledge of the treatment options, risk perception, preparedness to make a decision, and can facilitate patient-centered care.[13] Patients diagnosed with colorectal cancer want to be more involved in the decision-making process and have information needs that are not currently being addressed.[33-35] In addition, this population has different levels of engagement in the decision making process and has expressed that many treatment decisions, such as chemotherapy and surgical choice, are preference sensitive.[3,4,36] The need to improve healthcare delivery, and the desire for patients to be involved in the preference-sensitive decision regarding treatment, indicates that PDAs would be beneficial for patients diagnosed with colorectal cancer. Future studies, ideally RCTs, should focus on high quality PDAs to see if they can truly improve knowledge, increase facilitated decision making, and are associated with increased patient satisfaction.

CONCLUSIONS

There has been limited research on PDAs for patients facing treatment decisions for colorectal cancer. We identified only three studies, two of which are low quality, constituting insufficient evidence to make any definitive conclusions on PDA for the treatment of colorectal cancer. There is some indication that these tools are associated with positive outcomes in this population such as increased knowledge and patient satisfaction. Future studies should develop tools that are usable and acceptable to both patients and clinicians, and evaluate these tools for effectiveness in improving decision making for patients facing treatment decisions for colorectal cancer.

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FIGURE AND TABLE LEGEND

Figure 1: Summary of the review process

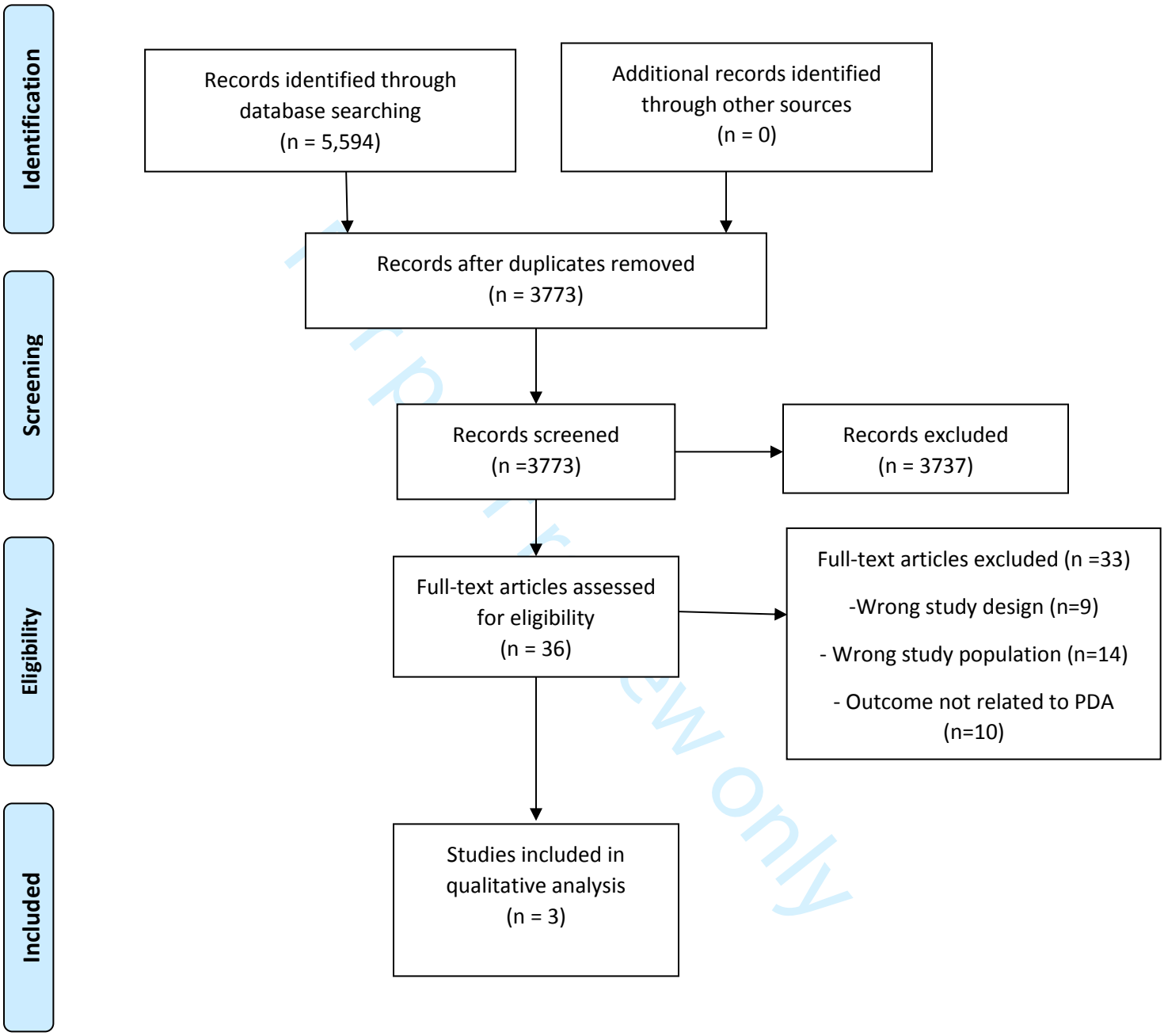
Table 1: Characteristics of three reviewed studies

Appendix 1: Summary of search results

Appendix 2: Search strategies

Appendix 3: Cochrane Collaborations Risk of Bias Tool

Figure 1: Summary of the review process



APPENDIX 1

Summary of search results

Database	Platform	Years covered	Date conducted	# results
Medline	PubMed	1946-current	April 11, 2018	964
		April 11,2018-current	June 17, 2019	156
CINAHL	EBSCO	1981- current	April 11, 2018	626
		April 11,2018 - current	June 17, 2019	127
Embase	Embase.com	1974-current	April 11, 2018	1,283
		2018- current	June 17, 2019	226
Web of Science (Core Collection)	WOS	1900-current	April 11, 2018	15
Web of Science SCI-EXPANDED SSCI A&HCI CPCI-S CPCI-SSH ESCI	Clarivate Analytics	1900-current	June 17, 2019	1642
Cochrane Library	Wiley	CDSR : Issue 4 of 12, April 2018 CCRCT : Issue 3 of 12, March 2018 CMR: Issue 3 of 4, July 2012	April 11, 2018	187
Cochrane	Wiley	April 2018-present Reviews & Trials: Issue 6 of 12, June 2019	6/20/2019	368 (excluding 2 editorials)
American Society of Colorectal Surgery annual meeting	Conference proceedings	2010-current	2019	0
Total				5,594
Total with Duplicates Removed				3773

APPENDIX 2

Search strategies

Since we updated the review from April 2018 to include articles up to June 2019 the new search strategies (updated dates) are listed below the original search.

PubMed (Medline)

History

Download history Clear history

Search	Add to builder	Query	Items found	Time
#7	Add	Search **(#3 AND #6)**	964	10:34:18
#6	Add	Search **(#4 OR #5)**	229794	10:34:11
#5	Add	Search **((Rectal[tiab] OR rectum[tiab] OR colon[tiab] OR colorectal[tiab]]) AND (cancer*[tiab] OR neoplasm*[tiab] OR malignanc*[tiab] OR Tumor*[tiab]))**	197997	10:34:02
#4	Add	Search **((Colorectal neoplasms[mesh:noexp] OR Rectal Neoplasms[mesh:noexp])) OR (((Rectum[mesh]OR colon[mesh]) AND (neoplasms[mesh])))**	126428	10:33:58
#3	Add	Search **(#1 OR #2)**	66696	10:32:48
#2	Add	Search **(((Decision Making[mesh] OR Decision support techniques[mesh] OR Decision making[tiab] OR Decision support[tiab]))) AND ((Patient preference[mesh] OR Patient-Centered Care[mesh] OR Patient Participation[Mesh] OR Professional-Patient Relations[mesh] OR Professional-Family Relations[mesh] OR Patient participation[tiab] OR Patient engagement[tiab] OR Patient involvement[tiab] OR Client participation[tiab] OR Client engagement[tiab] OR Client involvement[tiab] OR Patient relation*[tiab] OR Patient preference*[tiab] OR Patient centered[tiab] OR Patient centred[tiab]))**	24186	10:32:41
#1	Add	Search **((Decision[tiab] AND (aid*[tiab] OR tool*[tiab] OR box*[tiab])) OR Option grid*[tiab] OR Issue card*[tiab] OR Drug fact box*[tiab] OR Shared decision*[tiab] OR Informed decision*[tiab] OR Informed choice*[tiab] OR Collaborative decision*[tiab] OR Decision support intervention*[tiab]) OR Decision Support Systems, Clinical[mesh])**	47589	10:32:11

Search	Add to builder	Query	Items found	Time
#8	Add	Search **(#3 AND #6)** Sort by: **PublicationDate** Filters: **Publication date from 2018/04/11**	156	15:35:48
#7	Add	Search **(#3 AND #6)** Sort by: **Best Match**	1117	15:29:04
#6	Add	Search **(#4 OR #5)**	247839	15:28:48
#5	Add	Search **((Rectal[tiab] OR rectum[tiab] OR colon[tiab] OR colorectal[tiab])) AND (cancer*[tiab] OR neoplasm*[tiab] OR malignanc*[tiab] OR Tumor*[tiab]))**	214907	15:28:15
#4	Add	Search **(Colorectal neoplasms[mesh:noexp] OR Rectal Neoplasms[mesh:noexp] OR ((Rectum[mesh]OR colon[mesh]) AND neoplasms[mesh]))**	135037	15:27:56
#3	Add	Search **(#1 OR #2)**	75025	15:26:20
#2	Add	Search **((Decision Making[mesh] OR Decision support techniques[mesh] OR Decision making[tiab] OR Decision support[tiab]) AND (Patient preference[mesh] OR Patient-Centered Care[mesh] OR Patient Participation[Mesh] OR Professional-Patient Relations[mesh] OR Professional-Family Relations[mesh] OR Patient participation[tiab] OR Patient engagement[tiab] OR Patient involvement[tiab] OR Client participation[tiab] OR Client engagement[tiab] OR Client involvement[tiab] OR Patient relation*[tiab] OR Patient preference*[tiab] OR Patient centered[tiab] OR Patient centred[tiab]))**	26356	15:26:10
#1	Add	Search **((Decision[tiab] AND (aid*[tiab] OR tool*[tiab] OR box*[tiab])) OR Option grid*[tiab] OR Issue card*[tiab] OR Drug fact box*[tiab] OR Shared decision*[tiab] OR Informed decision*[tiab] OR Informed choice*[tiab] OR Collaborative decision*[tiab] OR Decision support intervention*[tiab] OR Decision Support Systems, Clinical[mesh])**	54629	15:25:56

CINAHL

Select / deselect all | Search with AND | Search with OR | Delete Searches

Search ID#	Search Terms	Search Options	Actions
S16	S8 AND S15	**Search modes** - Find all my search terms	View Results (488)
S15	S11 OR S14	**Search modes** - Find all my search terms	View Results (58,816)
S14	S12 AND S13	**Search modes** - Find all my search terms	View Results (19,044)
S13	MH (patient-centered care and outcomes) OR MH Professional-Family Relations OR MH Professional-Patient Relations OR MH Consumer Participation OR (Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)	**Search modes** - Find all my search terms	View Results (222,187)
S12	MH Decision Making OR MH Decision Support Techniques+ OR MH Decision Making, Family OR (Decision making OR Decision support)	**Search modes** - Find all my search terms	View Results (93,583)
S11	(Decision AND (aid* OR tool* OR box*)) OR (Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention*) OR MH Decision Making, Clinical	**Search modes** - Find all my search terms	View Results (48,134)
S10	(MH "Patient Centered Care")	**Search modes** - Find all my search terms	View Results (17,878)
S9	(MH "Decision Support Techniques+") OR (MH "Decision Making, Clinical") OR (MH "Decision Making, Family")	**Search modes** - Find all my search terms	View Results (26,932)
S8	S6 OR S7	**Search modes** - Find all my search terms	View Results (18,745)
S7	(Rectal OR rectum OR colon OR colorectal[mesh]) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*)	**Search modes** - Find all my search terms	View Results (8,578)
S6	S1 OR S2 OR S5	**Search modes** - Find all my search terms	View Results (13,557)
S5	S3 AND S4	**Search modes** - Find all my search terms	View Results (49)
S4	(MH "Rectum") OR (MH "Colon+")	**Search modes** - Find all my search terms	View Results (3,481)
S3	(MH "Neoplasms")	**Search modes** - Find all my search terms	View Results (42,133)
S2	(MH "colorectal Neoplasms")	**Search modes** - Find all my search terms	View Results (11,835)
S1	(MH "Rectal Neoplasms")	**Search modes** - Find all my search terms	View Results (1,760)

#	Query	Limiters/Expanders	Last Run Via	Results
S4	S1 AND S2	Limiters - Published Date: 20180101-20191231 Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	127
S3	S1 AND S2	Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	849
S2	((MH "Rectal Neoplasms") OR (MH "colorectal neoplasms) OR (MH "Neoplasms") AND ((MH "Rectum") OR (MH "Colon+"))) OR ((Rectal OR rectum OR colon OR colorectal) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*))	Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	43,468
S1	((Decision AND (aid* OR tool* OR box*)) OR Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR MH "Decision Making, Clinical") OR (((MH "Decision Making" OR MH "Decision Support Techniques+" OR MH "Decision Making, Family" Decision making OR Decision support) AND (MH "Patient Centered Care" OR MH Consumer Participation OR MH "Professional-Patient Relations" OR MH "Professional-Family Relations" OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)))	Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	81,370

Embase

1. exp clinical decision support system/
2. decision.ti. or decision.ab.
3. aid*.ti. or aid*.ab.
4. tool*.ti. or tool*.ab.
5. box*.ti. or box*.ab.
6. 3 or 4 or 5
7. 2 and 6
8. "Option Grid*".ti. or "Option Grid*".ab.
9. "Issue Card*".ti. or "Issue Card*".ab.
10. "Drug fact box*".ti. or "Drug fact box*".ab.
11. "Shared Decision*".ti. or "Shared Decision*".ab.
12. "Informed Decision*".ti. or "Informed Decision*".ab.
13. "Informed Choice*".ti. or "Informed Choice*".ab.
14. "Collaborative decision*".ti. or "Collaborative decision*".ab.
15. "Decision support intervention*".ti. or "Decision support intervention*".ab.
16. 1 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17. exp decision making/
18. exp decision support system/
19. "decision making".ti. or "decision making".ab.
20. "decision support".ti. or "decision support".ab.

21. 17 or 18 or 19 or 20
22. exp patient preference/
23. "patient-centered care".ti. or "patient-centered care".ab.
24. exp patient participation/
25. exp professional-patient relationship/
26. "professional-family relation*".ti. or "professional-family relation*".ab.
27. "patient participation".ti. or "patient participation".ab.
28. "patient engagement".ti. or "patient engagement".ab.
29. "patient involvement".ti. or "patient involvement".ab.
30. "client participation".ti. or "client participation".ab.
31. "client engagement".ti. or "client engagement".ab.
32. "client involvement".ti. or "client involvement".ab.
33. "patient relation*".ti. or "patient relation*".ab.
34. "patient preference*".ti. or "patient preference*".ab.
35. "patient centered".ti. or "patient centered".ab.
36. "patient centred".ti. or "patient centred".ab.
37. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38. 21 and 37
39. 16 or 38
40. colorectal tumor/
41. rectum tumor/

42. exp rectum/
43. exp colon/
44. exp neoplasm/
45. 40 or 41 or 42 or 43
46. 44 and 45
47. rectal.ti. or rectal.ab.
48. rectum.ti. or rectum.ab.
49. colon.ti. or colon.ab.
50. colorectal.ti. or colorectal.ab.
51. 47 or 48 or 49 or 50
52. cancer*.ti. or cancer*.ab.
53. neoplasm*.ti. or neoplasm*.ab.
54. malignanc*.ti. or malignanc*.ab.
55. tumor*.ti. or tumor*.ab.
56. 52 or 53 or 54 or 55
57. 51 and 56
58. 39 and 57

Web of Science

Search History Web of Science Core Collection Learn More

Set	Results	Save History / Create Alert / Open Saved History	Edit Sets	Combine Sets (AND / OR) Combine	Delete Sets Select All / Delete
# 5	15	#4 AND #1 *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 4	9,909	#3 OR #2 *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 3	605	**TOPIC:** ((Decision making OR Decision support)) *AND* **TOPIC:** ((Consumer participation OR Consumer engagement OR Consumer involvement OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Family participation OR Family engagement OR Family involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)) *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 2	9,607	**TOPIC:** ((Decision AND (aid* OR tool* OR box*))) *OR* **TOPIC:** (Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR Clinical decision making) *Indexes=CPCI-SSH Timespan=All years*	Edit		
# 1	119	**TOPIC:** ((Rectal OR rectum OR colon OR colorectal)) *AND* **TOPIC:** ((cancer* OR neoplasm* OR malignanc* OR Tumor*)) *Indexes=CPCI-SSH Timespan=All years*	Edit		

Set	Results	Save History / Create Alert	Open Saved History
# 6	206	#4 AND #3 **Refined by: PUBLICATION YEARS:** (2019 OR 2018) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 5	1,642	#4 AND #3 *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 4	171,310	**TOPIC:** ((Rectal OR rectum OR colon OR colorectal[mesh]) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*)) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 3	302,548	#2 OR #1 *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 2	37,041	**TOPIC:** ((Decision making OR Decision support) AND (Consumer participation OR Consumer engagement OR Consumer involvement OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Family participation OR Family engagement OR Family involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient-centred)) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	
# 1	288,995	**TOPIC:** ((Decision AND (aid* OR tool* OR box*)) OR Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR Clinical decision making) *Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years*	

Cochrane Library

Search | Search Manager | Medical Terms (MeSH) | Browse

To search an exact word(s) use quotation marks, e.g. "hospital" finds hospital; hospital (no quotation marks) finds hospital and hospitals; pay finds paid, pays, paying, payed)

Add to top View fewer lines

#1	(Rectal or rectum or colon or colorectal):ti,ab,kw and (cancer* or neoplasm* or malignanc* or Tumor*):ti,ab,kw (Word variations have been searched)	S	15693
#2	(Decision and (aid* or tool* or box*)):ti,ab,kw and Option grid* or Issue card* or Drug fact box* or Shared decision* or Informed decision* or Informed choice* or Collaborative decision* or Decision support intervention* or Clinical decision making:ti,ab,kw (Word variations have been searched)	S	2050
#3	(Decision making or Decision support):ti,ab,kw and (Consumer participation or Consumer engagement or Consumer involvement or Patient participation or Patient engagement or Patient involvement or Client participation or Client engagement or Client involvement or Family participation or Family engagement or Family involvement or Patient relation* or Patient preference* or Patient centered or Patient centred):ti,ab,kw (Word variations have been searched)	S	4044
Edit #4	#2 or #3		5264
Edit #5	#1 and #4		187

#1	((Rectal OR rectum OR colon OR colorectal) AND (cancer* OR neoplasm* OR malignanc* OR Tumor*)):ti,ab,kw	S	Limits	21483
#2	((Decision AND (aid* OR tool* OR box*)) OR Option grid* OR Issue card* OR Drug fact box* OR Shared decision* OR Informed decision* OR Informed choice* OR Collaborative decision* OR Decision support intervention* OR Clinical decision making):ti,ab,kw	S	Limits	16454
#3	((Decision making OR Decision support) AND (Consumer participation OR Consumer engagement OR Consumer involvement OR Patient participation OR Patient engagement OR Patient involvement OR Client participation OR Client engagement OR Client involvement OR Family participation OR Family engagement OR Family involvement OR Patient relation* OR Patient preference* OR Patient centered OR Patient centred)):ti,ab,kw	S	Limits	3186
#4	#2 OR #3		Limits	16777
#5	#1 AND #4		Limits	229

with Cochrane Library publication date from Apr 2018 to Dec 2019

APPENDIX 3

Cochrane Collaborations Risk of Bias Tool

Leighl et al, 2011		
Domain	**Support for judgement**	**Authors' judgement**
Selection bias		
Random sequence generation	"Eligible consenting patients with advanced colorectal cancer who were seeing a medical oncologist for an initial consultation regarding first line chemotherapy were randomly assigned…" "randomization lists stratified by the consulting oncologist were computer generated…" Comment: No statistically significant differences in the intervention and control group except English as first language in intervention arm (see table 2)	**Low**
Allocation concealment	"randomization lists…were computer generated and the code was concealed in a sealed envelope until the time of random assignment" "…oncologists and patients were actively informed of the randomization arm only when patients received the DA."	**Low**
Performance bias		
Blinding of participants and personnel	"Although not blinded, oncologists and patients were actively informed of the randomization arm only when patients received the DA." "Those receiving the DA were counselled not to share it with others in the waiting room to avoid contamination of the standard arm." "…five consultations were audiotaped before study commencement as a baseline for comparison with consultations in the standard arm. Oncologists were to be provided with feedback in the event of marked deviation during the course of the trial, but no deviation occurred" "Oncologists were trained to use the DA during the consultation…"	**Moderate**
Detection bias		
Blinding of outcome assessment	Comment: The study does not specify whether or not the outcomes assessment was done in a blinded fashion	**Low**
Attrition bias		
Incomplete outcome data	Comment: 18 patients declined to participate initially and a total of 32 patients were lost to follow up in control, and 33 were lost to follow up in intervention with similar amounts between groups at similar intervals Comment: All patients who participated in at least one survey were included in the analysis Comment: All the outcome assessments are linked together with the surveys, no significant difference in data collection for outcomes	**Low**
Reporting bias		
Selective reporting	Comment: All outcome measures appear to be addressed within the results and discussion Comment: the researchers did not mention how many of the patients were from Canada or Australia but do mention some statistically significant differences in readiness to make a treatment decision and consultation satisfaction scores	**Low/ Moderate**
Other bias		
Other sources of bias	Comment: Insufficient information to judge	**Unclear**

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7-8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	7-8
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	NA

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9-10
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	11-13
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	10-11
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	11-13
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15-16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	2

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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