Effectiveness of self-administered decision aids for people invited to participate in colorectal cancer screening: a systematic review protocol

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Review question/objective: The objective is to assess the effectiveness of self-administered decision aids for people invited to participate in colorectal cancer screening. We will evaluate effects on informed choice, decisional conflict, knowledge, and participation in colorectal cancer screening.

Keywords Colorectal neoplasms; decision support techniques; decisional conflict; informed choice; mass screening


Background

Colorectal cancer is the second most common cancer in Europe with 447,000 new cases and 215,000 deaths each year. Among the Northern European countries, Denmark has the highest age-standardized incidence rate of colorectal cancer for men (69.2 per 100,000) and the second-highest for women (53.4 per 100,000).1

Most colorectal cancers arise from benign polyps. Progression from this precursor lesion to colorectal cancer is a multistep process that has a natural history of at least 10 years.2,3 Survival is strongly associated with the stage at the time of diagnosis. The five-year stage-specific survival ranges from above 90% when the disease is diagnosed at an early stage, to less than 10% when distant organ metastasis is present.4 Symptoms of colorectal cancer are diffuse, with low positive predictive values, and they are often only detected in the advanced stages of the disease,5,6 thus, early detection is often not achieved in asymptomatic patients. Screening may be a feasible method for reducing mortality from colorectal cancer because polyps can be removed or early-stage cancers detected.

Population-based screening for colorectal cancer is recommended for individuals at average-risk of colorectal cancer, including individuals with no previous diagnoses of colorectal cancer or pre-malignant lesions, no positive family history, and no other factors that are known to elevate the risk of colorectal cancer.7,8 Tests that have been considered for population-based screening fall into two categories: stool tests, which include fecal occult blood tests (FOBT) and structural exams, which include flexible sigmoidoscopy (FS) and colonoscopy.7

In European guidelines, the only recommended screening test is FOBT with a maximum screening interval of three years, in citizens aged between 45 and 80 years.8 American guidelines recommend structural examinations as the primary screening method, with FS every five years or colonoscopy every ten years; alternatively a FOBT is recommended every year in citizens 50 years or older.7 Regardless of the screening method, participation is essential for program effectiveness. Population-based colorectal cancer screening programs are generally underused; this problem is often more pronounced in programs that use structural examinations compared to those that use FOBTs.6,9

In countries that follow the European guidelines, individuals must decide whether to participate in screening with FOBT; however, in countries following the American guidelines, individuals must decide whether to participate, and also, which screening method to use. These decisions are made without first contacting a health professional; therefore information must be available to enable citizens to...
One way of providing information is through decision aids (DAs), which are evidence-based tools designed to prepare citizens for making specific, deliberated choices among healthcare options. In general, DAs have three main purposes: i) to provide evidence-based information about a health condition, including the available options and the associated benefits, harms, probabilities and uncertainties; ii) to emphasize the value-sensitivity of the decision, i.e. to clarify the values that an individual places on the benefits and harms, and to guide the individual in determining which benefits and harms are most important; and iii) to provide structured guidance in the steps involved in making the decision and communicating their informed values to others involved in the decision (e.g. clinicians, family, friends). Various types of DAs are available, including leaflets, interactive media, videos or audio tapes.

Several studies have well described the role that DAs play in decisions about screening that individuals make in dialogue with health care professionals. These DAs increase citizens’ interest in screening, lower decisional conflict in making decisions about CRC screening participation, and increase participation in CRC screening. In a systematic review, DAs were shown to improve informed choice, reduce decisional conflict related to feeling uninformed and unclear about personal values, and improve people’s knowledge regarding different screening options (FOBT/structural exams/non-participation). However, in the case of colorectal cancer screening, the decision about participation is made in the privacy of the individual’s own home without consulting a clinician. In this context, a useful DA should be self-administered and assist individuals in making decisions without assuming any prior or later contact with health professionals. Self-administered DAs in some studies have been shown to have positive effects on informed choice, decisional conflicts and knowledge. However, studies on participation rates have reported conflicting results.

Preliminary searches in MEDLINE, the JBI Database of Systematic Reviews and Implementation Reports, the Cochrane Library, and PROSPERO were conducted to ensure that no systematic review has previously been published on the effectiveness of self-administered DAs in colorectal cancer screening. We found one ongoing and one published review on DAs for screening decisions. However, neither of those studies focused on self-administered DAs, which are essential in many screening-related decisions and particularly in decisions related to whether and how to participate in colorectal cancer screening.

This study aims to provide a systematic review to clarify the effectiveness of self-administered DAs. The result are expected to contribute to the existing knowledge about how to support citizens in making informed choices about screening participation.

**Inclusion criteria**

**Types of participants**

This review will consider studies that include men and women 45 years or older, at average-risk of colorectal cancer (as defined in the background section) that face the decision of participation in colorectal cancer screening without contact with health care professionals. Thus, we will exclude DAs that target individuals at an elevated risk of colorectal cancer (i.e. family history of colorectal cancer, personal history of colorectal cancer or polyps).

**Types of intervention(s)/phenomena of interest**

This review will consider studies that evaluate the effectiveness of self-administered decision aids among individuals that face the decision of whether to participate in colorectal cancer screening. Self-administered decision aids are decision aids used by citizens without any contact to health professionals. Self-administered decision aids are available online or mailed to citizens booklets. Hence, we will exclude studies based on DAs that are used in dialogue with health care professionals.

**Outcomes**

This review will consider studies that include the following outcomes: informed choice, decisional conflict, knowledge (about the risk of colorectal cancer and pros and cons of screening options and participation), and participation in colorectal cancer screening. Informed choice and decisional conflict will be outcome measures to estimate the ability to support citizens in making value
sensitive choices based on personal beliefs. Furthermore, knowledge helps citizens to determine whether the comprehensibility of the DAs is adequate.

Studies measuring informed choice based on adequate knowledge and consistency between screening attitudes and actual screening behavior as in Marteau’s informed choice scale\(^2\) will be included in the study. Further, studies considering decisional conflict assessed by the Decisional Conflict Scale\(^2\) will be considered for inclusion in this study. Studies considering knowledge about colorectal cancer and/or colorectal cancer screening assessed using interviews or validated questionnaires will be considered for inclusion in the study as well. Information on actual screening participation assessed using public or private registries, patient records or self-reported data will also be considered for inclusion in the study. Studies using scales other than those specified to estimate informed choice, knowledge or decisional conflict will not be excluded.

**Types of studies**

The review will consider both experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental studies, before and after studies, prospective and retrospective cohort studies, case control studies and analytical cross sectional studies for inclusion.

**Search strategy**

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference lists of all identified reports and articles will be searched for additional studies. Studies published in English, Danish, Swedish and Norwegian will be considered for inclusion in this review. Because both DAs and colorectal cancer screening are relatively new concepts, the search strategy will not set time limits for search periods.

The databases to be searched include:
- MEDLINE [PubMed interface]
- CINAHL
- PsycINFO [Ovid interface]
- Embase
- Scopus

The search for unpublished studies will include:
- ProQuest Dissertations and Theses Database
- Google Scholar
- Mednar
- WorldWideScience

Initial keywords to be used will be: “mass screening”, “early detection of cancer”, “screening”, “decision aid”, “decision support techniques”, “colorectal neoplasms”, and “colorectal cancer”.

**Assessment of methodological quality**

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

**Data extraction**

Quantitative data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. If data is missing from any study, we will attempt to contact the authors.

**Data synthesis**

Quantitative data will, where possible, be pooled in statistical meta-analysis using JBI-SUMARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and also explored using subgroup analyses based on the different study designs included in this review. Where statistical pooling is not possible, the findings will be presented.
in narrative form including tables and figures to aid in data presentation where appropriate.

Acknowledgements

Search strategies were developed in cooperation with librarian Henrik Laursen, Medical Library, Viborg Regional Hospital.

References

Appendix I: Appraisal instruments

**MAStARI appraisal instrument**

**JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not Applicable</th>
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<tbody>
<tr>
<td>1. Was the assignment to treatment groups truly random?</td>
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<td>2. Were participants blinded to treatment allocation?</td>
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<td>3. Was allocation to treatment groups concealed from the allocator?</td>
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<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<td>6. Were the control and treatment groups comparable at entry?</td>
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<td>7. Were groups treated identically other than for the named interventions</td>
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<td>8. Were outcomes measured in the same way for all groups?</td>
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<td>9. Were outcomes measured in a reliable way?</td>
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<td>10. Was appropriate statistical analysis used?</td>
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Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

___________________________________________________________

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JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer ___________________________ Date ___________________________

Author ___________________________ Year __________ Record Number __________

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<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not Applicable</th>
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<tbody>
<tr>
<td>1. Was study based on a random or pseudo-random sample?</td>
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<td>2. Were the criteria for inclusion in the sample clearly defined?</td>
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<td>3. Were confounding factors identified and strategies to deal with them stated?</td>
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<td>4. Were outcomes assessed using objective criteria?</td>
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<td>5. If comparisons are being made, was there sufficient descriptions of the groups?</td>
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<td>6. Was follow up carried out over a sufficient time period?</td>
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<td>7. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>8. Were outcomes measured in a reliable way?</td>
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<td>9. Was appropriate statistical analysis used?</td>
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Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (including reason for exclusion)

__________________________________________________________________
JBI Critical Appraisal Checklist for Comparable Cohort/Case Control

Reviewer ___________________________ Date ___________________________

Author ______________________________ Year ______ Record Number ______

1. Is sample representative of patients in the population as a whole? □ Yes □ No □ Unclear □ Not Applicable
2. Are the patients at a similar point in the course of their condition/illness? □ Yes □ No □ Unclear □
3. Has bias been minimised in relation to selection of cases and of controls? □ Yes □ No □ Unclear □
4. Are confounding factors identified and strategies to deal with them stated? □ Yes □ No □ Unclear □
5. Are outcomes assessed using objective criteria? □ Yes □ No □ Unclear □
6. Was follow up carried out over a sufficient time period? □ Yes □ No □ Unclear □
7. Were the outcomes of people who withdrew described and included in the analysis? □ Yes □ No □ Unclear □
8. Were outcomes measured in a reliable way? □ Yes □ No □ Unclear □
9. Was appropriate statistical analysis used? □ Yes □ No □ Unclear □

Overall appraisal: Include □ Exclude □ Seek further info. □

Comments (Including reason for exclusion)

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Appendix II: Data extraction instruments

**MAStARI data extraction instrument**

**JBI Data Extraction Form for Experimental / Observational Studies**

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<td>Author</td>
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<td>Journal</td>
<td>Record Number</td>
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**Study Method**

- [ ] RCT
- [ ] Quasi-RCT
- [ ] Longitudinal
- [ ] Retrospective
- [ ] Observational
- [ ] Other

**Participants**

<table>
<thead>
<tr>
<th>Setting</th>
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<tr>
<td>Population</td>
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**Sample size**

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<th>Group A</th>
<th>Group B</th>
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**Interventions**

- Intervention A

**Authors Conclusions:**

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**Reviewers Conclusions:**

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### Study results

#### Dichotomous data

<table>
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<tr>
<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
<th>Intervention ( ) number / total number</th>
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#### Continuous data

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<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
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