Title: Development and pilot-testing of a Colorectal Cancer Screening Decision Aid for individuals with varying health literacy levels

Article Type: Research Paper

Keywords: Decision Aid; Colorectal cancer screening; Health literacy; Informed decision making; Computer-based

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Research Data Related to this Submission

There are no linked research data sets for this submission. The following reason is given:
Data will be made available on request
We thank the reviewers for their detailed and relevant comments. We made use of these comments to the best of our ability and we believe that these adaptations added considerably to the clarity and readability of the manuscript. Adaptations in the text are marked in bold.

<table>
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<th>Reviewer 1</th>
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<td>First I would like to compliment the authors on the relevant study they conducted. The study contributes to the limited knowledge base on HL and informed decision making. Their paper is clearly written. I only have some minor comments.</td>
<td>Thank you.</td>
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<tr>
<td>Why was not Chew's set of brief screening questions used to identify those with adequate HL for the alpha-testing but instead the NVS-D?</td>
<td>For the alpha-testing, we administered both the Chew’s set of Brief Screening Questions and the NVS-D in our convenience sample. We did not use the NVS-D in the Dutch ABC panel because this panel consists of individuals with very low level of reading skills. The NVS-D seemed to be too cognitively demanding for these individuals with low HL. We have now more clearly explained in the text that we did use the Chew’s set of brief screening questions among the convenience sample. Page 6.</td>
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<td>And how were those with adequate HL exactly recruited for the alpha-testing?</td>
<td>The participants with adequate HL were recruited conveniently, based on networks of contacts, which has been reported to be sufficient for pilot studies. [3] We have now added this to the text: Participants with adequate HL, as assessed by Chew’s set of brief screening questions [1] and the Newest Vital Sign in Dutch (NVS-D) [2], were conveniently sampled from a network of social contacts. [3]</td>
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<td>Your definition of HL remains a bit vague and the extent to which your measures of HL reflect your definition. I therefore suggest to more clearly describe the definition of HL in the introduction section and to be more explicit on the extent to which your measures of HL are in line with your definition of HL</td>
<td>We thank you for this comment. We have now also added the general definition of HL in the text: Health literacy has been broadly defined as the degree to which individuals have the capacity to access, understand, appraise and apply health information to make informed health decisions. We recognize that no single HL measure can fully cover the broad HL skills that are needed for informed decision making about CRC screening. We have therefore decided to use at least two performance-based measures of HL (SAHL-D-13 and NVS-D). We now briefly explain in the methods that these provide an indication for an individual’s ability to understand and apply health information. Page 8. We do recognize the limitations of these</td>
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measures, as these instruments for instance, do not adequately capture the ability to appraise health information. We have now added this as a limitation in the discussion section:

**Third, we recognize that the HL measures in this study do not fully measure the broad range of skills that are needed for informed decision making about CRC screening (e.g. ability to appraise).**

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<td>The authors of this manuscript have taken on an important topic and developed a needed intervention for colorectal cancer with highlighting low health literacy. This manuscript would be of interest to readers, particular as organizations have seen how the use of decision aids can be quite effective in patient satisfaction. Overall the manuscript had much detail and presented their research and decision aid development in a thorough manner. The authors do a good job in presenting the background and the current state of the problem. Their methods were appropriate in how they developed and tested the decision aid. The tables and graphics are appropriate and adds some clarity. I would recommend this manuscript for publication with 2 minor revisions, which are stated below.</td>
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<td>Thank you.</td>
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In the introduction, the second sentence is not clear to me in how it is worded. Has the CRC screening recommendations been worked on since 2014 and now in 2019, the final recommendations will be revealed?

In the Netherlands, the CRC screening programme will be introduced in phases, between 2014 and 2019. We have now added **in phases** to the second sentence for clarification purposes.

Make sure to state what all abbreviations mean for at least the first time stating it in the manuscript. On page 16, 'GP" is not written all the way out on the first introduction of the abbreviation.

Thank you for this comment. We have now written GP all the way out. We have now checked the manuscript for abbreviations and made sure that all words written for the first time are written way out.

Highlights

- The DA is promising in supporting informed decision making about CRC screening
- Computer-based DAs can be acceptable for individuals with varying health literacy
- Further refinement of interactive features is needed to improve the DA’s usability
Development and pilot-testing of a Colorectal Cancer Screening Decision Aid for individuals with varying health literacy levels

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Abstract

Objective: Making an informed decision about colorectal cancer screening requires health literacy. Our aim was to develop and pilot-test a computer-based decision aid to support informed decision making about whether or not to participate in colorectal cancer screening for individuals with varying health literacy levels in the Netherlands.

Methods: First, we designed and adapted the decision aid prototype among 25 individuals with low (n=10) and adequate (n=15) health literacy. Second, we used a before/after study to assess changes in knowledge, attitude, intention, decisional conflict, deliberation, anxiety and risk perception in an online survey among 81 individuals eligible for colorectal cancer screening with low (n=35) and adequate (n=46) health literacy.

Results: The decision aid was acceptable, comprehensible, reduced decisional conflict, increased deliberation and improved knowledge about colorectal cancer screening, but not about colorectal cancer, among individuals with adequate and low health literacy. Usability was slightly higher for participants with adequate health literacy compared to those with low health literacy.

Conclusion: The decision aid is promising in supporting informed decision making about colorectal cancer screening, also among individuals with lower health literacy.

Practice implications: Further refinement of interactive features, such as videos, animations and the values clarification exercise, is needed to increase the usability of the decision aid.
1. INTRODUCTION

Population-based colorectal cancer (CRC) screening is an effective strategy that significantly reduces CRC mortality and morbidity in the population [1]. In the Netherlands, CRC screening is being implemented in phases since 2014; its roll-out will be completed in 2019. All individuals between the ages of 55 and 75 years old are invited once every two years to perform a faecal immunochemical test (FIT) at home. The invitation consists of an information leaflet, the FIT, and instructions on how to collect their stool sample, and a return envelope for the test to be sent to a laboratory. In case of a positive FIT sample (i.e. blood is detected in the stool sample), individuals are invited for a follow-up diagnostic test, a colonoscopy. Additional information in Dutch, as well as CRC screening information in other languages (i.e. English, Turkish and Arabic), is available on the website of the National Institute of Public health and the Environment (RIVM) [2]. Accordingly, the decision about (non-) participation is usually done alone, without involvement of a health care professional. As with any screening programme, CRC screening has inherent disadvantages, such as false positives, false negatives and potential harms associated with colonoscopy [3]. The benefit of CRC screening at the population level, may not outweigh the potential harms at the individual level. Hence, guidelines recommend that screening invitees should be able to make an informed decision about CRC screening participation [3]. An informed decision is commonly defined as, “one that is based on adequate knowledge and is consistent with an individual’s attitude and values“ [4].

Making an informed decision about CRC screening requires adequate health literacy (HL).

Health literacy has been broadly defined as the degree to which individuals have the capacity to access, understand, appraise and apply health information to make informed health decisions [5].
In the context of CRC screening, invitees need to be able to (1) understand that a choice has to be made, (2) understand the instructions, (3) understand the potential harms and benefits of screening, (4) evaluate the importance of this and (5) apply this information to one’s personal situation [6]. Previous research showed that written screening invitations are often too difficult and lengthy to understand to facilitate informed decisions, for individuals with low HL as well as individuals with adequate HL [7]. Low HL has been shown to be more prevalent among individuals with lower educational level. However, individuals with higher educational level may also have inadequate HL [8, 9]. In the Netherlands, approximately 25% of the population has low HL, meaning that understanding and using health information is particularly difficult for them [10].

Decision aids (DAs) can be developed to increase knowledge about CRC and CRC screening, and to encourage individuals to make a decision that is consistent with their personal preferences [11-13]. Many DAs have been developed in different CRC screening contexts and have shown mixed effects [12]. For instance, in the United States, CRC screening is opportunistic and its purpose is to increase uptake (‘the best test is the one that gets done’), [14] as opposed to enhancing informed decision making. Unfortunately, only one DA has been developed specifically for individuals with low HL in the context of informed decision making about whether or not to participate in CRC screening [15, 16].

Computer-based DAs may offer several advantages to individuals with low HL, as they have the potential of tailoring content to information needs and decision support needs by integrating interactive features, including videos, graphics and animations [12, 17]. Findings from the Dutch Adult Literacy and Life skills survey showed that most individuals, including those with low functional literacy skills, are familiar with working with computers and have
There is limited evidence on how decision support should guide DA development and what features of DAs facilitate informed decision making about CRC screening for individuals with low HL [13, 17].

The aim of this study was to develop and pilot-test a self-administered computer-based DA for CRC screening that is suitable and acceptable for individuals with varying HL levels. We explored the DA’s usability, acceptability and comprehensibility and assessed changes in knowledge, attitude, intention, decisional conflict, deliberation, risk perception, anxiety after use of the DA.

2. METHODS

This study included a mixed-methods approach. Following the International Patient Decision Aids Standards (IPDAS) [19], the DA was developed and evaluated in two stages: (1) Alpha-testing (design, user testing and adaptations) and (2) beta testing (field-testing in ‘real-life’ conditions among participants who were not involved in the design stage) [20].

2.1. Alpha-testing of the DA prototype

The DA prototype was developed in collaboration with a Dutch external internet agency ‘TRIMM’ (see appendix 1). The content (see box 1 for the DA content and elements) was based on information from the National Institute of Public Health and the Environment (RIVM), our previously developed conceptual framework of HL skills and decision making [6] and the IPDAS criteria (health condition, decision options, benefits and harms, outcome probabilities, values clarification) [19].

- Insert Box 1 here -
The purpose of the alpha-testing was to explore the DA’s usability, acceptability, and comprehensibility and to make adaptations to the DA prior to the next stage of evaluation (beta-testing). Usability describes the quality of a user’s experience with the DA, taking into account their needs, values, abilities and limitations [21]. Acceptability of the DA refers to the evaluation of the comprehensibility of the DA, its length, its pace, amount of information, balance in presentation of information about options and overall suitability for decision making [22]. Adaptations to the DA prototype were made in an iterative process after every 3-5 interviews, and the DA prototype was refined based on these findings. Participants’ preferences for three different risk presentation formats conveying information about the possible test results was assessed separately for practical reasons. These three risk presentations were: (I) a flow diagram, (II) a bar chart and (III) an icon array developed by the National Institute of Public health and the Environment (RIVM) in the context of CRC screening (see appendix B).

2.2.1. Data collection and analysis: Alpha-testing

We purposively sampled individuals eligible for CRC screening (ages 55-75 years old) with low HL (n=15) and adequate HL (n=10). Participants with low functional HL were recruited from an existing Dutch test panel (‘ABC’). This Dutch test panel consists of individuals with low literacy who have been trained to examine texts critically (http://www.a-b-c.nu/node/201). Participants with adequate HL, as assessed by Chew’s set of brief screening questions [23] and the Newest Vital Sign in Dutch (NVS-D) [24], were conveniently sampled from a network of social contacts [25]. The Chew’s set of brief screening questions consists of the following three questions: ‘How often do you have someone help you read hospital materials?’, ‘How confident are you filling out medical forms by yourself?’ and ‘How often do you have problems learning about your health because of difficulty
understanding written information?’ with response options: ‘always’, ‘often’, ‘sometimes’, ‘occasionally,’ or ‘never’ [23]. The NVS-D consists of six questions about an ice cream label. We only administered the Chew’s set of brief screening questions among the participants with low literacy who were recruited from the Dutch ABC panel, as the NVS-D appeared to be too cognitively demanding, in combination with the alpha-testing.

The 25 interviews were conducted at participants’ homes or in public libraries by JP between February and April 2018. JP brought a laptop to the participants’ homes, yet some participants accessed and evaluated the DA using their own tablet device. To explore the usability, acceptability and comprehensibility of the DA, we developed an interview protocol using the Three-Step Test Interview method [26]. This method includes (1) observation of participant in navigating through the DA and ask him/her to think aloud, (2) discussion of participant’s responses to fill remaining gaps in the observational data or to check information, and (3) eliciting experiences and opinions by asking additional specific questions regarding feelings, explanations and preferences of the participant [26]. Participants were explicitly instructed to think aloud and were observed by a researcher (JP) throughout the completion of the DA. JP registered all participants’ comments.

All interviews were recorded, summarized and thematically analysed. Data coding was done by JP and subsequently discussed with AW, following a coding scheme about the usability and acceptability of web-based health information tools by Bol, van Weert, de Haes, Loos, de Heer, Sikkel and Smets [27]. We coded participants’ navigation strategy and problems (i.e. how do participants navigate through the DA and which barriers do they encounter?) as indicators of usability and their information preferences and intention to use the DA as
indicators of acceptability. Regarding comprehensibility, we coded participants’ perceived understanding of the purpose of the DA and the values clarification exercise.

2.3. Beta-testing of the DA prototype

2.3.1 Participants and study design: Beta-testing

The DA’s acceptability, comprehensibility and usability was beta-tested in ‘real-life’ conditions among individuals not involved in the design stage [28]. A before/after study was conducted to assess changes in knowledge, attitude, intention, decisional conflict, deliberation, risk perception and anxiety among individuals with varying HL levels. Individuals were recruited by email from a large pool of participants by two ISO-certified market research companies (Flycatcher Internet Research, www.flycatcher.eu and PanelClix, www.panelclix.nl; ISO-26362). A stratified sample of individuals eligible for CRC screening was created in which low and middle/high educational levels were equally represented to enable inclusion of individuals with adequate HL as well as individuals with low HL. Educational level was categorized as low, middle or high according to the International Standard Classification of Education (ISCED) [29]. Eligible participants for the before/after study included individuals who (1) will be invited for the first time for the Dutch CRC screening programme in 2019 (birth year 1962 and 1964) and (2) who were able to read and understand Dutch. All eligible participants were invited to participate by email. After one week of completing the before-questionnaire, participants were invited to complete the DA and the after-questionnaire.

2.3.2. Data collection: Beta-testing

At baseline we assessed self-reported age (year of birth), gender, educational level and HL. HL was measured by two performance-based measures: the NVS-D [24] and the short version
of the Short Assessment of Health Literacy (SAHL-D-13) (Woudstra et al., 2018 submitted).

**These two HL measures provide an indication for an individual’s ability to understand and apply health information.** HL scores were dichotomized into low and adequate HL, following predefined cut-offs. For the NVS-D this was < 3 [30] and for the short SAHL-D-13 this was < 9 (Woudstra et al., submitted). HL was categorized as low if participants’ scores were indicative of low HL on the SAHL-D-13 and/or the NVS-D. HL was categorized as adequate when participants’ scores were indicative of adequate HL on both the SAHL-D-13 and the NVS-D.

2.3.3. Measures

The IPDAS [19] and the Ottawa Decision Support Framework (ODSF) [31] was used to inform the selection of outcome measures in the before/after study. Table 1 presents an explanation of the following outcome measures before and after use of the DA: knowledge [32, 33], attitude [32, 33], intention to participate [33], decisional conflict [32, 33], deliberation [34], anxiety [35], risk perception [32] and benefit of screening [32]. The additional outcome measures after use of the decision aid were preparation for decision making [36], usability [37] and acceptability [27].

- Insert table 1 -

2.3.4. Statistical analysis Beta-testing

Descriptive statistics were generated for all outcome measures (before and after). We used the Wilcoxon signed rank test to assess changes in knowledge, attitude, intention, decisional conflict, deliberation, risk perception and anxiety by HL. Independent samples t-tests were used to assess acceptability, usability and decision making preparation by HL. Following O’Connor and Jacobsen [20], we aimed to include a minimum of 80 participants to detect an
effect size of at least 0.40 on the decisional conflict scale with type I error of 0.05 and Type II error of 0.20. All analyses were completed using Statistical Package for the Social Sciences (SPSS), version 24.

3. Results Alpha-testing

3.1. Study population

In the alpha-testing stage, 11 out of 25 (44%) participants were male. Twenty-two (88%) participants were born in the Netherlands. The mean age was 62.6 (S.D. = 6.83). Fifteen individuals had lower educational level and ten individuals had higher educational level. All ten individuals with adequate HL scored the maximum of six points on the NVS-D scale and the maximum score on the Chew’s set of brief screening questions. About 76% (19/25) had received an invitation for CRC screening a priori and 50% (12/25) of the participants had already participated in CRC screening.

3.2. Usability

Compared to participants with adequate HL, participants with low HL experienced more difficulty navigating through the DA. Navigation problems included difficulty with understanding the navigation menu on the left-side margin, navigating to and from links in a new tab, finding the ‘previous’ and ‘next’ buttons, scrolling, using the dropdown function to ‘read more’ and clicking on tooltips. During the alpha-testing, we encountered some problems with the lay-out of the DA when used on different devices, often a tablet device. With regard to the readability of the text, eight individuals, of which seven with low HL, mentioned that the font size was too small and that there should be more colour contrast. We included an option to adapt font size, but this was not used by the participants (see table 2 for the adaptations to the DA prototype).
3.3. Acceptability

Two of the 15 participants with low HL mentioned a need for more pictures. Six participants with low HL mentioned that there was too much text on one page. These six participants preferred watching videos, as opposed to reading texts. In addition, four participants with low HL considered the DA to be too lengthy: ‘There is more?’ and ‘There are lots of questions, eh?’. However, most participants with adequate HL mentioned that the length of the DA was acceptable. ‘Oh, this is the end already? No, it is not lengthy, no.’ Even so, participants with adequate HL expressed a preference for more information and seven of them expressed a preference for reading text. Six of the ten participants with adequate HL explicitly reported that the links for reading more information are a strength of the tool. Three of the 25 participants spontaneously expressed that they would recommend the DA to someone else.

Five participants with adequate HL mentioned that they did not necessarily see the added value of the decision aid in comparison to the existing leaflet of the RIVM.

3.4 Comprehensibility

For one participant with low HL the meaning of DA was not clear: ‘What does decision aid mean exactly?’. Moreover, for a number of individuals, the purpose of the DA (i.e. supporting informed decision making) was not clear, since many participants already had positive attitudes toward CRC screening and felt that there was no decision to be made. Accordingly, the decision to not participate was not always recognized. For some individuals with low HL, the purpose of the quiz with knowledge statements was unclear. A number of them expressed concerns that they might get the answers wrong, and asked whether their scores would be made public. In addition, some participants were concerned that their decision about whether or not to participate would be made public.
3.4.1 Risk information formats

Fourteen participants, of whom ten with low HL, expressed a preference for the icon array from the RIVM above the box diagram and flow diagram (appendix A). Three participants with low HL, but none of the participants with adequate HL, expressed a preference for the box diagram. Two participants with low HL and three participants with adequate HL expressed a preference for the flow diagram. Almost all participants with low HL expressed that the information about false positives and false negatives was too difficult and confusing. With regard to the information about false-positives, one participant with low HL concluded: ‘So, I am misled [by the information]’. One participant with low HL and four participants with adequate HL mentioned that the text about false positives and false negatives might increase anxiety among screening invitees: ‘What do you mean being unjustly reassured? So the result is fine, but you can still have cancer? I would be really nervous about that.’

3.4.2 Values Clarification Exercise

Several participants with low HL did not understand the purpose of listing the pros and cons of screening, that is, they thought that the pros reflected the correct information and the cons reflected the incorrect information, similar to the knowledge statements: ‘This last bit is really difficult. I would really quit [the DA], yes.’ Participants with low and adequate HL had difficulty reading all the pros and cons and selecting the ones that were most important to them. Selecting cons was found to be challenging in particular: ‘Some cons are not cons [for me].’

- Insert table 2 here –

4. Results Beta-testing
4.1. Participant characteristics

Of the participants in the beta-testing stage (n=81), 36 (44.4%) were male, 45 (55.6%) had low educational level, and 15 (18.5%) had middle/high educational level. In total 35 participants scored low on either NVS-D (n=5) or SAHL-D-13 (n=20), or on both tests (n=10). All, but one participant, were born in the Netherlands (table 3).

- Insert table 3 here -

4.2. Before/after study findings

Changes in outcome variables after using the DA are shown in table 4. There was a significant difference in knowledge about CRC screening among participants with low HL (p = 0.01) and adequate HL (p = 0.03) after use of the DA. There was no significant difference in knowledge about CRC among those both groups.

Participants’ decisional conflict showed a significant decrease after use of the DA across adequate HL and low HL. The informed, values clarity and uncertainty subscales showed significant reductions after use of the DA among both participants with adequate HL and low HL. The support subscale showed a significant reduction after use of the DA among those with adequate HL, but not among those with low HL.

Deliberation scores increased significantly after use of the DA for participants with adequate HL (p < 0.001) and low HL (p < 0.001).

There was no significant difference in attitude, intention, risk perception, perception about the benefit of screening and anxiety towards CRC screening before and after use of the DA by HL (see table 4).

- Insert table 4 here –

4.3. DA acceptability, credibility, usability and decision-making preparation
With regard to the DA acceptability, there were no significant differences in *attractiveness, comprehensibility, emotional support, credibility, relevance and decision making preparation* by HL (table 5). The only significant difference was found for the DA’s *usability*. Participants with low HL scored significantly lower on the System Usability Scale (SUS) (Mean = 65.64; S.D. = 13.54) compared to those with adequate HL (Mean = 74.46; S.D. = 15.62; \( p = 0.008 \)).

- Insert table 5 here –

5. Discussion and conclusion

5.1. Discussion

This study used a mixed-methods design (alpha-and beta-testing stage) to develop and pilot-test a DA for CRC screening. The DA was acceptable, improved knowledge, reduced decisional conflict and increased deliberation for participants with adequate HL as well as participants with low HL. We found no differences in attitude, intention, risk perception and anxiety after use of the DA. These findings are encouraging in the context of informed decision-making, as this is an indication that the DA does not influence screening intention by changing attitudes, risk perception or anxiety toward CRC screening. Nevertheless, the results demonstrate room for improvement concerning its usability, especially for individuals with low HL.

The alpha-testing stage demonstrated that most participants with low HL preferred a short DA with little detail. Participants with adequate HL more often expressed a preference for a ‘read more’ option. Although the links in the decision aid helped to keep the information in the DA concise, the struggle between informing and complexity [38] remained throughout the development stage. This was especially true for the values clarification exercise in which participants were encouraged to weigh up the potential benefits and potential harms (e.g. false
positives and false negatives) of screening. Similar to our previous findings [6], some participants mentioned that the information about potential harms of a colonoscopy should not be included in the DA, as this could increase anxiety about CRC screening and refrain individuals from participating.

In line with previous research on the public opinion about CRC screening among the Dutch population [39], the majority of the participants were positive toward CRC screening and were more aware of its potential benefits than its potential harms. Accordingly, similar to previous research [40], a number of participants did not recognize the decision to be made and were less knowledgeable (or less engaged) about the decision option to not participate. In line with our findings, a previous study on the development of a Danish DA for CRC screening showed that the values clarification exercise was found to be irrelevant as the exercise did not exemplify participants’ actual decision making [41]. Recently, a Dutch study has shown that individuals tend to process information about CRC screening in such a way that it confirms their existing beliefs of cancer begin serious and screening being preventive, which might explain why individuals tend to focus on the benefits of CRC screening, rather than on the potential harms of screening [42]. Further research should explore ways in which the DA can be tailored to participants’ prior knowledge, attitudes and beliefs about cancer and screening to facilitate engagement with the screening decision and guide deliberation about the decision options.

The majority of the participants preferred the icon array above the box and flow diagram, which has been shown to be a valuable method of communication risks [43, 44]. Yet, some participants had strong preferences for the box and diagram formats. This suggests that perhaps we should offer participants a choice of risk presentation formats, allowing them to
select the one that they find most attractive and comprehensible (i.e. ‘self-tailoring’). Further research should examine whether the preference for a certain risk information format indicates improvement of comprehensibility with regard to the risk information and whether ‘self-tailoring’ may contribute to experiencing more autonomy [45], and not information overload.

Across all HL levels, participants were satisfied with the attractiveness, comprehensibility and emotional support of the DA. No significant differences were found in decision making preparation between the HL groups. Regarding the DA’s usability, there were significant differences by HL. Participants with low HL had a mean System Usability Scale (SUS) score < 70, which indicates the need for further improvement of the decision aid with regard to its usability. Although we adapted and simplified the DA prototype using the findings from the alpha-test, our findings show that the self-administered computer-based DA is unlikely to take away all navigational barriers among those with lowest HL levels. Further tailoring is therefore needed to those with lowest health literacy, thereby focusing on the preferred mode of information presentation (e.g. text with visuals or audio visuals) [46] and refinement of the CRC screening videos (e.g. easier explanation of medical words and shorter) and the values clarification exercise to facilitate informed decision making about CRC screening. Further improvements should also focus on developing interactive graphics and animations with spoken text to tailor information, present risks and clarify values in co-creation with low HL individuals [47]. In addition, the feasibility of application of the DA in consultation settings should be tested among general practitioners (GPs), as the DA encourages screening invitees to discuss their decision options with their GP, if needed.
The beta-testing results showed significant changes in knowledge, decisional conflict and deliberation after use of the decision aid, regardless of HL. Improvements were pronounced in the decisional conflict scales *feeling informed* (knowing the pros and cons of CRC screening), *clarity of values* (being clear about what was important) and *uncertainty* (knowing what to decide) for all groups, but not in *feeling supported* (support in making the decision) for those with low HL. These findings on changes in knowledge and decisional conflict are in line with other DA CRC screening studies [12].

Although the results are promising, this study has important limitations that need to be addressed. The first limitation is the absence of a control group, which limits our ability to confirm that changes in the outcome variables can specifically be attributed to use of the DA. It should be noted here that this study provides pilot data to further support a subsequent large-scale effectiveness study. Further DA evaluation using a randomized controlled trial design will enable the comparison with standard information materials and the evaluation of its effects on actual decision making about CRC screening. Future research should explore which DA elements contribute to informed decision making about CRC screening for individuals with low HL. Second, the generalizability is limited because our participants were recruited from an online panel, which requires a certain level of digital and literacy skills. However, a strength is that we were able to recruit participants with lowest HL in the alpha-testing stage and conducted a think-aloud study. Nevertheless, this was sometimes challenging as participants with low HL experienced difficulty commenting on the information in the DA. Third, we recognize that the HL measures used in this study did not fully measure the broad range of skills that are needed for informed decision making about CRC screening (e.g. ability to appraise). Fourth, the knowledge questions may have caused some unresponsiveness due to the (unnecessary) anxiety of making (incorrect)
answers public. However, we encouraged participants to also express all their comments, positive as well as negative, as our main purpose is to make the DA suitable and acceptable for all individuals.

5.2 Conclusion

Our study showed that it is possible to develop a computer-based decision aid about CRC screening that is suitable and acceptable for individuals with varying HL levels. While our findings are encouraging, the findings also point to room for improvement, especially with regard to its usability. Further refinement of the CRC screening videos and the values clarification exercise is needed to facilitate informed decision making about CRC screening. In conclusion, this study is an important first step in supporting informed decision making about CRC screening for individuals with low HL.

**Declarations of interest**

None.

**Author contributions**

*Study concept and design:* All authors (AW, ES, ED, TB, JP, SS, KM, MF) contributed to the design of the study. MF secured funding for the project and led the initial development of the study).

*Data acquisition:* AW, JP and MP facilitated the recruitment of participants. JP conducted interviews with participants.

*Analysis and interpretation:* AW and MP conducted the thematic analysis.

*Manuscript draft:* AW, ES and MP drafted the study manuscript and all other authors (ED, TB, JP, SS, KM) provided critical feedback.
Critical revision: All authors (AW, ES, ED, TB, JP, SS, KM, MF) read and approved the final version of the manuscript.

Data and Decision aid availability
The dataset generated and the decision aid prototype during the current study are available from the corresponding author upon reasonable request.

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Informed consent and participant details
According to Dutch law, this study was waived from requiring ethical approval. Nonetheless, we ensured anonymity of the participants and obtained informed consent prior to conducting the interviews.
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