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The LEAD trial—The effectiveness of a decision aid on decision making among citizens with lower educational attainment who have not participated in FIT-based colorectal cancer screening in Denmark: A randomised controlled trial

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ABSTRACT

Objectives: This trial tested the effectiveness of a self-administered web-based decision aid, targeted at citizens with lower educational attainment, on informed choice about colorectal cancer screening participation as assessed by group levels of knowledge, attitudes and uptake.
Methods: The randomised controlled trial was conducted among 2702 screening-naïve Danish citizens, 53–74 years old, with lower educational attainment. Baseline questionnaire respondents (62%) were allocated to intervention and control groups. Intervention group citizens received the decision aid. Outcomes were informed choice, worries and decisional conflict.
Results: Analyses were conducted among 339 eligible citizens. The mean difference in knowledge score change between intervention and control group was 0.00 (95% confidence interval (CI): -0.38;0.38). Trends towards more positive screening attitudes (mean difference in score change: 0.72, 95% CI: -0.38;1.81) and higher screening uptake (7.6%, 95% CI: −2.2;17.4%) were observed. Worries (−0.33, 95% CI: −0.97;0.32) and decisional conflict (mean difference: −3.5, 95%CI: −7.0;−0.1) were slightly reduced.
Conclusions: The decision aid did not affect informed choice or knowledge. However, there were trends towards increased screening uptake and more positive screening attitudes.
Practice implications: Being a simple intervention and easily administered, the decision aid could represent a cost-effective way of enhancing screening uptake, and some elements of informed decision-making.

1. Introduction

In 2018 the age standardised annual colorectal cancer (CRC) mortality rates in very highly developed countries [1] reached 13.9 and 8.9 per 100,000 men and women respectively, making it a common cause of cancer-related deaths world-wide. [2] CRC screening decreases incidence, morbidity and mortality [3,4]. However, there are also possible harms with risks of false positive or negative results, colonoscopy complications and over-diagnosis [4,5]. Thus, the decision to participate in screening should be an informed choice, based on adequate knowledge about relevant options, followed by weighing up benefits and harms according to individual personal values, and acting in accordance with personal values [6–8].

Acquiring adequate knowledge about CRC screening requires accessible and comprehensible information material, since the decision to take up screening often does not involve health care professionals. However, citizens with lower levels of health literacy tend to respond to higher level messages from headlines and images rather than reading the contents of conventional information materials. [9] Lower health literacy is also associated with lower educational attainment [10].

Decision aids are tailored interventions which are designed to support specific populations in making health care related informed decisions. Decision aids for CRC screening programmes

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using faecal samples obtained at home must be self-administered. In earlier studies, such self-administered decision aids have been observed to increase knowledge and informed choice, while decreasing decisional conflict in the targeted population. [11–15] However, less positive screening attitudes have been observed after using a self-administered decision aid [12,13], while the effects on worries [12,14] and uptake [11–13,16,17] are conflicting. Few self-administered decision aids have been developed specifically targeting lower educational attainment citizens [12] and until now web-based decision aids have only been tested in uncontrolled trials [14] or in comparison to other decision aids [16].

We aimed to investigate the effectiveness of a web-based self-administered CRC screening decision aid developed especially for citizens with lower educational attainment [18] on informed choice, as assessed by knowledge of CRC and CRC screening, attitudes towards screening, and screening uptake. The effects of the decision aid on CRC worries and decisional conflict were also assessed.

2. Methods

The trial was conducted in the Central Denmark Region which has 1.3 million inhabitants, corresponding to about 23% of the Danish population. [19] The region includes the second largest city in Denmark and rural areas.

CRC screening using the faecal immunochemical test (FIT) is offered biennially to all 50–74-year-old Danish citizens. During the four year implementation period (2014–2017), eligible citizens were invited once according to month of birth or one month before their 50th or 75th birthday. Invitations are sent out by postal mail, containing the formal invitation letter, national information material, a screening kit, and a return envelope. Screening reminders are sent by digital mail to citizens who do not return a stool sample within 45 days. Citizens with a positive stool test are scheduled to have a diagnostic colonoscopy.

Digital communication with health authorities is mandatory in Denmark. Hence, all citizens are obliged to have a digital signature, which acts as a login for a secure email platform. Elderly or disabled citizens can be exempted from digital communication, and receive postal mail via a remote printing service. [20] In March 2018, 7.9% of 45-74-year-old citizens were exempt from digital communication in the Central Denmark Region [21].

This trial was conducted in accordance with the LEAD trial protocol, in which the trial design has been described. [22] Briefly, the study was conducted as a randomised controlled trial, with two parallel groups (intervention and control), using simple randomisation in a 1:1 ratio [22]. In order to assess a possible Hawthorne effect [23], a historic cohort was also included (Fig. 1).

The intervention was a self-administered web-based decision aid to citizens in the intervention group provided via a link in a separate digital mail, a few days after receiving the standard screening reminder. The control group and historical cohort had no access to the decision aid (Fig. 1).

The decision aid was developed for lower educational attainment citizens as described previously. [18] In brief, it was designed to support an informed decision about screening uptake, presenting the option to take up FIT-based screening or not to take up screening. In 16 steps the decision aid presented benefits and harms to both options along with basic information about CRC (incidence, mortality, development, symptoms, treatment etc.) and CRC screening (effectiveness, FIT-test, colonoscopy).Information was presented in figures and charts. In each step pop-ups with more details and text were available. Most pop-ups had "read more" functions, giving citizens the opportunity to access the level of information they wanted. By using figures and charts as well as values clarification questions, the decision aid encouraged citizens to consider the information they had just seen or read. On the last page of the decision aid, the citizens were presented with a "choice indicator", summing up the results of the values clarification questions. Further discussion of the choice with family or a doctor was encouraged. [18] The decision aid is available in Danish at www.skaljegdeltage.dk.

Citizens with lower educational attainment, 53–74 years old and resident in the Central Denmark Region on August 1 st 2017 were eligible for inclusion in this study. Lower educational attainment was defined as a maximum of 10 years of education, corresponding to ISCED 2011 levels 1–2 [24], which amounts to 26% of the 50-69-year-old citizens in Denmark [25]. Only 53–74 year-old citizens were included in the study as citizens aged 50–52 years had previously received a screening invitation at their 50th birthday. Furthermore, citizens returning a stool sample within 45 days of receiving the screening invitation were excluded, since they received no screening reminder. Citizens in both the intervention and control groups were screening naïve, and citizens in the historic cohort had been invited to take up CRC screening 6–12 months earlier.

The study population was identified using two random samples of citizens provided from the Danish Civil Registration System [26] by the Danish Health Data Authority: random sample 1 (intervention and control group) consisted of 10,030 citizens and random sample 2 (historic cohort) consisted of 4232 citizens. Data included names, postal addresses and unique civil registration numbers for each citizen. [26] At this level we had no knowledge about educational attainment, and therefore the final study population was identified retrospectively after the data collection had been completed. Totals of 2702 citizens from random sample 1 and 1123 citizens from the historic cohort had lower educational attainment and thus posed the final study population (Fig. 1).

Data sources and variables are listed in Table 1, and will only be briefly described here, since they have been further described elsewhere. [22]

The primary outcome was informed choice, which is defined as "one that is based on relevant knowledge, consistent with the decision-maker's values, and behaviourally implemented". [8] Marteau et al have developed a measure for informed choice, based on the following proxy measures: knowledge, attitudes and screening uptake [8,27]. Due to great interpersonal variance, knowledge and attitudes are difficult to categorise objectively as 'good' or 'positive' using arbitrary cut-off values [28]. Consequently, we chose to use ordinal scales instead of dichotomising these outcomes. Informed choice was interpreted from group level changes and consistency of direction of effects for knowledge, attitudes and screening uptake measures [28].

Data on screening uptake were obtained from the CRC screening programme administrative system. All other outcomes (primary and secondary) were assessed in questionnaires that were pilot tested, evaluating comprehensibility and relevance. Validity and reliability were evaluated in a subsequent field test. Both tests were carried out among 50–74 year-old citizens with lower educational attainment.

Knowledge was measured using true/false statements similar to those used in previous studies. [13,14,29–31] We developed the scale and found that internal consistency was acceptable (Cronbach's α: 0.58). Attitudes were measured using a 4-item attitudes scale developed for prenatal screening [27] and previously also used for CRC screening [13]. We translated the scale into Danish using a conventional forward-backward translation [32] (Cronbach's α: 0.71).

Secondary outcomes were CRC screening induced worries, and decisional conflict. We developed the worry scale based on prior literature [33,34], and internal consistency was good (Cronbach's α: 0.81). Decisional conflict was measured using the decisional

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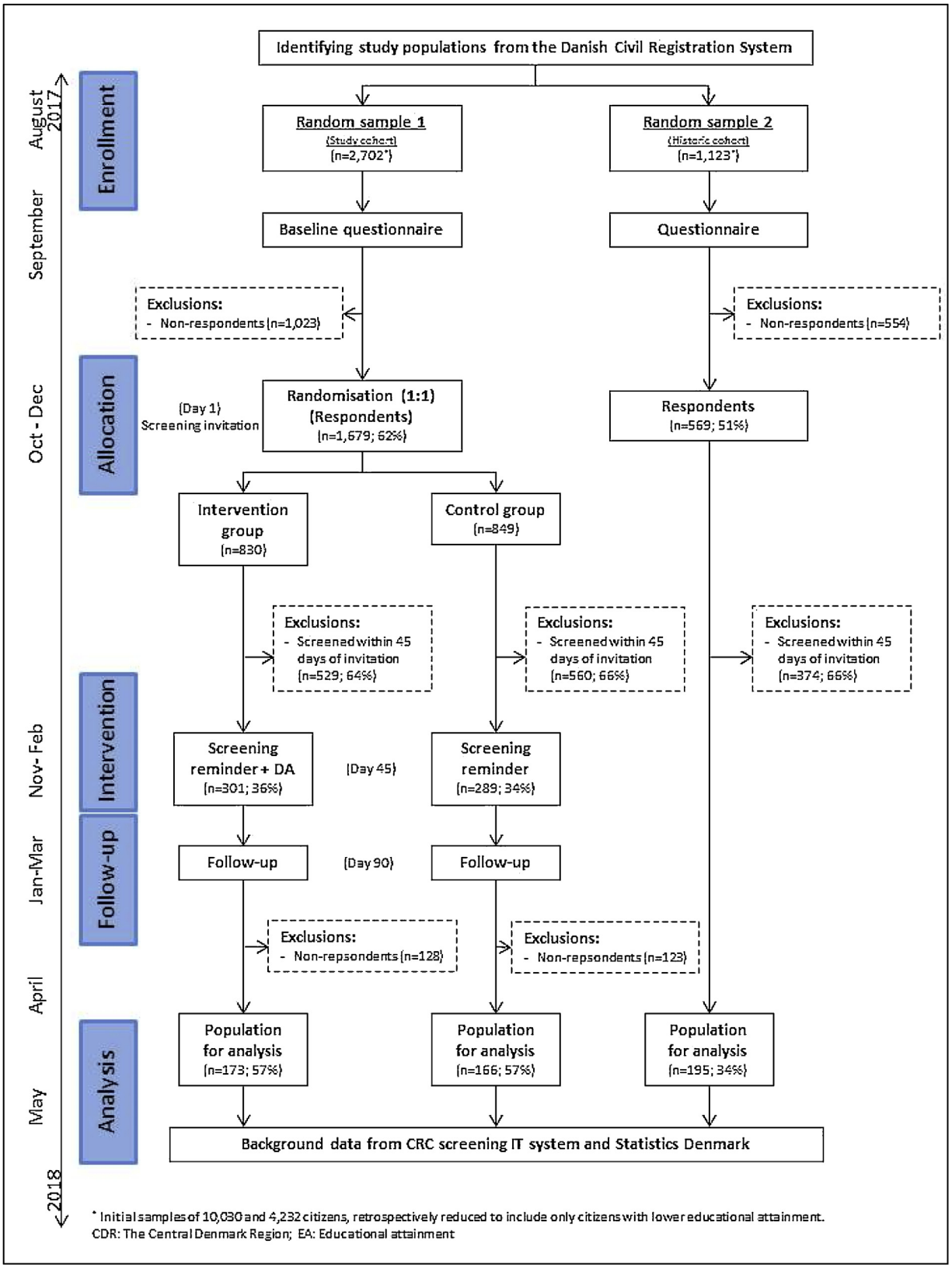

Fig. 1. Study flow-chart.

conflict scale, which has previously been translated into Danish and validated [35] (Cronbach's α: 0.95).

Health literacy was a background variable, measured using the validated HLS-EU-Q16 scale [36], which has been translated into Danish by another research group (Helle Terkildsen Maindal, personal communication) and previously used among Danish type-2 diabetes patients with different educational attainment and a mean age of 64 years [37] (Cronbach's α: 0.88).

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Table 1
Data description.

Variable	Source (development)	Items	Scoring	Score range	Missing values	Time of measure-ment[§]
Outcomes						
Knowledge	Literature review and LEA citizens information needs [44]	7 items True/ false statements	1 point for a correct indication, 0 points for incorrect or don't know indications	0-7	Scored 0 No more than 1 missing value accepted.	Baseline Follow-up Historic
Attitudes	Developed for prenatal screening [27], translated using forward-backward translation [32]	4 items	1-7 points per item Lower scores = more negative attitudes	4-28	Not accepted, total score coded missing	Baseline Follow-up Historic
Screening uptake	CRC screening IT system data	1 item	Dichotomous	Yes/no	No missing values	90 days after screening invitation
Worries	Literature review [11,12,33,34]	3 items	1-5 points per item Lower scores = less worry	3-15	Not accepted, total score coded missing	Baseline Follow-up Historic
Decisional conflict	Decisional conflict scale [35]	16 items	0-1 point per item Lower scores = lower decisional conflict	0-100	Missing items not included in scoring, according to manual. [35]	Follow-up Historic
Use of decision aid link	Ad hoc question	1 item	Dichotomous	Yes/no	No missing values	Follow-up
Socio-demographic data						
Health literacy	HLS-EU-Q16 [49]	16 items	0-1 point per item	Inadequate (0-8) Problematic (9-12) Adequate (13-16)	No more than two missing values accepted according to manual (scored 0). [50]	Baseline Historic
Educational attainment	Statistics Denmark	1 item	Categorised	Lower (≤10 years) Medium (10-15 years) Higher (>15 years)	Coded missing	Highest level of education January 2017
Ethnicity	Statistics Denmark	1 item	Categorised	Danish Western immigrant[†] Non-western immigrant	Coded missing	January 2017
Marital status	Statistics Denmark	1 item	Categorised	Married/cohabitant Single	Coded missing	January 2017
Income	Statistics Denmark	1 item	Categorised	Lower tertile (<€30,000) Medium tertile (€30,000-€43,000) Upper tertile (≥€43,000)	Coded missing	Mean income 2016
Occupation	Statistics Denmark	1 item	Categorised	Self-employed/chief executive Employed Unemployed/receiving benefits Retired Social welfare recipients Other	Coded missing	Primary type of occupation during 2016, evaluated January 2017
Population area	Civil Registration System	1 item	Categorised[‡]	Densely populated area Intermediate density Thinly populated area	Coded missing	August 2017

[§] Baseline questionnaires were sent out in August 2017; Questionnaires for the historic cohort were sent out in September 2017; Follow-up questionnaires were sent out during January-March 2018.
[†] According to Statistics Denmark classification, western immigrants originates from the EU, Andorra, Australia, Canada, Iceland, Liechtenstein, Monaco, New Zealand, Norway, San Marino, Switzerland, the US, or the Vatican state [51].
[‡] According to Statistics Denmark categorisation [52].

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Lastly, citizens in the intervention group were asked to indicate whether or not they had used the link for the decision aid using one item in the follow-up questionnaire.

Socio-demographic data were collected from Statistics Denmark [38] and consisted of data on educational attainment as well as ethnicity, marital status, income, occupation and degree of urbanisation (see details in Table 1).

The baseline questionnaire assessed knowledge, attitudes, worries and health literacy and was mailed to eligible citizens in random sample 1 in August 2017, i.e. before the citizens received their standard screening invitation for CRC screening during October-December 2017 (Fig. 1). Questionnaire respondents were randomised to the intervention or control groups. [22] However, citizens who took up screening within 45 days were excluded from further analyses. Thus, the final intervention group received the decision aid link 1–2 days after receiving the standard screening reminder. Follow-up questionnaires assessing knowledge, attitudes, worries and decisional conflict were sent out to the intervention and control group citizens 90 days after receiving the screening invitation (January-March 2018). The historic cohort received only one questionnaire to assess knowledge, attitudes, worries, health literacy and decisional conflict in September 2017, 6–12 months after having received their standard screening invitations.

For all questionnaires, we mailed two week questionnaire reminders to non-respondents. Further, at four weeks, non-respondents received a telephone call from an external research and insights management solutions company [39], offering to complete the questionnaire via the telephone.

In April 2018 questionnaire data collection was completed, and data on screening uptake at 90 days after screening invitation, were collected from the CRC screening programme's database. Lastly, the dataset was linked with socio-demographic data from Statistics Denmark in May 2018. (Table 1) [38]

Blinding of study participants was not possible, due to the nature of the intervention.

Demographic data on respondents and non-respondents were assessed by frequency calculations. Tests for difference between groups were done using Pearson's Chi^2-test. Age was presented as a mean value, and test for difference was done using the Kruskal-Wallis non-parametric test.

Distribution of socio-demographic data between study arms was also assessed by frequency calculations. Pearson's Chi^2 test was used to test the difference between the intervention and the control groups.

The effectiveness of the decision aid was assessed using intention-to-treat analyses. The uptake was evaluated using a binary regression model, presenting absolute risk differences and relative risks with 95% confidence intervals (CI). Comparisons were done for the intervention group using the control group (study arm 2) as a reference. Further, the control group was used as the reference in comparison to the historic cohort. Model checks were performed for knowledge, attitudes, worry and decisional conflict. Linear regression models were used when the ordinal variables resembled normally distributed data. In cases where assumptions on normally distributed data were violated, ordinal regression analyses were conducted. For linear models, mean differences with 95% CI were presented. For ordinal regression analyses, odds ratios indicating the odds of higher scores in the comparison groups as compared to the reference groups were presented with 95% CI. Comparisons between the control group and the historic cohort were adjusted for age, gender, and population density, since the historic group was not part of the randomisation. Supplementary per-protocol analyses were conducted comparing decision aid users and non-users.

Lastly, possible effect modification by socio-demographic variables and health literacy on the effect of the decision aid on knowledge, attitudes and uptake was assessed. This was done conducting the ordinal/linear (knowledge/attitudes) or logistic (uptake) regression models with each of the socio-demographic variables as secondary independent variables. The analyses were conducted allowing for different slopes in different groups of background variables, and p-values for the hypothesis of no effect modification were estimated using the Wald test.

All analyses were carried out un-stratified in Stata/MP 15.1 for Windows (StataCorp LLC, College Station, Texas, USA) with 5% significance levels.

Power calculations, considering a 5% significance level and 80% statistical power, indicated that 200 citizens with lower educational attainment should be included in each study arm for analyses in order to be able to detect an expected 14% difference in proportions having a positive attitude towards screening between the groups. [22] In order to end up with 200 citizens in the analyses, 5000 citizens needed to be included at baseline. This number was based on assumptions regarding 1) citizens having lower educational attainment (26%) [25], 2) expected proportion of citizens receiving a standard screening reminder, corresponding to experiences from the ongoing screening programme (47%) [40], 3) questionnaire response rates in random sample 1 at baseline (60%) and follow-up (80%) and 4) response rate in the historic cohort (50%).

3. Results

A total of 1679 (62%) citizens with lower educational attainment completed the baseline questionnaire. Of the 830 and 849 citizens in the intervention and control groups, respectively, 301 (36%) and 289 (34%) did not submit a faecal sample within 45 days and were therefore eligible for final inclusion in this study. The response rate at follow-up was 57% in both groups, corresponding to 173 and 166 citizens in the two groups, respectively. (Fig. 1)

In the historic cohort, 569 (51%) out of 1123 citizens, who had lower educational attainment, completed the questionnaire. Of these, 195 (34%) did not submit a faecal sample within 45 days, and were thus eligible for further analyses in this study. (Fig. 1)

Non-respondents in all groups tended to have lower incomes, were more often living alone and were more often of non-Western origin than respondents (Supplementary files, Table A1). Non-respondents at follow-up were more often living alone than respondents (Supplementary files, Table A2).

Differences in baseline data between the intervention group and control group were minimal. The historic cohort had a higher mean age, more men and a higher proportion of employed citizens as compared with the control group (Table 2).

A total of 74 citizens (43%) in the intervention group stated that they used the link for the decision aid.

In the intention-to-treat analysis (Table 3), the knowledge score increased significantly between baseline and follow-up in both intervention and control groups (mean difference 0.48, 95% CI: 0.21;0.75 and 0.48, 95% CI: 0.21;0.74, respectively), but with no difference between the study groups (mean difference: 0.00, 95% CI: -0.38;0.38). For attitudes, there was a statistically non-significant tendency towards being more positive if having access to the decision aid (intervention group) as compared to having no access (control group) (mean difference: 0.72, 95% CI: -0.38;1.81). Screening uptake was 7.6% (95% CI: -2.2;17.4%) higher in the intervention group than the control group. Individuals in the intervention group were less worried at follow-up as compared to baseline (-0.43, 95% CI: -0.85;0.00), but the same tendency was observed in the control group (-0.10, 95% CI: 0.59;0.39) leaving a statistically non-significant effect of the decision aid on worries

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Table 2
Demographic characteristics and baseline data of enrolled study subjects at randomisation (only citizens with lower educational attainment were enrolled)[¥].

		Intervention group (n = 830)	Control group (n = 849)	Historic cohort (n = 569)
		N (%)	N (%)	N (%)
Gender				
	Male	349 (42)	341 (40)	254 (45)
	Female	481 (58)	508 (60)	315 (55)
Age				
	Mean (CI)[§]	64.7 (64.2;65.1)	64.9 (64.5;65.3)	65.1 (64.6;65.6)
	53-59	232 (28)	219 (26)	146 (26)
	60-64	196 (24)	223 (26)	142 (25)
	65-69	193 (23)	172 (20)	130 (23)
	70-74	209 (25)	235 (28)	151 (27)
Ethnicity				
	Danish	803 (97)	827 (97)	554 (97)
	Western immigrant	11 (1)	9 (1)	9 (2)
	Non-western immigrant	16 (2)	13 (2)	9 (1)
Marital status				
	Married/ cohabitant	617 (74)	616 (73)	422 (74)
	Single	213 (26)	233 (27)	147 (26)
Income				
	< €30,000	362 (44)	391 (46)	255 (45)
	€30,000-€43,000	272 (33)	259 (31)	182 (32)
	≥ €43,000	196 (24)	199 (23)	132 (23)
Occupation				
	Self-employed/Chief executive	50 (6)	34 (4)	21 (4)
	Employed	275 (33)	268 (32)	195 (34)
	Not employed/welfare benefits	35 (4)	33 (4)	18 (3)
	Retired	462 (56)	497 (59)	330 (58)
	Other	8 (1)	17 (2)	5 (1)
Population area				
	Densely populated	94 (11)	124 (15)	92 (16)
	Intermediate density	275 (33)	260 (31)	163 (29)
	Thinly populated	461 (56)	465 (55)	314 (55)
Health literacy				
	Adequate	331 (42)	337 (42)	205 (38)
	Problematic	312 (39)	291 (36)	209 (39)
	Inadequate	147 (19)	175 (22)	122 (23)
Baseline knowledge				
	Mean score (CI)[§]	4.78 (4.67;4.90)	4.67 (4.55;4.78)	4.99 (4.86;5.13)[†]
Baseline attitude				
	Mean score (CI)[§]	21.2 (20.8;21.5)	21.1 (20.8;21.4)	21.7 (21.3;22.1)[†]
Baseline worries				
	Mean score (CI)[‡]	9.36 (9.17;9.56)	9.39 (9.19;9.58)	9.08 (8.85;9.31)[†]

[¥] Chi2 to test for differences between the intervention group and the control group showed no statistically significant differences ($p > 0.05$) Test for difference between the historic cohort and the control group showed a statistically significant difference for gender, age and occupation.
[§] Kruskal-Wallis test for difference in means (intervention vs. control ($p > 0.05$)).
[‡] Student's *t*-test to test for difference in means (intervention vs. control ($p > 0.05$).
[†] Knowledge, attitude and worry scores are measured after screening invitation for the historic cohort.

(mean difference between groups: -0.33, 95% CI: -0.97;0.32). The decisional conflict score after having the CRC screening offer was statistically significantly lower in the intervention group, compared with the control group (mean difference: -3.5, 95% CI: -7.0;-0.0).

Per protocol analyses based on the stated users of the decision aid compared with the stated non-users confirmed the observed directions of the intention-to-treat analyses (data not shown).

Neither health literacy nor sociodemographic variables modified the effect of the decision aid. Only marital status seemed to affect the effect of the decision aid. Hence, uptake among citizens living alone increased more than among cohabitant citizens (uptake difference among those living alone: 30%, 95% CI: 11;49% vs. uptake difference among those married/cohabitant: -0.2%, 95% CI: -12;11%) (Supplementary files, Table A3).

4. Discussion and conclusion

4.1. Discussion

We performed a randomised controlled trial investigating the effectiveness of a self-administered web-based decision aid for CRC screening, targeting lower educational attainment citizens. We hypothesized, that the decision aid would increase the proportion of citizens making an informed choice by increasing knowledge and having more citizens act in accordance with their

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Table 3
Intention-to-treat analysis of the effect of the decision aid on knowledge, attitudes, uptake, worry and decisional conflict (n = 534).

	Baseline	Follow-up	Group comparison (follow-up)		Score change (follow-up – baseline)	Group comparison (score change)
Knowledge score	Mean (CI)	Mean (CI)	OR (CI)†		Mean (CI)	Mean difference (CI)§
Intervention group	4.76 (4.50;5.02)	5.21 (4.96;5.46)	–		**0.48 (0.21;0.75)**	–
Control group	4.56 (4.29;4.84)	5.02 (4.77;5.27)	–		**0.48 (0.21;0.74)**	–
Historic cohort	–	4.80 (4.53;5.06)	–		–	–
Intervention vs. control	–	–	1.27 (0.87;1.86)		–	0.00 (-0.38;0.38)
Control vs. historic	–	–	1.23 (0.84;1.77)*		–	–
Attitude score	Mean (CI)	Mean (CI)	Mean difference (CI)§		Mean (CI)	Mean (CI)
Intervention group	20.0 (19.2;20.8)	20.5 (19.7;21.2)	–		0.49 (-0.28;1.26)	–
Control group	20.2 (19.3;21.0)	19.9 (19.1;20.8)	–		−0.22 (-1.01;0.56)	–
Historic cohort	–	19.7 (19.0;20.4)	–		–	–
Intervention vs. control	–	–	0.33 (-0.80;1.45)		–	0.72 (-0.38;1.81)
Control vs. historic	–	–	0.32 (-0.76;1.41)*		–	–
Screening uptake		% (CI)	RD Uptake‡	RR Uptake‡		
Intervention group		34.7 (28.0;42.1)	–	–		
Control group		27.1 (20.9;34.4)	–	–		
Historic cohort		25.1 (19.5;31.7)	–	–		
Intervention vs. control		–	7.6 (-2.2;17.4)	1.28 (0.93;1.77)		
Control vs. historic		–	2.0 (-7.0;11.1)*	1.08 (0.76;1.52)*		
Worry score	Mean (CI)	Mean (CI)	Mean difference (CI)§		Mean (CI)	Mean difference (CI)§
Intervention group	9.2 (8.7;9.6)	8.8 (8.4;9.2)	–		−0.43 (-0.85;0.00)	–
Control group	9.0 (8.6;9.4)	8.9 (8.5;9.4)	–		−0.10 (0.59;0.39)	–
Historic cohort	–	9.0 (8.6;9.4)	–		–	–
Intervention vs. control	–	–	−0.13 (-0.73;0.48)		–	−0.33 (-0.97;0.32)
Control vs. historic	–	–	−0.07 (-0.66;0.52)*		–	–
Decisional conflict score	Mean (CI)	Mean (CI)	Mean difference (CI)§		Mean (CI)	Mean difference (CI)§
Intervention group		29.7 (27.4;32.0)				
Control group		33.2 (30.8;35.6)				
Historic cohort		36.4 (33.9;38.9)				
Intervention vs. control		–	−3.5 (-7.0;-0.0)			
Control vs. historic		–	−3.2 (-6.6;0.3)*			

RR = Relative risk; RD = Risk difference; OR = Odds ratio; CI = 95% confidence interval.
† Ordinal regression analysis, estimates in bold types are statistically significantly different from 1 ($p < 0.05$).
§ Linear regression analysis, estimates in bold types are statistically significantly different from 0 ($p < 0.05$).
* Analyses adjusted for age, gender, and population density.
‡ Binary regression model, RR estimates in bold types are statistically significantly different from 1 ($p < 0.05$). Likewise RD estimates in bold are statistically significantly different from 0 ($p < 0.05$).

attitudes. However, even though knowledge increased for all citizens invited to CRC screening, the decision aid had no specific effect on knowledge. Access to the decision aid was associated with a tendency towards somewhat more positive attitudes and increased uptake in CRC screening, but since the decision aid did not increase or decrease the level of knowledge, no overall effect on informed choice was shown.

Worries tended to decrease marginally and the level of decisional conflict was slightly reduced when compared with those without access to the decision aid.

The main strength of this study is the randomised controlled effectiveness design conducted in the existing Danish CRC screening programme. [41,42]

Although the baseline response rate was 62%, the differences in sociodemographic factors between respondents and non-respondents might cause selection bias if outcomes differ between the groups. However, since randomisation was performed after baseline responses, non-response is not associated with the intervention.

Receiving a baseline questionnaire before receiving the CRC screening invitation might affect the outcomes. This effect was illustrated by assessing the differences between the historic cohort and the control group, indicating a slight increase in knowledge, positive attitudes and uptake. This Hawthorne effect was similar across intervention and control groups, and is unlikely to have affected the differences in scores between the groups.

The fact that the decision aid was distributed in a separate mail may introduce uncertainty as to whether the tested intervention is in fact a second screening reminder, the decision aid or a combination of both. Based on this, some information bias cannot be ruled out, possibly affecting attitudes, uptake or worries (either increased or decreased), depending on the perception of the extra reminder as helpful and caring or annoying and over-informing.

It is a limitation of this study that power calculations were based on assumptions that were not met. We assumed that 47% [40] of lower educational attainment citizens would be eligible for having a screening reminder corresponding to data from the ongoing CRC screening program, but, this proportion was only 34–36%, indicating that those who filled in the baseline questionnaire were also those more likely to take up screening. Further, we expected that most (80%) baseline respondents receiving a follow-up questionnaire would complete it, but several citizens expressed difficulty understanding the necessity for completing two questionnaires. Thus, the response rate at follow-up of 57% contributed further to a decrease in statistical power.

The external validity of this study is considered acceptable, since the initial study sample was representative of the general Danish population of 53–74-year-olds due to random sampling.

All protocol outcomes have been presented, minimising reporting bias.

Previous studies have found an increase in the proportion of citizens making an informed choice when offered a decision aid. [11,13] We observed a similar increase in knowledge across groups, which could indicate that the national information material mailed to all citizens and the frequent mentioning of CRC screening in the media since 2014 have enhanced knowledge in the general Danish population. Knowledge was therefore not further increased by the decision aid. Attitudes towards CRC screening were generally

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positive, corresponding to an acceptable screening uptake (62.6%) in the Danish CRC screening programme. [42] Danish citizens have a high general trust towards the authorities [43], and expect that offers from the health authorities are beneficial [44]. However, several factors influence actual uptake of health offers, such as self efficacy, social norms and normative beliefs, feelings towards the offer and personal beliefs [45]. Therefore, the positive attitudes observed in this study may have contributed to a high screening uptake, but other factors are also important to reach even higher uptake levels. The tendency towards more positive attitudes and higher screening uptake among individuals having access to the decision aid might indicate that the decision aid can help citizens to act in accordance with their personal values. The observed tendencies are considered valid, but due to the wide confidence intervals the results should be interpreted with caution.

Effects of decision aids on CRC screening uptake are conflicting. A comparable Australian study using a paper-based decision aid [12], suggested no increased screening uptake, but a positive effect on screening uptake was observed in an American study comparing an interactive to a non-interactive web-based decision aid [16]. This may indicate that interactive web-based decision aids can have more impact on screening uptake than comprehensive paper-based versions, consistent with findings from a previous study demonstrating that some citizens find the latter too overwhelming. [44]

Decisional conflict decreased in the intervention group as compared to the control group. This is consistent with previous studies. [12,46] In general, the tendencies observed in this study are all small and they might be of limited clinical significance. However, considering the preventive paradox; that "a measure that brings large benefits to the community offers little to each participating individual" [47], the possible small shifts of the population means towards increased uptake, along with slightly more positive attitudes, and somewhat decreased decisional conflict and worries could be consistent with achieving public health benefits at population level.

Our results indicated that a web-based decision aid might be effective in increasing screening uptake in lower educational attainment citizens, perhaps particularly among citizens living alone compared with cohabitant or married citizens. Citizens living alone are a hard-to-reach group who participate less in CRC screening [48], and thus the support offered by a web-based decision aid could contribute to increasing uptake in this group. However, since the present study was not designed to investigate this association, and considering the several associations tested in table A3 (yielding 32 p-values), the possibility of this being a chance finding cannot be ruled out.

4.2. Practice implications

Implementing the decision aid requires only adding a link to the existing invitation or reminder letters and maintenance of and updating the decision aid. As such, it could represent a highly cost-effective intervention to achieve screening programme goals as assessed by screening uptake and elements and mediators of informed choice such as decisional conflict, attitudes and worries.

Further, the decision aid has been carefully developed, and is considered useful by citizens with lower educational attainment. [18] By implementing the decision aid instead of the conventional screening information, public goals of more patient-centred care and information could be easily achieved without adversely affecting the screening programme goals of participation thresholds.

The decision aid could easily be translated and implemented into other CRC screening programs, especially in countries where digital communication is the norm.

The study was underpowered and more research is still needed to investigate how best to approach citizens with lower educational attainment, regarding informed decision-making and CRC screening participation. Interventions that target the most deprived citizens (migrants, social welfare recipients, and low income citizens) should also be investigated further, including cost-effectiveness.

Further, the effects of the decision aid on citizens with medium or higher educational attainment should be investigated further.

4.3. Conclusions

The web-based decision aid tested in this study did not affect knowledge or informed choice. However, it may be able to contribute to an increase in screening uptake and some elements of informed choice, and as such contribute to an increase in screening programme effectiveness.

Implementation of a web-based decision aid could be effective and cost-effective upon development and further evaluation, especially in communities where digital communication is the norm.

Trial registration and approvals

The trial has been registered in ClinicalTrials.gov (NCT03253888) at 17. August 2017.

The collection of data from questionnaires and registries was permitted by The Danish Data Protection Agency (*J*.no.: 2012-58-006 / Case no.: 1-16-02-94-16). Ethical approval was evaluated by the Danish Patient Safety Authorities (*J*.no.: 3-313-1729-1) and the Central Denmark Region Committee on Health Research Ethics (143/2016). In both instances the study achieved clearance.

Author contributions

All authors contributed to the planning of the trial. The first author was in charge of the daily running of the data collection, with all authors involved in remedying unforeseen obstacles and decisions along the way. The first author had access to all data at all times, and conducted the data analyses. The statistics plan was agreed upon by all authors, and statistical guidance was obtained from a biostatistician. The first author drafted the first version of the manuscript in collaboration with the second author. All authors have contributed to the final manuscript subsequently. The guarantor of the paper is the first author.

All authors have had access to data outputs (reports and tables), and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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Sponsors and financial contributors have had no role in the planning, conducting, or reporting of the study. They also had no say in the decision to publish the results of the study.

Transparency statement

The first author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that

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no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Declaration of Competing Interest

None.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.pec.2019.08.029.

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