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Patient-rated importance of key information on screening colonoscopy in Germany

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Patient-rated importance of key information on screening colonoscopy in Germany

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Abstract

Introduction

Screening colonoscopy is considered to have great benefit but also has the potential to cause severe harm. This study aims to identify information on screening colonoscopy that patients view as particularly important for informed decision-making.

Methods

Members of a German health insurance company (age: 50-65) were asked to rate the importance of key information about screening colonoscopy using a questionnaire containing 15 questions on potential benefits, risks and side effects, baseline risk of colorectal cancer/polyps, and practical aspects of the procedure on a four-point scale. Subjects with prior colonoscopy were excluded. Data were stratified by sex and educational level. Logistic regression models were used to predict 'very important' ratings.

Results

Of 1,871 respondents (response rate: 31%), a subgroup of 370 colonoscopy-naïve subjects was eligible for inclusion (average age: 55 years, 47% male). While information on the risks was most frequently rated as very important, one quarter rated quantitative information on benefits as not important. Low-educated persons rated most information items as relevant more often than high-educated subjects. A greater proportion of women rated several items, particularly details regarding pain and practical aspects, as very important. Logistic regression analysis showed similar information needs between the groups and identified low-educated subjects living alone as the group with the least interest in information on risks.

Discussion

The predominant preference for information on risks reflects patients' desire to make informed decisions. A lack of numeracy skills may be responsible for the substantially lower interest in quantitative information on benefits. This should be addressed in future research as numeracy is essential for informed choice. The observed differences in information needs by sex and educational level suggest that tailoring information to these consumers may be warranted.

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Strength and limitations

- This study provides a unique insight into the self-reported importance of key information on screening colonoscopy of colonoscopy-naïve persons
- Multivariable analyses adjusted for several potentially associated factors enhance the validity of the results.
- Study population included members of one German statutory health insurance company; however, as 85% of Germans are covered by statutory health insurances, and German residents are largely free to choose between the companies, all of which offer very similar benefits and premium costs, our results are likely generalizable to German residents.

Introduction

Colorectal cancer (CRC) is one of the most common cancers, accounting for one-third of all newly diagnosed cases of cancer and 25% of all cancer-related deaths worldwide.[1] However, since colonoscopy has a high accuracy rate for detecting colorectal cancer, CRC is probably one of the best screenable cancer diseases. Moreover, endoscopic procedures have the potential to reduce not only CRC mortality but also CRC incidence.[2] However, their benefits are also associated with harms such as bleeding, perforation, or even death in rare cases. [3, 4]

Considering these risks, the question of whether or not to attend CRC screening and of which test to perform is a very preference-sensitive decision. Persons eligible for CRC screening should be able to make an informed decision based on knowledge about the specific benefits and risks of the procedure, including quantitative information and individual values.[5–7] In recent years, the demand for evidence-based, balanced, neutral information to support informed choice has been increasingly met in cancer screening guidelines.[8, 9] Germany will initiate a legally defined colorectal cancer screening program with screening information letters including explicit information on the benefits and risks of the procedure in order to enable patients to make an informed decision for or against CRC screening.[10] The fecal occult blood test and colonoscopy are currently the only two CRC screening tests covered under statutory insurance plans in Germany without additional payment. Since October 2002, insurees aged 55 and older have been eligible to receive a screening colonoscopy once every 10 years. [3]

Evidence-based health education often includes extensive information, but brief information may be more appropriate for some target groups and situations. The prioritization of content

is essential for providing short summaries such as option grids.[11] Following a patient-centered strategy, we explored the information needs of subjects entitled to attend CRC screening currently or in the future. The focus was on colonoscopy because of its higher benefit and risk potentials. Our goal was to collect systematic and detailed data on which specific information about colonoscopy subjects with no history of colonoscopy considered important and relevant, and to identify any potential differences between different groups in the study population. The results of this cross-sectional survey may contribute to the patient-centered development and revision of evidence-based decision aids on CRC screening, including information tailored according to the information needs of individual target groups.

Methods

In November 2015, randomly selected members of a large German statutory health insurance company (Barmer GEK) with 8.5 million members were sent a questionnaire survey of colonoscopy experience and information needs in subjects with and without a previous history of colonoscopy. 2,011,579 women and men aged 50 to 65 years were eligible. The random sample was stratified by age, sex and colonoscopy status to account for higher expected response rates in subjects with a history of colonoscopy. The sample of 6,000 individuals included subjects with a history of colonoscopy in the previous year from April 2014 to March 2015 (n=2,400) to minimize recall bias, as well as subjects with no documented history of colonoscopy in the available period from January 2010 to March 2015 (n=3,600) (Figure 1).

To address the informational needs of colonoscopy-naïve subjects, we included a subgroup of the whole survey population, i.e. those participants with no documented or self-reported history of prior colonoscopy (Figure 1). Subjects with a self-reported history of colorectal cancer were excluded because they do not belong to the target group for CRC screening, which addresses people with an average CRC risk.

The standardized questionnaire was sent by the insurance company to the selected members and could be returned to our research unit at Hannover Medical School directly. In order to minimize any inconvenience to their customers, the insurance company did not use reminders. The first page described the colonoscopy procedure and provided a schematic drawing showing the colon and the endoscope. The questionnaire was in German and included 51 questions on the patient's prior history of colonoscopy, experiences from the latest colonoscopy, the importance of key information about colonoscopy, history of cancer, and socio-demographic characteristics. To ensure comprehensibility, the questionnaire had been subjected to 10 cognitive pretests and modified accordingly. Data on the importance of key information were collected in 15 questions covering the following four categories:

- (1) Potential benefits (three items: reduction of incidence, reduction of mortality, removal of polyps);
- (2) Risks and side effects (five items: risks present, frequency of risks, chances of overlooking CRC, pain, side effects of laxatives);
- (3) Baseline risk of CRC/polyps (two items: risk of disease next 10 years, prevalence of polyps),
- (4) Practical aspects of the procedure (five items: laxative use, examination intervals, effect on driving ability, ability to work, sex of the endoscopist).

The chosen items were based on recommendations for evidence-based health information,[5] prior evaluations,[12] and on a list of criteria for evaluating consumer education material on colorectal cancer screening.[13] The response options were included on a four-point Likert scale with the response categories: very important, moderately important, relatively unimportant, very unimportant. The English translations of the questions are shown in Figure 2. Education level was classified according to the date of the final examination as low (after grade 9), intermediate (after grade 10), or high (after grade 12 or 13). Persons not born in Germany or whose father or mother was not born in Germany were said to have an 'immigrant background'.[14] Health literacy was assessed using the validated screening question: 'How confident are you filling out medical forms by yourself?'.[15]

Data were combined via a key variable with selected anonymous individual data from the insurance company. All data used for this analysis were derived from the questionnaire except for the subject's occupational status, which came from the insurance data set. Self-reported information on age, sex, and prior colonoscopy was validated by comparison with the health insurance data. All analyses were performed using IBM SPSS Statistics, version 24. Frequency analyses and cross tabulations were performed. Logistic regression modeling was performed for the outcomes/ratings 'very important' vs. 'other' for each of the 15 questions. All variables and interaction terms shown in a bivariate model to be associated with the outcome ($p < 0.25$) were included simultaneously. The following variables were initially considered: sex, age group, education, profession, health literacy, self-reported health, living alone, living in eastern/western Germany, immigrant background. The following interaction terms were tested: sex*education, sex*living alone, sex*self-reported health, and education*living alone. Other interaction terms were not included due to the low numbers of single cells. All statistical tests were two-sided. A p-value less than 0.05 was considered statistically significant.

While the response rate of the whole survey population was 31,8% (Figure 1), the proportion of persons without a prior colonoscopy of the whole survey population was unclear as information on documented prior colonoscopy from the insurance data was restricted to the

period from January 2010 to March 2015. Information on colonoscopy ever status was derived from documented and self-reported colonoscopy, the latter was necessary to cover the period before 2010 and between April 2015 and the time of the survey. From the preselected insurees without a documented colonoscopy (n=3,600), 21,6% (n=776) responded, thereof half of them reported a prior colonoscopy. The number of subjects without a prior colonoscopy within the initially preselected 3,600 insurees was unknown as the actual colonoscopy status of the non-responders remained unknown without the self-reported status. For that reason it was impossible to calculate a response rate or to do a non-responder-analysis. However, the best option for a group comparison was to include the initial preselected 3,600 insurees with no documented colonoscopy in the non-responder-analysis and thereby comparing available data from the insurance company (age, sex and 5-year-uptake of a biannually offered health check-up).

The study protocol was approved by the ethics committee of Hannover Medical School (Application No. 2918-2015). The study was conducted in cooperation with Bertelsmann Foundation (non-profit organization) und Barmer GEK, who paid for printing and postage of the questionnaires and for third-party data entry services. Barmer GEK sampled the study population according to our specifications and provided anonymous data on the study population. Precautions were taken to ensure that Barmer GEK could not de-anonymize their members' questionnaires by sending the questionnaire back to us, and we sent the questionnaire to the data entry service, which was not allowed to return data with IDs to Barmer GEK. The cooperation agreement ensured the authors independence in designing the study, interpreting the data, and writing and publishing the report.

Results

A total of 1,871 (31,8%) subjects completed the survey questionnaire. A subpopulation of 370 colonoscopy-naïve respondents was eligible for inclusion in this study (Figure 1). The response rate of this subpopulation remained unknown due to an unknown denominator (subgroup was based on criteria collected within the survey), which is explained in detail in the methods section. Comparison of the responders (n=776)/non-responders (n=3,586) of the initially sampled subjects with no documented colonoscopy showed no relevant differences in the mean age (responder/non-responder: 57,9/57,2 years) and proportion of sex (47,9/50,6%), but indicated a slightly higher uptake of a health check-up in the responder group (72/63%).

As shown in Table 1, the study population had an average age of 55 years, was 47% male, and had a high education level in more than 40% of cases. The vast majority (85%) perceived their health as good or better.

Most of the participants (60-93 %) rated the information as moderately or very important except for information on the sex of the endoscopist, which was important for only 27% (Figure 2). Information on the types and frequencies of risks and side effects was most frequently rated as being important, and was rated as not important by 6% and 10%, respectively. Further analysis showed that 7 items covering the categories 'risks and side effects' (4 of 5 items), baseline risks (1 of 2 items), practical aspects (1 of 5 items), and benefits (1 of 3 items) were perceived as the most important issues (very important for at least 50% of the population) (Figure 2). Key information on benefits, i.e., on how many cases of colorectal cancer or CRC-related deaths could be prevented by screening, was rated as 'very important' by 40% of the participants, and as either relatively or very unimportant by 26%. The analyses below focus on the information rated as 'very important'.

Stratification by sex and education showed variation in the 'very important' ratings. Women rated information as very important more often than men (Figure 3). The biggest differences were seen in information on risks, pain, laxative use, and driving ability after colonoscopy. Conversely, quantitative information on issues like the frequency of risks and polyps and the number of lives saved and deaths prevented seems to be equally important for both sexes. The ratings also varied according to educational level. Persons with high education levels rated most of the information as being less important than those with intermediate or low levels of school education (Figure 4). No significant gender and education differences were detected for information on the risks of colonoscopy ($p=0.063$) or the number of cases of CRC that could be prevented by colonoscopy screening ($p=0.055$). Absolute ranking of the importance of the information yielded very similar results.

Table1: Characteristics of the study population (n=370)

Characteristics	Categories	n	%
Age, years (n=368)	50-54	162	44,0
	55-59	129	35,1
	60-64	77	20,9
Sex (n=368)	Male	173	47,0
	Female	195	53,0
Education level (n=362)	High	152	41,1
	Intermediate	133	36,7
	Low	77	21,3
Employment status (n=325)	White-collar worker	158	48,6
	Blue-collar worker	61	18,8
	Unemployed	24	7,4
	Retired	38	11,7
	Self-employed	29	8,9
	Other	15	4,6
Household size (n=359)	1 person	51	14,2
	2 persons	188	52,4
	3 persons	64	17,8
	>3 persons	56	15,6

City of residence, inhabitants (n=357)	<5,000	118	33,1
	5,000-20,000	77	20,8
	20,000-100,000	81	22,7
	>100,000	81	22,7
Region (n=362)	Eastern Germany	94	26,0
	Western Germany	268	74,0
Immigrant background (n=364)	Yes	40	11,0
Self-reported health (n=360)	Excellent	18	5,0
	Very good	112	31,1
	Good	183	50,8
	Not so good	36	10,0
	Poor	11	3,1
Health literacy (n=362)	Extremely or very confident	261	72,1
	Moderately/slightly or/not at all confident	101	27,9
History of cancer? (n=365)	Yes	26	7,1
First-degree relatives with CRC? (n=365)	Yes	31	8,5
Related persons with cancer? (n=365)	Yes	226	61,9

Logistic regression models adjusted for further characterization of factors associated with a ranking of 'very important' produced results very similar to those of the stratified analyses, showing that sex and education were the main associated factors (Table 2). In addition to sex and education, the final models included the variables 'living alone', 'self-reported health', 'age group', 'living in eastern or western Germany' and/or the interaction term 'education*living alone'. Deviating from the stratified analyses, the perceived importance of information on risks and side effects was higher than expected in the low education group compared to the high education group, while the intermediate education group considered numeric information on the benefits (e.g. the number of cases of bowel cancer or death that could be prevented) more often as very important than the high education group. Low-educated subjects living alone were significantly less interested in information on the types and frequencies of screening risks (See interaction terms in table 2). This association is illustrated in Figure 5. Further stratification to characterize this group more accurately was not feasible due to the low number of cases. When adjusted for the other variables, health literacy, age and self-reported health were not associated with importance ratings.

Table 2: Factors associated with ‘very important’ ratings of specific information about screening colonoscopy as identified by multivariable logistic regression analysis. Numbers represent odds ratios and their 95% confidence intervals.

		How important to you personally is information on:						
		Risks and side effects of colonoscopy?	Incidence of risks and side effects?	Whether bowel cancer might be overlooked by colonoscopy?	Whether polyp removal makes sense?	Your risk of getting bowel cancer within the next 10 years?	Whether the examination is painful?	How to take laxatives to prepare for colonoscopy?
n	(Percentage of study population included)	339 (91.6)	333 (90.0)	337 (91.1)	332 (89.7)	337 (91.1)	336 (90.8)	332 (89.7)
Sex	Female vs. male (Ref.)	2.24 (1.34-3.74)**	0.74 (0.34-1.58)	1.4 (0.86-2.28)	1.25 (0.77-2.04)	1.40 (0.87-2.27)	2.33 (1.47-3.70)***	1.98 (1.26-3.13)**
Age (years)	50-54 vs. 55-65 (Ref.)	1.47 (0.88-2.48)	0.97 (0.61-1.55)	1.06 (0.67-1.68)	1.53 (0.96-2.43)	1.18 (0.75-1.84)	1.45 (0.92-2.29)	1.05 (0.67-1.65)
Education	Low	4.06 (1.63-10.09)**	3.93 (1.79-8.62)***	2.76 (1.37-5.54)**	2.65 (1.30-5.41)**	2.13 (1.13-4.0)*	1.89 (1.0-3.57)*	2.39 (1.20-4.75)*
	Intermediate	1.41 (0.78-2.55)	1.57 (0.90-2.75)	1.90 (1.09-3.31)*	1.51 (0.87-2.61)	1.78 (1.07-2.97)*	1.94 (1.15-3.27)*	1.60 (0.92-2.78)
	High (Ref.)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Household size	Living alone vs. not living alone (Ref.)	1.88 (0.63-5.68)	1.40 (0.53-3.68)	0.39 (0.10-1.57)	0.50 (0.14-1.81)	0.54 (0.22-1.33)	0.73 (0.38-1.41)	0.75 (0.29-1.99)
Immigrant background	Yes vs. no (Ref.)	1.05 (0.47-2.38)	1.22 (0.59-2.54)	0.77 (0.36-1.63)	1.16 (0.56-2.42)	1.23 (0.60-2.52)	0.73 (0.34-1.55)	1.21 (0.59-2.49)
Self-reported health	Good/less vs. very good/excellent (Ref.)	1.44 (0.83-2.49)	0.90 (0.43-1.87)	1.69 (1.03-2.79)*	1.31 (0.80-2.16)	1.13 (0.70-1.84)	1.36 (0.83-2.24)	0.96 (0.58-1.59)
Region	Eastern vs. western (Ref.)	0.67 (0.37-1.19)	0.83 (0.48-1.41)	0.58 (0.34-0.99)*	0.65 (0.38-1.10)	0.73 (0.43-1.23)	0.82 (0.48-1.41)	0.75 (0.44-1.29)
Health literacy	Confident vs. slightly confident/not confident (Ref.)	1.14 (0.62-2.09)	0.77 (0.44-1.33)	0.80 (0.47-1.38)	1.06 (0.62-1.84)	1.31 (0.77-2.21)	1.31 (0.77-2.23)	1.04 (0.61-1.76)
Interaction terms								
Living alone* education	Living alone*intermediate	0.76 (0.12-4.43)	0.88 (0.20-3.99)	2.66 (0.50-14.26)	2.69 (0.55-13.22)			1.28 (0.30-5.52)
	Living alone*low	0.02 (0.00-0.15)***	0.04 (0.01-0.28)***	0.36 (0.05-2.54)	0.18 (0.02-1.33)			0.10 (0.01-1.02)
Sex*self-reported health			1.81 (0.69-4.75)					
Sex*living alone				3.13 (0.70-13.99)	2.01 (0.47-8.50)	2.99 (0.79-11.25)		

Table 2 (Cont.): Factors associated with 'very important' ratings of specific information about screening colonoscopy as identified by multivariable logistic regression analysis. Numbers represent odds ratios and their 95% confidence intervals.

		How important to you personally is information on:							
		Incidence of polyps?	Number of cases of bowel cancer that could be prevented by attending colonoscopy regularly?	Number of deaths from bowel cancer that could be prevented by attending colonoscopy regularly?	Recommended intervals between colonoscopies?	Whether laxative prep is unpleasant?	Whether you can go home on your own after the procedure?	Whether you will be able to work on the day of the procedure?	Whether the endoscopist is male or female?
n	(Percentage of study population included)	329 (88.9)	330 (89.2)	331 (89.5)	332 (89.7)	331 (89.5)	329 (88.9)	263 (92.6)	329 (90.0)
Sex	Female vs. male (Ref.)	1.09 (0.68-1.74)	0.80 (0.50-1.26)	1.01 (0.63-1.59)	1.08 (0.65-1.78)	2.26 (0.98-5.19)	2.53 (1.50-4.28)***	1.79 (0.99-3.23)	1.89 (0.95-3.74)
Age (years)	50-54 vs. 55-65 (Ref.)	0.98 (0.62-1.57)	0.88 (0.56-1.39)	0.79 (0.50-1.26)	1.76 (1.10-2.81)*	1.10 (0.68-1.77)	1.77 (1.07-2.92)*	1.70 (0.95-3.06)	1.85 (0.95-3.57)
Education	Low	5.27 (2.59-10.72)***	1.56 (0.83-2.95)	1.76 (0.94-3.30)	2.10 (1.09-4.01)*	2.60 (0.96-7.06)	2.72 (1.33-5.57)**	2.53 (1.13-5.66)*	1.64 (0.68-3.95)
	Intermediate	2.10 (1.18-3.73)*	1.89 (1.11-3.20)*	1.77 (1.04-3.01)*	1.96 (1.13-3.40)*	3.66 (1.45-9.24)**	3.18 (1.75-5.79)***	1.46 (0.74-2.87)	0.81 (0.37-1.80)
	High (Ref.)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Household size	Living alone vs. not living alone (Ref.)	1.69 (0.63-4.57)	0.78 (0.40-1.52)	0.77 (0.39-1.50)	0.70 (0.26-1.88)	0.99 (0.33-3.00)	0.81 (0.38-1.76)	0.29 (0.10-0.88)*	1.04 (0.40-2.73)
Immigrant background	Yes vs. no (Ref.)	1.10 (0.52-2.33)	1.34 (0.63-2.79)	1.31 (0.63-2.74)	1.49 (0.69-3.25)	0.88 (0.42-1.85)	0.86 (0.39-1.90)	0.94 (0.36-2.41)	1.69 (0.47-6.0)
Self-reported health	Good/less vs. very good/excellent (Ref.)	1.03 (0.62-1.72)	1.39 (0.84-2.30)	1.70 (1.02-2.82)*	1.22 (0.72-2.04)	1.30 (0.77-2.22)	1.11 (0.63-1.96)	1.25 (0.66-2.38)	2.75 (1.21-6.21)*
Region	Eastern vs. western (Ref.)	1.10 (0.64-1.90)	0.97 (0.57-1.67)	1.09 (0.63-1.87)	0.73 (0.42-1.29)	0.89 (0.51-1.57)	0.91 (0.49-1.66)	0.69 (0.34-1.42)	1.38 (0.64-2.99)
Health literacy	Confident vs. slightly confident/not confident (Ref.)	0.67 (0.38-1.16)	0.65 (0.38-1.11)	0.59 (0.34-1.01)	0.90 (0.52-1.57)	1.04 (0.60-1.80)	1.33 (0.75-2.35)	1.39 (0.72-2.68)	0.61 (0.27-1.35)
Interaction terms									
Living alone* education	Living alone*intermediate	2.42 (0.50-11.67)				1.43 (0.30-6.88)			
	Living alone*low	0.04 (0.00-0.38)**				0.15 (0.01-1.71)			
Sex*self-reported health									
Sex*living alone					3.26 (0.82-12.92)				

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All models included the following variables: sex, age, education, migration background, self-reported health, eastern/western Germany, household size, health literacy; bold numbers represent p-values ≤ 0.05 ; * $p \leq 0.05$ ** $p \leq 0.01$ *** $p \leq 0.001$; Interaction terms are presented when included into the model; Ref.: reference group

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Discussion

Our survey of the perceived need for information on screening colonoscopy among 370 German health insurance company members with no prior history of colonoscopy showed that the vast majority rated information on all but one item as being moderately or very important. While information on the risks and side effects of screening was most frequently rated as very important, roughly a quarter of the respondents rated information on screening benefits as not important. The ratings differed by sex and education level. Women more often viewed most of the items as being very important, especially information on risks (e.g., pain) and practical aspects of the procedure. Generally, less educated subjects more frequently rated nearly all of the information as being important, but a significantly higher percentage of low-educated people living alone rated information on the types and frequencies of screening risks as being less important.

One of the main pillars of informed decision-making is information on risks.[5, 6] The predominant focus of patient interest on information about the potential risks and side effects of colonoscopy screening underscores the fact that people want to be able to make informed decisions. This has particularly important implications in Germany, where a systematic evaluation of the available print information on CRC showed that nearly one-third of all information materials investigated failed to mention basic information on potential harms associated with CRC screening.[16] The DECISIONS survey of U.S. adults aged 50 and older yielded similar results: Almost 30% of women and men surveyed said that their health care providers did not discuss any of the cons of CRC screening with them, while over 95% said that they had discussed the pros.[17] Further effort is needed to empower patients to make informed decisions by providing health communication with appropriate information on all relevant factors, including the risks of CRC screening. The consumers seem to agree.[18]

In contrast, 26% of subjects perceived key information on the benefits of screening (e.g., on the potential of screening to reduce the incidence and mortality of CRC) as unimportant. This suggests a clear lack of understanding of the gist of screening in a substantial part of the population, as has already been described in the literature.[19] Several factors may be responsible for this. First, the benefits of a screening examination are assumed as given or overestimated by many people.[20, 21] Second, consumers might assume that all examinations covered by their health insurance companies are beneficial. Third, the item used to rate the importance of the potential of screening to reduce the incidence and mortality of CRC was presented in quantitative terms describing absolute risk reduction, i.e., 'the number of bowel cancer-related deaths that could be prevented by regular colonoscopy screenings'. Subjects with low numeracy may perceive quantitative information as less important because of their inability to understand these statistics.[22] We did not measure

numeracy skills directly but used educational level as a surrogate.[23] Although the final models for the respective questions did not fully support our assumption, subjects with lower education levels tended to regard quantitative information as less important than other types of information. Fourth, goal framing might be present due to the use of a gain message (e.g., the number of deaths that could be prevented by regular screening) instead of a loss message (e.g., the number of deaths that will occur due to failure to attend screening). Loss messages are shown to be associated with a more positive perception of the effectiveness of a procedure.[24] Therefore, the framing of information on the benefits of screening colonoscopy as a loss message might have resulted in a higher rating of the importance of information on screening benefits.

To our knowledge, the only available study that examines the patient-rated importance of information on colorectal cancer was conducted in the USA.[25] Similarly to our results, the highest rating of 'very important' was predominant even though the American colleagues used a 7-point scale. More than 80% of their participants rated 4 of 5 types of information as 'very important', including information on the purpose of screening (type of screening disease), followed by the pros and cons, test accuracy, and alternative tests. No data was provided on differences in the prevalence of 'very important' ratings between the different groups.

Women in our study showed higher information needs than men. This might be partially due to different strategies to overcome their fears. In a study using focus groups interviews, woman demanded more information in terms of both quantity and detail, while men preferred little or no information on endoscopic procedures.[26] Furthermore, women in our study seemed to consider quantitative information (frequency of polyps, risks, number of CRC cases and deaths that could be prevented) as less important than the other types of information. Studies suggest that this might be partly explained by lower numeracy skills in women than men.[27, 28] Numeracy skills are, however, crucial to understanding quantitative information which, in turn, is essential to informed decision-making. [29] Pictographs are increasingly being used in patient decision aids on cancer screening in Germany.[30] This may help to improve patient understanding of important quantitative messages in screening information.[31–33]

We detected significantly higher information needs in less educated groups. Similarly, a study on information needs in cancer patients using a 5-point scale to measure importance also showed that a low educational level is associated with higher information needs.[34] Likewise, this might be due to lower levels of knowledge about CRC screening in low-education versus high-education groups. As in our study, health literacy was not associated with information needs.[34] However, other studies have shown that people with high health

literacy have lower information needs,[35] and that health literacy is positively associated with educational level.[22]

Our results suggest that, as a group, low-educated subjects living alone are clearly less interested in information on the risks and side effects of screening colonoscopy. Apparently, they are not interested in making an informed decision or are unable to do so for low health literacy reasons. Living alone might serve as a surrogate for an increased risk of social isolation and low social support. Thus, this group is likely to be the most vulnerable group with the highest health risks.[36] However, we could not ascertain the actual screening behavior of this group based on the available data. Besides, results on living alone must be interpreted with caution because of the low case number. Future research is needed to obtain deeper insights into the contrasting information needs of low-educated people living alone, who may constitute an important risk group.

This study has some limitations and potential constraints, which are discussed below. First, the study population consisted solely of persons with Barmer GEK statutory health insurance, who might not be representative of the German population at large. However, we think that this can be assumed to a great extent for two reasons: A) 85% of Germans are covered by statutory health insurance (and most of the rest by private insurance), and B) Since 1996, German residents are largely free to choose between health insurance companies, all of them offer very similar benefits and charge similar premiums. Second, analysis was restricted to the subgroup of colonoscopy-naïve subjects. This was explained by the fact that the target group for evidence-based information about colonoscopy screening comprises above all people who have not yet experienced this examination. Third, as the insurance data did not provide the lifetime colonoscopy status, our final study population was based on self-reported status, which made it impossible to identify the denominator in the initial sample of our study population. Without a precise denominator, the response rate and potential differential response remained unknown. With the non-responder-analysis we did instead as a substitute, we cannot exclude a substantial selection bias. However, the proportion of participation is not necessarily associated with the magnitude of bias. [37] Besides, a response bias is mainly restricted to the prevalence of exposures or outcomes, while associations are only affected, if the response is both associated with exposure and outcome. The risk of misclassification of the self-reported colonoscopy status (i.e. confusion with other endoscopic procedures) was considered low, as the questionnaire included a description of the procedure and knowledge about colonoscopy is common because screening colonoscopy had been introduced for more than ten years. Fourth, the fact that subjects rated most items as either very or moderately important and almost never as 'very unimportant' indicates that the four-point scale of importance may have resulted in a ceiling

effect. Nevertheless, all of the response options were used by the respondents, and the fact that most respondents considered the sex of the endoscopist to be relatively unimportant by most respondents shows that they were able to discriminate across the different types of information. In further analyses, the responses were dichotomized to 'very important' vs. 'other'. Focusing on the 'very important' ratings in this manner allowed us to detect relevant differences. Fifth, we did not include information on overdiagnosis as a potential harm. Although this is a huge problem in PSA testing for prostate cancer screening, there is probably little overdiagnosis associated with screening colonoscopy.[38] Sixth, the models on the associated factors of the attributed importance of specific information about screening colonoscopy may suffer from residual confounding.

Even in light of these potential limitations, the findings of this study are important because they demonstrate that roughly three-quarters of the population regarded information on the risks and side effects of screening colonoscopy as being very important. Surprisingly, one-quarter of respondents considered data on the potential benefits of screening, which is essential for making an informed decision, to be unimportant. A lack of numeracy skills may have contributed this outcome. Therefore, future health information and communication should convey such statistics in an easily comprehensible manner. Moreover, tailoring future information according to gender-specific needs may be warranted in light of the observed differences in information preferences between women and men. Especially the high demand of less educated people to become informed provides a strong motivation for further efforts to tackle the challenge of designing evidence-based information materials that adequately inform this population, and enable them to make informed decisions regarding screening colonoscopy.

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Contributorship:

MD, KK, and UW developed the conception and design of the study. MD and KK analysed and interpreted the data, and drafted the manuscript. MD, KK, and UW revised the work critically for intellectual content. All authors approved the final version of the manuscript and are accountable for all aspects of the work.

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Figure 1: Flow chart of the study population

Figure 2: Importance of key information about screening colonoscopy (n=354-365)

*Responses from employed persons only (n=279)

Figure 3: Importance of key information about screening in women and men (n=352-363)

* Responses from employed persons only (n=279)

Figure 4: Importance of key information about screening colonoscopy by educational level (n=346-357)

* Responses from employed persons only (n=278)

Figure 5: Information on risks and side effects of colonoscopy – Percentage of 'very important' ratings stratified by sex, education level and household size (n=353)

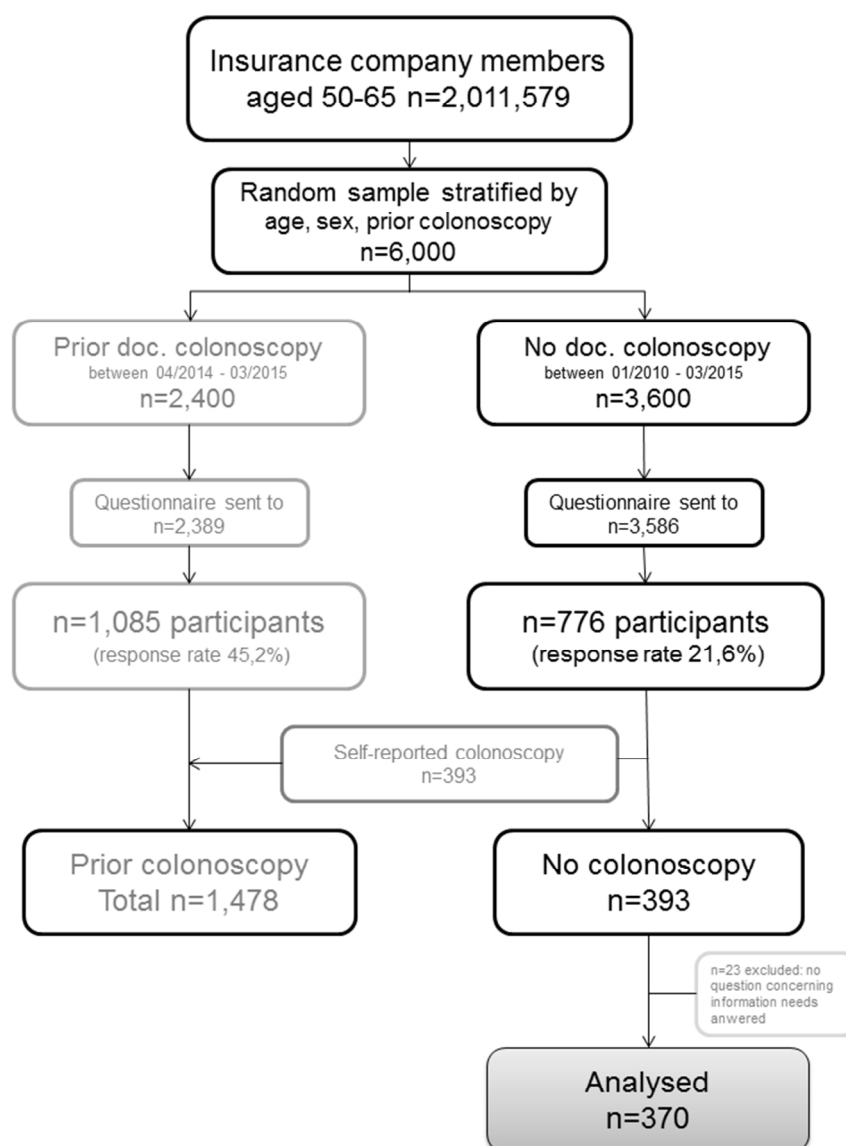


Figure 1: Flow chart of the study population

190x254mm (96 x 96 DPI)

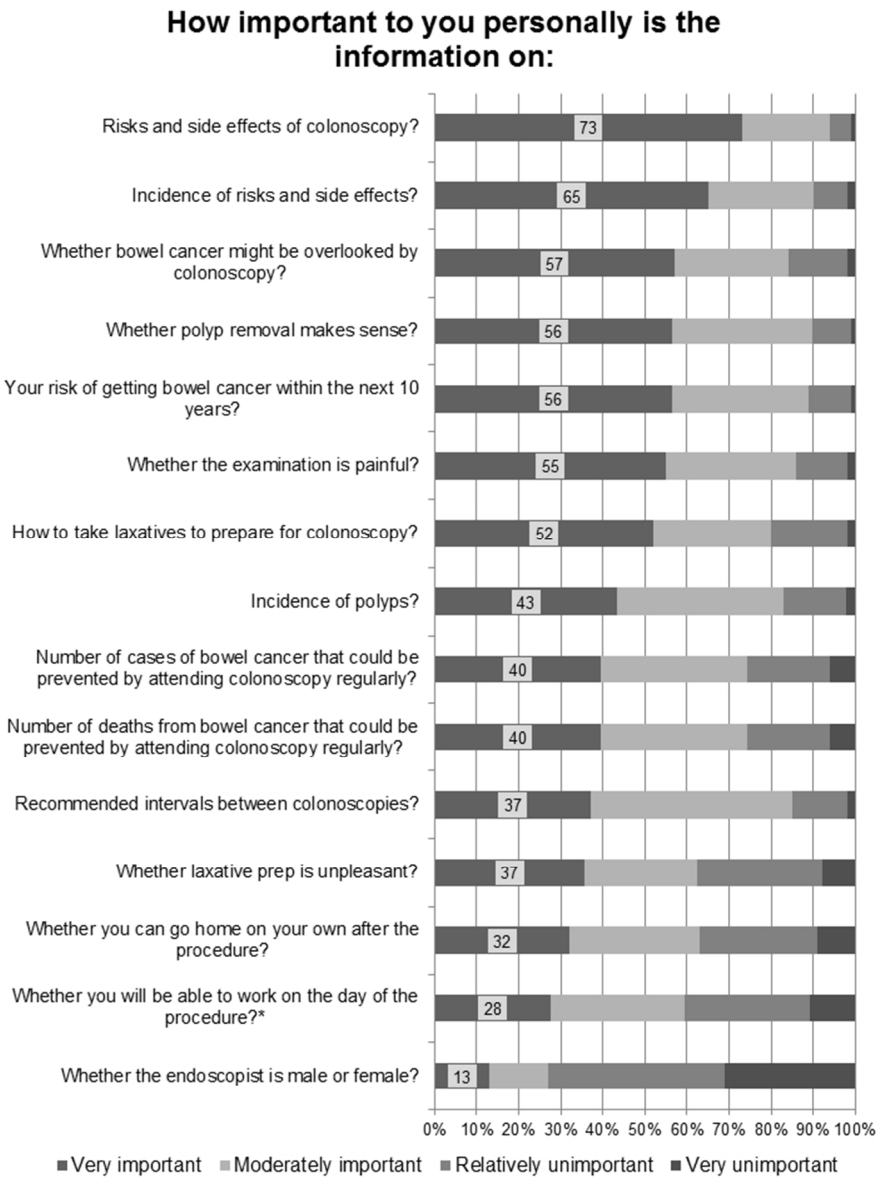


Figure 2: Importance of key information about screening colonoscopy (n=354-365)

190x254mm (96 x 96 DPI)

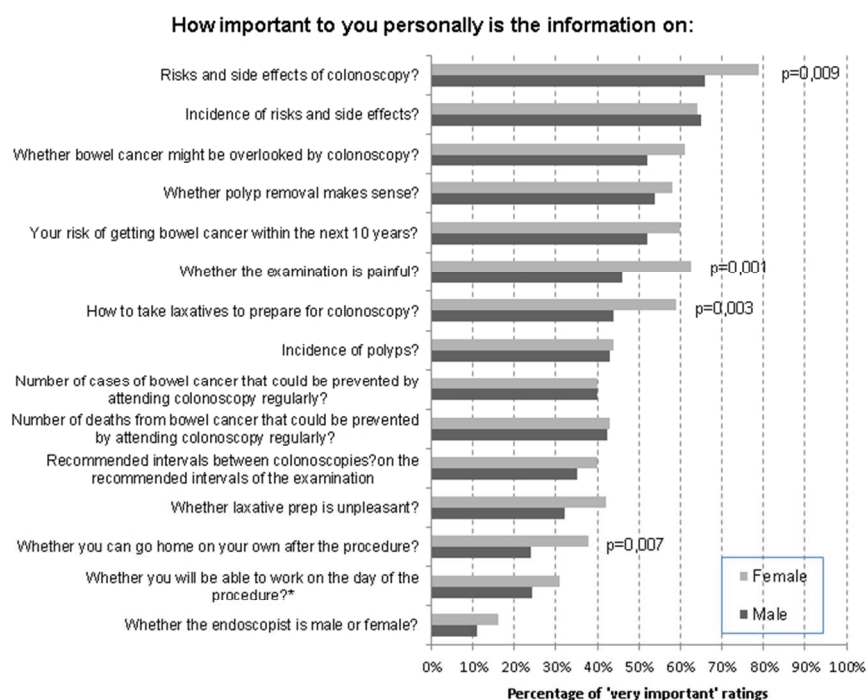


Figure 3: Importance of key information about screening in women and men (n=352-363)

190x254mm (96 x 96 DPI)

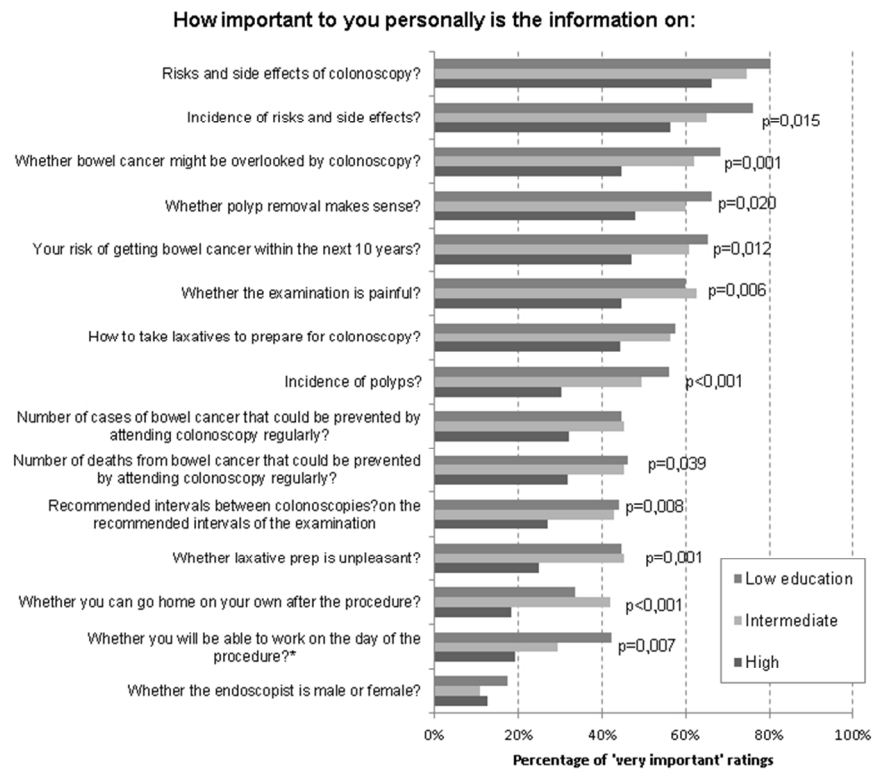


Figure 4: Importance of key information about screening colonoscopy by educational level (n=346-357)

190x254mm (96 x 96 DPI)

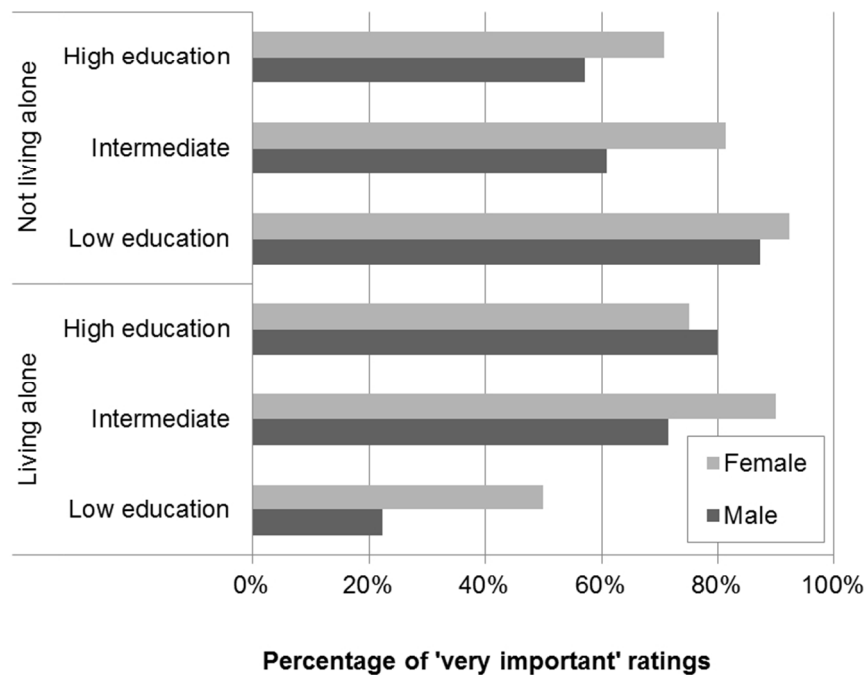


Figure 5: Information on risks and side effects of colonoscopy – Percentage of 'very important' ratings stratified by sex, education level and household size (n=353)

254x190mm (96 x 96 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Met?
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Yes
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	yes
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	yes
Objectives	3	State specific objectives, including any prespecified hypotheses	yes
Methods			
Study design	4	Present key elements of study design early in the paper	Yes
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Yes
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Yes
		<i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	
		<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed	n.a.
		<i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes
Bias	9	Describe any efforts to address potential sources of bias	Yes
Study size	10	Explain how the study size was arrived at	Yes

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Yes
		(b) Describe any methods used to examine subgroups and interactions	Yes
		(c) Explain how missing data were addressed	Yes
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	Yes
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	
		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	n.a.
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Yes
		(b) Give reasons for non-participation at each stage	Yes
		(c) Consider use of a flow diagram	Yes
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Yes
		(b) Indicate number of participants with missing data for each variable of interest	Yes
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	n.a.
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	Yes
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes
		(b) Report category boundaries when continuous variables were categorized	Yes
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n.a.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Yes

Discussion			
Key results	18	Summarise key results with reference to study objectives	Yes
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes
Generalisability	21	Discuss the generalisability (external validity) of the study results	Yes
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes

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Patient-rated importance of key information on screening colonoscopy in Germany

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Patient-rated importance of key information on screening colonoscopy in Germany – a survey of German statutory health insurance members

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Abstract

Background

Primary screening with colonoscopy is considered to have great benefit but also has the potential to cause severe harms. Thus, eligible subjects should be supported to make an informed choice whether or not to participate.

Objectives

To identify information on screening colonoscopy that subjects, who have not yet experienced a colonoscopy, rate as particularly important for decision-making.

Design

Survey of German statutory health insurance members using a written questionnaire in November 2015.

Study population Colonoscopy-naïve individuals aged 50 to 65 years.

Main outcome measures Importance of key information about screening colonoscopy including potential benefits, risks and side effects, baseline risk of colorectal cancer/polyps, and practical aspects of the procedure, as well as associations between participants' characteristics and 'very important' ratings on these information.

Results

Of 1,871 respondents (overall response rate: 31%), a subgroup of 370 colonoscopy-naïve subjects was eligible for inclusion (average age: 55 years, 47% male). While information on the risks was most frequently rated as very important, 26% rated quantitative information on benefits as unimportant. Regression analysis showed that low educated persons regarded most items more often as being relevant than high educated subjects. A greater proportion of women compared to men rated several items, particularly details regarding pain and practical aspects, as being very important. Low educated subjects living alone were identified as the group with the least interest in information on risks.

Conclusion

The awareness of the central meaning of the (quantitative) benefits of screening in informed decision-making should be strengthened in future information materials. The high demand of less educated people to become informed provides a strong motivation for further efforts to develop evidence-based information that adequately inform this group. Tailoring information

according to gender-specific needs may be warranted in light of the observed differences in information preferences between women and men.

Strength and limitations

- This study provides an unique insight into the self-reported importance of key information needs on screening colonoscopy of colonoscopy-naïve persons
- Multivariable analyses adjusted for several potentially associated factors enhance the validity of the results.
- Study population included members of one German statutory health insurance company; however, as 85% of Germans are covered by statutory health insurances, and German residents are largely free to choose between the companies, all of which offer very similar benefits and premium costs, our results are likely generalizable to German residents.

Introduction

Colorectal cancer (CRC) is one of the most common cancers, accountable for one-third of all newly diagnosed cases of cancer and 25% of all cancer-related deaths worldwide.[1] However, since colonoscopy has a high accuracy rate for detecting colorectal cancer, CRC is probably one of the best screenable cancer diseases. Moreover, endoscopic procedures have the potential to reduce not only CRC mortality but also CRC incidence.[2] However, their benefits are also associated with adverse events such as bleeding (5 per 10,000), perforation (8 per 10,000), or even death in very rare cases.[3, 4]

Considering these risks, the question of whether or not to attend CRC screening and of which test to perform is a very preference-sensitive decision. Persons eligible for CRC screening should be able to make an informed decision based on knowledge about the specific benefits and risks of the procedure, including quantitative information to realize their extent in absolute frequencies, and individual values.[5–7] In recent years, the demand for evidence-based, balanced, neutral information to support informed choice has been increasingly included in cancer screening guidelines.[8, 9] Germany will initiate a legally defined colorectal cancer screening program with screening information letters including explicit information on the benefits and risks of the procedure in order to enable patients to make an informed decision for or against CRC screening.[10] The fecal immunochemical testing and colonoscopy are currently the only two CRC screening tests covered under

statutory insurance plans in Germany without additional payment. Since October 2002, insurees aged 55 and older have been eligible to receive a colonoscopy for primary screening once every 10 years.[3] Primary screening colonoscopy is currently offered in Austria, Czech Republic, Poland, Switzerland and the USA.[11]

Evidence-based health education often includes extensive information, whereas brief information may be more appropriate for some target groups and situations. The prioritization of content is essential for providing short summaries such as option grids.[12] Following a patient-centered strategy, we explored the information needs of subjects entitled to attend CRC screening currently or in future. The focus was on colonoscopy because of its higher benefits and risk potentials.[13] Our goal was to systematically collect detailed data on which specific information about colonoscopy subjects with no history of colonoscopy considered important and relevant, and to identify any potential differences between different groups in the study population. Colonoscopy-naïve subjects were chosen, because having experienced a colonoscopy could affect the importance rating. The results of this cross-sectional survey may contribute to the patient-centered development and revision of evidence-based decision aids on CRC screening, including information tailored according to the information needs of individual target groups.

Methods

In November 2015, randomly selected members of a large German statutory health insurance company (Barmer GEK) with 8.5 million members were sent a questionnaire survey of colonoscopy experience and information needs in subjects with and without a previous history of colonoscopy. 2,011,579 women and men aged 50 to 65 years were eligible. The random sample was stratified by age, sex and colonoscopy status to account for higher expected response rates in subjects with a history of colonoscopy. The sample of 6,000 individuals included subjects with a history of colonoscopy in the previous year, respectively, from April 2014 to March 2015 (n=2,400) to minimize recall bias, as well as subjects with no documented history of colonoscopy in the available period from January 2010 to March 2015 (n=3,600) (Figure 1).

To address the information needs of colonoscopy-naïve subjects, we included a subgroup of the whole survey population, i.e. those participants with no documented or self-reported history of prior colonoscopy (Figure 1). Subjects with a self-reported history of colorectal cancer were excluded, because they do not belong to the target group for CRC screening, which addresses people with an average CRC risk.

The standardized questionnaire was sent by the insurance company to the selected members and could be returned to our research unit at Hannover Medical School. In order to

minimize any inconvenience to their customers, the insurance company did not use reminders. The first page described the colonoscopy procedure and provided a schematic drawing showing the colon and the endoscope. The questionnaire was in German and included 51 questions on the patient's prior history of colonoscopy, experiences from the latest colonoscopy, the importance of key information about colonoscopy history of cancer, and socio-demographic characteristics. To ensure comprehensibility, the questionnaire had been subjected to 10 cognitive pretests and modified accordingly. Participants of the pretests 'were 23-75 years old, among them were 3 experts, 6 females, 5 were colonoscopy-naïve, and 3 less educated. Data on the importance of key information were collected in 15 questions covering the following four categories:

- (1) Potential benefits (three items: reduction of incidence, reduction of mortality, removal of polyps);
- (2) Risks and side effects (five items: risks present, frequency of risks, chances of overlooking CRC, pain, side effects of laxatives);
- (3) Baseline risk of CRC/polyps (two items: risk of disease next 10 years, prevalence of polyps),
- (4) Practical aspects of the procedure (five items: laxative use, examination intervals, effect on driving ability, ability to work, sex of the endoscopist).

The chosen items were based on recommendations for evidence-based health information,[5] prior evaluations,[14] and on a list of criteria for evaluating consumer education material on colorectal cancer screening.[15] The response options were included in a four-point Likert scale with the response categories: very important, moderately important, relatively unimportant, very unimportant. The English translations of the questions are shown in Figure 2. Education level was classified according to the date of the final examination as low (after grade 9), intermediate (after grade 10), or high (after grade 12 or 13). Persons not born in Germany or whose father or mother was not born in Germany were said to have an 'migrant background'.[16] Health literacy was assessed using the validated screening question: 'How confident are you filling out medical forms by yourself?'.[17]

Data were combined via a key variable with selected anonymous individual data from the insurance company. All data used for this analysis were derived from the questionnaire except for the subject's occupational status, which came from the insurance data set. Self-reported information on age, sex, and prior colonoscopy was validated by comparison with the health insurance data. All analyses were performed using IBM SPSS Statistics, version 24. Frequency analyses and cross tabulations were performed. Multivariable logistic regression modeling was performed to identify associations between the participants' characteristics and the outcomes/ratings 'very important' vs. 'other' for each of the 15

questions. The following variables were included: sex, age group, education, profession, health literacy, self-reported health, household size, living in eastern/western Germany, migrant background. The following interaction terms were tested: sex*education, sex*household size, sex*self-reported health, and education*household size. Other interaction terms were not included due to the low numbers of single cells. Interaction terms shown to be associated with the outcome below $p < 0.25$ were included; otherwise the number of terms would have been too high. All statistical tests were two-sided. A p-value less than 0.05 was considered statistically significant.

While the response rate of the whole survey population was 31.8% (Figure 1), the proportion of persons without a prior colonoscopy of the whole survey population was unclear as information on documented prior colonoscopy from the insurance data was restricted to the period from January 2010 to March 2015. Information on colonoscopy ever status was derived from documented and self-reported colonoscopy, the latter was necessary to cover the period before 2010, as well as between April 2015 and the time of the survey. From the preselected insurees without a documented colonoscopy ($n=3,600$), 21.6% ($n=776$) responded, thereof half of them reported a prior colonoscopy. The number of subjects without a prior colonoscopy within the initially preselected 3,600 insurees was unknown as the actual colonoscopy status of the non-responders remained unknown without the self-reported status. For that reason it was impossible to calculate a response rate or to do a non-responder-analysis. However, the best option for a group comparison was to include the initial preselected 3,600 insurees with no documented colonoscopy in the non-responder-analysis and thereby comparing available data from the insurance company (age, sex and 5-year-uptake of a biannually offered health check-up).

The study protocol was approved by the ethics committee of Hannover Medical School (Application No. 2918-2015). The study was conducted in cooperation with Bertelsmann Foundation (non-profit organization) und Barmer GEK, who paid for printing and postage of the questionnaires and for third-party data entry services. Barmer GEK sampled the study population according to our specifications and provided anonymous data on the study population. Precautions were taken to ensure that Barmer GEK could not de-anonymize their members' questionnaires by sending the questionnaire back to us, and we sent the questionnaire to the data entry service, which was not allowed to return data with IDs to Barmer GEK. The cooperation agreement ensured the authors independence in designing the study, interpreting the data, and writing and publishing the report.

Results

A total of 1,871 (31.8%) subjects completed the survey questionnaire. A subpopulation of 370 colonoscopy-naïve respondents was eligible for inclusion in this study (Figure 1). The response rate of this subpopulation remained unknown due to an unknown denominator (subgroup was based on criteria collected within the survey), which is explained in detail in the methods section. Comparison of the responders (n=776)/non-responders (n=3,586) of the initially sampled subjects with no documented colonoscopy showed no relevant differences in the mean age (responder/non-responder: 57.9/57.2 years) and proportion of sex (47.9/50.6%), but indicated a slightly higher uptake of a health check-up in the responder group (72/63%).

As shown in Table 1, the study population had an average age of 55 years, 47% were male, and had a high education level in more than 40% of cases. The vast majority (85%) perceived their health as good or better.

Most of the participants (60-93 %) rated the information as moderately or very important except for information on the sex of the endoscopist, which was important for only 27% (Figure 2). Information on the types and frequencies of risks and side effects was most frequently rated as being important, and was rated as not important by 6% and 10%, respectively. Further analysis showed that 7 items covering the categories 'risks and side effects' (4 of 5 items), baseline risks (1 of 2 items), practical aspects (1 of 5 items), and benefits (1 of 3 items) were perceived as the most important issues (very important for at least 50% of the population) (Figure 2). Key information on benefits, i.e., on how many cases of colorectal cancer or CRC-related deaths could be prevented by screening, was rated as 'very important' by 40% of the participants, and as either relatively or very unimportant by 26%. The analyses below focus on the information rated as 'very important'.

Stratification by sex and education showed variations in the 'very important' ratings. Women rated information as very important more often than men (Figure 3). The biggest differences were seen in information on risks, pain, laxative use, and going home independently afterwards. Conversely, quantitative information on issues like the frequency of risks and polyps and the number of lives saved and deaths prevented seems to be equally important for both sexes. The ratings also varied according to the educational level. Subjects with high education rated most of the information as being less important than those with lower levels of school education (Figure 4). No significant sex and education differences were detected for information on the risks of colonoscopy ($p=0.063$) or the number of cases of CRC that could be prevented by colonoscopy screening ($p=0.055$). Absolute ranking of the importance of the information yielded very similar results.

Table1: Characteristics of the study population (n=370)

Characteristics	Categories	n	%
Age, years (n=368)	50-54	162	44.0
	55-59	129	35.1
	60-64	77	20.9
Sex (n=368)	Male	173	47.0
	Female	195	53.0
Education level (n=362)	High	152	41.1
	Intermediate	133	36.7
	Low	77	21.3
Employment status (n=325)	White-collar worker	158	48.6
	Blue-collar worker	61	18.8
	Unemployed	24	7.4
	Retired	38	11.7
	Self-employed	29	8.9
	Other	15	4.6
Household size (n=359)	1 person	51	14.2
	2 persons	188	52.4
	3 persons	64	17.8
	>3 persons	56	15.6
City of residence, inhabitants (n=357)	<5,000	118	33.1
	5,000-20,000	77	20.8
	20,000-100,000	81	22.7
	>100,000	81	22.7
Region (n=362)	Eastern Germany	94	26.0
	Western Germany	268	74.0
Migrant background (n=364)	Yes	40	11.0
Self-reported health (n=360)	Excellent	18	5.0
	Very good	112	31.1
	Good	183	50.8
	Not so good	36	10.0
	Poor	11	3.1
Health literacy (n=362)	Extremely or very confident	261	72.1
	Moderately/slightly or/not at all confident	101	27.9
History of cancer? (n=365)	Yes	26	7.1
First-degree relatives with CRC? (n=365)	Yes	31	8.5
Related persons with cancer? (n=365)	Yes	226	61.9

Multivariable logistic regression models produced very similar results to those of the stratified analyses, showing that sex and education were the main factors associated with the importance ratings (Table 2). Health literacy was not associated with importance ratings in the regression models. Deviating from the stratified analyses, the perceived importance of information on risks and side effects was higher than expected in the low education group compared to the high education group, while the intermediate education group considered information on the benefits (e.g. the number of cases of bowel cancer or death that could be prevented) more often as very important than the high education group.

Low-educated subjects living alone (single household size) were significantly less interested in information on the types and frequencies of screening risks (See interaction terms in table 2). As interpretation of results that include interaction terms may be difficult, we illustrate this interaction (Figure 5). However, while the main direction is correctly represented, there might

be slight differences to the multivariable association. Further stratification to characterize low-educated subjects living alone more accurately was not feasible due to the low number of cases.

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Table 2: Factors associated with 'very important' ratings of specific information about screening colonoscopy as identified by multivariable logistic regression analysis. Numbers represent odds ratios and their 95% confidence intervals.

		How important to you personally is information on:						
		Risks and side effects of colonoscopy?	Incidence of risks and side effects?	Whether bowel cancer might be overlooked by colonoscopy?	Whether polyp removal makes sense?	Your risk of getting bowel cancer within the next 10 years?	Whether the examination is painful?	How to take laxatives to prepare for colonoscopy?
n	(Percentage of study population included)	339 (91.6)	333 (90.0)	337 (91.1)	332 (89.7)	337 (91.1)	336 (90.8)	332 (89.7)
Sex	Female vs. male (Ref.)	2.24 (1.34-3.74)**	0.74 (0.34-1.58)	1.4 (0.86-2.28)	1.25 (0.77-2.04)	1.40 (0.87-2.27)	2.33 (1.47-3.70)***	1.98 (1.26-3.13)**
Age (years)	50-54 vs. 55-65 (Ref.)	1.47 (0.88-2.48)	0.97 (0.61-1.55)	1.06 (0.67-1.68)	1.53 (0.96-2.43)	1.18 (0.75-1.84)	1.45 (0.92-2.29)	1.05 (0.67-1.65)
Education	Low	4.06 (1.63-10.09)**	3.93 (1.79-8.62)***	2.76 (1.37-5.54)**	2.65 (1.30-5.41)**	2.13 (1.13-4.0)*	1.89 (1.0-3.57)*	2.39 (1.20-4.75)*
	Intermediate	1.41 (0.78-2.55)	1.57 (0.90-2.75)	1.90 (1.09-3.31)*	1.51 (0.87-2.61)	1.78 (1.07-2.97)*	1.94 (1.15-3.27)*	1.60 (0.92-2.78)
	High (Ref.)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Household size	Living alone vs. not living alone (Ref.)	1.88 (0.63-5.68)	1.40 (0.53-3.68)	0.39 (0.10-1.57)	0.50 (0.14-1.81)	0.54 (0.22-1.33)	0.73 (0.38-1.41)	0.75 (0.29-1.99)
Migrant background	Yes vs. no (Ref.)	1.05 (0.47-2.38)	1.22 (0.59-2.54)	0.77 (0.36-1.63)	1.16 (0.56-2.42)	1.23 (0.60-2.52)	0.73 (0.34-1.55)	1.21 (0.59-2.49)
Self-reported health	Good/less vs. very good/excellent (Ref.)	1.44 (0.83-2.49)	0.90 (0.43-1.87)	1.69 (1.03-2.79)*	1.31 (0.80-2.16)	1.13 (0.70-1.84)	1.36 (0.83-2.24)	0.96 (0.58-1.59)
Region	Eastern vs. western (Ref.)	0.67 (0.37-1.19)	0.83 (0.48-1.41)	0.58 (0.34-0.99)*	0.65 (0.38-1.10)	0.73 (0.43-1.23)	0.82 (0.48-1.41)	0.75 (0.44-1.29)
Health literacy	Extremely/very confident vs. moderately/slightly /not confident (Ref.)	1.14 (0.62-2.09)	0.77 (0.44-1.33)	0.80 (0.47-1.38)	1.06 (0.62-1.84)	1.31 (0.77-2.21)	1.31 (0.77-2.23)	1.04 (0.61-1.76)
Interaction terms								
Living alone* education	Living alone*intermediate	0.76 (0.12-4.43)	0.88 (0.20-3.99)	2.66 (0.50-14.26)	2.69 (0.55-13.22)			1.28 (0.30-5.52)
	Living alone*low	0.02 (0.00-0.15)***	0.04 (0.01-0.28)***	0.36 (0.05-2.54)	0.18 (0.02-1.33)			0.10 (0.01-1.02)
Sex*self-reported health			1.81 (0.69-4.75)					
Sex*living alone				3.13 (0.70-13.99)	2.01 (0.47-8.50)	2.99 (0.79-11.25)		

Table 2 (Cont.): Factors associated with ‘very important’ ratings of specific information about screening colonoscopy as identified by multivariable logistic regression analysis. Numbers represent odds ratios and their 95% confidence intervals.

		How important to you personally is information on:							
		Incidence of polyps?	Number of cases of bowel cancer that could be prevented by attending colonoscopy regularly?	Number of deaths from bowel cancer that could be prevented by attending colonoscopy regularly?	Recommended intervals between colonoscopies?	Whether laxative prep is unpleasant?	Whether you can go home on your own after the procedure?	Whether you will be able to work on the day of the procedure?	Whether the endoscopist is male or female?
n	(Percentage of study population included)	329 (88.9)	330 (89.2)	331 (89.5)	332 (89.7)	331 (89.5)	329 (88.9)	263 (92.6)	329 (90.0)
Sex	Female vs. male (Ref.)	1.09 (0.68-1.74)	0.80 (0.50-1.26)	1.01 (0.63-1.59)	1.08 (0.65-1.78)	2.26 (0.98-5.19)	2.53 (1.50-4.28)***	1.79 (0.99-3.23)	1.89 (0.95-3.74)
Age (years)	50-54 vs. 55-65 (Ref.)	0.98 (0.62-1.57)	0.88 (0.56-1.39)	0.79 (0.50-1.26)	1.76 (1.10-2.81)*	1.10 (0.68-1.77)	1.77 (1.07-2.92)*	1.70 (0.95-3.06)	1.85 (0.95-3.57)
Education	Low	5.27 (2.59-10.72)***	1.56 (0.83-2.95)	1.76 (0.94-3.30)	2.10 (1.09-4.01)*	2.60 (0.96-7.06)	2.72 (1.33-5.57)**	2.53 (1.13-5.66)*	1.64 (0.68-3.95)
	Intermediate	2.10 (1.18-3.73)*	1.89 (1.11-3.20)*	1.77 (1.04-3.01)*	1.96 (1.13-3.40)*	3.66 (1.45-9.24)**	3.18 (1.75-5.79)***	1.46 (0.74-2.87)	0.81 (0.37-1.80)
	High (Ref.)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Household size	Living alone vs. not living alone (Ref.)	1.69 (0.63-4.57)	0.78 (0.40-1.52)	0.77 (0.39-1.50)	0.70 (0.26-1.88)	0.99 (0.33-3.00)	0.81 (0.38-1.76)	0.29 (0.10-0.88)*	1.04 (0.40-2.73)
Migrant background	Yes vs. no (Ref.)	1.10 (0.52-2.33)	1.34 (0.63-2.79)	1.31 (0.63-2.74)	1.49 (0.69-3.25)	0.88 (0.42-1.85)	0.86 (0.39-1.90)	0.94 (0.36-2.41)	1.69 (0.47-6.0)
Self-reported health	Good/less vs. very good/excellent (Ref.)	1.03 (0.62-1.72)	1.39 (0.84-2.30)	1.70 (1.02-2.82)*	1.22 (0.72-2.04)	1.30 (0.77-2.22)	1.11 (0.63-1.96)	1.25 (0.66-2.38)	2.75 (1.21-6.21)*
Region	Eastern vs. western (Ref.)	1.10 (0.64-1.90)	0.97 (0.57-1.67)	1.09 (0.63-1.87)	0.73 (0.42-1.29)	0.89 (0.51-1.57)	0.91 (0.49-1.66)	0.69 (0.34-1.42)	1.38 (0.64-2.99)
Health literacy	Extremely/very confident vs. moderately/slightly /not confident (Ref.)	0.67 (0.38-1.16)	0.65 (0.38-1.11)	0.59 (0.34-1.01)	0.90 (0.52-1.57)	1.04 (0.60-1.80)	1.33 (0.75-2.35)	1.39 (0.72-2.68)	0.61 (0.27-1.35)
Interaction terms									
Living alone* education	Living alone*intermediate	2.42 (0.50-11.67)				1.43 (0.30-6.88)			
	Living alone*low	0.04 (0.00-0.38)**				0.15 (0.01-1.71)			
Sex*self-reported health									
Sex*living alone					3.26 (0.82-12.92)				

All models included the following variables: sex, age, education, migrant background, self-reported health, eastern/western Germany, household size, health literacy; bold numbers represent p-values ≤ 0.05 ; * $p \leq 0.05$ ** $p \leq 0.01$ *** $p \leq 0.001$; Interaction terms are presented when included into the model; Ref.: reference group

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Discussion

Our survey of the perceived need for information on screening colonoscopy among 370 German health insurance company members with no prior history of colonoscopy showed that the vast majority rated information on all but one item as being moderately or very important. While information on the risks and side effects of screening was most frequently rated as very important, roughly a quarter of the respondents rated information on screening benefits as not important. The ratings differed by sex and education level. Women more often regarded most of the items as being very important, especially information on risks (e.g. pain) and practical aspects of the procedure. Generally, less educated subjects more frequently rated nearly all of the information as being important, but a significantly higher percentage of low-educated people living alone rated information on the types and frequencies of screening risks as being less important.

One of the main pillars of informed decision-making is information on risks.[5, 6] The predominant focus of patient's interest on information about the potential risks and side effects of colonoscopy screening underscores the fact that people want to be able to make informed decisions. This has particularly important implications in Germany, where a systematic evaluation of the available print information on CRC showed that nearly one-third of all information materials investigated failed to mention basic information on potential harms associated with CRC screening.[18] The DECISIONS survey of U.S. adults aged 50 and older yielded similar results: Almost 30% of women and men surveyed said that their health care providers did not discuss any of the cons of CRC screening with them, while over 95% said that they had discussed the pros.[19] Further effort is needed to empower patients to make informed decisions by providing health communication with appropriate information on all relevant factors, including the risks of CRC screening. The consumers seem to agree.[20]

In contrast, 26% of subjects perceived key information on the benefits of screening (e.g., on the potential of screening to reduce the incidence and mortality of CRC) as unimportant. This suggests a clear lack of understanding of the gist of screening in a substantial part of the population, as has already been described in the literature.[21] Several factors may be responsible for this. First, the benefits of a screening examination are assumed as given or overestimated by many people.[22, 23] Second, consumers might assume that all examinations covered by their health insurance companies are beneficial. Third, the item used to rate the importance of the potential of screening to reduce the incidence and mortality of CRC was presented in quantitative terms describing the absolute risk reduction, i.e., 'the number of bowel cancer-related deaths that could be prevented by regular colonoscopy screenings'. Subjects with lower numeracy may perceive quantitative

information as less important because of their inability to understand these statistics.[24] Fourth, goal framing might be present due to the use of a gain message (e.g., the number of deaths that could be prevented by regular screening) instead of a loss message (e.g., the number of deaths that will occur due to failure to attend screening). Loss messages are shown to be associated with a more positive perception of the effectiveness of a procedure.[25] Therefore, the framing of information on the benefits of screening colonoscopy as a loss message might have resulted in a higher rating of the importance of information on screening benefits.

To our knowledge, the only available study that examines the patient-rated importance of information on colorectal cancer was conducted in the USA.[26] Similarly to our results, the highest rating of 'very important' was predominant even though the American colleagues used a 7-point scale. More than 80% of their participants rated 4 of 5 types of information as 'very important', including information on the purpose of screening (type of screening disease), followed by the pros and cons, test accuracy, and alternative tests. No data was provided on differences in the prevalence of 'very important' ratings between the different groups.

Information needs were different according to sex and educational level. Women in our study showed higher information needs than men on risks, pain, laxative use, and going home independently afterwards. This might be partially due to different strategies to overcome their fears. In a study using focus groups interviews, women demanded more information in terms of both quantity and detail, while men preferred little or no information on endoscopic procedures.[27] We detected significantly higher information needs in less educated groups. Similarly, a study on information needs in cancer patients using a 5-point scale to measure importance also showed that a low educational level is associated with higher information needs.[28] Likewise, this might be due to lower levels of knowledge and understanding about CRC screening. However, in our study, health literacy was not associated with information needs while other studies showed found a relation.[22, 29, 30] The screening question we used to explore health literacy may not be sensitive in our study population.

In contrast to the finding of higher information needs in less educated groups, our results suggest that the subgroup of low-educated subjects living alone is clearly less interested in information on the risks and side effects of screening colonoscopy. Apparently, they are not interested in making an informed decision or are unable to do so for low health literacy reasons. Living alone might serve as a surrogate for an increased risk of social isolation and low social support. Thus, this group is likely to be the most vulnerable group with the highest health risks.[31] However, we could not ascertain the actual screening behavior of this group based on the available data. Besides, results on living alone must be interpreted with caution

because of the low number of cases. Future research is needed to obtain deeper insights into the contrasting information needs of low-educated people living alone, who may constitute an important risk group.

While colonoscopy is widely considered as the gold standard to diagnose CRC, only a few countries offer colonoscopy for primary screening [11]. Most screening programs use colonoscopy only after a positive stool test, and in such case, colonoscopy is a diagnostic and not a screening procedure. Individuals with a positive stool test cannot be considered asymptomatic and have an increased CRC risk. Therefore, our results are not generalizable to this situation as our study refers to colonoscopy for primary screening.

This study has some limitations, which are discussed below. First, the study population consisted solely of persons with Barmer GEK statutory health insurance, who might not be representative of the German population at large. However, we believe that this can be assumed to a great extent for two reasons: A) 85% of Germans are covered by statutory health insurance (and most of the remaining by private insurance), and B) Since 1996, German residents are largely free to choose between health insurance companies, all of them offer very similar benefits and charge similar premiums. However, as a German questionnaire was used, subjects with minor German language skills may be underrepresented. Second, analysis was restricted to the subgroup of colonoscopy-naïve subjects. This was explained by the fact that the target group for evidence-based information about colonoscopy for primary screening comprises above all people who have not yet experienced this examination and have different preferences.[32] Third, by selecting this subgroup, the validity of the results may be limited. However, this subgroup analysis was derived from an a priori research question that addressed colonoscopy-naïve subjects. Therefore, multiple testing is not a predominant issue. Fourth, as the insurance data did not provide the lifetime colonoscopy status, our final study population was based on self-reported status, which made it impossible to identify the denominator in the initial sample of our study population. Without a precise denominator, the response rate and potential differential response remained unknown. Using the non-responder-analysis we did instead as a substitute, we cannot exclude a substantial selection bias. However, the proportion of participation is not necessarily associated with the magnitude of bias.[33] Besides, a response bias is mainly restricted to the prevalence of exposures or outcomes, while associations are only affected, if the response is both associated with exposure and outcome. The risk of misclassification of the self-reported colonoscopy status (i.e. confusion with other endoscopic procedures) was considered low, as the questionnaire included a description of the procedure and knowledge about colonoscopy is common because screening colonoscopy had been introduced for more than ten years. Fifth, the fact that

subjects rated most items as either 'very' or 'moderately important', and almost never as 'very unimportant' indicates that the four-point scale of importance may have resulted in a ceiling effect. Nevertheless, all of the response options were used by the respondents, and the fact that most respondents considered the sex of the endoscopist to be relatively unimportant shows that they were able to discriminate across the different types of information. In further analyses, the responses were dichotomized to 'very important' vs. 'other'. Focusing on the 'very important' ratings allowed us to detect relevant differences. Sixth, we did not include information on overdiagnosis as a potential harm. Although this is a huge problem in PSA testing for prostate cancer screening, there is probably little overdiagnosis associated with screening colonoscopy.[34] Seventh, the models on the associated factors of the attributed importance of specific information about screening colonoscopy may suffer from residual confounding.

The findings of our study have several implications. As an informed choice requires knowledge about the absolute frequencies of the risks and benefits of screening [5-7], and one-quarter of respondents considered such data on the numbers of prevented death as being unimportant, future information on screening colonoscopy should comprehensibly describe the benefits including quantitative information. A former evaluation of information materials on CRC screening had shown that benefits are often presented in general terms, and not specific for colonoscopy, and without quantifying the associated risk reduction.[18] However, numeracy skills are crucial to understanding quantitative information which in turn is essential to informed decision-making.[35] Pictographs are increasingly being used in patient decision aids on cancer screening in Germany.[36] This may help to improve patient understanding of essentially quantitative messages in screening information.[37-39]

In light of the observed differences in information preferences between women and men, tailoring future information according to sex-specific needs may be warranted. There are already health information materials for women and men available that differ in the sex-specific baseline risks of getting CRC.[40, 41] Further modifications according to the perceived information needs should be tested. Health information should also be adjusted to individuals with lower education or literacy. The high demand of less educated people to become informed encourages further efforts to design evidence-based information materials that adequately inform this population. To date, several studies revealed that individuals with low health literacy or low educational level have deficits in informed decision-making.[42-44] However, identifying these groups, e.g. via screening questions, and then offering health information may not be practical or even stigmatizing. Strategies to address educational and literacy inequalities may be implemented via self-selection, and may include offering information in simple language, with a shorter extent of information, using different

information channels like web-based information and videos, and improving communication with health professionals.[45-47]

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Contributorship:

MD, KK, and UW developed the conception and design of the study. MD and KK analysed and interpreted the data, and drafted the manuscript. MD, KK, and UW revised the work critically for intellectual content. All authors approved the final version of the manuscript and are accountable for all aspects of the work.

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Figure 1: Flow chart of the study population

Figure 2: Importance of key information about screening colonoscopy (n=354-365)

*Responses from employed persons only (n=279)

Figure 3: Importance of key information about screening in women and men (n=352-363)

* Responses from employed persons only (n=279)

Figure 4: Importance of key information about screening colonoscopy by educational level (n=346-357)

* Responses from employed persons only (n=278)

Figure 5: Information on risks and side effects of colonoscopy – Percentage of 'very important' ratings stratified by sex, education level and household size (n=353)

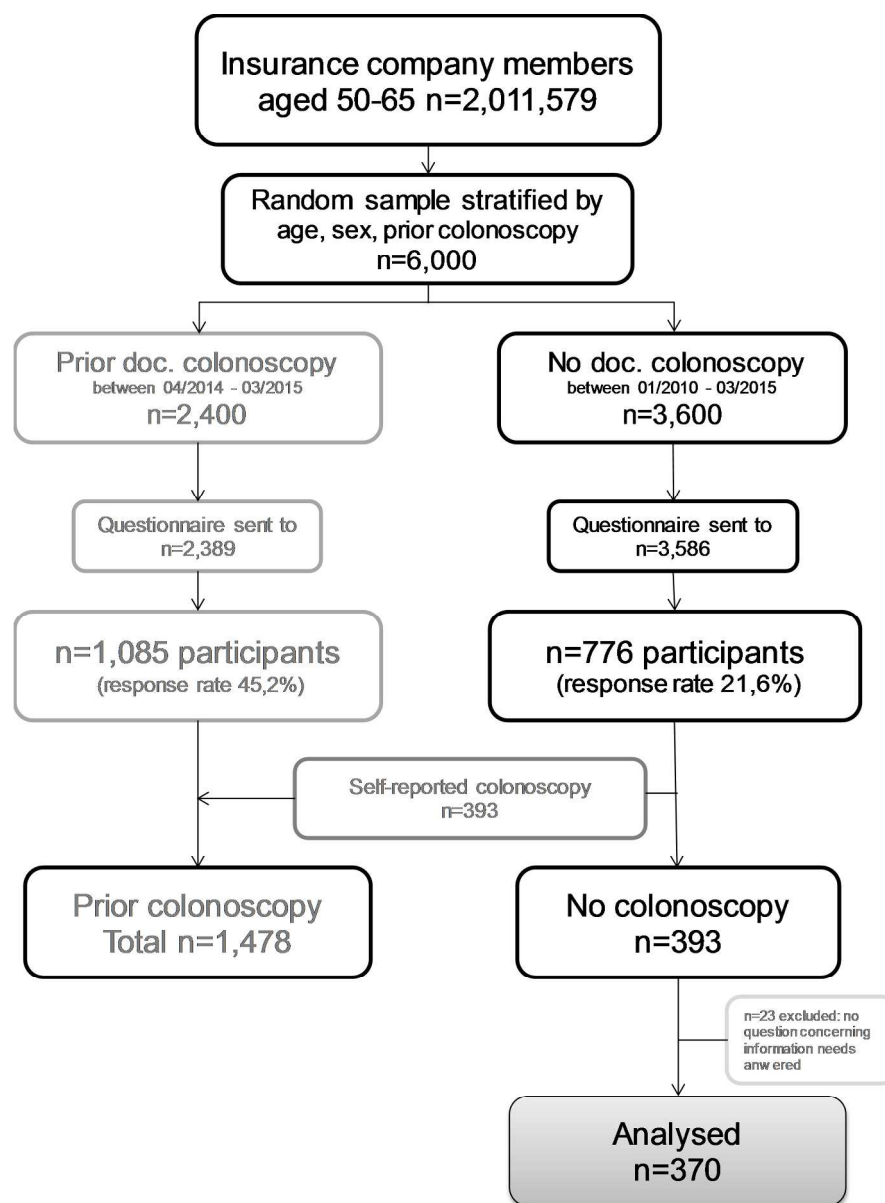


Figure 1 Flow chart of the study population

178x240mm (300 x 300 DPI)

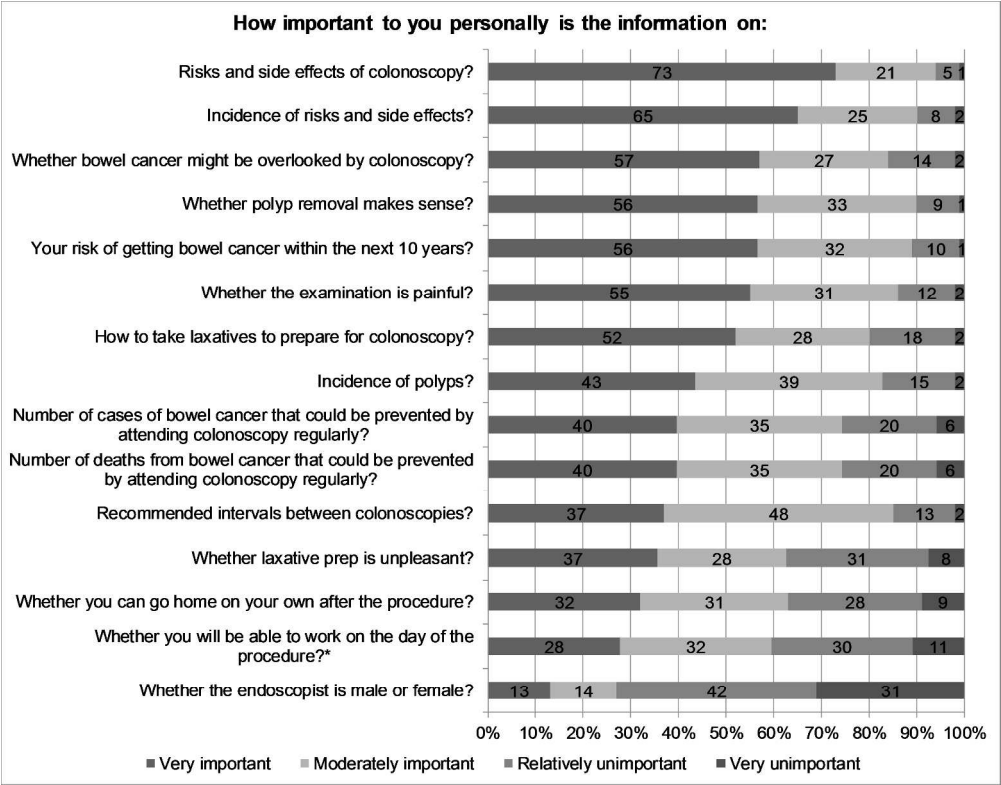


Figure 2: Importance of key information about screening colonoscopy (n=354-365)
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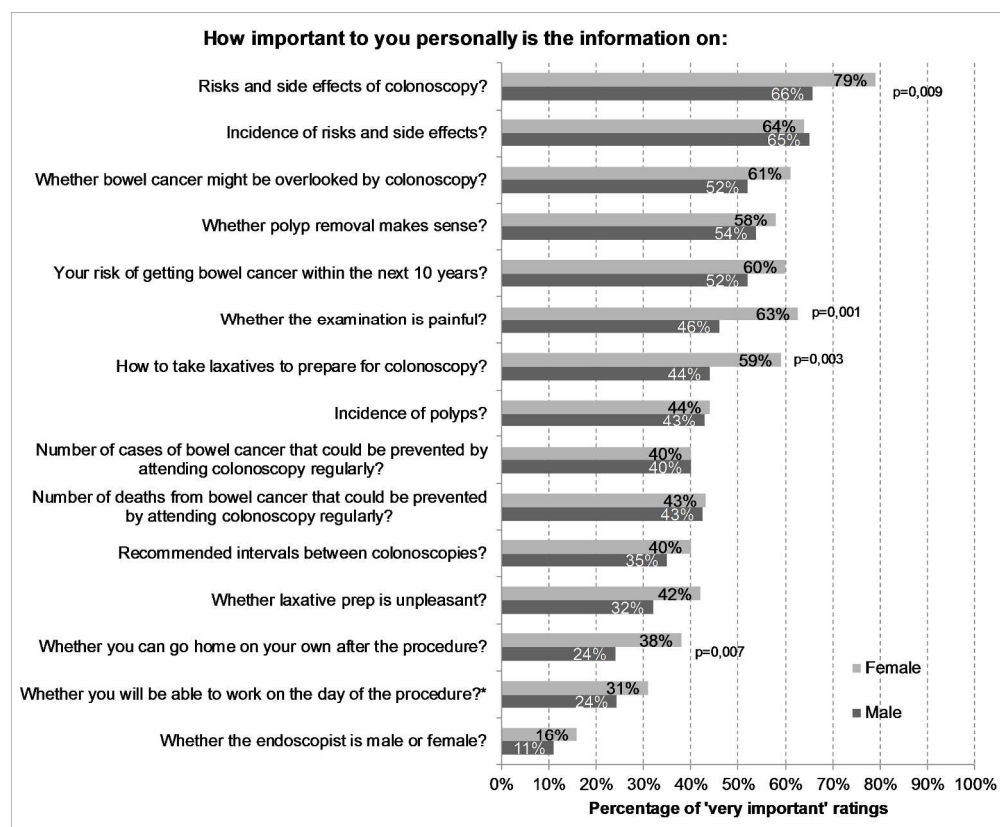


Figure 3: Importance of key information about screening in women and men (n=352-363)

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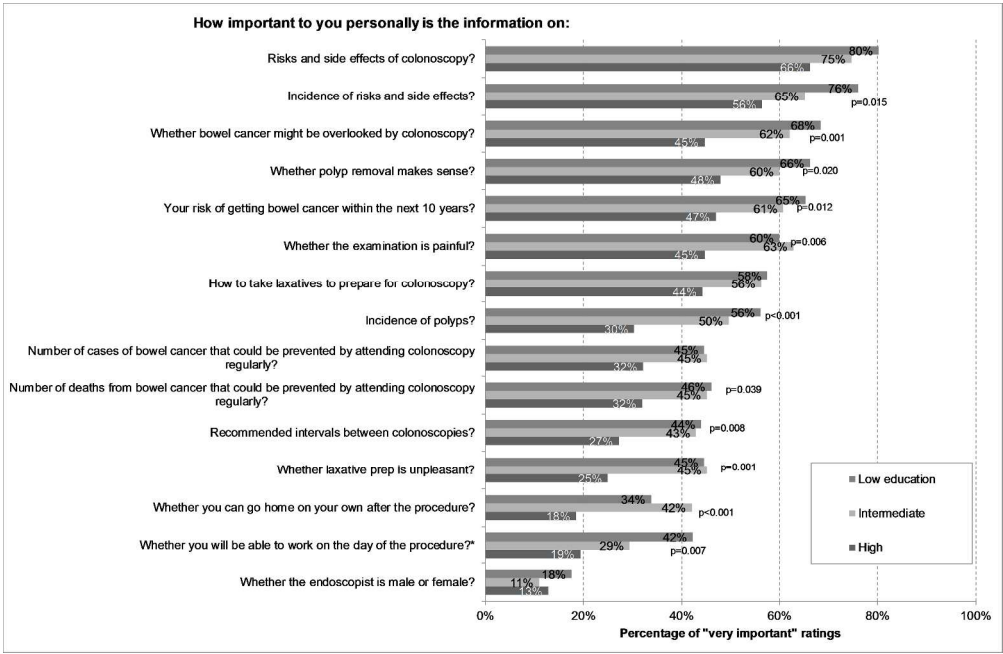


Figure 4: Importance of key information about screening colonoscopy by educational level (n=346-357)

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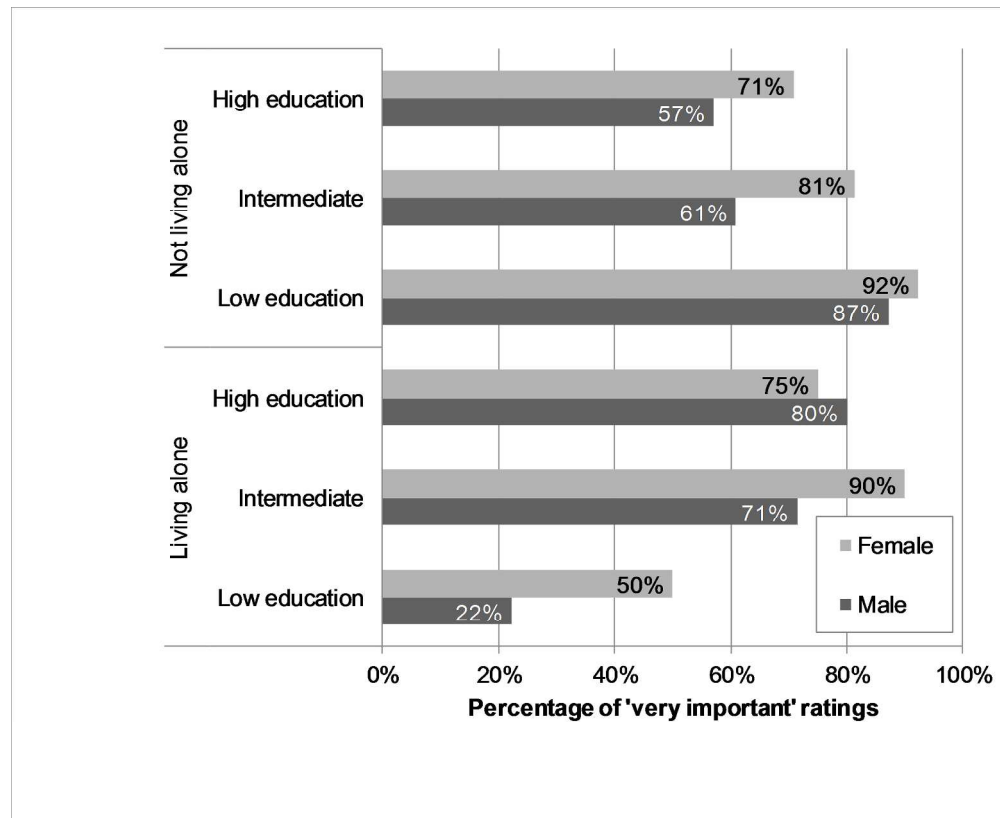


Figure 5: Information on risks and side effects of colonoscopy – Percentage of 'very important' ratings stratified by sex, education level and household size (n=353)

216x175mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any prespecified hypotheses	1, 3
Methods			
Study design	4	Present key elements of study design early in the paper	1, 3-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	3-5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-5
Bias	9	Describe any efforts to address potential sources of bias	4-5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	4-5
		(b) Describe any methods used to examine subgroups and interactions	4-5
		(c) Explain how missing data were addressed	Reported n’s in legends of the tables
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	-

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Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	3-5
		(b) Give reasons for non-participation at each stage	Not applicable
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-7, table 1
		(b) Indicate number of participants with missing data for each variable of interest	6-7
Outcome data	15*	Report numbers of outcome events or summary measures	7-9, tables 2-5
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-7
		(b) Report category boundaries when continuous variables were categorized	8-9
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-7
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13-14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	2, 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	5

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Patient-rated importance of key information on screening colonoscopy in Germany – a survey of statutory health insurance members

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Abstract

Background

Primary colonoscopic screening is considered to be of great benefit but also has the potential to cause severe harm. Thus, eligible subjects should be supported in making an informed choice whether or not to participate.

Objectives

To identify information on screening colonoscopy that colonoscopy-naïve subjects rate as particularly important for decision-making.

Design

Survey of German statutory health insurance members using a written questionnaire in November 2015.

Study population Colonoscopy-naïve individuals aged 50 to 65 years.

Main outcome measures Importance of key information about screening colonoscopy, including potential risks and benefits, baseline risk of colorectal cancer/polyps, and practical aspects of the procedure, as well as associations between participants' characteristics and their judgement of information as to being 'very important'.

Results

Of 1,871 respondents (overall response rate: 31%), a subgroup of 370 colonoscopy-naïve subjects was eligible for inclusion (average age: 55 years, 47% male). Information on the risks was rated as very important by most respondents, unimportant by 6%. Information on the benefits was considered unimportant by 26%. Regression analysis showed that less educated persons regarded most items to be more often relevant than highly educated subjects. A greater proportion of women than men rated details regarding pain and practical aspects as very important. Subjects with a low educational level living alone were identified as the group with the least interest in information on risks.

Conclusion

Cultivating awareness around the central meaning of the (quantitative) benefits of screening in informed decision-making should be focused on more in future information materials. The high requirement of less educated people to become more informed provides a strong motivation for further efforts to develop evidence-based information that adequately informs

this group. Tailoring information according to gender-specific needs may be warranted in light of the observed differences in information preferences between women and men.

Strength and limitations

- This study provides a unique insight into the perceived importance of key informational needs in regards to screening colonoscopy as reported by colonoscopy-naïve persons themselves.
- Multivariable analyses adjusted for several potentially associated factors enhance the validity of the results.
- The study population included members of a single German statutory health insurance company; however, as 85% of Germans are covered by statutory health insurances, and German residents are largely free to choose between companies, all of which offer very similar benefits and competitive prices, our results are likely generalizable among all German residents.

Introduction

Colorectal cancer (CRC) is one of the most common cancers, accountable for one-third of all newly diagnosed cases of cancer and 25% of all cancer-related deaths worldwide.[1] Since colonoscopy has a high accuracy rate for detecting colorectal cancer, CRC is nonetheless probably one of the best screenable cancer diseases. Moreover, endoscopic procedures have the potential to reduce not only CRC mortality but also CRC incidences.[2] However, their benefits are also associated with adverse events such as bleeding (5 in 10,000), perforation (8 in 10,000), or even death in very rare cases.[3, 4]

Considering these risks, the question of whether or not to go to CRC screenings and which test to undergo outlines a very preference-sensitive decision. Persons eligible for CRC screening should be able to make an informed decision based on knowledge about the specific benefits and risks of the procedure, including quantitative information, in order to realize their extent in absolute frequencies, and individual values.[5–7] In recent years, the demand for evidence-based, balanced, neutral information to support informed decision-making has been increasingly included in cancer screening guidelines.[8, 9] Germany will thus initiate a legally defined colorectal cancer screening program with screening information letters, including explicit information on the benefits and risks of the procedure in order to enable patients to make an informed decision for or against CRC screening.[10] The fecal

immunochemical testing and colonoscopy are currently the only two CRC screening tests covered under statutory insurance plans in Germany without additional payment. Since October 2002, insurees aged 55 and older have been eligible to receive a colonoscopy for primary screening once every 10 years.[3] Primary screening colonoscopy is currently offered in Austria, the Czech Republic, Poland, Switzerland and the USA.[11]

Evidence-based health education often includes extensive information, even though brief information may be more appropriate for some target groups and situations. The prioritization of content is essential for providing short summaries such as option grids.[12] Following a patient-centered strategy, we explored the information needs of subjects currently entitled to attend CRC screenings or who will be in the future. Our focus was on colonoscopy because of its greater benefits and higher risk potential.[13], with our goal being to systematically collect detailed data on which specific information about colonoscopy subjects with no history of colonoscopy considered important and relevant, and to identify any potential variations between different groups in the study population. Colonoscopy-naïve subjects were chosen, because having experienced a colonoscopy may affect the subject's importance ratings. The results of this cross-sectional survey may contribute to the patient-centered development and the revision of evidence-based decision aids on CRC screenings, including information tailored to the informational needs of individual target groups.

Methods

Study design and setting

In November 2015, randomly selected members of a large German statutory health insurance company (Barmer GEK, 8.5 million members) were sent a questionnaire survey on colonoscopy experience and information needs of subjects with and without a previous history of colonoscopy. 2,011,579 women and men aged 50 to 65 years were eligible. The random sample was stratified by age, sex and colonoscopy status to account for higher expected response rates in subjects with a history of colonoscopy. The sample of 6,000 individuals included subjects with a history of colonoscopy within the previous year, from April 2014 to March 2015 (n=2,400) to minimize recall bias, as well as subjects with no documented history of a colonoscopy in the available period from January 2010 to March 2015 (n=3,600) (Figure 1).

To address the information needs of colonoscopy-naïve subjects, we included a subgroup in the whole survey population, i.e., those participants with no documented or self-reported history of prior colonoscopies (Figure 1). Subjects with a self-reported history of colorectal cancer were excluded, because they do not belong to the CRC screening target group comprised only of people with an average CRC risk.

Survey instrument

The standardized questionnaire was sent to the selected members by the insurance company and could be returned to our research unit at Hannover Medical School. In order to minimize any inconvenience to their customers, the insurance company did not issue reminders. The first page described the colonoscopy procedure and provided a schematic drawing showing the colon and the endoscope. The questionnaire was in German and included 51 questions on the patients' prior history of colonoscopy, experiences with the latest colonoscopy, the importance of key information on the colonoscopic history of cancer, and socio-demographic characteristics. To ensure comprehensibility, the questionnaire had been subjected to 10 cognitive pretests and modified accordingly. Participants of the pretests were 23-75 years old, amongst these were 3 experts, 6 females, 5 colonoscopy-naïve, and 3 less educated. Data on the importance of key information were collected in 15 questions covering the following four categories:

- (1) Potential benefits (three items: reduction of incidence, reduction of mortality, removal of polyps);
- (2) Risks and side effects (five items: risks present, frequency of risks, chances of overlooking CRC, pain, side effects of laxatives);
- (3) Baseline risk of CRC/polyps (two items: risk of disease next within the next 10 years, prevalence of polyps),
- (4) Practical aspects of the procedure (five items: laxative use, examination intervals, effect on driving ability, ability to work, sex of the endoscopist).

The chosen items were based on recommendations for evidence-based health information,[5] prior evaluations,[14] and on a list of criteria for evaluating consumer education material on colorectal cancer screenings.[15] The response options were included in a four-point Likert scale with the categories: very important, moderately important, relatively unimportant, very unimportant. The English translations of the questions are shown in Figure 2. Education levels were classified according to the date of the final examination: low (after grade 9), intermediate (after grade 10), or high (after grade 12 or 13). Persons not born in Germany or whose father or mother was not born in Germany were said to have a 'migrant background'. [16] Health literacy was assessed using the validated screening question: 'How confident are you filling out medical forms by yourself?'. [17]

Data analysis

Data were combined via a key variable with selected anonymous individual data from the insurance company. All data used for this analysis were derived from the questionnaire except the subjects' occupational statuses, which came from the insurance data set. Self-

reported information on age, sex, and prior colonoscopies was validated through comparison with the health insurance data. All analyses were performed using IBM SPSS Statistics, version 24. Frequency analyses and cross tabulations were performed. Multivariable logistic regression modeling was performed to identify associations between the participants' characteristics and the outcomes/ratings 'very important' vs. 'other' for each of the 15 questions. The following variables were included: sex, age group, education, profession, health literacy, self-reported health, household size, living in Eastern/Western Germany, migrant background. The following interaction terms were tested: sex*education, sex*household size, sex*self-reported health, and education*household size. Other interaction terms were not included due to the low numbers of single cells. Interaction terms shown to be associated with the outcome below $p < 0.25$ were included; otherwise the number of terms would have been too high. All statistical tests were two-sided. A p-value less than 0.05 was considered statistically significant.

Response of the study population

While the response rate of the whole survey population was 31.8% (Figure 1), the proportion of persons without a prior colonoscopy in relation to the whole survey population was unclear as information on documented prior colonoscopies from the insurance data was restricted to the period January 2010 to March 2015. Information on whether the participants had a prior colonoscopy or were colonoscopy-naïve was derived from documented and self-reported colonoscopy, the latter was necessary to cover the period before 2010, as well as between April 2015 and the time of the survey. From the preselected insurees without a documented colonoscopy ($n=3,600$), 21.6% ($n=776$) responded, half thereof reported a prior colonoscopy. The number of subjects within the initially preselected 3,600 insurees without a prior colonoscopy was unknown as the actual colonoscopic status of non-responders remained unknown due to the missing self-reported statuses. For this reason, it was impossible to calculate a response rate or to do a non-responder-analysis. However, the best option for a group comparison was to include the initial preselected 3,600 insurees with no documented colonoscopy in the non-responder analysis and thereby compare available data from the insurance company (age, sex and 5-year-uptake of a biannually offered health check-up).

Ethical consideration

The study protocol was approved by the ethics committee of Hannover Medical School (Application No. 2918-2015). The study was conducted in cooperation with the Bertelsmann Foundation (a non-profit organization) und Barmer GEK, who paid for printing and postage of the questionnaires and for third-party data entry services. Barmer GEK sampled the study population according to our specifications and provided anonymous data on the study

population. Precautions were taken to ensure that Barmer GEK could not de-anonymize their members' questionnaires by sending the questionnaire back to us. The data entry service, to which we sent the questionnaire, was also not allowed to return data with IDs to Barmer GEK. The cooperation agreement ensured the authors' independence in designing the study, interpreting the data, and writing and publishing the report.

Patient and Public Involvement

There were no individuals involved in the development of the research question, the design of the study or the recruitment to and conduct of the study. The research question was derived in the context of the future colorectal cancer screening program in order to get deeper insights into the individual's preferences on evidence-based health information. The authors will communicate the findings through national conferences.

Results

A total of 1,871 (31.8%) subjects completed the survey questionnaire. A subpopulation of 370 colonoscopy-naïve respondents was eligible for inclusion in this study (Figure 1). The response rate of this subpopulation remained unknown due to an unknown denominator (the subgroup was based on criteria collected within the survey), which is explained in detail in the methods section. Comparison of the responders (n=776)/non-responders (n=3,586) of the initially sampled subjects with no documented colonoscopy showed no relevant differences in the mean age (responder/non-responder: 57.9/57.2 years) and proportion of sex (47.9/50.6%), but indicated a slightly higher uptake of a health check-up in the responder group (72/63%). As shown in Table 1, the study population had an average age of 55 years, 47% were male, and more than 40% were highly educated. The vast majority (85%) perceived their health as good or better.

Most of the participants (60-93%) rated the different items on screening information as moderately important or very important except for information on the sex of the endoscopist, which was important for only 27% (Figure 2). Information on the types and frequencies of risks and side effects was most frequently rated as being important and not important by 6% and 10%, respectively. Overall 7 items covering the categories 'risks and side effects' (4 of 5 items), baseline risks (1 of 2 items), practical aspects (1 of 5 items), and benefits (1 of 3 items) were perceived as the most important issues (very important for at least 50% of the population) (Figure 2). Key information on benefits, i.e., on how many cases of colorectal cancer or CRC-related deaths could be prevented by screening, was rated as 'very important' by 40% of the participants, and as either relatively or very unimportant by 26%. Further analyses focus on the information rated as 'very important'.

Stratification by sex showed some variations in the 'very important' ratings. Women rated information as very important more often than men (Figure 3). The biggest differences were seen in regard to risks, pain, laxative use, and going home independently afterwards. Conversely, quantitative information on issues, like the frequency of risks and polyps and the number of lives saved and deaths prevented seems to be equally important for both sexes.

The ratings varied substantially according to the educational level. Subjects with high education rated most of the information as being less important than those with lower levels of school education (Figure 4). No significant educational differences were detected in regard to information on the risks of colonoscopy ($p=0.063$) or the number of cases of CRC that could be prevented by colonoscopic screening ($p=0.055$). The absolute ranking on the percentage of very important information yielded very similar results across the different educational categories.

Table1: Characteristics of the study population (n=370)

Characteristics	Categories	n	%
Age, years (n=368)	50-54	162	44.0
	55-59	129	35.1
	60-64	77	20.9
Sex (n=368)	Male	173	47.0
	Female	195	53.0
Education level (n=362)	High	152	41.1
	Intermediate	133	36.7
	Low	77	21.3
Employment status (n=325)	White-collar worker	158	48.6
	Blue-collar worker	61	18.8
	Unemployed	24	7.4
	Retired	38	11.7
	Self-employed	29	8.9
	Other	15	4.6
Household size (n=359)	1 person	51	14.2
	2 persons	188	52.4
	3 persons	64	17.8
	>3 persons	56	15.6
City of residence, inhabitants (n=357)	<5,000	118	33.1
	5,000-20,000	77	20.8
	20,000-100,000	81	22.7
	>100,000	81	22.7
Region (n=362)	Eastern Germany	94	26.0
	Western Germany	268	74.0
Migrant background (n=364)	Yes	40	11.0
Self-reported health (n=360)	Excellent	18	5.0
	Very good	112	31.1
	Good	183	50.8
	Not so good	36	10.0
	Poor	11	3.1
Health literacy (n=362)	Extremely or very confident	261	72.1
	Moderately/slightly or/not at all confident	101	27.9
History of cancer? (n=365)	Yes	26	7.1
First-degree relatives with CRC? (n=365)	Yes	31	8.5

Related persons with cancer? (n=365)	Yes	226	61.9
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Multivariable logistic regression models produced very similar results to those of the stratified analyses, showing that sex and education were the main factors associated with the importance ratings (Table 2). Health literacy was not associated with importance ratings in the regression models. Deviating from the stratified analyses, the perceived importance of information on risks and side effects was higher than expected in the low education group compared to the high education group, while the intermediate education group considered information on the benefits (e.g. the number of cases of bowel cancer or death that could be prevented) more often as very important than the high education group.

Subjects with a low educational level living alone (single household size) were significantly less interested in information on the types and frequencies of screening risks (see interaction terms in Table 2). As the interpretation of results that include interaction terms may be difficult, we shall illustrate this interaction (Figure 5). However, while the main direction is correctly represented in this figure, there may be slight differences to the multivariable association. Further stratification to characterize subjects with a low educational level living alone more accurately was not feasible due to the low number of subjects.

Table 2: Factors associated with 'very important' ratings of specific information about screening colonoscopy as identified by multivariable logistic regression analysis. Numbers represent odds ratios and their 95% confidence intervals.

		How important to you personally is information on:						
		Risks and side effects of colonoscopy?	Incidence of risks and side effects?	Whether bowel cancer might be overlooked by colonoscopy?	Whether polyp removal makes sense?	Your risk of getting bowel cancer within the next 10 years?	Whether the examination is painful?	How to take laxatives to prepare for colonoscopy?
n	(Percentage of study population included)	339 (91.6)	333 (90.0)	337 (91.1)	332 (89.7)	337 (91.1)	336 (90.8)	332 (89.7)
Sex	Female vs. male (Ref.)	2.24 (1.34-3.74)**	0.74 (0.34-1.58)	1.4 (0.86-2.28)	1.25 (0.77-2.04)	1.40 (0.87-2.27)	2.33 (1.47-3.70)***	1.98 (1.26-3.13)**
Age (years)	50-54 vs. 55-65 (Ref.)	1.47 (0.88-2.48)	0.97 (0.61-1.55)	1.06 (0.67-1.68)	1.53 (0.96-2.43)	1.18 (0.75-1.84)	1.45 (0.92-2.29)	1.05 (0.67-1.65)
Education	Low	4.06 (1.63-10.09)**	3.93 (1.79-8.62)***	2.76 (1.37-5.54)**	2.65 (1.30-5.41)**	2.13 (1.13-4.0)*	1.89 (1.0-3.57)*	2.39 (1.20-4.75)*
	Intermediate	1.41 (0.78-2.55)	1.57 (0.90-2.75)	1.90 (1.09-3.31)*	1.51 (0.87-2.61)	1.78 (1.07-2.97)*	1.94 (1.15-3.27)*	1.60 (0.92-2.78)
	High (Ref.)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Household size	Living alone vs. not living alone (Ref.)	1.88 (0.63-5.68)	1.40 (0.53-3.68)	0.39 (0.10-1.57)	0.50 (0.14-1.81)	0.54 (0.22-1.33)	0.73 (0.38-1.41)	0.75 (0.29-1.99)
Migrant background	Yes vs. no (Ref.)	1.05 (0.47-2.38)	1.22 (0.59-2.54)	0.77 (0.36-1.63)	1.16 (0.56-2.42)	1.23 (0.60-2.52)	0.73 (0.34-1.55)	1.21 (0.59-2.49)
Self-reported health	Good/less vs. very good/excellent (Ref.)	1.44 (0.83-2.49)	0.90 (0.43-1.87)	1.69 (1.03-2.79)*	1.31 (0.80-2.16)	1.13 (0.70-1.84)	1.36 (0.83-2.24)	0.96 (0.58-1.59)
Region	Eastern vs. Western (Ref.)	0.67 (0.37-1.19)	0.83 (0.48-1.41)	0.58 (0.34-0.99)*	0.65 (0.38-1.10)	0.73 (0.43-1.23)	0.82 (0.48-1.41)	0.75 (0.44-1.29)
Health literacy	Extremely/very confident vs. moderately/slightly /not confident (Ref.)	1.14 (0.62-2.09)	0.77 (0.44-1.33)	0.80 (0.47-1.38)	1.06 (0.62-1.84)	1.31 (0.77-2.21)	1.31 (0.77-2.23)	1.04 (0.61-1.76)
Interaction terms								
Living alone* education	Living alone*intermediate	0.76 (0.12-4.43)	0.88 (0.20-3.99)	2.66 (0.50-14.26)	2.69 (0.55-13.22)			1.28 (0.30-5.52)
	Living alone*low	0.02 (0.00-0.15)***	0.04 (0.01-0.28)***	0.36 (0.05-2.54)	0.18 (0.02-1.33)			0.10 (0.01-1.02)
Sex*self-reported health			1.81 (0.69-4.75)					
Sex*living alone				3.13 (0.70-13.99)	2.01 (0.47-8.50)	2.99 (0.79-11.25)		

Table 2 (Cont.): Factors associated with ‘very important’ ratings of specific information about screening colonoscopy as identified by multivariable logistic regression analysis. Numbers represent odds ratios and their 95% confidence intervals.

		How important to you personally is information on:							
		Incidence of polyps?	Number of cases of bowel cancer that could be prevented by attending colonoscopy regularly?	Number of deaths from bowel cancer that could be prevented by attending colonoscopy regularly?	Recommended intervals between colonoscopies?	Whether laxative prep is unpleasant?	Whether you can go home on your own after the procedure?	Whether you will be able to work on the day of the procedure?	Whether the endoscopist is male or female?
n	(Percentage of study population included)	329 (88.9)	330 (89.2)	331 (89.5)	332 (89.7)	331 (89.5)	329 (88.9)	263 (92.6)	329 (90.0)
Sex	Female vs. male (Ref.)	1.09 (0.68-1.74)	0.80 (0.50-1.26)	1.01 (0.63-1.59)	1.08 (0.65-1.78)	2.26 (0.98-5.19)	2.53 (1.50-4.28)***	1.79 (0.99-3.23)	1.89 (0.95-3.74)
Age (years)	50-54 vs. 55-65 (Ref.)	0.98 (0.62-1.57)	0.88 (0.56-1.39)	0.79 (0.50-1.26)	1.76 (1.10-2.81)*	1.10 (0.68-1.77)	1.77 (1.07-2.92)*	1.70 (0.95-3.06)	1.85 (0.95-3.57)
Education	Low	5.27 (2.59-10.72)***	1.56 (0.83-2.95)	1.76 (0.94-3.30)	2.10 (1.09-4.01)*	2.60 (0.96-7.06)	2.72 (1.33-5.57)**	2.53 (1.13-5.66)*	1.64 (0.68-3.95)
	Intermediate	2.10 (1.18-3.73)*	1.89 (1.11-3.20)*	1.77 (1.04-3.01)*	1.96 (1.13-3.40)*	3.66 (1.45-9.24)**	3.18 (1.75-5.79)***	1.46 (0.74-2.87)	0.81 (0.37-1.80)
	High (Ref.)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Household size	Living alone vs. not living alone (Ref.)	1.69 (0.63-4.57)	0.78 (0.40-1.52)	0.77 (0.39-1.50)	0.70 (0.26-1.88)	0.99 (0.33-3.00)	0.81 (0.38-1.76)	0.29 (0.10-0.88)*	1.04 (0.40-2.73)
Migrant background	Yes vs. no (Ref.)	1.10 (0.52-2.33)	1.34 (0.63-2.79)	1.31 (0.63-2.74)	1.49 (0.69-3.25)	0.88 (0.42-1.85)	0.86 (0.39-1.90)	0.94 (0.36-2.41)	1.69 (0.47-6.0)
Self-reported health	Good/less vs. very good/excellent (Ref.)	1.03 (0.62-1.72)	1.39 (0.84-2.30)	1.70 (1.02-2.82)*	1.22 (0.72-2.04)	1.30 (0.77-2.22)	1.11 (0.63-1.96)	1.25 (0.66-2.38)	2.75 (1.21-6.21)*
Region	Eastern vs. Western (Ref.)	1.10 (0.64-1.90)	0.97 (0.57-1.67)	1.09 (0.63-1.87)	0.73 (0.42-1.29)	0.89 (0.51-1.57)	0.91 (0.49-1.66)	0.69 (0.34-1.42)	1.38 (0.64-2.99)
Health literacy	Extremely/very confident vs. moderately/slightly /not confident (Ref.)	0.67 (0.38-1.16)	0.65 (0.38-1.11)	0.59 (0.34-1.01)	0.90 (0.52-1.57)	1.04 (0.60-1.80)	1.33 (0.75-2.35)	1.39 (0.72-2.68)	0.61 (0.27-1.35)
Interaction terms									
Living alone* education	Living alone*intermediate	2.42 (0.50-11.67)				1.43 (0.30-6.88)			
	Living alone*low	0.04 (0.00-0.38)**				0.15 (0.01-1.71)			
Sex*self-reported health									
Sex*living alone					3.26 (0.82-12.92)				

All models included the following variables: sex, age, education, migrant background, self-reported health, Eastern/Western Germany, household size, health literacy; bold numbers represent p-values ≤ 0.05 ; * $p \leq 0.05$ ** $p \leq 0.01$ *** $p \leq 0.001$; interaction terms are presented when included in the model; ref.: reference group

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Discussion

Our survey of the perceived needs for information on screening colonoscopy of 370 German insurees with no prior history of colonoscopy showed that the vast majority rated information on all but one item as being important. While information on the risks and side effects of screening was most frequently rated as very important, roughly a quarter of the respondents rated information on screening benefits as unimportant. The ratings differed by sex and education level. Women regarded most of the items as being very important more often, especially information on risks (e.g. pain) and practical aspects of the procedure. Generally, less educated subjects rated nearly all of the information as being important more frequently, but a significantly higher percentage of people with a low educational level living alone rated information on screening risks as being less important.

Information on the risks and benefits

One of the main pillars of informed decision-making is information on risks.[5, 6] The predominant focus on information about the potential risks and side effects of colonoscopy screening underlines the fact that people want to make informed decisions. However, this information is not regularly provided, as a systematic evaluation of the available print information on CRC screening in Germany showed: Nearly one-third of all information materials investigated failed to mention basic information on potential harms associated with CRC screening.[18] The DECISIONS survey of U.S. adults aged 50 and older yielded similar results: Almost 30% of women and men surveyed said that their health care providers did not discuss any of the drawbacks of CRC screening with them, while over 95% said that they had discussed the advantages.[19] Further effort is needed to empower patients to make informed decisions by providing health communication with appropriate information on all relevant factors, including the risks of CRC screening. The consumers seem to agree.[20]

In contrast, a minority of subjects appreciated key information regarding benefits of screening colonoscopy. In our study, 26% of subjects actually perceived the reduction in incidence and mortality of CRC as unimportant. Several factors may be responsible for this. First, the benefits of a screening examination are assumed as obvious or overestimated by many people.[21, 22, 23] Second, consumers might assume that all examinations covered by their health insurance companies are beneficial anyway. Third, the items on the reduction in incidences and mortality of CRC were presented in quantitative terms describing the absolute risk reduction, i.e., 'the number of bowel cancer-related deaths that could be prevented'. Subjects with lower numeracy skills may perceive quantitative information as less important because of their inability to understand these statistics.[24] Fourth, goal framing might be present due to the use of a gain message (e.g., the number of deaths that could be

prevented by regular screening) instead of a loss message (e.g., the number of deaths that will occur due to failure to attend screening). Loss messages are shown to be associated with a more positive perception of the effectiveness of a procedure.[25] Therefore, the framing of information on the benefits of screening colonoscopy as a loss message might have resulted in a higher rating of the importance of information on screening benefits.

Differences in sex and educational levels

In our study, women showed higher information needs than men on risks, pain, laxative use, and going home independently afterwards. Similar results were found in a study using focus groups interviews in which the women demanded more information in terms of both quantity and detail, while men preferred little or no information on endoscopic procedures.[26] These differences between women and men might be due to the use of different strategies to overcome their fears.

We detected significantly higher information needs in less educated groups. Similarly, a study on information needs in cancer patients using a 5-point scale to measure importance also showed that a low educational level is associated with higher information needs.[27] Likewise, this might be due to a lower level of knowledge and understanding on CRC screening. However, in our study, health literacy was not associated with information needs while other studies showed a relation.[22, 28, 29] A reason for this could be that the screening question we used to explore health literacy was not of a sensitive nature within our study population.

In contrast to the finding of higher information needs in less educated groups, our results suggest that, as a group, subjects with low education level living alone are clearly less interested in information on the risks and side effects of screening colonoscopy. Apparently, they are not interested in making an informed decision or are unable to do so due to low health literacy. Living alone might serve as a surrogate for an increased risk of social isolation and low social support. Thus, this group is likely to be the most vulnerable group with the highest health risks.[30] However, we could not ascertain the actual screening behavior of this group based on the available data. Moreover, results on living alone must be interpreted with caution because of the low number of cases. Future research is needed to obtain deeper insights into the contrasting information needs people with low education level living alone, who may constitute an important risk group.

Limitations

This study has some limitations, which are discussed below. First, while colonoscopy is widely considered as the gold standard to diagnose CRC, only a few countries offer

colonoscopy for primary screening [11]. Most screening programs use colonoscopy only after a positive stool test, in which case colonoscopy is a diagnostic and not a screening procedure, as individuals with a positive stool test cannot be considered asymptomatic and have an increased CRC risk. Therefore, our results are not generalizable to this situation as our study refers to colonoscopy for primary screening. Second, the study population consisted solely of persons with Barmer GEK statutory health insurance, who might not be representative of the German population at large. However, we believe that this can be assumed to a great extent for two reasons: A) 85% of Germans are covered by statutory health insurance (and most of the remaining by private insurance), and B) Since 1996, German residents are largely free to choose between health insurance companies, all of them offer very similar benefits and charge similar premiums. However, as a German questionnaire was used, subjects with minor German language skills may be underrepresented. Third, analysis was restricted to the subgroup of colonoscopy-naïve subjects, because evidence-based information on colonoscopy for primary screening mainly addresses people who have not yet experienced this procedure.[31] By selecting this subgroup, the validity of the results may be limited. However, this subgroup analysis was derived from an a priori research question that addressed colonoscopy-naïve subjects. Therefore, multiple testing is not a predominant issue. Fourth, as the insurance data did not provide the lifetime colonoscopy status, our final study population was based on self-reported statuses, which made it impossible to identify the denominator in the initial sample of our study population. Without a precise denominator, the response rate and potential differential response remained unknown. Using the non-responder-analysis instead as a substitute, we cannot exclude a substantial selection bias. However, the proportion of participation is not necessarily associated with the magnitude of bias.[32] Moreover, a response bias is mainly restricted to the prevalence of exposures or outcomes, while associations are only affected, if the response is both associated with the exposure and outcome. The risk of misclassification of the self-reported colonoscopy status (e.g. confusion with other endoscopic procedures) was considered low, as the questionnaire included a description of the procedure and knowledge about colonoscopy is common because screening colonoscopies were introduced more than ten years ago. Fifth, the fact that subjects rated most items as either 'very' or 'moderately important', and almost never as 'very unimportant' indicates that the four-point scale of importance may have resulted in a ceiling effect. Nevertheless, all of the response options were used by the respondents, and the fact that most respondents considered the sex of the endoscopist to be relatively unimportant shows that they were able to discriminate across the spectrum of different types of information. In further analyses, the responses were dichotomized to 'very important' vs. 'other'. Focusing on the 'very important' ratings allowed us to detect relevant differences. Sixth, we did not include information on overdiagnosis as a

potential harm. Although this is a huge problem in PSA testing for prostate cancer screening, there is probably little overdiagnosis associated with screening colonoscopy.[33] Seventh, the models on the associated factors of the attributed importance of specific information on screening colonoscopy may suffer from residual confounding.

Implications

The findings of our study have several implications. As an informed choice requires knowledge about the absolute frequencies of the risks and benefits of screening [5-7], and one-quarter of respondents considered data on the numbers of prevented death as being unimportant, future information on screening colonoscopy should comprehensively describe the benefits including quantitative information. A former evaluation of information materials on CRC screening had shown that benefits are often presented in general terms, not based specifically on colonoscopy, and without quantifying the associated risk reduction.[18] However, numeracy skills are crucial to understanding quantitative information which in turn is essential to informed decision-making.[34] Pictographs are being used increasingly in patient decision aids on cancer screening in Germany.[35] This may help to improve patient understanding of essentially quantitative messages in screening information.[36–38]

In light of the observed differences in information preferences between women and men, tailoring future information according to sex-specific needs may be warranted. Health information materials for women and men that differ in the sex-specific baseline risks of getting CRC are already available.[39, 40] Further modifications according to the perceived information needs should be tested. Health information should also be adjusted to individuals with lower-level education or literacy. The high demand of less educated people to become informed encourages further efforts to design evidence-based information materials that adequately inform this population. To date, several studies revealed that individuals with lower health literacy or educational levels show deficits in informed decision-making.[41-43] However, identifying these groups, e.g. via screening questions, and then offering health information may not be practical or even stigmatizing. Strategies to address educational and literacy inequalities may be implemented via self-selection, and may include offering information in simple language, with a shorter extent of information, using different information channels like web-based information and videos, and improving communication with health professionals.[44-46]

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Contributorship:

MD, KK, and UW developed the conception and design of the study. MD and KK analysed and interpreted the data, and drafted the manuscript. MD, KK, and UW revised the work critically for intellectual content. All authors approved the final version of the manuscript and are accountable for all aspects of the work.

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Figure 1: Flow chart of the study population

Figure 2: Importance of key information about screening colonoscopy (n=354-365)

*Responses from employed persons only (n=279)

Figure 3: Importance of key information about screening in women and men (n=352-363)

* Responses from employed persons only (n=279)

Figure 4: Importance of key information about screening colonoscopy by educational level (n=346-357)

* Responses from employed persons only (n=278)

Figure 5: Information on risks and side effects of colonoscopy – Percentage of 'very important' ratings stratified by sex, educational level and household size (n=353)

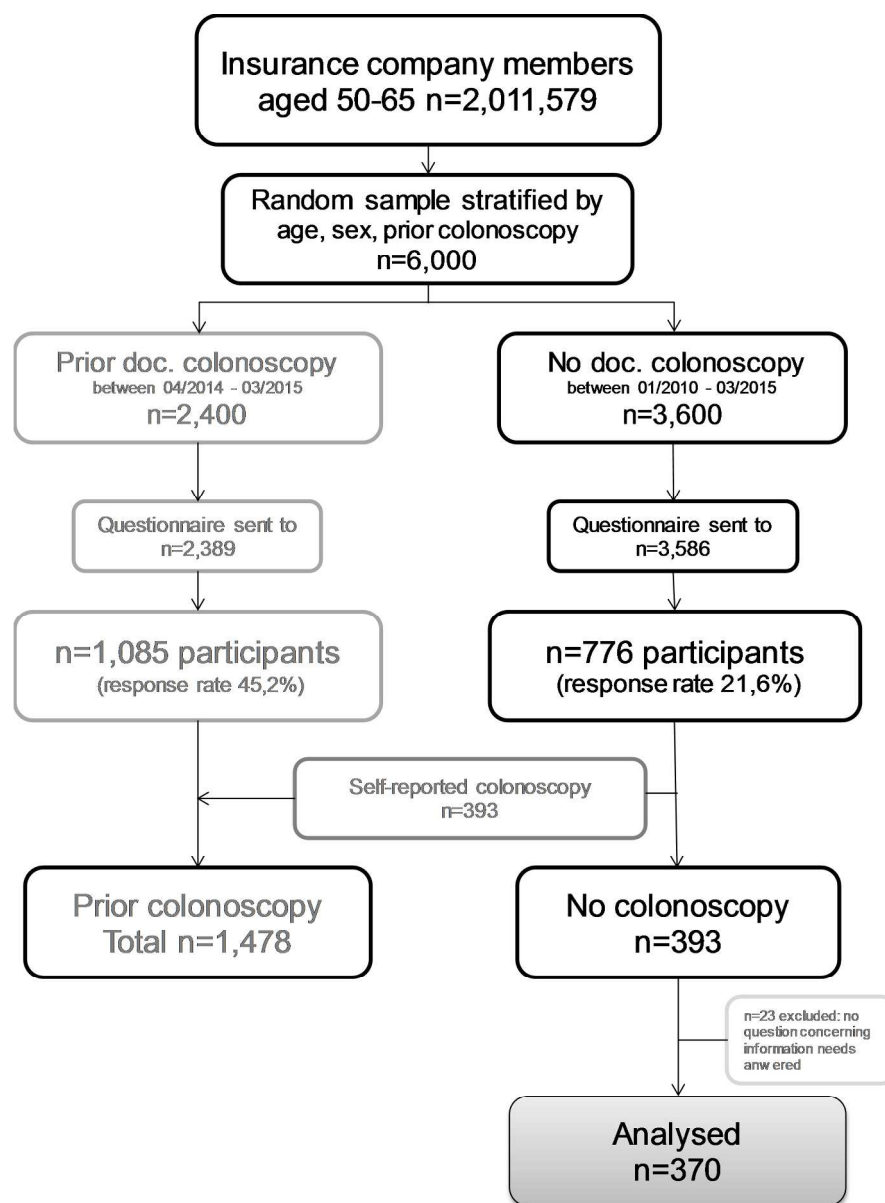


Figure 1 Flow chart of the study population

178x240mm (300 x 300 DPI)

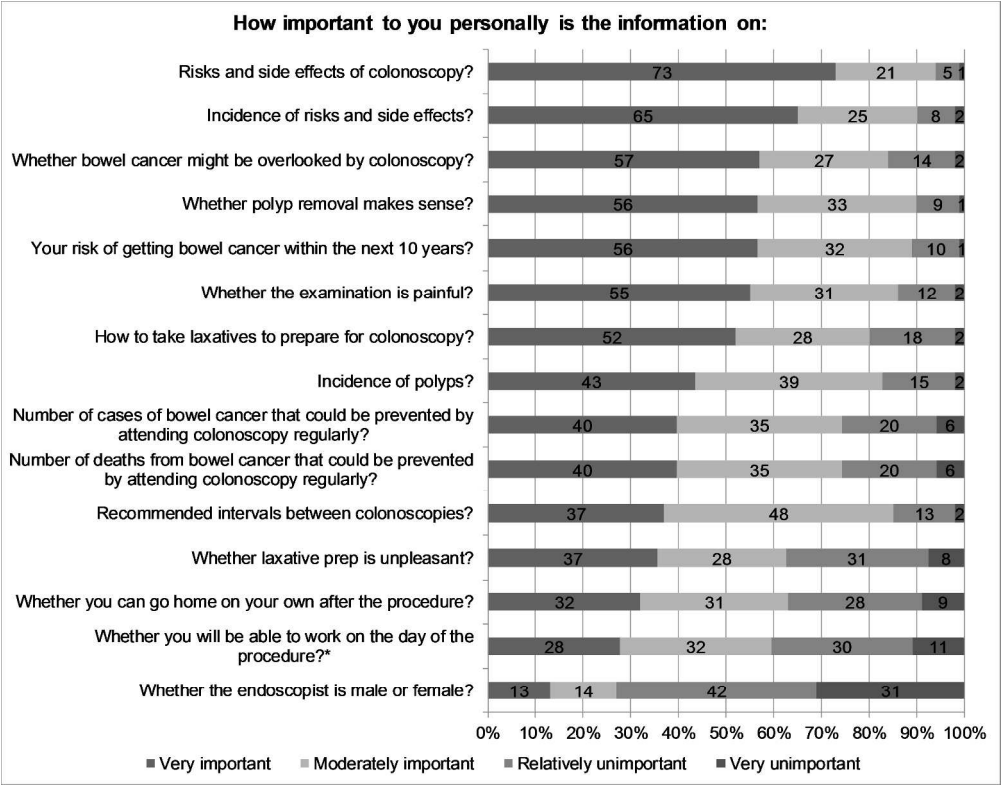


Figure 2: Importance of key information about screening colonoscopy (n=354-365)
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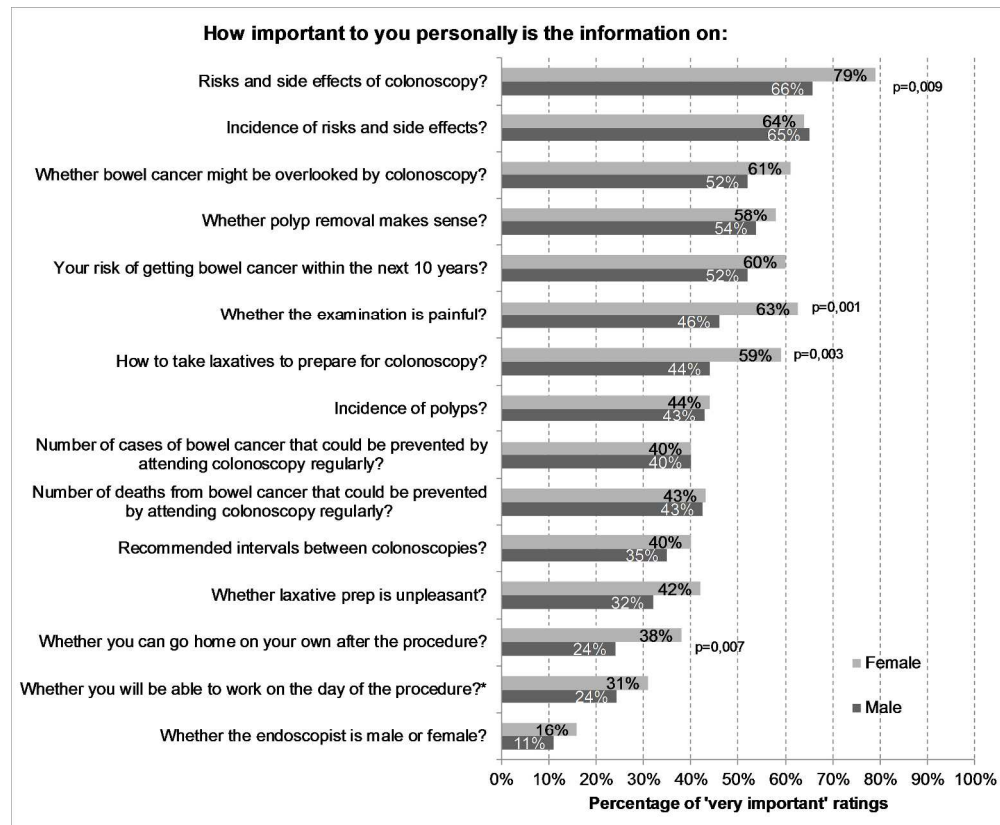


Figure 3: Importance of key information about screening in women and men (n=352-363)

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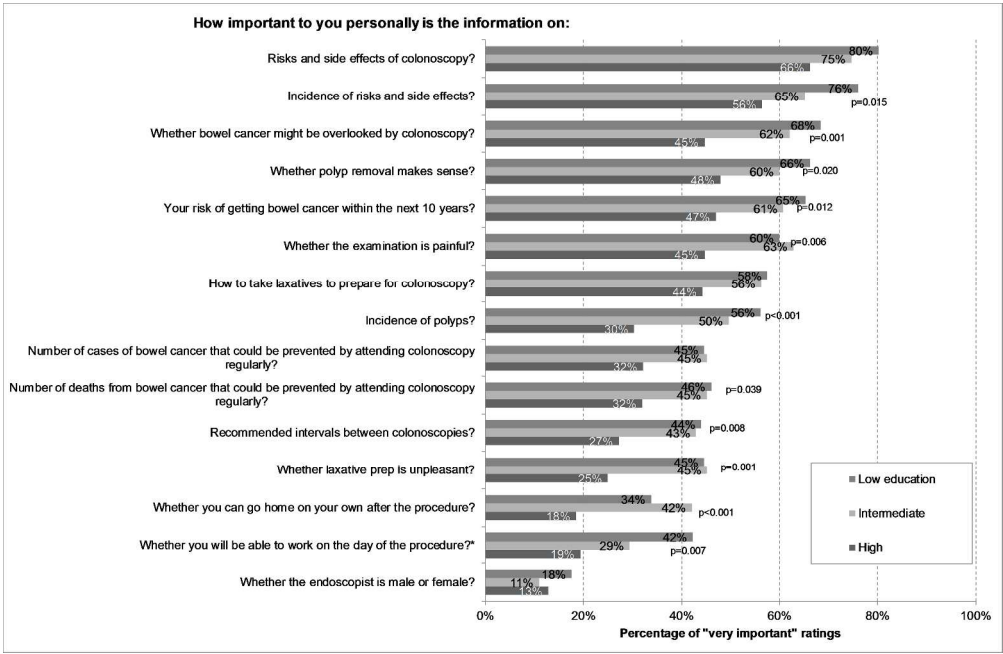


Figure 4: Importance of key information about screening colonoscopy by educational level (n=346-357)

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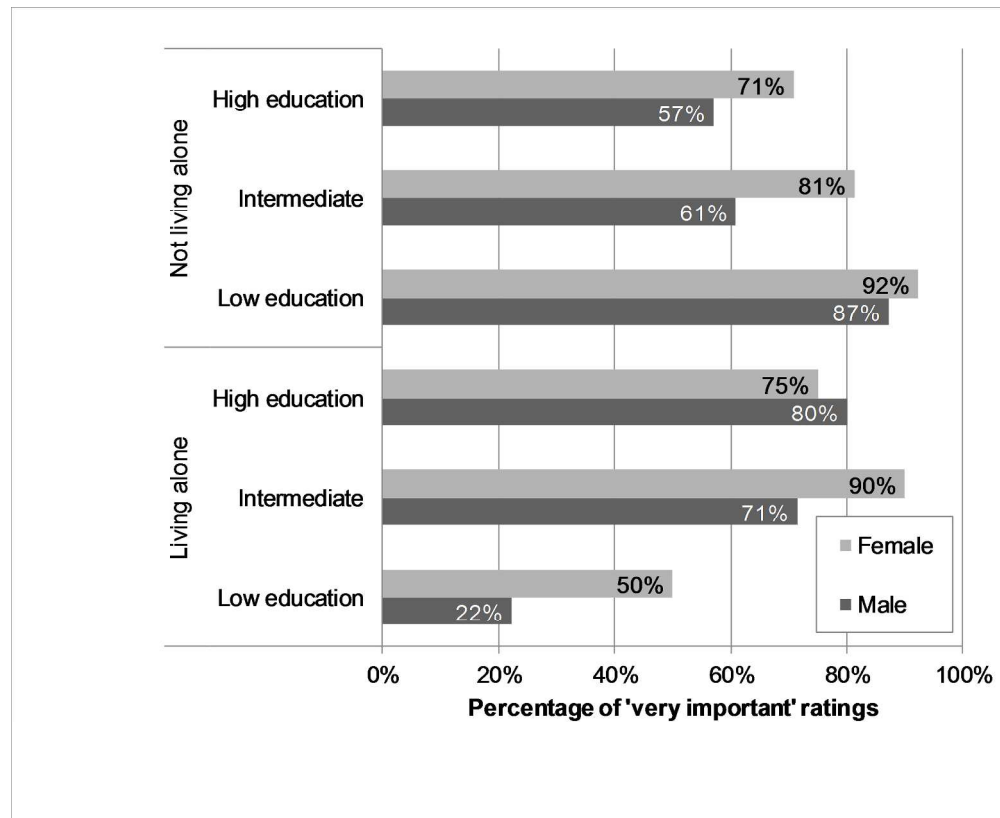


Figure 5: Information on risks and side effects of colonoscopy – Percentage of 'very important' ratings stratified by sex, education level and household size (n=353)

216x175mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any prespecified hypotheses	1, 3
Methods			
Study design	4	Present key elements of study design early in the paper	1, 3-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	3-5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-5
Bias	9	Describe any efforts to address potential sources of bias	4-5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	4-5
		(b) Describe any methods used to examine subgroups and interactions	4-5
		(c) Explain how missing data were addressed	Reported n’s in legends of the tables
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	-

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Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	3-5
		(b) Give reasons for non-participation at each stage	Not applicable
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-7, table 1
		(b) Indicate number of participants with missing data for each variable of interest	6-7
Outcome data	15*	Report numbers of outcome events or summary measures	7-9, tables 2-5
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-7
		(b) Report category boundaries when continuous variables were categorized	8-9
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-7
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13-14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	2, 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	5

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.