Research article

Socioeconomic differences in discrepancies between expected and experienced discomfort from colonoscopy and colon capsule endoscopy

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ABSTRACT

Background: Social inequalities in colorectal cancer screening participation are evident. Barriers to screening participation include discomfort from diagnostic modalities. We aimed to describe the discomfort experienced from colonoscopy and colon capsule endoscopy (CCE) and investigate the discrepancy between expected and experienced discomfort stratified by socioeconomic status.
Methods: A randomised controlled trial was conducted offering half of the colorectal cancer screening invitees the choice between CCE and colonoscopy after a positive faecal immuno-chemical test. This paper includes those who elected to undergo CCE. A positive CCE elicited referral for a therapeutic colonoscopy. Participants reported their discomfort from CCE and from any following colonoscopies in electronically distributed questionnaires. Discomfort was measured using visual analogue scales and compared between socioeconomic subgroups determined by educational level and income.
Results: The experienced discomfort from CCE and colonoscopy differed significantly between educational levels but not income levels. The bowel preparation contributed the most to the experienced discomfort in both CCE and colonoscopy. The discrepancy between expected and experienced discomfort from colonoscopy increased with increasing educational and income levels. A similar trend was seen in CCE between educational levels but not income levels.
Conclusions: None of the results indicated a higher discomfort in lower socioeconomic subgroups. Regardless of the investigation modality, the bowel preparation was the main contributor to experienced discomfort. The discrepancy between expected and experienced discomfort did not seem to be larger in lower socioeconomic subgroups, indicating that this is not a major barrier causing inequalities in screening uptake. This is the first study investigating individual discomfort discrepancy in both CCE and colonoscopy, while being able to stratify by socioeconomic status.

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1. Introduction

Colorectal cancer incidence, more advanced stage at diagnosis, and higher mortality are associated with lower socioeconomic status [1,2]. Screening with faecal occult blood testing followed by optical diagnostics have proven beneficial in reducing both overall mortality, colorectal cancer mortality and colorectal cancer incidence [3–7]. However, social inequalities in participation are evident in colorectal cancer screening programmes across the globe [8–10]. We have previously demonstrated that non-participants have a similar all-cause mortality as participants with the highest concentrations of blood in their stool [11]. The underlying pathways are currently unknown, but it is a good indicator, that non-participants as a group are worse off than the average screening participants are.

It has proven difficult to reduce inequalities between socioeconomic subgroups as most interventions targeted at the entire population, are less efficient in the less privileged subgroups [12–18]. Previous research have identified barriers to screening participation such as perceived risk of disease, fear of the result, the faecal collection, expected discomfort, and invasiveness of the procedures [19–27]. These barriers are very unlikely to be of equal relevance to all individuals. Also, whether it is the presence of either one of these barriers or a combination of more, the underlying mechanisms of non-participation is probably very individual. For each person, theoretically, the combination of perceived barrier(s) must not exceed the perceived gain for them to engage in the intended behaviour i.e. participate in screening [27]. Yet still we see behaviour patterns that elicits us to believe that the barriers and gains are somehow connected to socioeconomic status.

We argue that the perceived barriers or the perceived gain from colorectal cancer screening differ significantly between socioeconomic subgroups thereby causing inequalities in participation, and in the benefits from screening. Recently, we published the results from our cohort of screening participants who underwent both colonoscopy and colon capsule endoscopy. Participants reported their expected level of discomfort from both procedures. Results showed that the expected discomfort from these optical diagnostic modalities increased with increasing socioeconomic status as measured by educational level and income [28]. However, it is unknown whether such socioeconomic differences translates into experienced discomfort, and whether any potential discrepancies between expected and experienced discomfort differ between socioeconomic subgroups. If the discrepancy between expected and experienced discomfort is larger in some socioeconomic subgroups than others, it may indicate that the information targeted at the population is better suited for some than others. Therefore, the aim of this study was to describe the perceived discomfort experienced from colonoscopy and colon capsule endoscopy and to investigate the discrepancy between expected and experienced discomfort stratified by socioeconomic status.

2. Materials and methods

The Danish colorectal cancer screening programme invites citizens aged 50–74 for a faecal immunochemical test (FIT) biennially. This is proceeded by an invitation to colonoscopy if the faecal haemoglobin concentration exceeds 20 µg/g faeces (100 ng/mL buffer). The screening programme is managed by the five Danish Administrative Regions responsible for the operation of the health care system. In the Region of Southern Denmark, we conducted a randomised trial (CareForColon2015) offering the intervention arm a colon capsule endoscopy as a filter test after positive FIT [29–31]. Individuals in the intervention arm were therefore free to choose whether they wanted a referral for colonoscopy or if they wanted to undergo colon capsule endoscopy to determine whether a diagnostic or therapeutic colonoscopy was needed. The overall aim of the CareForColon2015 trial was to investigate the number of cancers, high risk adenomas, and intermediate risk adenomas between the intervention arm and the control arm (default referral for colonoscopy) of the trial. This current manuscript includes the participants of the intervention arm who elected to undergo colon capsule endoscopy as the first diagnostic modality following positive FIT. Any colonoscopy data included here are therefore reported from individuals who have also undergone colon capsule endoscopy. Participants with suspected neoplastic findings (adenomas) in colon capsule endoscopy or an incomplete investigation would subsequently be referred for colonoscopy. Prior to an investigation, participants reported their expected discomfort in a physical questionnaire. In addition, participants were invited to fill in a digital questionnaire about the experienced discomfort three days after the procedures. Among other things, participants were also asked to report their educational level, household income and whether they had previously undergone colonoscopy. Think-aloud tests were employed to qualitatively validate the questionnaires before launching the trial [32,33].

2.1. Socioeconomic status

Socioeconomic status was self-reported by the participant prior to colon capsule endoscopy. Socioeconomic status was derived from a physical questionnaire filled in by the participants on the morning of their colon capsule endoscopy investigation. They would partially fill in the questionnaire while awaiting their time slot for capsule ingestion. After capsule ingestion, they would fill in the remainder of the questionnaire, which typically would be limited to the questions regarding the experience of swallowing the capsule. As part of the questionnaire, they reported their highest completed educational level from a set of standard answer options: Elementary/Basic school, High-school education, Vocational education, Short higher education, medium-long higher education, or long higher education. Individuals indicating more than one option would be categorized by the highest indicated level. High-school and vocational education were grouped together in our analyses. This was also the case for medium-long and long higher education. Participants also reported their annual household income from standard answer options ranging from less than 100.000 DKK (13.426 EUR) to more than 900.000 DKK (120.835 EUR) with increments of 100.000 DKK in between. Participants were then grouped into

household incomes of 300.000 DKK or less (40.283 EUR), 300.000–500.000 DKK (40.283–67.138 EUR), >500.000–700.000 DKK (67.138–93.993 EUR), and more than 700.000 DKK (93.993 EUR), reflecting the range of the income in the target population as determined previously [9].

2.2. Discomfort

In addition to socioeconomic status, the questionnaire filled in by the participants prior to their colon capsule investigation also asked the participants to provide their expected discomfort from five phases of both colon capsule endoscopy and colonoscopy. These elements were; 'bowel preparation', 'transportation to investigation', 'the procedure', 'the rest of the day', and 'the following three days'. The participants were to estimate this using visual analogue scales (VAS). The extremes of the scales were labelled *'No discomfort'* and *'A very high degree of discomfort',* and the scales had no subdivisions. The participants also reported their experienced discomfort from the phases of 'bowel preparation' and 'transportation' in the questionnaire filled in prior to colon capsule endoscopy [28].

The actual experienced discomfort from the remainder of the phases ('the procedure', 'the rest of the day', and 'the next three days') for colon capsule endoscopy were estimated by the participants using electronic VAS in a questionnaire received three days post the colon capsule endoscopy. The experienced discomfort from colonoscopy for all five phases were also estimated by the participants using electronic VAS in a questionnaire received three days post the colonoscopy. The experienced discomfort scores from colonoscopy was therefore only obtained from individuals whose colon capsule endoscopy was incomplete, or had identified pathology in need of further diagnostics or therapeutic actions.

The electronic VAS included a moveable indicator point located at the middle of the scale, for the participants to move to any point on the line. To activate the discomfort score, the participant had to click/tap the indicator point, before moving it. Individuals not tapping the indicator were registered as non-responders. The phrasing of the questions regarding expected and experienced discomfort were identical throughout the questionnaires but specific to each of the five phases and for each investigation modality. E.g., *"What degree of physical and mental discomfort did you experience overall from the bowel cleansing"?* The questions were provided in Danish (full questionnaire provided in **Appendix A**).

To sum up, the participants were asked to provide their:

- Expected discomfort from colonoscopy and colon capsule endoscopy prior to undergoing any investigations in the first questionnaire (physical).
- Experienced discomfort from colon capsule endoscopy in the first questionnaire for two phases, and for the remaining three phases in a second questionnaire (electronic).
- Experienced discomfort from colonoscopy in the third questionnaire (electronic) for all five phases.
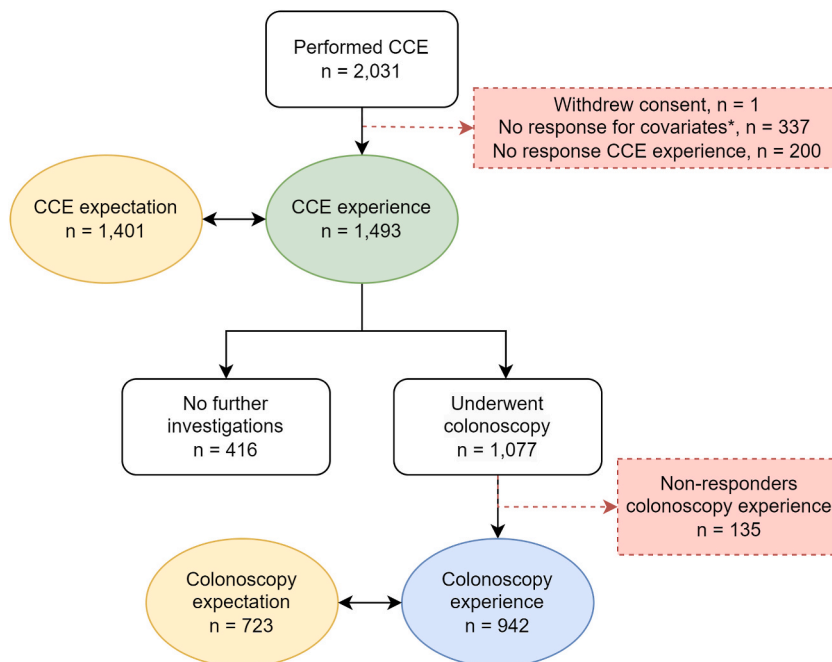

Fig. 1. Flow of participants from the 2031 who underwent colon capsule endoscopy in the intervention arm of CareForColon2015 to those eligible for experienced discomfort analyses (green and blue circles), and discomfort discrepancy analyses (yellow circles) *Previous colonoscopy experience (n = 35), educational level (n = 59), household income (n = 302).

This data collection enabled us to calculate the individual discrepancy between expected and experienced discomfort.

2.3. Statistics and covariates

The sum of scores derived from the VAS from each of the five phases of the investigations were used as a measure of the overall discomfort. The individual discomfort discrepancy was calculated by subtracting the expected discomfort from the experienced discomfort (i.e. a negative discrepancy indicated an expected discomfort higher than the discomfort actually experienced). The overall discomfort scores and discrepancies were treated as continuous ordinal variables with severely skewed distributions described by median. The overall discomfort score had a possible range from zero to 750 (0–150 per VAS), whereas the range of discrepancies had a possible range from −750 to 750. Kruskal-Wallis rank sum tests were used for univariate comparisons between subgroups of non-ordered categories (sex and previous colonoscopy), whereas the Jonckheere-Terpstra test was used for ordered categories

Table 1
Visual analogue scale median scores for overall discomfort (possible range: 0–750), discrepancy between expected and experienced discomfort (possible range: 750-750) by subgroups, stratified by investigation modality.

Colon capsule endoscopy

Variable	Total n = 1493 n (%)	Overall discomfort Median	p-value	Total n = 1401 n (%)	Discrepancy between expected and experienced discomfort[a] Median	p-value
Highest achieved educational level						
Basic school	219 (14.7 %)	112.0		199 (14.2 %)	−13.0	
High school or vocational	525 (35.2 %)	121.0		490 (35.0 %)	−27.5	
Short higher education	239 (16.0 %)	150.0		220 (15.7 %)	−28.5	
Long higher education	510 (34.2 %)	144.3	0.002	492 (35.1 %)	−37.75	0.170
Annual household income						
Low	340 (22.8 %)	124.5		308 (22.0 %)	−28.0	
Medium-Low	430 (28.8 %)	130.0		400 (28.6 %)	−17.3	
Medium-High	324 (21.7 %)	138.5		310 (22.1 %)	−34.0	
High	399 (26.7 %)	135.0	0.618	383 (27.3 %)	−36.0	0.242
Previous colonoscopy						
No	1019 (68.3 %)	124.5		960 (68.5 %)	−35.5	
Yes	474 (31.7 %)	144	0.002	441 (31.5 %)	−14.5	<0.001
Sex						
Females	666 (44.6 %)	173.8		630 (45.0 %)	−20.8	
Males	827 (55.4 %)	106.5	<0.001	771 (55.0 %)	−34.5	<0.001
Age						
49–59	599 (40.1 %)	140.0		576 (41.1 %)	−32.3	
60–70	621 (41.6 %)	127.5		577 (41.2 %)	−31.5	
> 70	273 (18.3 %)	122.5	0.068	248 (17.7 %)	−17.5	0.232

Colonoscopy

Subgroup	Total n = 942 n (%)	Overall discomfort Median	p-value	Total n = 723 n (%)	Discrepancy between expected and experienced discomfort[a] Median	p-value
Highest achieved educational level						
Basic school	138 (14.6 %)	151.5		101 (14.0 %)	−25.5	
High school or vocational	344 (36.5 %)	139.5		262 (36.2 %)	−64.3	
Short higher education	148 (15.7 %)	177.0		111 (15.4 %)	−89.0	
Long higher education	312 (33.1 %)	165.0	0.018	249 (34.4 %)	−92.5	0.002
Annual household income						
Low	238 (25.3 %)	160.5		178 (24.6 %)	−44.8	
Medium-Low	275 (29.2 %)	141.0		216 (29.9 %)	−75.5	
Medium-High	203 (21.5 %)	174.0		162 (22.4 %)	−86.5	
High	226 (24.0 %)	157.5	0.356	167 (23.1 %)	−83.0	0.036
Previous colonoscopy						
No	659 (70.0 %)	151.5		504 (69.7 %)	−95.5	
Yes	283 (30.0 %)	187.5	0.004	219 (30.3 %)	−29.5	<0.001
Sex						
Females	389 (41.3 %)	196.5		303 (41.9 %)	−89.0	
Males	553 (58.7 %)	136.5	<0.001	420 (58.1 %)	−58.8	0.064
Age						
49–59	328 (34.8 %)	173.3		259 (35.8 %)	−59.5	
60–70	413 (43.8 %)	153.0		306 (42.3 %)	−86.8	
> 70	201 (21.3 %)	135.0	0.002	158 (21.9 %)	−64.8	0.060

[a] Negative discrepancies indicate higher expected than experienced discomfort.

(educational level, income, and age groups). Continuous ordinal regression models were conducted in order to test differences in VAS score discrepancy [34,35] between socioeconomic subgroups. The regression models were adjusted for categorical covariates age (49–59, 60–70, >70 years), sex (male, female) and previous colonoscopy (yes, no). For each regression model outcome, the assumption of normally distributed residuals was tested and confirmed (appendix B, Fig. B1). Using the exponential function, the log-odds ratio estimates were converted to odds ratios (OR), in order to ease the interpretation of the estimates [36]. Data management and statistical analyses were performed in SAS (SAS Institute Inc. SAS 9.4. Cary, North Carolina, USA) and RStudio statistical software package, Version February 1, 5019 [37]. Analyses and visualizations performed in RStudio were completed using the ordinalCont and Publish packages [36,38]. The significance level was set at 5 %, and 95 % confidence intervals (CI) were calculated. Non-responders were excluded from analysis.

3. Results

3.1. Participants

A total of 1493 individuals were eligible for analyses of colon capsule endoscopy experience, i.e. had responded to questions regarding colon capsule endoscopy experience in the first two questionnaires. In this group, 1077 (72.1 %) underwent subsequent colonoscopy of whom 942 (87.5 %) reported their colonoscopy experience in the third questionnaire. Of the 1493 reporting their colon capsule endoscopy experience, 1401 (93.8 %) had also provided their expected experience prior to the procedure in the first questionnaire. Of the 942 who reported their colonoscopy experience, 723 (76.8 %) had also provided their expected experience prior to the procedure in the first questionnaire (Fig. 1). The trial had initiated 2031 colon capsule endoscopies, but exclusions were made prior to analyses. Most (2,019, 99.4 %) responded to the questionnaire prior to the investigations. One (<0.1 %) participant withdrew consent, 200 (9.8 %) did not report their colon capsule endoscopy experience, and 337 (16.6 %) did not report their covariate characteristics (previous colonoscopy, educational level, and/or household income).

3.2. Experienced discomfort

The median reported overall discomfort differed significantly between educational levels, but not household incomes, for both investigation modalities. Individuals with previous colonoscopy experience reported more discomfort from both colon capsules endoscopy and colonoscopy than those with no prior experience. Females reported a higher degree of discomfort from both modalities
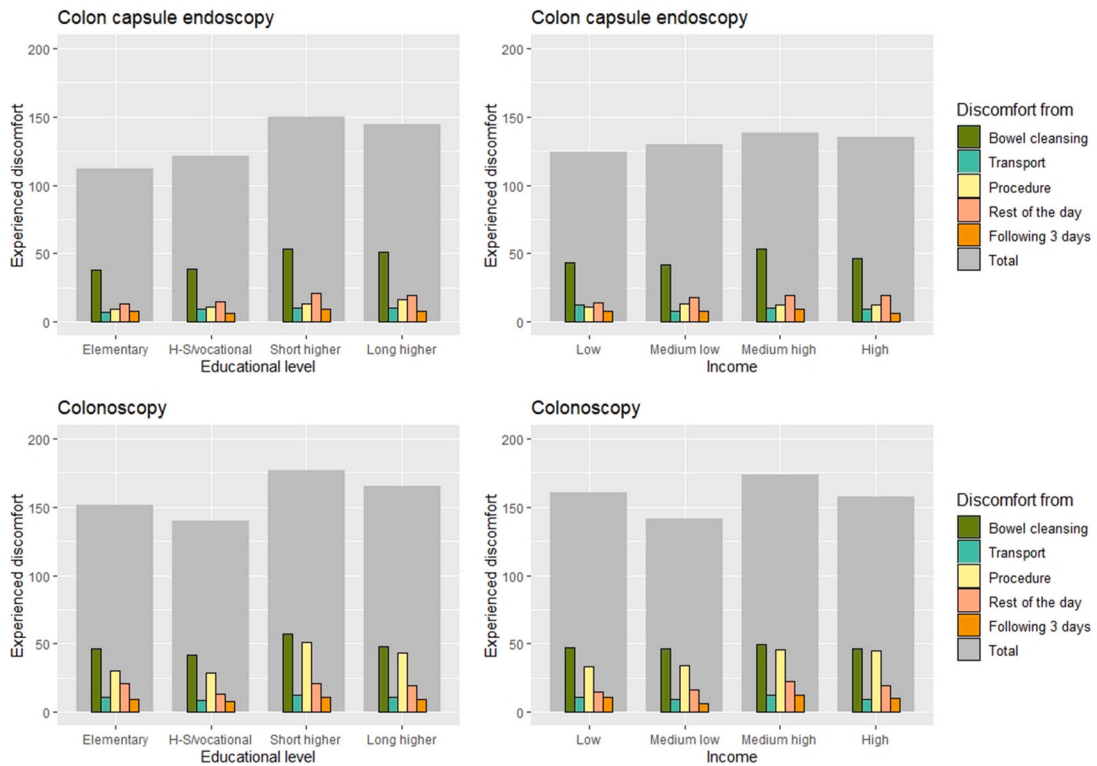

Fig. 2. Median experienced discomfort from each of the five phases included in the overall experienced discomfort VAS score[†], stratified by investigation modality and socioeconomic measure.

compared to males. The degree of discomfort decreased significantly with age in colonoscopy, but not in colon capsule endoscopy, although, a similar trend was seen (Table 1).

The median discomfort reported from each of the five phases followed a similar pattern between socioeconomic subgroups for each investigation modality, respectively. For colon capsule endoscopy, 'the bowel preparation' contributed the most to the overall discomfort, followed by 'the rest of the day', 'the procedure', 'the transport' and 'the following three days'. The latter four being relatively close in degree of discomfort, while 'the bowel preparation' contributed more than double the discomfort compared to the second-largest contributor (Fig. 2). For colonoscopy, 'the bowel preparation' also contributed the most to discomfort in all socioeconomic subgroups, but relatively closer to 'the procedure' than the remaining three phases ('the rest of the day', 'the transport', and 'the following three days') (Fig. 2).

3.3. Discrepancy between expected and experienced discomfort

The median discrepancy in discomfort was negative in all subgroups for both colon capsule endoscopy and colonoscopy, meaning that the expected discomfort was generally higher than the experienced discomfort. Univariate tests regarding colon capsule endoscopy, showed how the discrepancy did not differ significantly between socioeconomic subgroups or age groups, but was higher in males compared to females, and higher for individuals without versus with prior colonoscopy experience. Univariate tests regarding colonoscopy, showed that the discrepancy did not differ between subgroups of sex or age. On the contrary, the discomfort discrepancy increased with higher educational levels and income, and was higher in the subgroup with prior versus without prior colonoscopy (Table 1).

The adjusted regression models for colon capsule endoscopy discomfort discrepancy showed a significantly higher OR in long higher educational level (OR 1.41, 95 % CI 1.05–1.90) compared to elementary school. No significant differences were seen between other educational levels, but an insignificant trend of higher discrepancy with higher educational level was evident (Fig. 3). No significant differences were observed between income subgroups for colon capsule endoscopy discomfort discrepancy (Fig. 4).

The adjusted regression models for colonoscopy discomfort discrepancy showed significantly higher OR in short higher educational level (OR 1.68, 95 % CI 1.05–2.70) and long higher educational level (OR 1.70, 95 % CI 1.12–2.57) compared to elementary school. No significant differences were seen between high-school/vocational education and elementary school (Fig. 3). Highest income level had a significantly increased OR (OR 1.75, 95 % CI 1.16–2.62) compared to lowest. No significant differences were observed between other income subgroups for colonoscopy discomfort discrepancy, but an insignificant trend of higher discrepancy with higher income was evident (Fig. 4).

4. Discussion

We aimed to describe possible socioeconomic differences in discomfort experienced from colon capsule endoscopy and colonoscopy, and to investigate discrepancies between expected and experienced discomfort in a screening population. We found significant differences in median overall discomfort between socioeconomic subgroups defined by educational level in both colonoscopy and colon capsule endoscopy. This was not the case for subgroups of differing income levels. There was a trend of lower socioeconomic subgroups reporting less discomfort. Non-significant trends of highest degree of discomfort in the second highest socioeconomic subgroups (medium-high income, and short higher education) were seen in both colon capsule endoscopy and colonoscopy. The bowel preparation contributes with the most discomfort to all socioeconomic subgroups for both colonoscopy and colon capsule endoscopy. Of greater importance, we found that the discrepancy between expected and experienced discomfort from colonoscopy was significantly different between subgroups of educational and income levels. The OR estimates for increased discrepancy increased with increasing educational level. A similar trend was seen for colon capsule endoscopy between educational levels, but no such indication was evident for colon capsule endoscopy between income levels.

It is of no surprise that bowel preparation and endoscopy includes discomfort to the patient, but to our knowledge, only one other
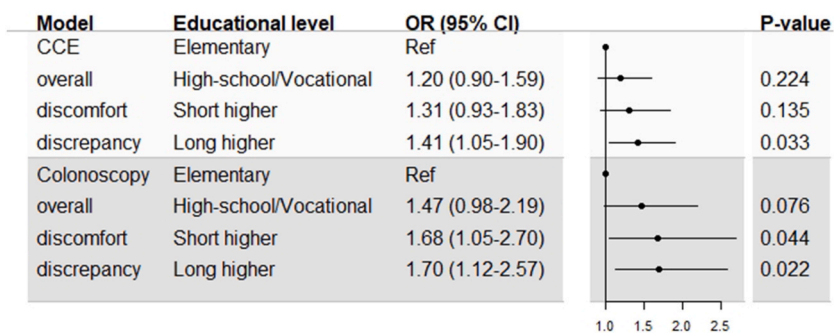

Model	Educational level	OR (95% CI)		P-value
CCE	Elementary	Ref		
overall	High-school/Vocational	1.20 (0.90-1.59)		0.224
discomfort	Short higher	1.31 (0.93-1.83)		0.135
discrepancy	Long higher	1.41 (1.05-1.90)		0.033
Colonoscopy	Elementary	Ref		
overall	High-school/Vocational	1.47 (0.98-2.19)		0.076
discomfort	Short higher	1.68 (1.05-2.70)		0.044
discrepancy	Long higher	1.70 (1.12-2.57)		0.022

Fig. 3. Odds ratios of having a higher discrepancy between expected and experienced overall discomfort from colon capsule endoscopy and colonoscopy based on educational level, estimated from continuous ordinal regression models*. n = 1401 *Adjusted for household income, previous colonoscopy experience, sex, and age.
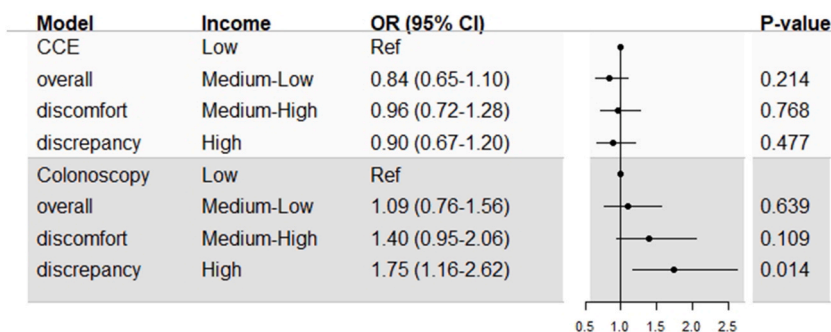
Model	Income	OR (95% CI)		P-value
CCE	Low	Ref		
overall	Medium-Low	0.84 (0.65-1.10)		0.214
discomfort	Medium-High	0.96 (0.72-1.28)		0.768
discrepancy	High	0.90 (0.67-1.20)		0.477
Colonoscopy	Low	Ref		
overall	Medium-Low	1.09 (0.76-1.56)		0.639
discomfort	Medium-High	1.40 (0.95-2.06)		0.109
discrepancy	High	1.75 (1.16-2.62)		0.014

Fig. 4. Odds ratios of having a higher discrepancy between expected and experienced overall discomfort from colon capsule endoscopy and colonoscopy based on income, estimated from continuous ordinal regression models *. n = 723 *Adjusted for educational level, previous colonoscopy experience, sex, and age.

study has previously described the discomfort experienced in endoscopy stratified by socioeconomic measures [39]. They describe how the most deprived individuals more often experienced the colonoscopy as more uncomfortable than their expectation, compared to the least deprived. This does not in itself indicate whether the degree of discomfort was higher in the most deprived, but relates only to the discrepancy between expected and experienced discomfort in the deprived. This does not align very well with the findings of our study as we see greater discrepancies in higher educational levels. In a previous publication, we have described how the expected discomfort increased with increasing socioeconomic status [28], whereas we now are able to show how these differences were not transferred into the experience. Further, the experienced discomfort was much more aligned with the expected discomfort for colon capsule endoscopy compared to colonoscopy. The expected procedural discomfort from colonoscopy [28] seem to be a lot higher than the experienced discomfort reported here. Systematic screening using colon capsules has yet to be introduced in routine settings, but follow-up colonoscopy after positive faecal blood test or even first line colonoscopy is very common. The discrepancy between expected and experienced colonoscopy discomfort could therefore very well present a barrier that could be reduced by targeting subgroups with tailored information materials or add-ons to the ones in place. However, our results do not indicate this to be a larger problem for lower socioeconomic subgroups. Quite the contrary was seen, and therefore acting on these discrepancies leaves little hope for reducing the social inequalities in screening uptake. The direct discomfort from the endoscopic diagnostic modalities, even though documented as a barrier, may simply not be significant enough to be a relevant target to reduce inequalities.

Further, in all socioeconomic subgroups the bowel preparation contributed with the most discomfort in both colon capsule endoscopy and colonoscopy. The participants expected this in regards to colon capsule endoscopy, whereas they expected the procedure to be the top contributor in colonoscopy. An Austrian study also stated that 20 % of patients reported bowel preparation as the most worrisome prior to the procedure [40]. Efforts to decrease discomfort related to endoscopy procedures should therefore focus on efficient and easy compliable bowel cleansing procedures.

It seems plausible that the expected discomfort would affect screening participation up front, whereas experienced discomfort may affect long-term participation as the next rounds of screening commence. However, as the expected [28] and the experienced discomfort from screening colonoscopy was not higher in lower socioeconomic subgroups, and the discrepancy between expected and experienced discomfort increased with educational levels, it does not seem plausible that investigation discomfort is the major barrier to screening participation causing the inequalities in uptake. However, the generalizability of our results may be limited by the risk of selection bias. Individuals participating in our study and reporting their discomfort all chose to participate in both the screening programme and the trial, regardless of any perceived barriers and had indicated a preference for colon capsule endoscopy. In those undergoing colon capsule endoscopy, 72 % additionally underwent colonoscopy. This re-investigation rate does not favour the tested screening design. If it turns out that the sensitivity the significant pathology is higher in the intervention arm than in the control group, some rate of re-investigation could be both cost-efficient and preferred by the screening invitees. The sample size is one of the main strengths of trial, as no publication prior to this, has included this quantity of colon capsule endoscopies. This enables us to perform the analyses comparing socioeconomic subgroups, rather than only report on overall sample measures. Our study provided new evidence of the discomfort differences between socioeconomic subgroups. Our trial design enabled us to make individual estimates of the discrepancy between expected and experienced discomfort, while examining each of the phases in the process of undergoing colorectal optical diagnostics using colon capsule endoscopy and colonoscopy, which has not been done before.

5. Conclusion

Educational level was associated with discomfort experienced from colon capsule endoscopy and colonoscopy. Income level was not. Thereby, we have shown an association, but the patterns does not support a linear correlation of increased discomfort with increasing educational level or income. Regardless of investigation modality, the bowel preparation was the main contributor of discomfort. However, in colon capsule endoscopy, the discrepancy between discomfort from bowel preparation and the procedure itself was higher than in colonoscopy. The discrepancy between expected and experienced discomfort from colonoscopy increased with increasing educational level. A similar trend was seen for colon capsule endoscopy between educational levels, but no such indication

was evident for colon capsule endoscopy between income levels.

Ethics

The Regional Health Research Ethics committee approved the trial prior to launch (journal number S-20190100). Further, it was registered with the Regional Data Protection Agency (journal number 19/29858), and ClinicalTrials (identifier NCT04049357). Consent forms was obtained from all participants and all had received verbal and written study information prior to.

Data availability

The data from this current study has not been deposited in a publicly available depository, as the authors do not have permission to share the data.

CRediT authorship contribution statement

Ulrik Deding: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing. **Henrik Bøggild:** Formal analysis, Methodology, Supervision, Writing – review & editing. **Lasse Kaalby:** Formal analysis, Investigation, Methodology, Project administration, Writing – review & editing. **Jacob Hjelmborg:** Supervision, Writing – review & editing, Formal analysis, Methodology. **Morten Kobaek-Larsen:** Conceptualization, Funding acquisition, Methodology, Project administration, Supervision, Writing – review & editing. **Marianne Kirstine Thygesen:** Methodology, Project administration, Supervision, Writing – review & editing. **Benedicte Schelde-Olesen:** Investigation, Methodology, Project administration, Writing – review & editing. **Thomas Bjørsum-Meyer:** Funding acquisition, Investigation, Methodology, Project administration, Supervision, Writing – review & editing. **Gunnar Baatrup:** Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing – review & editing, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:Gunnar Baatrup reports financial support was provided by OUH Innovation Fund. Gunnar Baatrup reports financial support was provided by Aage og Johanne Louis-Hansens Fond. Gunnar Baatrup reports financial support was provided by The Danish Cancer society. Gunnar Baatrup reports financial support was provided by The Medtronic Research Foundation. Gunnar Baatrup reports financial support was provided by The Region of Southern Denmark's Excellence Centre.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e34274.

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