

# Associations between patient characteristics and completeness of colon capsule endoscopy in colorectal cancer screening participants: a cross-sectional study

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## ABSTRACT

**Objective** Incomplete investigations challenge the clinical use of colon capsule endoscopy (CCE). This results in added cost to healthcare systems and added discomfort to patients. In order to potentially lower the re-investigation rate, we aimed to investigate the association between multiple patient characteristics and complete CCE.

**Methods** In 2020, the CareForColon2015 (CFC2015) Trial was initiated in the Region of Southern Denmark, investigating the performance of CCE in colorectal cancer screening. Data from the CFC2015 Trial were combined with data from multiple national registers. Completion rates were calculated and their relation to the different patient characteristics was analysed in univariate and multivariate logistic regression models.

**Results** We analysed 1472 participants, of whom 1016 (69.1%) had complete investigations. We investigated the associations between 17 patient characteristics and complete CCE investigation. The multivariate analysis showed that smokers and heavy drinkers had a higher probability of a complete investigation, with ORs of 1.69 (95% CI 1.12 to 2.55) and 2.72 (95% CI 1.52 to 4.87), respectively, compared with non-consumers. We also found that increasing income was associated with increased odds of CCE completion (OR 1.78, 95% CI 1.30 to 2.43, for the highest quartile). High body mass index (>40) and self-reported constipation or laxative use were significantly associated with incomplete CCE, with ORs of 0.40 (95% CI 0.17 to 0.97) and 0.65 (95% CI 0.47 to 0.90), respectively.

**Conclusion** This study tested multiple factors for association with CCE completion. The results indicate that some factors are associated with higher odds of completion, while others are associated with lower odds of completion. These results confirm that specific patient characteristics correlate with the odds of complete investigation. This can, in turn, be used to determine the individual diagnostic pathway. Additional studies are needed for less frequently reported characteristics and to further support these findings.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The adoption of colon capsule endoscopy (CCE) is limited by high rates of incomplete investigations due to insufficient bowel cleansing and limited interventional capability.

## WHAT THIS STUDY ADDS

⇒ High body mass index (>40), self-reported constipation or regular laxative use, lower income and use of daily pain medication are significantly associated with incomplete CCE.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study encourages the development and validation of predictive models guiding patient selection for CCE versus colonoscopy, incorporating both clinical factors and socioeconomic indicators.

## INTRODUCTION

Capsule endoscopy is considered the reference standard in small bowel diagnostics.<sup>1 2</sup> Colon capsule endoscopy (CCE) is not commonly used in colonic diagnostics, despite studies indicating that it is superior to CT colonography and comparable to colonoscopy in detecting colorectal cancer and polyps.<sup>3 4</sup> Implementation of CCE in clinical practice is currently hampered by a high re-investigation rate caused by the lack of interventional capacity and a high rate of incomplete investigations.<sup>5</sup>

To improve the rate of incomplete CCE investigations, several different cleansing regimens have been tested alongside efforts to improve the battery lifetime and other technical aspects of the capsules.<sup>6–8</sup> Previous studies have identified patient characteristics

related to poor colonic cleansing as risk factors for incomplete colonoscopy.<sup>9 10</sup> Only one study has previously investigated risk factors for incomplete CCE, but it did not include socioeconomic factors such as income, which have been previously associated with incomplete colonoscopy.<sup>10 11</sup>

Identifying the patient characteristics that impact the likelihood of incomplete CCE may enable triaging patients for CCE or colonoscopy, improving the patient experience, cost of investigation and the diagnostic quality. Furthermore, the correct identification of mitigating or non-mitigating circumstances for CCE could help improve the performance of CCE.

In 2020, the Danish CareForColon2015 (CFC2015) Trial was initiated.<sup>12</sup> The trial was a parallel group randomised controlled trial with the aim of investigating the sensitivity for colorectal neoplasia in a screening design, including the free choice between CCE and colonoscopy in the Danish Colorectal Cancer Screening Programme.<sup>12 13</sup> The interim analysis of the CFC2015 Trial showed that 32.1% of the participants had an incomplete investigation and were subsequently referred for a follow-up colonoscopy.<sup>14</sup>

Based on the CFC2015 cohort, this cross-sectional study aimed to investigate the association between patient characteristics and complete CCE investigations.

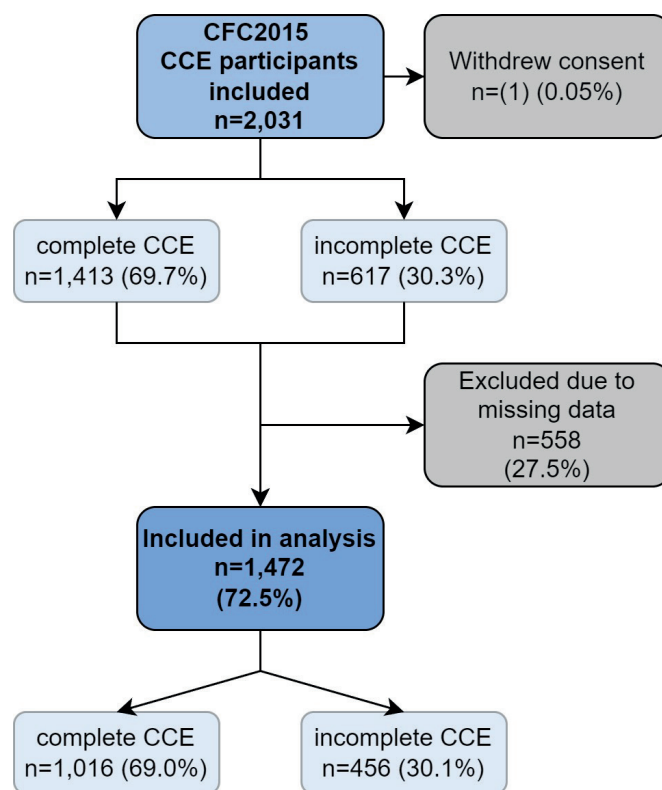
## METHODS

This cross-sectional study on association between CCE completion and patient characteristics was prepared in accordance with Strengthening the Reporting of Observational Studies in Epidemiology guidelines (online supplemental material).<sup>15</sup>

## Population

The population consisted of all participants from the CFC2015 Trial.<sup>13</sup> The trial randomised all citizens from the Region of Southern Denmark eligible for colorectal cancer screening during the trial period (August 2020 to December 2022). The randomisation depended on the week the screening invitation was sent out; individuals in 1 week were assigned to the control group, while those in the following week were assigned to the intervention group. This alternation continued throughout the study period (for details see Baatrup *et al*, 2024<sup>13</sup>). The control group participants received standard care consisting of a faecal immunochemical test (FIT) followed by colonoscopy if FIT was positive ( $\geq 20 \mu\text{g}$  Hb/g buffer). The participants in the intervention arm were offered the opportunity to undergo CCE instead of colonoscopy.<sup>12 13</sup>

During the 3-year trial period, the CFC2015 Trial included 2031 participants for CCE investigation. All 2031 participants were investigated based on the CFC2015 protocol, using the Pillcam Colon 2, and a bowel preparation regimen consisting of polyethylene glycol (PEG) sachets (Movicol, Norgine Danmark A/S, Herlev, Denmark) and PEG solutions (MoviPrep,



**Figure 1** Flow chart of CFC2015 Trial participants. CCE, colon capsule endoscopy; CFC2015, CareForColon2015.

Norgine Danmark A/S, Herlev Denmark) prior to capsule ingestion, and Eziclen (Ipsen Pharma, Boulogne-Billancourt, France) as booster.<sup>12</sup> Following the interim analysis, a 2 mg tablet of prucalopride was added to the regimen 45–60 min prior to capsule ingestion.<sup>16</sup> The data collected from these participants are evaluated in this study. Control group participants were excluded from the analysis.

Exclusion criteria for CFC2015 were history of major abdominal surgery, symptomatic Crohn's disease, cardiac pacemaker, allergy towards bowel preparation or booster medication, and known severe constipation.<sup>12</sup> Furthermore, we excluded participants from the analysis due to missing data on either of the factors included in the analysis (figure 1).

## Data sources

The participants of the CFC2015 Trial received four questionnaires.<sup>12</sup> Data from the first of these (Q1) have been included in this study. Q1 contained five modules covering demographics, baseline characteristics and health behaviour, participant discomfort, experience of bowel preparation, and expected discomfort from CCE and colonoscopy. The questionnaire is available in online supplemental appendix 1. The Q1 questionnaire was developed for the CFC2015 Trial and was qualitatively validated before the trial's launch.<sup>12 17</sup>

Certified readers assessed all CCE videos and formulated a report, stating and photo documenting the following: basic anatomical reference points, all



abnormal findings including polyps, completeness of capsule transit and evaluation of bowel cleanliness per segment. We included data from the CCE reports for the evaluation of completeness of investigation.

FIT concentrations were reported on daily lists on a closed server from the Department of Clinical Immunology and Biochemistry at the University Hospital Lillebaelt, Vejle, Denmark.

Additionally, we combined the CFC2015 data with information from three Danish national databases containing individual participant data. The Danish National Patient Register was used for information about comorbidities to calculate the Charlson Comorbidity Index (CCI).<sup>18</sup> The Danish Population Register provided sex and age of participants.<sup>19</sup> In addition, the Danish Registers on Personal Income and Transfer Payments provided information on income.<sup>20</sup>

## Outcome

The outcome evaluated in this study was the completeness of the CCE investigation. A complete investigation was based on the following factors from the CCE report: (1) Complete investigation (anal valve seen) or capsule excreted, (2) No technical fallouts or only short interruptions, (3) Caecal valve seen, and (4) Adequate bowel preparation in all segments (fair or better on the Leighton Rex Scale<sup>21</sup>).

## Patient characteristics

The following parameters were harvested from the self-reported questionnaire, *QI*: height, weight, civil status, educational level, smoking, alcohol consumption, coffee consumption, exercise, constipation, laxative use, pain medication, antidepressive medication, psychiatric medication and Bristol Stool Form Scale (BSFS). These are further described in table 2.

Age was divided into groups with 5-year intervals from 50 to 75. Body mass index (BMI) was calculated from self-reported height and weight and categorised based on the definition from the National Institute of Health: <18.5 (underweight), 18.5 to <25.0 (normal weight), 25.0 to <30.0 (preobesity), 30.0 to <35.0 (obesity class I), 35.0 to <40.0 (obesity class II) and ≥40 (obesity class III).<sup>22</sup> Smoking, alcohol consumption, coffee consumption and exercise were incorporated in the analysis as presented in the questionnaire. However, the coffee categories '1–3 cups' and '4–6 cups' were combined into '6 cups or less'. Civil status was categorised as living alone/in a relationship, married/cohabiting with partner and widow/widower/divorced. Educational level was categorised as elementary school, high school/vocational education, short-intermediate higher education and long higher education. Participants were asked to report on their most typical stool form using the BSFS. They were allowed to answer with more than one variation. We collected the answers in four groups. 'Hard' stool form for participants answering 1 or 2 on BSFS, 'Normal' stool form for participants answering 3, 4 or 5, 'Soft' stool form for 6 or 7, and

'varying' stool form for participants with answers across the three groups. Self-perceived constipation during the week prior to investigation and regular use of laxatives were combined in one variable.

The individuals' baseline annual income (5-year average) was extracted from the Danish Registers on Personal Income and Transfer Payments. Participants were divided into quartiles. Participants' CCIs were categorised into CCI=0, CCI=1, CCI=2 and CCI>2.<sup>23</sup> We evaluated participants' income and comorbidities until the year before the investigation. FIT values were categorised into <50 µg Hb/g buffer, 50–99 µg Hb/g buffer and ≥100 µg Hb/g buffer. We performed a sensitivity analysis on CCI and combined the three groups CCI=1, CCI=2 and CCI>2.

## Statistical analysis

The completion proportion was calculated for each subgroup and tested using the  $\chi^2$  test. Due to a value below 5 in one of the BMI groups, we performed a Fischer's exact test instead of  $\chi^2$  test on this variable. Complete case analyses were used to estimate the OR and 95% CI of completion based on each variable using univariable and multivariate logistic regression models.

Interactions between sex and all other variables were tested for significance. Education, income and civil status were all assessed for significant interaction with smoking, BMI and alcohol. In addition, we tested for interactions between the following combinations: FIT and comorbidity, income and age, BMI and exercise, smoking and alcohol, income and education. Data management and all calculations have been conducted using Stata V.17.0 software and SAS software V.9.4 (SAS Institute, Cary, North Carolina, USA).<sup>24</sup>

## Ethics

The data have been stored in a government-approved secure logged server hosted by Statistics Denmark. All data have been pseudo-anonymised during analysis. All participants from CFC2015 received oral and written information before giving signed consent for participation and the use of their data for scientific purposes, including analysis of completion rates.<sup>12</sup>

The trial was registered at ClinicalTrials.gov (Reg. no. NCT04049357) prior to study launch.

## RESULTS

We retrieved data from all 2031 participants who underwent CCE (one withdrew consent). Of them, 1413 (69.6%) had a complete CCE. 558 participants were excluded due to missing covariate data. Data from 1472 participants, with 1016 (69.1%) complete investigations, were included for analyses (figure 1). The percentage of female participants was 45%, and the age range was 50–75 years (mean 62 years). We found no significant interactions between the variables tested in the multivariate model.



**Table 1** Completion rate and variables from CFC2015, including all 1472 patients from the intervention arm

|                                                         | Yes (%)     | No (%)     |
|---------------------------------------------------------|-------------|------------|
| Anal valve seen or capsule excreted                     | 1354 (92.2) | 115 (7.8)  |
| Technical score—no fallouts or only short interruptions | 1460 (99.2) | 12 (0.8)   |
| Caecal valve seen                                       | 1436 (97.8) | 32 (2.2)   |
| Adequate bowel cleansing, for visualised segments       | 1121 (76.1) | 351 (23.9) |
| Complete investigation                                  | 1016 (69)   | 456 (31)   |
| CFC2015, CareForColon2015.                              |             |            |

Table 1 provides the distribution of each complete investigation input. Adequate bowel cleansing, with 23.8% inadequate, was the largest factor in the number of incomplete investigations.

We tested 17 variables for association with completion (table 2). Alcohol consumption, constipation, laxative use, pain medication use and income were significantly associated with the completion of CCE.

### Logistic regression models

The results from the univariate and multivariate regression models are described in the following paragraphs and have been visualised in figures 2 and 3, respectively.

### Sex and age

The univariate analysis (figure 2) showed no significant difference in completion for men and women or between the different age groups. The multivariate analysis (figure 3) indicated an insignificant favour for women having a complete CCE, with an OR 1.26 (95% CI 0.97 to 1.65) compared with men.

### Body mass index

We found a significantly lower probability of completion for the participants with a BMI  $\geq 40$  compared with participants with a BMI of 18.5–24.9. This difference was apparent in both the univariate analysis in figure 2, OR 0.32 (95% CI 0.14 to 0.75) and the multivariate analysis in figure 3, OR 0.40 (95% CI 0.17 to 0.97).

### Civil status, education and income

We found no significant differences between groups of civil status or educational levels, whereas a significant association between completion and increasing income was demonstrated. The highest quartile of income had the highest probability of complete investigation in the univariate analysis in figure 2, OR 1.78 (95% CI 1.30 to 2.43). The third quartile had an OR of 1.74 (95% CI 1.26 to 2.39), and the second quartile had an OR of 1.43 (95% CI 1.03 to 1.97). The same pattern was seen when adjusting for confounders in the multivariate analysis, as shown in figure 3.

### Smoking, alcohol, exercise and coffee

Smokers had a significantly higher probability of a complete CCE, OR 1.54 (95% CI 1.06 to 2.24), than non-smokers. There was no significant association with completion among non-smokers, previous smokers and current smokers. The univariate analysis showed that drinking  $\geq 15$  units of alcohol per week was associated with an elevated probability of a complete investigation compared with participants who did not drink, OR 2.88 (95% CI 1.67 to 4.95). The same result was found in the multivariate analysis. The logistic regression models on exercise or coffee showed no association with completion.

### Constipation or use of laxatives and BSFS

Participants who reported self-perceived constipation during the week prior to the investigation or who frequently used laxatives had a significantly lower probability of complete CCE than those who reported neither. This is shown with an OR of 0.64 (95% CI 0.47 to 0.86) in the univariate analysis (figure 2), and a similar OR in the multivariate analysis (figure 3). BSFS was not significantly associated with completion.

### Pain medication, antidepressive medication and psychiatric medication

Participants who took pain medication daily/weekly had a significantly lower probability (OR 0.55; 95% CI 0.36 to 0.82) of complete investigation, compared with those who had never taken pain medication. In addition, participants who took antidepressive medication daily/weekly had a lower probability of complete investigation (OR 0.61; 95% CI 0.37 to 1.01). However, both of these ORs were statistically insignificant in the multivariate analysis (figure 3). Lastly, the analyses of psychiatric medication showed no significant association with CCE completion.

### FIT concentration and comorbidities

We found no significant association between FIT concentration or CCI and CCE completion, respectively.

The sensitivity analysis of CCI  $>0$  compared with CCI=0, found no significant association with CCI  $>0$  and completion on the multivariate analysis (OR 0.86; 95% CI 0.65 to 1.12).

## DISCUSSION

Our analyses show that multiple patient characteristics are associated with the odds of having a complete CCE. Daily smoking and a weekly consumption of  $\geq 15$  units of alcohol were both significantly associated with increased probability of a complete CCE investigation. Even though our results indicate better performance among daily smokers and those consuming 15 or more units of alcohol, this is not suited for recommendations. We must consider that there could be a behavioural, physiological or sociodemographic association among factors like alcohol consumption and smoking, which causes the association found in this study. This should be investigated further, as lower socioeconomic status

**Table 2** Descriptive baseline characteristics of Danish Colorectal Cancer Screening participants in the intervention arm of the randomised-controlled trial CFC2015, stratified by completion of CCE (only participants with a complete data set have been included in the analysis (n=1468))

| Predictor                 | Subgroup                       | Incomplete (%) | Complete (%) | Total | P value |
|---------------------------|--------------------------------|----------------|--------------|-------|---------|
| Sex                       | Male                           | 246 (30)       | 563 (70)     | 809   | 0.601   |
|                           | Female                         | 210 (32)       | 453 (68)     | 663   |         |
| Age, years                | 50–54                          | 110 (29)       | 263 (71)     | 373   | 0.365   |
|                           | 55–59                          | 69 (29)        | 167 (71)     | 236   |         |
|                           | 60–64                          | 83 (29)        | 208 (71)     | 291   |         |
|                           | 65–69                          | 99 (33)        | 204 (67)     | 303   |         |
|                           | 70–75                          | 95 (35)        | 174 (65)     | 269   |         |
|                           | ≥75                            | 95 (35)        | 174 (65)     | 269   |         |
| BMI (kg/m <sup>2</sup> )  | <18.5                          | 4 (33)         | 8 (67)       | 12    | 0.115*  |
|                           | 18.5–24.9                      | 151 (31)       | 333 (69)     | 484   |         |
|                           | 25–29.9                        | 172 (29)       | 414 (71)     | 586   |         |
|                           | 30–34.9                        | 88 (32)        | 188 (68)     | 276   |         |
|                           | 35–39.9                        | 27 (30)        | 63 (70)      | 90    |         |
|                           | ≥40                            | 14 (58)        | 10 (42)      | 24    |         |
| Civil status              | Living alone/in a relationship | 75 (33)        | 149 (67)     | 224   | 0.667   |
|                           | Married/living with a partner  | 358 (30)       | 817 (70)     | 1175  |         |
|                           | Widow/widower/divorce          | 23 (32)        | 50 (68)      | 73    |         |
| Education                 | Elementary school              | 63 (34)        | 125 (66)     | 188   | 0.385   |
|                           | High/vocational school         | 146 (29)       | 356 (71)     | 502   |         |
|                           | Short/intermediate             | 221 (32)       | 462 (68)     | 683   |         |
|                           | Long                           | 26 (26)        | 73 (74)      | 99    |         |
| Smoking                   | Yes                            | 43 (23)        | 140 (77)     | 183   | 0.140   |
|                           | Sometimes                      | 13 (32)        | 28 (68)      | 41    |         |
|                           | Previously                     | 164 (32)       | 348 (68)     | 512   |         |
|                           | Never                          | 236 (32)       | 500 (68)     | 736   |         |
| Alcohol                   | None                           | 99 (33)        | 201 (67)     | 300   | <0.001  |
|                           | 1–7                            | 278 (34)       | 541 (66)     | 819   |         |
|                           | 8–14                           | 60 (27)        | 163 (73)     | 223   |         |
|                           | ≥15                            | 19 (15)        | 111 (85)     | 130   |         |
| Exercise                  | Light activity                 | 51 (33)        | 104 (67)     | 155   | 0.802   |
|                           | Moderate activity              | 330 (31)       | 751 (69)     | 1081  |         |
|                           | High activity                  | 75 (32)        | 161 (68)     | 236   |         |
| Coffee                    | None                           | 58 (30)        | 137 (70)     | 195   | 0.764   |
|                           | ≤6 cups                        | 339 (31)       | 760 (69)     | 1099  |         |
|                           | >6 cups                        | 59 (33)        | 119 (67)     | 178   |         |
| Laxatives or constipation | No                             | 373 (30)       | 890 (70)     | 1263  | 0.003   |
|                           | Yes                            | 83 (40)        | 126 (60)     | 209   |         |
| Pain medication           | Daily/weekly                   | 48 (45)        | 59 (55)      | 107   | 0.009   |
|                           | Monthly                        | 16 (26)        | 46 (74)      | 62    |         |
|                           | Previously                     | 109 (28)       | 275 (72)     | 384   |         |
|                           | Never                          | 283 (31)       | 636 (69)     | 919   |         |
| Antidepressive            | Daily/weekly                   | 27 (42)        | 38 (58)      | 65    | 0.125   |
|                           | Previously                     | 34 (34)        | 66 (66)      | 100   |         |
|                           | Never                          | 395 (30)       | 912 (70)     | 1307  |         |

Continued



**Table 2** Continued

| Predictor               | Subgroup        | Incomplete (%) | Complete (%) | Total | P value      |
|-------------------------|-----------------|----------------|--------------|-------|--------------|
| Psychiatric             | Daily/weekly    | 6 (43)         | 8 (57)       | 14    | 0.192        |
|                         | Previously      | 12 (44)        | 15 (56)      | 27    |              |
|                         | Never           | 438 (31)       | 993 (69)     | 1431  |              |
| Bristol Stool           | Hard            | 34 (29)        | 85 (71)      | 119   | 0.689        |
|                         | Normal          | 370 (31)       | 834 (69)     | 1204  |              |
|                         | Soft            | 10 (33)        | 20 (67)      | 30    |              |
|                         | Varying         | 42 (35)        | 77 (65)      | 119   |              |
| Income                  | First quartile  | 120 (40)       | 181 (60)     | 301   | <b>0.001</b> |
|                         | Second quartile | 112 (32)       | 241 (68)     | 353   |              |
|                         | Third quartile  | 108 (28)       | 283 (72)     | 391   |              |
|                         | Fourth quartile | 116 (27)       | 311 (73)     | 427   |              |
| FIT value (µg/g buffer) | <50             | 243 (31)       | 536 (69)     | 779   | 0.899        |
|                         | 50–99           | 86 (30)        | 202 (70)     | 288   |              |
|                         | >100            | 127 (31)       | 278 (69)     | 405   |              |
| CCI                     | 0               | 328 (29)       | 785 (71)     | 1113  | 0.159        |
|                         | 1               | 48 (37)        | 81 (63)      | 129   |              |
|                         | 2               | 55 (34)        | 106 (66)     | 161   |              |
|                         | >2              | 25 (36)        | 44 (64)      | 69    |              |

Significant values are referred to in bold font.

\*Fischer's exact, instead of  $\chi^2$  test.

BMI, body mass index; CCE, colon capsule endoscopy; CCI, Charlson Comorbidity Index; CFC2015, CareForColon2015; FIT, faecal immunochemical test.

usually is related to poor health, and in this case, it is associated with better outcome. Even though our results on smoking and alcohol are unexpected and not usable for recommendations, the knowledge about smoking or use of nicotine prior to the procedure can still be used when evaluating if a person is a 'good' candidate for CCE.

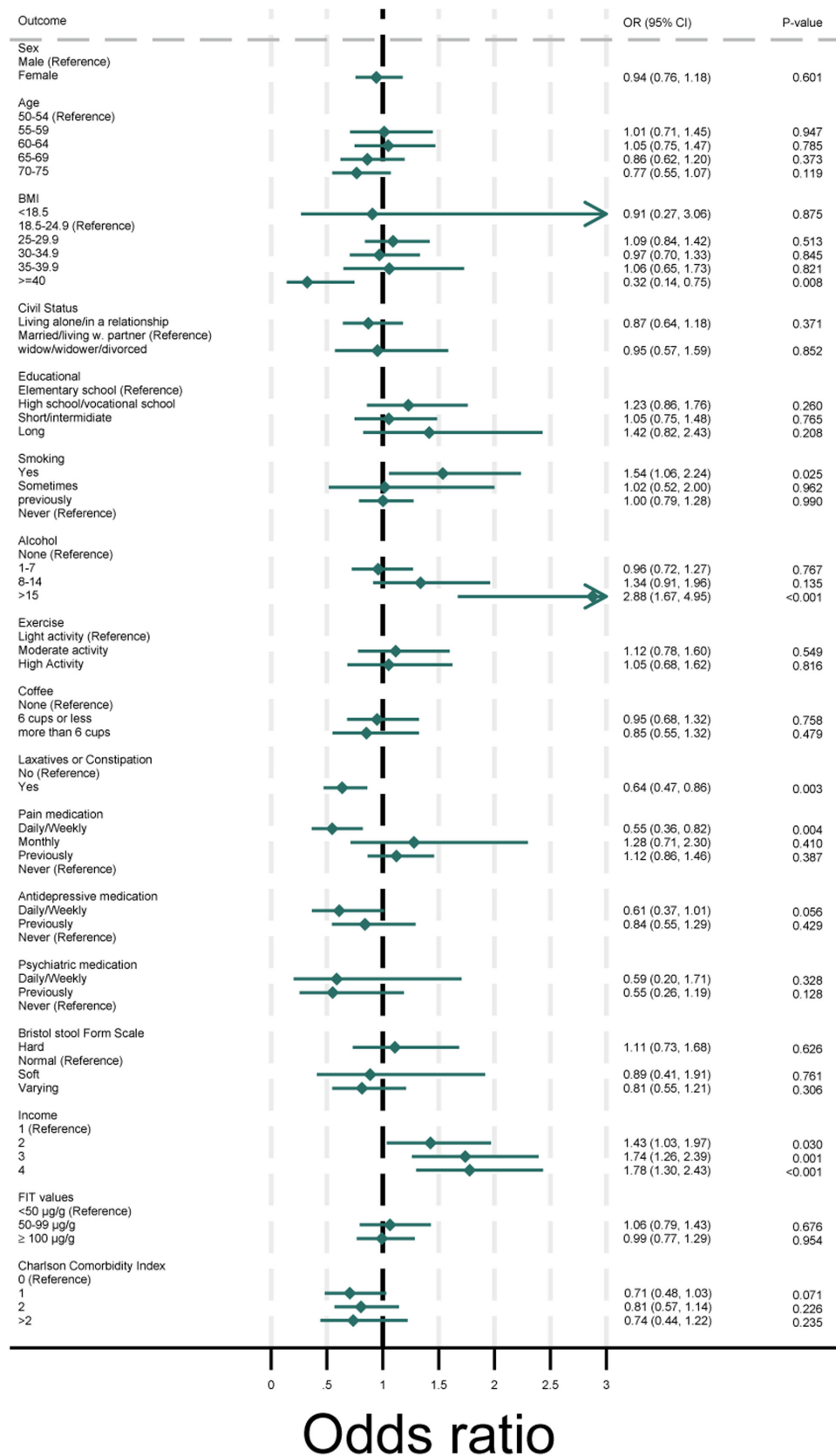
BMI  $\geq 40$ , self-reported constipation or regular laxative use, lower income and daily pain medication use were significantly associated with incomplete CCE. These factors may therefore be used when determining the right candidates for the modality. Previous studies have suggested that obese patients are more likely to have inadequate bowel preparation at colonoscopy, and it may be possible that the same mechanism can be translated to preparation for CCE.<sup>25–27</sup> The accumulated evidence that bowel preparation in obese persons is challenging for both CCE and colonoscopy strongly indicates that obese patients should be preferred for colonoscopy, with the ability to rinse during the investigation.

Surprisingly, exercise level had no significant impact on CCE completion. This could indicate that gut motility rather than physical mobility is a factor related to incomplete CCE. However, this makes for further discrepancy with low completion in the group of BMI  $\geq 40$ . So with the results of this study, these factors do not help to discriminate, and further studies should be carried out to understand this. Not surprisingly, participants who regularly used or reported self-perceived constipation

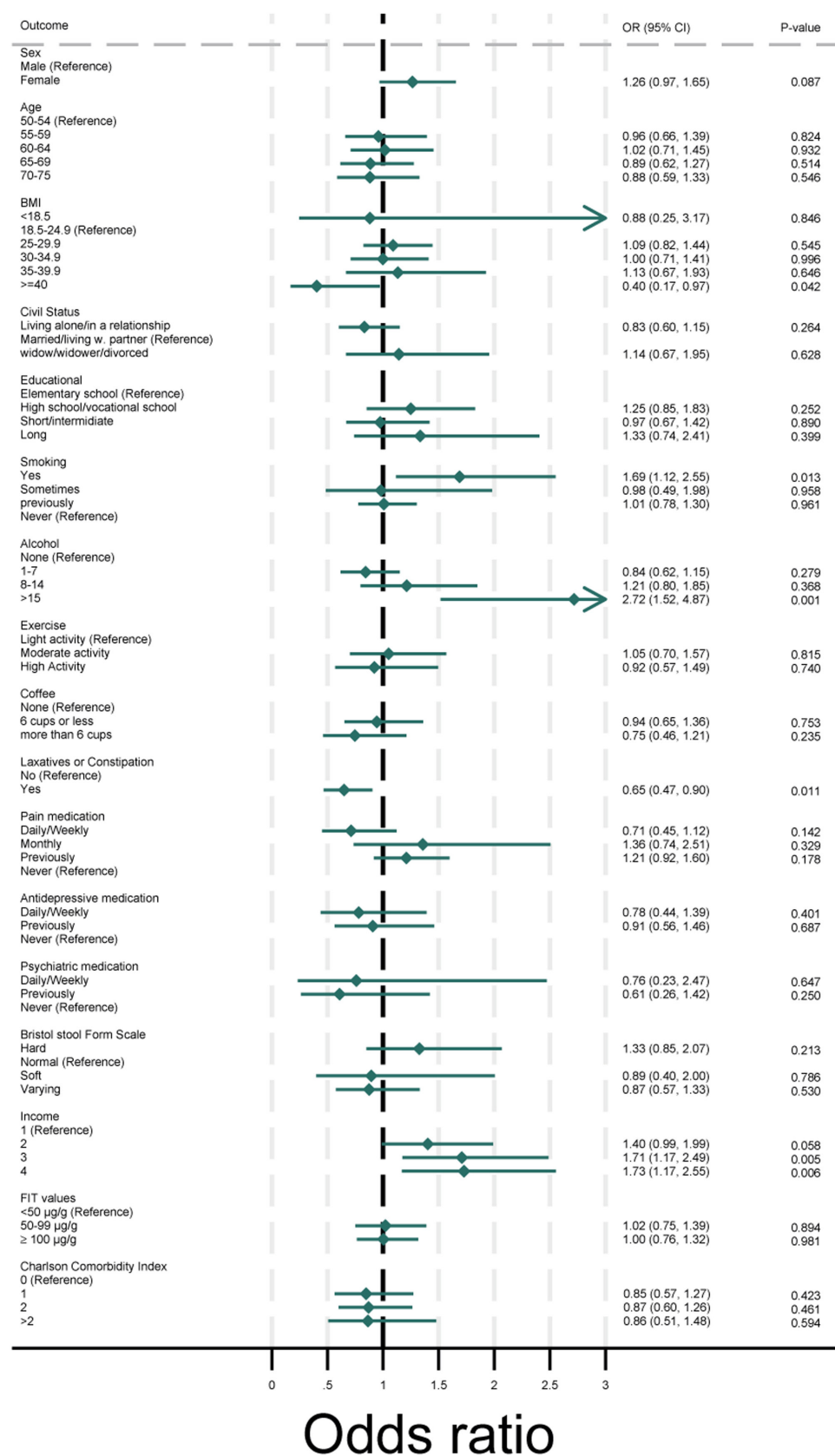
had a significantly lower probability of complete CCE. These factors can be used as an indicator of referral for a different modality. It would be highly beneficial to ask about these factors prior to deciding on modality, rather than asking about Bristol Stool Scores. Bowel preparation for CCE has been optimised thoroughly and the preparation used in this study is already more extensive than what is used for colonoscopy. Patient acceptability of bowel preparation for CCE has, in a previous study, been described as a shortcoming for patient preferences of CCE.<sup>28</sup> To our knowledge, there is still no published research comparing the tolerability of CCE preparation and colonoscopy preparation, and this seems to be a lack of evidence for this field.

We also found that participants with an increasing income had a higher probability of completing the CCE investigation. They often have better health and better compliance.<sup>29</sup> One recent publication by Skau *et al* supports this.<sup>10</sup> The authors found that the probability of having an incomplete colonoscopy due to poor bowel preparation was significantly increasing as income decreased. Their results indicate that people with higher incomes comply better with guidelines and therefore receive a more efficient bowel cleansing procedure.<sup>10</sup>

Pain medication, antidepressive medication and psychiatric medication did not have a significant effect on the completion rate. A significant association was anticipated since it is known that these types of medications can have



**Figure 2** Forest plot of the results from univariate logistic regression model analyses testing the association between each patient characteristic and the completion of CCE investigation (n=1472). BMI, body mass index; CCE, colon capsule endoscopy; FIT, faecal immunochemical test.



**Figure 3** Forest plot of the results from the multivariate logistic regression model analyses testing the association between patient characteristics and the completion of CCE investigation (n=1472). BMI, body mass index; CCE, colon capsule endoscopy; FIT, faecal immunochemical test.

an inhibitory effect on bowel motility.<sup>30</sup> Initially, we did see a trend for lower completion rates among those who took daily pain medication; however, this was not significant when adjusting for confounders in the multivariate logistic regression. The non-significant association could be explained by the small size of the groups. This is something that surely should be further investigated.

Previous studies on the completion rate of colonoscopy have found that women have a lower probability of having a complete colonoscopy.<sup>31–33</sup> However, we found that women had a slightly higher probability of completing a CCE investigation than men. Women often experience more pain with colonoscopy due to scar tissue from previous pelvic surgeries, such as hysterectomies and caesarean sections, along with having less abdominal circumference. These are some of the reasons for incomplete colonoscopy among women, both of which do not influence the completion of CCE.

CCI was surprisingly found to have no significant association with completion of CCE. We do see a trend that even a CCI Score of 1 gives lower odds of completion; however, there is nothing to indicate that an increased CCI Score is associated with decreasing odds of completion. This could be explained by the way the CCI Score is developed, where different diseases have different scores, and some diseases with a score of 1 have a larger association with bowel mobility than other diseases with the same CCI Score, which might pollute the results. A previous study included diseases individually and found that diabetes was associated with lower bowel preparation.<sup>34</sup> The CCI calculated from the Danish National Patient Register has high validity. Future studies should consider evaluating diseases separately instead of pooling with the CCI Score.

A recent Scottish study evaluated the association between patient factors and successful CCE on symptomatic and surveillance patients.<sup>11</sup> They found that younger age was associated with a successful CCE test. We did not see any significant associations between age and complete investigation. This might be due to the differences in populations. The population in the study by MacLeod *et al*<sup>11</sup> comprised those at least 18 years of age, whereas the present study only included colorectal cancer screening participants, between 50 years and 75 years of age.

### Strengths and limitations

The large sample size of the CFC2015 Trial is a major strength of this study, as it is the largest randomised controlled trial on CCE to date. The information collected through CFC2015 and through Danish national registers with high validity gives this study a large set of parameters to investigate and allows adjustments for confounders, thereby strengthening this study.

The total population was randomised. However, the participants within the intervention arm of the CFC2015 Study had the option to choose between CCE and colonoscopy, if FIT positive. This might have caused selection

bias, since all participants elected for CCE over colonoscopy. This risk of selection bias highlights the need for further research on the topic.

We also must recognise that the CFC2015 Trial was not prestudy-powered for the analysis used here. Some included groups are small, and results show rather wide CIs.

The use of self-reported data may cause recall and response bias. Questions about the use of narcotics, alcohol and psychiatric medication are especially known to be subject to bias. Self-reporting of alcohol is notoriously uncertain, and the categories used here are, for some, within the range of what could be considered 'social drinking' rather than alcoholism, and the questionnaire does not differ between these.

This study was solely based on colorectal cancer screening participants, which cannot directly translate to symptomatic patients undergoing this investigation. However, it does translate fairly well with the general population. Furthermore, screening participants may have limited insight into the practical and physiological challenges of colorectal examinations.

### Future perspectives

It is well documented that CCE has some advantages compared with colonoscopy, including less discomfort, lower risk of adverse events and it can be performed out of the hospital.<sup>4</sup> It is therefore essential to improve the completion rates of CCE to equal that of colonoscopy. One way to ensure a lower re-investigation rate is by allocating the right patients to CCE, or finding interventions which can support the patient to have complete CCE. The data presented here can be a guide for this. The results of this study are, therefore, essential knowledge for clinicians when considering the use of CCE and for the future development of a predictor model of qualified patients for CCE. Such a model needs to be based on further research, and the included predictors should be decided based on multiple studies. There should preferably be a systematic review with a high level of evidence. Future studies investigating more interventions to support the completion of CCE should likewise be added to the literature.

### CONCLUSION

Our results demonstrate an association between income and the probability of complete CCE among colorectal cancer screening participants in the Region of Southern Denmark. An association between completion and smoking, and alcohol consumption is also demonstrated. In addition, a lower probability of completion was associated with high BMI ( $\geq 40$ ), self-reported constipation or regular laxative use. These factors should be considered when evaluating patients' suitability for CCE. However, since some subgroups were very small, further studies should be performed on larger or more diverse populations to provide power for such subgroup conclusions.



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**Contributors** Conception: LØH, UD, GB, TB-M; Design of the work: LØH, UD, GB, TB-M; The acquisition, analysis and interpretation of data: LØH, UD, OS, LKM, BS-O, GB, AK and TB-M; Drafted the work or substantively revised it: LØH, UD, OS, LKM, BS-O, GB, AK and TB-M. UD is the guarantor.

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**Data availability statement** No data are available. We used pseudo-anonymised data from all participants, which were stored on secure logged servers hosted by Statistics Denmark. The data will therefore not be available upon request.

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