Psychosocial consequences of invitation to colorectal cancer screening: a matched cohort study

Jessica Malmqvist,1,2 Volkert Siersma,1 Mie Sara Hestbech,1 Dagný Rós Nicolaisdóttir,1 Christine Winther Bang,1 John Brodersen1,2

ABSTRACT

Background Psychosocial consequences of colorectal cancer (CRC) screening can arise anywhere in the screening cascade. Previous studies have investigated the consequences of participating in CRC screening; however, we have not identified any studies investigating the psychosocial consequences of receiving the invitation. Therefore, the objective of this study was to investigate psychosocial consequences of invitation to CRC screening.

Methods The study was a longitudinal study performed in Region Zealand, Denmark. Participants included in this study were a random sample of 1000 CRC screening invitees and 1000 control persons, not invited to screening, matched in a 1:1 design on sex, age and municipality. We assessed psychosocial consequences before and after invitation in both study groups concurrently. The primary outcomes were psychosocial consequences measured with the condition-specific questionnaire Consequences of Screening in ColoRectal Cancer.

Results Preinvitation response rates were 575 (57.5%) and 610 (61.0%) for the invitation group and control group, respectively. Postinvitation response rates were 442 (44.2%) for the invitation group and 561 (56.1%) for the control group.

No differences in mean change in scale score were seen except for the scale ‘Change in body perception’. The invitation group had a 0.39 lower change (99% CI (−0.78 to −0.004), p=0.009) in mean score than the control group.

Conclusions This study did not identify an association between invitation to CRC screening and negative psychosocial consequences.

BACKGROUND

Harms of screening are less frequently reported than benefits.1 Harms of colorectal cancer (CRC) screening may include negative psychosocial consequences. Psychosocial consequences can arise not only from individuals’ attention being drawn to disease through the screening invitation but also from the screening procedure itself and from fear of the screening result.2

To adequately assess the psychosocial consequences of screening, changes in psychosocial consequences from before the screening invitation to after the final screening result have to be compared between a group invited to screening and a control group not invited to screening. The control group is necessary to correct for the potential psychosocial consequences it may create and to receive a questionnaire raising awareness of one’s psychological health.3,4 Moreover, it is important to compare potential changes in psychosocial consequences both before and after the screening invitation, in relation to the screening procedure and after the final screening result. Consequently, measurement of psychosocial consequences in cancer screening settings should be performed using questionnaires with adequate measurement properties, for example, high content validity and unidimensionality.5,6

Previous Danish research has shown that receiving an invitation to mammography screening may have a reassuring effect;8 however, a systematic review on mammography screening showed that women got nervous and worried by the invitation to screening.9 We performed a systematic literature search on studies investigating the psychosocial consequences of CRC screening and did not identify any studies specifically addressing the potential psychosocial impact of being invited to CRC screening.

In Denmark, a national CRC screening programme was implemented from 2014 to 2017, targeting all individuals aged 50–74 years, using an faecal immunochemical test (FIT) as the screening test.10 The screening invitation was sent by mail together with a home test kit and a leaflet with information about the programme and the test (online supplemental appendix 1,2).

During the implementation period, individuals from three different birth months were invited to screening each year. Hence, four screening naïve cohorts were invited in 4 different years, providing the opportunity for an evaluation of the screening programme. Primo 2018, the programme, was implemented in full and subsequently individuals in the target population were invited biennially. In Denmark, all healthcare actions are publicly funded, which also include governmental preventive initiatives such as screening programmes. There are publicly funded screening programmes for breast cancer, cervix cancer and, since 2014, for CRC as well. Hence, Danish women have been used to receiving invitations to cancer screening programmes while the CRC screening programme is the first population-based cancer screening programme in Denmark also targeting men. The perceptions of CRC screening in the Danish population have been described qualitatively in participants receiving a false-positive result.11,12 Participants described that they felt a moral and
societal obligation to participate and the perception of CRC screening in general were predominantly positive.

The evaluation of a cancer screening programme should cover all aspects of the benefits and harms of the screening programme, including the psychosocial consequences of the invitation to and participation in the screening.2 3

Since no identified literature has focused on the psychosocial effects of a CRC screening invitation, we aimed to investigate the psychosocial consequences of invitation to CRC screening in a Danish CRC screening naïve cohort receiving the invitation 9 months prior to the control group.

Our a priori hypothesis was that the screening invitation group would experience more negative psychosocial consequences compared with the control group.

MATERIAL AND METHODS

Design and setting

We performed a longitudinal study in Region Zealand, one of five health administrative regions in Denmark, with 835 000 inhabitants of which approximately 319 000 individuals were in the CRC screening target population. We used the roll-out and target population of the screening programme to form an invitation group planned to be invited to screening in the beginning of 2017 and a control group planned to be invited to screening 9 months later.

Primary outcomes were psychosocial consequences.

Study population and data collection

In January 2017, we received a random sample of 1,000 CRC screening invitees and 1000 control persons matched 1:1 on sex, age and municipality from the Danish Invitation and Administration Module (IAM). IAM is used by the CRC screening steering committee to register and administrate invitations, reminders and results of the screening programme.

We sent a questionnaire assessing psychosocial consequences together with information on the study to both study groups 5 weeks prior to the invitation group would receive their mailed CRC screening invitation (23–24 January 2017). We sent a reminder to nonrespondents in both groups 25 days later (17 February 2017).

One to 3 days after the invitation group received their invitation to CRC screening, both groups received the same questionnaire on psychosocial consequences again (4–6 March 2017). During this assessment, we only sent reminders to the control group (29 March 2017) since many screening invitees by now had participated in the CRC screening. No incentive for participation was given.

We linked questionnaire data with sociodemographic variables obtained from the national electronic registers from Statistics Denmark. We obtained register data on age, sex, municipality, cohabitation status, educational level, employment status, annual income, wealth and Charlson’s Comorbidity Index (CCI). Questionnaire data were linked to register data by the unique civil registration numbers that all citizens in Denmark have.

Exclusion criteria

During the roll out of the screening programme, individuals turning 50 or 75 were also invited to participate 1 month prior to their birthday, in a nonrandomised design. This group was not included in our study.

| COS-CRC Part II: item order in the questionnaire | Scales |
|-------------------------------------------------|--------|
| 13. Worried                                      | Depiction |
| 14. Wished about my future                      | Anxiety |
| 15. Scared                                       | Anxiety |
| 16. Inhabitant                                   | Behaviour |
| 17. Quieter than normal                         | Behaviour |
| 18. Slept badly                                  | Sleep    |
| 19. Hard to concentrate                          | Behaviour |
| 20. Time passed slowly                           | Behaviour |
| 21. Change in appetite                           | Behaviour |
| 22. Sad                                          | Depiction |
| 23. Upset                                        | Anxiety  |
| 24. Restless                                    | Anxiety  |
| 25. Nervous                                      | Anxiety  |
| 26. Uneasy                                       | Depiction |
| 27. Taken long time to fall asleep               | Sleep    |
| 28. Withdrawn into myself                       | Behaviour |
| 29. Unable to cope                              | Depiction |
| 30. Depressed                                   | Depiction |
| 31. Difficulty dealing with or other commitments| Behaviour |
| 32. Woken up far too early in the morning        | Sleep    |
| 33. Difficulty doing things around the house     | Behaviour |
| 34. Tired                                        | Anxiety  |
| 35. Awake most of the night                     | Sleep    |
| 36. Felt sorry for myself                       | Intention |
| 37. Shocked                                      | Anxiety  |
| 38. Insecure                                    | Intention |
| 39. Felt as though something is wrong with my body| Change in body perception |
| 40. Felt as though my body was a machine that does not work | Change in body perception |
| 41. Thought my situation was hopeless            | Intention |
| 42. Experienced mood swings                      | Intention |
| 43. Thought my body was vulnerable               | Change in body perception |
| 44. Kept my thoughts to myself                   | Intention |
| 45. Felt older than my age                       | Change in perception of own age |
| 46. Felt sour (attitude)                         | Emotional reactions |
| 47. Felt angry                                    | Emotional reactions |
| 48. Felt I have been in a vacuum                  | Fear & Powerlessness |
| 49. Felt older than my age                       | Change in perception of own age |
| 50. Felt powerless                               | Fear & Powerlessness |
| 51. Felt I was sick                            | Fear & Powerlessness |
| 52. Have changed diet                            | Lifestyle changes, single item |
| 53. Negative impact on sex-life                 | Sensuality, single item |

Figure 1 COS-CRC, part I. COS-CRC, consequences of screening for colorectal cancer.

Questionnaire

We used part one of the condition-specific questionnaire Consequences Of Screening in CRC (COS-CRC) to assess psychosocial consequences (figure 1).13 We used the nine scales and two single items of the COS-CRC that do not require that the respondents have been through the screening cascade. For all items, the response options are arranged in four categories from ‘Not at all’ to ‘A lot’ with corresponding scores 0–3 (online supplemental appendix 3). Hence, high scores on the scales and the single items indicate more negative psychosocial consequences. COS-CRC was developed through focus group interviews with CRC screenees to ensure high content validity.13 Subsequently COS-CRC was statistically validated using Item Response Theory Rasch Models.

Furthermore, three questions on whether the participant had received the screening invitation, had performed and sent the FIT and had received the FIT result were added to the questionnaire. The responses to these questions enabled us to omit the study subjects that would possibly have higher psychosocial consequences, not only because of the screening invitation but also because they already had received the FIT result or were waiting for the FIT result, at the time they responded to the questionnaire.

Sample size

The COS-CRC was developed from similar questionnaires for consequences of screening for other life-threatening diseases containing a common core set of items called consequences of screening (COS).14–17 COS has high sensitivity and has previously shown ability to measure differences in a group of minimum 100 screening participants and in a group of minimum 500 individuals in the general population.8 18–21 Furthermore, the response rate to COS in previous mammography screening...
studies has been approximately 70% for control groups (persons not invited to screening). We expected the response rate to be lower in our mixed population. We took that into consideration when determining the sample size to 1000 individuals in each study group.

Statistics

Questionnaire data

Questionnaire data were typed in two different databases by two independent administrative personnel. Then, we compared the two databases by analysing the differences between each item. Errors were identified and corrected by rereading the original questionnaires. If any item in a questionnaire was not completed, the scale to which the item belonged was set to missing. We defined a questionnaire completed if one item was completed.

Statistical analyses

We analysed differences in study population characteristics at baseline with $\chi^2$ tests for categorical variables and $t$-tests for continuous variables. We analysed the mean COS-CRC score at each time point for each COS-CRC scale compared between the study groups using multivariable regression models. We performed both unadjusted analyses and analyses adjusted for age, urbanicity, educational level, annual income, wealth, employment status, sex, cohabitation status and CCI.

We adjusted for differential nonresponse by weighting the observations that were available at baseline and follow-up measurement by the inverse of the probability of not being missing; the latter estimated from logistic regression models including the above-listed potential confounders, an indicator of whether the baseline observation was missing and indicators whether the FIT was sent or screening result received before responding to the questionnaire.22 23 We adjusted for repeated measures and weighting with generalised estimating equations (GEE) methods. All analyses were performed in SAS V.9.4 (SAS Institute, Cary, North Carolina, USA), except the GEE models that were performed in R V.3.5.0 with geepack. To adjust for multiple testing, a $p$ value $<0.01$ was considered significant.

RESULTS

At baseline, the response rate in the control group was 3.6 percentage points (pp) higher than the response rate in the invitation group (61.0% n=610 vs 57.5% n=575) (figure 2). This difference increased at follow-up, where the response rate was approximately 12 pp higher (56.1% n=561 vs 44.2% n=442) in the control group.

Table 1 summarises the sociodemographic characteristics for both groups. There were no significant statistical differences in sociodemographic characteristics between the study groups at baseline. Baseline and follow-up mean scale scores for each of the two study groups are shown in table 2.

Figure 2 Study flowchart. COS-CRC, consequences of screening for colorectal cancer.
The unadjusted mean changes in scale scores before compared with after invitation were not statistically significantly different between the groups (table 2) (figure 3). In the adjusted analyses, the invitation group had a 0.39 lower change (99% CI (−0.78 to −0.004), p=0.009) in mean score in the scale ‘Change in body perception’ than the control group in the direction of a less negative body perception after invitation (table 3). In the invitation group, 245 individuals had registered that they had sent the test or received the FIT result before they completed the COS-CRC. Therefore, we performed sensitivity analyses where we excluded these individuals. In these analyses, the change in score for the scale ‘Change in body perception’ was not statistically significant any longer, although the effect was larger (−0.43, 99% CI (−0.89 to −0.039), p=0.018).

**DISCUSSION**

This study did not show negative psychosocial consequences of invitation to CRC screening. Hence, our results do not support our a priori hypothesis that the invitation group would experience more negative psychosocial consequences than the control group.

The study design with a baseline assessment performed before invitation to screening and a follow-up assessment after invitation but before the screening procedure was a strength of this study.

Furthermore, the measurements of psychosocial consequences in a screening and a control cohort concurrently at two different time points as well as the use of a condition-specific questionnaire with adequate measurement properties were other strengths of the study. Finally, the large sample size and the statistical methods used to adjust for differential nonresponse are other strengths of this study.

The high nonresponse rate in the invitation group could be considered a limitation of the study. Knowledge about sociodemographics, psychosocial consequences at baseline and subsequent participation status of this subgroup could shed further light on the consequences of being invited to a cancer screening programme.

Many of the individuals who actively withdrew their consent mentioned chronic and sometimes terminal diseases as the reason for withdrawal of consent. Hence, the remaining participants may have been a healthier subset with more favourable sociodemographics than dropouts.

Moreover, the control persons’ attention was drawn to CRC and CRC screening through our questionnaire and information leaflet. This is an inevitable prerequisite in studies with patient-reported outcomes: the questionnaire and the attention drawn to the disease will often induce more negative psychosocial consequences. Moreover, control persons cannot be blinded to the fact that they are not exposed to an intervention, for example, are specifically not invited to screening. This is also the main reason for a control group: to correct for psychosocial consequences that cannot be attributed to the invitation to screening; however, this will naturally lead to smaller differences in changes between the groups, for example, smaller effects.

‘Change in body perception’ was the only adjusted scale score mean change in which there was a significant difference in change between the invitation group and the control group. Interpreting this result, a mean change of −0.39 points corresponds to 39% of the individuals in the invitation group changing their answer from ‘a bit’ to ‘not at all’ from before to after the invitation in direction of a more positive body perception after invitation (table 3). The adjusted post hoc analyses confirmed this result as seen by the similar effect size. However, since many respondents were omitted from the analyses, the study did not any longer have the statistical power to show a significant change.

The invitation to cancer screening itself may have had a reassuring effect, which could explain the decrease in scale scores after the invitation. Furthermore, the Danish information pamphlet on CRC screening may have diminished the negative expected effect by its CRC screening positive framing and inaccurate risk communication (online supplemental appendix 2). Inaccurate risk communication makes it difficult to interpret the actual benefits and harms of taking part in an intervention and lay persons may exaggerate the benefits and underestimate the harms.

Individuals’ perception of risk information on cancer screening has been described using the theory of planned behaviour and cognitive dissonance. Hence, even though individuals might have experienced negative psychosocial consequences, they might not have reported these since their perception of CRC screening is that it has no harmful effects.
These plausible explanations were strengthened by messages, written by participants, on the backside of the returned questionnaires that they thought CRC screening was a fantastic initiative and a gift from the government.

Finally, the large subset of dropout in the invitation group may have been the individuals with the least robust psychosocial status and sociodemographics, which may also have been their reason for nonrespondence. Hence, the results may be a consequence of healthy volunteer bias.18 32

The psychosocial consequences of invitation to CRC screening is a sparsely investigated area. We have not identified any studies investigating the psychosocial consequences of being invited to CRC screening, using a proper design, that is, a baseline before-invitation assessment followed by an after-invitation assessment, using a questionnaire with adequate measurement properties.

Since the purpose of CRC screening is to find the few people in high risk of having CRC in a healthy general population, a baseline before-invitation assessment with continuous assessments at

| Table 2: Psychosocial consequences before and after invitation to screening |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| COS-CRC scales (range of values) | Group | Before | After | Before invitation | After invitation |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| | | N | N | Mean (SD) | Mean (SD) | Mean (SD) | Mean (SD) |
| Dejection (0–18) | Invitation | 571 | 438 | 1.26 (2.51) | 1.20 (2.49) |
| Anxiety (0–21) | Control | 604 | 555 | 1.24 (2.34) | 1.16 (2.33) |
| Behaviour (0–21) | Invitation | 565 | 433 | 1.20 (2.57) | 1.15 (2.45) |
| Sleep (0–12) | Control | 598 | 551 | 1.19 (2.19) | 1.17 (2.44) |
| Introvert (0–15) | Invitation | 569 | 437 | 1.65 (2.64) | 1.25 (2.37) |
| Change in body perception (0–9) | Control | 602 | 557 | 1.71 (2.64) | 1.59 (2.48) |
| Fear and powerlessness (0–12) | Invitation | 571 | 437 | 0.78 (1.53) | 0.55 (1.34) |
| Change in perception of own age (0–6) | Control | 601 | 557 | 0.73 (1.50) | 0.68 (1.56) |
| Emotional reactions (0–6) | Invitation | 564 | 437 | 1.20 (2.19) | 1.05 (2.04) |
| Control | 598 | 553 | 1.16 (1.97) | 1.07 (2.00) |
| COS-CRC single items (range of values) | | | | | |
| | Negative impact on sex life (0–3) | Invitation | 485 | 380 | 0.27 (0.73) | 0.24 (0.67) |
| Lifestyle changes (0–3) | Control | 516 | 469 | 0.34 (0.81) | 0.29 (0.73) |

COS-CRC, consequences of screening in colorectal cancer.

| Table 3: Difference in change from before to after invitation in the invitation group relative to the control group |
|-----------------------------|-----------------------------|-----------------------------|
| COS-CRC scales (range of values) | Mean change unadjusted (99% CI) | P value* |
|-----------------------------|-----------------------------|-----------------------------|
| Dejection (0–18) | −0.18 (−0.94 to 0.58) | 0.54 |
| Anxiety (0–21) | −0.28 (−1.11 to 0.55) | 0.38 |
| Behaviour (0–21) | −0.37 (−1.27 to 0.54) | 0.30 |
| Sleep (0–12) | −0.37 (−1.07 to 0.33) | 0.18 |
| Introvert (0–15) | −0.20 (−0.83 to 0.43) | 0.41 |
| Change in body perception (0–9) | −0.37 (−0.77 to 0.03) | 0.017 |
| Fear and powerlessness (0–12) | −0.22 (−0.76 to 0.32) | 0.29 |
| Change in perception of own age (0–6) | −0.25 (−0.59 to 0.089) | 0.056 |
| Emotional reactions (0–6) | −0.17 (−0.42 to 0.069) | 0.065 |
| Negative impact on sexuality (0–3) | 0.054 (−0.18 to 0.29) | 0.57 |
| Lifestyle changes (0–3) | −0.011 (−0.15 to 0.13) | 0.84 |

COS-CRC, consequences of screening in colorectal cancer.
the time for screening and after screening requires a very large sample size. Furthermore, electronic distribution of the questionnaire may not be a feasible approach in the target population of CRC screening. Therefore, economic and practical reasons may be the explanation for the lack of evidence in this field. Moreover, it is time-consuming to develop a new condition-specific measure with adequate measurement properties. That may explain the frequent use of generic questionnaires in the area of psychosocial consequences of screening, although proved inferior to condition-specific questionnaires.\(^7\)

To our knowledge, this is the first study to investigate psychosocial consequences of being invited to CRC screening with both a before and after invitation to screening assessment and with a condition-specific questionnaire with adequate measurement properties.

The results of the present study may be generalisable to other CRC screening programmes where participants receive the invitation to CRC screening in their mailbox. Finally, this study contributes with new and important evidence in a sparsely investigated research area.

**Contributors** JB designed the study. JM was responsible for the data collection. DRN generated all datasets. VS planned and supervised the statistical analyses. CWB performed the statistical analyses. JM drafted the manuscript. All authors contributed to different parts of the manuscript. JM and JB are guarantors of the study.

**Funding** This study was funded by the Region Zealand foundation.

**Disclaimer** The funding source had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing interests** None declared.

**Patient consent for publication** Not required.

**Ethics approval** According to Danish legislation, ethical approval is automatically granted for survey studies without clinical interventions. The study has been registered by the Danish Data Protection Agency, 12 January 2016 (file number:...
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