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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 Brodersen [1,2]

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[1]The Research Unit for General Practice and Section of General Practice, Department of Public Health, University of Copenhagen, Copenhagen, Denmark
[2]Primary Health Care Research Unit, Region Zealand, Soroe, Denmark

Correspondence to
Dr Jessica Malmqvist, Department of Public Health, University of Copenhagen, 1017 Kobenhavn, Denmark; jessica.malmqvist@sund.ku.dk

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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 in the direction of a less negative body perception after invitation.

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 rising awareness of one's psychological health.[2–4] 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. Finally, measurement of psychosocial consequences in cancer screening settings should be performed using questionnaires with adequate measurement properties, for example, high content validity and unidimensionality.[5–7]

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 I: item order in the questionnaire	Scales
1. Worried	Dejection
2. Worried about my future	Anxiety
3. Scared	Anxiety
4. Irritable	Behaviour
5. Quieter than normal	Behaviour
6. Slept badly	Sleep
7. Hard to concentrate	Behaviour
8. Time passed slowly	Dejection
9. Change in appetite	Behaviour
10. Sad	Dejection
11. Upset	Anxiety
12. Restless	Anxiety
13. Nervous	Anxiety
14. Uneasy	Dejection
15. Taken long time to fall asleep	Sleep
16. Withdrawn into myself	Behaviour
17. Unable to cope	Dejection
18. Depressed	Dejection
19. Difficulty dealing with work or other commitments	Behaviour
20. Woken up far too early in the morning	Sleep
21. Difficulty doing things around the house	Behaviour
22. Terrified	Anxiety
23. Awake most of the night	Sleep
24. Felt sorry for myself	Introvert
25. Shocked	Anxiety
26. Insecure	Introvert
27. Felt as though something is wrong with my body	Change in body perception
28. Felt as though my body was a machine that does not work	Change in body perception
29. Thought my situation was hopeless	Introvert
30. Experienced that I lost control	Fear & Powerlessness
31. Experienced mood swings	Introvert
32. Thought my body was vulnerable	Change in body perception
33. Kept my thoughts to myself	Introvert
34. Felt older than my age	Change in perception of own age
35. Felt sour (attitude)	Emotional reactions
36. Angry	Emotional reactions
37. Felt I have been in a vacuum	Fear & powerlessness
38. Felt older than my age	Change in perception of own age
39. Felt powerless	Fear & powerlessness
40. Felt I was unlucky	Fear & powerlessness
41. Have changed diet	Lifestyle changes, single item
42. Negative impact on sex-life	Sexuality, 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.[11] 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 to 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 χ^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.

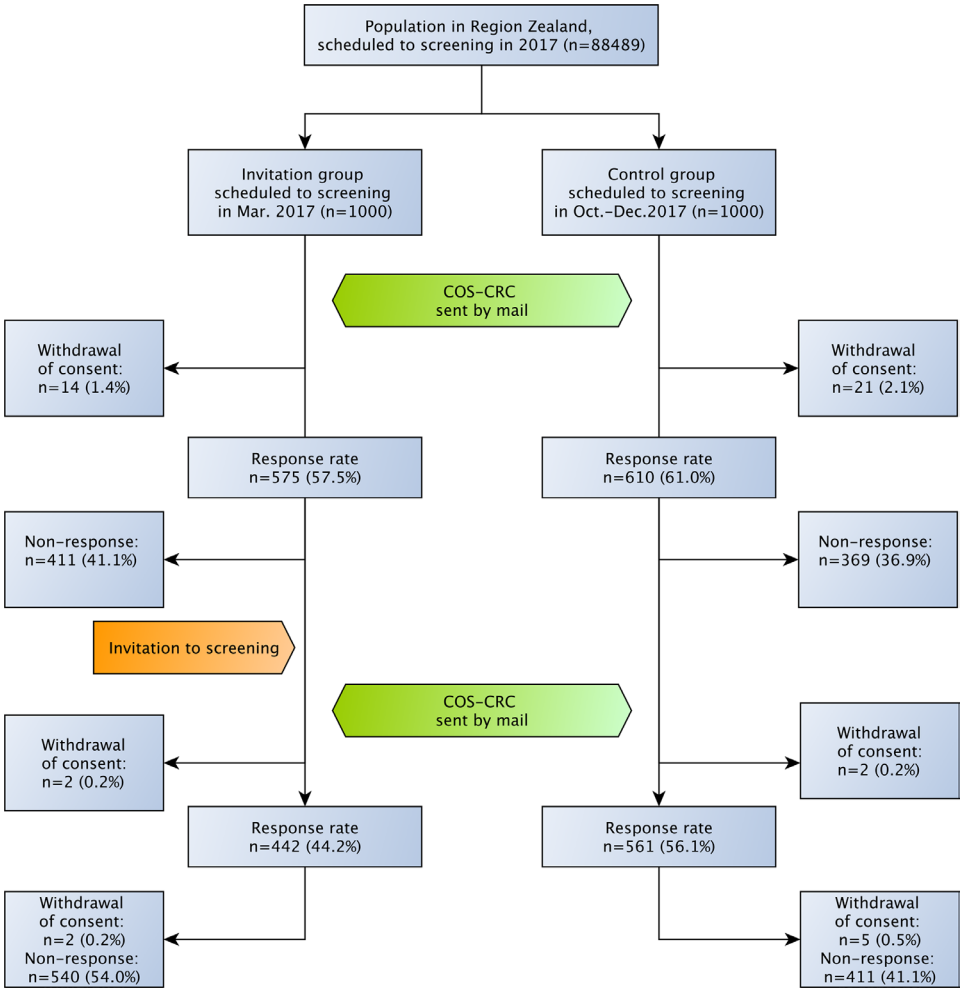

Figure 2 Study flowchart. COS-CRC, consequences of screening for colorectal cancer.

Table 1 Sociodemographics

	Invitation group n=1000	Control group n=1000	P value*
Sex n (%)			1.00
Male	497 (49.7)	497 (49.7)	
Female	503 (50.3)	503 (50.3)	
Age, mean (SD)	62.5 (6.1)	62.5 (6.1)	1.00
Urbanicity n (%)			1.00
Capital city	72 (7.2)	72 (7.2)	
Small town	406 (40.6)	406 (40.6)	
Rural area	522 (52.2)	522 (52.2)	
Educational level n (%)			0.21
Elementary school (10 years)	270 (27.0)	251 (25.1)	
Secondary school including vocational education	465 (46.5)	466 (46.6)	
Short/medium further education	187 (18.7)	222 (22.2)	
Long further education	59 (5.9)	45 (4.5)	
None registered	19 (1.9)	16 (1.6)	
Employment status n (%)			0.95
Employed	495 (49.5)	502 (50.2)	
Unemployed	140 (14.0)	139 (13.9)	
Retired	365 (36.5)	359 (35.9)	
Annual income (€) n (%)			0.77
<26 800	421 (42.1)	399 (39.9)	
26 800–40 200	301 (30.1)	308 (30.8)	
40 201–67 000	217 (21.7)	231 (23.1)	
>67 000	61 (6.1)	62 (6.2)	
Wealth (€)			0.21
<11 800†	450 (45.0)	414 (41.4)	
11 800–67 000	208 (20.8)	210 (21.0)	
>67 000	342 (34.2)	376 (37.6)	
CCI, mean (SD)	0.54 (1.2)	0.47 (1.1)	0.17
Living alone n (%)			0.21
No	710 (71.0)	735 (73.5)	
Yes	290 (29.0)	265 (26.5)	

*P values of a t-test (continuous variables) or χ^2 test (categorical variables).
†Retired persons with a wealth below this amount are given a governmental economic aid corresponding to a maximum of 2350€.
CCI, Charlson's Comorbidity Index.

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.[24]

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.[25] 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.[8] 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).[26] 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.[27–29]

Individuals' perception of risk information on cancer screening has been described using the theory of planned behaviour and cognitive dissonance.[30] 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.[31]

Table 2 Psychosocial consequences before and after invitation to screening

COS-CRC scales (range of values)	Group	Before N	After N	Before invitation Mean (SD)	After invitation Mean (SD)
Dejection (0–18)	Invitation	571	438	1.26 (2.51)	1.20 (2.49)
	Control	604	555	1.24 (2.34)	1.16 (2.33)
Anxiety (0–21)	Invitation	565	433	1.20 (2.57)	1.15 (2.45)
	Control	598	551	1.19 (2.19)	1.17 (2.44)
Behaviour (0–21)	Invitation	562	431	1.45 (2.79)	1.18 (2.51)
	Control	597	552	1.39 (2.52)	1.29 (2.44)
Sleep (0–12)	Invitation	569	437	1.65 (2.64)	1.25 (2.37)
	Control	602	557	1.71 (2.64)	1.59 (2.48)
Introvert (0–15)	Invitation	564	437	1.20 (2.19)	1.05 (2.04)
	Control	598	553	1.16 (1.97)	1.07 (2.00)
Change in body perception (0–9)	Invitation	571	437	0.78 (1.53)	0.55 (1.34)
	Control	601	557	0.73 (1.50)	0.68 (1.56)
Fear and powerlessness (0–12)	Invitation	571	439	0.67 (1.74)	0.59 (1.62)
	Control	604	554	0.66 (1.55)	0.64 (1.66)
Change in perception of own age (0–6)	Invitation	572	440	0.87 (1.23)	0.75 (1.10)
	Control	606	556	0.80 (1.11)	0.75 (1.12)
Emotional reactions (0–6)	Invitation	572	438	0.38 (0.91)	0.28 (0.81)
	Control	607	559	0.36 (0.88)	0.30 (0.81)
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)
	Control	516	469	0.34 (0.81)	0.29 (0.73)
Lifestyle changes (0–3)	Invitation	572	440	0.23 (0.56)	0.19 (0.52)
	Control	608	559	0.24 (0.59)	0.20 (0.54)

COS-CRC, consequences of screening in colorectal cancer.

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 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*	Mean change adjusted (99% CI)	P value*
Dejection (0–18)	−0.18 (−0.94 to 0.58)	0.54	−0.23 (−0.98 to 0.52)	0.42
Anxiety (0–21)	−0.28 (−1.11 to 0.55)	0.38	−0.33 (−1.14 to 0.48)	0.29
Behaviour (0–21)	−0.37 (−1.27 to 0.54)	0.30	−0.40 (−1.28 to 0.48)	0.24
Sleep (0–12)	−0.37 (−1.07 to 0.33)	0.18	−0.39 (−1.08 to 0.30)	0.14
Introvert (0–15)	−0.20 (−0.83 to 0.43)	0.41	−0.24 (−0.86 to 0.38)	0.33
Change in body perception (0–9)	−0.37 (−0.77 to 0.03)	0.017	−0.39 (−0.78 to −0.0080)	0.0085
Fear and powerlessness (0–12)	−0.22 (−0.76 to 0.32)	0.29	−0.24 (−0.77 to 0.29)	0.24
Change in perception of own age (0–6)	−0.25 (−0.59 to 0.089)	0.056	−0.27 (−0.60 to 0.061)	0.036
Emotional reactions (0–6)	−0.17 (−0.42 to 0.069)	0.065	−0.18 (−0.42 to 0.049)	0.042
COS-CRC single items				
Negative impact on sexuality (0–3)	0.054 (−0.18 to 0.29)	0.57	0.066 (−0.18 to 0.31)	0.49
Life-style changes (0–3)	−0.011 (−0.15 to 0.13)	0.84	−0.014 (−0.16 to 0.13)	0.80

*P value of difference in mean increase between the study groups.
COS-CRC, consequences of screening in colorectal cancer.

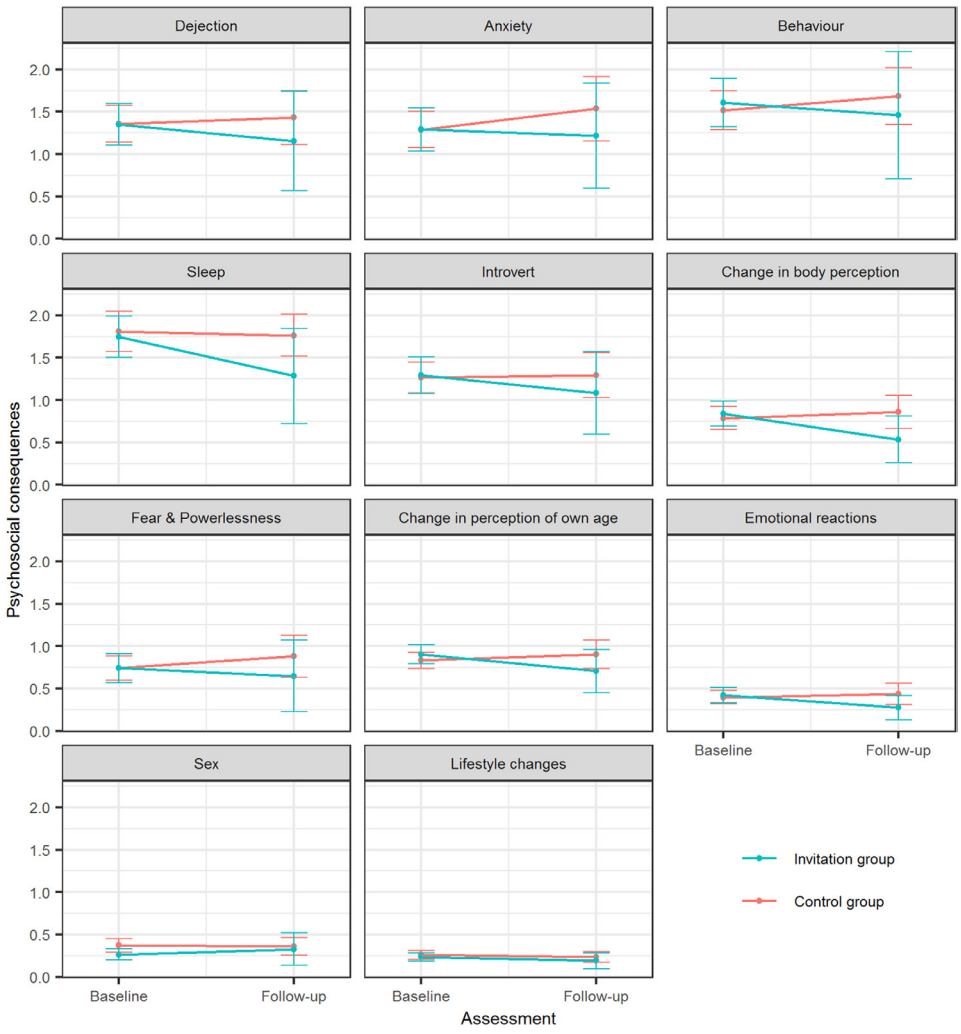

Figure 3 Unadjusted analyses.

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.[7] That may explain the frequent use of generic questionnaires in the area of psychosocial consequences of screening, although proved inferior to condition-specific questionnaires.[3 5]

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.

What is already known on this subject

- There is a gap in the evidence of psychosocial consequences of receiving an invitation to colorectal cancer screening.

What this study adds

- Our study did not show any negative psychosocial consequences of receiving an invitation to colorectal cancer screening.
- The results add important knowledge to this research field and may change invitation policies in countries where the invitation is given in primary care facilities.

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.

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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:

2015-41-4514 and 2014-54-0804) and by the Danish Patient Safety Authority, 13 September 2016 (file number: 3-3013-1753/1/).

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Data availability statement The corresponding author can provide the questionnaires and datasets generated and analysed during the study on reasonable request.

ORCID iDs
Jessica Malmqvist http://orcid.org/0000-0002-9299-4369
Volkert Siersma http://orcid.org/0000-0003-1941-2681
Mie Sara Hestbech http://orcid.org/0000-0001-8247-3642
John Brodersen http://orcid.org/0000-0001-9369-3376

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