Chapter 7

Informed decision making in colorectal cancer screening using colonoscopy or CT-colonography

Margriet C. de Haan
Thomas R. de Wijkerslooth
Esther M. Stoop
Patrick M.M. Bossuyt
Paul Fockens
Maarten Thomeer
Ernst J. Kuipers
Marie-Louise Essink-Bot
Monique E. van Leerdaam
Evelien Dekker
Jaap Stoker

Submitted
Abstract

Objective
To evaluate the level of informed decision making in a randomised controlled trial comparing colonoscopy and CT-colonography for colorectal cancer screening.

Materials and methods
8,844 citizens aged 50 to 75 were randomly invited to colonoscopy (n=5,924) or CT-colonography (n=2,920) screening. All invitees received an information leaflet. Participants received a questionnaire within 4 weeks before the planned examination, non-participants 4 weeks after the invitation. A decision was categorized as informed, when characterized by sufficient decision-relevant knowledge and consistent with personal attitudes towards screening participation.

Results
Both knowledge and attitude items were completed by 1,032/1,276 of colonoscopy participants (81%), by 698/4,648 of colonoscopy non-participants (15%), by 824/982 of CT-colonography participants (84%) and by 192/1,938 of CT-colonography non-participants (10%). Participants: 1,027 colonoscopy (>99%) and 815 CT-colonography participants (99%) had adequate knowledge; 915 (89%) and 742 (90%) had a positive attitude. Non-participants: 675 invited to colonoscopy (97%) and 182 invited to CT-colonography (95%) had adequate knowledge; 344 (49%) and 94 (49%) expressed a negative attitude.

Conclusion
The large majority of participants made an informed decision on participation. Almost half of responding non-participants made an uninformed decision, suggesting additional barriers to participation. Efforts to understand the additional barriers will create opportunities to facilitate informed participation to colorectal cancer screening.
Introduction
Colorectal cancer (CRC) is the second most prevalent cause of cancer related deaths in the Western world\textsuperscript{1-3}. Without screening the lifetime risk of CRC is 5% to 6% in Western countries\textsuperscript{4}. The majority of CRCs develop from adenomatous polyps – benign precursors - after a long premalignant period. CRC screening can reduce both the incidence and mortality of CRC by early detection and removal of adenomatous polyps and CRC\textsuperscript{5-11}. A recent study showed that the lifetime risk decreases to 4.4% when CRC screening is offered to the general population\textsuperscript{12}.

Patient autonomy requires that people should be able to choose, free from coercion, whether they wish to participate in screening or not. To make a balanced decision invitees require unbiased information on both the benefits as well as the harms of screening\textsuperscript{13,14}. Following the definition of Marteau\textsuperscript{15,16}, an informed decision should be based on adequate decision-relevant knowledge and should be consistent with personal attitudes towards participation to screening. Participants with adequate knowledge about CRC and CRC screening and a positive attitude towards participation make an informed decision to participate. Analogously, non-participants with adequate knowledge and a negative attitude towards participation, make an informed decision not to take part in screening. In case of inadequate understanding or when making a decision that is not in line with one’s attitudes, the action cannot be classified as an informed decision.

Colonoscopy and computed tomography-colonography (CT-colonography) are attractive options for CRC screening as they are both full colonic examinations with a high accuracy for advanced neoplasia\textsuperscript{17,18}. As both are invasive techniques, requiring preparation by laxatives or contrast agents, invitees may be more inclined to reject participation to screening than when invited for less invasive tests. It is therefore important that invitees have enough decision-relevant understanding about screening, to be able to make an informed decision on participation.

It is unclear whether population-based CRC screening programs based on colonoscopy or CT-colonography can be organised in such a way that participants can make informed decisions about participation. We therefore evaluated the level of informed decision making on participation in a randomised trial comparing colonoscopy and CT-colonography screening.
Materials and methods

Patients and settings
Between June 2009 and August 2010, Dutch citizens aged 50 to 75 years were identified in the population registry in the regions of Amsterdam and Rotterdam, and randomly allocated 2:1 to colonoscopy or CT-colonography. Invitees were stratified for age, sex (individual level data from the Dutch population registry) and socioeconomic status (very low – very high, data at postal area code level) derived from the Dutch population registry and based on data of Statistics Netherlands. The latter provides information on income level, education, and type of occupation of Dutch citizens. This information is used to estimate the socioeconomic status that is linked to each postal code in the Netherlands. Individuals were invited by postal mail to a population-based CRC screening trial and were only allowed to undergo the allocated screening modality. The trial protocol has been described in detail elsewhere. Ethical approval was obtained before study initiation from the Dutch Health Council (2009/03WBO, The Hague, the Netherlands). The trial was registered in the Dutch trial register: NTR1829 (www.trialregister.nl).

Information leaflet and prior consultation
Together with an invitation by mail, all colonoscopy and CT-colonography screening invitees received identically designed information leaflets with information on CRC and CRC screening, derived from previous CRC screening pilots. The information leaflet for colonoscopy invitees contained specific information on benefits and risks of colonoscopy, while the information leaflet of CT-colonography invitees contained information on benefits and risks of CT-colonography. Both leaflets contained information on follow-up in case of a positive test result (e.g. follow-up colonoscopy for positive CT-colonography).

Persons who responded to the invitation were scheduled for a standardized consultation with a research fellow or research nurse to inform them about the bowel preparation and the procedure itself. Respondents were excluded from participation when they had undergone a full colonic examination in the previous five years, when they had a life expectancy of less than 5 years, or had been previously scheduled for surveillance colonoscopy because of a personal history of CRC, adenomatous polyps or inflammatory bowel disease. CT-colonography respondents were also excluded when they had been exposed to ionizing radiation for research purposes within the
previous 12 months and when they had hyperthyroidism or iodine contrast allergy.

**Questionnaire**

All invitees received a questionnaire containing previously validated measures of knowledge and an attitude measure based on Marteau’s Multidimensional Measure of Informed Choice. Participants received the questionnaire within 4 weeks before the screening procedure with the appointment confirmation. All invitees who actively declined the invitation or did not respond received the same questionnaire 4 weeks after the invitation.

Knowledge among colonoscopy invitees was measured by eight knowledge statements on CRC and CRC screening and three statements on characteristics of colonoscopy and the consequences of a positive test result. For each statement, respondents were invited to indicate whether these were true or false. Knowledge among CT-colonography invitees was measured by the same eight knowledge statements on CRC and CRC screening and six statements on the characteristics of CT-colonography and follow-up colonoscopy in case of a positive CT-colonography (Tables 2 and 3). Knowledge was classified as adequate if more than half of the items had been answered correctly.

Attitude towards screening among colonoscopy and CT-colonography invitees was measured by offering respondents four statements, to which they could respond each on a seven-point Likert-scales: participation in this population-based CRC screening trial is a ‘bad idea-not a bad idea’ for me, ‘useful-not useful’, ‘harmful-beneficial’ and ‘a good idea-not a good idea’. An attitude score was calculated by summing up the responses to the four items. These scores ranged from 4 to 28. Attitude scores of 17 points or higher were classified as reflecting a positive attitude.

The questionnaire also contained questions on marital status, children, education and employment status. All participants were asked to complete the questionnaire prior to the screening procedure and to return it by mail or to bring it to the screening procedure. Questionnaires filled out after the screening procedure were excluded.

**Definition of informed decision**

Invitees with adequate decision-relevant knowledge and a positive attitude towards screening who actually participated were classified as having
made an informed decision, as well as invitees with adequate knowledge and a negative attitude who declined the invitation. All other combinations – inadequate knowledge or actions inconsistent with attitudes towards screening – were considered to be uninformed decisions.

**Statistical analysis**
We calculated the proportion of people with adequate knowledge, the proportion of people with a positive attitude, and the proportion that made an informed decision for the colonoscopy group and for the CT-colonography group. These proportions were calculated for the group of participants and for the group of non-participants who returned the questionnaire. Differences in knowledge scores between participants and non-participants were assessed using χ²-statistics.

**Results**
Between June 2009 and August 2010, a total of 8,844 persons aged 50 to 75 years were randomly allocated to colonoscopy (n=5,924) or to CT-colonography (n=2,920). Of these invitees, 1,194 (94%) colonoscopy participants and 945 (96%) CT-colonography participants returned the questionnaire; 915 (20%) of colonoscopy non-participants and 257 (13%) of CT-colonography non-participants returned the questionnaire (Figure 1).

**Figure 1 Overview of response**
Twenty-seven questionnaires of colonoscopy participants and 18 questionnaires of CT-colonography participants had to be excluded, as they were completed after the examination.

Both knowledge and attitude items were completed by 1,032 of 1,276 colonoscopy participants (81%), by 698 of 4,648 colonoscopy non-participants (15%), by 824 of 982 CT-colonography participants (84%) and by 192 of 1,938 CT-colonography non-participants (10%). There was no difference between responding participants and responding non-participants in age or socioeconomic status. In both colonoscopy and CT-colonography non-participants, women more often returned the questionnaire than men (Table 1).

Table 1 Demographic characteristics of respondents

<table>
<thead>
<tr>
<th></th>
<th>Coloscopy</th>
<th></th>
<th>CT-colonography</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=5,924</td>
<td>n=2,920</td>
<td></td>
</tr>
<tr>
<td>Total invitees (n)</td>
<td>participants n=1,276</td>
<td>non-participants n=4,648</td>
<td>participants n=982</td>
</tr>
<tr>
<td>Responding invitees</td>
<td>1,167 (91%) 915 (20%)</td>
<td>927 (94%) 257 (13%)</td>
<td></td>
</tr>
<tr>
<td>Median age in years (IQR)</td>
<td>60 (55-65) 60 (55-65)</td>
<td>59 (55-65) 61 (56-67)</td>
<td></td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>50.8 44.3</td>
<td>51.1 41.2</td>
<td></td>
</tr>
<tr>
<td>Married/living together (%)</td>
<td>86.4 85.5 83.5 87.2 89.1</td>
<td>85.0 80.8 80.8</td>
<td></td>
</tr>
<tr>
<td>Children (% yes)</td>
<td>85.5 83.5</td>
<td>87.2 89.1</td>
<td></td>
</tr>
<tr>
<td>Socioeconomic status (mean, SD)*</td>
<td>3.2 (SD 1.4) 3.1 (SD 1.4)</td>
<td>3.1 (SD 1.4) 3.1 (SD 1.4)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>- elementary (%)</td>
<td>3.8 6.1</td>
<td>5.0 8.1</td>
</tr>
<tr>
<td></td>
<td>- secondary (%)</td>
<td>67.8 68.1</td>
<td>60.5 57.9</td>
</tr>
<tr>
<td></td>
<td>- tertiary and postgraduate (%)</td>
<td>26.1 24.4</td>
<td>31.9 31.6</td>
</tr>
<tr>
<td></td>
<td>- other (%)</td>
<td>2.3 1.4</td>
<td>2.6 2.4</td>
</tr>
<tr>
<td>Employment status</td>
<td>- paid job (%)</td>
<td>50.1 47.6</td>
<td>50.4 40.5</td>
</tr>
<tr>
<td></td>
<td>- not able to work (%)</td>
<td>4.9 5.8</td>
<td>3.4 6.1</td>
</tr>
<tr>
<td></td>
<td>- retired (%)</td>
<td>33.8 34.3</td>
<td>35.0 42.1</td>
</tr>
<tr>
<td></td>
<td>- other (%)</td>
<td>11.2 12.4</td>
<td>11.2 11.3</td>
</tr>
</tbody>
</table>

* Socioeconomic status was categorized as very low, low, medium, high and very high (1-5).

Knowledge

Overall, 99% of colonoscopy participants and 98% of CT-colonography participants could be classified as having adequate knowledge about CRC (screening) and the allocated screening modality, compared to 95% of colonoscopy non-participants and 92% of CT-colonography non-participants.
Knowledge statements on CRC and CRC screening

Details are displayed in Table 2.

Participants: Five of the eight knowledge statements on CRC and screening were answered correct by a large majority of colonoscopy and CT-colonography participants: statement 2 (97% vs. 96%), 4 (98% vs. 98%), 5 (96% vs. 97%), 6 (98% vs. 96%), and 7 (96% vs. 94%).

Non-participants: Five out of eight knowledge statements on CRC and screening were answered correct by ≥86% of colonoscopy and CT-colonography non-participants: statement 2 (89% vs. 91%), 3 (both 87%), 4 (both 94%), 6 (both 91%), and 7 (89% vs. 86%).

Participants versus non-participants: The largest difference between participants and non-participants in percentage of correct responses was found for the following statement: ‘if an invitee feels healthy, it is not useful to participate’: 96% of colonoscopy participants indicated this was false vs. 84% of non-participants (p<0.001); 97% of CT-colonography participants indicated this was false vs. 83% of non-participants (p<0.001). In colonoscopy invitees, the second largest difference was found for the following statement: ‘population-based screening can detect CRC before it becomes symptomatic’ (97% of participants vs. 89% of non-participants indicated this was true; p<0.001). In CT-colonography, the second largest difference was found for: ‘early removal of polyps reduces the future chance of being diagnosed with CRC in the future’ (94% of participants vs. 86% of non-participants indicated this was true; p<0.001).

Knowledge statements on the screening modality:

Results on the knowledge statements about the screening modality are displayed in Table 3.

Participants: Two out of three statements on colonoscopy were answered correctly by a large majority of colonoscopy participants: “colonoscopy can lead to a bleeding and/or perforation” (91%) and “if polyps are detected during colonoscopy, they can be directly removed in most cases” (98%). Two out of six statements on CT-colonography were answered correctly by a large majority of CT-colonography participants: “during CT-colonography CO₂ will be insufflated in the bowel” (95%) and “if polyps and/or CRC are detected on CT-colonography, a follow-up examination (colonoscopy) is needed” (97%).

Non-participants: The percentage of correct responses of colonoscopy non-participants on three statements on colonoscopy, ranged from 73% to 80%.
Table 2 Knowledge statements on CRC and on CRC screening, participants versus non-participants

<table>
<thead>
<tr>
<th>Information in leaflet</th>
<th>Statements (correct answer in parentheses)</th>
<th>Colonoscopy</th>
<th>CT-colonography</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>participants n=1,165 non-participants n=909</td>
<td>p value</td>
<td>p value</td>
</tr>
<tr>
<td>CRC is the most prevalent cancer in men after prostate cancer and lung cancer. In women, CRC is the most prevalent cancer after breast cancer.</td>
<td>1. CRC is one of the most prevalent cancers. (TRUE)</td>
<td>79.1 74.8</td>
<td>0.02</td>
</tr>
<tr>
<td>Population-based CRC screening can detect CRCs in an early stage, when a patient is still asymptomatic.</td>
<td>2. Population-based CRC screening can detect CRCs in participants before they become symptomatic. (TRUE)</td>
<td>96.6 88.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Participation to this population-based CRC screening is voluntary.</td>
<td>3. Participation to the population-based CRC screening is obliged for all subjects aged 50 to 75 years. (FALSE)</td>
<td>82.3 87.2</td>
<td>0.002</td>
</tr>
<tr>
<td>If CRC is detected early, it can be treated well. The chance on curing the disease by treatment becomes larger.</td>
<td>4. If CRC is detected in an early stage, the chance of being deathly becomes smaller. (TRUE)</td>
<td>98.2 94.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Colorectal polyps are usually not symptomatic. CRC in an early stage is usually asymptomatic.</td>
<td>5. If an invitee feels healthy, it is not useful to participate. (FALSE)</td>
<td>96.3 83.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CRC in an early stage is usually asymptomatic.</td>
<td>6. It is possible to have CRC, even if you are not symptomatic. (TRUE)</td>
<td>97.6 90.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Precursors of CRC can be removed before they become malignant.</td>
<td>7. Early removal of polyps reduces the future chance of being diagnosed with CRC in the future becomes smaller. (TRUE)</td>
<td>96.0 89.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Not stated.</td>
<td>8. If CRC is detected on colonoscopy, the most common treatment is surgical removal. (TRUE)</td>
<td>82.2 72.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Information in leaflet</td>
<td>Knowledge among colonoscopy invitees on characteristics of colonoscopy (correct answer in parentheses)</td>
<td>participants</td>
<td>non-participants</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>--------------</td>
<td>-----------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n=1,156</td>
<td>n=909</td>
</tr>
<tr>
<td>In 1 on 1000-10.000 examinations complications occur, like a bleeding. In addition, it is possible that the bowel wall is perforated during the examination.</td>
<td>9. A colonoscopy can lead accidentally to a bleeding and/or perforation of the bowel. (TRUE)</td>
<td>90.6</td>
<td>77.8</td>
</tr>
<tr>
<td></td>
<td>10. There is a small chance that colorectal cancer will be missed during colonoscopy (&lt;1%).</td>
<td>86.4</td>
<td>72.7</td>
</tr>
<tr>
<td></td>
<td>In most cases, polyps will be removed during the colonoscopy.</td>
<td>97.7</td>
<td>80.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information in leaflet</th>
<th>Knowledge among CT-colonography invitees on characteristics of CT-colonography (correct answer in parentheses)</th>
<th>participants</th>
<th>non-participants</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n=923</td>
<td>n=256</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>The colon can be visualised using a CT-scanner. This makes it possible to examine the colon from outside, without the need for an endoscope.</td>
<td>9. During CT-colonography the large bowel is visualised using an endoscope. (FALSE)</td>
<td>83.7</td>
<td>51.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10. To prepare the large bowel, CO₂ will be insufflated. (TRUE)</td>
<td>94.7</td>
<td>73.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>11. If 100 subjects underwent CT-colonography, it would detect polyps or colorectal cancer in about 6 subjects.</td>
<td>64.9</td>
<td>57.8</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>12. If suspicious colorectal lesions are detected on CT-colonography, you will be referred for a colonoscopy. (FALSE)</td>
<td>89.1</td>
<td>62.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>13. If suspicious colorectal lesions are detected on CT-colonography, you will be referred for a colonoscopy. (FALSE)</td>
<td>96.5</td>
<td>90.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>During this follow-up colonoscopy, polyps and colorectal cancer can be detected and if possible they can also be removed directly.</td>
<td>73.3</td>
<td>67.2</td>
<td>0.05</td>
</tr>
</tbody>
</table>
The following statement was answered most often correctly: “if polyps are detected during colonoscopy, they can be directly removed in most cases”. The percentage of correct responses for the statements on CT-colonography and follow-up colonoscopy among CT-colonography non-participants ranged between 51% and 90%. Low scores were observed for the following statements: ‘during CT-colonography the large bowel is visualized using an endoscope’ (51%) and ‘in 100 participants, CT-colonography will detect polyps or CRC in approximately 14 subjects’ (58%).

Participants versus non-participants: The largest difference in correct answers between colonoscopy participants and non-participants was found for the following statement: ‘if polyps are detected during colonoscopy, they can be directly removed in most cases’ (98% vs. 80%; p<0.001). All statements presented to CT-colonography invitees were more often answered correctly by participants. The largest differences in correct responses were observed for the following statements: ‘during CT-colonography the large bowel is visualized using an endoscope’ (84% of participants vs. 51% of non-participants; p<0.001), ‘if polyps are detected on CT-colonography, they can be removed directly’ (89% vs. 62%; p<0.001) and ‘during CT-colonography CO₂ will be insufflated in the bowel’ (95% vs. 73%; p<0.001).

Attitude
The results on the attitude of participants and non-participants are shown in Figure 2. Cronbach’s alphas of the attitude scales of colonoscopy and CT-colonography were 0.83 and 0.82, respectively, indicating high internal consistency. Overall, 89% of colonoscopy and 91% of CT-colonography participants had an attitude score ≥17 and were classified as having a positive attitude towards screening. Forty-eight percent of responding colonoscopy and CT-colonography non-participants had a positive attitude towards screening.

Informed decision making
Table 4a and 4b show the results on informed decision making for participants and non-participants, respectively.

Participants: 1,027 of 1,032 (>99%) colonoscopy participants who completed both knowledge and attitude items had adequate knowledge; 915 (89%) colonoscopy participants also had a positive attitude; 815 of 824 (99%) CT-colonography participants who completed both items had adequate knowledge and 742 (90%) also had a positive attitude.
Non-participants: 675 of 698 (97%) colonoscopy non-participants had adequate knowledge, 344 (49%) also had a negative attitude. Of the 192 responding CT-colonography non-participants, 180 (94%) had adequate knowledge and 94 (49%) also had a negative attitude.

Uninformed decision making
Non-participants often had adequate knowledge and a positive attitude towards screening: 47% of responding colonoscopy non-participants (331/698) and 45% of responding CT-colonography non-participants (86/192).

Figure 2 Combined scores on individual attitude statements on colorectal cancer screening using either colonoscopy or CTC (total score <17 points indicating a negative attitude and ≥17 points indicating a positive attitude towards CRC screening) — participants vs non-participants. CS=colonoscopy; CTC=CT-colonoscopy; NP=non-participant; P=participant
**Table 4a** informed decisions among participants

<table>
<thead>
<tr>
<th></th>
<th>Colonoscopy n=1,032</th>
<th>CT-colonography n=824</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sufficient knowledge, positive attitude</td>
<td>88.7% (915)*</td>
<td>90.0% (742)*</td>
</tr>
<tr>
<td>Sufficient knowledge, negative attitude</td>
<td>10.9% (112)</td>
<td>8.7% (72)</td>
</tr>
<tr>
<td>Insufficient knowledge, positive attitude</td>
<td>0.5% (5)</td>
<td>0.8% (7)</td>
</tr>
<tr>
<td>Insufficient knowledge, negative attitude</td>
<td>0% (0)</td>
<td>0.4% (3)</td>
</tr>
</tbody>
</table>

* Participants in these categories made an informed decision

**Table 4b** informed decisions among non-participants

<table>
<thead>
<tr>
<th></th>
<th>Colonoscopy n=698</th>
<th>CT-colonography n=192</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sufficient knowledge, positive attitude</td>
<td>47.4% (331)</td>
<td>44.8% (86)</td>
</tr>
<tr>
<td>Sufficient knowledge, negative attitude</td>
<td>49.3% (344)*</td>
<td>49.0% (94)*</td>
</tr>
<tr>
<td>Insufficient knowledge, positive attitude</td>
<td>0.6% (4)</td>
<td>3.6% (7)</td>
</tr>
<tr>
<td>Insufficient knowledge, negative attitude</td>
<td>2.7% (19)</td>
<td>2.6% (5)</td>
</tr>
</tbody>
</table>

* Non-participants in these categories made an informed decision

**Discussion**

Our study shows that a large majority of colonoscopy and CT-colonography participants make informed decisions about taking part in a population-based CRC screening program, compared to about half of responding non-participants. Both in the colonoscopy and in the CT-colonography the large majority of the remaining non-participants had adequate knowledge and a positive attitude, suggesting the existence of additional barriers to participation.

Our study has several strengths. Data were collected in a large pilot CRC screening program, designed as a randomised trial. All invitations were sent in the same time period, minimizing external influences through general public awareness. The information leaflets of both examinations were identically designed where appropriate and all participants received a standardized consultation to inform them about the entire screening procedure.

At the time of our study, the Netherlands did not have a population-based CRC screening program. The decision to participate in a randomised trial, like this one, differs from the decision to participate in a population-based program in that the latter may not only involve informed individual decision making but also potential adverse effects on others.
based screening program. It is very well possible that the willingness to
do the latter does not translate to participation in a trial. This would imply
that the proportions observed in our study do not automatically apply to
population-based screening programs in general. In addition, knowledge
scores among participants may be overestimated, as trial invitees may
have been more eager to read the information leaflet carefully. Finally,
the definition of informed decision making defined by Marteau et al is not
100% perfect. In decision making about screening there may be predictable
barriers to participation, like expected burden and immobility of an invitee,
and unpredictable barriers, such as an acute illness, which might result in
differences between intended and actual behavior\textsuperscript{24}.

We defined adequate knowledge as more than 50% correct responses
to the knowledge items, an arbitrary norm-based cut-off point. There are
several other ways to define adequate knowledge like using the mean score
as a distribution-based cut-off point\textsuperscript{15}. By using a norm-based cut-off point,
sufficient knowledge of an individual is not based on the relative knowledge
of other subjects, but on a minimum of desired knowledge.

Since the introduction of the definition of informed decision as
defined by Marteau et al, several studies have evaluated the level of informed
decision making in cancer screening\textsuperscript{23,25}. Compared to previous studies, we
found a relatively high number of participants and non-participants with
adequate knowledge, while the percentage of participants with a positive
attitude in our study was only slightly lower. The first study on informed
decision making in screening was performed within a RCT of CT screening
for lung cancer in high risk individuals\textsuperscript{23}. That study was most comparable to
our study, as they also defined adequate knowledge and positive attitude as
scores above the midpoint of the complete scales. Overall, 73% of participants
and 54% of non-participants were found to have adequate knowledge, while
99% of participants and 64% of non-participants had a positive attitude
towards screening. Another study\textsuperscript{25} was conducted in a population-based
cervical cancer screening program using a Pap smear. Invitees received a
questionnaire, together with their invitation and standard information leaflet.
Sixty-four percent of responding participants had sufficient knowledge and
99% was found to have a positive attitude towards screening. That study was
less comparable to our study, as at least 6 out of 7 knowledge items had to
be answered correctly. As far as we know, no previous studies have been
published on informed decision making in CRC screening using colonoscopy
or CT-colonography.
Compared to these previous studies, a relative high number of participants made an informed decision in our study. This might be explained by variety in methods like differences in the type or amount of information given in the information leaflet, by differences in defining adequate knowledge, or by the fact that all participants in this trial had a prior consultation before they underwent the examination. A second explanation for the different results could be the variety in diseases under evaluation, including the subsequent possibility of differences in prior knowledge among invitees.

Both in colonoscopy and CT-colonography, some knowledge statements were more often answered incorrectly by non-participants than by participants, such as ‘If an invitee feels healthy, it is not useful to participate’. These results indicate that participants are more often aware than non-participants that someone can have cancer without being symptomatic. This contrast is consistent with findings of a previous study. Our results also show that invitees were not always familiar with the difference between colonoscopy and CT-colonography, as 49% of CT-colonography non-participants thought that the large bowel was visualized with an endoscope during CT-colonography. Since adequate knowledge regarding these statements is important for understanding the primary aim of a screening program and a necessary condition for making an informed decision on participation, we should invest additional efforts in developing future leaflets and further improving the information process.

Unfortunately, only a minority of non-participants returned their questionnaire. A low response rate among non-participants is a common problem in studies. It can be argued that these non-participants represent a selected group, with an overrepresentation of knowledgeable people with a positive attitude. We found no difference in median age and mean socioeconomic status between responding participants and non-participants in either arm, and only a small difference in ratio of responding men and women. Nevertheless, we do not suggest that the results can unconditionally be generalized to all non-participants. Despite the likelihood of selective response, the existence of a relatively large group of people with adequate decision-relevant knowledge and a positive attitude towards screening participation who nonetheless decided not to participate suggests that there are additional barriers towards participation. Exploration of these barriers may offer new opportunities to eradicate them and to facilitate informed participation.
Conclusion

Our results show that a large majority of participants in a randomised CRC screening trial comparing colonoscopy and CT-colonography made an informed decision on participation. This shows that it is possible to organise population-based CRC screening programs in such a way that the principle of informed decision making can be adhered to. In contrast, only half of responding non-participants made an informed decision on non-participation, suggesting that there are additional barriers towards participation.

Practice implications

The finding that non-participation was based on uninformed decision making in half of the responding non-participants suggests additional barriers towards participation. Future efforts should offer more insight in these additional participation barriers. This information could be of help in the design of future information campaigns and in creating circumstances to further facilitate informed participation.

Acknowledgements

The authors acknowledge ZonMw for funding (project numbers 120720012 and 121010005) and NutsOhra Foundation, as well as Maaike Delters, Marije Deutekom, Marjolein Liedenbaum and Aafke van Roon for their help in designing the questionnaires. The authors acknowledge Harriet Blaauwgeers, Lisa Hoogstins, Hans ‘t Mannetje, Jacqueline Reijerink, Sandra van der Togt and all other co-workers of the comprehensive cancer centres for their support and for helping us with the realization of this population-based CRC screening trial. In addition we would like to acknowledge Caroline van Bavel, Laurens Groenendijk, Karin de Groot and Esther van Huissteden for their professional support.
References


