Diagnostic yield using a FIT-based risk model versus FIT-only: a randomized controlled trial

Tim Kortlever, Manon van der Vlugt, Floor Duijkers, Ad Masclee, Roderik Kraaijenhagen, Manon Spaander, Iris Lansdorp-Vogelaar, Patrick Bossuyt, Evelien Dekker.
Yield of advanced neoplasia did not improve using a FIT-based risk model versus FIT-only in this study.

Adding a short questionnaire did not affect screening participation.
In the Netherlands...

- Sensitivity of FIT for CRC is 80-85%
- Sensitivity for AA is substantially lower
- Positive predictive value of FIT for advanced neoplasia is less than 40%

Imperiale et al, Ann Intern Med. DOI: 10.7326/M18-2390
AN risk factors:

• Age
• Sex
• Current smoking
• Family history of CRC
• Quantitative FIT result
Background
Informed consent

Risk ≥ 0.10 and/or FIT ≥ 15 µg Hb/g

Randomized Controlled Trial

23,000 selected second-round invitees

FIT Group

Informed consent

FIT ≥ 15 µg Hb/g

Risk Model Group
Randomized Controlled Trial

Risk Model Group

Informed consent

Risk ≥ 0.10 and/or FIT ≥ 15 µg Hb/g

FIT Group

Informed consent

FIT ≥ 15 µg Hb/g

23,000 selected second-round invitees
Primary outcome:
Yield of advanced neoplasia

Secondary outcomes:
Participation rate
Standardized yield of advanced neoplasia
Yield of proximal advanced neoplasia
Results

Risk Model Group

- 22748 invitees
- 11364 invitees
  - 3397 consented
    - 3113 returned questionnaire and FIT (27.4%)
      - 186 tested positive (6.0%)
        - 164 underwent colonoscopy (88%)
          - 42 diagnosed with AN (26%)

FIT Group

- 11348 invitees
  - 3342 consented
    - 3061 returned FIT (27.0%)
      - 161 tested positive (5.3%)
        - 146 underwent colonoscopy (91%)
          - 39 diagnosed with AN (27%)
Results

Risk Model Group

22748 invitees

11364 invitees

3397 consented

3113 returned questionnaire and FIT (27.4%)

186 tested positive (6.0%)

164 underwent colonoscopy (88%)

42 diagnosed with AN (26%)

FIT Group

11348 invitees

3342 consented

3061 returned FIT (27.0%)

161 tested positive (5.3%)

146 underwent colonoscopy (91%)

39 diagnosed with AN (27%)

p = 0.49
Results

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FIT Group

11348 invitees

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$p = 0.49$
Results

Yield of AN

Yield per 1000 invitees

Groups
- Risk Model
- FIT
Results

Standardized yield of AN

Yield per 1,000 invitees

Groups

Risk Model

FIT
Limited variability age of study population

Fewer smokers compared to development study (9.6% versus 13%)
Yield of advanced neoplasia did not improve using a FIT-based risk model versus FIT-only in this study.

Adding a short questionnaire did not affect screening participation.
Acknowledgments

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