

The FIT for Follow-Up Study

Sensitivity of annual Faecal Immunochemical Tests for haemoglobin (FIT) for detecting advanced neoplasia in patients undergoing three-yearly surveillance colonoscopy

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Introduction

- Increasing demand for colonoscopy in the NHS BCSP.
- Need for effective non-colonoscopy approaches to surveillance.

Primary aim of FIT for Follow-Up Study

- To compare the sensitivity and specificity of annual FIT in detecting advanced adenomas (AA) and/or colorectal cancer (CRC) with colonoscopy surveillance.

Secondary aims

- Acceptability of FIT compared with colonoscopy.
- Potential of FIT screening to replace colonoscopic surveillance for groups at intermediate-risk of developing CRC.
- Costs and cost-effectiveness of an annual FIT as an alternative to three-yearly colonoscopic surveillance.

Study Outline

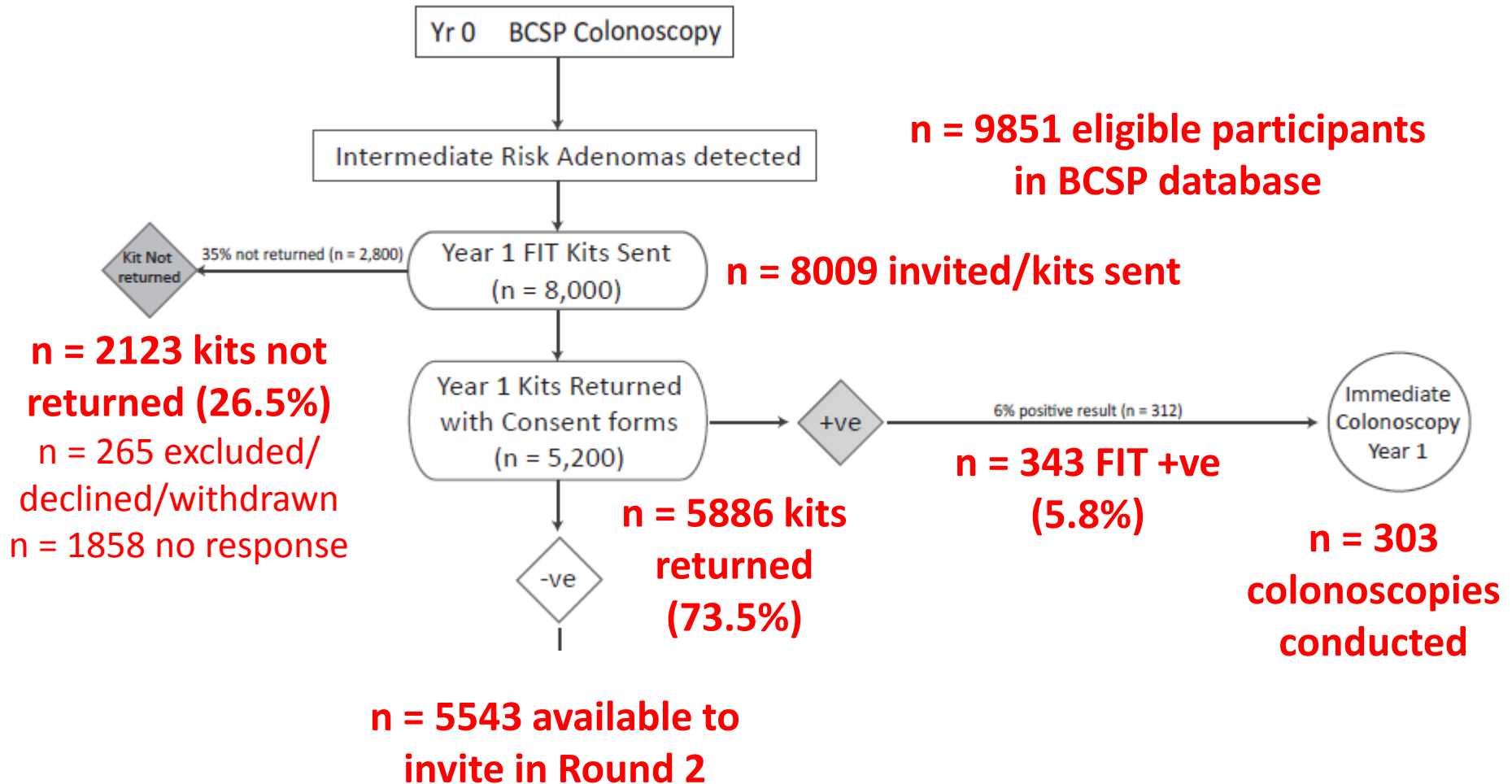
Eligibility

- Aged 60-71 years.
- Recently diagnosed with intermediate-risk adenomas in the BCSP.
- Awaiting first surveillance colonoscopy in three years time.

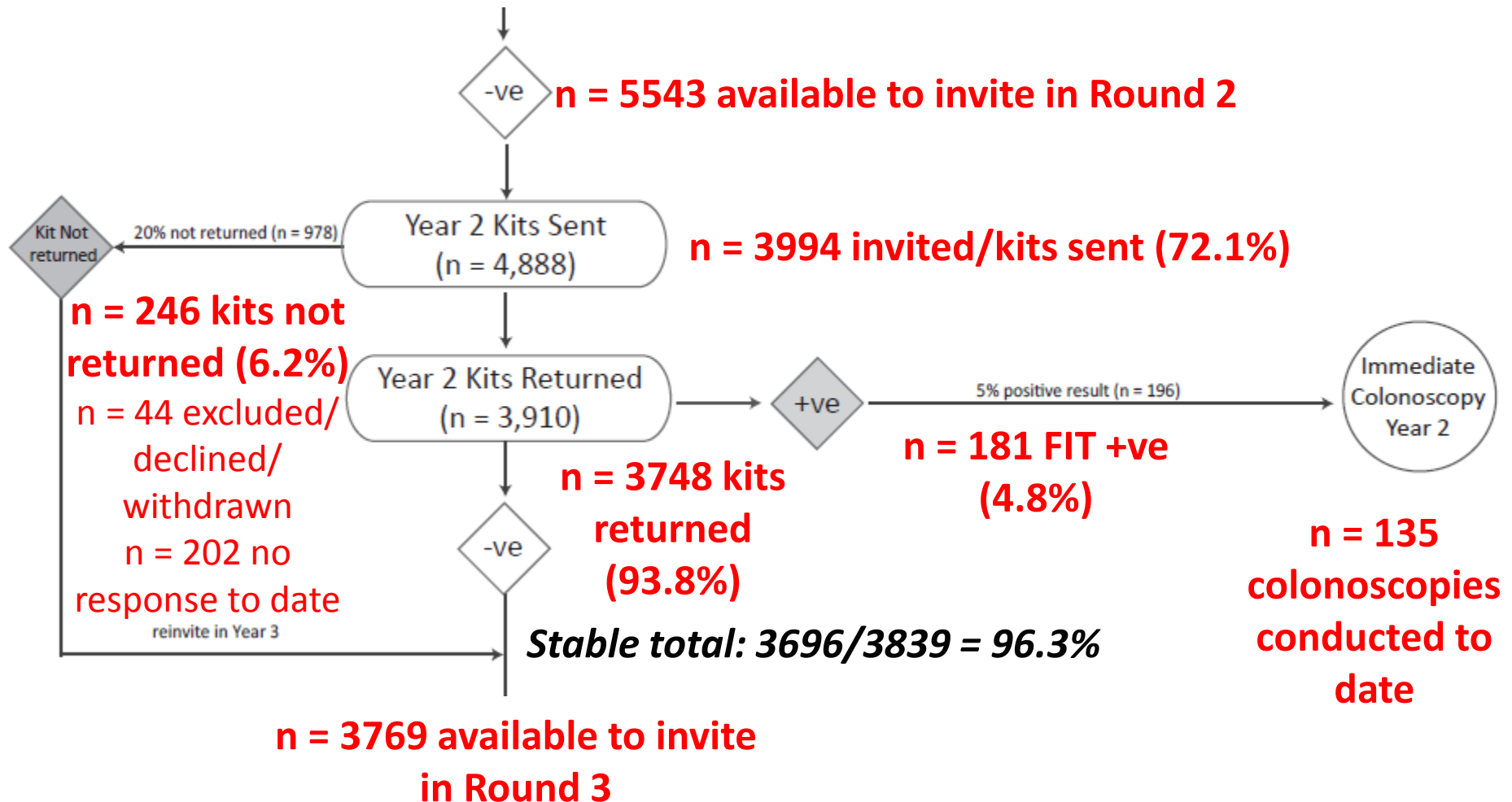
Protocol

- Participants invited to complete a FIT kit annually in the three year interval between screening and surveillance colonoscopy.
- If the FIT kit is positive ($>40 \mu\text{g Hb/g faeces}$), the participants are invited to have their colonoscopy brought forward to investigate this result further.
- Findings at surveillance colonoscopy will be used as the gold standard against which we will measure the programme sensitivity and specificity of the FIT kit.

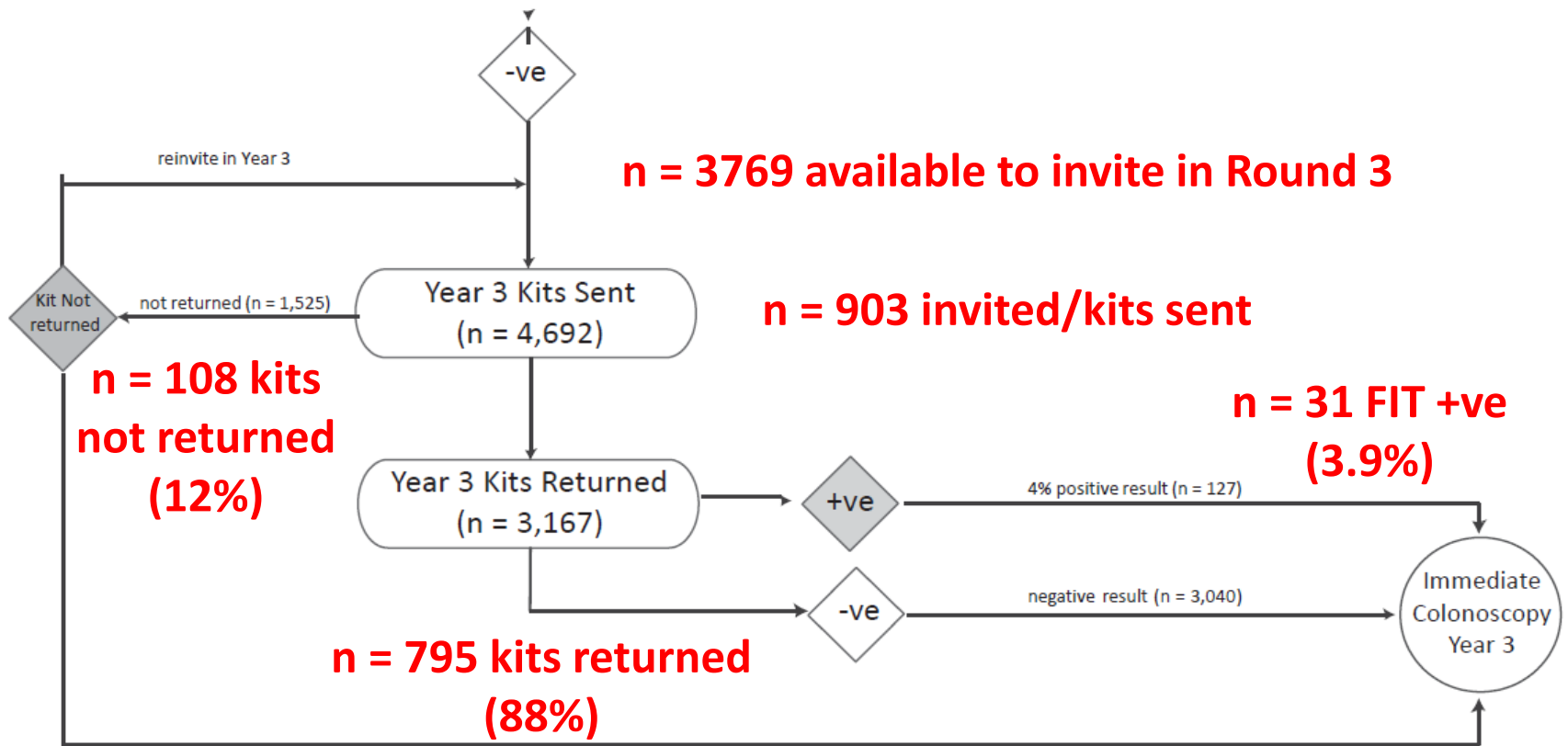
Progress: Recruitment – Round 1



Progress: Recruitment – Round 2



Progress: Recruitment – Round 3



Round 1 FIT +ve

Round 1

- FIT positivity rate:
- $343/5886 = 5.8\%$
- Invited to attend early colonoscopy:

| | n | % |
|---------------------------------|------------|-------------|
| Attended | 303 | 88.3 |
| Awaiting reports from SC | 5 | 1.5 |
| Did not attend | 1 | 0.3 |
| Declined | 28 | 8.2 |
| Unable to contact | 5 | 1.5 |
| Symptomatic pathway | 1 | 0.3 |
| Total | 343 | 100 |

Round 1 Colonoscopy Findings

Colonoscopy results

- 303 participants had an early colonoscopy:
 - 72 (23.8%) F, 231 (76.2%) M
- Colonoscopy findings:

| | n | % |
|---------------------|------------|-------------|
| Normal | 90 | 29.7 |
| Polyps found | 207 | 68.3 |
| Cancer | 6 | 2.0 |
| <i>Total</i> | 303 | 100 |

Round 1 Advanced Adenomas

Advanced adenomas

- 73/303 (24.1%) participants classed as having AA
- 64/73 (87.7%) had one AA

| | n | % |
|----------------------|----|------|
| >10mm | 26 | 40.6 |
| TVA/VA | 12 | 18.8 |
| >10mm + TVA/VA | 25 | 39.1 |
| >10mm + TVA/VA + HGD | 1 | 1.6 |
| <i>Total</i> | 64 | 100 |

- 7/73 (9.6%) had two AA
- 2/73 (2.7%) had three AA

Round 2 FIT +ve

Round 2

- FIT positivity rate:
- $181/3748 = 4.8\%$
- Invited to attend early colonoscopy:

| | n | % |
|-----------------------------------|------------|-------------|
| Attended | 129 | 71.3 |
| Awaiting appt date from SC | 16 | 8.8 |
| Awaiting reports from SC | 21 | 11.6 |
| Did not attend | 1 | 0.6 |
| Declined | 13 | 7.2 |
| Unable to contact | 1 | 0.6 |
| Total | 181 | 100 |

Round 2 Colonoscopy Findings

Colonoscopy results

- 129 had an early colonoscopy:
 - 39 (30.2%) F, 90 (69.8%) M
- Colonoscopy findings:

| | n | % |
|---------------------|------------|-------------|
| Normal | 40 | 31.0 |
| Polyps found | 87 | 67.4 |
| Cancer | 2 | 1.6 |
| <i>Total</i> | 129 | 100 |

Round 2 Advanced Adenomas

Advanced adenomas

- 25/129 (19.4%) participants classed as having AA
- 21/25 (84.0%) had one AA

| | n | % |
|----------------------|-----------|------------|
| >10mm | 2 | 9.5 |
| TVA/VA | 4 | 19.0 |
| >10mm + TVA/VA | 10 | 47.6 |
| >10mm + HGD | 1 | 4.8 |
| >10mm + TVA/VA + HGD | 4 | 19.0 |
| <i>Total</i> | 21 | 100 |

- 3/25 (12.0%) had two AA
- 1/25 (4.0%) had three AA

Round 1 + 2 Colorectal Cancers

Cancer

- Six participants Round 1
- Two participants Round 2

| | Site | Type |
|----|--------|--|
| R1 | APP/CM | Carcinoid ex-goblet cell type (type B) (pT3 N1 Mx) |
| R1 | CM | Adenocarcinoma (pT4 N0 Mx) |
| R1 | SC | Adenocarcinoma (pT4 N2 M1) |
| R1 | SC | Adenocarcinoma in TVA |
| R1 | RS | Adenocarcinoma |
| R1 | RM | Adenocarcinoma |
| R2 | TC | Adenocarcinoma |
| R2 | DC | Adenocarcinoma |

Participant Satisfaction

Participants agree/strongly agree would complete a FIT kit again in the future:

- 4483/4736 (94.7%) Round 1 FIT-ve
- 251/276 (91%) Round 1 FIT+ve
- 2544/2648 (96.1%) Round 2 FIT-ve

Participants agree/strongly agree they found it easier to complete a FIT kit for the second time:

- 2470/2648 (93.3%) Round 2 FIT-ve
- 91/102 (89.2%) Round 2 FIT+ve

Conclusion

- Of those testing FIT+ve, 79/303 (26.1%) in Round 1 and 27/129 (20.9%) in Round 2 were diagnosed with AA or CRC.
- Participant compliance and satisfaction very high.
- FIT testing and findings at three-year surveillance colonoscopy - gold standard against which we will measure the programme sensitivity and specificity of the FIT kit.