

SCREESCO SCREEning of Swedish Colons - An update

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Agenda

- Baseline publication after completed intervention - short report
- Publications
- Ongoing work
- Primary endpoint: dead in colorectal cancer. Simulations of power analyses to decide date for evaluation of primary endpoint



Flowchart SCREESCO

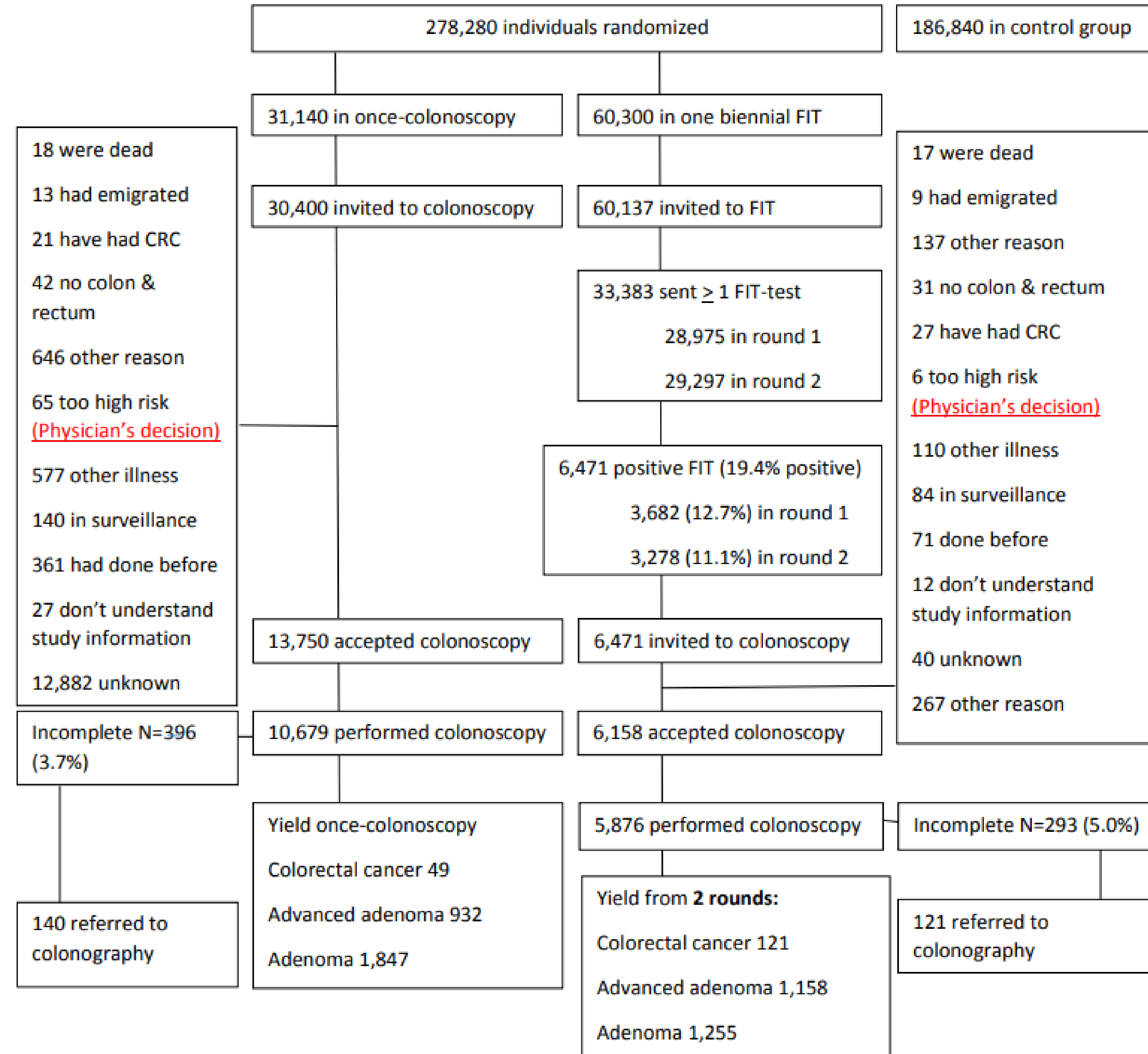
Randomization

Invitation

- /FIT

Colonoscopy/
work-up colonoscopy

Yield



	Colonoscopy group (n=31140*)	FIT group (n=60300†)	RR‡ (95% CI)	p value
Cancer				
Right-sided colon	12 (0.04%)	23 (0.04%)	1.01 (0.50–2.03)	0.98
Left-sided colon	25 (0.08%)	60 (0.10%)	0.81 (0.51–1.29)	0.37
Rectum	13 (0.04%)	38 (0.06%)	0.66 (0.35–1.24)	0.20
Total	49 (0.16%)	121 (0.20%)	0.78 (0.56–1.09)	0.15
Advanced adenoma				
Right-sided colon	262 (0.84%)	280 (0.46%)	1.81 (1.53–2.14)	<0.0001
Left-sided colon	288 (0.92%)	558 (0.93%)	1.00 (0.87–1.15)	1.00
Rectum	150 (0.48%)	248 (0.41%)	1.17 (0.96–1.43)	0.13
Total	637 (2.05%)	968 (1.61%)	1.27 (1.15–1.41)	<0.0001
Non-advanced adenoma				
Right-sided colon	1058 (3.40%)	666 (1.10%)	3.08 (2.79–3.39)	<0.0001
Left-sided colon	836 (2.68%)	687 (1.14%)	2.36 (2.13–2.60)	<0.0001
Rectum	300 (0.96%)	237 (0.39%)	2.45 (2.07–2.91)	<0.0001
Total	1916 (6.15%)	1317 (2.18%)	2.82 (2.63–3.02)	<0.0001
≥3 adenomas				
Total	443 (1.42%)	614 (1.02%)	1.40 (1.24–1.58)	<0.0001
Sessile serrated polyp ≥10 mm diameter				
Right-sided colon	217 (0.70%)	155 (0.26%)	2.71 (2.21–3.33)	<0.0001
Left-sided colon	44 (0.14%)	42 (0.07%)	2.03 (1.33–3.10)	0.0010
Rectum	4 (0.01%)	11 (0.02%)	0.70 (0.22–2.21)	0.55
Total	261 (0.84%)	202 (0.33%)	2.50 (2.08–3.01)	<0.0001

Baseline publication

Lancet gastroenterolepatol 2022

Yield of colonoscopy versus two FIT screening rounds 2 years apart, in the intention-to-screen population

**Randomization intervention 2014-2018
Last intervention dec 2020**



Summary of results baseline

- ▶ **In the ITS analysis, CRC was detected in 49 (0.16%) of 31 140 in the colonoscopy group vs 121 (0.20%) of 60 300 in the FIT group (RR 0.78, 95% CI 0.56–1.09)**
- ▶ **Advanced adenomas were detected in 637 (2.05%) in the colonoscopy group and 968 (1.61%) in the FIT group (RR 1.27, 95% CI 1.15–1.41)**
- ▶ **More right-sided advanced adenomas in colonoscopy group than in FIT**
- ▶ **Two perforations and 15 major bleeds in 16 555 colonoscopies**
- ▶ **The diagnostic yield and the low number of adverse events indicate that satisfactory screening quality is obtained**



Publications 2022-2023

18 in total up to now

- ▶ Forsberg A, et al. Once-only colonoscopy or two rounds of faecal immunochemical testing 2 years apart for colorectal cancer screening (SCREESCO): preliminary report of a randomised controlled trial. *Lancet Gastroenterol Hepatol.* 2022;7(6):513-21.
- ▶ Fritzell K et al. Different information needs-The major reasons for calling the helpline when invited to colorectal cancer screening. *Health Expect.* 2022;25(4):1548-54.
- ▶ Sekiguchi Met al. Detection rates of colorectal neoplasia during colonoscopies and their associated factors in the SCREESCO study. *J Gastroenterol Hepatol.* 2022;37(11):2120-30.
- ▶ Stromberg U et al. Colorectal cancer screening with fecal immunochemical testing or primary colonoscopy: An analysis of health equity based on a randomised trial. *EClinicalMedicine.* 2022;47:101398.
- ▶ Nilsson A et al. Examining the continuum of resistance model in two population-based screening studies in Sweden. *Prev Med Rep.* 2023;35:102317.
- ▶ Sekiguchi M et al. Endoscopist Characteristics and Polyp Detection in Colonoscopy: Cross-Sectional Analyses of Screening of Swedish Colons. *Gastroenterology.* 2023;164(2):293-5 e4.
- ▶ Westerberg Met al. The role of endoscopist adenoma detection rate in in sex differences in colonoscopy findings: cross-sectional analysis of the SCREESCO randomized controlled trial. *Scand J Gastroenterol.* 2023:1-9.



Ongoing - milestone publication

- ▶ Intervention completed. Data from health registers on the control population obtained.
- ▶ Analyses Once-colonoscopy vs control; and FITx2 vs control ongoing. Ready autumn 2024?
- ▶ To be analysed: incidence in CRC, stages of CRCs and adverse events including death
- ▶ Do we detect prevalent cancers? Detection in earlier stages? Is screening safe?



Ongoing cont

- ▶ Cohort study: individuals in FITx2 who performed colonoscopy in both rounds.
 1. Diagnostic performance of FIT
 2. Factors associated with presence of advanced neoplasia at 2nd round colonoscopy: screening characteristics, 1st round colonoscopy factors (including endoscopist factors), and FIT values
- ▶ Variation of FIT-values: Regional? Seasonal? Gender?
- ▶ Socio-economic inequality related to yield in the intervention arms
- ▶ Health economics



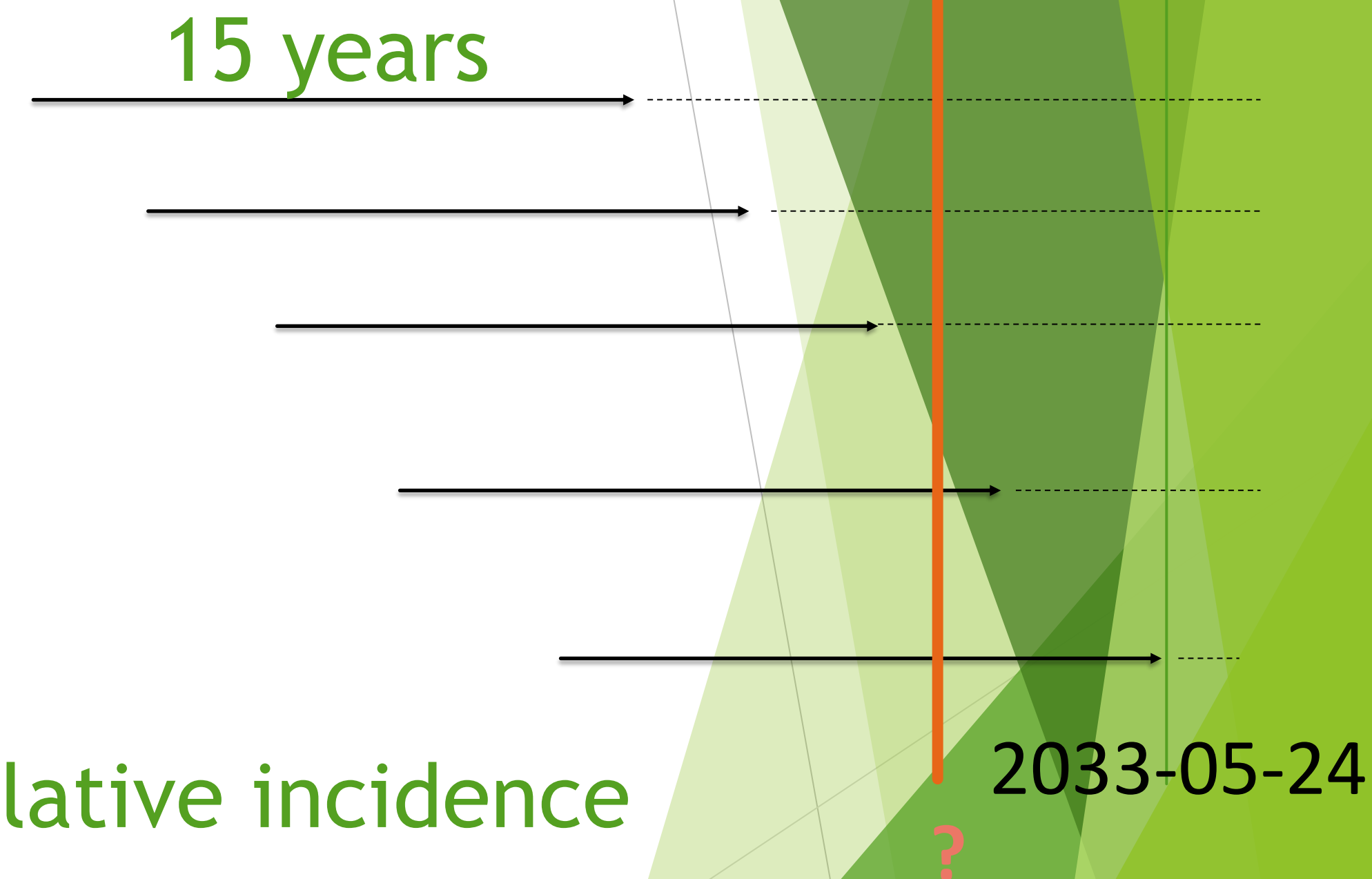
Timing of evaluation primary end-point death in CRC

- ▶ Low participation once-colonoscopy arm (35% instead of 50% as anticipated)
- ▶ 5520 more had to be randomized 2017 and 2018, respectively + controls
- ▶ If final evaluation 15 years after last randomization: delay until 2033-05-24
- ▶ Therefore re-evaluation of power analyses



SCREESCO design

Year	PCOL	FITx2	CONTROL	Date randomization
2014	6700	20 100	40 200	2014-02-11
2015	6700	20 100	40 200	2015-03-31
2016	6700	20 100	40 200	2016-03-01
2017	5520	0	33 120	2017-05-30
2018	5520	0	33 120	2018-05-25



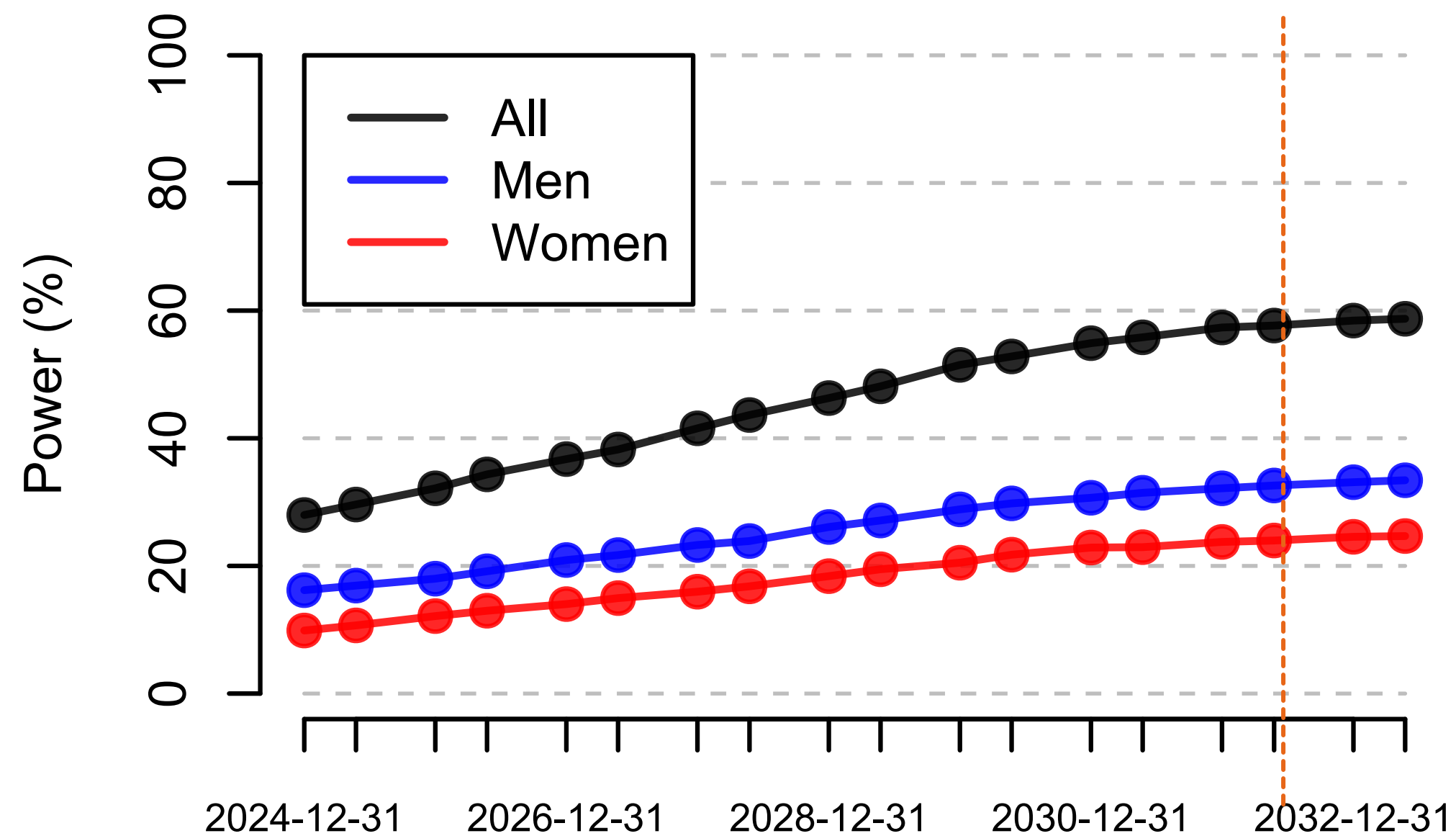
Aggregated register data to estimate hazard/cumulative incidence of death from CRC and other causes
Simulations on power for difference interventions vs control



Power analysis: simulations

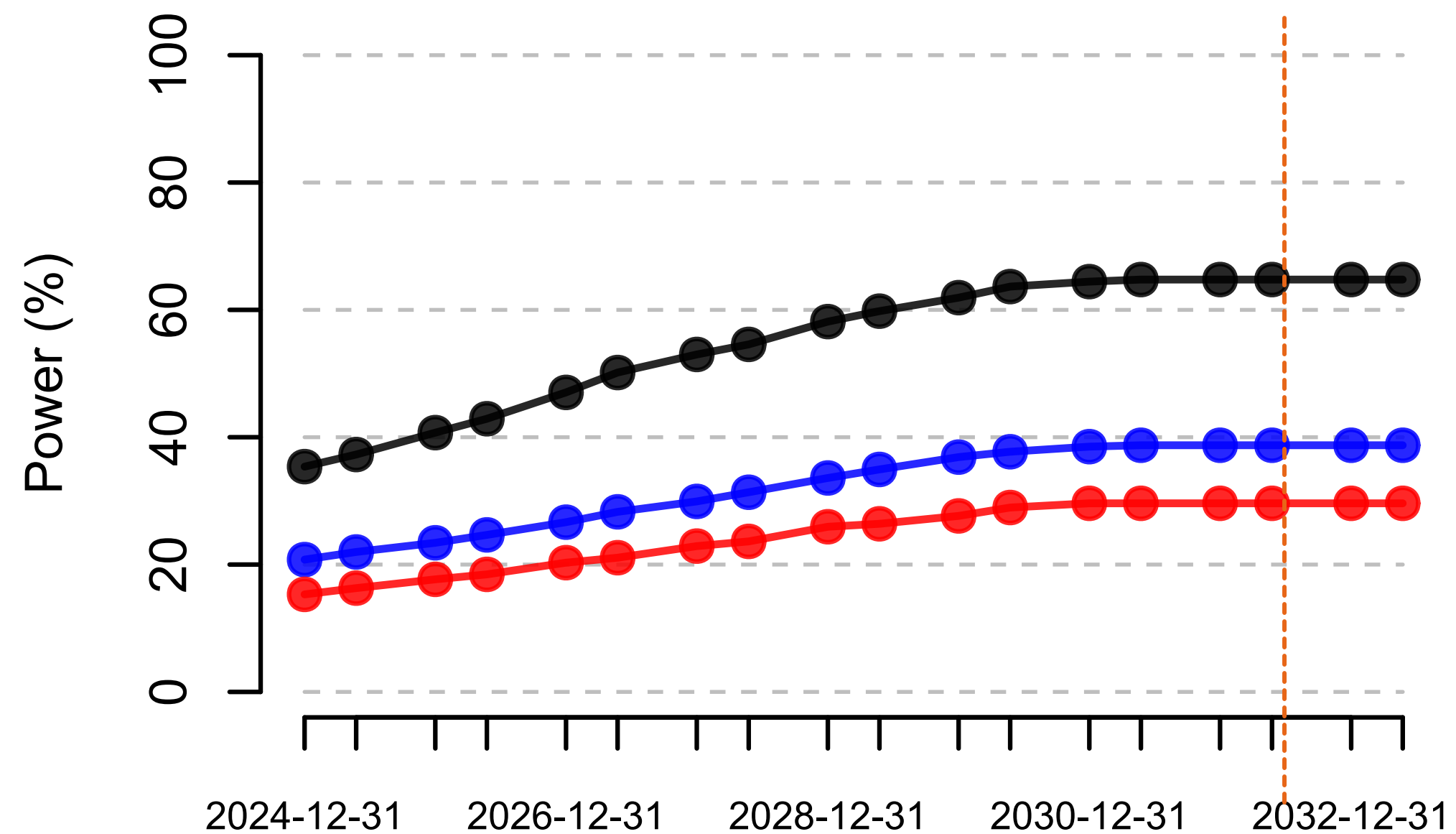
Outcome: death from colorectal cancer
Follow-up: at the first of date X,
date of death from other causes and
15 years after date of randomization

PCOL vs Control



X = End date

FIT vs Control



End date



Power analysis and simulations. Decision.

- ▶ Power simulations shows small loss in power if final evaluation is performed 2030-20-31 instead of 2033-05-24 (15 years after the last ranimization).
- ▶ Of national interest to get evaluation within reasonable time without loss of quality of data.
- ▶ No interim analysis regarding death will be performed



Final evaluation of SCREESCO 2030-12-31





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