GISCOR 2012

LA SIGMOIDOSCOPIA NEI PROGRAMMI DI SCREENING: IERI,OGGI ,DOMANI

NEREO SEGNAN
CPO PIEMONTE e AO Città della Salute e della Scienza, Torino

Mantova 9 novembre 2012


CARLO PONTI PRESENTA
SOPHIA LOREN E MARCELLO MASTROIANNI
IN UN FILM DI
VITTORIO DE SICA
IERI, OGGI, DOMANI
EDUARDO DE FILIPPO . CESARE ZAVATTINI
TECHNICOLOR - TECHNISCOPE

IERI

Estimate of efficacy of Sigmoidoscopy in the prevention of distal CRC

First author	Year of publication	N. of cases	Reduction in incidence (%)	Type of study
Gilbertson	1978	27,000	60-85	Prospective cohort
Friedman	1986	10,713	60	Randomized trial
Atkin	1992	1,618	85	Retrospective cohort
Selby	1992	1,129	70	Case-control
Newcomb	1992	290	75	Case-control
Muller	1995	32,702	40	Case-control
Kavanagh	1998	174	42	Case-control
Thiis-Evens	1999	400	80	Randomized trial

Atkin Eur. J. Gastr. Hepat. 1998; 10: 219-223 (modified)

OGGI

J Natl Cancer Inst. 2011 Sep 7;103(17):1310-22

Once-Only Sigmoidoscopy in Colorectal Cancer Screening: Follow-up Findings of the Italian Randomized Controlled Trial—SCORE

Nereo Segnan, Paola Armaroli, Luigina Bonelli, Mauro Risio, Stefania Sciallero, Marco Zappa, Bruno Andreoni, Arrigo Arrigoni, Luigi Bisanti, Claudia Casella, Cristiano Crosta, Fabio Falcini, Franco Ferrero, Adriano Giacomin, Orietta Giuliani, Alessandra Santarelli, Carmen Beatriz Visioli, Roberto Zanetti, Wendy S. Atkin, Carlo Senore; and the SCORE Working Group

Manuscript received February 11, 2011; revised June 28, 2011; accepted June 30, 2011.

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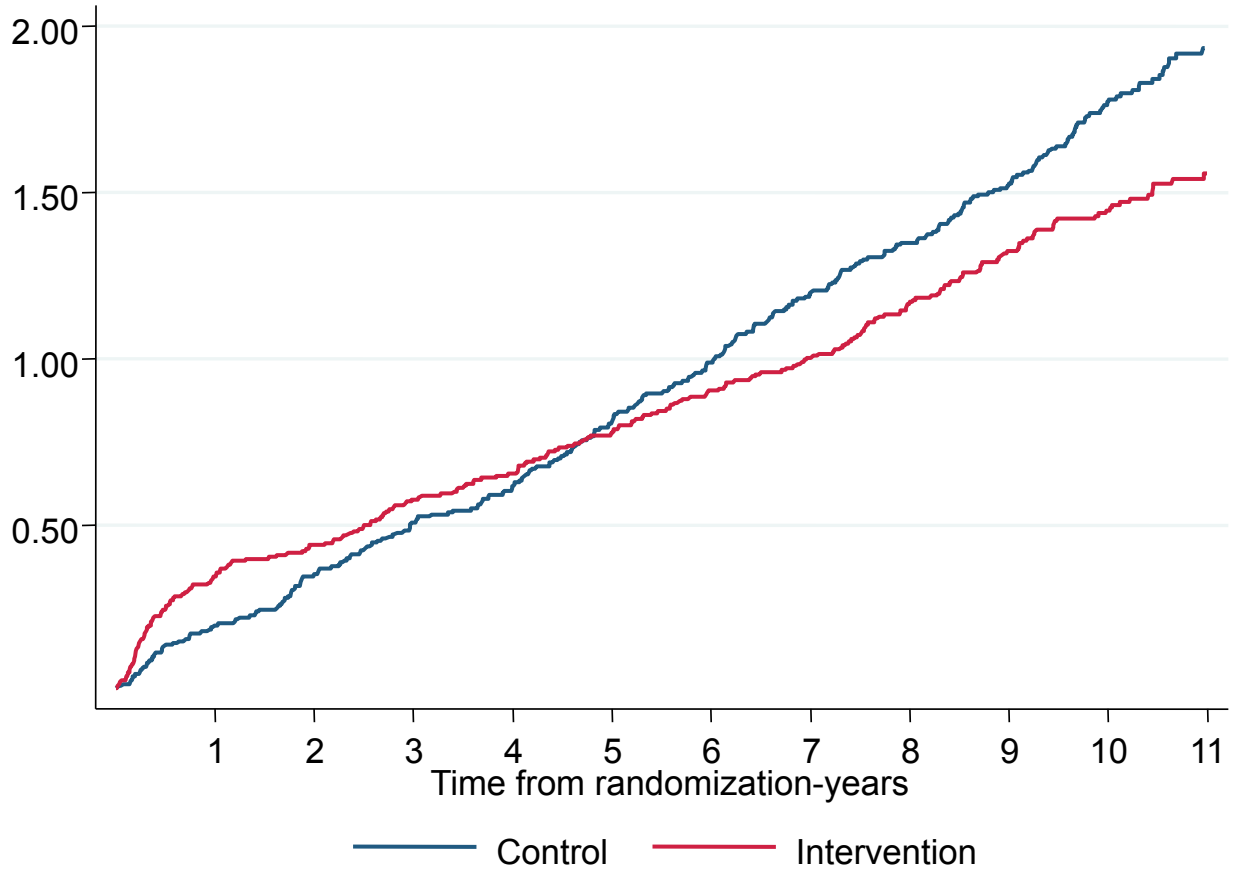
Intention to treat analysis - Colorectal cancer

INCIDENCE, ALL SITES

Nelson Aalen Cumulative Hazard (%) by time from randomization



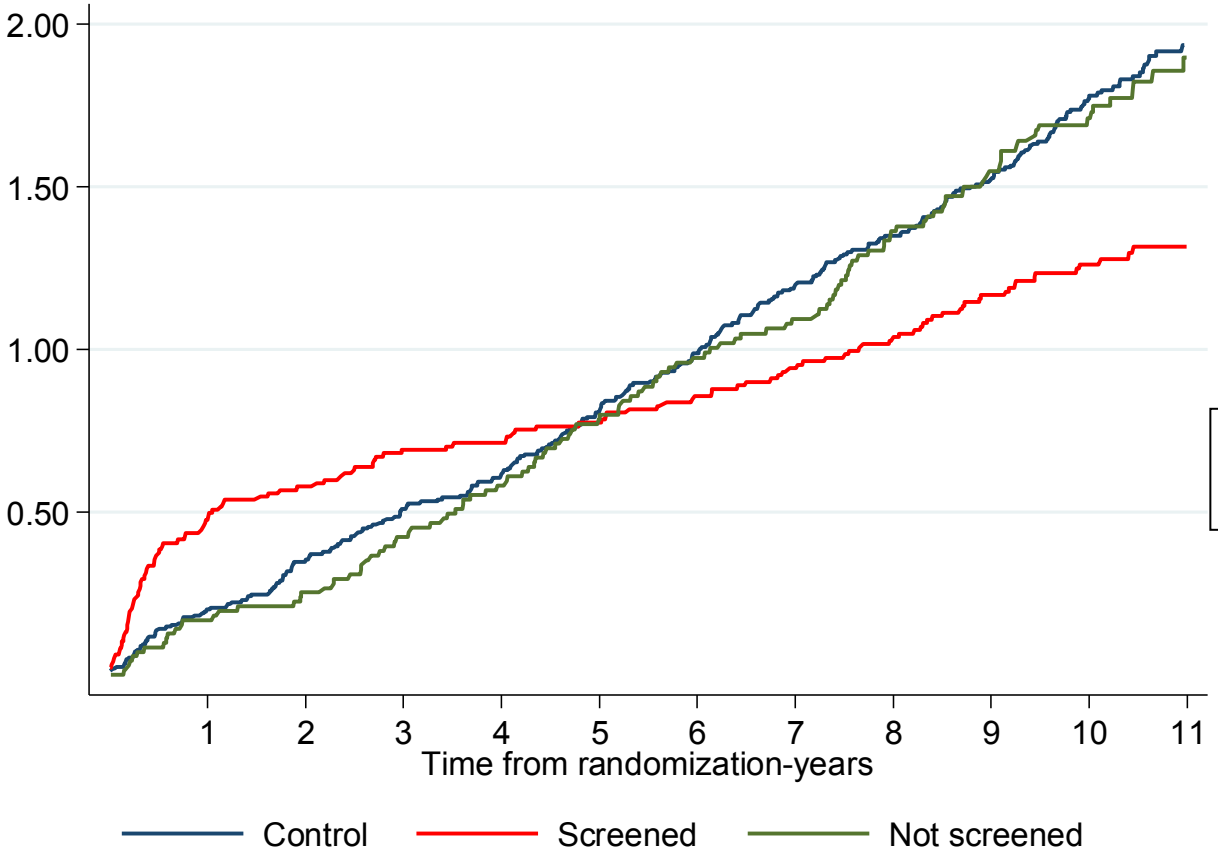
RR (95%CI) = 0.82 (0.69-0.96)

Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	60	104	165	223	286	**306**
Intervention	75	111	152	195	237	**251**

Per protocol analysis-Colorectal cancer

INCIDENCE, ALL SITES

Nelson Aalen Cumulative Hazard (%) by time from randomization

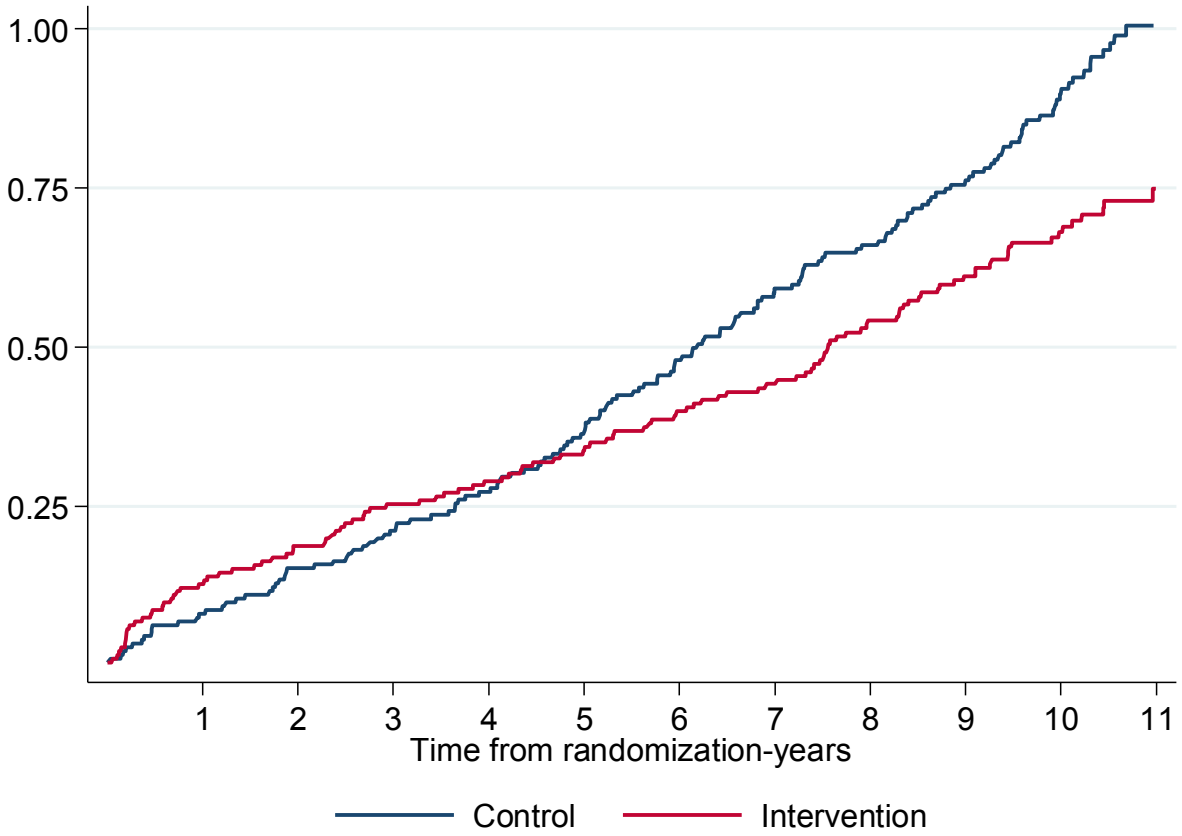


RR (95%CI) = 0.69 (0.56-0.86)

Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	60	104	165	223	286	**306**
Not Screened	18	41	68	94	116	**125**
Screened	57	70	84	101	121	**126**

Intention to treat analysis-Colorectal cancer
INCIDENCE, All sites **Advanced**

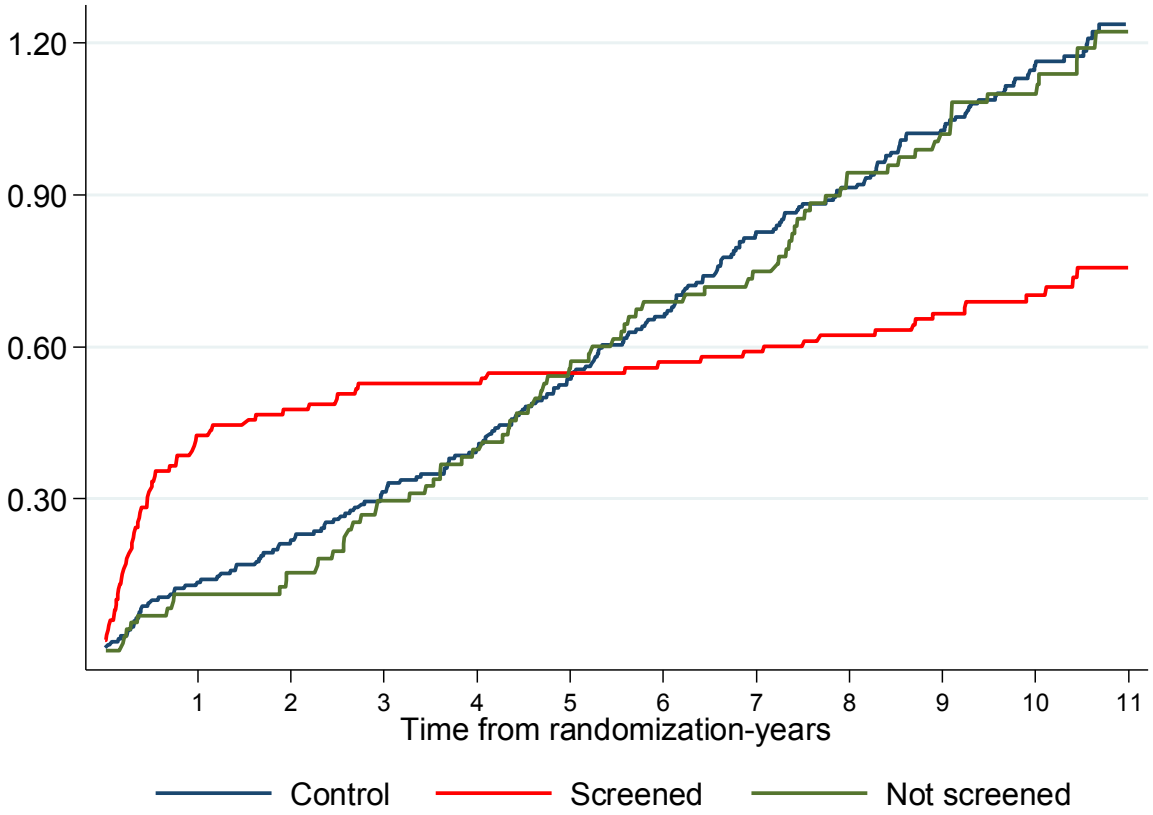
Nelson Aalen Cumulative Hazard (%) by time from randomization



RR (95%CI) = 0.73 (0.57-0.94)

Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	26	44	77	105	140	**152**
Intervention	30	46	63	85	104	**112**

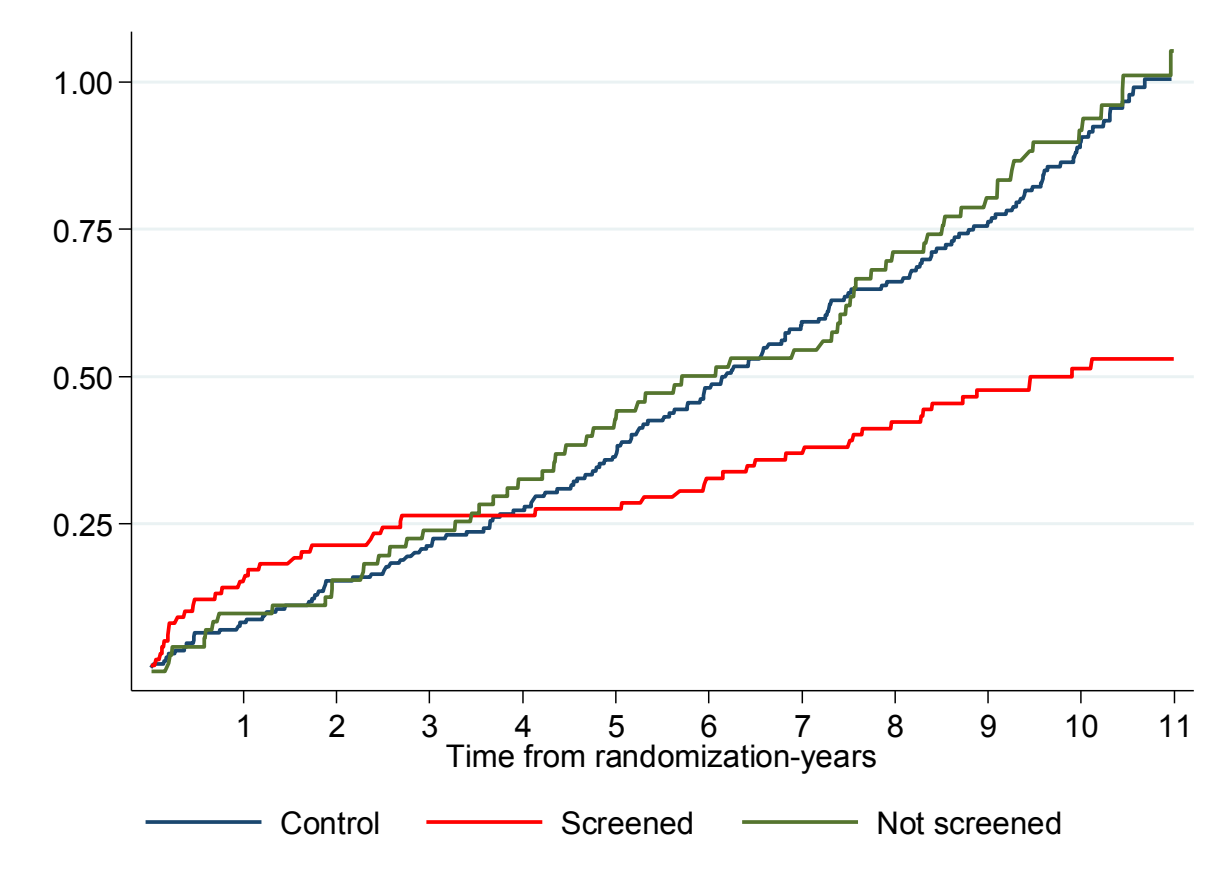
Per protocol analysis-Colorectal cancer
INCIDENCE, Distal&Descendent
Nelson Aalen Cumulative Hazard (%) by time from randomization



RR (95%CI) = 0.60 (0.46-0.80)

Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	37	67	110	151	187	**198**
Not Screened	11	28	48	65	75	**81**
Screened	47	52	56	61	68	**71**

Per protocol analysis-Colorectal cancer
INCIDENCE, All sites **Advanced**
Nelson Aalen Cumulative Hazard (%) by time from randomization



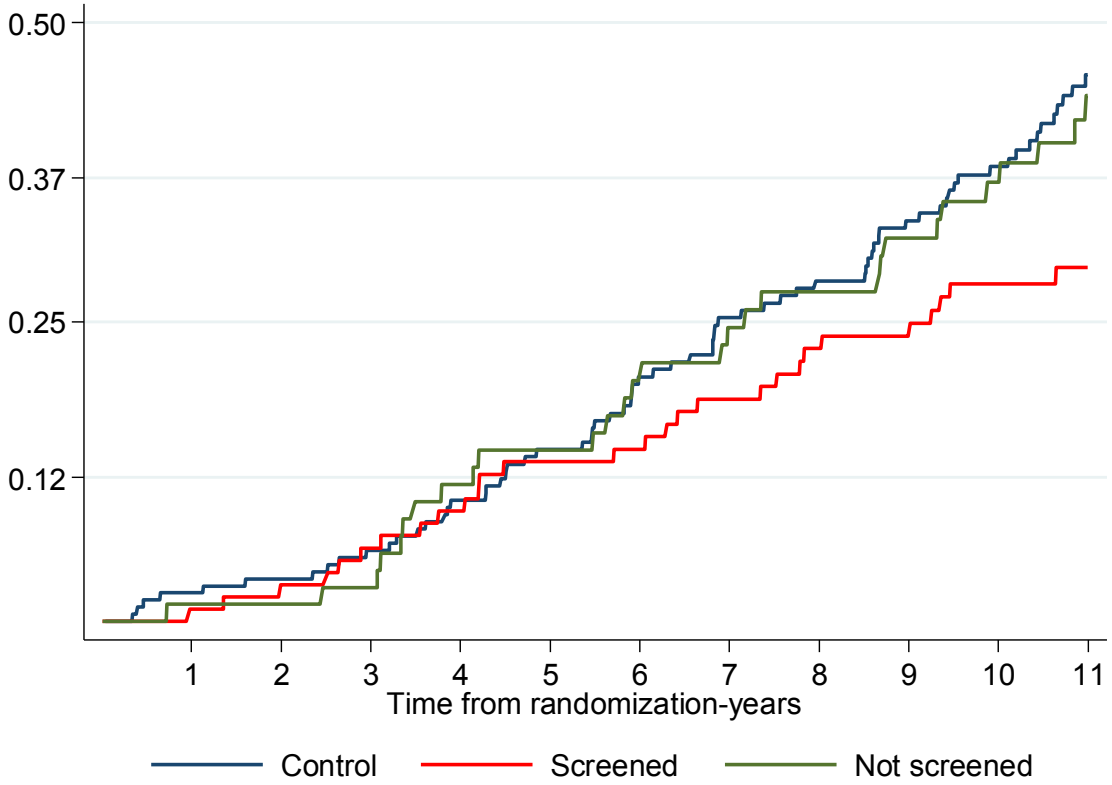
RR (95%CI) = 0.54 (0.39-0.76)

Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	26	44	77	105	140	**152**
Not Screened	9	20	31	45	57	**64**
Screened	21	26	32	40	47	**48**

Per protocol analysis-Colorectal cancer

MORTALITY, ALL SITES

Nelson Aalen Cumulative Hazard (%) by time from randomization



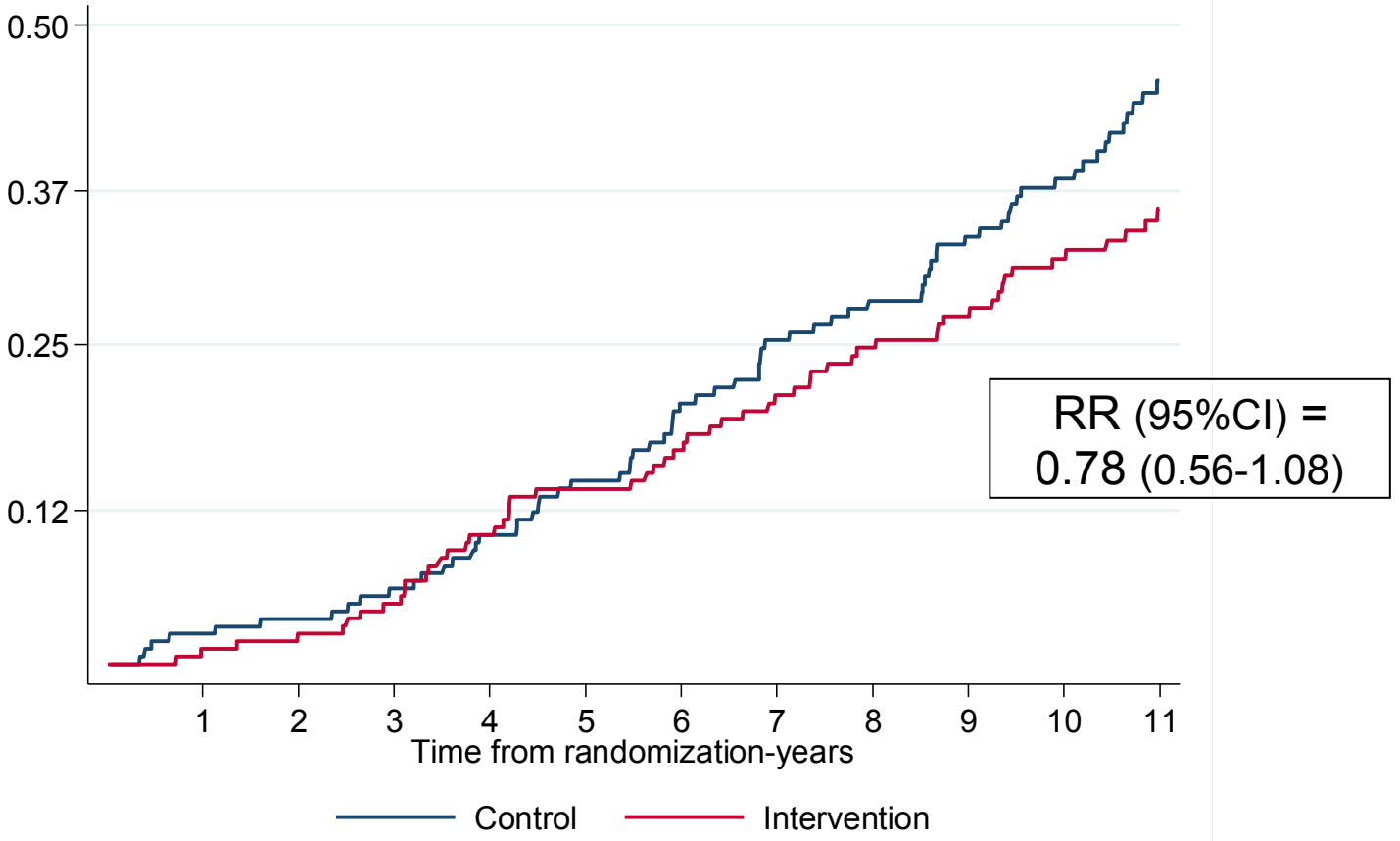
RR (95%CI) = 0.62 (0.40-0.96)

Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	6	17	34	47	62	**83**
Not Screened	1	8	14	19	25	**35**
Screened	3	9	14	22	27	**30**

Intention to treat analysis-Colorectal cancer

MORTALITY, ALL SITES

Nelson Aalen Cumulative Hazard (%) by time from randomization



Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	6	17	34	47	62	**83**
Intervention	4	17	28	41	52	**65**

THE LANCET
Volume 375, Issue 9726, 8 May 2010-14 May 2010, Pages 1624-1633

Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: a multicentre randomised controlled trial

Wendy S Atkin, Rob Edwards, Ines Kralj-Hans, Kate Wooldrage, Andrew R Hart, John M A Northover, D Max Parkin, Jane Wardle, Stephen W Duffy, Jack Cuzick, UK Flexible Sigmoidoscopy Trial Investigators

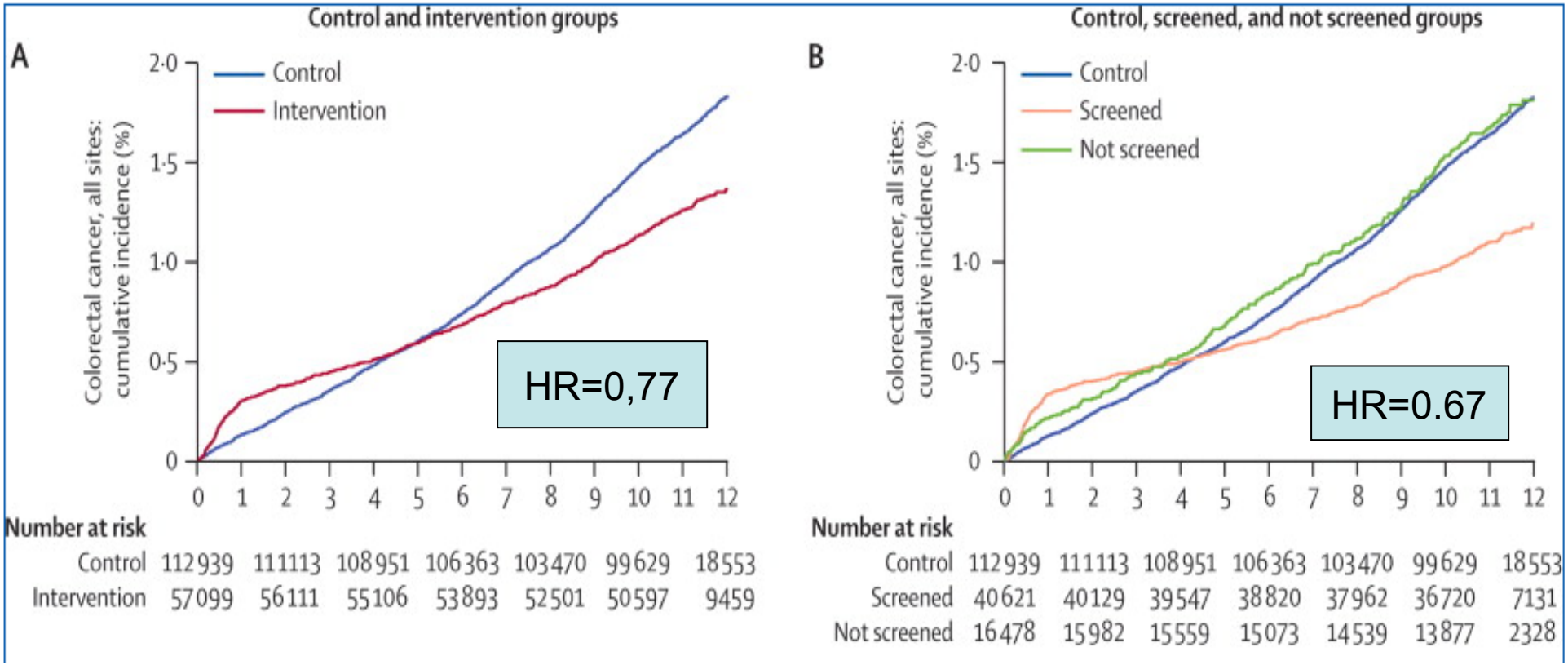
Lancet 2010; 375: 1624–33
Published Online April 28, 2010
DOI:10.1016/S0140-6736(10)60551-X
See Comment page 1582

Summary

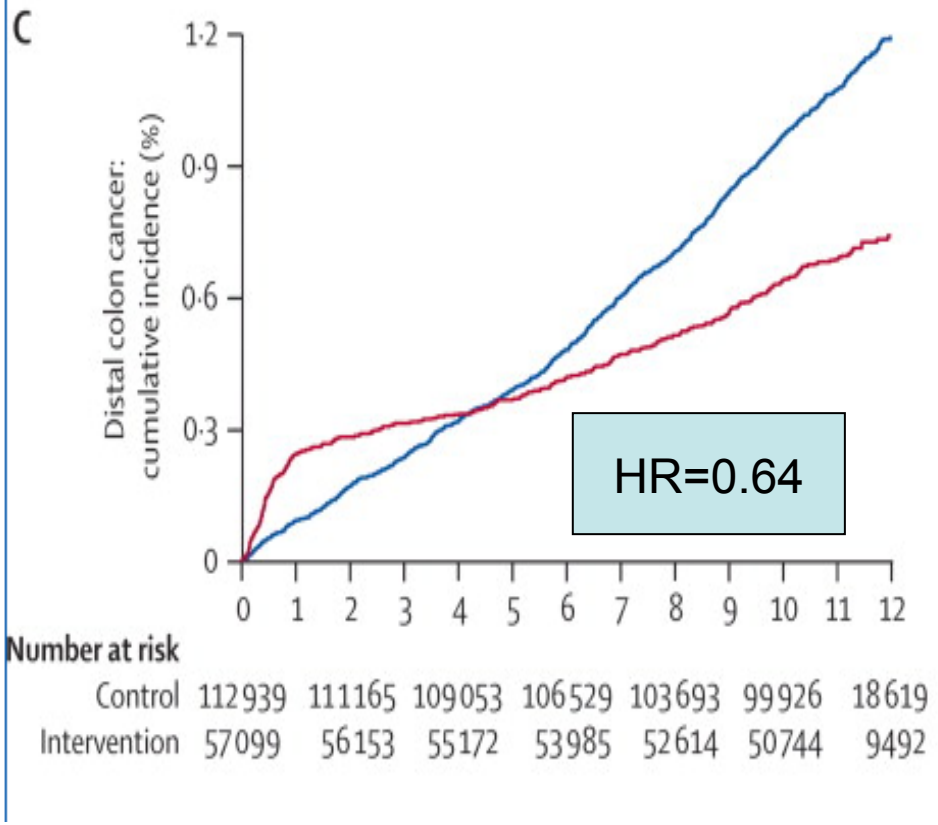
Background Colorectal cancer is the third most common cancer worldwide and has a high mortality rate. We tested the hypothesis that only one flexible sigmoidoscopy screening between 55 and 64 years of age can substantially reduce colorectal cancer incidence and mortality.

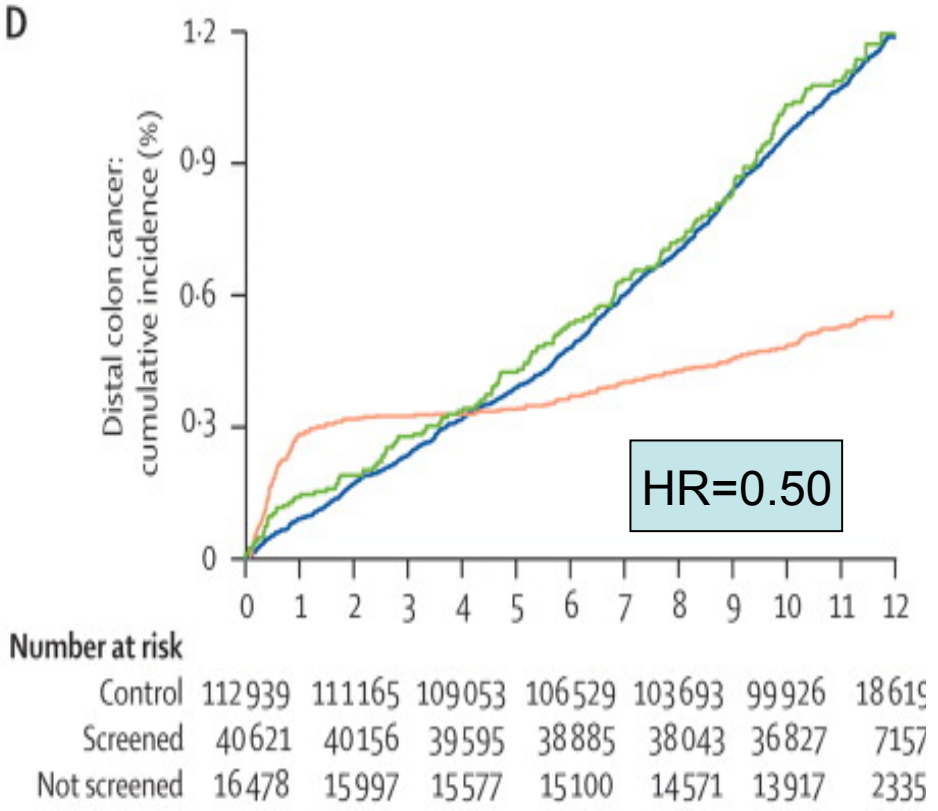
Methods This randomised controlled trial was undertaken in 14 UK centres. 170 432 eligible men and women, who had indicated on a previous questionnaire that they would accept an invitation for screening, were randomly allocated

Colorectal cancer incidence (Kaplan-Meier estimates)



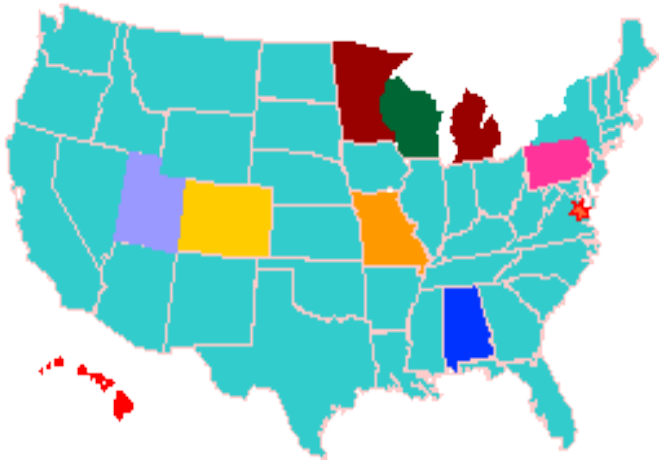
Distal cancer incidence (Kaplan-Meier estimates)





The PLCO Trial

- Multicenter (10) randomized trial
- Intervention vs. Usual Care



- N = 154,906 Enrolled
- ≈ 77,000 in each arm
- 50:50 by Gender
- 13 Year follow up from end of screen, 23 yrs overall

The NEW ENGLAND JOURNAL of MEDICINE

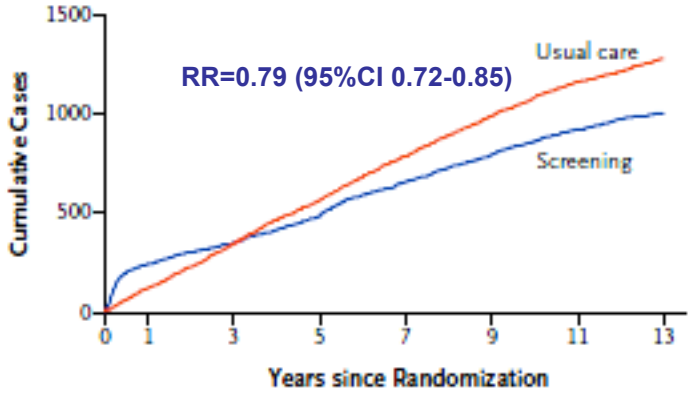
ESTABLISHED IN 1812 JUNE 21, 2012 VOL. 366 NO. 25

Colorectal-Cancer Incidence and Mortality with Screening Flexible Sigmoidoscopy

Robert E. Schoen, M.D., M.P.H., Paul F. Pinsky, Ph.D., Joel L. Weissfeld, M.D., M.P.H., Lance A. Yokochi, M.D., M.P.H., Timothy Church, Ph.D., Adeyinka O. Laiyemo, M.D., M.P.H., Robert Bresalier, M.D., Gerald L. Andriole, M.D., Saundra S. Buys, M.D., E. David Crawford, M.D., Mona N. Fouad, M.D., Claudine Isaacs, M.D., Christine C. Johnson, M.D., Ph.D., M.P.H., Douglas J. Reding, M.D., M.P.H., Barbara O'Brien, M.P.H., Danielle M. Carrick, Ph.D., Patrick Wright, B.S., Thomas L. Riley, B.S., Mark P. Purdue, Ph.D., Grant Izmirlian, Ph.D., Barnett S. Kramer, M.D., M.P.H., Anthony B. Miller, M.D., John K. Gohagan, Ph.D., Philip C. Prorok, Ph.D., and Christine D. Berg, M.D., for the PLCO Project Team*

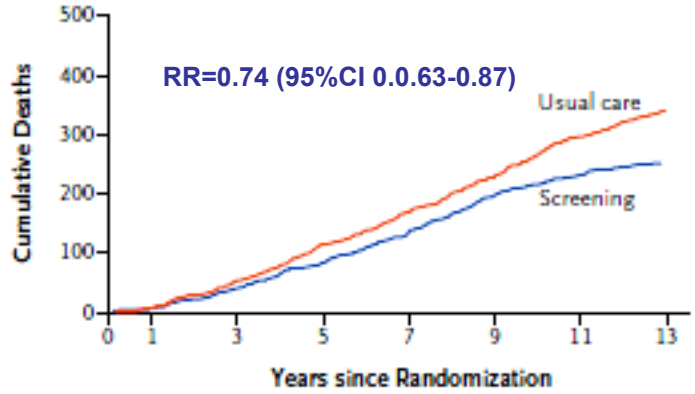
ABSTRACT

A Overall Colorectal-Cancer Incidence



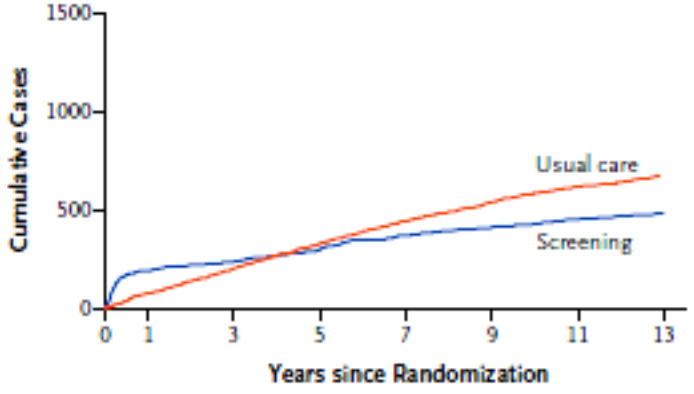
No. at Risk							
Screening							
Cases	242	347	487	659	797	927	1,012
Person-yr	76,520	227,007	373,895	516,773	654,740	772,625	848,403
Usual care							
Cases	119	344	564	790	998	1,169	1,287
Person-yr	76,592	227,438	374,467	517,055	654,447	771,744	847,103

B Overall Colorectal-Cancer Mortality



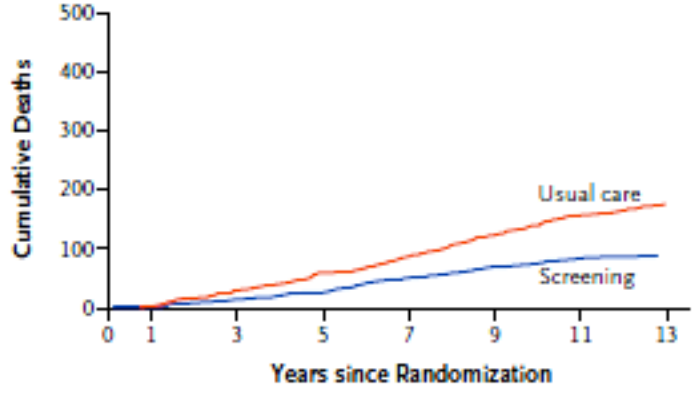
No. at Risk							
Screening							
Deaths	6	39	83	135	198	232	252
Person-yr	77,276	230,295	380,730	528,006	670,832	793,203	871,930
Usual care							
Deaths	6	51	114	169	228	296	341
Person-yr	77,228	230,354	380,731	527,828	670,526	792,674	871,275

C Incidence of Distal Colorectal Cancer



No. at Risk							
Screening							
Cases	190	234	295	367	407	450	479
Person-yr	76,520	227,007	373,895	516,773	654,740	772,625	848,403
Usual care							
Cases	71	200	324	439	538	617	669
Person-yr	76,592	227,438	374,467	517,055	654,447	771,744	847,103

D Mortality from Distal Colorectal Cancer



No. at Risk							
Screening							
Deaths	1	14	27	51	69	84	87
Person-yr	77,276	230,295	380,730	528,006	670,832	793,203	871,930
Usual care							
Deaths	3	30	58	87	123	156	175
Person-yr	77,288	230,354	380,731	527,828	670,526	792,674	871,275

Evidence of efficacy of colonoscopy

	Year	Outcome	Left side	Right side
Singh	2010	Mortality	0.53	0.95
Baxter	2009	Mortality	0.33	0.99
Brenner	2009	High Risk Adenomas	0.33	1.02
Lakoff	2008	Incidence	0.21	varied by year
Cotterchio	2005	Incidence	0.68	1.02

Courtesy of W.Atkin

Singh et al. Gastroenterology 2010;139:1128–1137
Baxter et al. Ann Intern Med. 2009;150:1-8.
Brenner et al. JNCI. 2010;102(2): 89-95.
Lakoff et al. Clin Gastroenterol Hepatol. 2008 Oct;6(10):1117-21
Cotterchio et al. Cancer Causes Control. 2005 Sep;16(7):865-75.

ATTENDANCE RATE

		Invited	FS performed	Attendance rate	Invited to FIT	FIT performed	Attendance rate	Overall coverage
Verona	**MEN**	9662	4152	**43.0%**	5040	1201	**23.8%**	**55,4%**
	WOMEN	10308	3705	**35.9%**	6139	1974	**32.2%**	**55,1%**
Torino	**MEN**	20947	7019	**33.5%**	12183	1518	**12.5%**	**40.8%**
	WOMEN	22801	6068	**26.6%**	14329	2588	**18.1%**	**38.0%**

DETECTION RATE

		FS performed	Advanced adenomas		Cancers		FIT returned	Advanced adenomas		Cancers	
Verona	MEN	4152	358	8.6%	24	0.6%	1201	28	2.3%	5	0,4%
	WOMEN	3705	129	3.5%	12	0.3%	1974	17	0.9%	3	0,2%
Torino	MEN	6723	476	7.0%	35	0.5%	1518	39	2.6%	9	0.6%
	WOMEN	5806	228	3.9%	15	0.3%	2558	24	0.9%	6	0.2%
Total	MEN	10829	834	7.7%	59	0.5%	2719	67	2.5%	13	0.5%
	WOMEN	9467	357	3.8%	27	0.3%	4562	41	0.9%	9	0.2%

NNS

		MEN		WOMEN	
		Number of screening exams	Number of CT *	Number of screening exams	Number of CT *
FS	ADVANCED ADENOMA	13	5,4	27	11,3
		12-14		24-29	
	CRC	184	77,0	351	146,8
		143-244		238-526	
FIT	ADVANCED ADENOMA	41	2,7	111	3,5
		32-55		81-154	
	CRC	209	13,9	507	15,8
		119-385		256-1042	

* 3 FS corresponding to 1 TC

To detect one advanced neoplasm (CRC or advanced adenoma)

51 PEOPLE HAD TO BE INVITED FOR FS

209 PEOPLE HAD TO BE INVITED FOR FIT

DOMANI

RELATORI:

W.Atkin – Imperial College London
L.Bisanti - ASL Città di Milano
E.DiGiulio - SIED, Roma
A.Ederle - Ospedale Fracastoro, S.Bonifacio, Verona
A.Federici - CCM, Ministero del Welfare, Roma
G.Grazzini - ISPO, Firenze
C.Hassan - Ospedale Nuovo Regina Margherita Roma
E.Kuipers - Erasmus University Medical Center, Rotterdam, Netherlands
R.Sassatelli - Arcispedale S. Maria Nuova, Reggio Emilia
N.Segnan - CPO Piemonte
C.Senore – CPO, Piemonte
M.Zappa - ISPO, Firenze - ONS
M.Zorzi - IOV, Padova

L'evento è accreditato presso l'ECM Regione Piemonte; sono stati attribuiti 5 crediti formativi.

COME RAGGIUNGERE LA SEDE DEL SEMINARIO:

In auto: la rete autostradale collega Torino a Milano, Venezia, Trieste (A4), a Bologna, Firenze, Roma, Napoli (A21 + A1), a Genova (A21 + A26). Tutte le autostrade si raccordano alla tangenziale di Torino; si consiglia di uscire in Corso Unità d'Italia e di seguire le indicazioni "Lingotto".

In treno: Dalle stazioni di Torino Porta Susa e Torino Porta Nuova prendere la metropolitana in direzione Lingotto, scendere alla fermata capolinea "Lingotto", uscire dal lato "Centro Polifunzionale Lingotto". Su Via Nizza, girare a sinistra e raggiungere il civico n° 230 interno (di fronte ingresso Eataly).

LO SCREENING CON SIGMOIDOSCOPIA

EVIDENZE DI EFFICACIA E VALUTAZIONE DI POSSIBILI MODALITÀ DI IMPLEMENTAZIONE NEI PROGRAMMI DI POPOLAZIONE

Torino, Venerdì 2 marzo 2012

Aula magna Dental School - Lingotto Via Nizza, 230 interno TORINO 3° piano

Direttori: **M Zappa, N Segnan**

In collaborazione con:

What is the best screening strategy to detect advanced colorectal adenomas? Simulation from ongoing Italian screening experiences

Observed compliance (45% FIT and 30% FS)

Esame	Round	Anni	Sesso	Scenario	Adenomi	Cum Adenomi
FOBT	1	0	M+F	Adesione 45%	552	552
FOBT	2	2	M+F	Adesione 45%	380	932
FOBT	3	4	M+F	Adesione 45%	377	1309
FOBT	4	6	M+F	Adesione 45%	419	1728
FOBT	5	8	M+F	Adesione 45%	360	2088
RSS	1	0	M+F	Adesione 30%	1112	1112
RSS	2	1	M+F	Adesione 30%	138	1250
RSS	3	2	M+F	Adesione 30%	76	1326

M.Zappa 2012

M Zorzi 2012

Strategia	SOF 50-69	RS osservato	RS solo AAV	RS + SOF 61-69	RS (AAV) + SOF 61-69
invitati	50000	5300	5300	17870	17870
aderenti	34758	2135	2135	9182	9182
positivi	1670	425	75	852	502
colonscopie	1429	387	68	758	439
carcinomi	72	5	5	27	27
ad. avanzati	426	95	82	210	197
colonscopie	1429	1455	1136	1826	1507
equivalenti (RS = 0,33 CT)	1429	1099	780	1470	1151

UPTAKE		FS 58 YEARS n=	FIT 50-69 YEARS n=	
			4 rounds	5 rounds
30%	NUMBER OF EXAMS (FS / FIT)	34710	395403	511645
	NUMBER OF TC	2950	16749	21488
	TC EQUIVALENT	14520	16749	21488
	NUMBER OF EXAMS NEEDED TO PREVENT ONE CRC	99,5	823,8	859,9
	COST PER PREVENTED CRC	€ 10.935	€ 18.516	€ 19.142
40%	NUMBER OF EXAMS (FS / FIT)	46280	448822	573508
	NUMBER OF TC	3934	19196	24302
	TC EQUIVALENT	19361	19196	24302
	NUMBER OF EXAMS NEEDED TO PREVENT ONE CRC	99,3	834,2	876,9
	COST PER PREVENTED CRC	€ 10.935	€ 18.647	€ 19.409
50%	NUMBER OF EXAMS (FS / FIT)	57850	502241	635370
	NUMBER OF TC	4917	21642	27116
	TC EQUIVALENT	24200	21642	27116
	NUMBER OF EXAMS NEEDED TO PREVENT ONE CRC	99,4	844,1	891,1
	COST PER PREVENTED CRC	€ 10.935	€ 18.784	€ 19.631
65%	NUMBER OF EXAMS (FS / FIT)	75205	582369	728164
	NUMBER OF TC	6392	25312	31337
	TC EQUIVALENT	31460	25312	31337
	NUMBER OF EXAMS NEEDED TO PREVENT ONE CRC	99,3	856,4	909,1
	COST PER PREVENTED CRC	€ 10.935	€ 18.961	€ 19.916

Cost-effectiveness of population-based screening for colorectal cancer: a comparison of guaiac-based faecal occult blood testing, faecal immunochemical testing and flexible sigmoidoscopy

L Sharp[1*], L Tilson[2], S Whyte[3], A O'Ceilleachair[1], C Walsh[2,4], C Usher[2], P Tappenden[3], J Chilcott[3], A Staines[5], M Barry[2] and H Comber[1]

[1]National Cancer Registry Ireland, Cork Airport Business Park, Building 6800, Kinsale Road, Cork, Ireland; [2]National Centre for Pharmacoeconomics, St James's Hospital, Dublin, Ireland; [3]School for Health and Related Research, University of Sheffield, Sheffield, England; [4]Department of Statistics, Trinity College Dublin, Dublin, Ireland; [5]School of Nursing, Dublin City University, Dublin, Ireland

Table 3 Lifetime rates[a] of colorectal cancer incidence and mortality per 100 000 population, percentage of cases which would be detected by screening, surveillance and symptomatically, and percentage reductions in incidence and mortality compared with no screening, for core screening scenarios

	Incidence							Mortality	
	Screen detected CRC		Surveillance-detected CRC[b]		Symptomatic CRC				
Scenario	**Rate**	**% of cases**	**Rate**	**% of cases**	**Rate**	**% of cases**	**% reduction in CRC incidence[c]**	**CRC mortality rate**	**% reduction in CRC mortality[c]**
No screening	0	—	0	—	5158	100	—	2287	—
gFOBT at 55–74 years	695	13.6	11	0.2	4401	86.2	1.0	2016	11.8
FIT at 55–74 years	1313	29.8	78	1.8	3010	68.4	14.7	1465	36.0
FSIG once at 60 years	138	2.8	25	0.5	4742	96.7	4.9	2116	7.5

Abbreviations: CRC = colorectal cancer; FIT = faecal immunochemical test; FSIG = flexible sigmoidoscopy; gFOBT = guaiac-based faecal occult blood test. [a]Over the entire lifetime of the cohort, therefore, for gFOBT and FIT includes 10 screening rounds. [b]CRC detected at surveillance among those with intermediate/high-risk adenomas found at screening. [c]Each incremental value compares values for that strategy with common baseline of no screening.

Table 4 Lifetime rates[a] per 100 000 population of screening-related endoscopic procedures[b], and associated complications[c], for the core screening scenarios

	Endoscopic procedures			Complications		
Scenario	**Flexible sigmoidoscopy**	**Colonoscopy**	**Polypectomy**	**Major bleeding[d]**	**Bowel perforation**	**Deaths due to perforation**
gFOBT at 55–74 years	—	3386	1215	12	5	0.26
FIT at 55–74 years	—	34 632	9486	132	57	3.00
FSIG once at 60 years	40 177	2543	2487	22	5	0.25

Abbreviations: FIT = faecal immunochemical test; FSIG = flexible sigmoidoscopy; gFOBT = guaiac-based faecal occult blood test. [a]Over the entire lifetime of the cohort, therefore, for gFOBT and FIT includes 10 screening rounds. [b]Related to screening, diagnosis, or surveillance. [c]Complications associated with diagnostic and surveillance colonoscopy and, where relevant, FSIG. [d]Major abdominal bleeding, requiring admission or intervention.

Table 2 ICER, based on QALYs per person, for core[a] and age-variant screening scenarios

Scenario	Cost of screening and CRC management per person[b]	Incremental costs per person[c]	Expected QALYs per person	Incremental QALYs per person[c]	ICER-Incremental cost per QALY gained
No screening	€ 1074	—	10.961	—	—
gFOBT at 55–74 years	€ 1107	€ 33.63	10.968	0.0076	€ 4428[d,e]
gFOBT at 55–64 years	€ 1092	€ 18.35	10.966	0.0051	€ 3613[e]
gFOBT at 65–74 years	€ 1089	€ 15.66	10.963	0.0026	€ 5919[e]
FIT at 55–74 years	€ 1114	€ 40.17	10.984	0.0237	€ 1696
FIT at 55–64 years	€ 1094	€ 20.06	10.978	0.0175	€ 1153
FIT at 65–74 years	€ 1088	€ 13.94	10.969	0.0082	€ 1698[e]
FSIG once at 60 years	€ 1077	€ 3.43	10.966	0.0058	€ 589
FSIG once at 55 years	€ 1092	€ 18.19	10.968	0.0069	€ 2659[e]

Abbreviations: FIT = faecal immunochemical test; FSIG = flexible sigmoidoscopy; gFOBT = guaiac-based faecal occult blood test; ICER = incremental cost-effectiveness ratios; QALYs = quality-adjusted life-years. Costs and outcomes discounted at 4%. [a]Core screening scenarios are shaded. [b]Includes costs of screening (including faecal testing kit and processing or FSIG examination, diagnostic colonoscopy/CT colonography, pathology, perforations and bleeds, adenoma surveillance) and diagnosis, treatment and follow-up of screen-detected cancers. Costs of CRC management are a weighted average of costs of managing screen-detected and symptomatic CRC. [c]Each incremental value compares values for that strategy with common baseline of no screening. [d]In comparison of core scenarios, strategy considered dominated by combination of FIT at 55–74 years and FSIG once at 60 years. [e]In comparison of all strategies, strategy considered dominated by FSIG at age 60, FIT at age 55–74, FIT at age 55–64 or combinations of these.

Cost-effectiveness of population-based screening for colorectal cancer: a comparison of guaiac-based faecal occult blood testing, faecal immunochemical testing and flexible sigmoidoscopy

L Sharp[1*], L Tilson[2], S Whyte[3], A O'Ceilleachair[1], C Walsh[2,4], C Usher[2], P Tappenden[3], J Chilcott[3], A Staines[5], M Barry[2] and H Comber[1]

[1]National Cancer Registry Ireland, Cork Airport Business Park, Building 6800, Kinsale Road, Cork, Ireland; [2]National Centre for Pharmacoeconomics, St James's Hospital, Dublin, Ireland; [3]School for Health and Related Research, University of Sheffield, Sheffield, England; [4]Department of Statistics, Trinity College Dublin, Dublin, Ireland; [5]School of Nursing, Dublin City University, Dublin, Ireland

once-only FSIG at 60 years. Although a programme based on FIT is expected to result in the greatest health improvement, it would require more colonoscopy resources and result in more individuals suffering adverse effects. The major challenges for policy makers are, therefore, balancing the benefits and harms of screening while ensuring sufficient capacity for follow-up of screen-detected adenomas and cancers.

Implementation of flexible sigmoidoscopy screening within the English Bowel Cancer Screening programme

- **October 2010, announcment by Prime Minister**

- £60m will be made available over the next four years to introduce the latest cancer screening technology.

FS in English Bowel Cancer Screening programme

- Flexible sigmoidoscopy screen just once at age 55 years

- small polyps (< 10 mm) removed during screening

- colonoscopy only for high-risk adenomas:

  ≥3, ≥ 10 mm, ≥ 25% villous, high grade dysplasia

Atkin et al., Lancet 2010, 375:1624-33

Implementing FS screening in the NHS BCSP

- **Important ssues**

  - Manpower: endoscopists

  - Uptake rates in population

  - Quality and safety of screening examinations

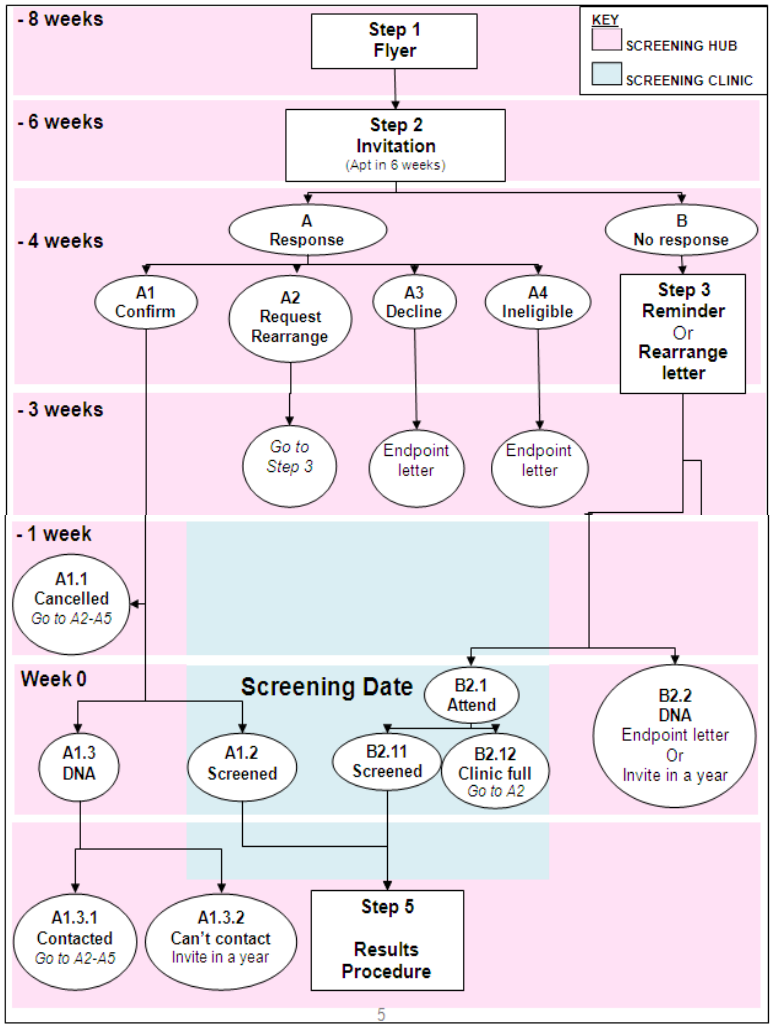
Specialist Nurse Endoscopists: FS + polypectomy

- At least as effective as specialist doctors
- More acceptable, particularly to women
  - 43% women prefer female endoscopist*
  - 80% gastroenterologists male

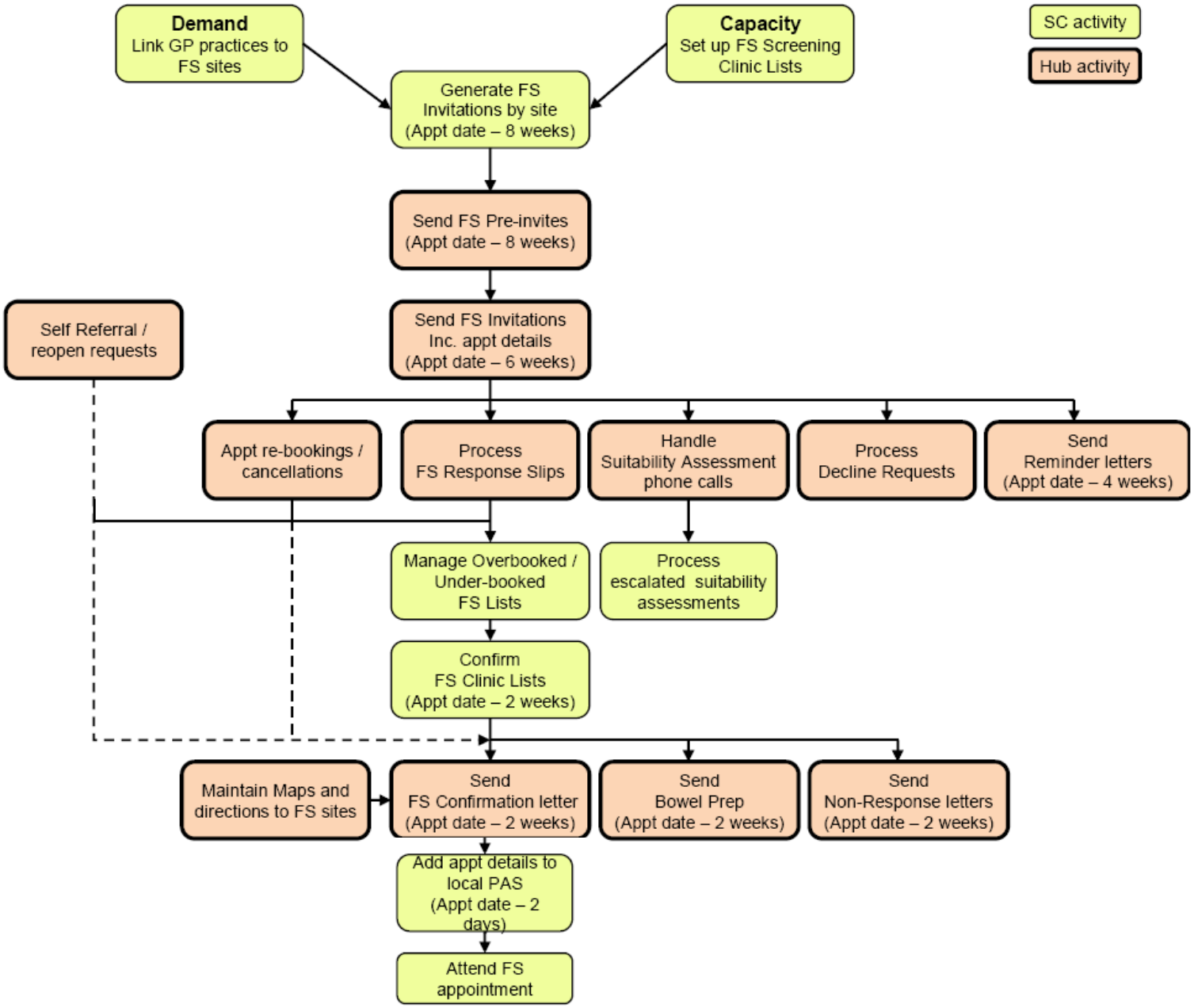
Roll-out of FS screening programme

- Pathfinder project January to May 2011
- 4 sites tested organisational arrangements
- Pilot: 2013:5 sites, one per region
- Expected coverage of England
  - –30% by March 2014
  - –60% by March 2015
  - –100% by 2015/6

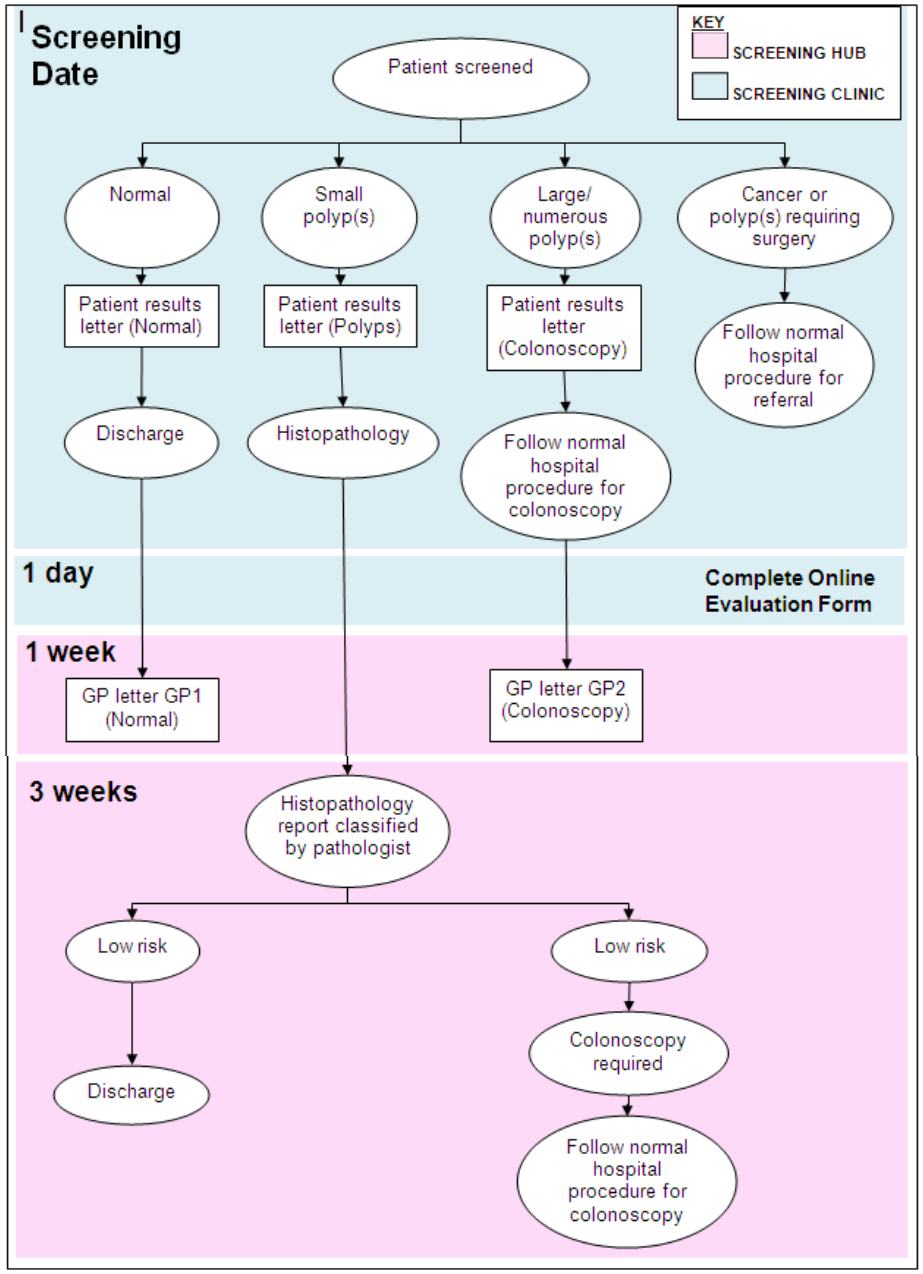
UK Flexible Sigmoidoscopy Screening Trial - Invitation procedure



Timeline


Demand
Link GP practices to FS sites
Capacity
Set up FS Screening Clinic Lists
SC activity
Hub activity
Generate FS Invitations by site (Appt date – 8 weeks)
Send FS Pre-invites (Appt date – 8 weeks)
Send FS Invitations Inc. appt details (Appt date – 6 weeks)
Self Referral / reopen requests
Appt re-bookings / cancellations
Process FS Response Slips
Handle Suitability Assessment phone calls
Process Decline Requests
Send Reminder letters (Appt date – 4 weeks)
Manage Overbooked / Under-booked FS Lists
Process escalated suitability assessments
Confirm FS Clinic Lists (Appt date – 2 weeks)
Maintain Maps and directions to FS sites
Send FS Confirmation letter (Appt date – 2 weeks)
Send Bowel Prep (Appt date – 2 weeks)
Send Non-Response letters (Appt date – 2 weeks)
Add appt details to local PAS (Appt date – 2 days)
Attend FS appointment

Results procedure



Dimensioni del confronto tra screening del CCR screening con FIT o FS e con FIT e FS

1. Outcomes per età e periodi solari :
   - Incidenza e distribuzione per stadio e sede
   - mortalità,
   - tasso di identificazione diagnostica cumulativo
   - Casi intervallo cumulativi per FIT e FS
   - Impatto dello screening in 10-30 anni per FS e FIT

2. Prospettiva di popolazione: adesione cumulativa e tasso di diagnosi di cancro e adenoma avanzati nello screening con FIT e FS per età

3. Prospettiva individuale: rischio di cancro e di morte per cancro per età e genere.

4. Modulazione dello screening

5. Carico di lavoro endoscopico:proporzione cumulativa di colonoscopie nello screening FIT e FSin FIT (inclusa la sorveglianza endoscopica postpolipectomia)

6. Costo del FIT per adenoma e cancro screen detected , in relazione al tasso diagnostico cumulativo e costodella FS per lesione diagnosticatra allo screening

7. Strategie di Screening in aree senza programmi di screening

8. Strategie di screening in aree con programmi di screening attivi
   - Attivi e con alta copertura con FIT
   - Attivi e con bassa copertura con FIT
   - Attivi e con bassa copertura con FS
   - Attivi e con alta copertura con FS

9.Screening con integrazione tra FS e FIT:
   - Approccio sequenziale(offerta del test alternativo ai non aderenti)
   - Scelta induviduale (FS o FIT)
   - Approccio combinato (5 FIT tra 50 e 58 anni e poi once only FS)
   - Approccio combinato (FS a 58-60 anni e FIT ogni 2 anni fino a 70-75)
   - altro

10. Quali studi e quali programmi pilota o sistemi di monitoraggio

Table 2 Prevalence of Advanced Neoplasia by Age Decade, Gender, and Location

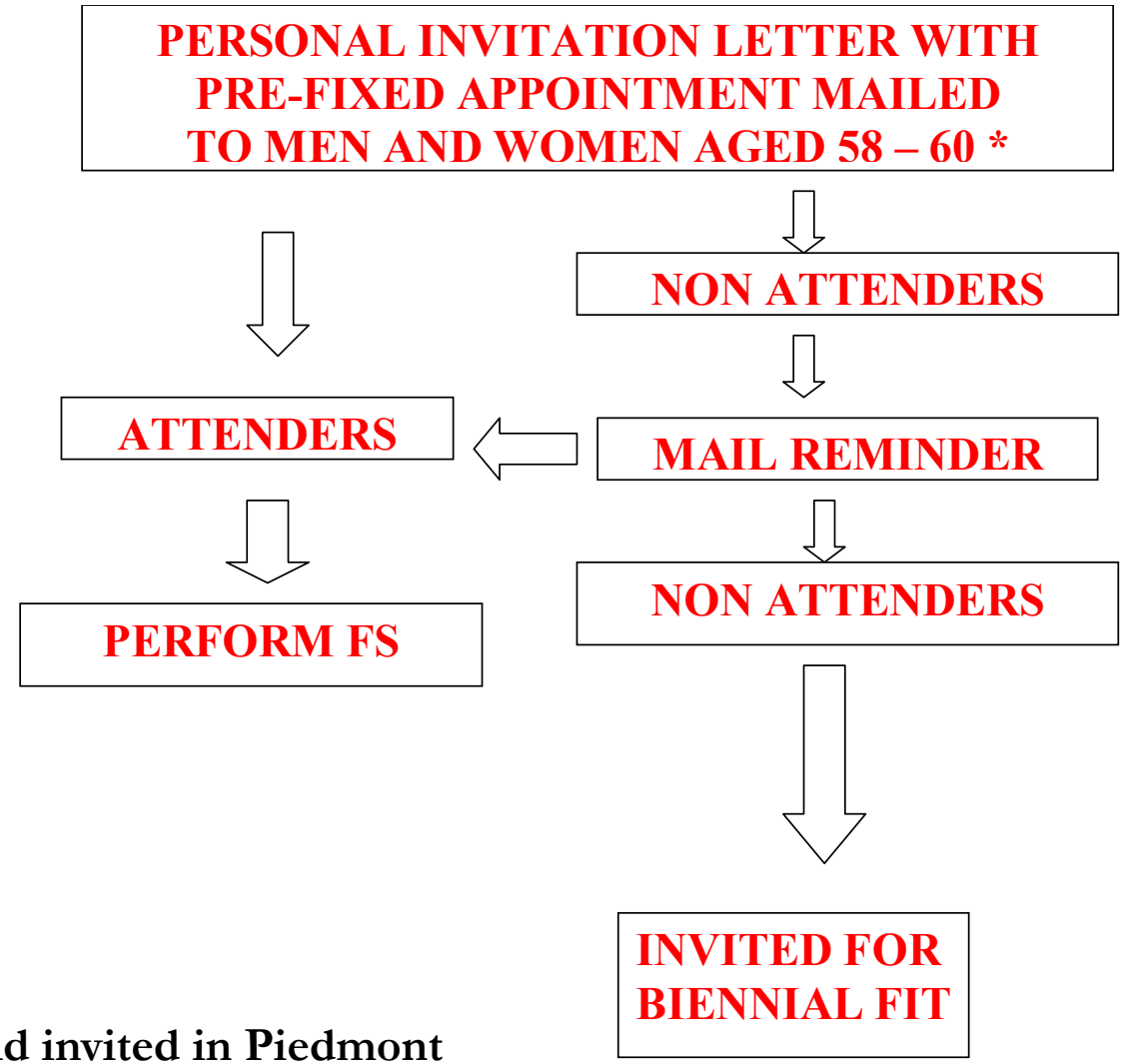
	Women			Men		
Age Category	Advanced Proximal Neoplasia*	Advanced Distal Neoplasia	Any Advanced Neoplasia	Advanced Proximal Neoplasia†	Advanced Distal Neoplasia	Any Advanced Neoplasia
50-59 y	36 (1)/3221 (1.12%)	44/3221 (1.37%)	74/3221 (2.30%)	70 (6)/3999 (1.75%)	115/3999 (2.88%)	173/3999 (4.33%)
60-69 y	11 (1)/1019 (1.08%)	22/1019 (2.16%)	32/1019 (3.14%)	49 (1)/1433 (3.42%)	66/1433 (4.61%)	107/1433 (7.47%)
≥70 y	9 (4)/214 (4.21%)	3/214 (1.40%)	11/214 (5.14%)	21 (2)/238 (8.82%)	17/238 (7.14%)	36/238 (15.1%)

The number of proximal cancers is in parentheses next to the numerator.

*Neither of the 2 proximal cancers in women aged < 70 y was associated with distal neoplasia; one cancer was associated with no distal polyps, while the other cancer was associated with a distal hyperplastic polyp(s). All 4 proximal cancers in women aged ≥ 70 years were associated with no distal polyps of any kind.

†Of the 6 proximal cancers in men aged 50-59 y, 2 had normal distal findings, 2 had only distal hyperplastic polyps, and 2 had distal nonadvanced adenomas. The only proximal cancer in men aged 60-69 y was associated with distal hyperplastic polyps.

SCREENING FLOW FS



* 58 years old invited in Piedmont

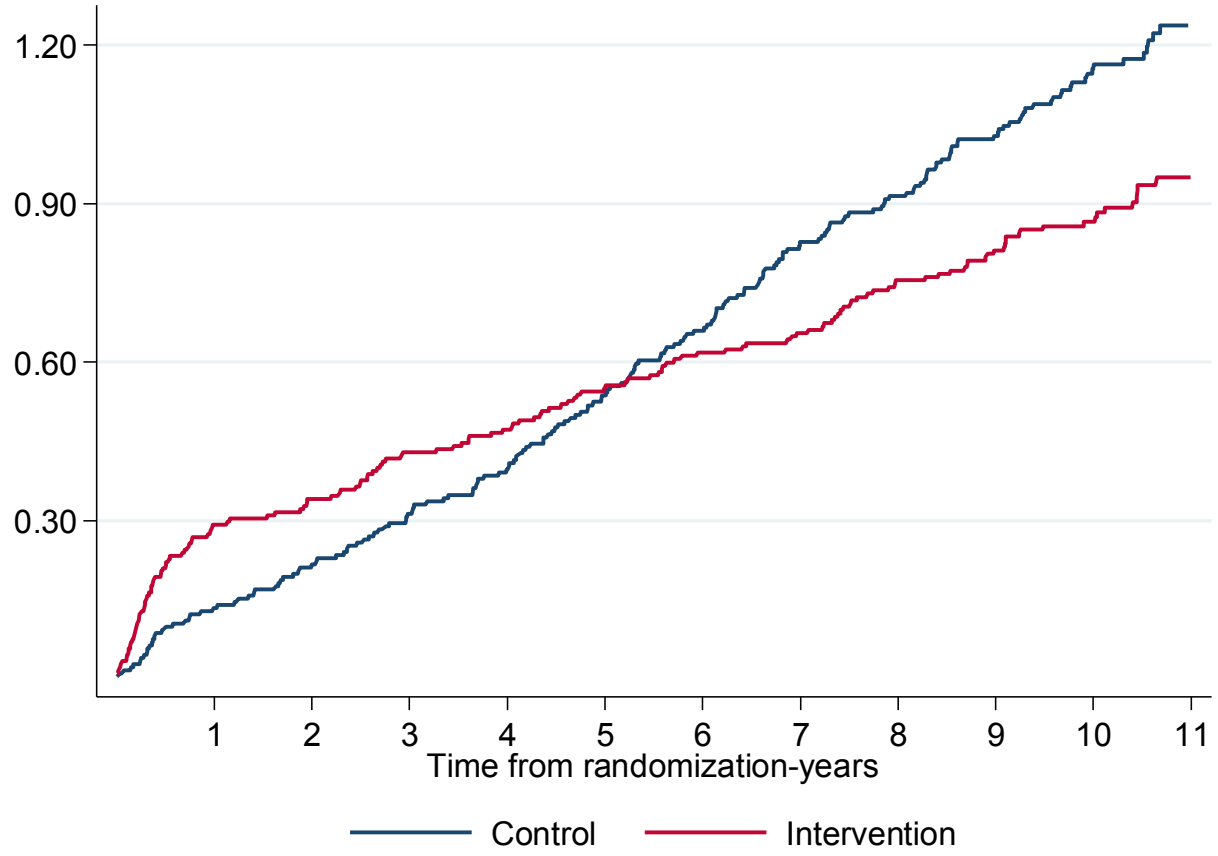
60 years old invited in Verona

One birth cohort targeted every year

Intention to treat analysis-Colorectal cancer

INCIDENCE, **Distal&Descendent**

Nelson Aalen Cumulative Hazard (%) by time from randomization



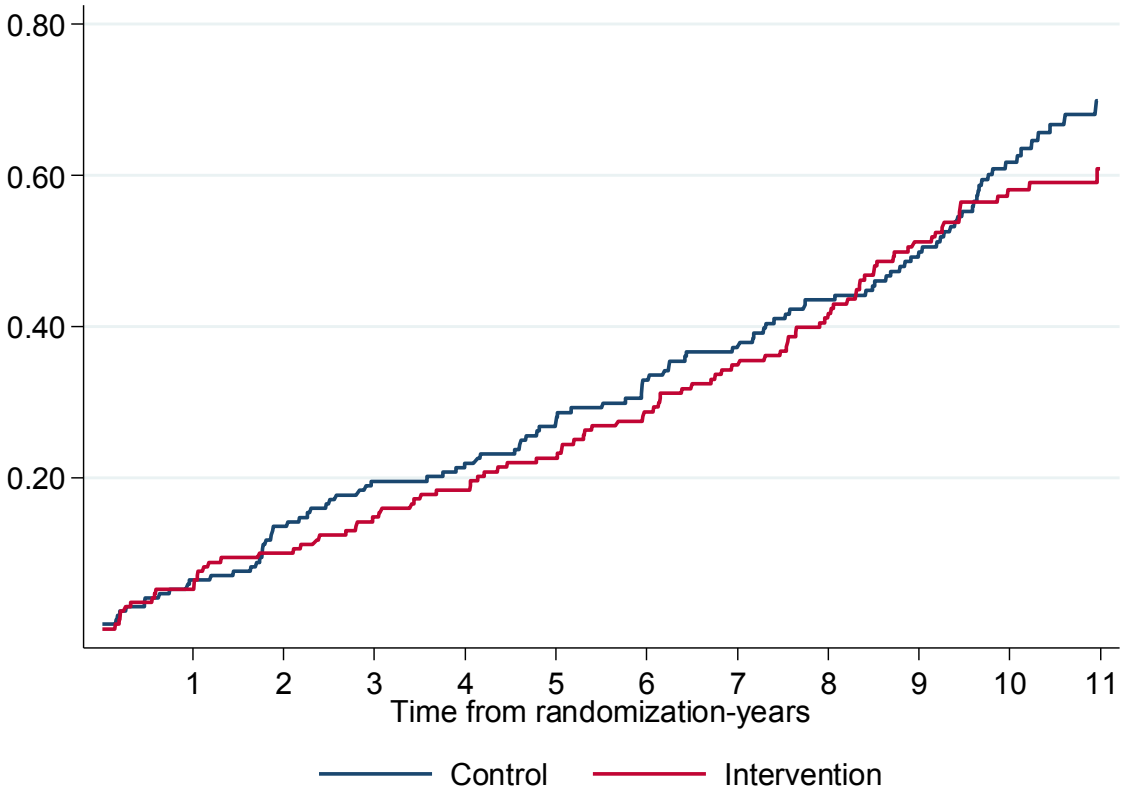
RR (95%CI) = 0.76 (0.62-0.94)

Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	37	67	110	151	187	**198**
Intervention	58	80	104	126	143	**152**

Intention to treat analysis - Colorectal cancer

INCIDENCE, PROXIMAL

Nelson Aalen Cumulative Hazard (%) by time from randomization



RR (95%CI) = 0.91 (0.69-1.20)

Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	23	37	55	72	99	**108**
Intervention	17	31	48	69	94	**99**

Table 1. CRC incidence and mortality among the SCORE trial subjects by intention-to-treat analysis*

CRC incidence	Control group† 173 437 person-years§ No. of subjects with CRC	Control group† 173 437 person-years§ Rate per 100 000 person-years (95% CI)	Intervention group‡ 174 177 person-years§ No. of subjects with CRC	Intervention group‡ 174 177 person-years§ Rate per 100 000 person-years (95% CI)	Intervention vs control group RR (95% CI)
All sites	306	176.43 (157.73 to 197.35)	251	144.11 (127.34 to 163.08)	0.82 (0.69 to 0.96)
Distal‖	198	114.16 (99.32 to 131.22)	152	87.27 (74.44 to 102.30)	0.76 (0.62 to 0.94)
Proximal¶	108	62.27 (51.57 to 75.19)	99	56.84 (46.68 to 69.21)	0.91 (0.69 to 1.20)
Advanced CRC#					
All sites	152	87.64 (74.76 to 102.74)	112	64.30 (53.43 to 77.38)	0.73 (0.57 to 0.94)
Distal‖	90	51.89 (42.21 to 63.80)	69	39.61 (31.29 to 50.16)	0.76 (0.56 to 1.04)
Proximal¶	62	35.75 (27.87 to 45.85)	43	24.69 (18.31 to 33.29)	0.69 (0.47 to 1.02)

CRC mortality	Control group† 186 745 person-years** No. of deaths	Control group† 186 745 person-years** Rate per 100 000 person-years (95% CI)	Intervention group‡ 187 532 person-years** No. of deaths	Intervention group‡ 187 532 person-years** Rate per 100 000 person-years (95% CI)	Intervention vs control group RR (95% CI)
All deaths among subjects diagnosed with CRC††					
All sites	94	50.34 (41.12 to 61.61)	71	37.86 (30.00 to 47.77)	0.75 (0.55 to 1.02)
Distal‖	55	29.45 (22.61 to 38.36)	40	21.33 (15.65 to 29.08)	0.72 (0.48 to 1.09)
Proximal¶	39	20.88 (15.26 to 28.58)	31	16.53 (11.62 to 23.50)	0.79 (0.49 to 1.27)
CRC deaths					
All sites	83	44.45 (35.84 to 55.11)	65	34.66 (27.18 to 44.20)	0.78 (0.56 to 1.08)
Distal‖	48	25.70 (19.37 to 34.11)	35	18.66 (13.40 to 25.99)	0.73 (0.47 to 1.12)
Proximal¶	35	18.74 (13.46 to 26.10)	30	16.00 (11.18 to 22.88)	0.85 (0.52 to 1.39)
Non-CRC deaths‡‡					
	1150	615.81 (581.23 to 652.45)	1137	606.30 (572.06 to 642.58)	0.98 (0.91 to 1.07)

Colorectal cancer MORTALITY
by screening arm and colonic site
(Number of cases, Persons Years, Rates Ratios and 95% CI)

INTENTION TO TREAT ANALYSIS

	Control	Intervention	Rate ratio (95% CI)
	Cases	**Cases**	**Intervention vs Control group**
Mortality among patients diagnosed with CRC (all deaths, related or unrelated to CRC)			
	186 745 PY	187 532 PY	
All sites	94	71	0.75 (0.55-1.02)
Distal & descendent	55	40	0.72 (0.48-1.09)
CRC Mortality	186 745 PY	187 532 PY	
All sites	83	65	0.78 (0.56-1.08)
Distal & descendent	48	35	0.73 (0.47-1.12)
NON CRC MORTALITY	1150	1137	0.98 (0.91-1.07)

Colorectal cancer MORTALITY
by screening arm and colonic site
(Number of cases, Persons Years, Rates Ratios and 95% CI)

PER PROTOCOL ANALYSIS

	Control	Not screened	Screened	Screened vs Control group
	Cases	**Cases**	**Cases**	**Rate ratio (95% CI) adjusted***
Mortality among patients diagnosed with CRC (all deaths, related or unrelated to CRC)				
	186 745 PY	78 586 PY	108 946 PY	
All sites	94	38	33	**0.58 (0.38-0.87)**
Distal & descendent	55	26	14	**0.50 (0.26-0.94)**
CRC Mortality	186 745 PY	78 586 PY	108 946 PY	
All sites	83	35	30	**0.62 (0.40-0.96)**
Distal & descendent	48	23	12	**0.48 (0.24-0.94)**
NON CRC Mortality	1150	603	534	0.97 (0.85-1.09)

*Cuzick et al method (1997)

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The PLCO CRC Screening Trial

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Colorectal-Cancer Incidence and Mortality with Screening Flexible Sigmoidoscopy

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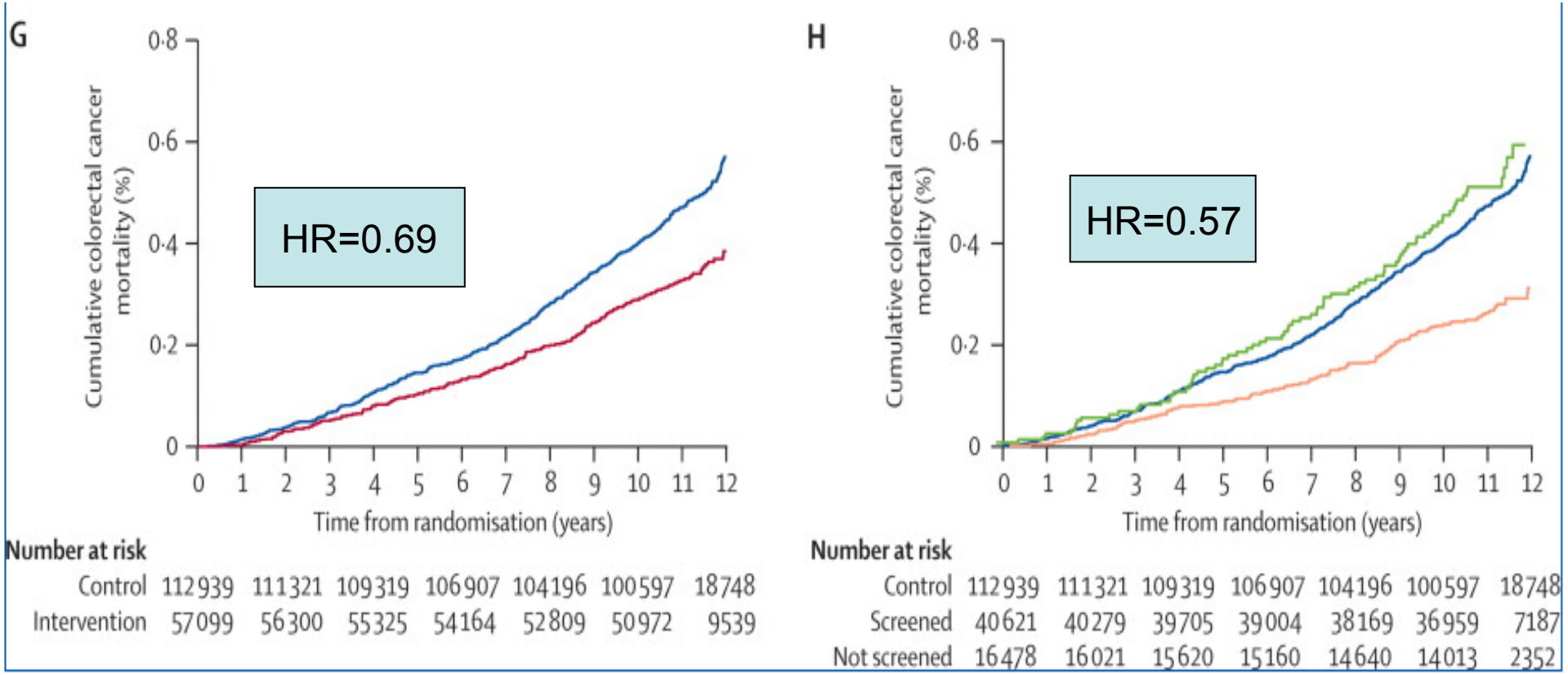
ABSTRACT

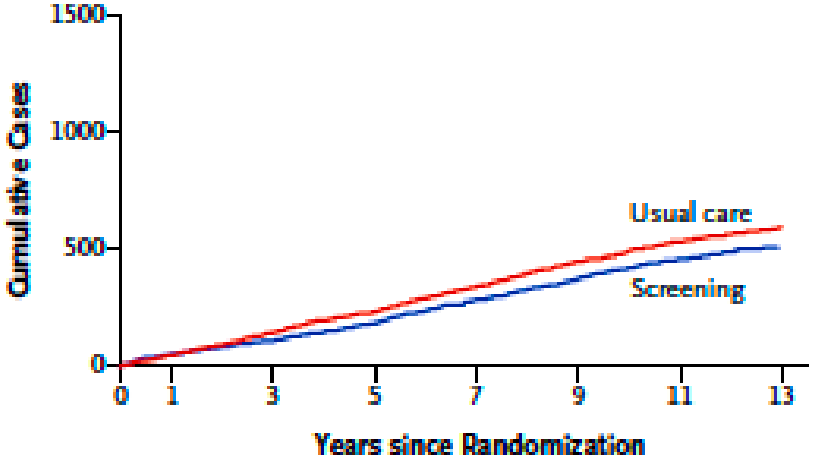
RESULTS

Of the 77,445 participants randomly assigned to screening (intervention group), 83.5% underwent baseline flexible sigmoidoscopy and 54.0% were screened at 3 or 5 years. The incidence of colorectal cancer after a median follow-up of 11.9 years was 11.9 cases per 10,000 person-years in the intervention group (1012 cases), as compared with 15.2 cases per 10,000 person-years in the usual-care group (1287 cases), which represents a 21% reduction (relative risk, 0.79; 95% confidence interval [CI], 0.72 to 0.85; P<0.001). Significant reductions were observed in the incidence of both distal colorectal cancer (479 cases in the intervention group vs. 669 cases in the usual-care group; relative risk, 0.71; 95% CI, 0.64 to 0.80; P<0.001) and proximal colorectal cancer (512 cases vs. 595 cases; relative risk, 0.86; 95% CI, 0.76 to 0.97; P=0.01). There were 2.9 deaths from colorectal cancer per 10,000 person-years in the intervention group (252 deaths), as compared with 3.9 per 10,000 person-years in the usual-care group (341 deaths), which represents a 26% reduction (relative risk, 0.74; 95% CI, 0.63 to 0.87; P<0.001). Mortality from distal colorectal cancer was reduced by 50% (87 deaths in the intervention group vs. 175 in the usual-care group; relative risk, 0.50; 95% CI, 0.38 to 0.64; P<0.001); mortality from proximal colorectal cancer was unaffected (143 and 147 deaths, respectively; relative risk, 0.97; 95% CI, 0.77 to 1.22; P=0.81).

Colorectal cancer mortality (Kaplan-Meier estimates)



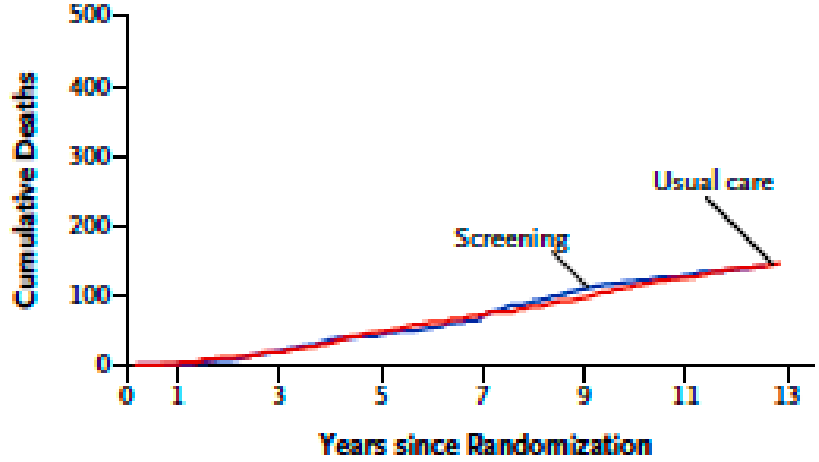
E Incidence of Proximal Colorectal Cancer



No. at Risk

Screening							
Cases	50	109	183	282	374	458	512
Person-yr	76,520	227,007	373,895	516,773	654,740	772,625	848,403
Usual care							
Cases	48	142	232	339	448	534	595
Person-yr	76,592	227,438	374,467	517,055	654,447	771,744	847,103

F Mortality from Proximal Colorectal Cancer



No. at Risk

Screening							
Deaths	3	20	45	71	111	128	143
Person-yr	77,276	230,295	380,730	528,006	670,832	793,203	871,930
Usual care							
Deaths	3	19	49	73	96	125	147
Person-yr	77,288	230,354	380,731	527,828	670,526	792,674	871,275

Figure 1. **Overall, Distal, and Proximal Colorectal-Cancer Incidence and Mortality.**

Directorate-General for Health & Consumers

Executive Agency for Health and Consumers

European guidelines for quality assurance in colorectal cancer screening and diagnosis

First Edition

Editors
N. Segnan
J. Patnick
L. von Karsa

Level of evidence

FOBT	I
Sigmoidoscopy	II
Colonoscopy	III

FS as part of NHS BSCP

Focus on quality to ensure accuracy, comfort and safety

- Minimum number of procedures to establish competency
- JAG accreditation- inclusive of safe polypectomy
- Minimum number of procedures per year to maintain proficiency
- Continuous monitoring of performance (ADR/100 exams) with feedback
- Scope guides to improve orientation and ensure completeness of the exam
- CO_2 to improve comfort