

Workshop 2011

Screening colon retto

Trial SCORe

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**ONCE-ONLY SIGMOIDOSCOPY SCREENING IN
COLORECTAL CANCER SCREENING:
FOLLOW UP FINDINGS
OF THE ITALIAN RANDOMIZED CONTROLLED TRIAL
SCORE**

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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 Giacomini, Orietta Giuliani, Alessandra Santarelli, Carmen Beatriz Visioli, Roberto Zanetti, Wendy S Atkin, Carlo Senore; SCORE working group collaborators

ARTICLE

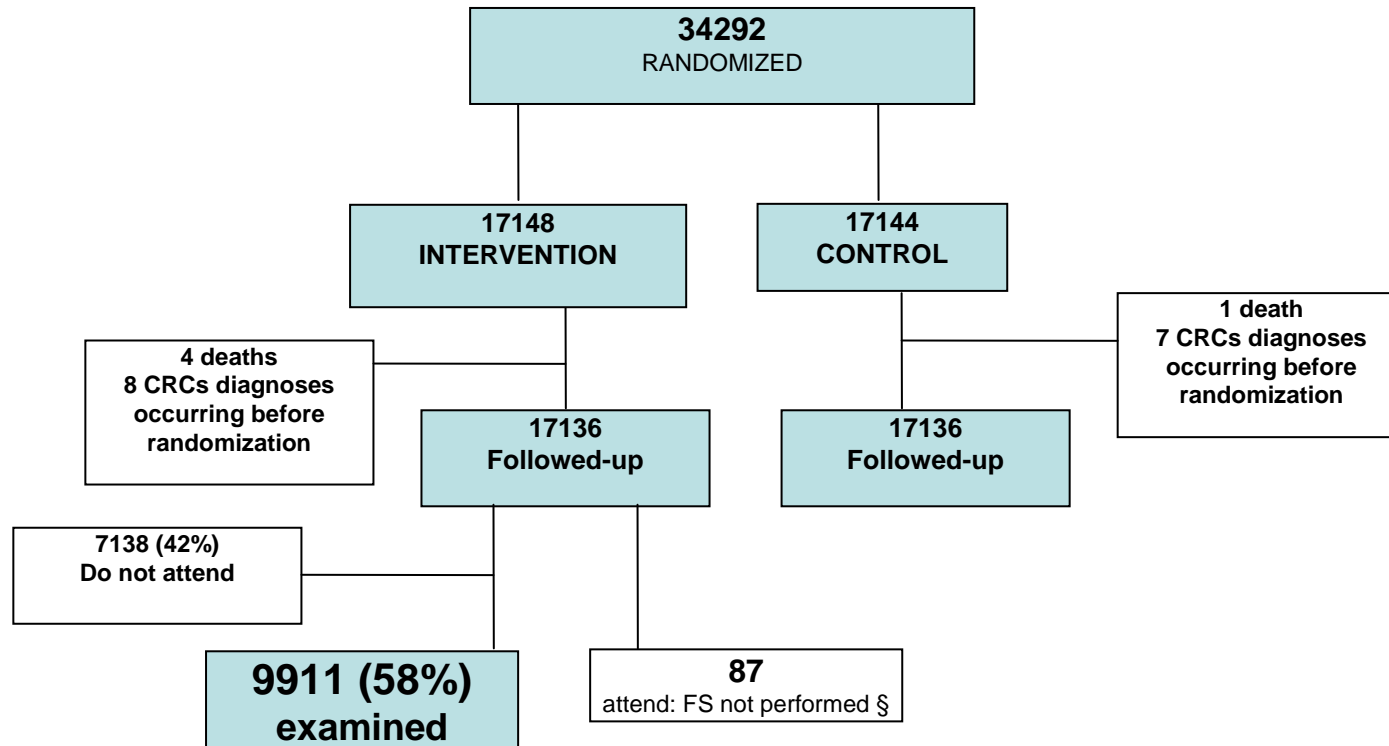
Once-Only Sigmoidoscopy in Colorectal Cancer Screening: Follow-up Findings of the Italian Randomized Controlled Trial—SCORE

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 Giacomini, Orietta Giuliani, Alessandra Santarelli, Carmen Beatriz Visioli, Roberto Zanetti, Wendy S. Atkin, Carlo Senore; and the SCORE Working Group

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SCORE Trial profile-2



§ 1 patient who refused to repeat the FS following inadequate preparation, had been diagnosed with a CRC prior to randomization. He was therefore excluded from the follow-up analysis.

FOLLOW-UP

Participants were followed-up until

31/12/2007 for incidence

31/12/2008 for mortality

Median follow-up time to death, emigration, or
end of follow-up:

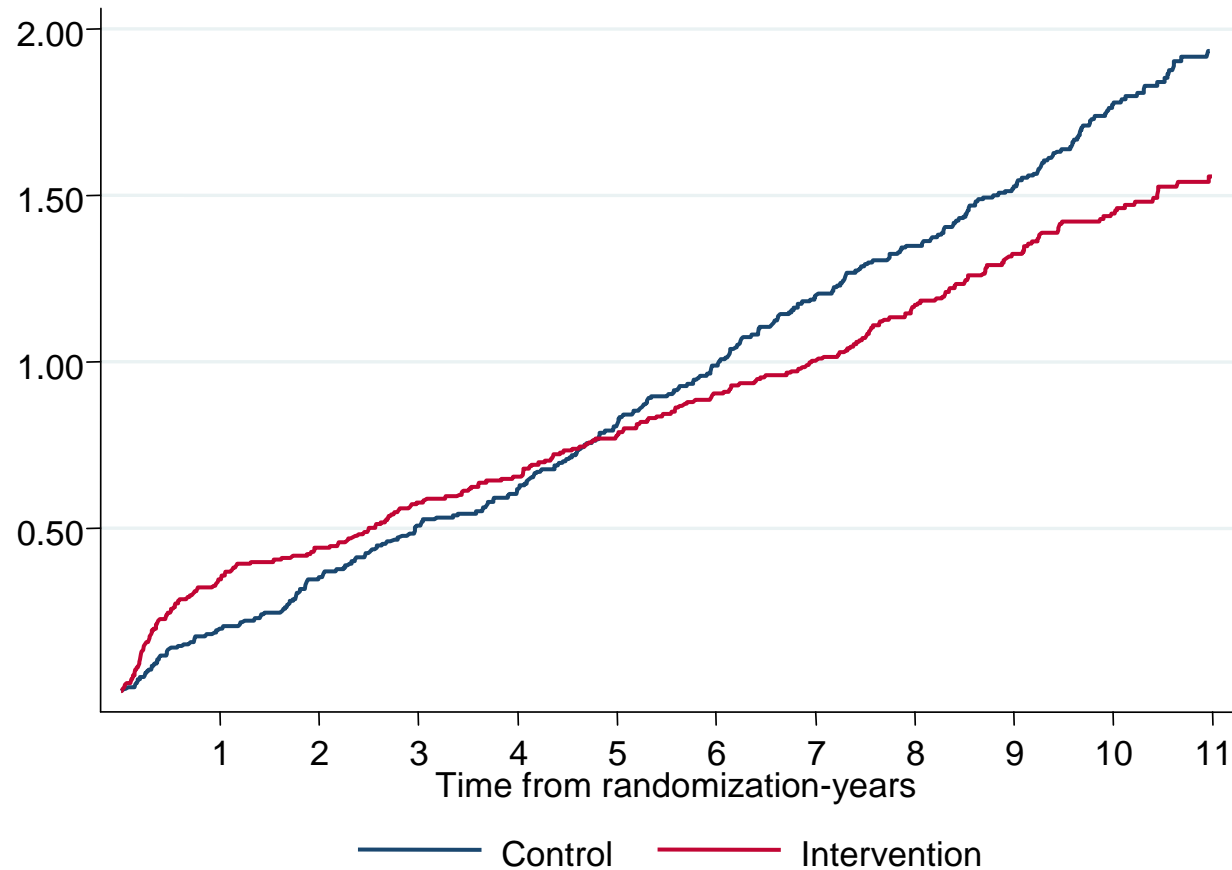
10.5 years (IQR=9.9-11.3) for incidence

11.4 years (IQR=10.8-11.9) for mortality

Intention to treat analysis - Colorectal cancer

INCIDENCE, ALL SITES

Nelson Aalen Cumulative Hazard (%) by time from randomization



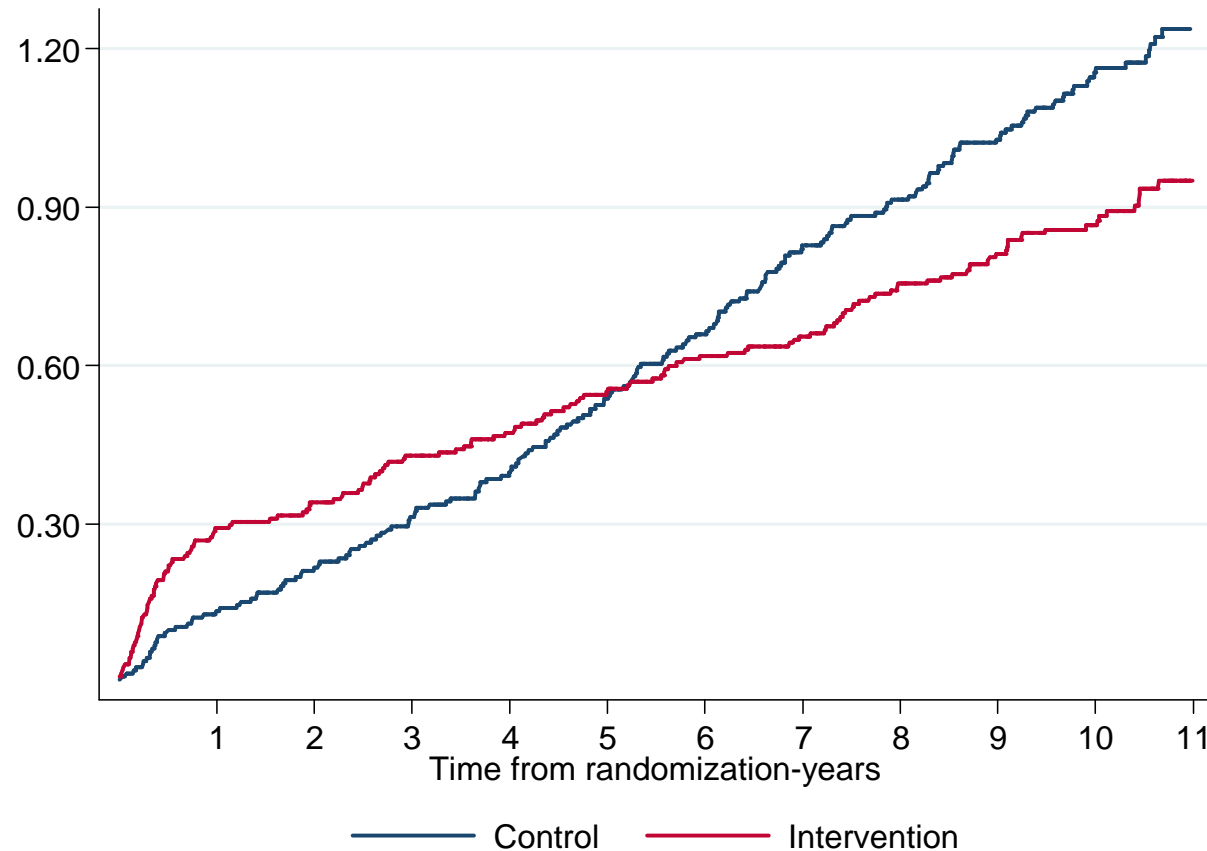
RR (95%CI) =
0.82 (0.69-0.96)

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

Intention to treat analysis-Colorectal cancer

INCIDENCE, Distal&Descendent

Nelson Aalen Cumulative Hazard (%) by time from randomization



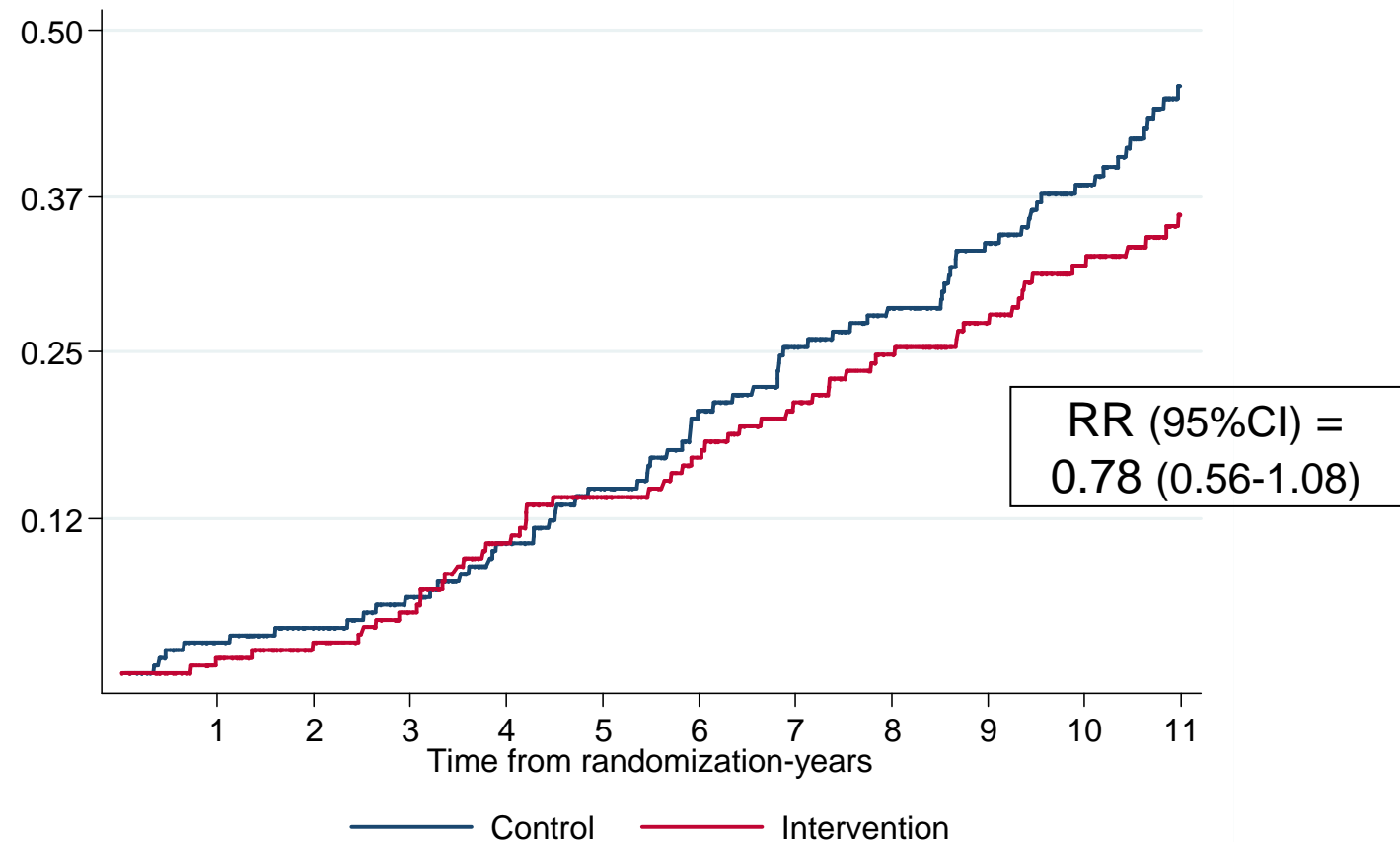
RR (95%CI) =
0.76 (0.62-0.94)

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

MORTALITY, ALL SITES

Nelson Aalen Cumulative Hazard (%) by time from randomization

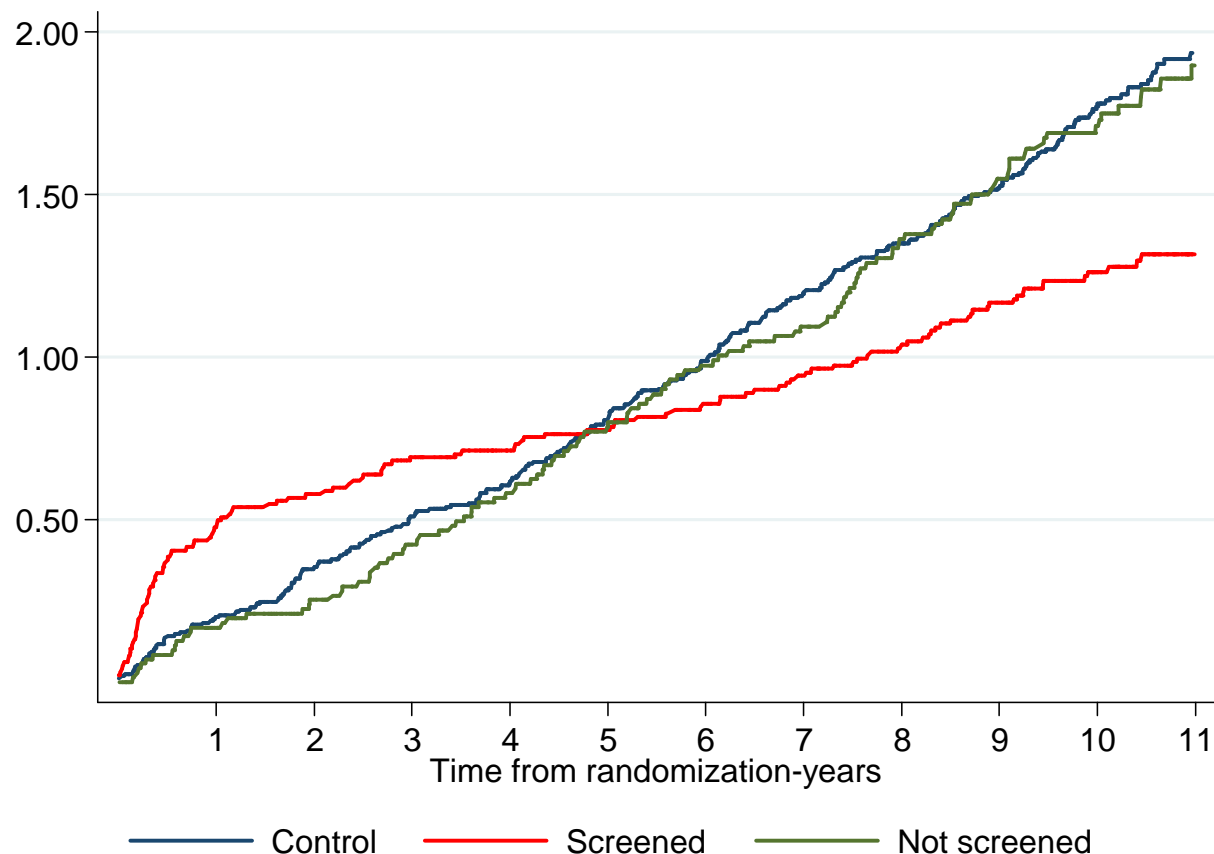


Cumulative Events by years from randomization						
	≤2	≤4	≤6	≤8	≤10	>10
Control	6	17	34	47	62	83
Intervention	4	17	28	41	52	65

Per protocol analysis-Colorectal cancer

INCIDENCE, ALL SITES

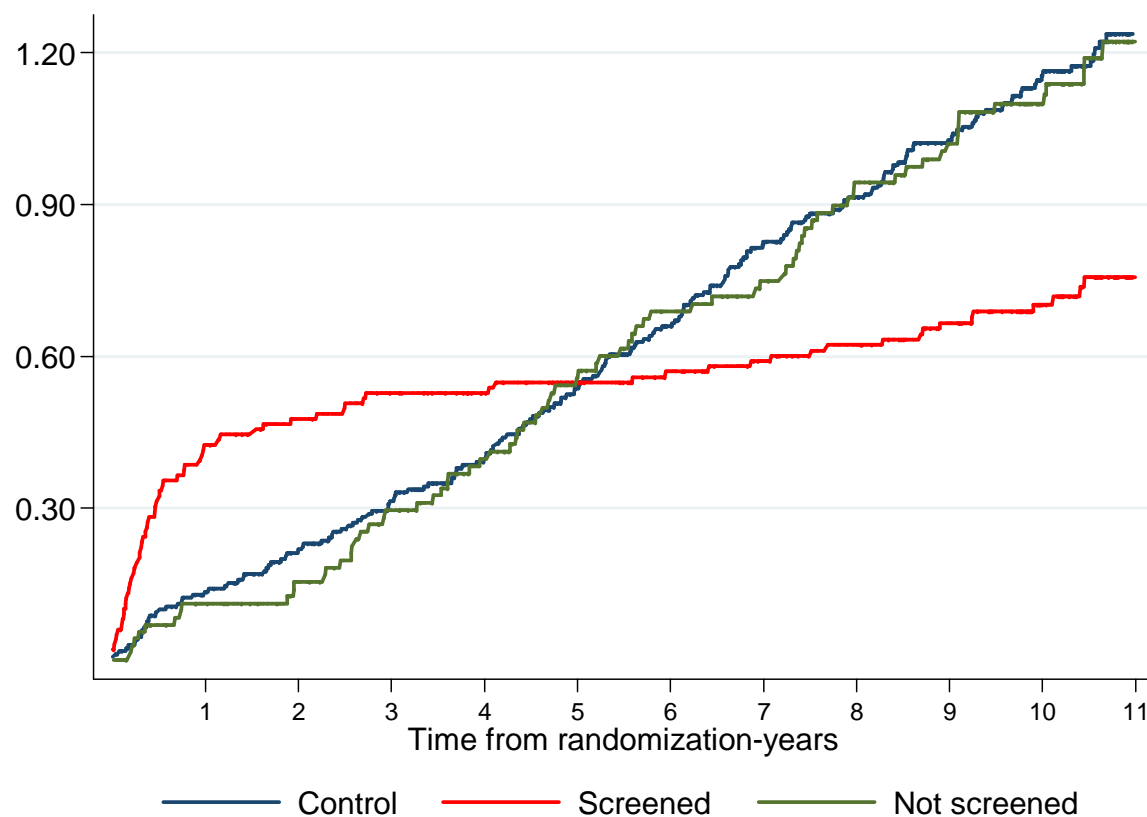
Nelson Aalen Cumulative Hazard (%) by time from randomization



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

Per protocol analysis-Colorectal cancer INCIDENCE, Distal&Descendent

Nelson Aalen Cumulative Hazard (%) by time from randomization



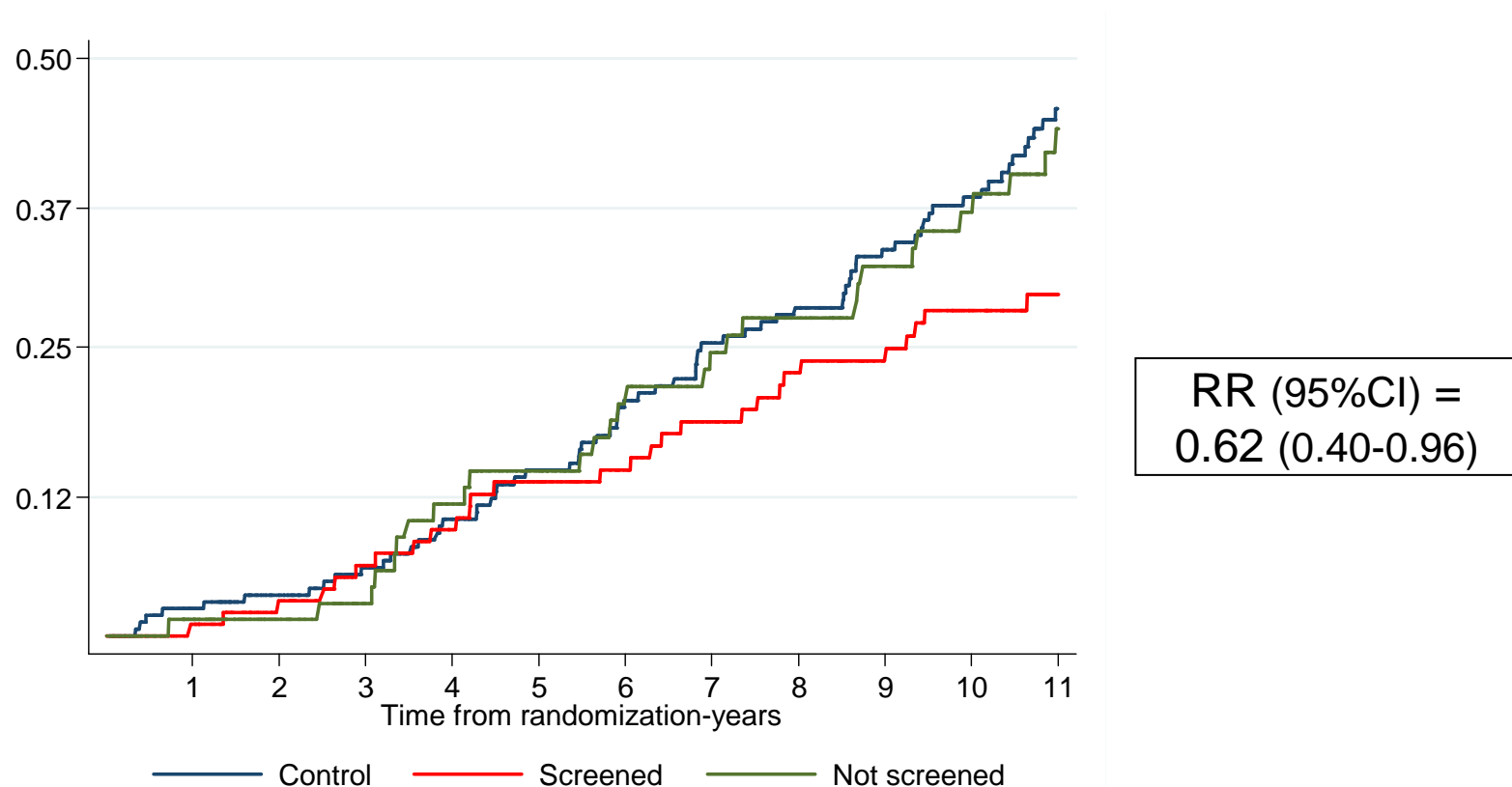
RR (95%CI) =
0.60 (0.46-0.80)

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

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
Not Screened	1	8	14	19	25	35
Screened	3	9	14	22	27	30

Contributing members of the SCORE Working Group:

Arezzo: A. Carnevali (Pathology Unit, San Donato Hospital, AUSL 8 Arezzo), A. Agnolucci and P. Ceccatelli (Endoscopy Unit, San Donato Hospital, AUSL 8 Arezzo), F. Mirri (Screening Unit, Valdarno Hospital);

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THE LANCET

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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

Summary

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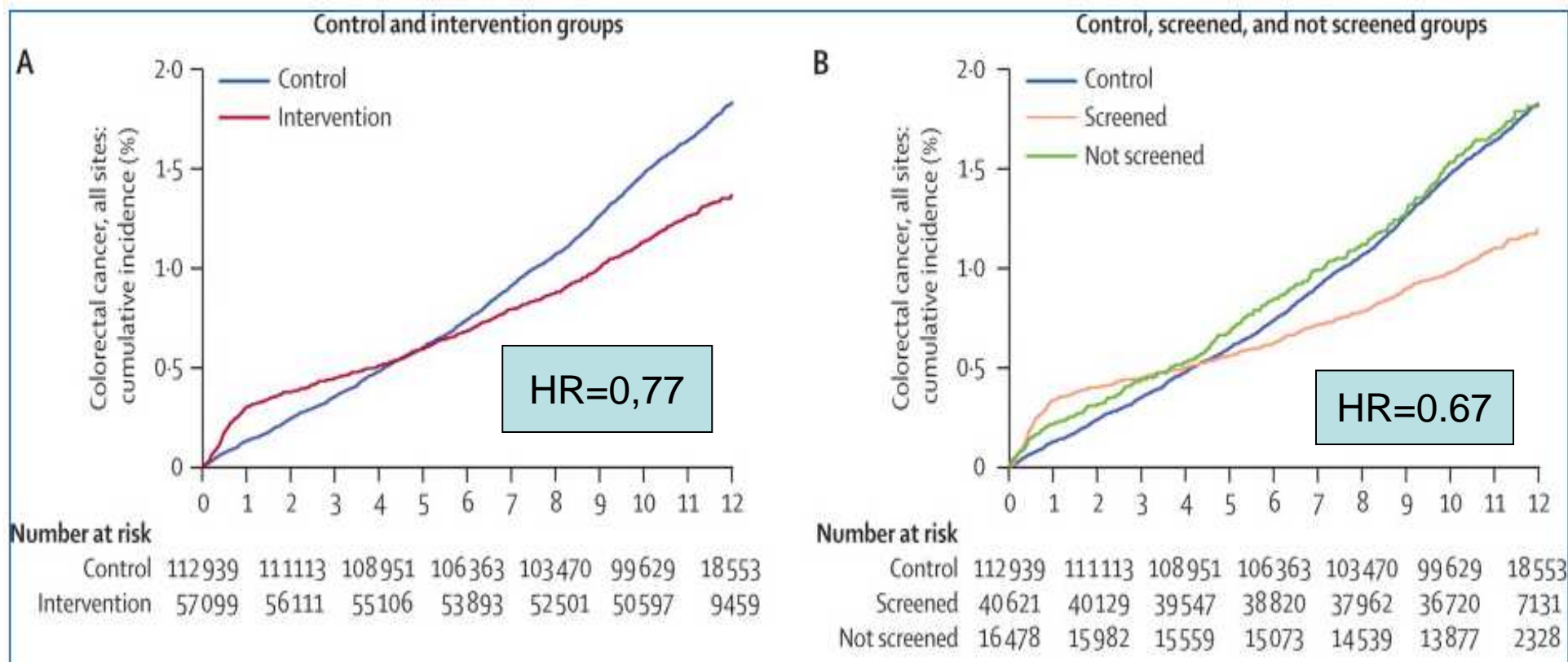
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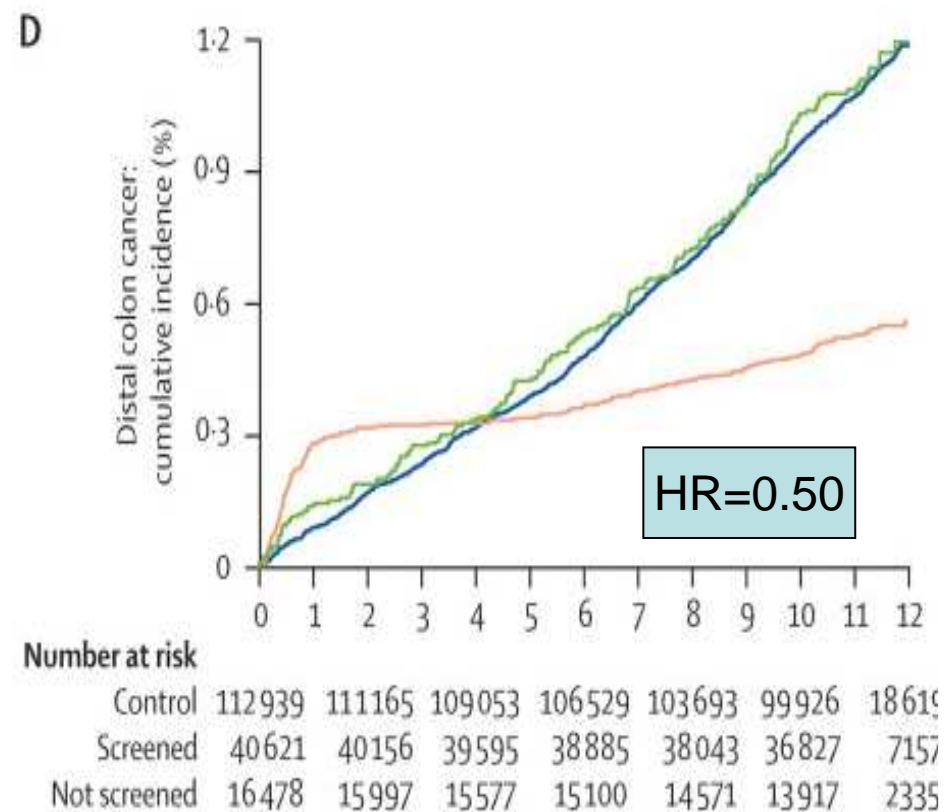
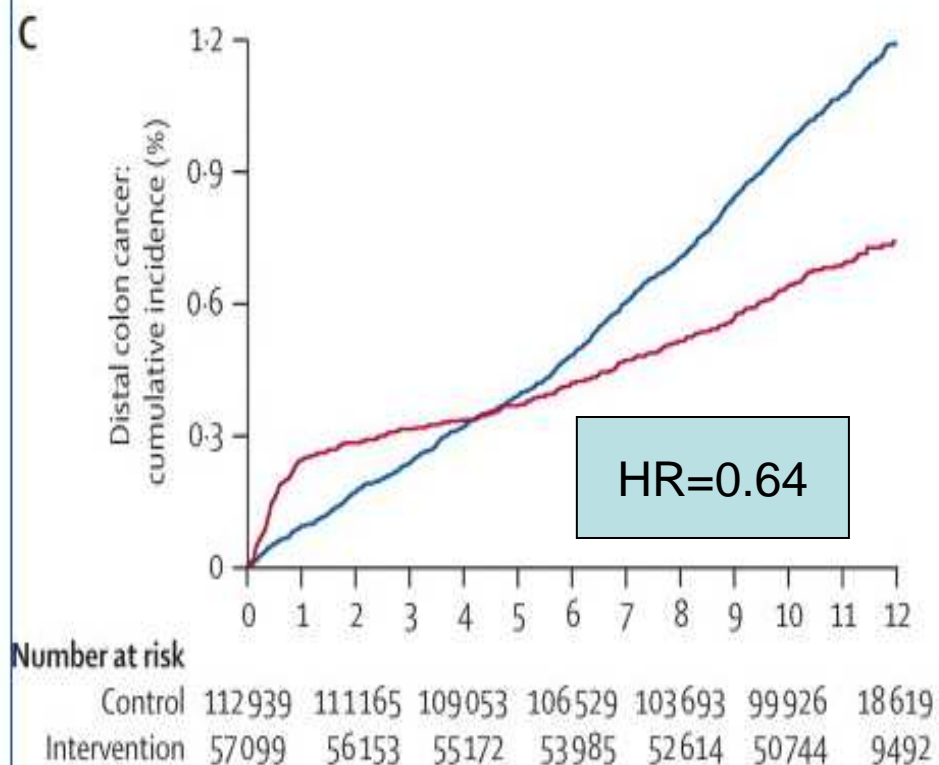
Background Colorectal cancer is the third most common cancer worldwide and has a high mortality rate. We tested the hypothesis that only one flexible sigmoidoscopy screening between 55 and 64 years of age can substantially reduce colorectal cancer incidence and mortality.

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

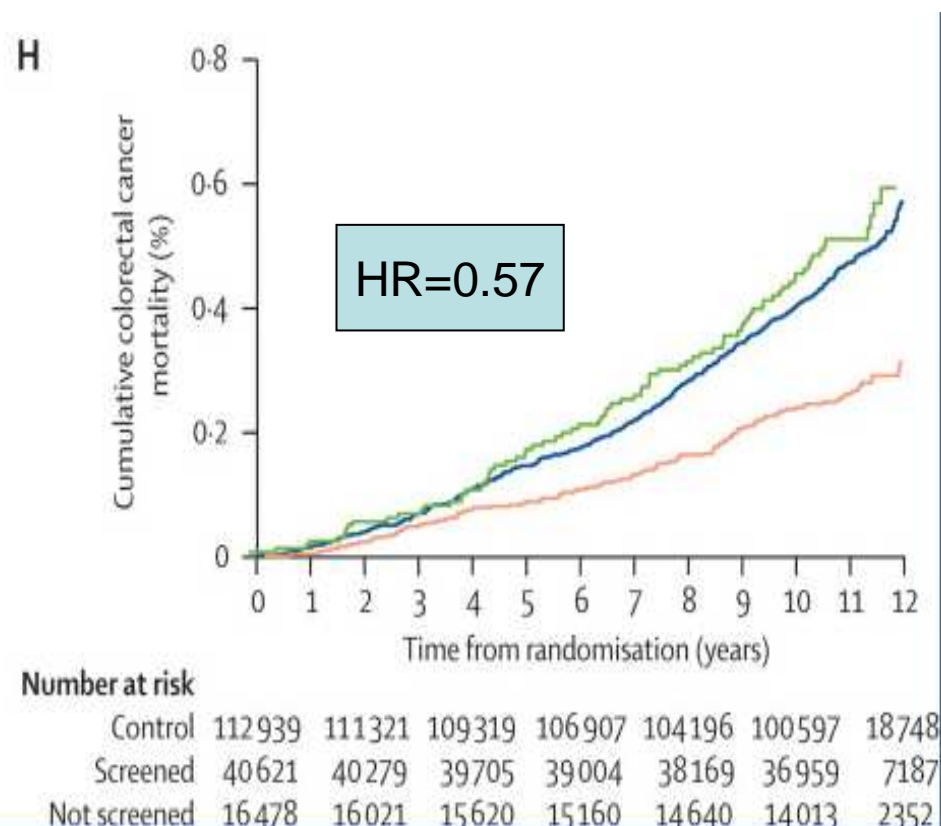
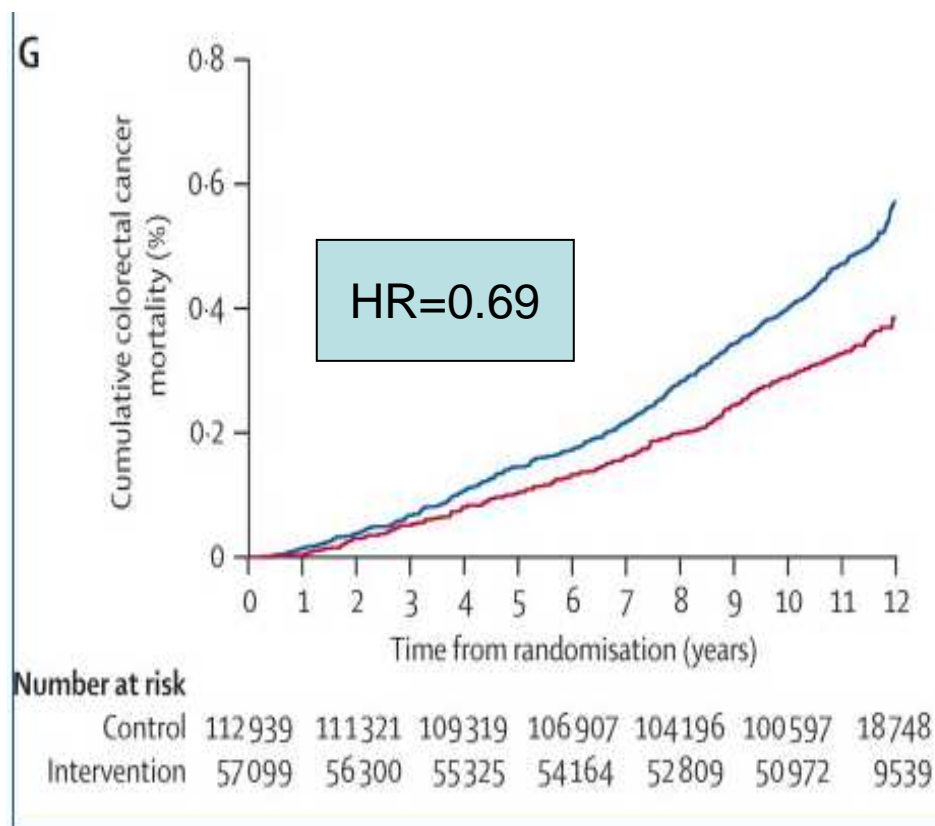
Colorectal cancer incidence (Kaplan-Meier estimates)



Distal cancer incidence (Kaplan-Meier estimates)



Colorectal cancer mortality (Kaplan-Meier estimates)



European guidelines on colorectal cancer screening

Level of evidence

FOBT	I
Sigmoidoscopy	II
Colonoscopy	III