LO SCREENING BASATO SUL RISCHIO:
L'esperienza di Barcellona

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GISCoR
gruppo italiano screening colorettale

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XVII CONGRESSO NAZIONALE 2024

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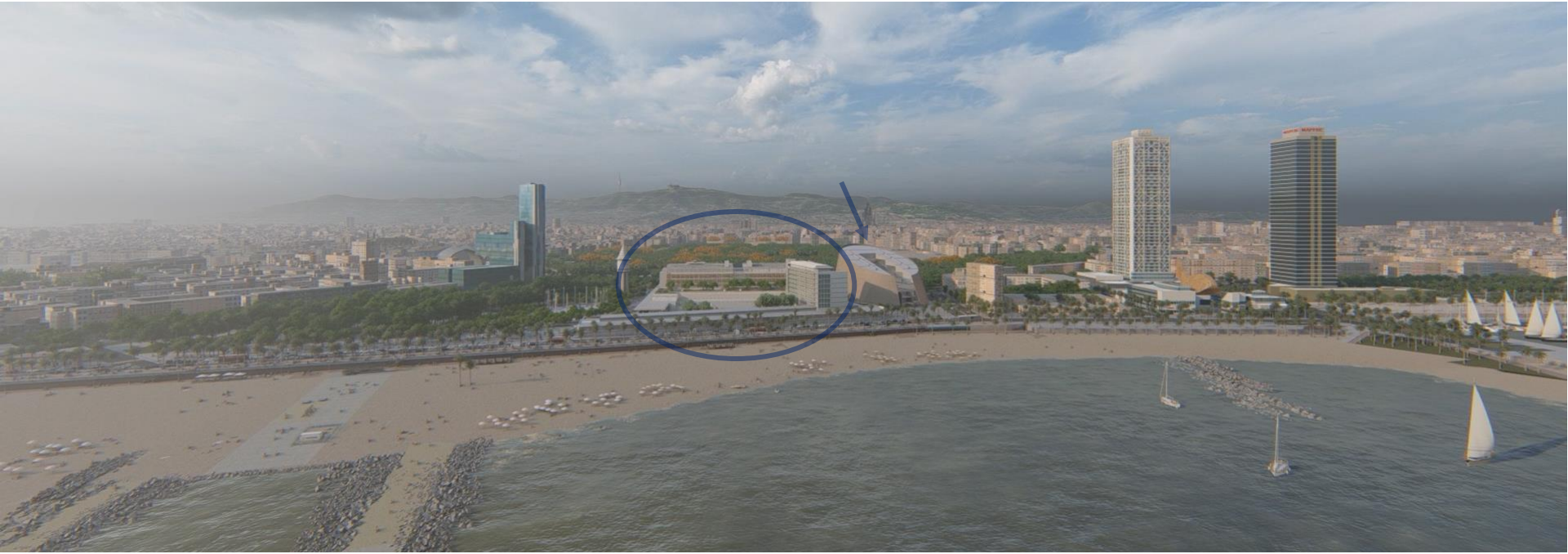

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I declare I have no conflict of interests

Outline

1. The CRC Programme in Catalonia and Barcelona
2. Risk based on two previous FIT negative results
3. Information needs regarding individualised screening
4. Feasibility evaluation of the tailored risk approach
5. Two vs 3 or 4 previous FIT negative results
6. Conclusions and challenges

1. The CRC Programme in Catalonia and Barcelona

Colorectal cancer screening in Catalonia

Spain NHS health care system type (decentralised)

7.970.428 inhabitants (June 2023)

Catalan Department of Health and Catalan Health Service (CatSalut) are responsible for organizing and providing health services at regional level

Catalan Colorectal Cancer Screening Programme

Population-based organized

One Programme but decentralised management:

- One central cancer screening office: coordination, IT system, evaluation
- 11 screening offices: management
- 7 (+4) FIT labs
- 43 endoscopy Units

Target population:

- aprox 2M men and women 50-69 years
- age extension **74** : planned 2025

PROGRAMA DE DETECCIÓ PRECOÇ DE CÀNCER DE CÒLON I RECTE

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Catalan Colorectal Cancer Screening Programme

Screening Test: FIT [20ug Hb/g faeces or 100ng/ml]

Screening interval: Biennial

Invitation: personal letter + one reminder

PROGRAMA DE DETECCIÓ PRECOÇ DE CÀNCER DE CÒLON I RECTE

FIT kit pick-up and return: **Community Pharmacy** *(or Primary Care Centers)*

Diagnostic test after FIT+: colonoscopy with sedation

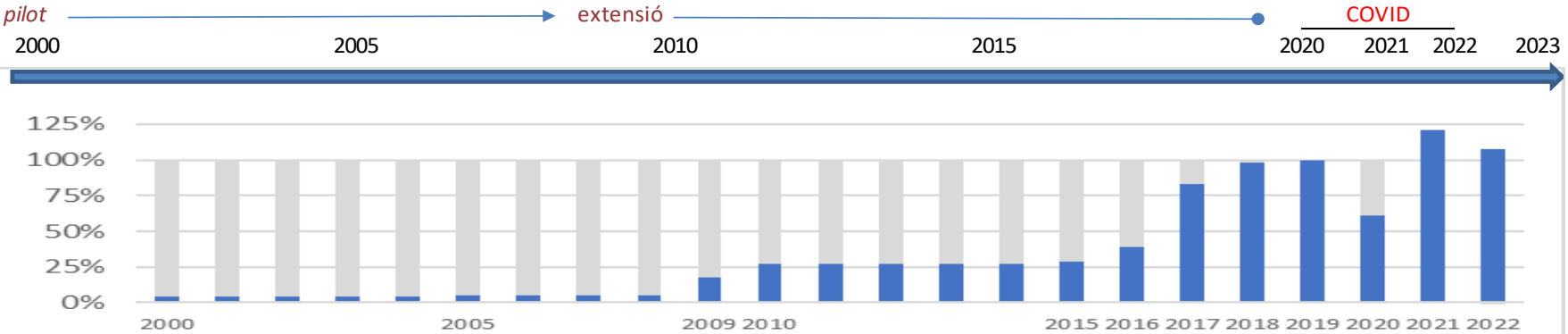
Catalan Colorectal Cancer Screening Programme

100% coverage by invitation reached in 2018-19

Pilot
Area: Hospitalet
Test: Guaic

Extension
FIT

4 months interruption
2 years higher cut-off point



PROGRAMA DE DETECCIÓ PRECOÇ DE CÀNCER DE CÒLON I RECTE

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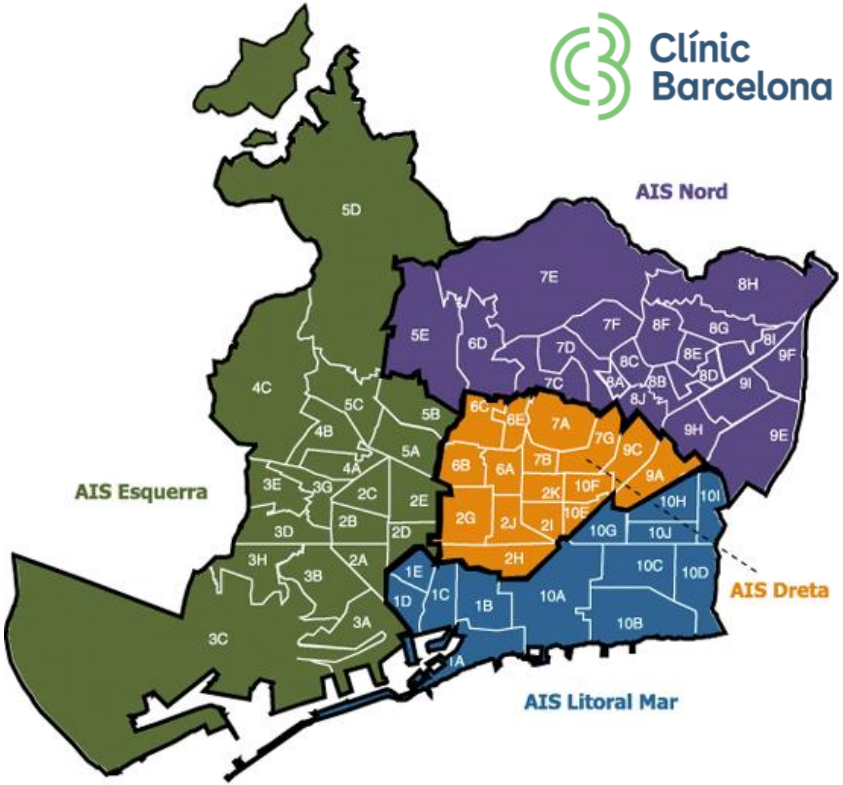
The programme in Barcelona

Clínic Barcelona

Hospital del Mar Barcelona



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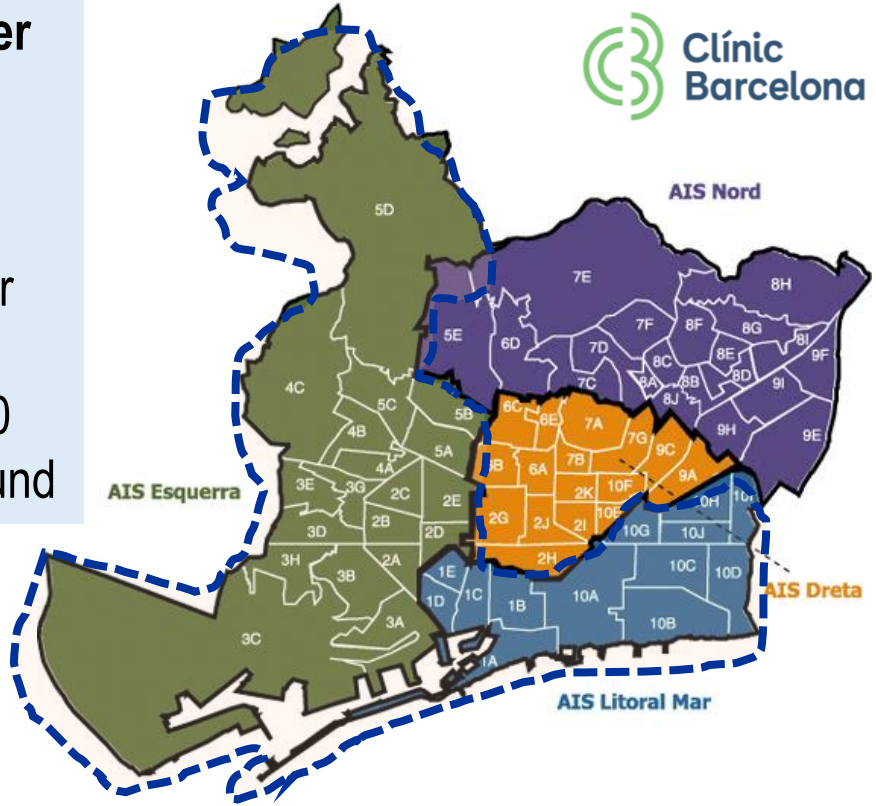
The programme in Barcelona

Start December 2009

AIS Esquerra
AIS Litoral Mar

Aprox 200,000
Currently 8th round



Clínic Barcelona

Hospital del Mar Barcelona

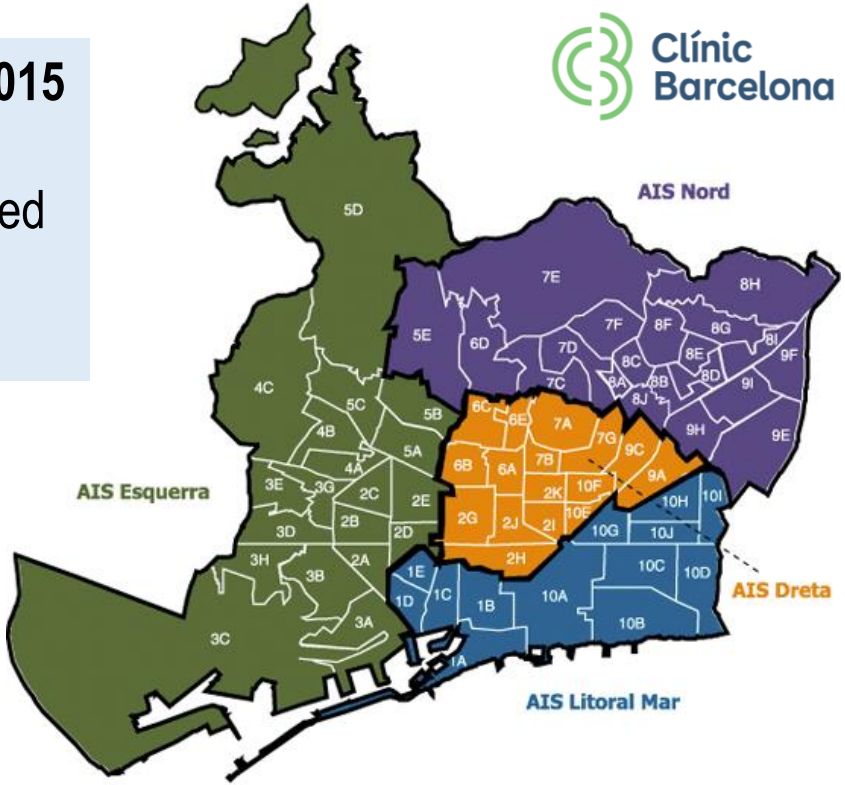
Hospital del Mar Research Institute Barcelona

The programme in Barcelona

Since September 2015

All Barcelona covered

Aprox 400,000



Clínic Barcelona

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2.

Risk based on two previous FIT negative results

The risk according to previous 2 negative FIT

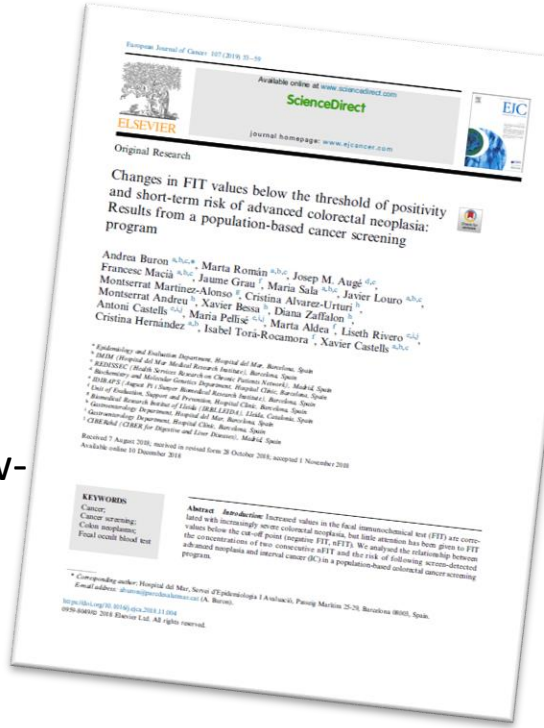
First 3 rounds of the Programme in Barcelona (2010-2015)

Change in the risk category of 2 previous nFIT:

- Non-detectable (Nd,0-3.8),
- Low (3.9-9.9);
- High (10.0-19.9 µg Hb/g feces)

9 categories: Nd-Nd, Nd-Low, Nd-High, Low-Nd, Low-Low, Low-High, High-Nd, High-Low, High-High

Risk of advanced neoplasia and CRC



Buron A, et al. Changes in FIT values below the threshold of positivity and short-term risk of advanced colorectal neoplasia: Results from a population-based cancer screening program. Eur J Cancer. 2019 Jan;107:53-59.

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The risk according to previous 2 negative FIT

FIT - 1st screen	FIT - 2nd screen: Non-detectable	Low negative FIT	High negative FIT
Non-detectable	1.00 -	4.02 (3.12 - 5.19)	7.45 (5.67 - 9.78)
Low negative FIT	4.00 (2.99 - 5.35)	10.79 (6.97 - 16.72)	20.38 (12.82 - 32.40)
High negative FIT	6.99 (5.06 - 9.65)	19.64 (11.95 - 32.26)	21.75 (12.44 - 38.04)

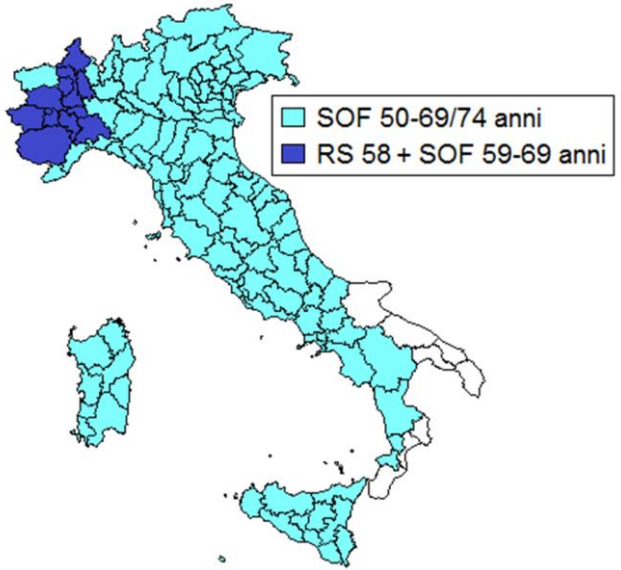
Non-detectable comprises FIT values ranging between 0 and 3.8µg/ml; Low negative FIT, values between 3.9 and 9.9µg/ml; High negative FIT, values between 10 and 19.9µg/ml.

Buron A, et al. Changes in FIT values below the threshold of positivity and short-term risk of advanced colorectal neoplasia: Results from a population-based cancer screening program. Eur J Cancer. 2019 Jan;107:53-59.

The risk according to previous 2 negative FIT

Italy

- Sum of FIT values of previous 2 rounds
- Categories: 0, 0.1-3.9, 4-9.9, 10-14.9, 15-19.9, ≥20 µg Hb/faeces



The risk according to previous 2 negative FIT

Predictors of CRC + advanced adenomas at the third exam

		CRC		Advanced adenoma		AN	
		OR	95%CI	OR	95%CI	OR	95%CI
GENDER	Women	1		1		1	
	Men	1.34	1.00-1.79	1.63	1.46-1.83	1.60	1.43-1.78
AGE (years)	50-54	0.54	0.32-0.91	0.67	0.55-0.82	0.65	0.55-0.79
	55-59	0.75	0.47-1.17	1.02	0.86-1.22	0.98	0.83-1.15
	60-64	0.95	0.67-1.36	1.00	0.86-1.16	0.99	0.87-1.14
	65-69	1		1		1	
INTERVAL SINCE LAST FIT (months)	18-22	0.67	0.30-1.49	0.80	0.59-1.08	0.78	0.58-1.03
	23-27	1		1		1	
	28-32	0.92	0.61-1.37	0.98	0.83-1.16	0.97	0.83-1.13
	33-36	0.96	0.39-2.40	1.23	0.86-1.77	1.19	0.85-1.67
	37-60	1.10	0.51-2.36	1.49	1.14-2.00	1.44	1.11-1.87
Cumulative f-Hb level at previous 2 FIT tests (FIT1+FIT2) µg Hb /gr faeces	0	1		1		1	
	0.1-3.9	2.26	1.47-3.46	1.75	1.47-2.07	1.81	1.55-2.12
	4-9.9	4.01	2.51-6.39	4.64	3.93-5.49	4.58	3.91-5.36
	10-14.9	10.11	6.04-16.93	9.13	7.48-11.15	9.32	7.73-11.23
	15-19.9	11.63	6.42-21.07	12.84	10.32-16.00	12.42	10.43-15.76
	≥ 20	38.92	22.50-67.31	30.40	24.09-38.38	32.52	26.19-40.39


ORIGINAL ARTICLE

Faecal haemoglobin concentration among subjects with negative FIT results is associated with the detection rate of neoplasia at subsequent rounds: a prospective study in the context of population based screening programmes in Italy

Carlo Senore, Marco Zappa, Cinzia Campari, Sergio Crotta, Paola Armaroli, Arrigo Arrigoni, Paola Cassoni, Rossana Colla, Mario Fracchia, Fabrizio Gili, Grazia Grazzini, Roberto Lolli, Patrizia Mercuzot, Lorenzo Orione, Salvatore Polizzi, Stefano Rapi, Emilia Rippi, Tiziana Rubeca, Romano Sassatelli, Carmen Visioli, Nereo Segnan

ABSTRACT

Objective

Design

Methods

Results

Conclusion

Significance of this study

What is already known about this subject?

What are the new findings?

How might it impact on clinical practice in the foreseeable future?

INTRODUCTION

BMJ

Senore C, et al. Faecal haemoglobin concentration among subjects with negative FIT results is associated with the detection rate of neoplasia at subsequent rounds: a prospective study in the context of population based screening programmes in Italy. Gut. 2020 Mar;69(3):523-530

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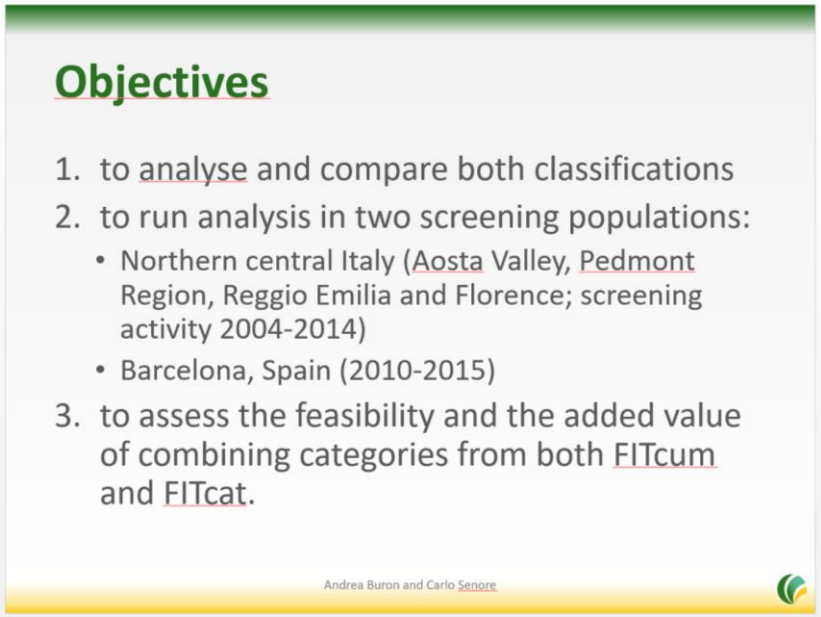
Combined analysis: ICSN 2019



Combined analysis: ICSN 2019

IV. OR for Advanced Neoplasia

		Advanced Neoplasia			
		Italy		Barcelona	
		OR	95% CI	OR	95% CI
Cumulative f-Hb level at previous 2 FITs (FIT1+FIT2)	0	1		1	
	0.1-3.9	1.81	1.55-2.12	3.09	2.35-4.07
	4-9.9	4.58	3.91-5.36	8.60	6.40-11.54
	10-14.9	9.32	7.73-11.23	17.15	12.39-23.72
	15-19.9	12.42	10.43-15.76	20.19	14.28-28.53
	≥ 20	32.52	26.19-40.39	44.94	30.25-66.77
Combinations of categories of previous 2 FITs	ND - ND	1		1	
	ND - Low	4.90	4.15 – 5.80	4.13	3.19-5.35
	ND - High	8.51	7.00 – 10.35	7.26	5.48-9.63
	Low - ND	2.70	2.26 – 3.24	4.15	3.09-5.57
	Low - Low	10.70	8.16 -14.03	10.93	6.99-17.06
	Low - High	17.18	12.71 - 23.22	19.29	11.94-31.18
	High - ND	5.66	4.55 – 7.03	7.04	5.06-9.78
	High - Low	18.63	13.64 – 25.44	18.42	10.99-30.88
	High - High	30.59	22.50 – 41.58	23.22	13.29-40.60

Logistic regression models adjusted by age and sex (in Italy also by interval since last FIT)

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Conclusions

- ✓ Similar risk (DR and OR) obtained in both populations for each classification; trend very consistent → *external validation*
- ✓ Both classifications have similar patterns in risk
- ✓ Combined algorithm → increase in predictive value
- ✓ Using 2 previous nFIT relevant for screening personalisation; e.g. when high risk and
  - Invited and not participating
  - Not invited due to age
  - FIT+ and Not accepting colonoscopy
  - Advance colonoscopy one round, e.g. by lowering cut-off point

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3. Information needs regarding individualised screening

From focus groups to co-creation workshops

To explore the **perceived feasibility** of the *tailored approach* from the target population's perspective, in terms of **acceptability** and **information resources** needed

→

To **develop a communication strategy <u>together</u> with the target population** for the future implementation of a tailored risk approach

TaiRiS
Prevenció del càncer segons el risc personal

Focus groups → Interviews & Co-creation workshops

TaiRiS: Objectives

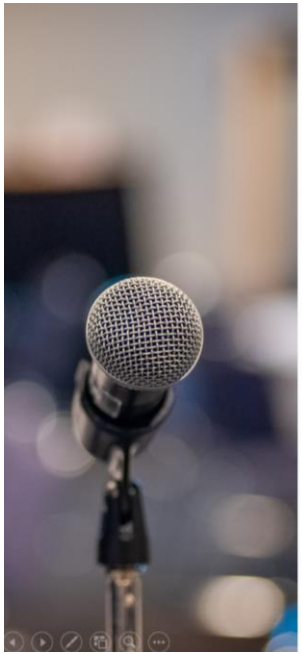
To **develop a communication strategy <u>together</u> with the target population** for the future implementation of a tailored risk approach

1. To identify target population's experiences and perceptions regarding CRC screening (mental model of risks)
2. To explore target population's believes and knowledge about the risk of developing CRC and CRC tailored screening approach
3. To co-design strategies and materials for the future communication plan of a tailored CRC screening approach
4. To collect and analyse the opinions of relevant stakeholders about the proposed communciation material, and to improve the materials including their imput

TaiRiS : Methods

- Inclusion criteria: Target population, women and men ages 50-69 invited to the Bcn-CRCSP
  - non-participants
  - participants with a negative FIT
  - participants with normal colonoscopies, without colorectal pathology or non-assessable colorectal tests
  - without any condition that might hinder oral communication
- Sample size defined by data saturation (foreseeably 6 co-creation sessions and 2 user testing groups with 6-8 informants)
- Presentation of prototypes (diagrams/flowchart, harm information…)?
- Audio and video recorded
- Carried out in cultural centers and at most convenient times for the informants

TaiRiS : Methods



Co-creation groups composition

- Segmentation variables:
  - socioeconomic
  - participation status
- Maximum variability criteria:
  - gender
  - age
  - previous CRC screening and surveillance outcomes

Materials?

- Personal risk of colorectal cancer;
- Leaflets explaining who is invited for screening and when, depending on the previous FIT values;
- Impact of the personalized screening program:
  - number of deaths from colorectal cancer that will be prevented;
  - number of people who will experience physical harm from screening (major adverse effects: hemorrhage, perforation or death).
- Expert messages
- Video framig the process

TaiRiS : Methods

Estudi TaiRiS

On es fan els Tallers

ABS:
- 5C Sarrià (EDB negatives),
- 4B Montnegre-Corts-Pedralbes,
- 4C Les Corts-Helios,
- 3I Sants-Badal

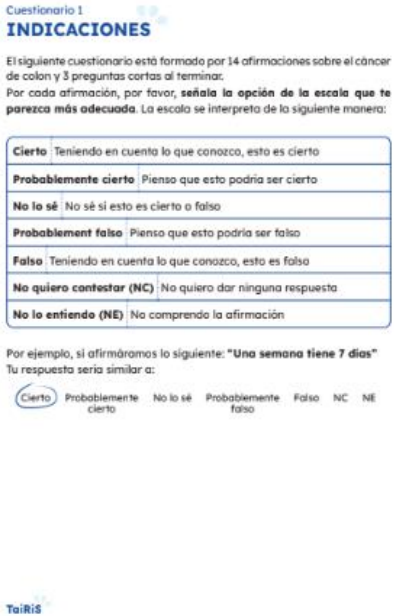
ABS:
- 8L Chafarinas,
- 8G Roquetes
- 8H Ciutat Meridiana Badal

Centre Cívic Can Deu (CCCD)

Centre Cívic Can Verdaguer (CCCV)

TaiRiS : Materials for the workshops

2 Questionnaires:
Risk perception
European Health Literacy (HLS-Q12)



Cuestionario 1

INDICACIONES

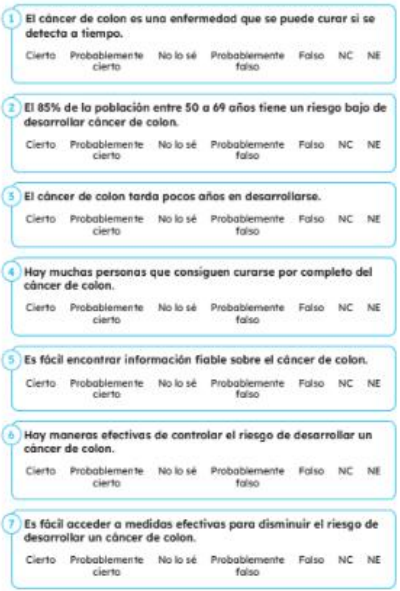
El siguiente cuestionario está formado por 14 afirmaciones sobre el cáncer de colon y 3 preguntas cortas al terminar.
Por cada afirmación, por favor, **señala la opción de la escala que te parezca más adecuada**. La escala se interpreta de la siguiente manera:

Cierto	Teniendo en cuenta lo que conozco, esto es cierto
Probablemente cierto	Pienso que esto podría ser cierto
No lo sé	No sé si esto es cierto o falso
Probablement falso	Pienso que esto podría ser falso
Falso	Teniendo en cuenta lo que conozco, esto es falso
No quiero contestar (NC)	No quiero dar ninguna respuesta
No lo entiendo (NE)	No comprendo la afirmación

Por ejemplo, si afirmáramos lo siguiente: **"Una semana tiene 7 días"**
Tu respuesta sería similar a:

Cierto | Probablemente cierto | No lo sé | Probablemente falso | Falso | NC | NE

TaiRiS



1. **El cáncer de colon es una enfermedad que se puede curar si se detecta a tiempo.**
   Cierto | Probablemente cierto | No lo sé | Probablemente falso | Falso | NC | NE
2. **El 85% de la población entre 50 a 69 años tiene un riesgo bajo de desarrollar cáncer de colon.**
   Cierto | Probablemente cierto | No lo sé | Probablemente falso | Falso | NC | NE
3. **El cáncer de colon tarda pocos años en desarrollarse.**
   Cierto | Probablemente cierto | No lo sé | Probablemente falso | Falso | NC | NE
4. **Hay muchas personas que consiguen curarse por completo del cáncer de colon.**
   Cierto | Probablemente cierto | No lo sé | Probablemente falso | Falso | NC | NE
5. **Es fácil encontrar información fiable sobre el cáncer de colon.**
   Cierto | Probablemente cierto | No lo sé | Probablemente falso | Falso | NC | NE
6. **Hay maneras efectivas de controlar el riesgo de desarrollar un cáncer de colon.**
   Cierto | Probablemente cierto | No lo sé | Probablemente falso | Falso | NC | NE
7. **Es fácil acceder a medidas efectivas para disminuir el riesgo de desarrollar un cáncer de colon.**
   Cierto | Probablemente cierto | No lo sé | Probablemente falso | Falso | NC | NE

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TaiRiS : Materials for the workshops

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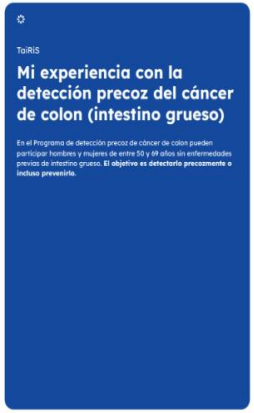

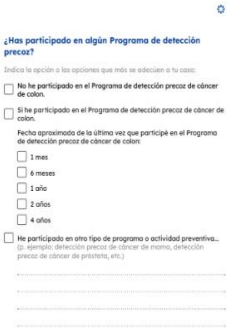

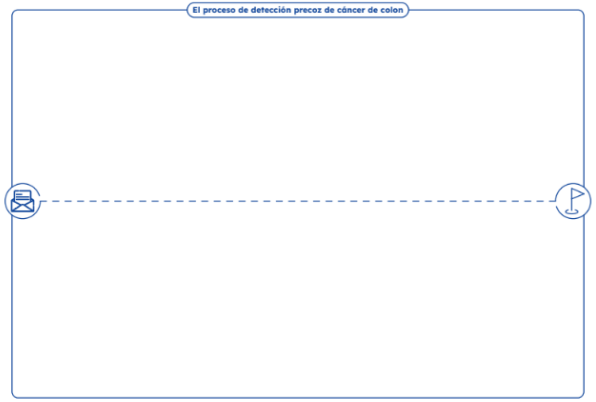

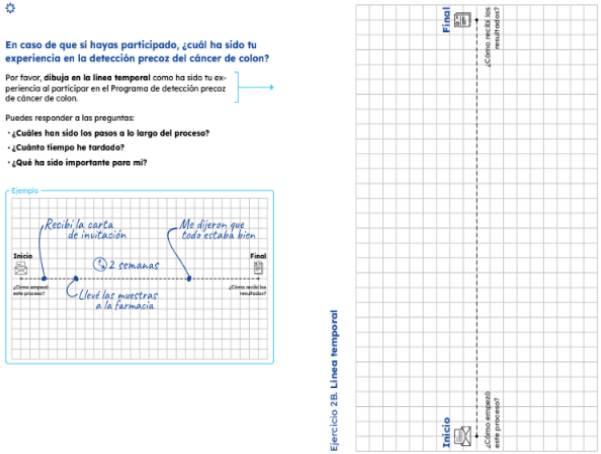

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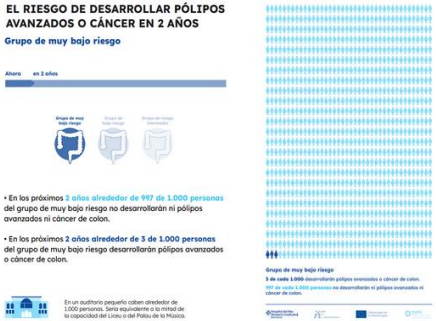
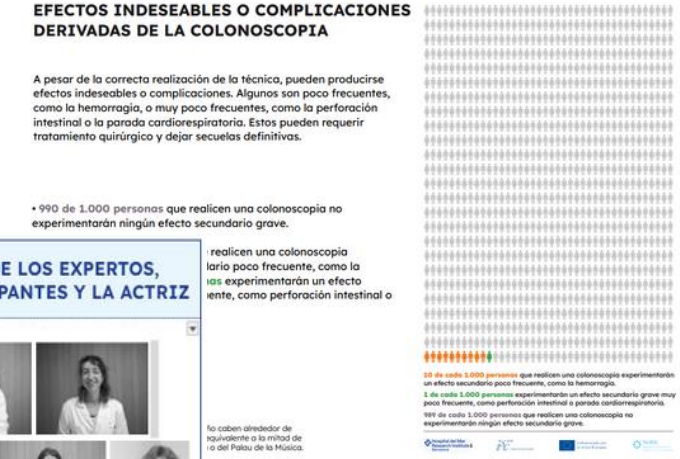
TaiRiS : Materials for the workshops

Castellà / Vídeo: Fraiming	Vídeo Fraiming

Format: vídeo mp4





TaiRiS
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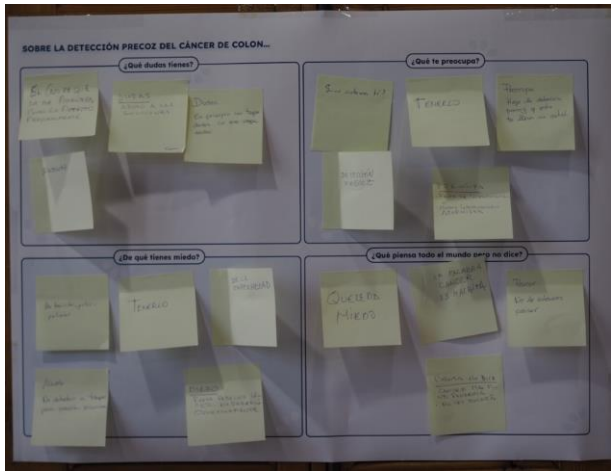
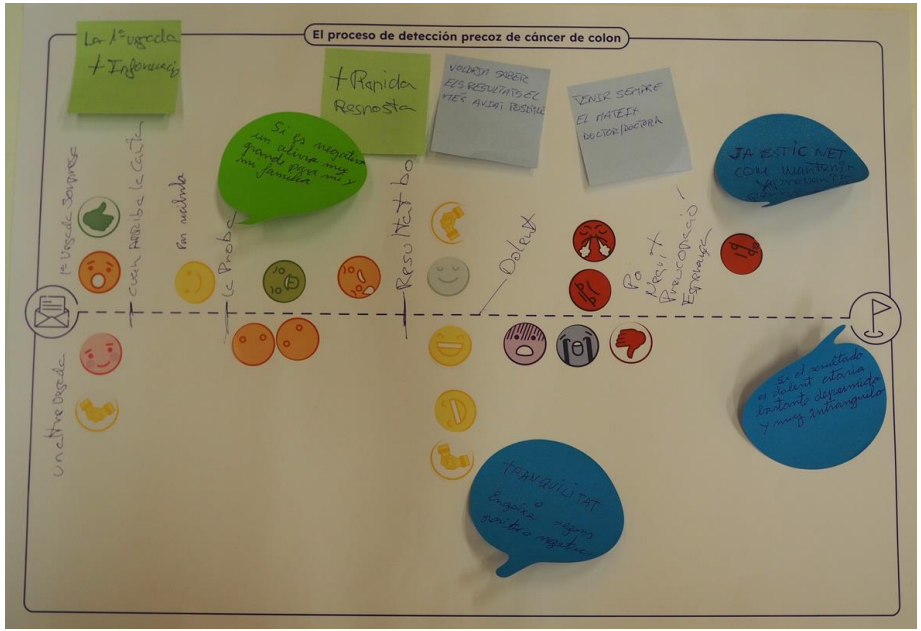
TaiRiS : some preliminary results



Ideas about CRC: stigma, bad luck, “quiet cancer”

CRC screening: good knowlege on how to participate, doubts about frequency and the validity of the tests, **no side effects nor harms identified**

TaiRiS : some preliminary results



Good knowledge about risk factors
CRC screening reduces risk of CRC

Risk communication should be direct and “optimistic”

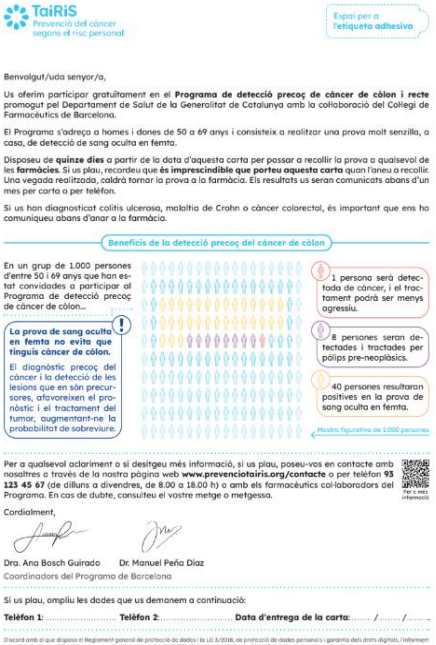
TaiRiS : some preliminary results

Mixed opinions about statistics representation in the materials, not too much at first but needed for those who want to know more or in later phase?

More information about benefits, and **less about side effects**

Overdiagnose not understood, not deemed relevant

TaiRiS : some preliminary prototypes



TaiRiS
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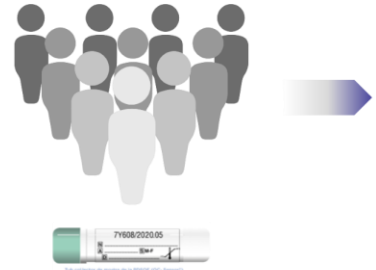
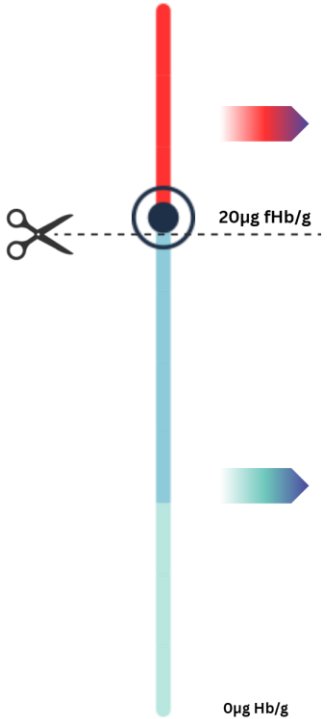
4.

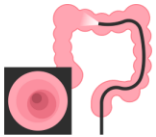
Feasibility evaluation of the tailored risk approach

The standard screening approach



1 FIT every 2 years

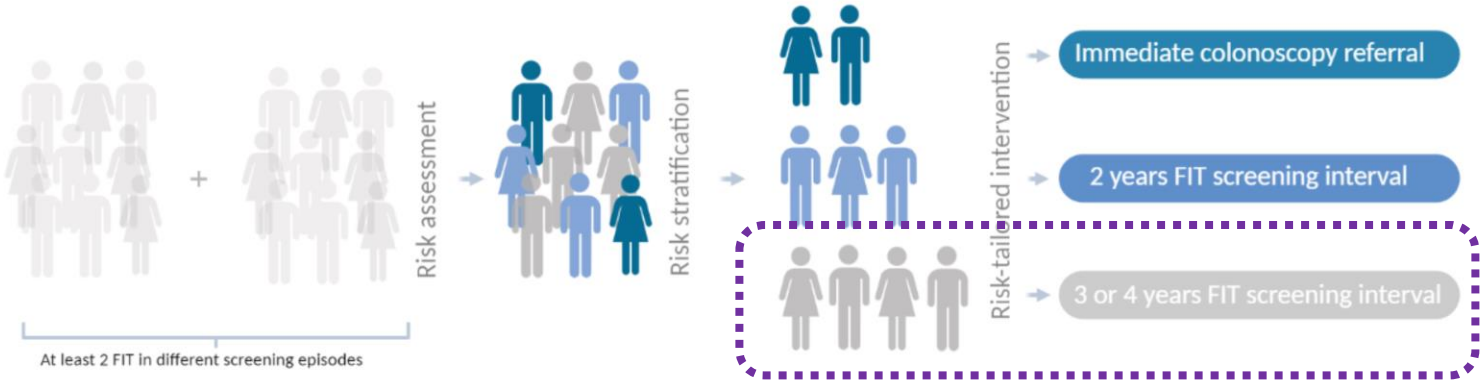




Inmediate colonoscopy referral

2 years FIT screening interval

A tailored screening approach based on neg-FITs



- High risk arm (HR, cumulative fHb ≥20µg Hb/g)
- Intermediate risk arm (IR, cumulative fHb between 3.8 µg Hb/g and 20µg Hb/g)
- Low risk arm (LR, cumulative fHb ≤3.8 µg Hb/g)

Personalization might be the screening strategy eventually

The tailored risk approach based on 2 neg FITs

- **Standard** (ongoing) screening approach: participants with fHb below the 20µg Hb/g cut-off are recommended a new FIT after 2 years and those with a fHb ≥ 20µg Hb/g are offered a total colonoscopy immediately.
- **Tailored screening** approach consists of recommending different screening interventions based on the risk according to the cumulative value of two consecutive negative FIT results:
  - **Low-risk arm** (LR, **cumulative fHb ≤ 3.8 µg Hb/g**): 3 or **4 year FIT interval**
  - Intermediate risk arm (IR, cumulative fHb between 3.8 µg Hb/g and 20µg Hb/g): 2 year FIT screening interval;
  - High-risk arm (HR, cumulative fHb ≥ 20µg Hb/g): immediate colonoscopy referral

Low risk neg FIT: standard vs tailored

- 5 screening rounds (2010-2019)
- Study population: participants with 2 neg FIT screening episodes and cumulative fHb ≤ 3.8 µg Hb/g, and another 2 consecutive screening episodes
- What would have happened if we did not invite them for their “3rd round”?
  - Resources: letters, FITs, nurse visits, colonoscopies (with and without biopsies)
  - Adenomas, CRC, interval cancer
  - Costs (based on Spanish literature)
- General assumptions for the “skipped round”: FIT positive and colonoscopy results stay the same or progress

Preliminary results

In comparison with the Standard approach, the tailored approach among those with Low risk results in:

- Aprox 50% less letters and FITs
- Decrease in nurse visits and colonoscopies much less (shift 2 years later)

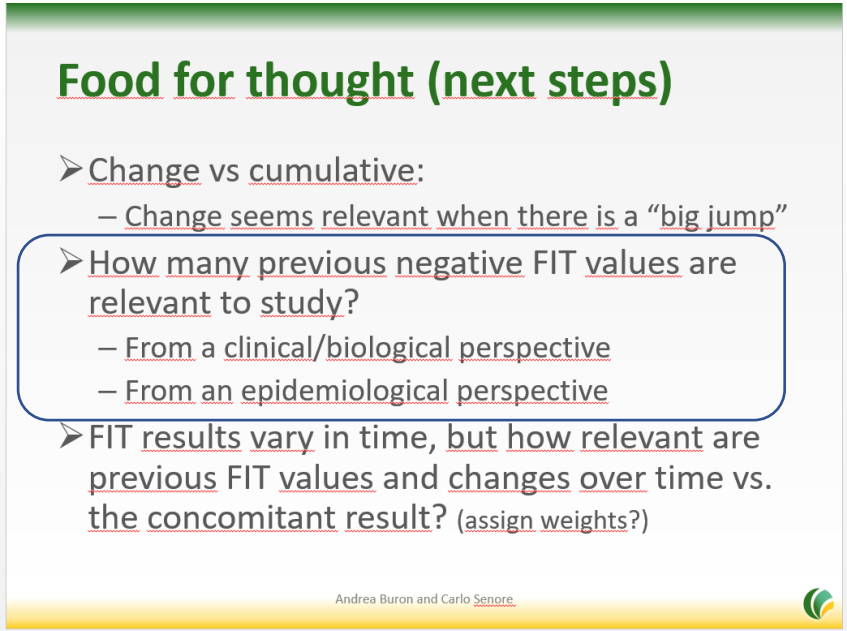
- Less pre-neoplastic lesions, BUT more advanced neoplasia

→ *increased cost* ?!

5.

Two vs 3 or 4 previous FIT negative results

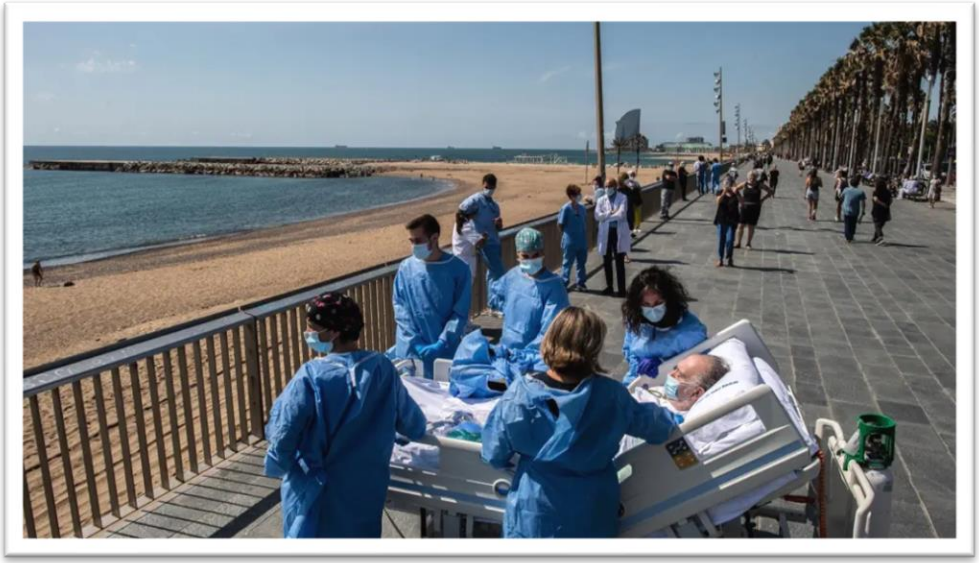
An unsawered question from 2019…



Added value of having a history of **3 or 4 negative FIT values** instead of only 2 in terms of **better predicting** the outcomes and adapting the screening intervals

Aims :

1. To describe the screening results of the 4th and 5th round of the PDPCCR-Bcn according to the previous combinations of results in the last 2, 3 and 4 rounds
2. To describe and compare different ways of measuring the history of FIT values (cumulative, average, categories?)
3. To describe and compare the accuracy of the prediction (precision) using 2, 3 and 4 rounds
4. To analyze the outcomes by age and sex



6. Conclusions and challenges

Conclusions

1. Opportunity of the **collaborations** between programmes and research groups with very similar protocols (and populations with “cultural” similarities)
2. **Individualised** screening offers a **great opportunity** to improve the “one for all” current screening approach, BUT
3. More insight needed into the actual **cost** and **potential savings**, as well into the **population’s opinions and needs to understand and accept it**

Challenges

1. Relevance of the research into individualised screening. Any change in the current evidence-based standard approach needs to come with good answers to relevant questions, and budget issues will be demanded
2. Population not always keen to changes, and sometimes suspicious
3. The low screening uptake rates should be a priority for the screening programmes, individualised screening has the potential to increase the inequalities
4. Individualised/personalised screening = personal choice ??

…based on focus groups with general population and communication experts on the use of masks and vaccines to prevent respiratory diseases :

"*People want to **know their risk** and then **make their own decisions based on their risks***"…

"risk knowledge as a form of empowerment"

Bhanu Bhatnagar

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Bhanu Bhatnagar is in charge of press and media relations for the WHO Regional Office for Europe, based in Copenhagen, Denmark. WHO/Europe is one of WHO's six regional offices, and covers 53 Member States across Europe and Central Asia, stretching from the Atlantic to the Pacific Oceans. His role involves leading WHO/Europe's media strategy and engagement, coordinating media events, advising senior leadership on media opportunities and reacting to reputational crises. Before joining WHO, Bhanu spent four years in communications roles at Save the Children, based in London and Bangkok. And prior to that, he worked as a journalist for ten years at Al Jazeera English, in London and Doha. Bhanu holds a Masters degree in Media & Communications from the London School of Economics and a Bachelor degree in Arts Management from the University of Greenwich.

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Thank you! Any questions?

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