Two-in-one FIT and HP Screening

Yi-Chia Lee, MD, PhD

National Taiwan University Hospital, Taipei, Taiwan

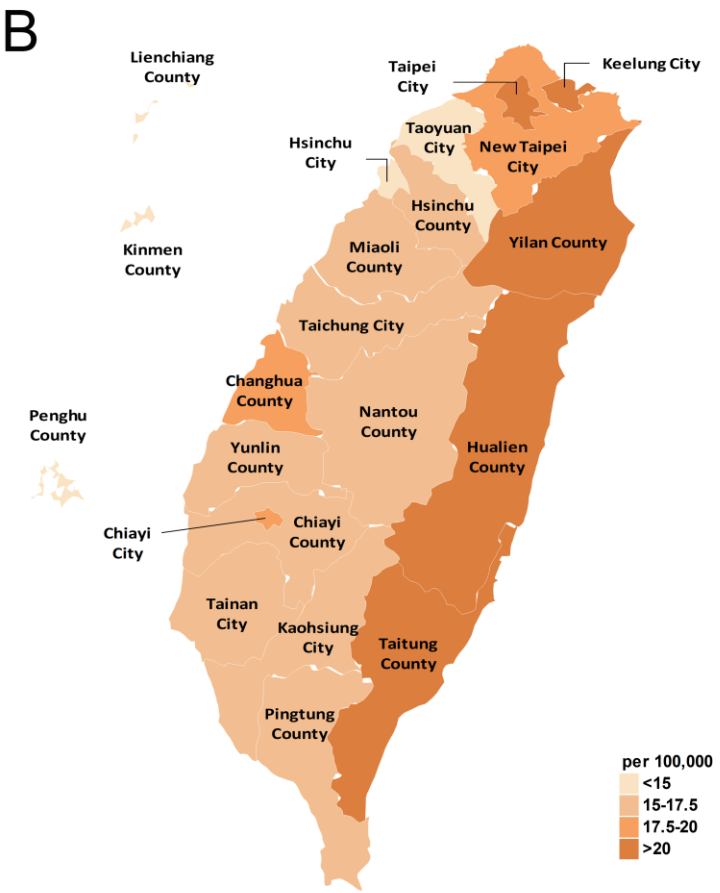
Contents

1. Need and readiness of implementing this strategy
2. The pragmatic RCT in Changhua County to prove the effectiveness
3. Cost-effectiveness analyses based on the trial
4. Conclusions and perspectives

1. Need and readiness of implementing this strategy

High-risk populations account for only a small proportion of the Taiwanese population; however, gastric cancer overall remains a significant public health threat. A systematic strategy is needed.

HP prevalence



GC crude rate

High-risk areas

- HP tends to be prevalent at a younger age.
- Familial transmission and aggregation.
- GC peaks around 65 years.

Intermediate-risk areas

- HP is often prevalent in the middle age.
- GC peaks around 70 years.

High risk communities

2004 Matsu Islands

N=14,000

≥ 30 of age
9 rounds of UBT screening (64% to 5%)
Proof of concept
Reducing GC incidence and mortality

2018 Indigenous communities

N=610,000

20-60 of age, extend to 20-74
55 townships
Screening with UBT for the minority groups
Establish the IT platform

2026 Healthcare policy

FIT >1,000,000 per year
HPSA 500,000 till now

A HPSA service screening after 2 year pilot
45-74 eligible for FIT

2014 HPSA on FIT screening

N=1,300,000

50-69 of age
A pragmatic RCT following 2 year pilot
To develop the strategy of HPSA and FIT co-testing
To inform policy making for the entire population

2024 NHI coverage

≥ 18 of age
Cover HP diagnosed by both non-invasive or invasive tests

Intermediate risk communities

All adult populations

2. The pragmatic RCT in Changhua County

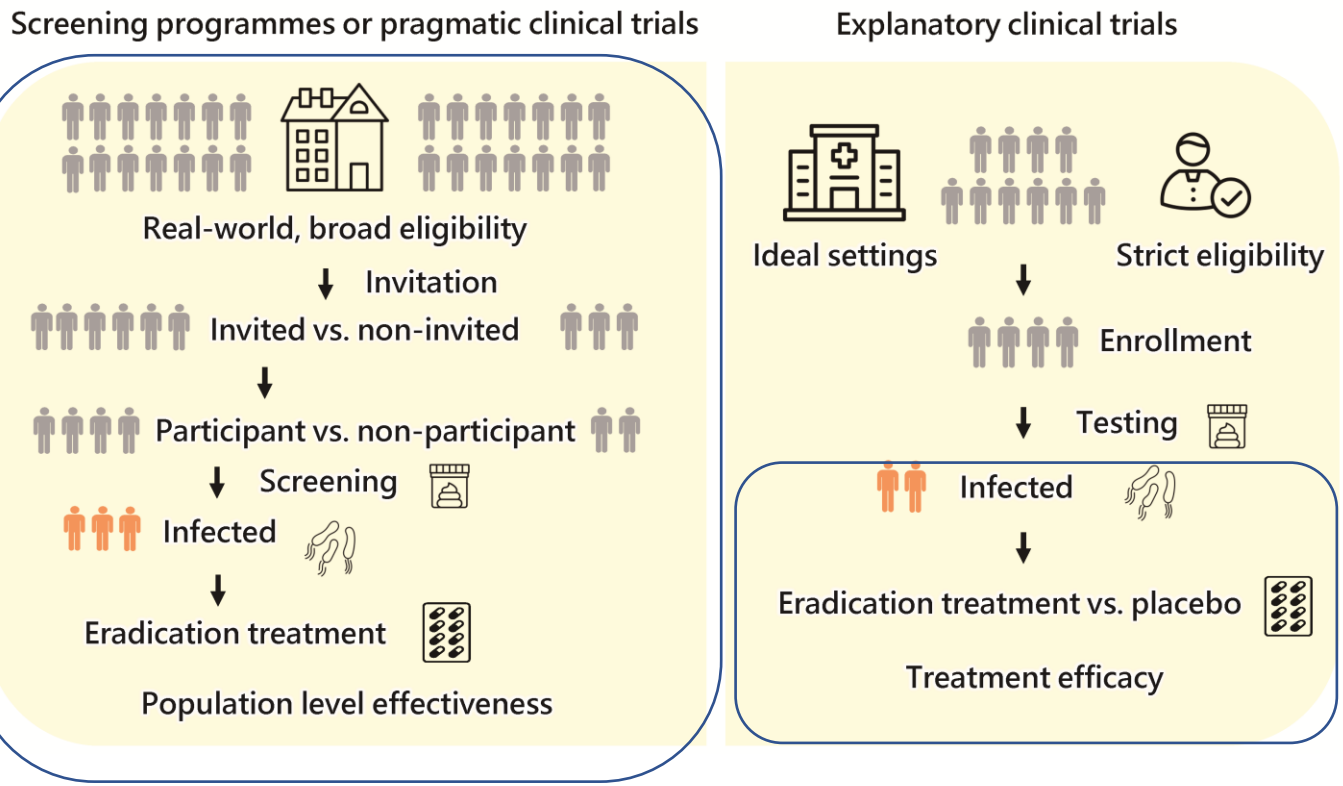
Hypothesis: Whether HP screen can reduce GC risk
Invitation to HP+FIT vs. FIT alone

- ✓ Provide additional benefit for stomach
- ✓ Optimize resource utilization
- ✓ Improve community participation

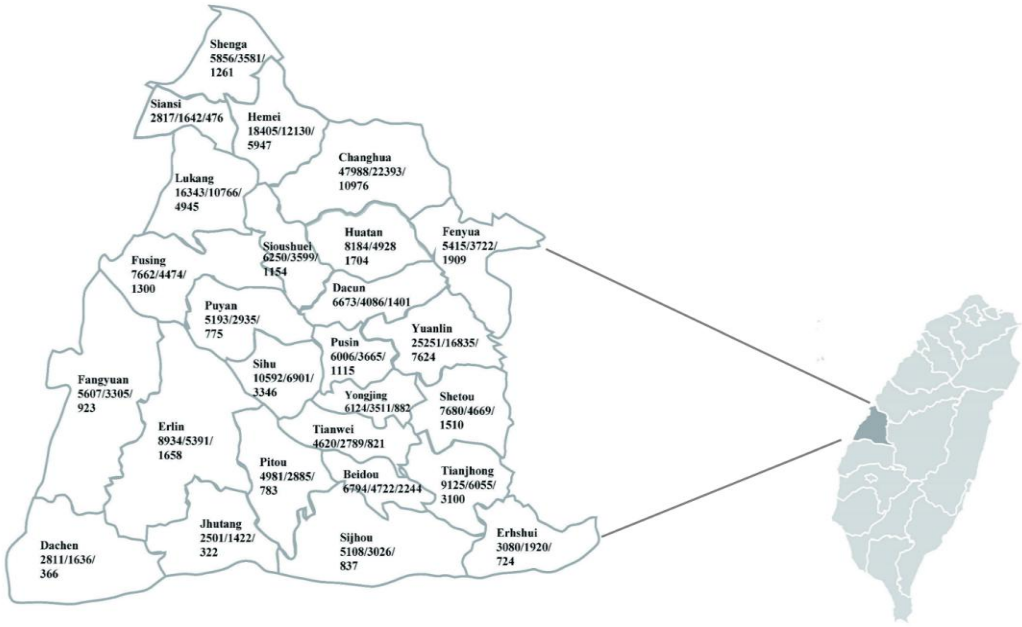
- Primary outcome:
  GC incidence and mortality
- Secondary outcome:
  CRC incidence and mortality
- Other outcome:
  Cost-effectiveness analysis

Pragmatic design

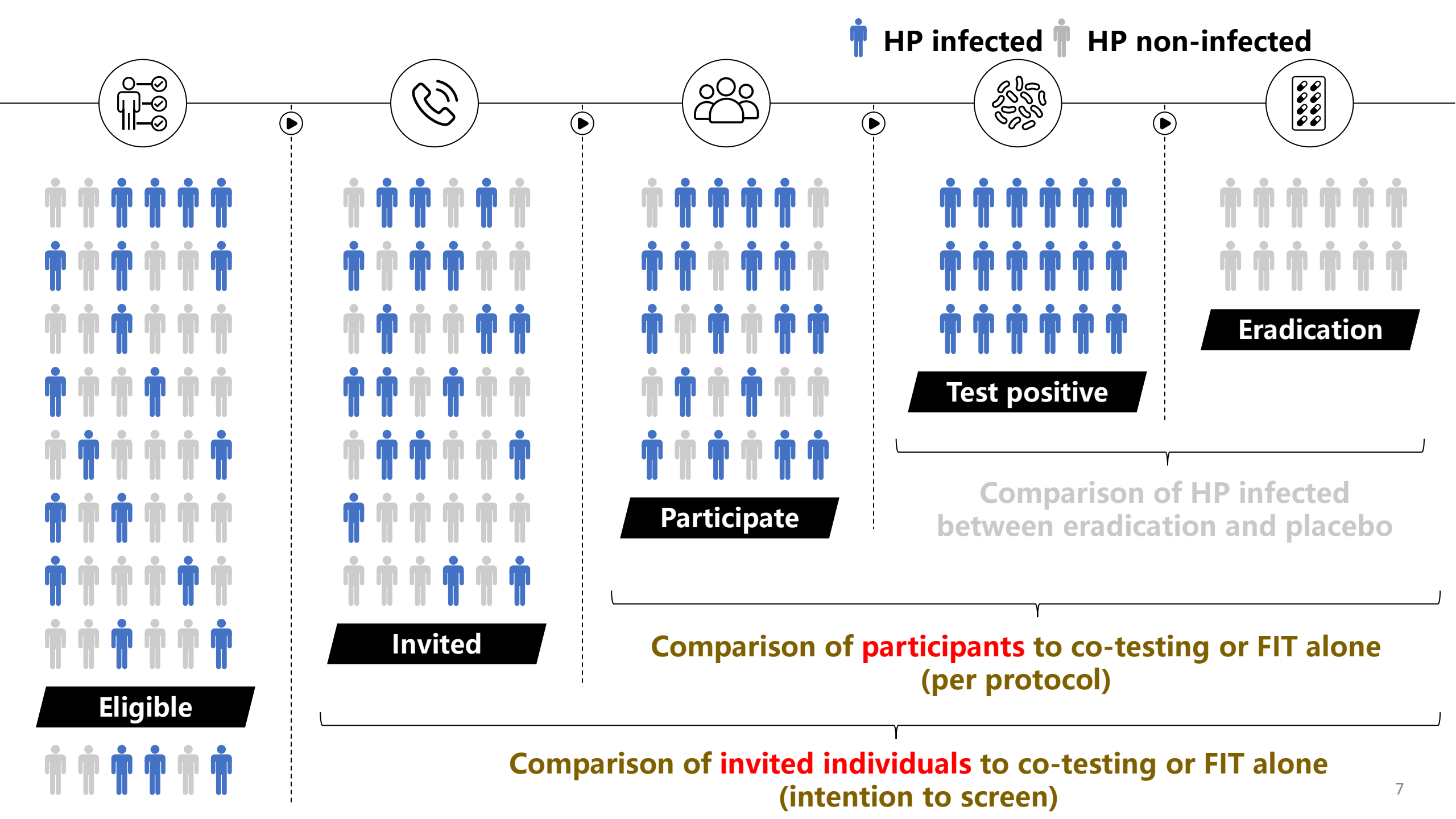
Real-world, broad eligibility to evaluate the population-level effectiveness



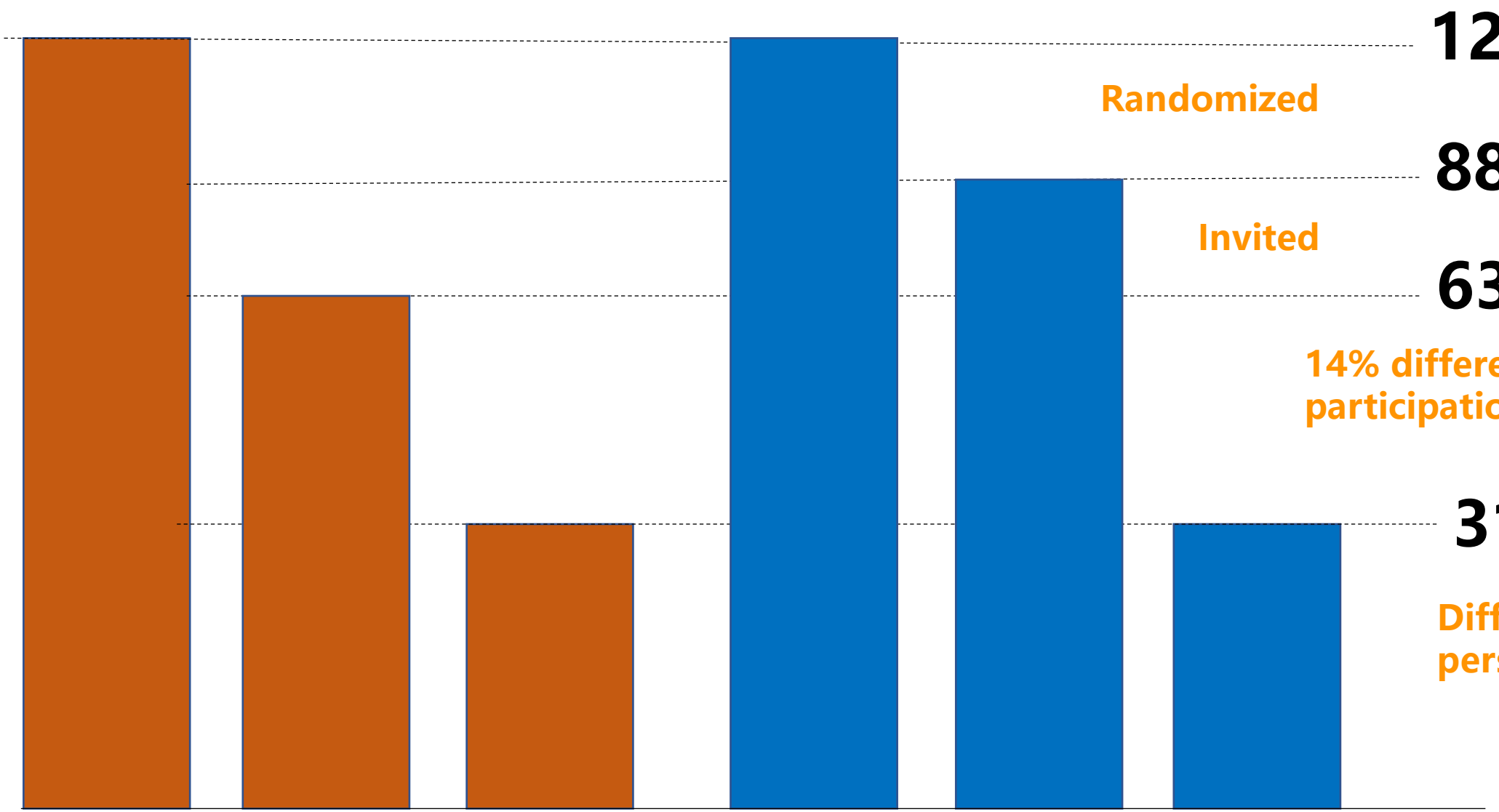
Study setting in Changhua County
269,870 list eligible for FIT in 2014
240,000 randomized to two groups



Taipei Global Consensus II. Gut. 2025;74:1767-1791.


HP infected
HP non-infected
Eligible
Invited
Participate
Test positive
Eradication
Comparison of HP infected between eradication and placebo
Comparison of participants to co-testing or FIT alone (per protocol)
Comparison of invited individuals to co-testing or FIT alone (intention to screen)

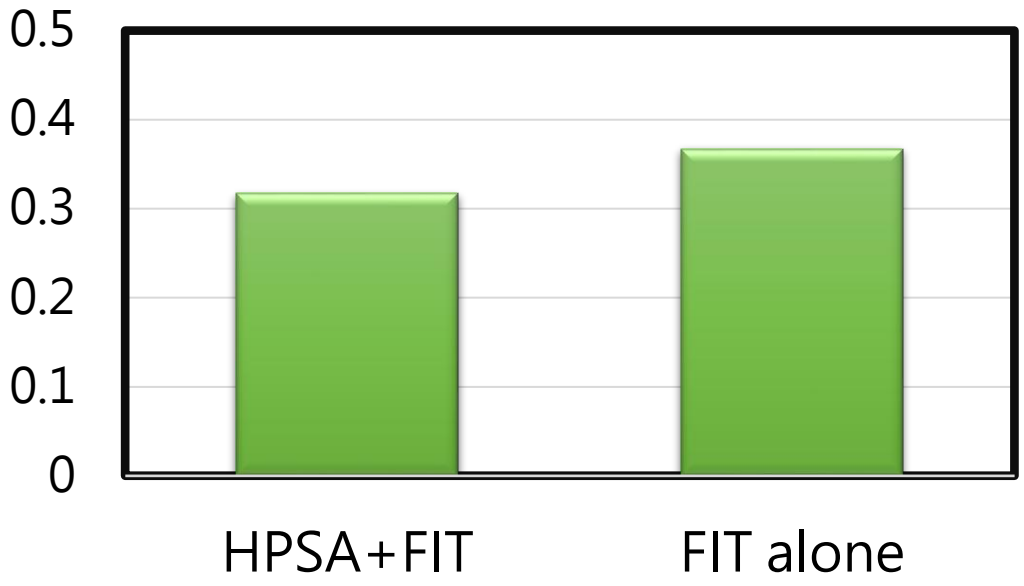
Randomized, Invited, & participated



Primary outcome: GC incidence (5.5 years)

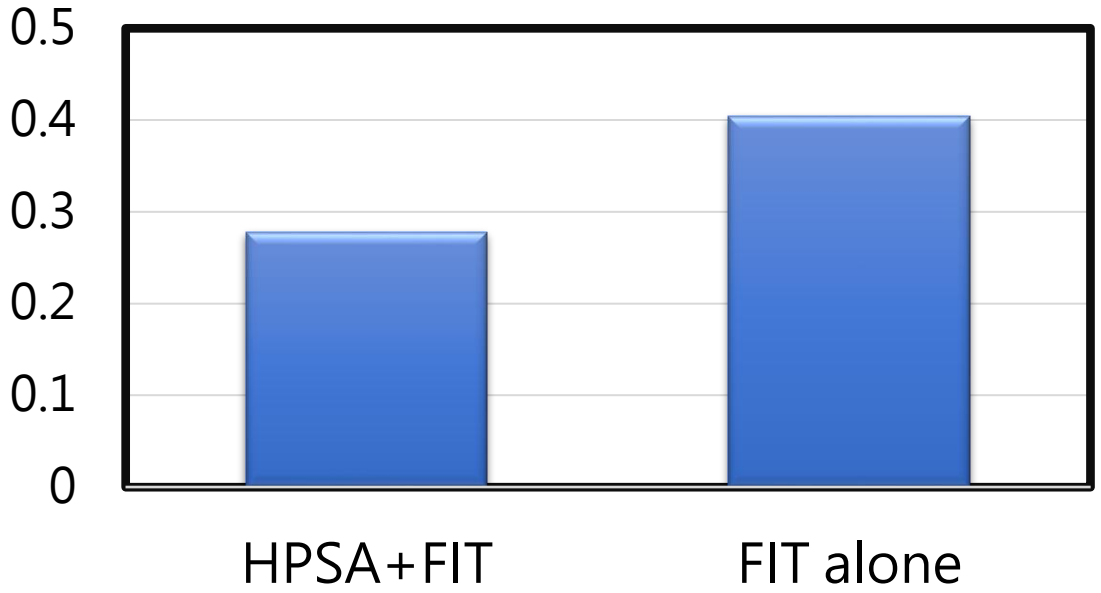
The change of GC incidence rate will be earlier than the mortality rate due to primary prevention.

Invited (per 1000)



Observed: 14%, non-significantly
Adjusted: reduced by 21% assuming the same adherence rate and risk factors, significantly

Participant (per 1000)

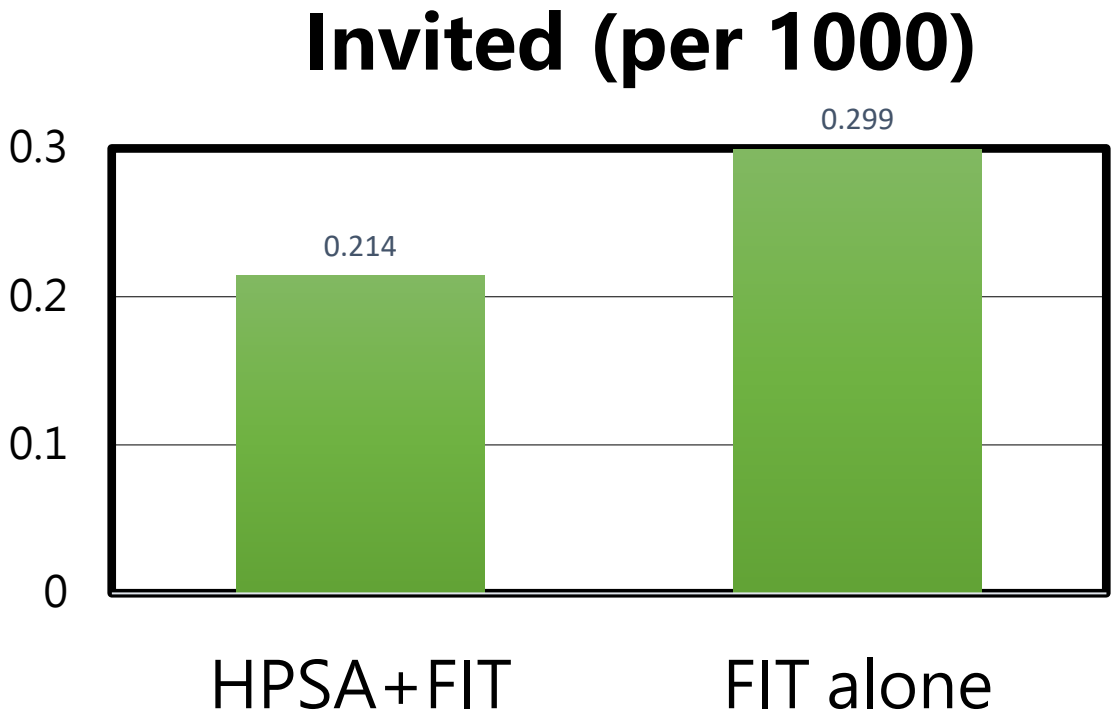


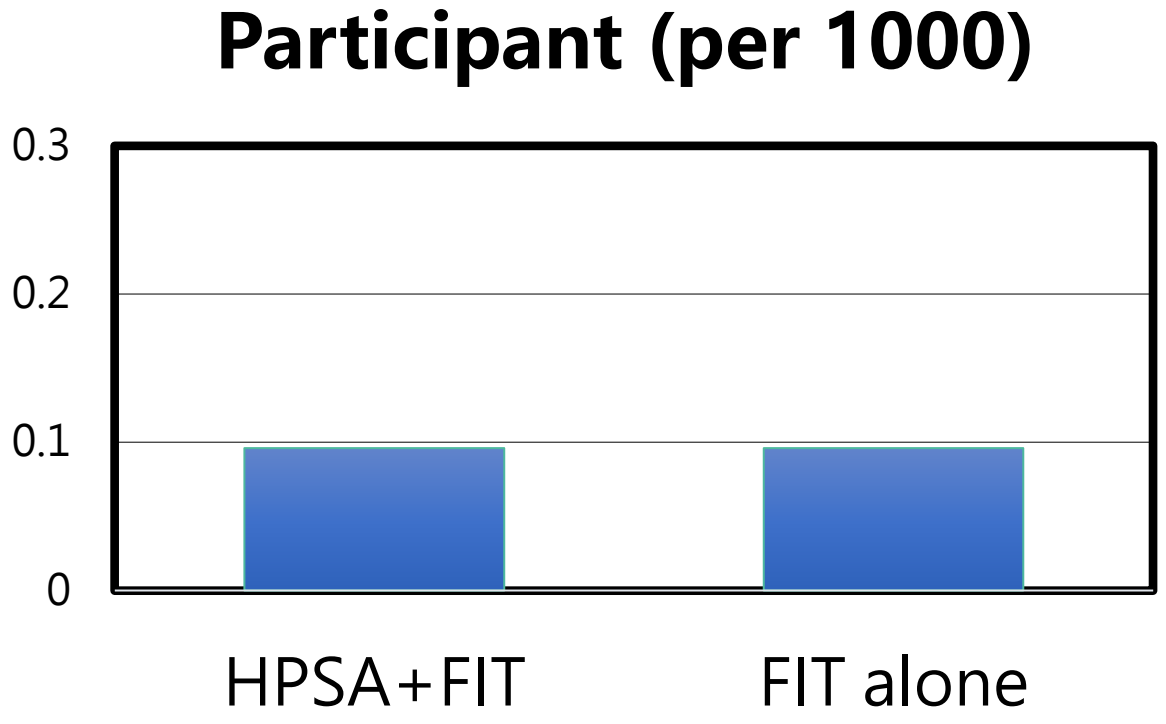
Observed: reduced by 32%, significantly
Adjusted: reduced by 42%, significantly

JAMA. 2024;332:1642-1651

Secondary outcome: CRC mortality

The change of CRC mortality rate will be earlier than the incidence rate due to secondary prevention





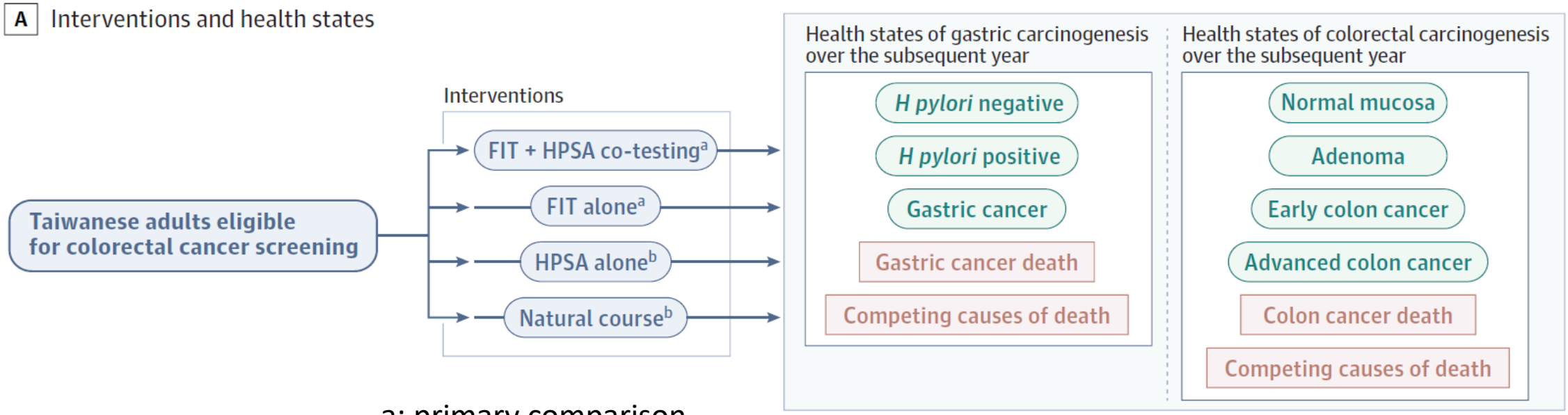
Observed: reduced by 28%, non-significantly
Adjusted: adjusted adherence and risk factors, results were similar

Two groups were similar for observed or adjusted analyses.

3. Cost-effectiveness analyses based on the RCT

Based on the trial results, the study projected the lifetime (50-80 years) health benefits and costs of invitation to 1-time HPSA added to biennial FIT screening compared with FIT alone.

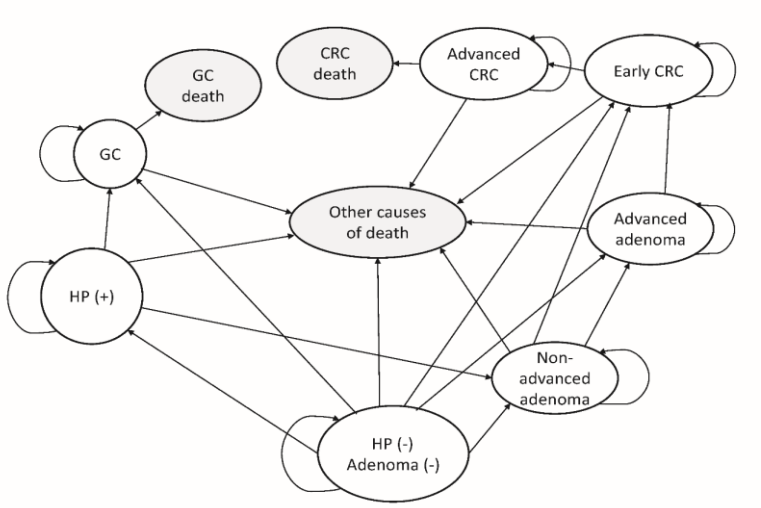
A Markov decision-analytic model was developed to compare different screening strategies

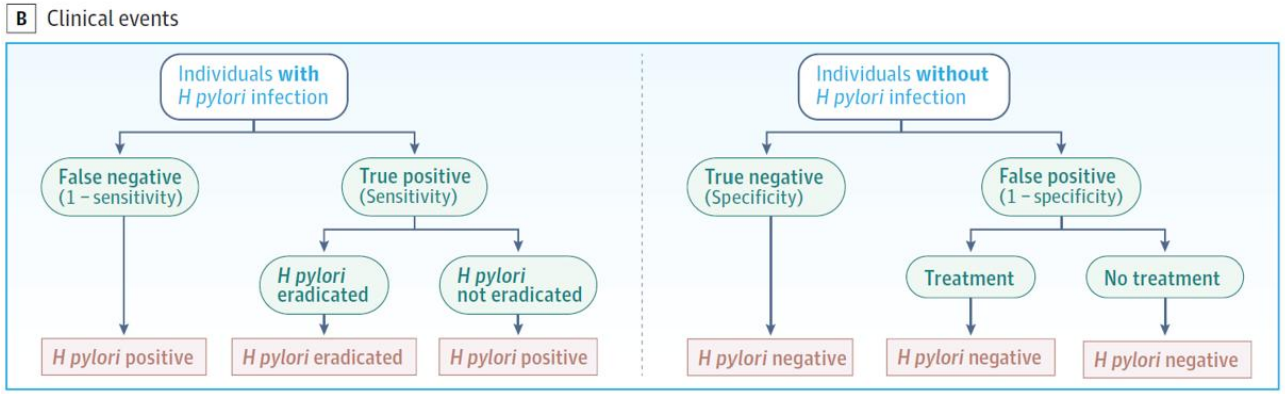


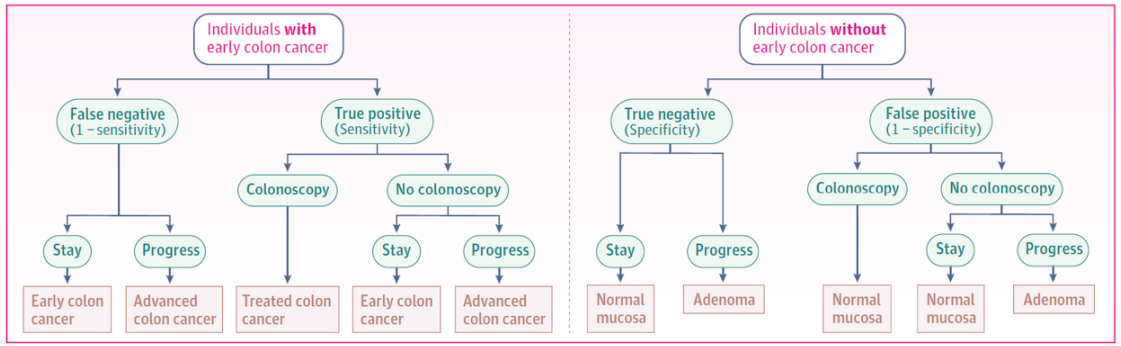
a: primary comparison
b: subsidiary comparison

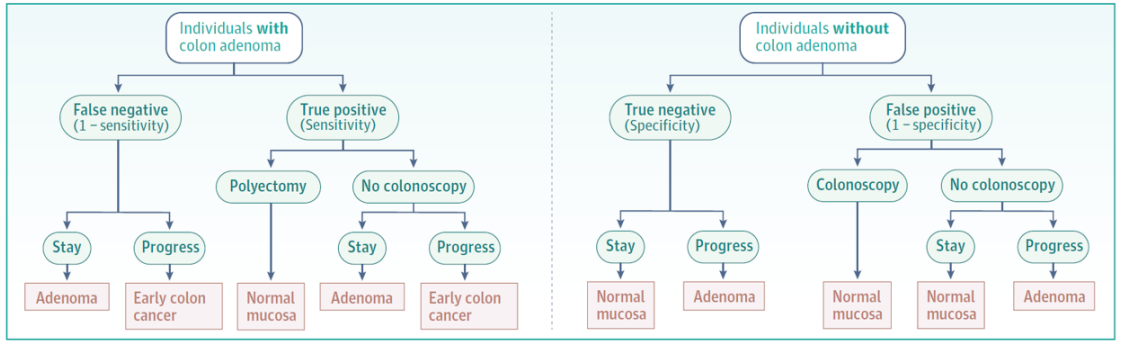
JAMA. 2026 Jun 1. doi: 10.1001/jama.2026.6908

An integrated GC and CRC decision tree model









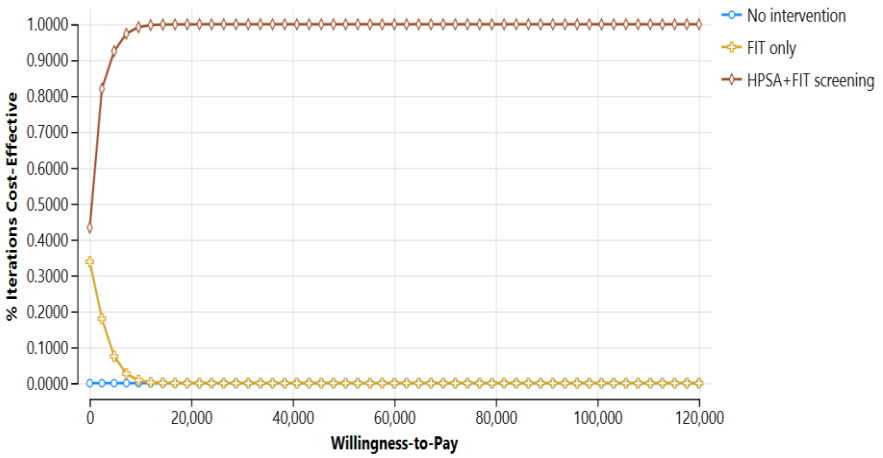
Individuals with *H. pylori* infection undergoing HPSA may have true-positive or false-negative results. They may receive eradication therapy or not.

Individuals with or without colorectal neoplasms who receive FIT or subsequent colonoscopy along the adenoma-carcinoma sequence.

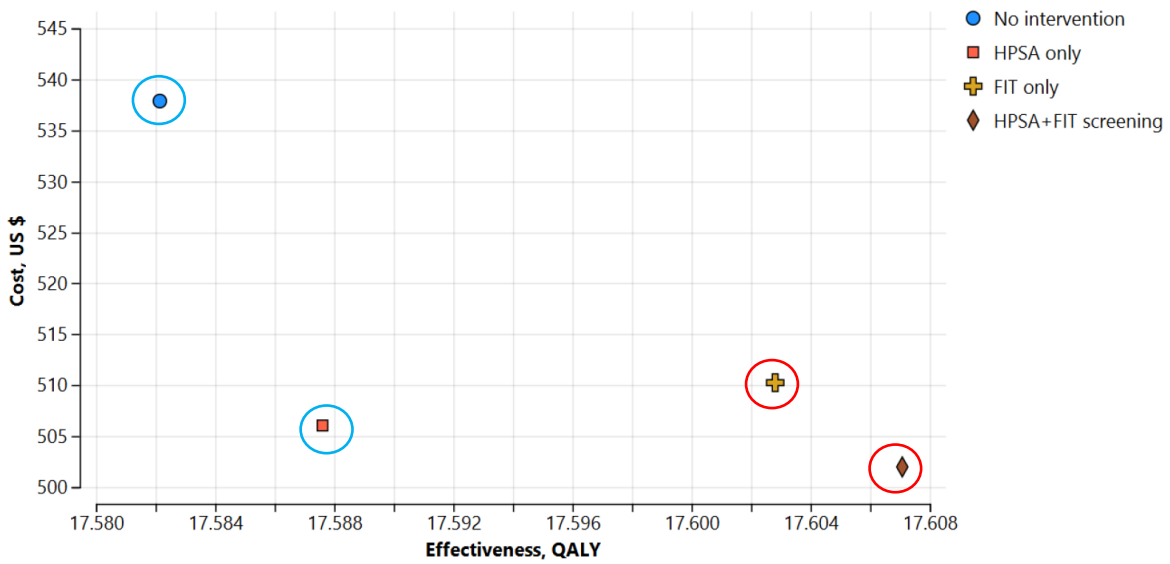
Results

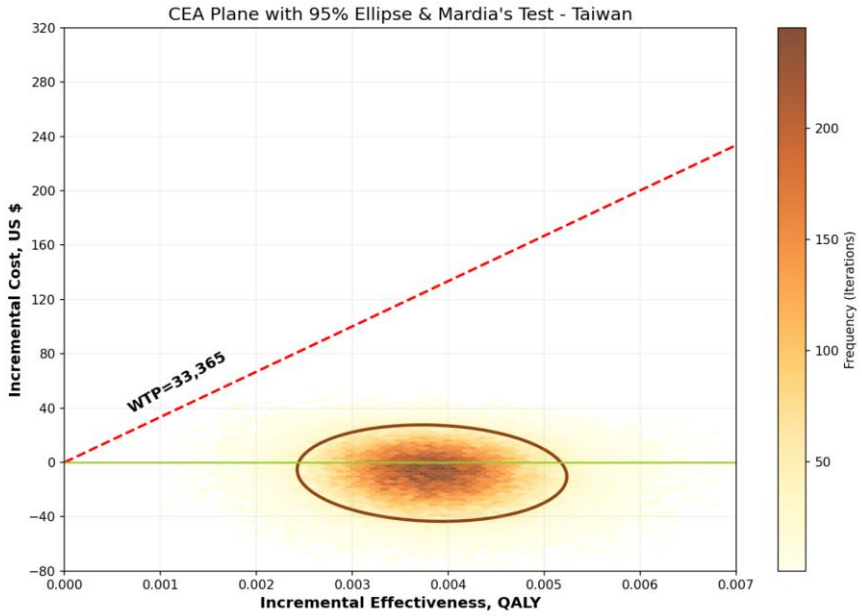
- Co-testing was cost saving compared with FIT alone.
- Co-testing, FIT alone, and HPSA alone were all cost saving compared with no screening.
- Invitation to co-testing for HPSA in addition to FIT was cost-saving in 66% of 100,000 simulations and cost-effective in the remaining 34% compared with FIT alone.

Acceptability curve analysis



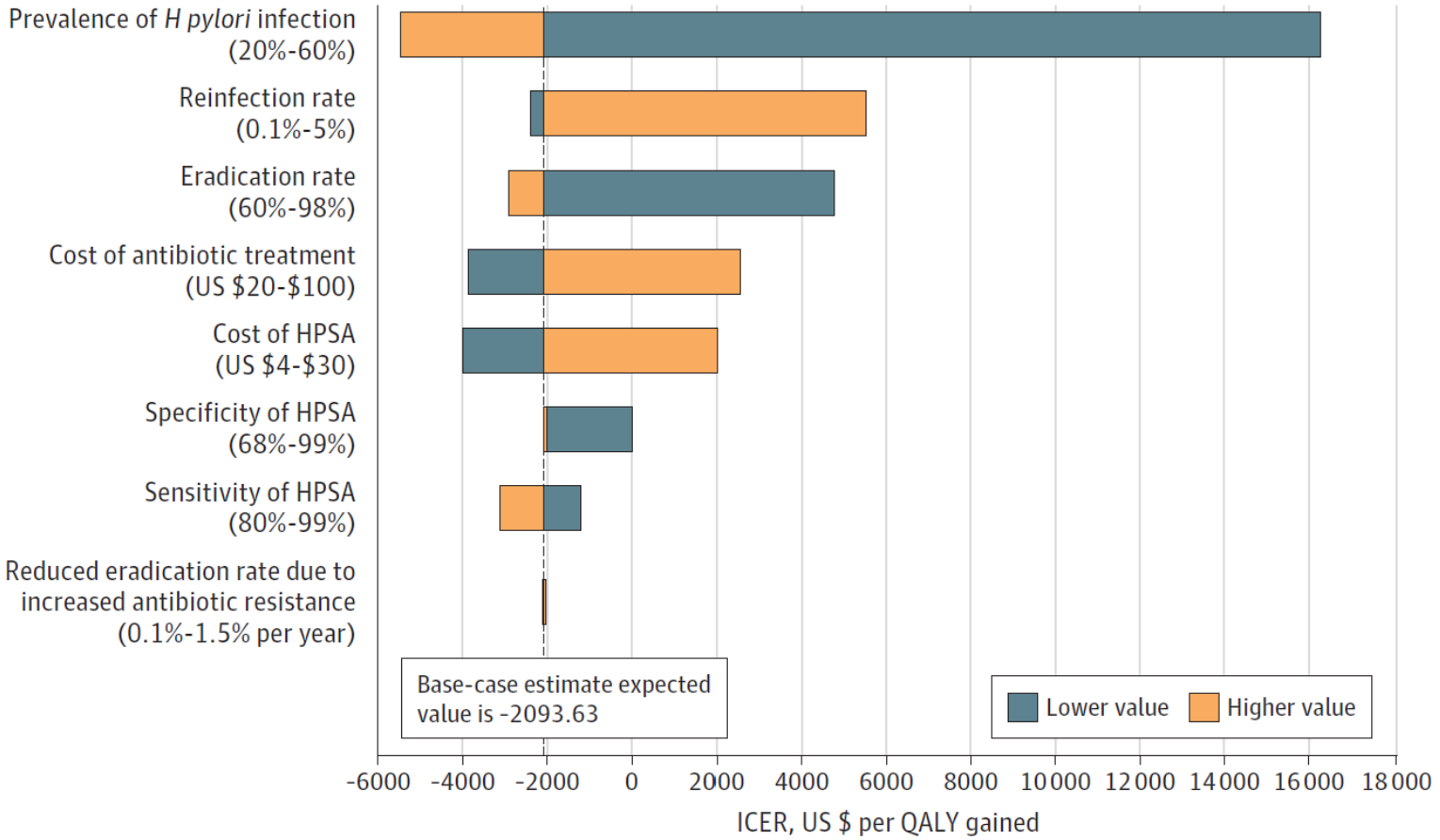
Cost-effectiveness plane





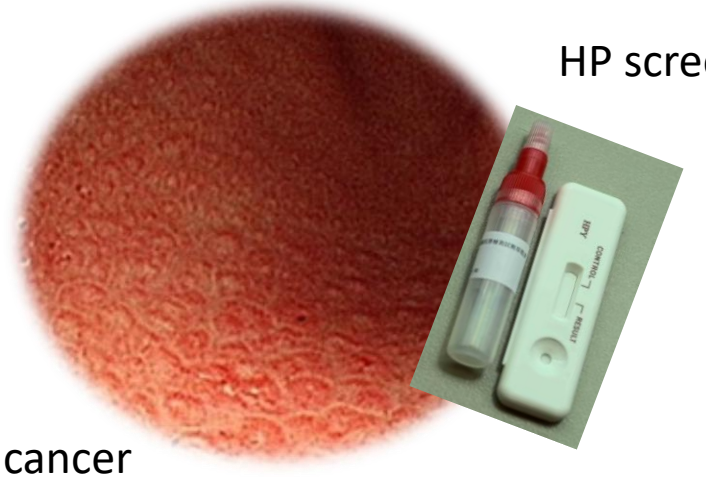
Sensitivity analyses

The most influential variables are the prevalence of HP, the eradication and reinfection rates, and the costs of antibiotics and the HPSA.

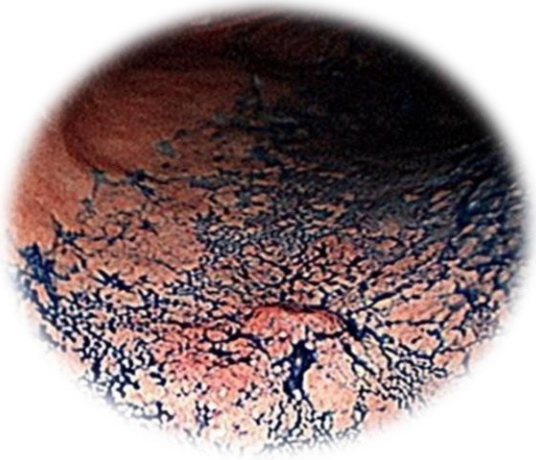


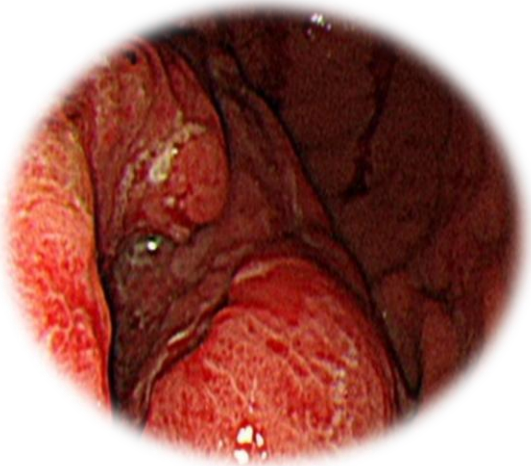
- Resource allocation should be guided primarily by the prevalence of HP infection
- The co-testing would be no longer be lost-saving compared to FIT alone if the prevalence dropped below 33% and the ICER will exceed the 33365 per QALY gained when the prevalence fell blow 17%.
- In high cost setting, the co-testing would remain cost-effective if the prevalence rate was lower than 21.9% given the WTP of 100,000 per QALY.

When to start GC prevention vs. CRC screening?



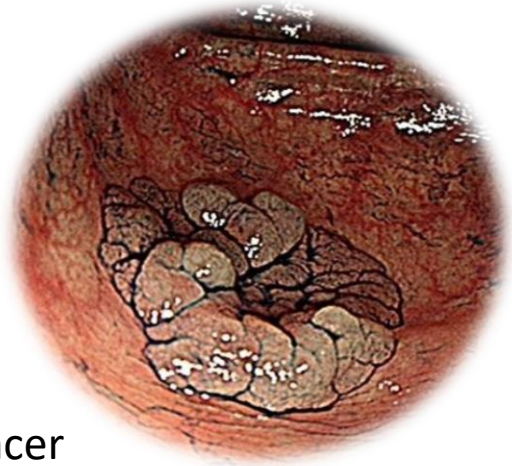
HP screening



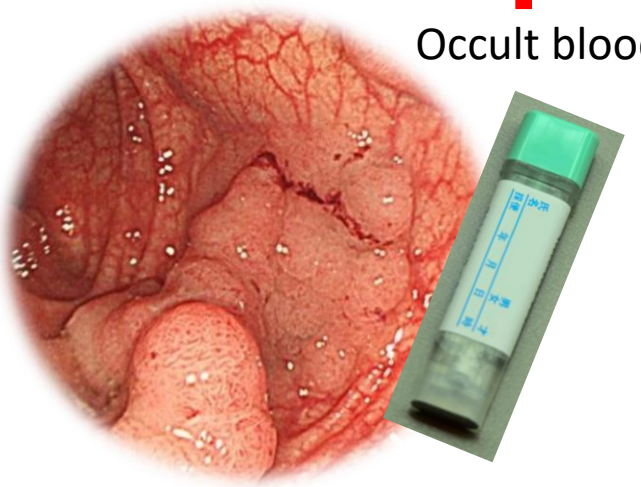


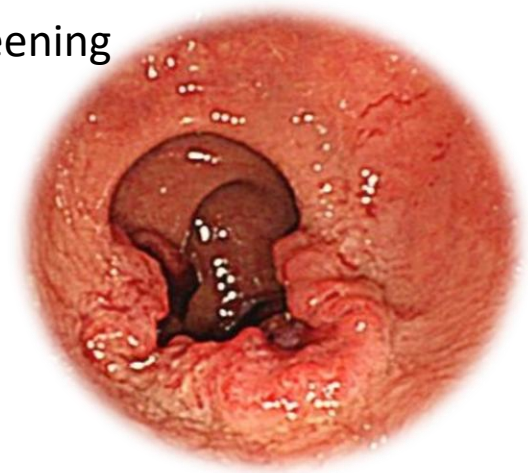
Gastric cancer

Carcinogenesis **Early cancer** **Advance cancer**



Occult blood screening

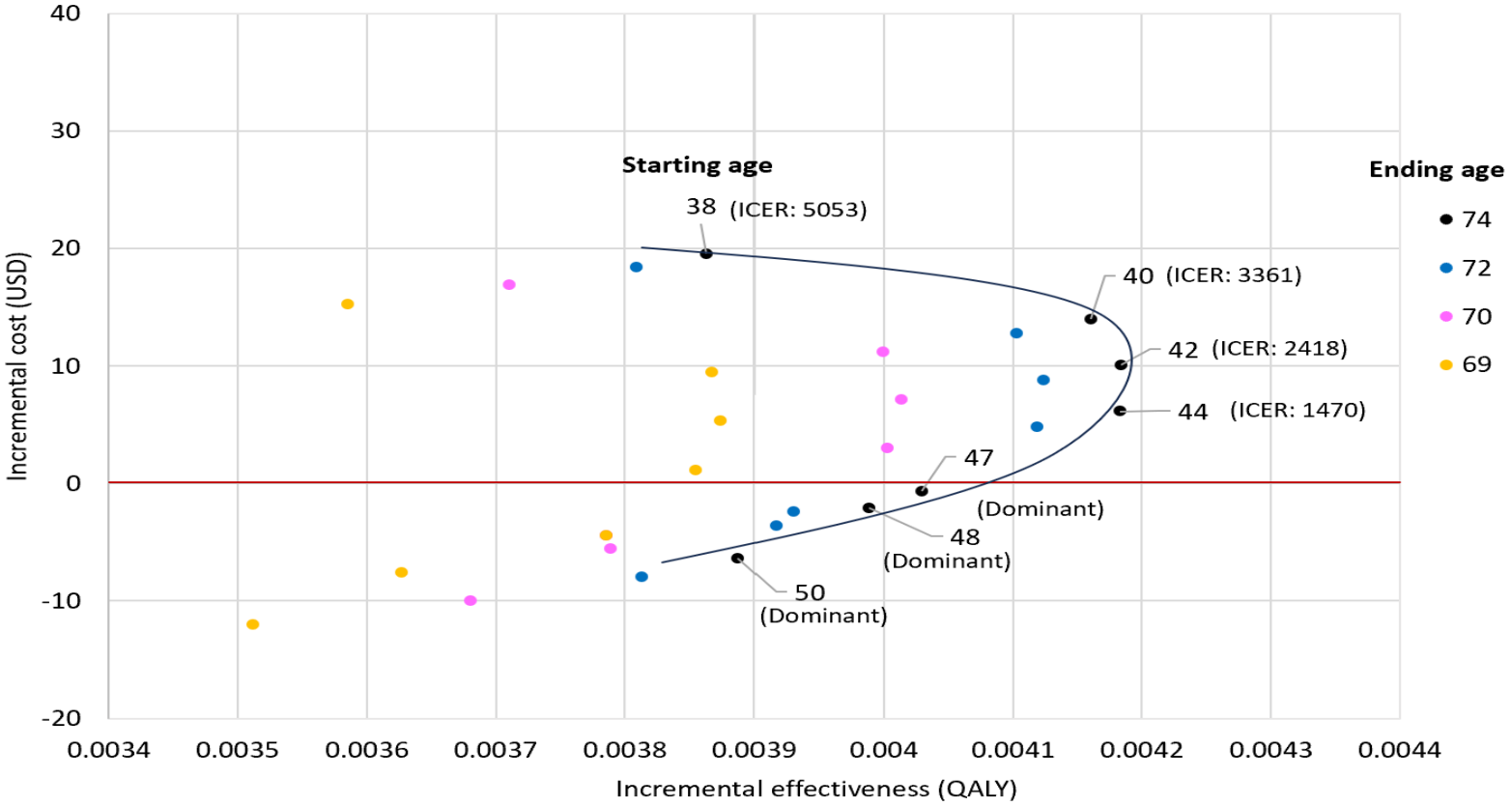




Colon cancer

Starting and ending age trade-offs

- HPSA provided primary prevention through eradication of *H. pylori* before malignant transformation, with stronger benefits at younger ages.
- FIT provided secondary prevention by detecting existing colorectal cancer, more beneficial at older ages.
- Younger age is associated with lower *H. pylo*ri prevalence.



Co-testing vs FIT alone

- Initial age between ages 40-50 increased the lifetime benefit.
- Continuing to age 74 years was more effective than stopping at age 69 years.

2012 Pilot

- To demonstrate proof of concept (7,630 participants)
- To optimize the screen and treatment

IARC WGR, 2014. Helicobacter pylori eradication as a strategy for preventing gastric cancer

2014 RCT

- To enroll 30,000 participants for both groups
- 63,508 invited for co-testing
- 88,995 invited for FIT alone

Gastroenterology. 2021;160:2159-2161

2023 Effectiveness

- To evaluate the outcomes after about 5.5-years FU in 2020, linked with cancer/death registries

JAMA. 2024;332:1642-1651.

2026 CEA

- Cost effectiveness analyses support the strategy

JAMA. 2026 Jun 1. doi: 10.1001/jama.2026.6908.

2027 Final evaluation

- Outcome evaluation till the end of 2025 (about 10 years of FU)
- Who should undergo additional endoscopy
- Service screening in 2026