The University of Melbourne acknowledges the Aboriginal and Torres Strait Islander Traditional Custodians of the land on which this research was conducted in Australia. The research team pay respect to their Elders, past and present, and emerging.

CRISP: DEVELOPING A COLORECTAL CANCER RISK PREDICTION TOOL FOR USE IN PRIMARY CARE

An example of the MRC Framework for Developing and Evaluating Complex Interventions

JENNIFER MCINTOSH[1] , MARK JENKINS[1] , SIBEL SAYA[1] , PATTY CHONDROS[1] , SHAKIRA MILTON[1] , LYNDAL TREVENA[2] , JAMES DOWTY[1] , GEORGE FISHMAN[3] , GRACE KIM[1] , PETER NGUYEN[1] , FIONA WALTER[4] , INGRID WINSHIP[5] , FINLAY MACRAE[5] , ADRIAN BICKERSTAFFE[1] , MARIE PIROTTA[1] , LOUISA FLANDER[1] , JON EMERY[1]

[1] THE UNIVERSITY OF MELBOURNE, MELBOURNE, AUSTRALIA. [2] THE UNIVERSITY OF SYDNEY, SYDNEY, AUSTRALIA. [3] CONSUMER, MELBOURNE, AUSTRALIA. [4] QUEEN MARY UNIVERSITY, LONDON, UNITED KINGDOM. [5] MELBOURNE HEALTH, MELBOURNE, AUSTRALIA

OR: TEN YEARS IN TEN MINUTES

WHY DEVELOP A COLORECTAL CANCER RISK TOOL IN PRIMARY CARE?

- **Bowel cancer incidence in Australia is persistently high**[1]
- **Screening in Australia is not always risk based**
  - Average risk people are not doing the FIT test[2,3]
  - Many having colonoscopic screening instead,
  - Too few people at increased risk are not having colonoscopies[4]

1 Globocan http://gco.iarc.fr/today; 2 www.cancerscreening.gov.au; 3 AIHW. NBCSP: monitoring report 2012-2013; 4 Ait Ouakrim, *et al*. Cancer Prev Res 2012. 5(2): 240-247

AIMS

To increase ‘risk-appropriate’ screening using a CRC risk prediction tool in general practice

Centre of Research Excellence: Optimising Screening for Colorectal Cancer

THE MRC FRAMEWORK[5,6]

CRISP program of research

Development

Identified evidence

1. Systematic review
2. Developed risk model

2. Expert consensus

CRE Centre of Research Excellence: Optimising Screening for Colorectal Cancer

5 Fitzpatrick, *et al*. BMJ 2000 321(694); 6 Craig, *et al* BMJ 2008 337(a1655)

THE MRC FRAMEWORK[5,6]

Feasibility and piloting

1. Built prototype
2. Acceptability and feasibility in general practice
3. Preliminary trial

Development

Identified evidence

1. Systematic review
2. Developed risk model

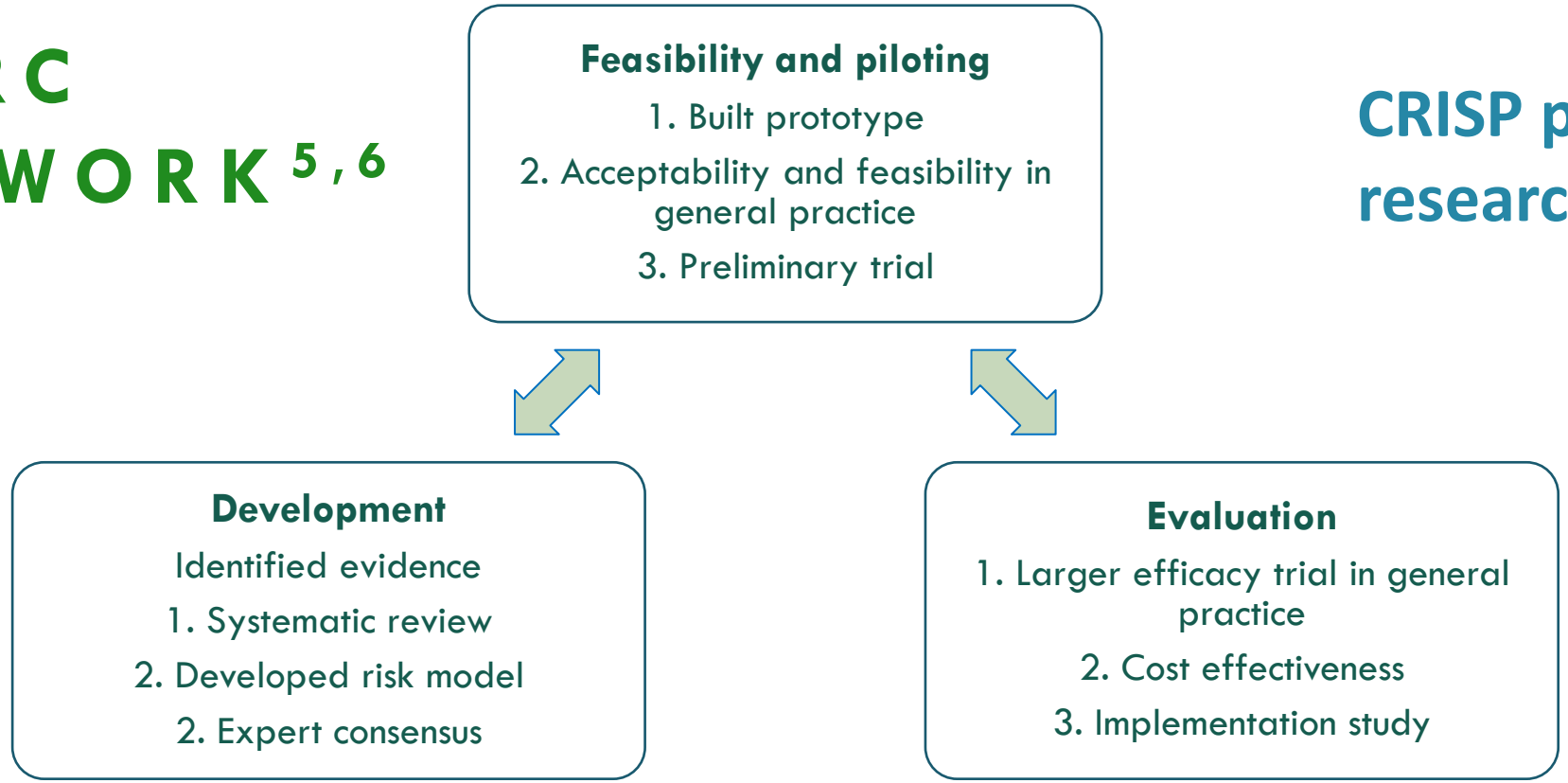
2. Expert consensus

CRISP program of research

Centre of Research Excellence: Optimising Screening for Colorectal Cancer

5 Fitzpatrick, *et al*. BMJ 2000 321(694); 6 Craig, *et al* BMJ 2008 337(a1655)

THE MRC FRAMEWORK[5,6]

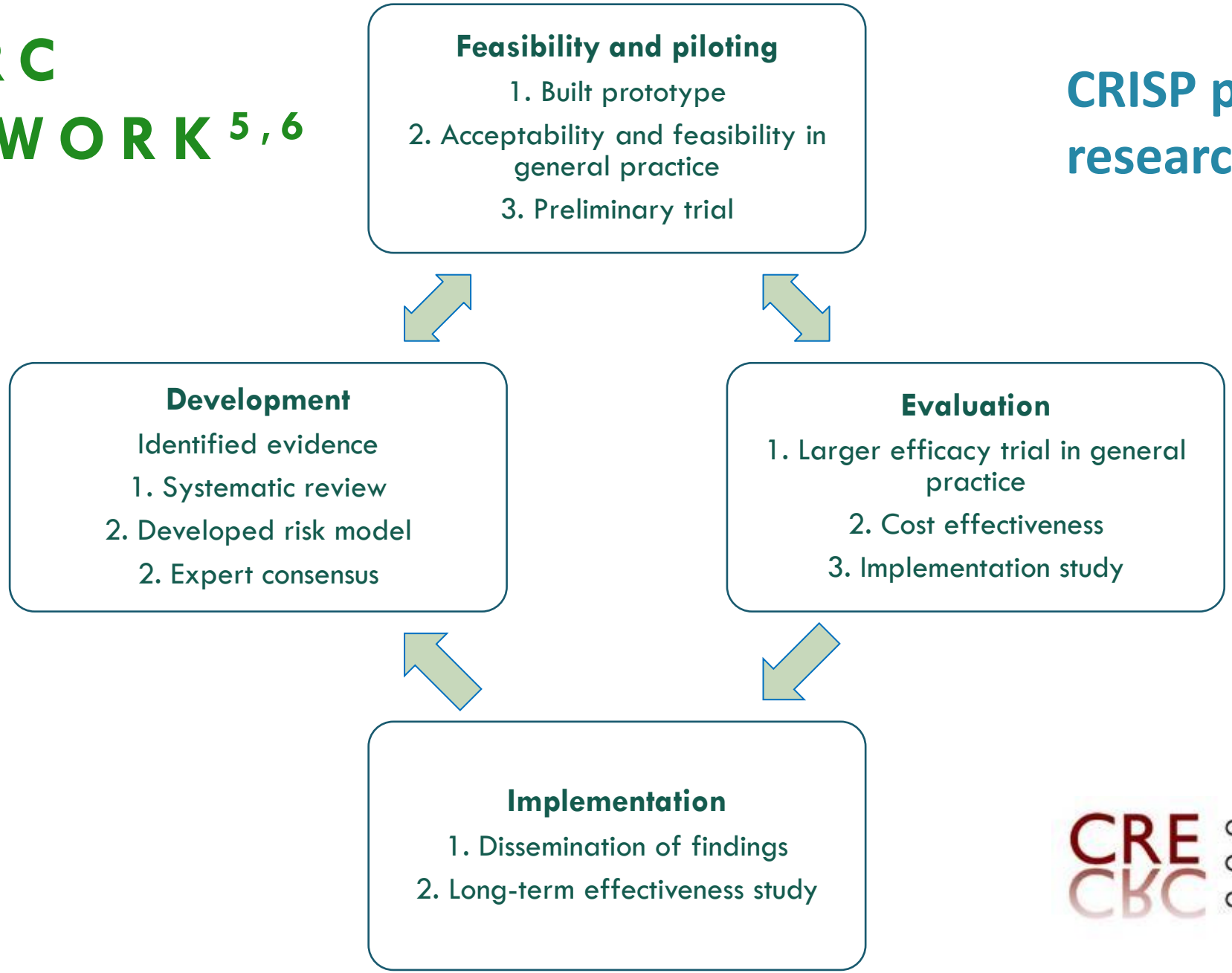


CRISP program of research

CRE CRC Centre of Research Excellence: Optimising Screening for Colorectal Cancer

5 Fitzpatrick, *et al*. BMJ 2000 321(694); 6 Craig, *et al* BMJ 2008 337(a1655)

THE MRC FRAMEWORK[5,6]

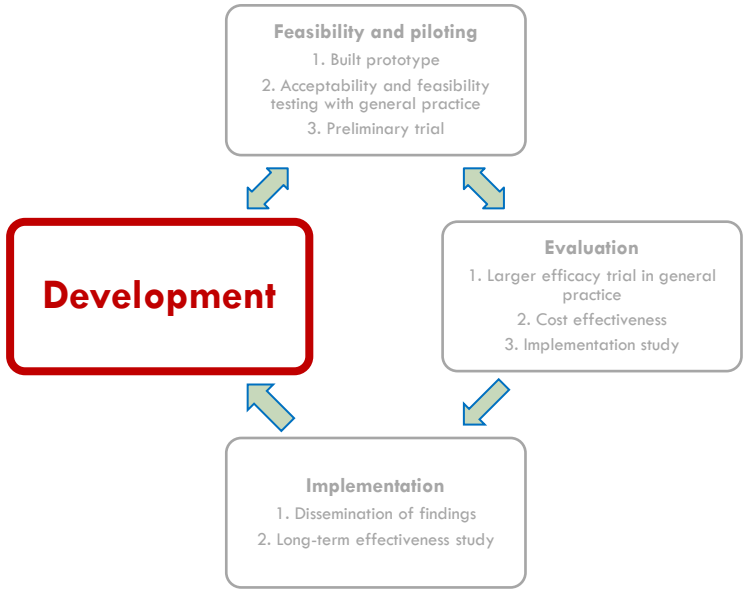


CRISP program of research

CRE CRC Centre of Research Excellence: Optimising Screening for Colorectal Cancer

5 Fitzpatrick, *et al*. BMJ 2000 321(694); 6 Craig, *et al* BMJ 2008 337(a1655)

Development: building CRISP



Evidence-based risk tool development

1. Systematic review of risk tools in primary care
2. Development of risk model
3. Expert consensus

Development: cancer risk tools in primary care

1. Systematic review of cancer risk tools in primary care[7]

- Limited evidence for improving screening behaviour
- Tool use increased if:
  - initiated by patient,
  - used by a dedicated clinician,
  - included health promotion and decision support

7 Walker (McIntosh), *et al* Ann Fam Med 2015 13

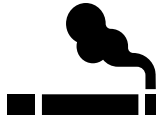
Development: the CRISP risk model

2. Development of CRISP risk model [8,9]

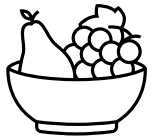
Age

Sex

BMI

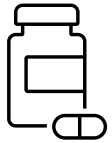


Smoking



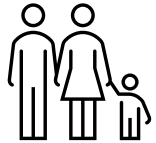
Fruit

Red meat



Medication
(NSAIDS, $Ca2^{+}$, HRT)

Screening history

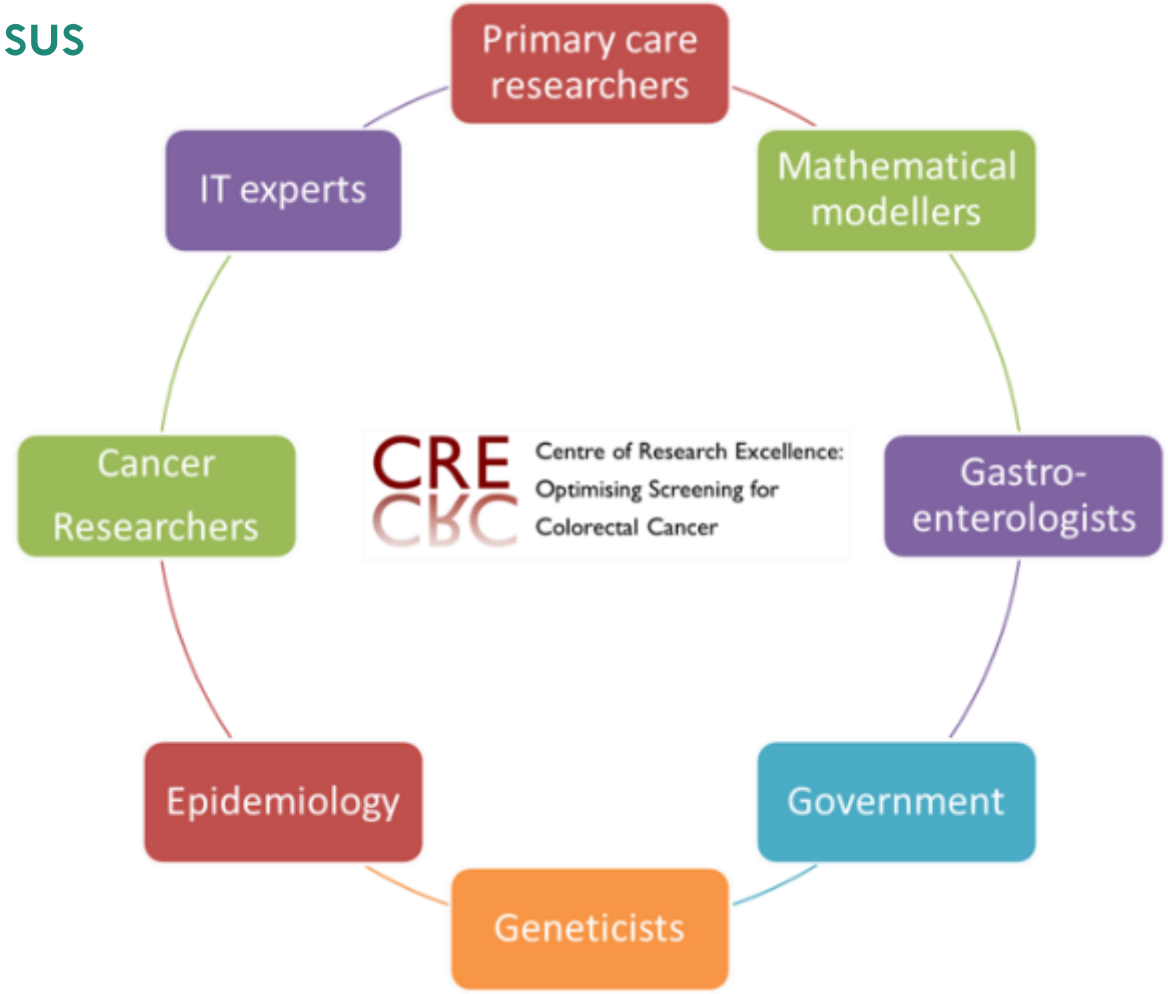


Family history

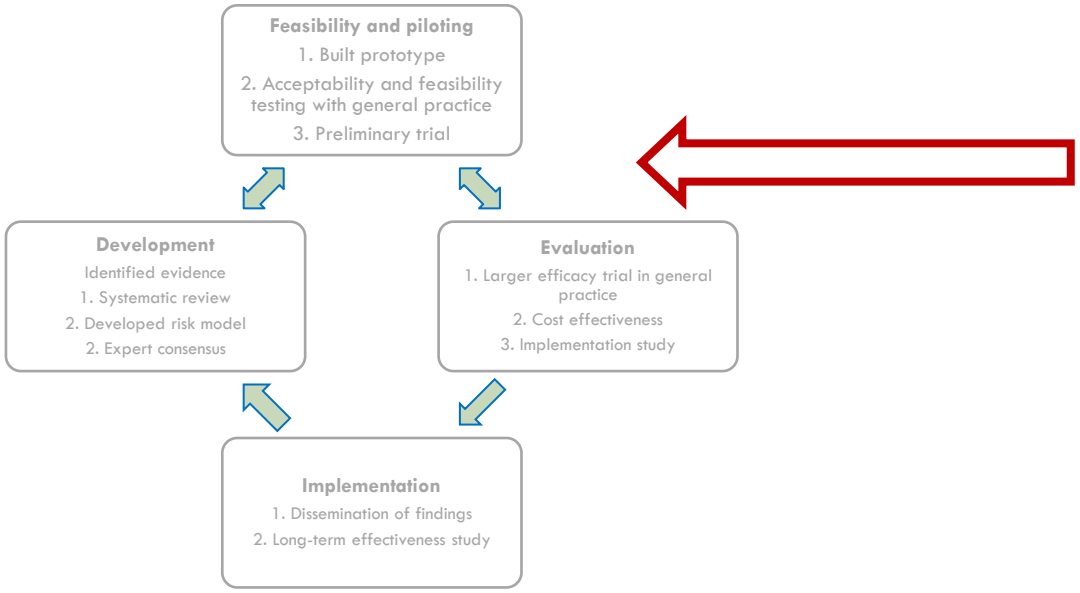
8 Freedman, *et al* JCO 2009 27(5):P. 686-6933; 9 Zheng, *et al* Cancer Epidemiol Biomarkers Prev 2020 29(3)

Development: a multidisciplinary team

3. Expert consensus



Additional study: Risk communication



'CRISP-Q'

Risk communication: 'CRISP-Q'[10]

Associated with intention to risk appropriate screening (n=204):

Government logo

Risk communication: 'CRISP-Q'[10]

Associated with intention to risk appropriate screening (n=204):

Government logo

Statement of absolute risk with National guideline advice

> Based on the National Health Guidelines (NHMRC)[1] and your level of risk of developing bowel cancer in the next 5 years, you are recommended to have a **Faecal Occult Blood Test (FOBT).**
>
> Your risk of developing bowel cancer in the next 5 years is 0.32%.

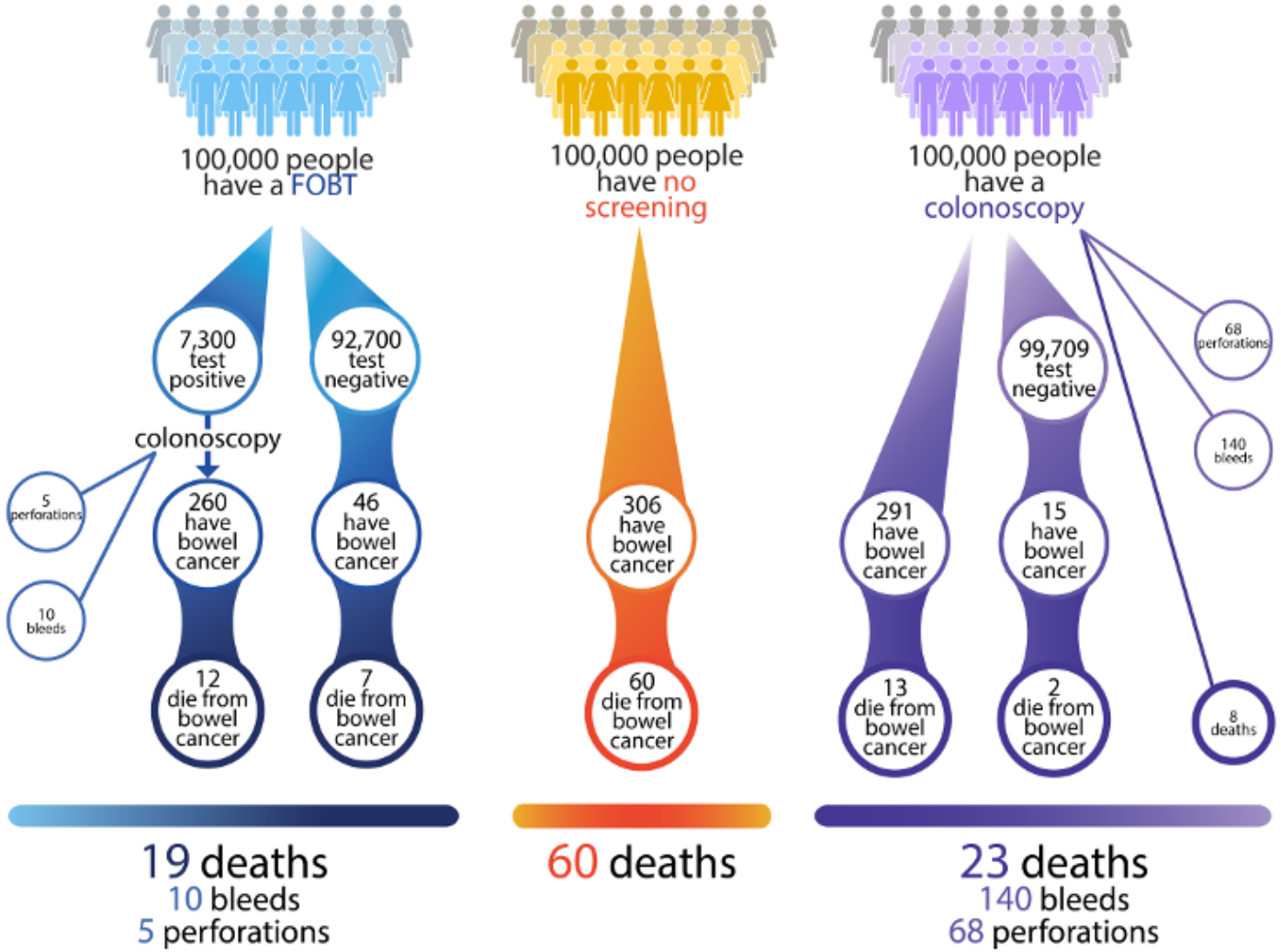
Risk communication: 'CRISP-Q'[10]

Associated with intention to risk appropriate screening (n=204):

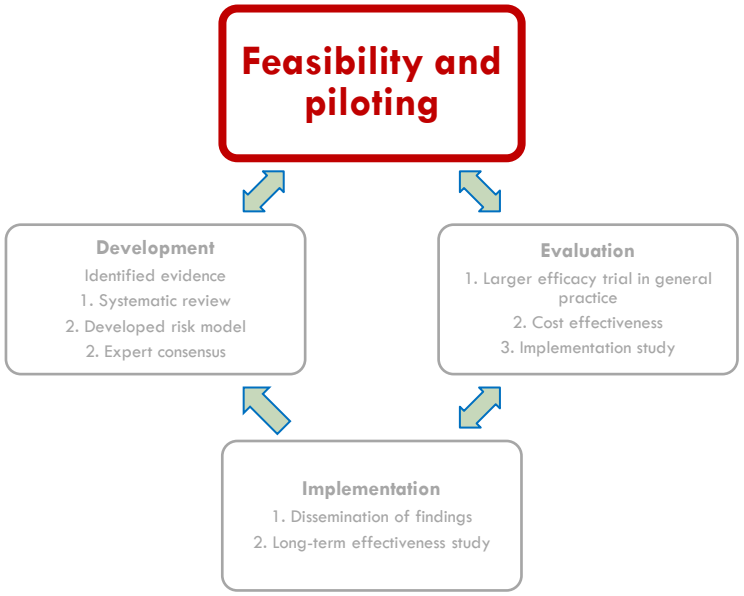
Government logo

Statement of absolute risk with National guideline advice

Expected frequency trees (risks and benefits)

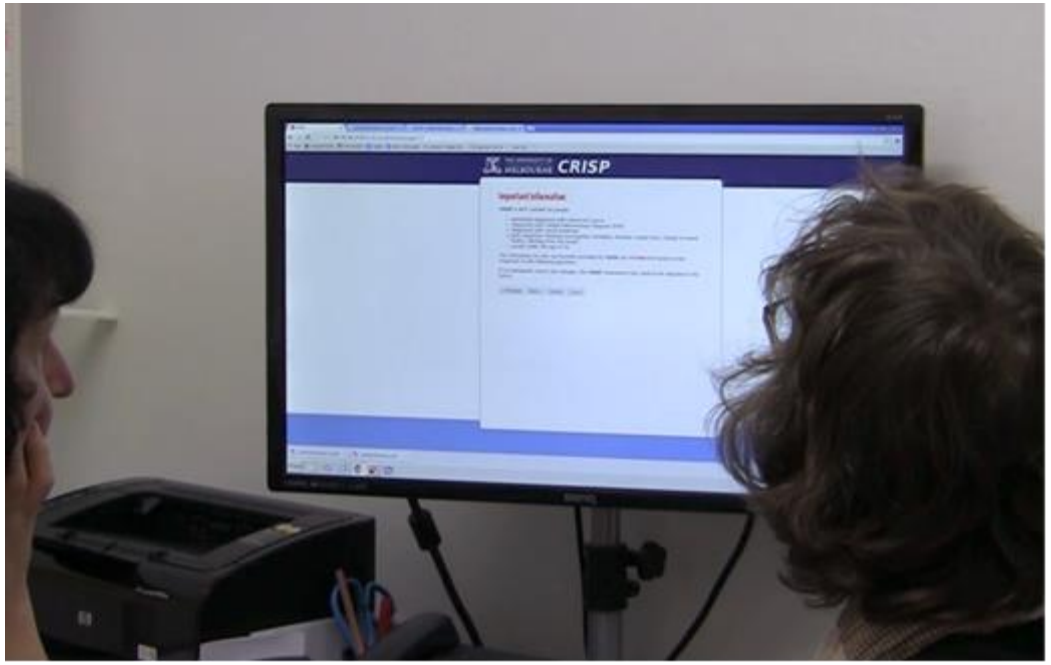


Feasibility and piloting



1. Prototype (CRISP V1.0)
2. Acceptability and feasibility testing in general practice
3. A feasibility trial was conducted in two practices.

Feasibility and piloting – acceptability and feasibility[11]



<u>GPs, Practice nurses & Practice managers</u>

- Simulated consultations with the prototype
- Interviews

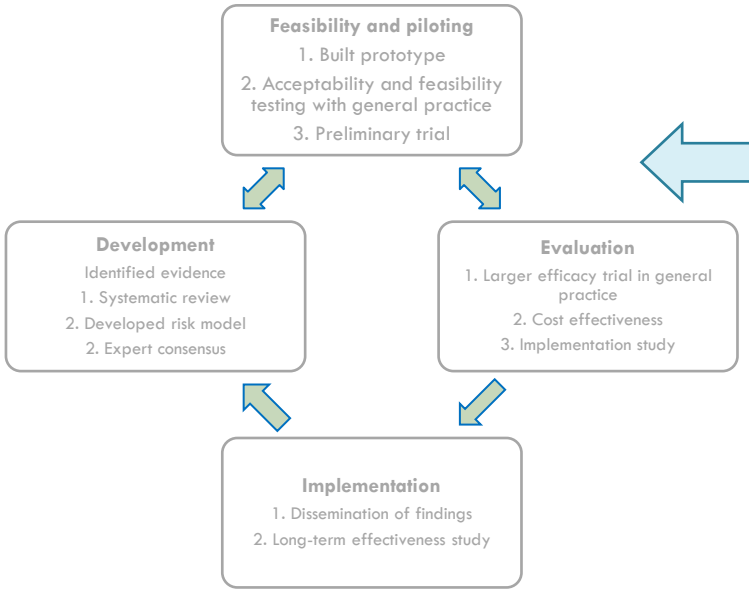
(Normalisation Process Theory[12])

<u>Results</u>

- Acceptable and feasible
- Video analysis: tool made shorter, more useable
- Practice nurse delivery

11 Walker (McIntosh), *et al* BMC Med Inf and Dec Mak 2017 17 (13); 12 May, *et al* BMC Health Services Research 2006

Additional study



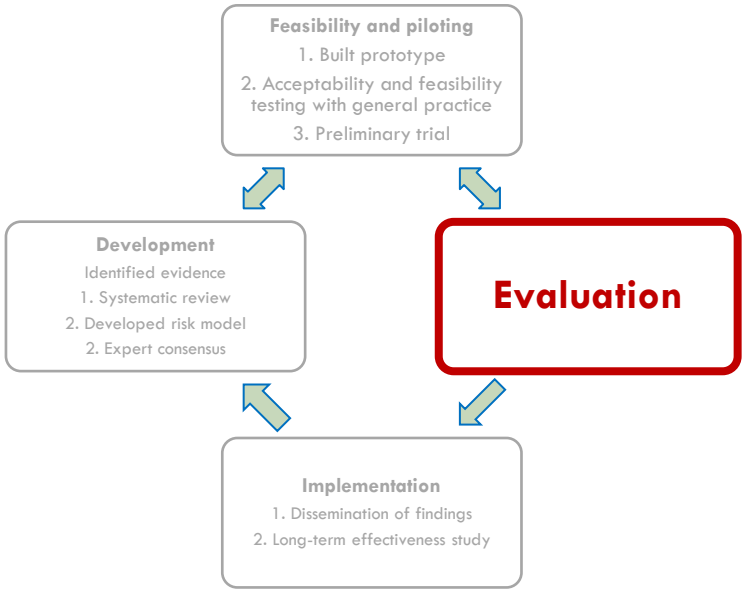
'CRISP-P'[13]: testing if people can use the tool without assistance

Why don't patients just complete CRISP in the waiting room?

- 41% (230) were unable to complete the tool without help
- People who were older, or had English as their second language more likely to need assistance ($P<0.001$)

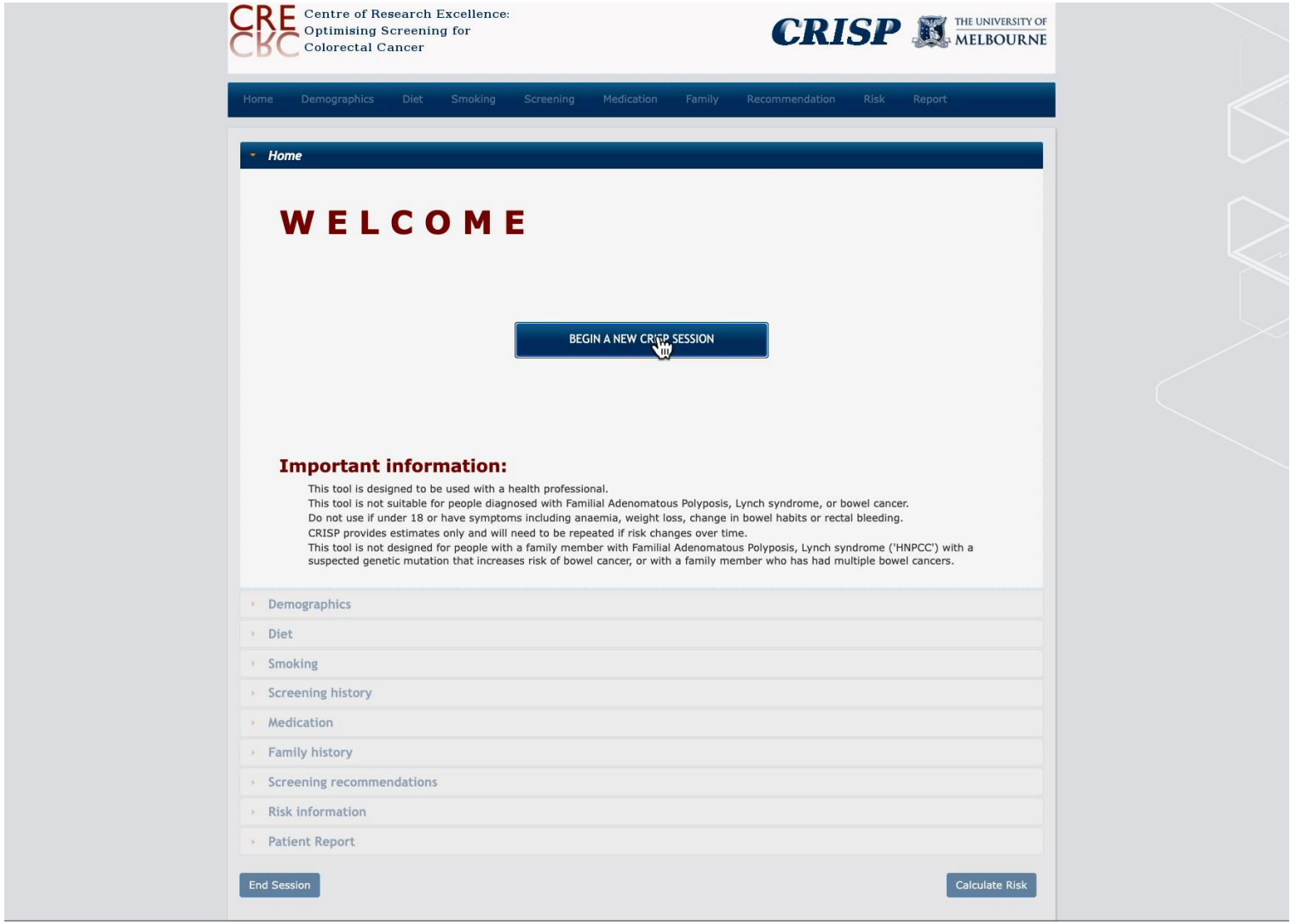
13. EC Harty, et al. Family Practice 36 (6), 730-735

Evaluation



1. Efficacy RCT
2. Implementation study
3. Cost effectiveness (due 2023)

CRISP V 2.0


Centre of Research Excellence:
Optimising Screening for
Colorectal Cancer
CRISP
THE UNIVERSITY OF MELBOURNE
Home
Demographics
Diet
Smoking
Screening
Medication
Family
Recommendation
Risk
Report
Home
WELCOME
BEGIN A NEW CRISP SESSION
Important information:
This tool is designed to be used with a health professional.
This tool is not suitable for people diagnosed with Familial Adenomatous Polyposis, Lynch syndrome, or bowel cancer.
Do not use if under 18 or have symptoms including anaemia, weight loss, change in bowel habits or rectal bleeding.
CRISP provides estimates only and will need to be repeated if risk changes over time.
This tool is not designed for people with a family member with Familial Adenomatous Polyposis, Lynch syndrome ('HNPCC') with a suspected genetic mutation that increases risk of bowel cancer, or with a family member who has had multiple bowel cancers.
Demographics
Diet
Smoking
Screening history
Medication
Family history
Screening recommendations
Risk information
Patient Report
End Session
Calculate Risk

Evaluation	Randomised controlled trial: method	

Both trial arms: 'How to cut your cancer risk' (Cancer Council Victoria)

Intervention arm: 'CRISP' risk tool delivered by a trained researcher before the patient's GP consultation

CRISP output discussed including risk information and clinical advice

Printouts given for patient and GP

Evaluation	Randomised controlled trial: method	

Primary outcome: 'Risk appropriate' screening at 12 months

Intervention group risk: calculated using CRISP risk of CRC over 5 years

Control group risk: NHMRC guidelines based on family history

Screening data (FIT, colonoscopy): self-report, GP records, hospital data (colonoscopies), Medicare data and NBCSP data

Clinical subcommittee: data discrepancies, complex polyp history

Evaluation	Randomised controlled trial: method	

Secondary outcomes:

- Risk perception, absolute and comparative risk
- State-Trait Anxiety Inventory (STAI) scale
- Cancer-specific anxiety
- Intentions to have CRC screening
- Questionnaires: B/line, 1 month, 6 months and 12 months

Evaluation

Randomised controlled trial: results[14]

The primary outcome [n=722 (362 intervention, 360 control)] 99% of primary data collected

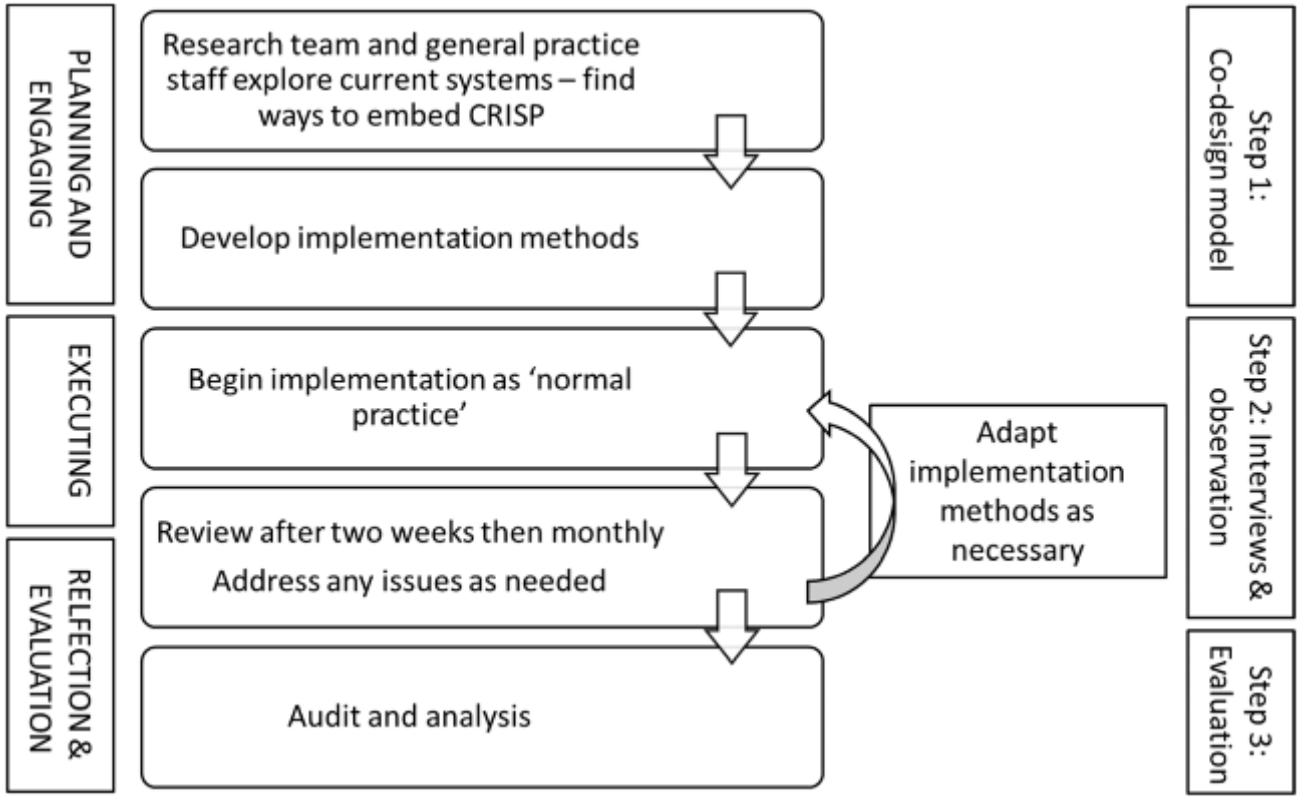
- **6.5% absolute increase in risk-appropriate screening (95% CI: -0.28 to 13.2%)** [intervention 71.6% vs control 65%; OR: 1.36 (95% CI: 0.99 to 1.86) p = 0.057]
- **20.3% absolute increase in those due CRC screening (95% CI:10.3 to 30.4%)** [intervention 59.8% vs control 38.9%; OR: 2.31 (95% CI 1.51 to 3.53) p < 0.001]
- Overscreening was higher in the intervention group [36 (9.9%):18 (5.0%)]

Secondary outcomes: Increase in intention to screen in intervention group at 1 month, no increase in cancer or generalized anxiety.

14 Emery, *et al*. BJGP 2023

Evaluation

Implementation study[15]



Methods using the Consolidated Framework for Implementation Research[15]

One practice an implementation laboratory

Co-designed implementation methods

12 months of interviews: testing and adapting implementation methods in an iterative way

15 Milton, *et al* Implementation Science 2022 17:31; 16 Damschroder, *et al* Implementation Science 2019

Implementation

Facilitators:

Valuable tool – encouraged discussion about diet, smoking and screening

Nurses engaged with the co-design and strategies for making it work

Clinic open to change

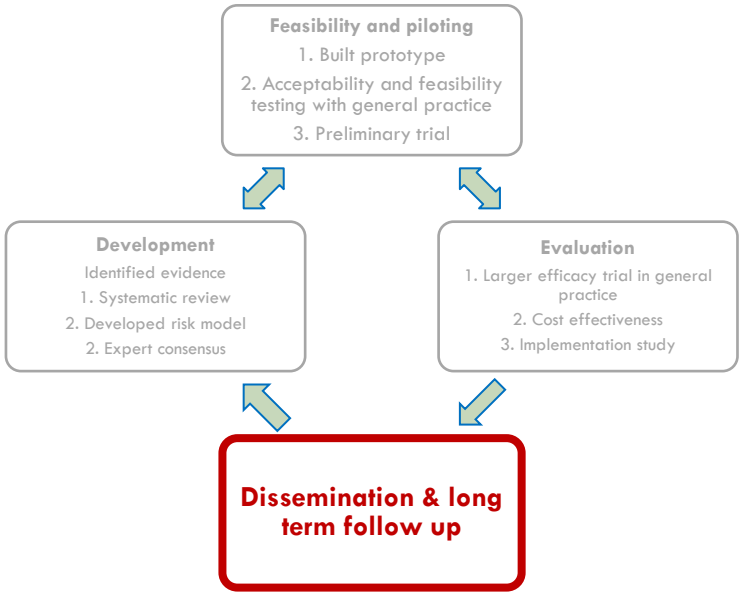
Barriers:

Time

Competing priorities

Changes in practice policies, staffing and then the pandemic

Dissemination and follow up



2023/24:

Five-year follow up of primary outcome

Economic evaluation

Dissemination and implementation plan still needed

Summary

We developed a novel Australian risk tool and risk model ‘CRISP’

Co-designed with consumers, clinicians, cancer researchers, epidemiologists and IT researchers. Iterative process using implementation science to test for translation into practice.

Summary

CRISP was effective in increasing risk appropriate screening in people due for screening. Overscreening was a limitation.

Implementation into clinical practice is acceptable but warrants further exploration to make it scalable and sustainable.

ACKNOWLEDGEMENTS

- NHMRC funding

Mark Jenkins, Jon Emery, Sibel Saya, Adrian Bickerstaffe, Patty Chondros, Finlay Macrae, Grace Y Kim, Elena Harty, Peter Nguyen, Shakira Milton, Jasmeen Oberoi, Louisa Flander, Fiona Walter, Kitty Novy, Kristi Milley and PC4, Lyndal Trevena, Nadira Hewabandu, Sanjay Maddumarachchi, James Dowty, Ingrid Winship, Marie Pirotta, Peggy Chiang, Emily Habgood, Napin Karnchanachari, Richard de Abreu Lourenco, Anna Crothers, Driss Ait Ouakrim, Malcolm Clark, Sally Doncovio, Dariush Etemadmoghadam, George Fishman, Jane Rinaldi, Joanne Kinder and the staff at Shepparton Medical Centre, Kara-Lynne Cummings, Ashleigh Qama, Alex Boussioutas

Cancer risk assessment tools in primary care: a systematic review of randomized controlled trials. JG Walker (McIntosh), S Licqurish, PPC Chiang, M Pirotta, JD Emery. The Annals of Family Medicine 13 (5), 480-489

The CRISP-Q study: communicating the risks and benefits of colorectal cancer screening. J Walker (McIntosh), A Bickerstaffe, N Hewabandu, M Pirotta, L Flander, M Jenkins, et al. Australian Journal of General Practice 47 (3), 139-145

The CRISP colorectal cancer risk prediction tool: an exploratory study using simulated consultations in Australian primary care. JG Walker (McIntosh), A Bickerstaffe, N Hewabandu, S Maddumarachchi, JG Dowty, et al. BMC Medical Informatics and Decision Making 17, 1-11

The CRISP-P study: feasibility of a self-completed colorectal cancer risk prediction tool in primary care. EC Harty, JG McIntosh, A Bickerstaffe, N Hewabandu, JD Emery. Family Practice 36 (6), 730-735

A new comprehensive colorectal cancer risk prediction model incorporating family history, personal characteristics, and environmental factors. Zheng, Yingye, et al. *Cancer Epidemiology, Biomarkers & Prevention* 29.3 (2020): 549-557.

The use of a risk assessment and decision support tool (CRISP) compared with usual care in general practice to increase risk-stratified colorectal cancer screening: study protocol for a randomised controlled trial. J Walker (McIntosh), F Macrae, I Winship, et al. Trials. 2018. 19(397)

The CRISP Trial: RCT of a decision support tool for risk-stratified colorectal cancer screening. Emery et al, BJGP, 2023; DOI: https://doi.org/10.3399/BJGP.2022.0480

QUESTIONS?

Feasibility and piloting – pilot trial[1]

- General practices (n=2)
- 73% recruitment rate (n=85)
- 88% retention (n=88%) over 6 months
- No increase in cancer worry
- Sample size developed for larger trial
- Modified methods to reduce time for CRISP delivery
- FIT given by GP if due

1 unpublished

In the intervenntion group n=36 (9.9%) were overscreened at 12 months (n = 17 iFOBT, 47.2% and n = 19 colonoscopies, 52.8%),

in the control group (n = 6 iFOBT, 33.3% and n = 12 colonoscopies, 66.7%)