The University of Sydney
School of Public Health

Supporting informed choices about bowel cancer screening among adults with lower levels of education and literacy: A randomized controlled trial of a decision aid

Sian Smith
Screening and Test Evaluation Program
School of Public Health, University of Sydney, Australia

STEP SCREENING & TEST EVALUATION PROGRAM

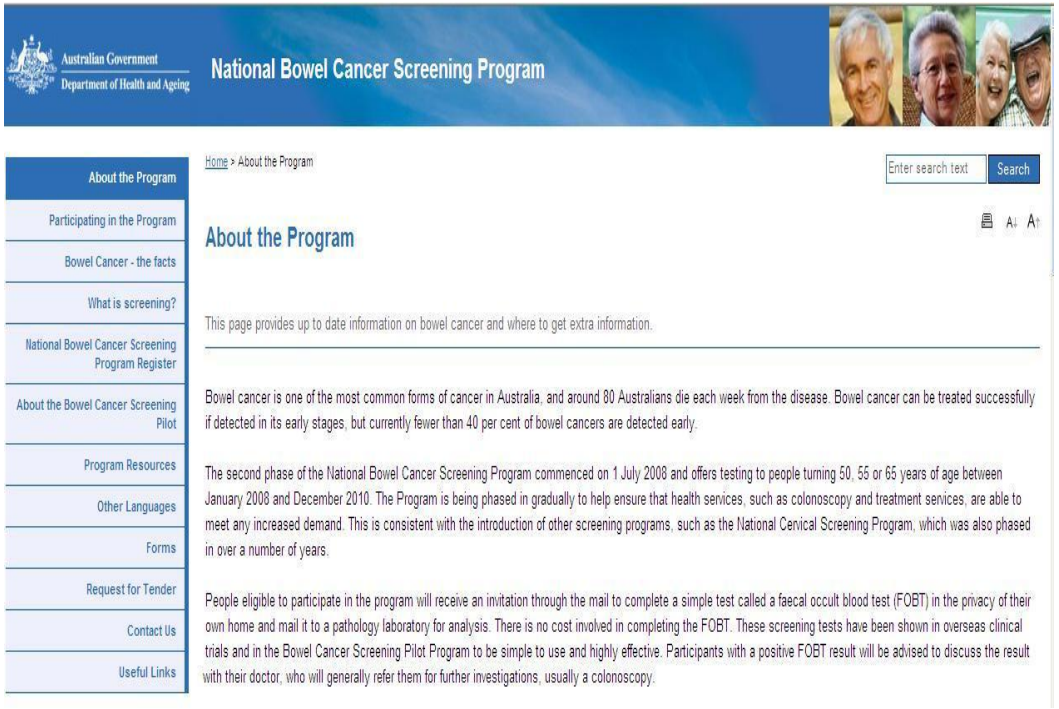
CeMPED Centre for Medical Psychology & Evidence-based Decision-making

Background

- Major advances in health care to increase patient involvement in health care decision making.
- Decision aids (DAs) have shown to be effective tools in supporting patient participation in decision making:
  - provide balanced information about the outcomes of different health care options
  - include exercises to help patients clarify their values regarding the benefits and harms of each option
- Decision aid research has generally not included adults with lower education and literacy.

Australian National Bowel Cancer Screening program

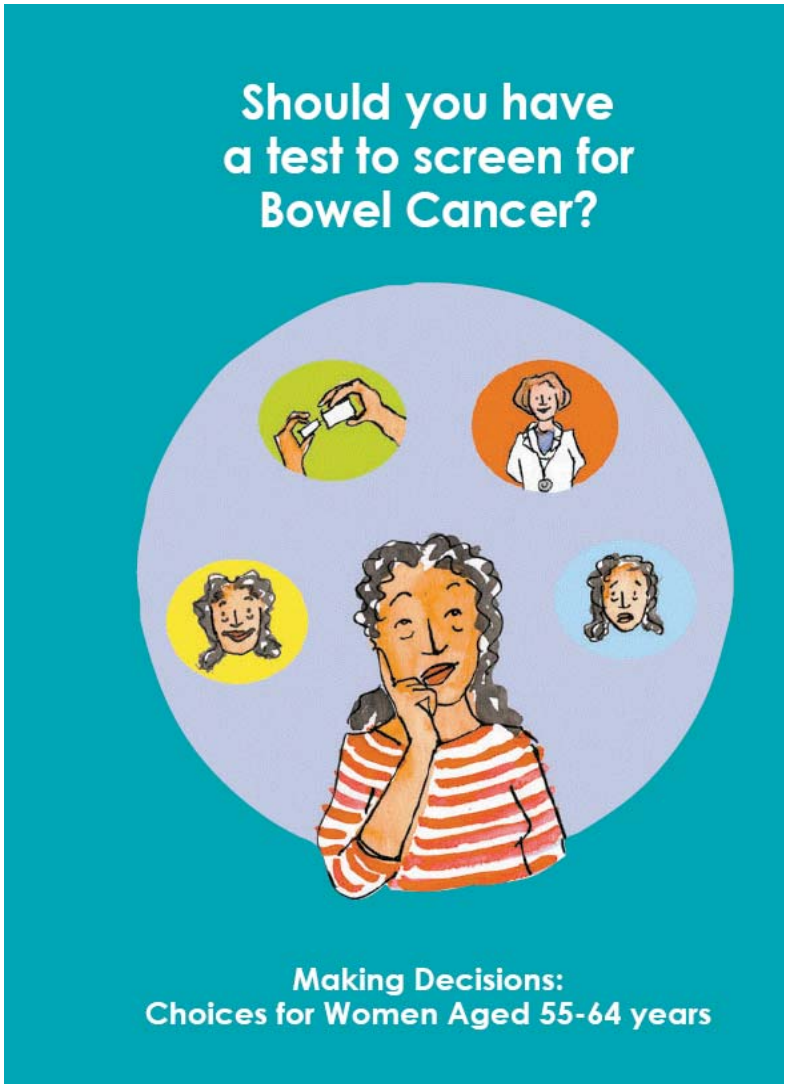
- Offers Faecal Occult Blood Testing (FOBT) to adults turning 50, 55 and 65 years.
- Primary communication between the screening provider and individual is via written materials, sent directly to their homes
- Decision to participate is typically made at home without consulting a health care professional.

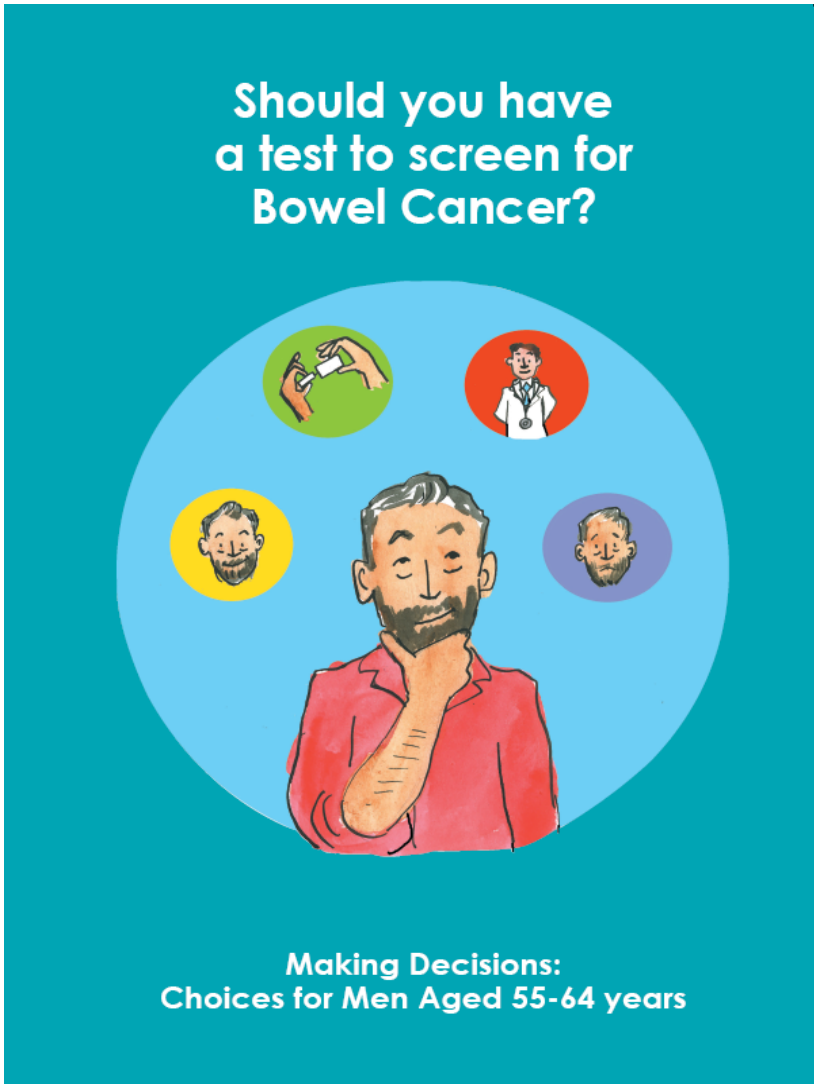


Research question

To what extent can people with lower levels of education be supported to make an informed choice about bowel cancer screening (FOBT) using a decision aid?

Decision aid booklet front cover



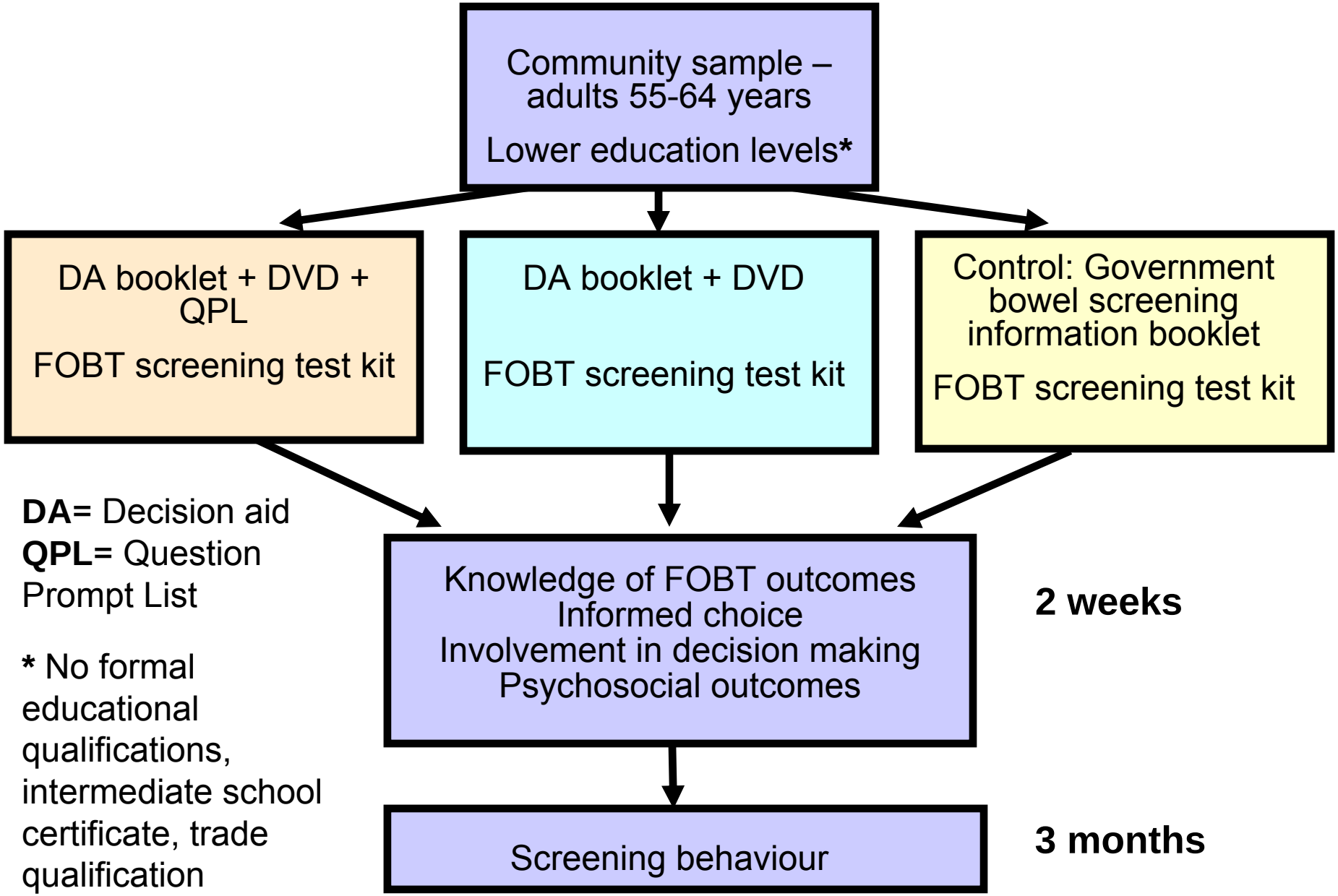


References:

Smith, SK., McCaffery , KJ et al. (2009). Development and preliminary evaluation of a bowel cancer screening decision aid for adults with lower literacy. Patient, Education and Counseling (Special issue: Health literacy research) 75 (3):358-367.

Smith, SK., McCaffery KJ et al. (2009). Information needs and preferences of low and high literacy consumers for decisions about colorectal cancer screening: utilising a linguistic framework. Health expectations 11 (2): 123-136.

Trial design



DA= Decision aid
QPL= Question Prompt List

***** No formal educational qualifications, intermediate school certificate, trade qualification

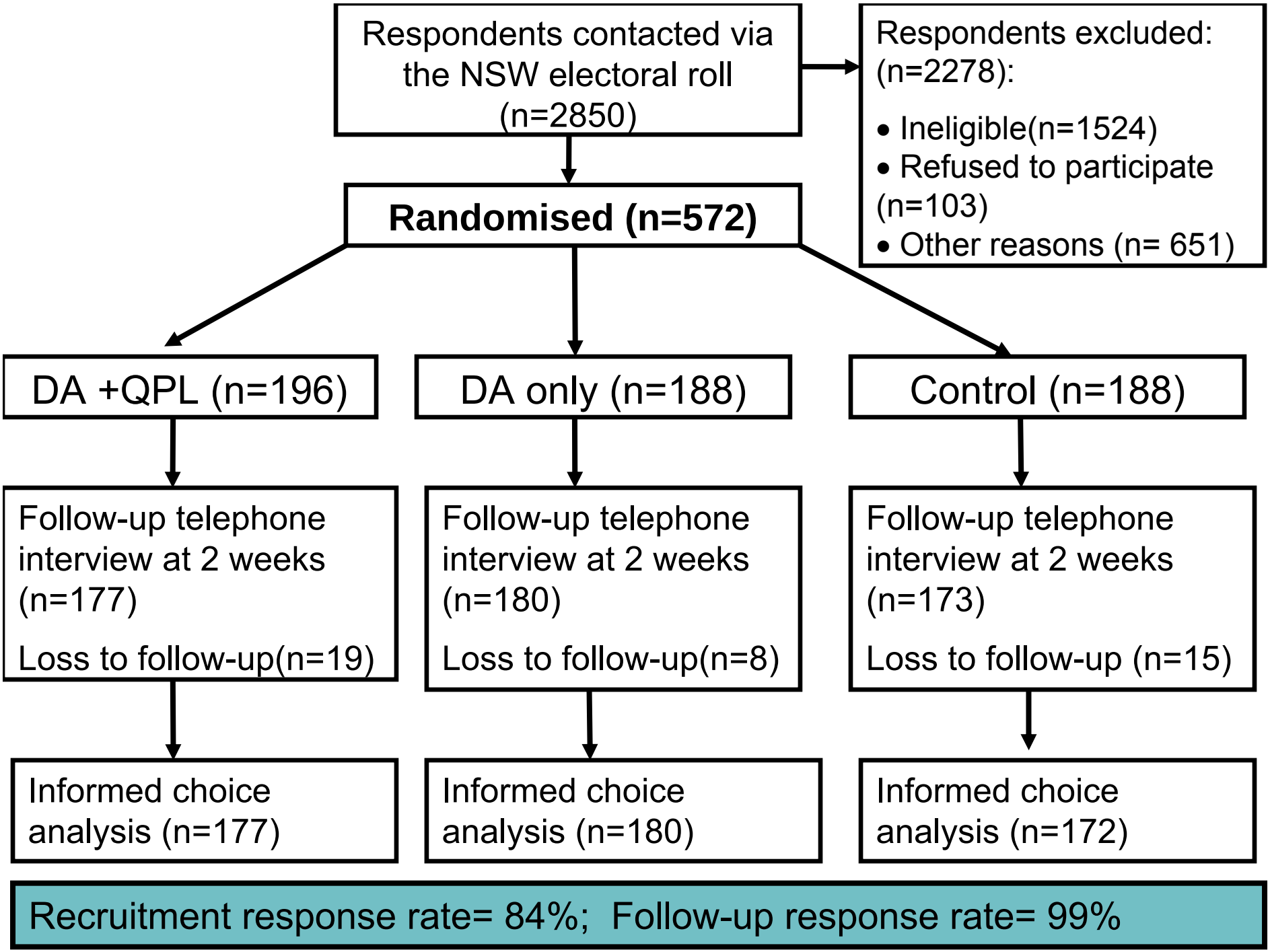
Outcomes Assessed

- **Primary outcomes**
  - Knowledge of FOBT outcomes (conceptual and numeric)
  - Informed choice (adequate knowledge and a decision consistent with attitudes and behaviour) (Marteau et al., 2001)
  - Involvement preferences in screening decision (Degner et al., 1997)
- **Secondary outcomes**
  - Decision quality (decisional conflict, satisfaction)
  - Psychosocial outcomes (anxiety, bowel cancer worry, confidence in decision making)
  - Acceptability of materials (booklet, DVD, Question Prompt List)

Knowledge of FOBT screening outcomes

Five key constructs (conceptual and numeric):

1. Baseline risk of bowel cancer (numeric)
2. Absolute risk reduction by FOBT screening (numeric)
3. False positive (concept)
4. False positive (numeric)
5. False negative (concept)


Respondents contacted via the NSW electoral roll (n=2850)
Respondents excluded: (n=2278):
• Ineligible(n=1524)
• Refused to participate (n=103)
• Other reasons (n= 651)
Randomised (n=572)
DA +QPL (n=196)
DA only (n=188)
Control (n=188)
Follow-up telephone interview at 2 weeks (n=177)
Loss to follow-up(n=19)
Follow-up telephone interview at 2 weeks (n=180)
Loss to follow-up(n=8)
Follow-up telephone interview at 2 weeks (n=173)
Loss to follow-up (n=15)
Informed choice analysis (n=177)
Informed choice analysis (n=180)
Informed choice analysis (n=172)
Recruitment response rate= 84%; Follow-up response rate= 99%

Characteristics of sample at baseline *	DA + QPL n=196 (%)	DA only n=188 (%)	Control n=188 (%)
Gender			
Female	97 (50)	93 (50)	94 (50)
Male	99 (50)	95 (50)	94 (50)
Highest educational qualification			
No formal qualifications	4 (2)	4 (2)	6 (3)
Intermediate school certificate	128 (65)	125 (67)	125 (67)
Trade certificate	64 (33)	59 (31)	57 (30)
Years in full time education			
0-10 yrs	116 (59)	106 (57)	107 (57)
11-20 yrs	78 (40)	81 (43)	79 (42)
Difficulties reading health information (self-report)			
Never	64 (33)	62 (33)	56 (30)
Occasionally/Sometimes	102 (52)	113 (60	118 (63)
Often/Always	29 (15)	11 (6)	12 (6)
Bowel cancer family history			
No	167 (85)	167 (89)	164 (87)
Yes	25 (13)	16 (9)	21 (11)
Bowel cancer worry			
None/ A bit	184 (94)	172 (92)	170 (90)
Quite/Very	11 (6)	16 (8)	17 (9)
Screening interest			
A bit/Not Very	57 (29)	49 (26)	51 (27)
Very/fairly	136 (69)	135 (72)	131 (70)
Involvement preferences in screening decision			
Make decision alone	68 (35)	75 (40)	78 (42)
Share with doctor	118 (60)	103 (54)	98 (52)
Doctor decide	8 (4)	8 (4)	9 (5)
Knowledge – concept only, Mean (out of 4)	2.37	2.32	2.23

***** In some cases, percentages do not round to 100% as there were data missing for ≤ 13 participants

Results- Primary outcomes

- Knowledge of FOBT outcomes
  - Mean score (out of 12) ($p<0.001$)
    - DAs combined = 6.50
    - Control group = 4.10
  - % Adequate knowledge (score ≥6/12) ($p<0.001$)
    - DAs combined – 56%
    - Control – 19%

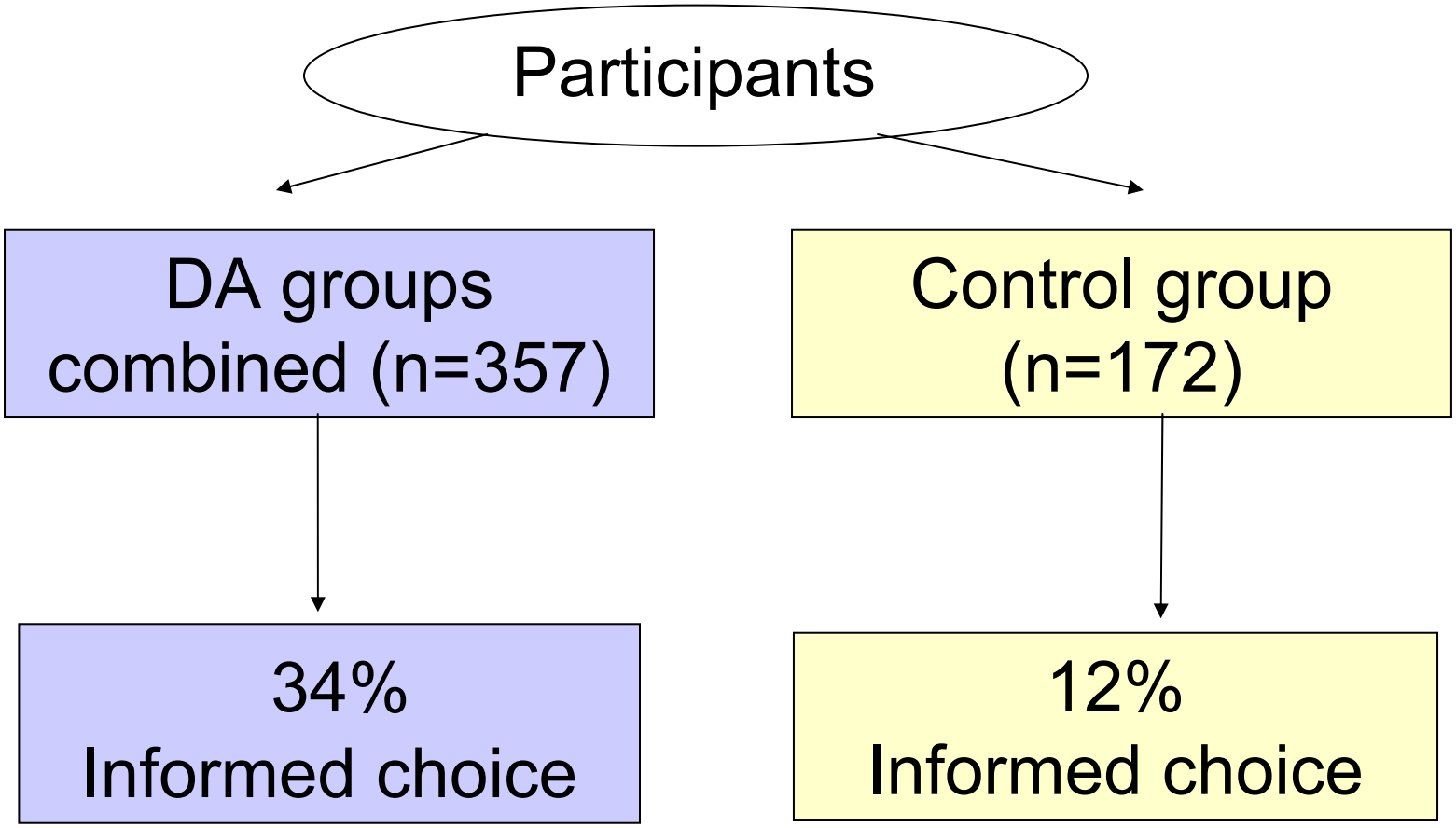
Understanding of key knowledge constructs

Knowledge constructs, accurate responses	DAs combined n=357 (%)	Control n=173 (%)	Difference	χ^2 (df)	*P* value
1. Baseline risk– numeric	172 (48)	13 (8)	40.7	88.39(2)	<0.001
2. Risk reduction – numeric	161 (45)	9 (5)	39.9	86.10(2)	<0.001
3. False positives –concept	328 (92)	160 (93)	–0.6	0.06 (1)	0.81
4. False positives – numeric	50 (14)	24 (14)	0.1	0.00 (1)	0.97
5. False negatives – concept	309 (87)	145 (84)	2.8	0.71 (1)	0.40

Results – Primary outcomes

- **Attitudes towards FOBT screening**
  - DA recipients slightly less positive about FOBT screening compared to controls (51% vs 65% respectively had positive attitudes; P=0.002)
- **Screening behaviour**
  - At 3 months, there was a difference in the proportion of participants who had completed the FOBT screening test (59% DA vs 75% Control; P<0.001).

Primary outcome - Informed choice



$\chi^2 = 28.83$; 1 df; $p<0.001$

Results – Primary outcomes

- **Involvement preferences in screening decision**

	DAs combined n=355 (%)	Control group n=171 (%)	*P* value
Participant decides	321 (91)	164 (96)	0.04
Participant decides after consulting	14 (4)	2 (1)	
Share decision equally	17 (5)	5 (3)	
Doctor decides after consulting	2 (1)	0 (0)	
Doctor decides	1 (0)	0 (0)	

Results- Secondary Outcomes

- No evidence of an effect on decision quality and psychosocial outcomes between groups

Secondary outcomes	DAs combined (n=357)	Control group (n=173)	*P* value
Decisional conflict, Mean (SD)	13.63 (20.55)	14.91 (18.34)	0.49
Confidence, Mean (SD)	4.67 (0.54)	4.61 (0.62)	0.26
Anxiety, Mean (SD)	8.46 (2.93)	8.53 (3.17)	0.80
Worry about bowel cancer, None %	53	54	0.78

Summary of key findings

- Compared to the standard information, the DA enhanced quantitative understanding of FOBT outcomes.
- Unlike other screening decision aid trials, this trial showed a difference in attitudes and FOBT screening uptake.
- Decision aid improved informed choice by 20%, without raising anxiety, worry, or decisional conflict.

Discussion

- Achieved informed choice in a lower education sample.
- Only 1/3 who received the decision aid made an informed choice about screening, but over 50% in DA arms had adequate knowledge.

Implications for policy & practice

Achieving equity in informed choice or maximising screening uptake?

- Nearly 90% of participants receiving the standard information made an uninformed choice. Of those, approximately 60% made a decision to screen without adequate knowledge.
- Indicates that knowledge about the benefits *and* harms of FOBT screening in the community are limited, particularly understanding about the frequency of false positives, as an outcome of screening
- As screening providers – are we willing to lose 20% participation overall to achieve equal access to informed choice?

Acknowledgments

Colleagues: Kirsten McCaffery, Lyndal Trevena, Alexandra Barratt, Judy Simpson, Don Nutbeam, Les Irwig, Ann Dixon, Andrew Hayen, Rowena Forsyth, Paul Kearney.

Screening & Test Evaluation Program, School of Public Health; Centre for Medical Psychology and Evidence-based Decision Making, University of Sydney

Participants, The Hunter Valley Research Foundation, NSW (special thanks to Caroline Veldhuizen and David Shellard), & Betty Lui at Insure Bowel Cancer Screening service.

National Health & Medical Research Council of Australia (Grant no. 402764); University of Sydney Cancer Research Fund

Thank you

Informed choice in screening

- The decision to screen for cancer should be based on an informed choice, in which people are given balanced information about the benefits *and* harms of screening.
- General Medical Council (2008) guidelines:

  "Health care providers must explain the options to the patient setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no screening." (p.7)

- Current screening information tends to overemphasise the benefits, with minimal information about the harms, risks or limitations (Gøtzsche et al. BMJ 2009)

Distribution of informed/uninformed choices across the eight classifications

	Adequate knowledge	Positive attitudes	Screening Uptake	DAs combined n =357 (%)	Control group n =172 (%)
Informed choices					
Accept screening	✓	✓	✓	72 (20)	18 (11)
Decline screening	✓	×	×	48 (13)	2 (1)
Uninformed choice– either adequate knowledge or consistent attitudes and behaviour					
To accept	✓	×	✓	51 (14)	9 (5)
To decline	✓	✓	×	29 (8)	3 (2)
To accept	×	✓	✓	52 (15)	71 (41)
To decline	×	×	×	40 (11)	17 (10)
Uninformed choice– both inadequate knowledge and inconsistent attitudes and behaviour					
To accept	×	×	✓	36 (10)	32 (19)
To decline	×	✓	×	29 (8)	20 (12)

Results - Secondary Outcomes

Acceptability of material (booklet, DVD, QPL)

- Vast majority found the DA information ‘clear and easy to understand’ (98%) and ‘helpful in their decision making’ (96%)
- Nearly half of participants (n=166) viewed the DVD, and large proportion (97%) found it clear and easy to follow
- Overall 26 (5%) participants reported that they discussed the screening information with their doctor
- Only 1 participant used the QPL to talk to their doctor

Other relevant randomised trials evaluating cancer screening decision aids			Adequate knowledge		Behaviour (screening uptake)		Informed choice	
Screening context and author(s)	**Country**	**Primary outcomes measured**	**% Adequate knowledge DA vs Control**	**Difference DA minus Control, %**	**% Screened DA vs Control**	**Difference DA minus Control, %**	**% Informed choice DA vs control**	**Difference DA minus Control, %**
Bowel cancer (FOBT) (Smith, McCaffery et al. 2009)	Australia	Knowledge Informed choice Preferences for involvement	56.0 vs 18.5	37.5	59.1 vs 75.1	-16.0	33.6 vs 11.6	22.0
Breast cancer Mathieu, Barratt et al. 2007	Australia	Knowledge Informed choice Participation in screening	76.6 vs 56.9	19.8	5.9 vs 7.0	-1.1	73.5 vs 48.8	24.72
Bowel cancer (FOBT) (Trevena et al. 2008)	Australia	Knowledge Informed choice	20.9 vs 5.8	15.1	5.2 vs 6.6	-1.4	10.4 vs 1.5	8.9
Bowel cancer (Wolf & Schorling, 2000)	US	Screening interest and intentions	71.1 vs 53.8	17.3	**	No diff in intentions	***	N/A
Prostate cancer (Volk et al. , 2008)	US	Acceptability Knowledge Decisional conflict Self-advocacy	*	N/A	**	N/A	***	N/A
Bowel cancer (Griffith et al., 2008)	US	Subjective rating of content Screening interest/intentions	*	N/A	**	No diff in intentions	***	N/A
Bowel cancer (Dolan & Frisina , 2002)	US	Decisional conflict Screening intentions and behaviour	*	N/A	49.0 vs 52.0	-3.0	***	N/A
Bowel cancer (Pignone et al., 2000)	US	Screening behaviour	*	N/A	36.8 vs 22.6	14.2	***	N/A

*Did not measure knowledge or provided limited information about the items used and/or no statistical information
** Did not measure behaviour or breakdown by groups not provided
*** Did not measure informed choice

Sample pages from the decision aid

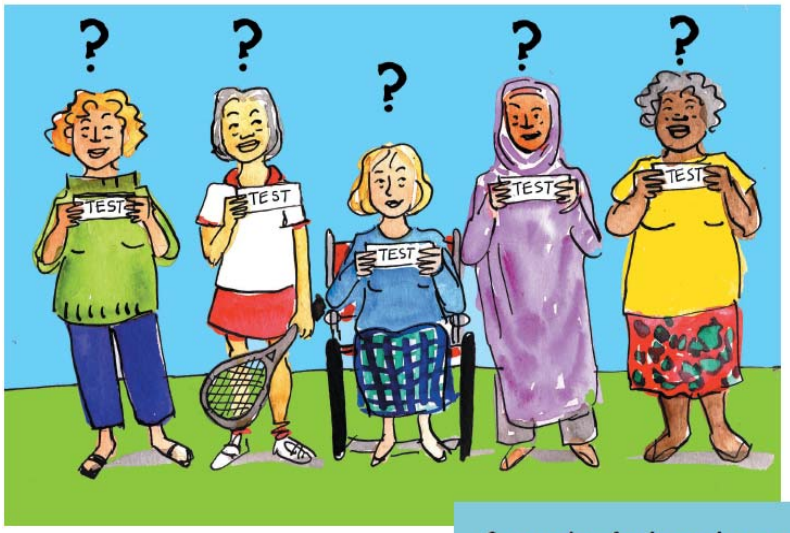
What is cancer screening?

Cancer screening means looking for early signs of cancer or pre-cancer, in people who are well and have no symptoms.

If cancer or pre-cancer is found at an early stage it can be treated more easily.

There are different types of screening tests to find early signs of different cancers. For example, mammograms to screen for breast cancer, Pap smears to screen for cervical cancer and prostate specific antigen (PSA) to screen for prostate cancer.

This booklet is about screening for bowel cancer with Faecal Occult Blood Testing (FOBT).



Screening for bowel cancer is your decision.

What increases your risk of getting bowel cancer?

Your age: bowel cancer is more common as you get older.

Your gender: bowel cancer is a little more common in men.

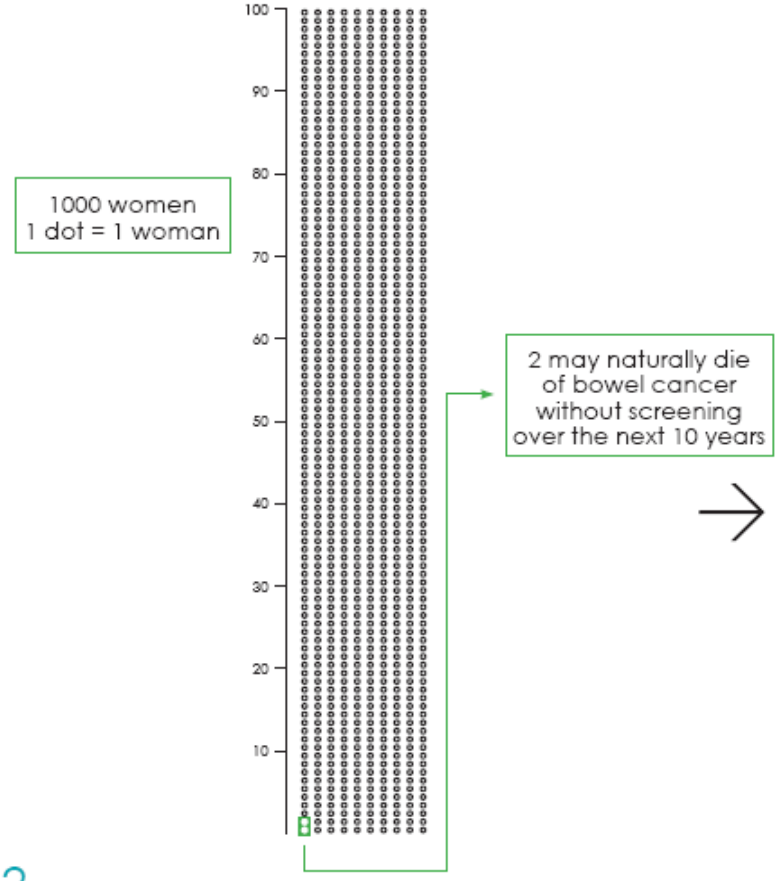
Your family history: bowel cancer is twice as likely to occur in women and men who have at least one family member with bowel cancer. See page 5 to find out your family history group or ask your doctor.

Note: Although diet is important for your general health, whether it affects your risk of bowel cancer is unclear.

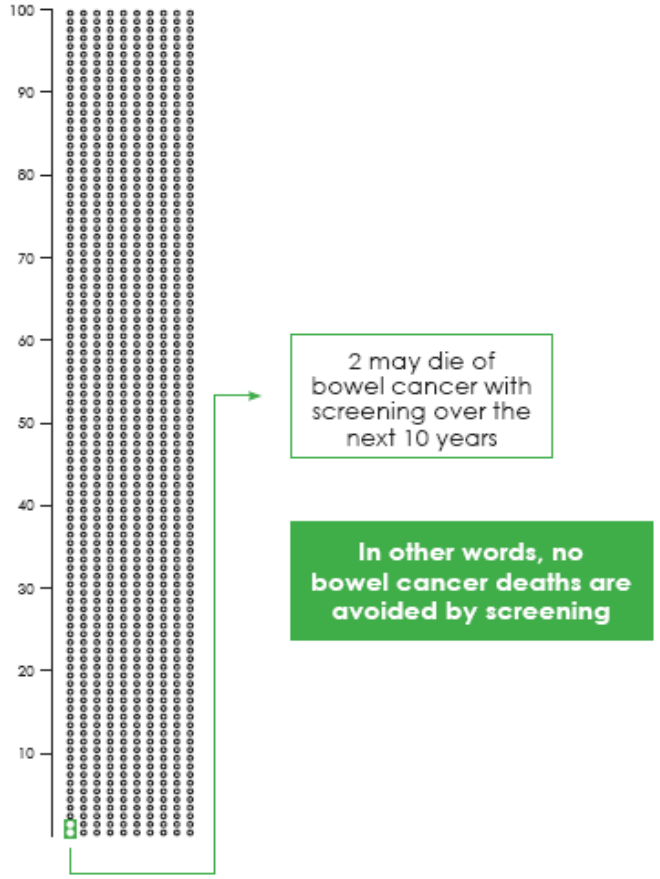
Presentation of risk information

How does the screening test help women with **no family history?**

Of 1000 women your age (55-64) with **NO FAMILY HISTORY** who **DO NOT HAVE SCREENING**, over the next 10 years:



Of 1000 women your age (55-64) with **NO FAMILY HISTORY** who **DO HAVE SCREENING**, over the next 10 years:



Values clarification exercise for men

Your Personal Worksheet
Weak Family History

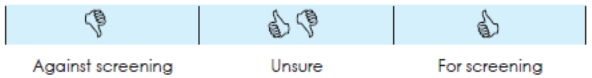
Think about how each point makes you feel about bowel cancer screening with FOBT.

Circle the thumbs to show how each point makes you feel about screening.

e.g. For screening

e.g. Against screening

Think about your current risk of bowel cancer
Your risk of dying from bowel cancer over the next 10 years without screening is about 5 in 1000 (see pages 16 – 17). How does this make you feel about screening?



Lowering your risk of bowel cancer by screening
If you have a screening test every 2 years over the next 10 years, you can lower your chances of dying from bowel cancer to about 4 in 1000 (see pages 16 – 17).
How does this make you feel about screening?