Engaging low health literacy populations for developing and evaluating health care interventions

PROFESSOR KIRSTEN MCCAFFERY

kirsten.mccaffery@sydney.edu.au

SYDNEY MEDICAL SCHOOL

Sydney School of Public Health
Screening and Test Evaluation Program
Centre for Medical Psychology & Evidence Based Decision-making

THE UNIVERSITY OF SYDNEY

- My research focuses on Shared Decision Making for adults with low education and literacy

- Communicative and critical health literacy (Nutbeam 2000, 2008 framework)

- As we shift towards greater involvement in decision making crucial that low literacy/health literacy are not left behind

3 Projects

1. Decision Aid to support informed choice in bowel cancer screening (FOBT) n=585.

2. Decision Aid to support informed choice in mammography screening including information about about *overdiagnosis n=879*.

3. SDM intervention for adults attending basic literacy and numeracy classes in Australia n= 319.

PROJECT 1 DA FOR BOWEL CANCER SCREENING.

Successful project resulting in 8 publications. PhD (Dr Sian Smith)

BMJ

RESEARCH

A decision aid to support informed choices about bowel cancer screening among adults with low education: randomised controlled trial

Sian K Smith, postdoctoral research fellow,[1] Lyndal Trevena, associate professor,[1] Judy M Simpson, professor of biostatistics,[2] Alexandra Barratt, associate professor in epidemiology,[1] Don Nutbeam, professor of public health,[3] Kirsten J McCaffery, senior research fellow[1]

[1]Screening and Test Evaluation Program, Centre for Medical Psychology and Evidence-Based Decision-Making, Sydney School of

ABSTRACT

Objective To determine whether a decision aid designed for adults with low education and literacy can support the decision aid group (22% difference, 15% to 29%; P<0.001). More participants in the decision aid group had no decisional conflict about the screening decision

doi: 10.1111/j.1369-7625.2008.00489.x

Information needs and preferences of low and high literacy consumers for decisions about colorectal cancer screening: utilizing a linguistic model

Sian K Smith BSc (Hons),* Lyndal Trevena MBBS (Hons) MPhilPH PhD,† Don Nutbeam BEd MA PhD FFPH,‡ Alexandra Barratt MBBS (Hons) PhD FAFPHM§ and Kirsten J McCaffery BSc (Hons) PhD¶

*PhD Candidate, Screening and Test Evaluation Program, Centre for Medical Psychology and Evidence-based Decision-making, ening and Test Evaluation Program, Centre for Medical Psychology and Evidence-lth, †Professor of Public Health, School of Public Health, ‡Associate Professor

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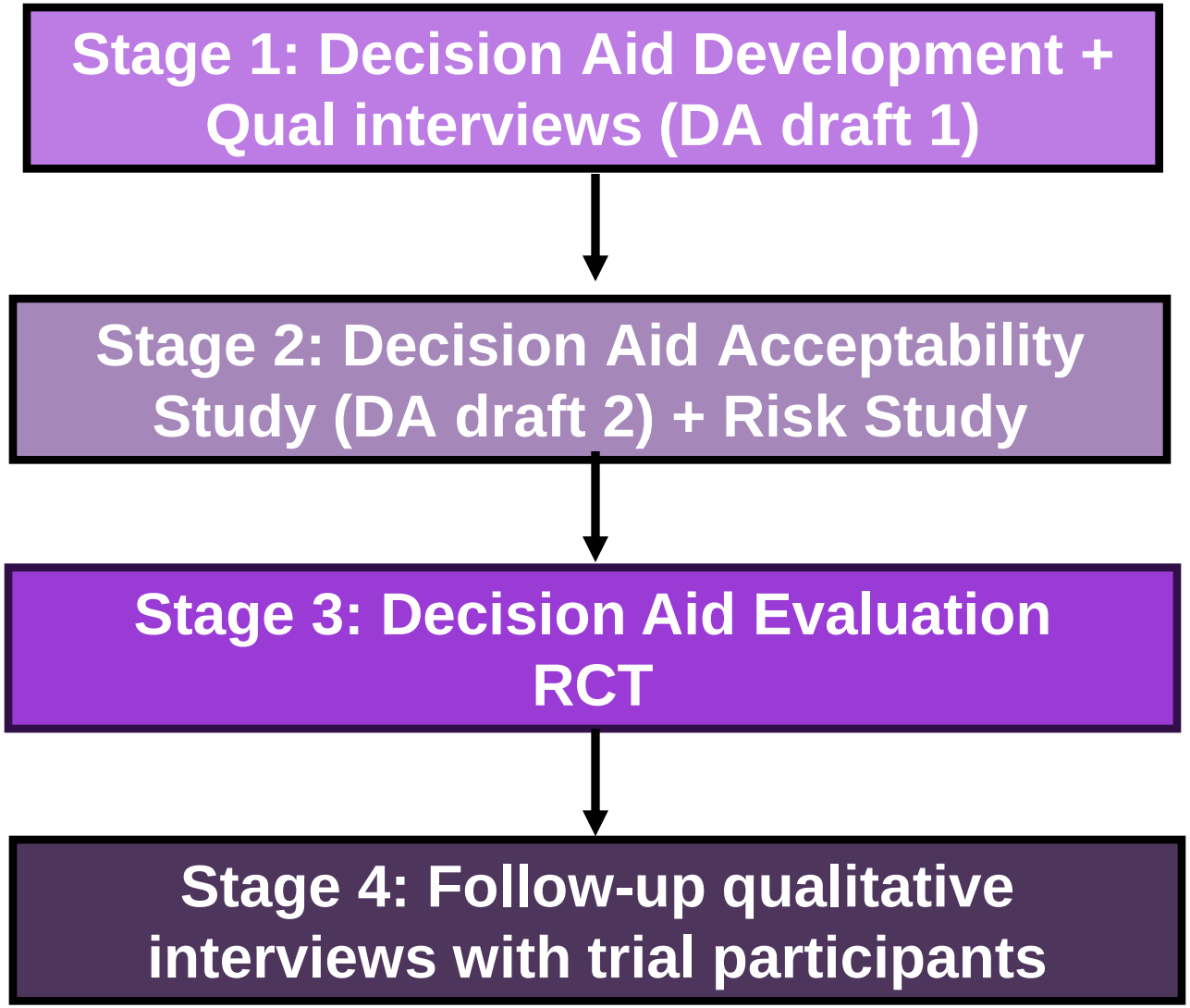
journal homepage: www.elsevier.com/locate/socscimed

Exploring patient involvement in healthcare decision making across different education and functional health literacy groups☆

Sian K. Smith [a,*], Ann Dixon [a], Lyndal Trevena [a], Don Nutbeam [b], Kirsten J. McCaffery [a]

[a] Screening and Test Evaluation Program, School of Public Health, Edward Ford Building (A27), University of Sydney, NSW, Australia
[b] Office of the Vice Chancellor, University of Southampton, Southampton UK

Project Design



Project Design: Stage 1

Decision Aid Development (DA draft 1)

↓

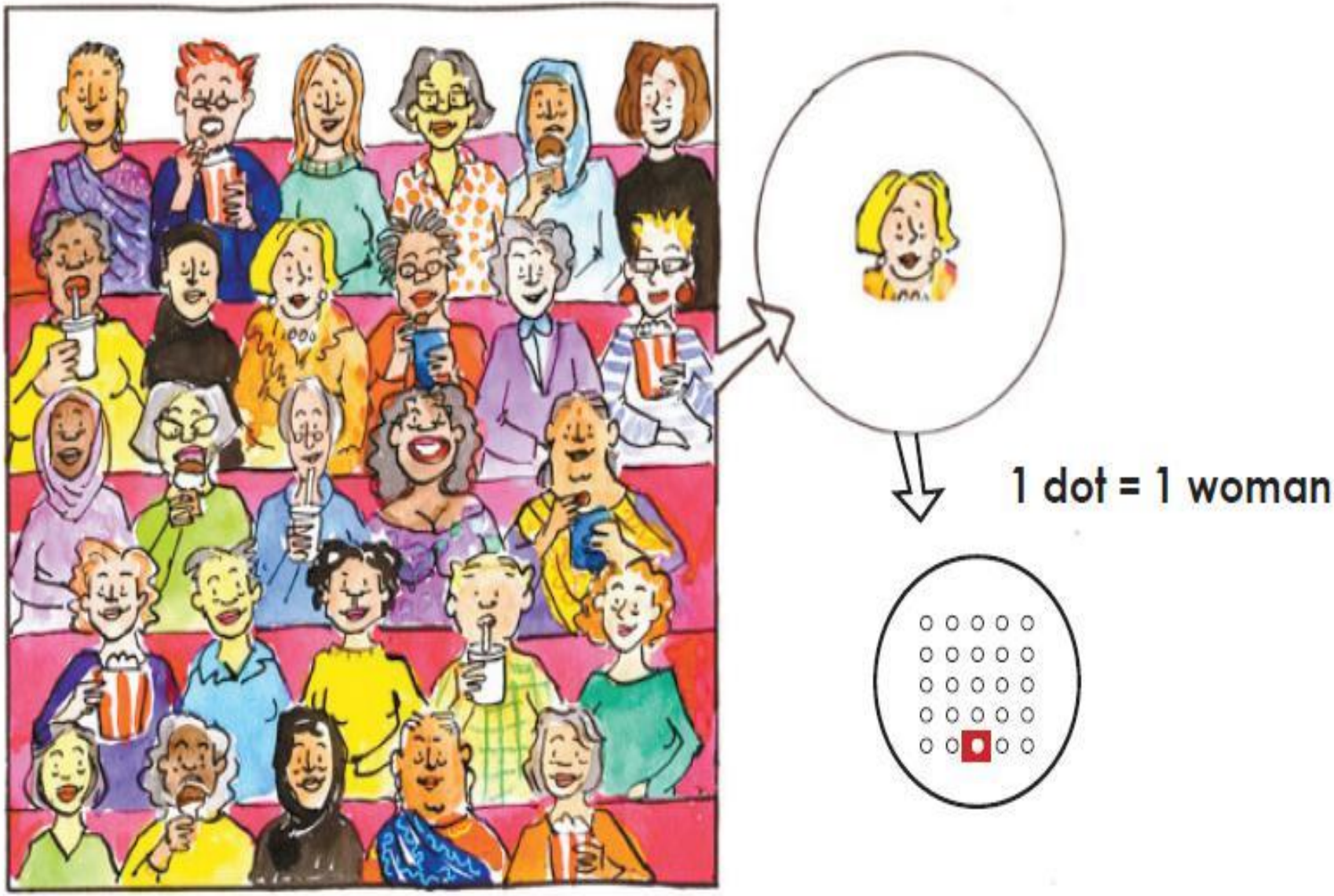
Qual interviews: Understanding information needs and design preferences (n=33)

Qualitative interview study
Smith et al Health Expectations 2008

Smith et al Soc Sci Med 2009

Key findings

- People misunderstood the risk diagrams (1000 systematic oval diagrams; 1 oval =1 person)
- Visuals attracted attention and were engaging
- Difficulties understanding the concept of informed choice in screening
- Values clarification exercises confusing



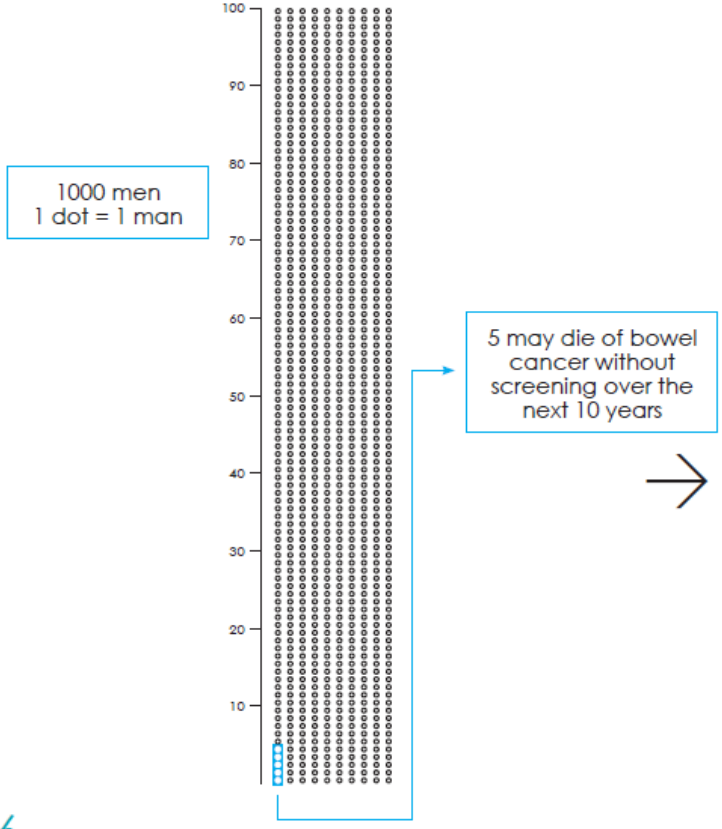
I'm just picturing half of the Enmore theatre. Nine people in there have bowel cancer. That's the way I look at it…

Participant 11, male, age 55, lower literacy

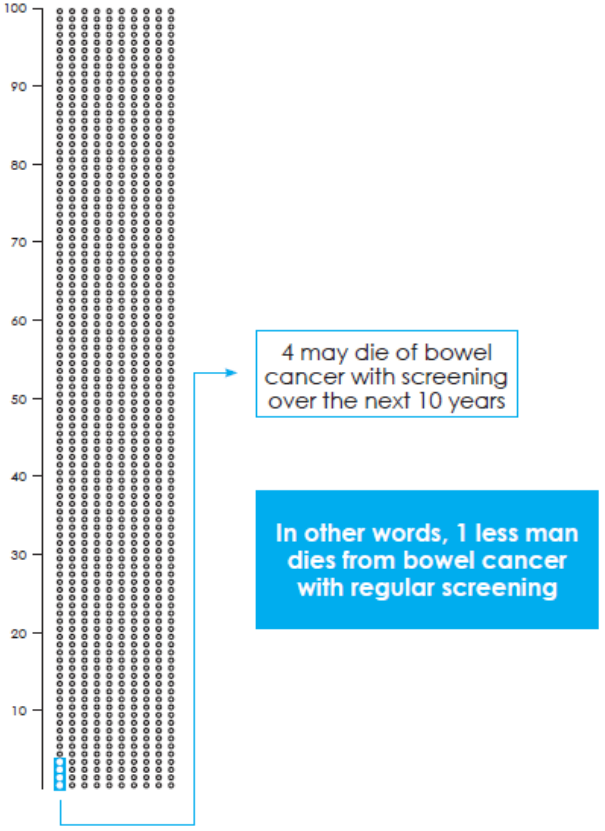
Risk information for men with a weak family history of bowel cancer: bowel cancer mortality with and without FOBT screening.

How does the screening test help men with a **weak family history?**

Of 1000 men your age (55-64) with a **WEAK FAMILY HISTORY** who **DO NOT HAVE SCREENING**, over the next 10 years:

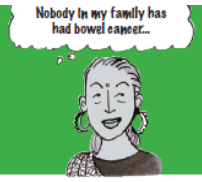


Of 1000 men your age (55-64) with **WEAK FAMILY HISTORY** who **DO HAVE SCREENING**, over the next 10 years:



Personal worksheet for women with no family history of bowel cancer to help clarify their values about the possible outcomes of screening

Your Personal Worksheet
No 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 2 in 1000 (see pages 12 – 13). How does this make you feel about screening?

Lowering your risk of bowel cancer by screening
Having a screening test every 2 years over the next 10 years does not effect your chances of dying from bowel cancer (see pages 12 – 13). How does this make you feel about screening?

Think about the possible screening test outcomes
Bowel cancer screening will tell a large number of people that their risk of bowel cancer is low, but it may not find all cancers and some people will have follow-up procedures (colonoscopy) they do not really need. There are also some rare risks linked to having a colonoscopy (see page 9 and 15). How does this make you feel about screening?

Doing the bowel cancer test at home
Some people find the test a bit unpleasant but it is simple to do and is designed to be done in the privacy of your own home. How does this make you feel about screening?

Other things important to you
Write down any other things that are important to your decision.

How does this make you feel about bowel cancer screening?

Making your decision about the bowel cancer screening test
Thinking about all the points above, how are you feeling about the screening test?

- ☐ Yes, I want to do the test
- ☐ No, I do not want to do the test
- ☐ I am unsure about whether I want to do the test

Sample pages from the decision aid

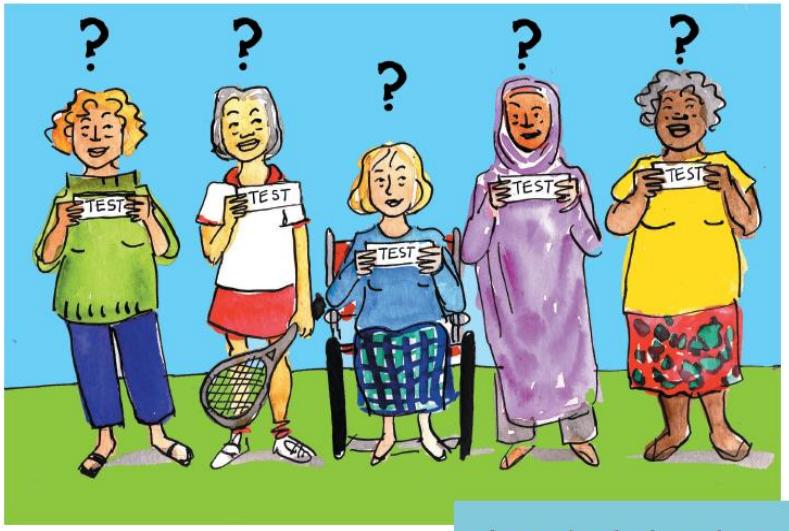
What is cancer screening?

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?

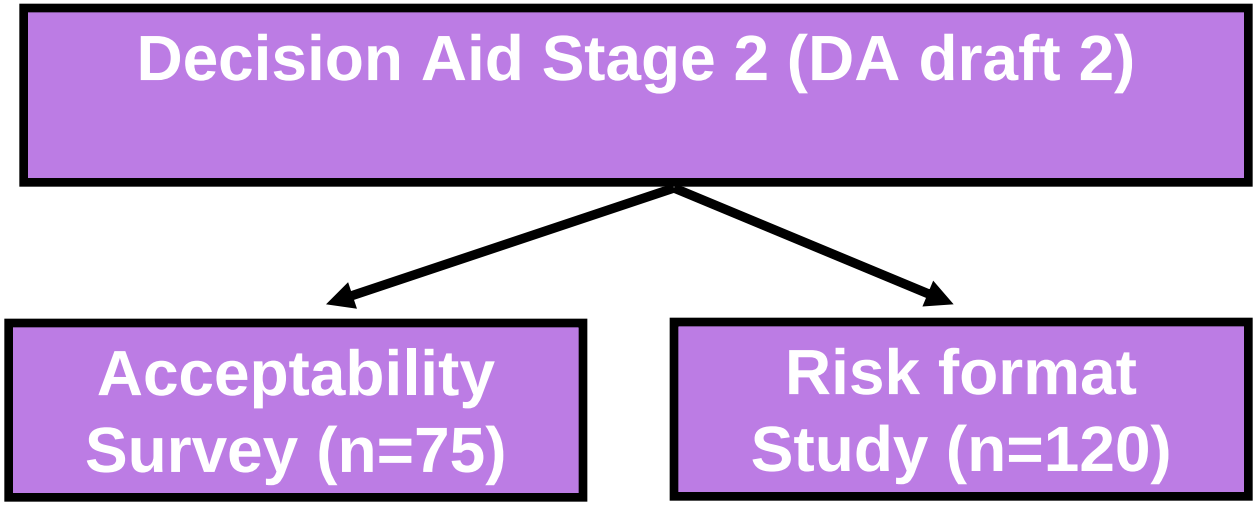
Your age: bowel cancer is more common as you get older.

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.

Project Design: Stage 2



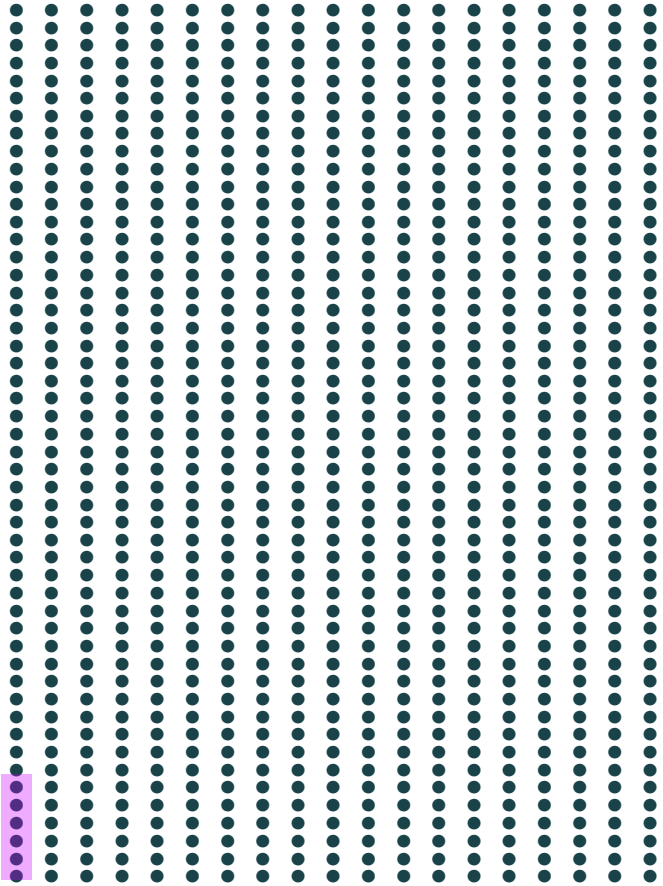
Acceptability findings: Smith et al PEC 2009,

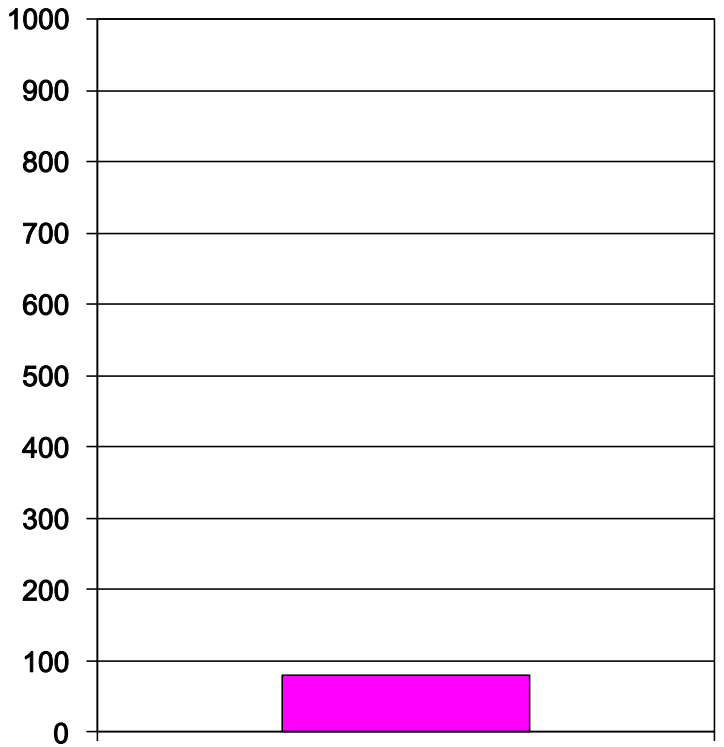
Risk communication study: McCaffery et al MDM 2011

Key findings

- DA used to talk to their GP about bowel screening- included question prompt list
- Produced an audio-visual DVD to accompany the booklet
- Wanted more contextual and procedural information (e.g. What is bowel cancer? How do I do the test?)
- Patient stories not found to be helpful
- Graphical risk communication study informed the choice of risk diagrams: systematic ovals used not bar graphs

GRAPH STUDY





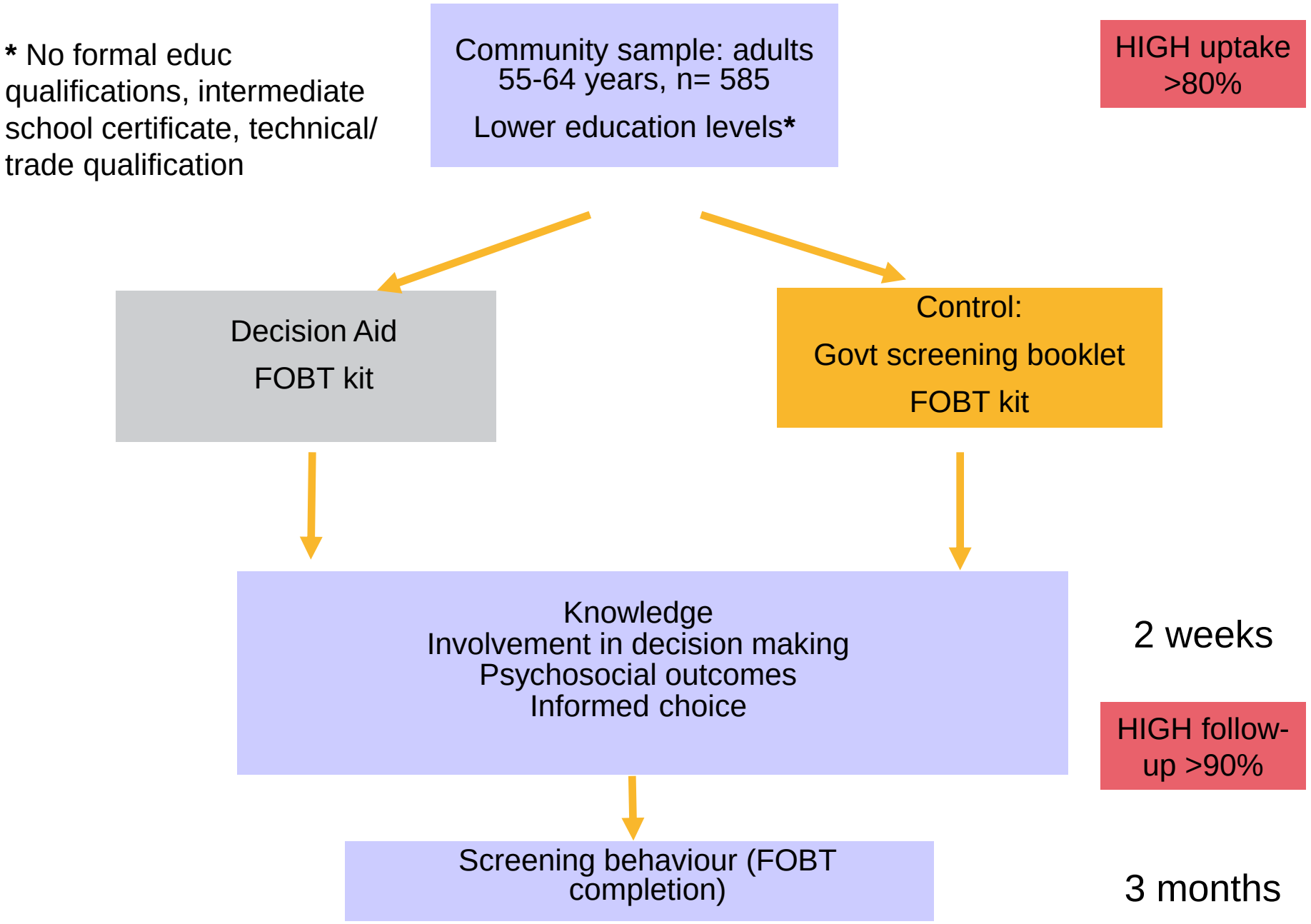
Tested pictographs vs bars among 120 adults with low education and literacy (size, orientation, shading)

Project Design: Stage 3

Decision Aid RCT (DA Final v3) n=585

RCT *Smith et al BMJ 2010, Predictors informed choice*
Smith et al MDM 2011
Qualitative fol up: *Smith et al PEC 2012*

Trial design



TRIAL RESULTS

PtDA had a significant effect on primary and secondary outcomes:

1. **Screening knowledge:** 38% (95%CI 30,45) increase inin PtDA arm (P<0.001).

2. **Informed choice:** 22% (95%CI 15,29) increase in PtDA arm (P<0.001).

3. **Decisional conflict and preferences for SDM:** Reduced uncertainty in DM (P=0.03), increased preferences for SDM (P=0.04).

3 Projects

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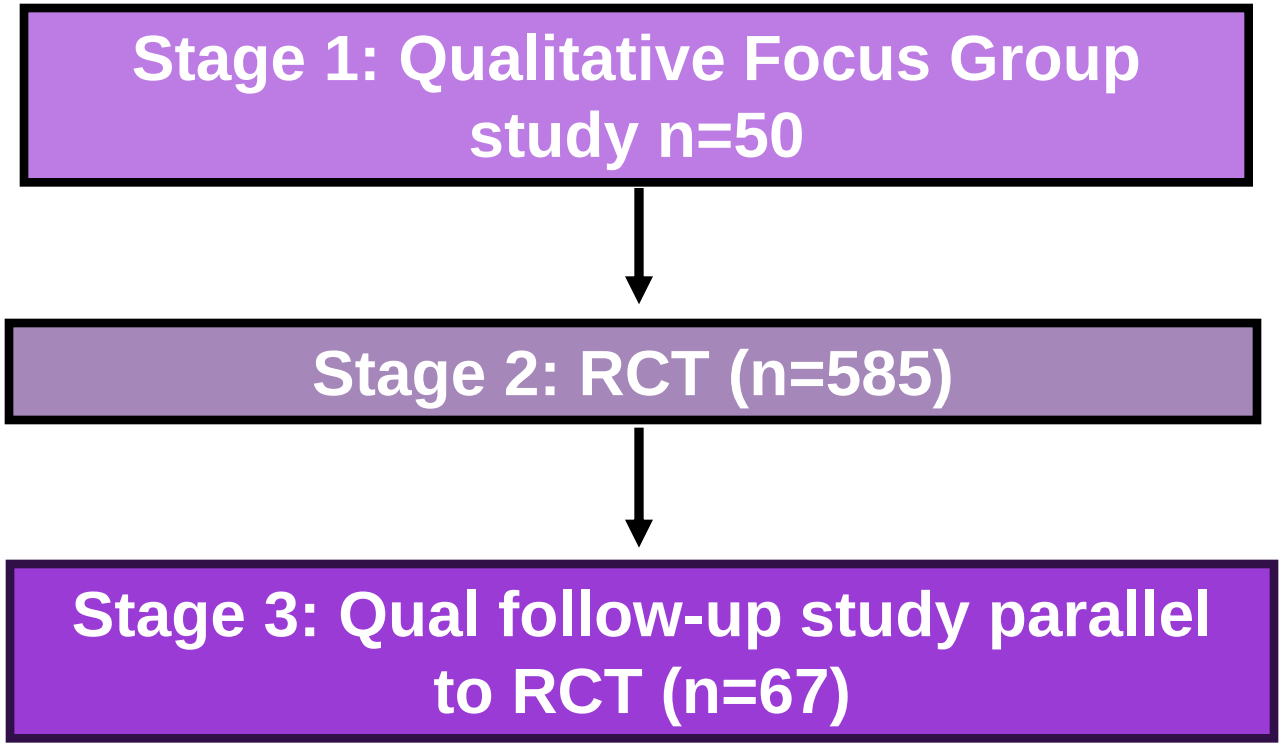
Project Design



RATIONALE FOR THIS RESEARCH

- Breast screening can cause overdetection, leading to over-diagnosis and overtreatment of inconsequential cancers
  - Harm to emotional wellbeing, physical health in short / long term

- Women unaware of risk of overdetection
  - This prevents them being able to make informed decisions about participation in screening
- Evidence lacking re how info on overdetection affects women's breast screening decisions

QUALITATIVE RESEARCH

- Focus groups with 50 diverse women
- Explained and discussed risk of overdetection
- Explored women's understanding and sources of confusion

BMJ 2013;346:f158 doi: 10.1136/bmj.f158 (Published 23 January 2013)

Women's views on overdiagnosis in breast cancer screening: a qualitative study

OPEN ACCESS

Jolyn Hersch *PhD candidate*[1 2], Jesse Jansen *research fellow*[1 2], Alexandra Barratt *professor of public health*[2], Les Irwig *professor of epidemiology*[1], Nehmat Houssami *breast physician and associate professor and principal research fellow*[1], Kirsten Howard *professor of health economics*[1], Haryana Dhillon *research fellow*[2], Kirsten McCaffery *associate professor and principal research fellow*[1 2]

Key findings

- Women wanted information about Odx
- Infographic helped them understand it
- Key misunderstandings: alternative forms of screening, and treatment decisions

Hersch *et al BMJ* 2013

Project Design

Stage 1: Qualitative Focus Group study n=50

Stage 2: RCT of a PtDA including ODx (n=585)

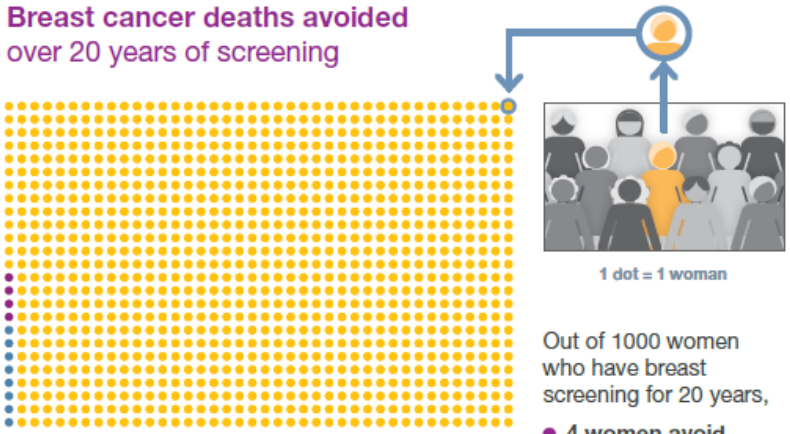
Breast cancer screening: It's your choice

New information to help women aged about 50 to make a decision

1. Screening leads to fewer women dying from breast cancer

The aim of breast screening is to lower the number of women who die of breast cancer.

Breast cancer deaths avoided over 20 years of screening



1 dot = 1 woman

- woman who avoids dying from breast cancer because of screening
- woman who still dies from breast cancer, in spite of screening
- woman who would not die from breast cancer anyway

Out of 1000 women who have breast screening for 20 years,

- **4 women avoid dying from breast cancer** because of screening

and

- **8** women still die from breast cancer.

2. Screening leads to finding some breast cancers that are not harmful (over-detection)*

The cancers found by screening are treated to try and prevent problems later. But some cancers found by screening would never cause problems anyway. Cancers like this may grow very slowly or just stay the same. Without screening, they would never be noticed or cause any trouble. **Finding these cancers through screening is called** over-detection **(or** over-diagnosis**).**

Even after further checks and examination, doctors cannot be sure which cancers will be harmless. Therefore, treatment is recommended. So, across all the women who have screening, some end up having treatment they do not need.

Breast cancer treatments include surgery, radiotherapy, hormone therapy, and chemotherapy. There are important side effects to these treatments which are described on page 8.

Over-detection over 20 years of screening

Out of 1000 women who have breast screening for 20 years,

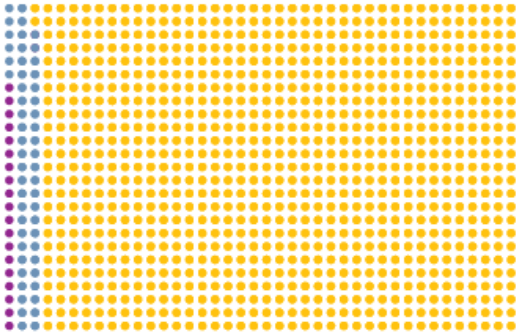
73 women are diagnosed with breast cancer.

Of these,

- **19 women experience over-detection:** they are diagnosed and treated for a cancer that would not have caused any trouble

and

- **54** women are diagnosed with breast cancer that is not over-detection.

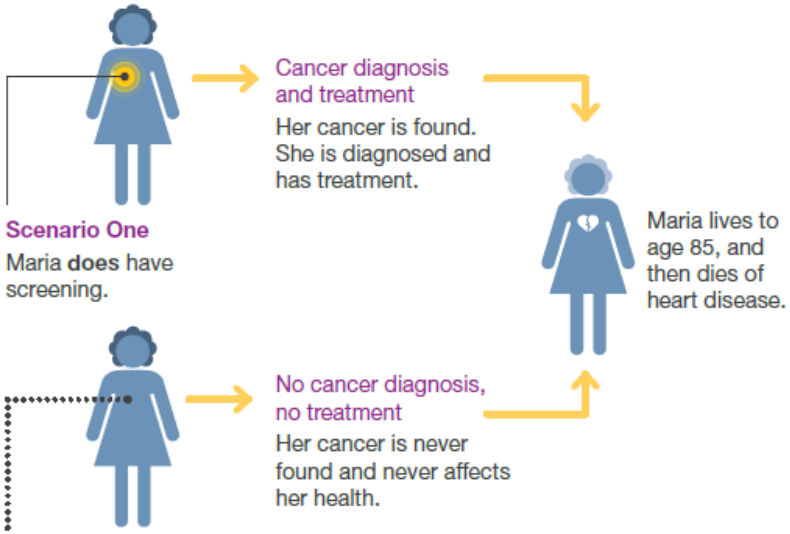


- extra woman diagnosed with breast cancer due to over-detection
- woman diagnosed with breast cancer that is not over-detection
- woman not diagnosed with breast cancer

As this information is new, there is an example of over-detection on the next page.

Over-detection: an example

Imagine a woman called Maria who develops a small, slow-growing breast cancer in her 50s or 60s. The picture below shows two possible scenarios that could happen to Maria: Scenario 1 (top) is with screening, and Scenario 2 (bottom) is without screening.



Scenario One

Maria **does** have screening.

Scenario Two

Maria **does not** have screening.

Maria's life span is the same, whether or not she has screening. So if she has screening, she experiences over-detection (a diagnosis and treatment she does not need).

Putting it together

For women in Australia who have breast screening over 20 years:

4 out of 1000 women avoid dying from breast cancer, and
19 out of 1000 women experience over-detection.

So that means **more women experience over-detection than avoid dying** from breast cancer.

Some questions you may have

1. **What happens after an abnormal screening result?**
   If her screening mammogram result is abnormal, the woman is called to a clinic for extra tests to check whether she has cancer or not. The extra tests may include more mammograms, ultrasound scans, clinical examination, and a biopsy (taking a sample of breast cells, usually with a needle).

2. **How is over-detection different from false positives?**
   False positives occur in women who do not have breast cancer. These women have an abnormal screening result, but then extra tests (see above) show they **do not** have cancer. By contrast, in cases of over-detection the women **do** have breast cancer confirmed by further tests, so they get a cancer diagnosis and treatment (see below).

3. **How is breast cancer treated?**
   As part of their treatment, nearly all women with breast cancer have surgery. Most also have radiotherapy or hormone therapy, and some have chemotherapy. For more information on breast cancer treatments, see below.

Nearly all breast cancer patients have **surgery** to either remove the cancer and a bit of surrounding tissue or to remove the whole breast. In addition, one or more of the other treatments described here may be recommended.

Hormone therapy blocks certain hormones in the body that may be contributing to tumour growth. Common side effects include hot flushes, vaginal dryness, and reduced libido (sex drive).

Radiotherapy uses X-rays to destroy cancer cells in the breast or stop them from growing. Common side effects include tiredness, and the skin of the breast becoming dry and red or darker in colour.

Some breast cancer patients have **chemotherapy**, which uses drugs to destroy cancer cells. Common side effects include nausea and vomiting, tiredness, hair loss, and diarrhoea or constipation.

4. **If I am diagnosed with breast cancer, can I just wait and see if it is growing fast or not before I decide about treatment, or maybe try alternative therapies instead?**
   Once a breast cancer is found, doctors cannot be sure whether it can safely be left alone. This is why they recommend treatment.

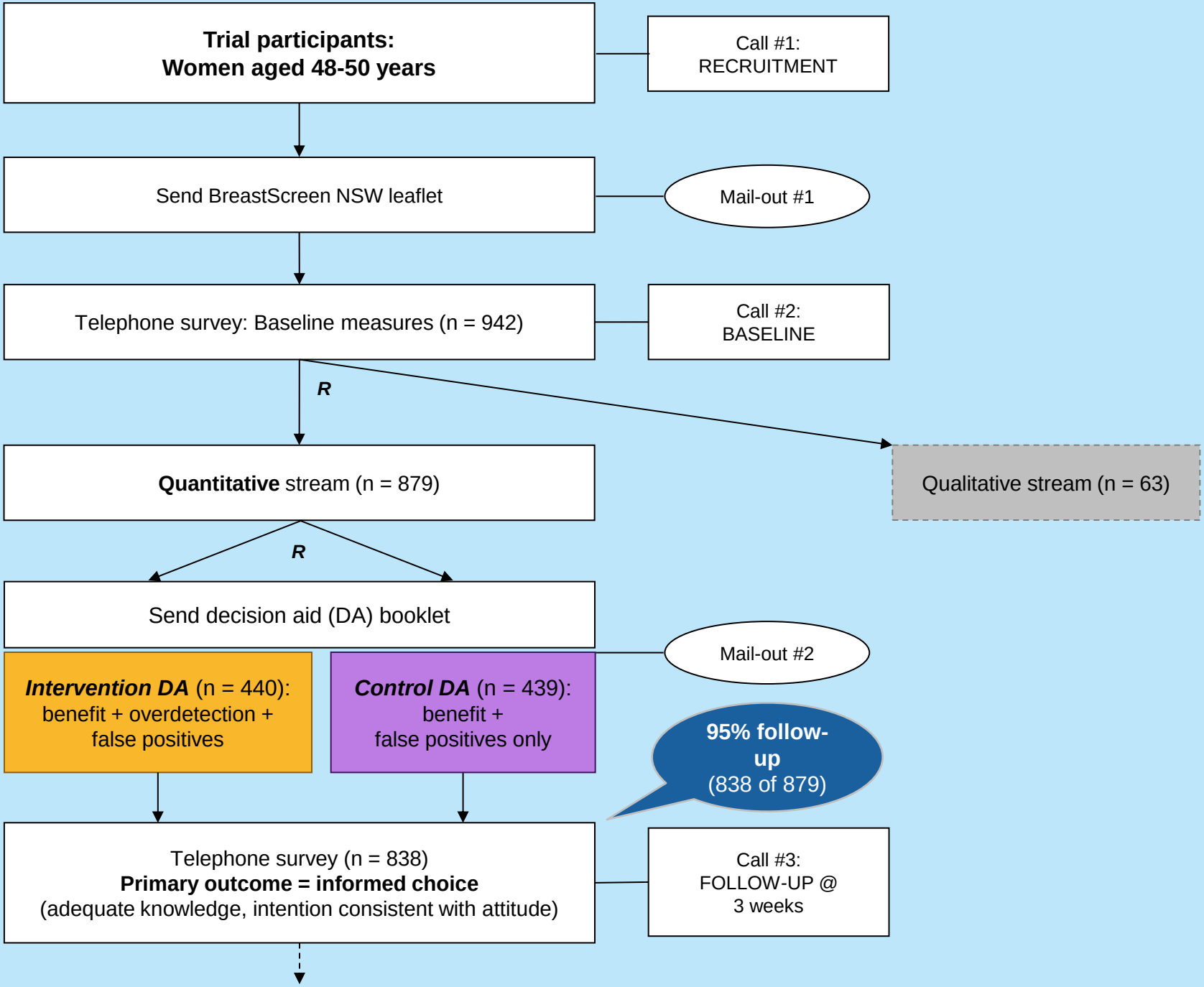
5. **Can I screen using ultrasound or some other test instead, or combine multiple tests?**
   Mammograms are the only tool scientifically shown to work for breast cancer screening in the general population. Having other tests instead of mammograms, or as well, cannot avoid over-detection and has not been shown to have any health benefits.

6. **How do we know that over-detection exists?**
   Over-detection research compares groups (populations) with and without screening. For example, there have been big studies that randomly allocated women to be invited to screening or not. This made two groups that were the same in every way; the only difference between them was whether or not they were offered screening. When researchers followed these groups over many years, they found that more women in the screened group were diagnosed with breast cancer. The reason is that some of the cancers found by screening would never cause symptoms; otherwise the unscreened group of women would have just as many cancers diagnosed.

Making a choice: summary over 20 years with and without screening

Key questions	Screening (over 20 years, from age 50)	No screening (over 20 years, from age 50)
1. What are the chances of dying from breast cancer?	8 out of 1000 women die from breast cancer.	12 out of 1000 women die from breast cancer.
2. What are the chances of being diagnosed and treated for a breast cancer that is not harmful?	19 out of 1000 women are diagnosed and treated for a breast cancer that is not harmful (over-detection).	Women who do not have screening will not experience over-detection caused by screening.
3. What are the chances of having a false positive screening result that leads to extra testing?	412 out of 1000 women have a false positive result and extra testing, when they do not have cancer.	Women who do not have screening will not experience a false positive screening result.
4. What would I need to do?	If you decide to start screening, you will be invited to have another mammogram every 2 years. If you have any breast symptoms, see your doctor.	If you decide not to start screening now, you can always reconsider in the future. If you have any breast symptoms, see your doctor.

Key scientific articles: (1) Barratt A, Howard K, Irwig L, Salkeld G, Houssami N. Model of outcomes of screening mammography: information to support informed choices. *British Medical Journal* 2005; 330: 936. (2) Independent UK Panel on Breast Cancer Screening. The benefits and harms of breast cancer screening: an independent review. *Lancet* 2012; 380: 1778.


Trial participants:
Women aged 48-50 years
Call #1:
RECRUITMENT
Send BreastScreen NSW leaflet
Mail-out #1
Telephone survey: Baseline measures (n = 942)
Call #2:
BASELINE
R
Quantitative stream (n = 879)
Qualitative stream (n = 63)
R
Send decision aid (DA) booklet
Mail-out #2
Intervention DA (n = 440):
benefit + overdetection +
false positives
Control DA (n = 439):
benefit +
false positives only
95% follow-up
(838 of 879)
Telephone survey (n = 838)
Primary outcome = informed choice
(adequate knowledge, intention consistent with attitude)
Call #3:
FOLLOW-UP @
3 weeks

RESULTS: PRIMARY OUTCOME

Outcome	Intervention Group	Control Group	Difference (IG – CG)	P value
Knowledge: Concept+numeric	29%	17%	-12%	<.01
Positive attitudes towards screening	69%	83%	-14%	<.01
Intending to undergo screening	74%	87%	-13%	<.01
MADE INFORMED CHOICE	24%	15%	-9%	<.01

Hersch *et al*
Lancet 2015

Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial

Jolyn Hersch, Alexandra Barratt, Jesse Jansen, Les Irwig, Kevin McGeechan, Gemma Jacklyn, Hazel Thornton, Haryana Dhillon, Nehmat Houssami, Kirsten McCaffery

Lancet 2015; 385: 1642–52
Published Online
February 18, 2015
http://dx.doi.org/10.1016/S0140-6736(15)60123-4
This online publication has been corrected. The corrected version first appeared at thelancet.com on March 26, 2015

Summary

Background Mammography screening can reduce breast cancer mortality. However, most women are unaware that inconsequential disease can also be detected by screening, leading to overdiagnosis and overtreatment. We aimed to investigate whether including information about overdetection of breast cancer in a decision aid would help women aged around 50 years to make an informed choice about breast screening.

Methods We did a community-based, parallel-group, randomised controlled trial in New South Wales, Australia, using a random cohort of women aged 48–50 years. Recruitment to the study was done by telephone; women were eligible if they had not had mammography in the past 2 years and did not have a personal or strong family history of
ith a computer program, we randomly assigned 879 participants to either the intervention decision
evidence-based explanatory and quantitative information on overdetection, breast cancer mortality
lse positives) or a control decision aid (including information on breast cancer mortality reduction
es). Participants and interviewers were masked to group assignment. The primary outcome was
(defined as adequate knowledge and consistency between attitudes and screening intentions), which
elephone interview about 3 weeks after random allocation. The primary outcome was analysed in all
npleted the relevant follow-up interview questions fully. This trial is registered with the Australian
nical Trials Registry, number ACTRN12613001035718.

n January, 2014, and July, 2014, 440 women were allocated to the intervention group and 439 were
ontrol group. 21 women in the intervention group and 20 controls were lost to follow-up; a further
gned to the intervention and 11 controls did not answer all questions on attitudes. Therefore,
e intervention group and 408 controls were analysed for the primary outcome. 99 (24%) of 409 women
on group made an informed choice compared with 63 (15%) of 408 in the control group (difference
; p=0·0017). Compared with controls, more women in the intervention group met the threshold for
knowledge (122/419 [29%] *vs* 71/419 [17%]; difference 12%, 95% CI 6–18; p<0·0001), fewer women
e attitudes towards screening (282/409 [69%] *vs* 340/408 [83%]; 14%, 9–20; p<0·0001), and fewer
to be screened (308/419 [74%] *vs* 363/419 [87%]; 13%, 8–19; p<0·0001). When conceptual knowledge
lered, 203 (50%) of 409 women in the intervention group made an informed choice compared with 79 (19%) of 408 in the control group (p<0·0001).

Interpretation Information on overdetection of breast cancer provided within a decision aid increased the number of women making an informed choice about breast screening. Becoming better informed might mean women are less likely to choose screening.

Funding Australian National Health and Medical Research Council.

Correspondence to:
Prof Kirsten McCaffery, School of Public Health, The University of Sydney, Sydney, NSW 2006, Australia
kirsten.mccaffery@sydney.edu.au

Significance:

- can communicate complex information about Odx to women
- it changes some women's screening decisions:
- ethical questions about responsibility to inform women

3 Projects

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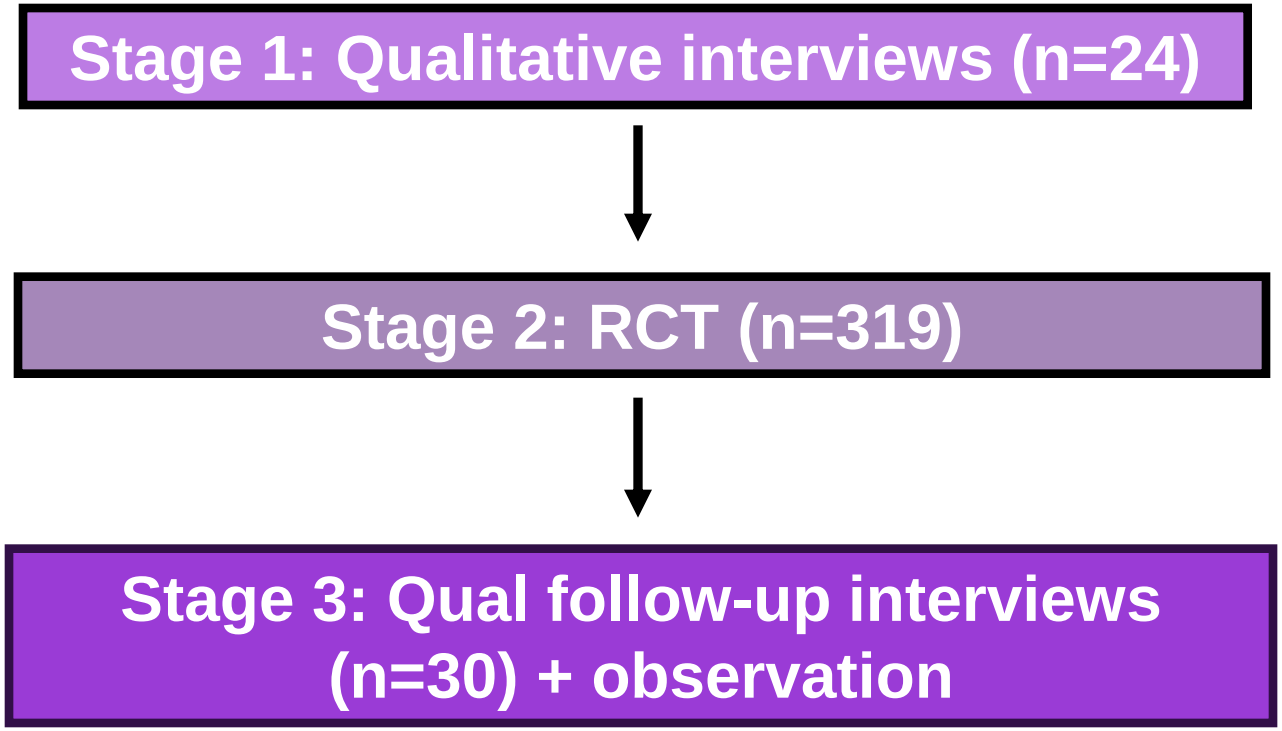
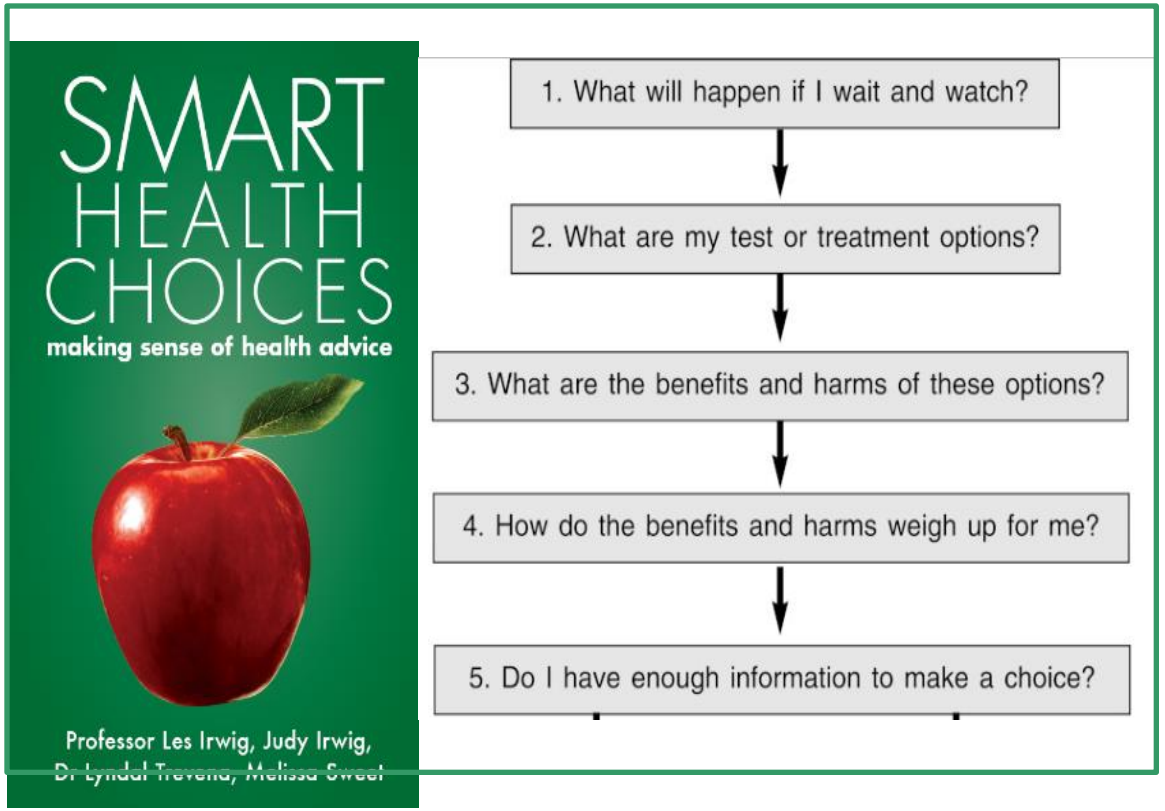
3. SDM intervention for adults attending basic literacy and numeracy classes in Australia n= 319

Project Design

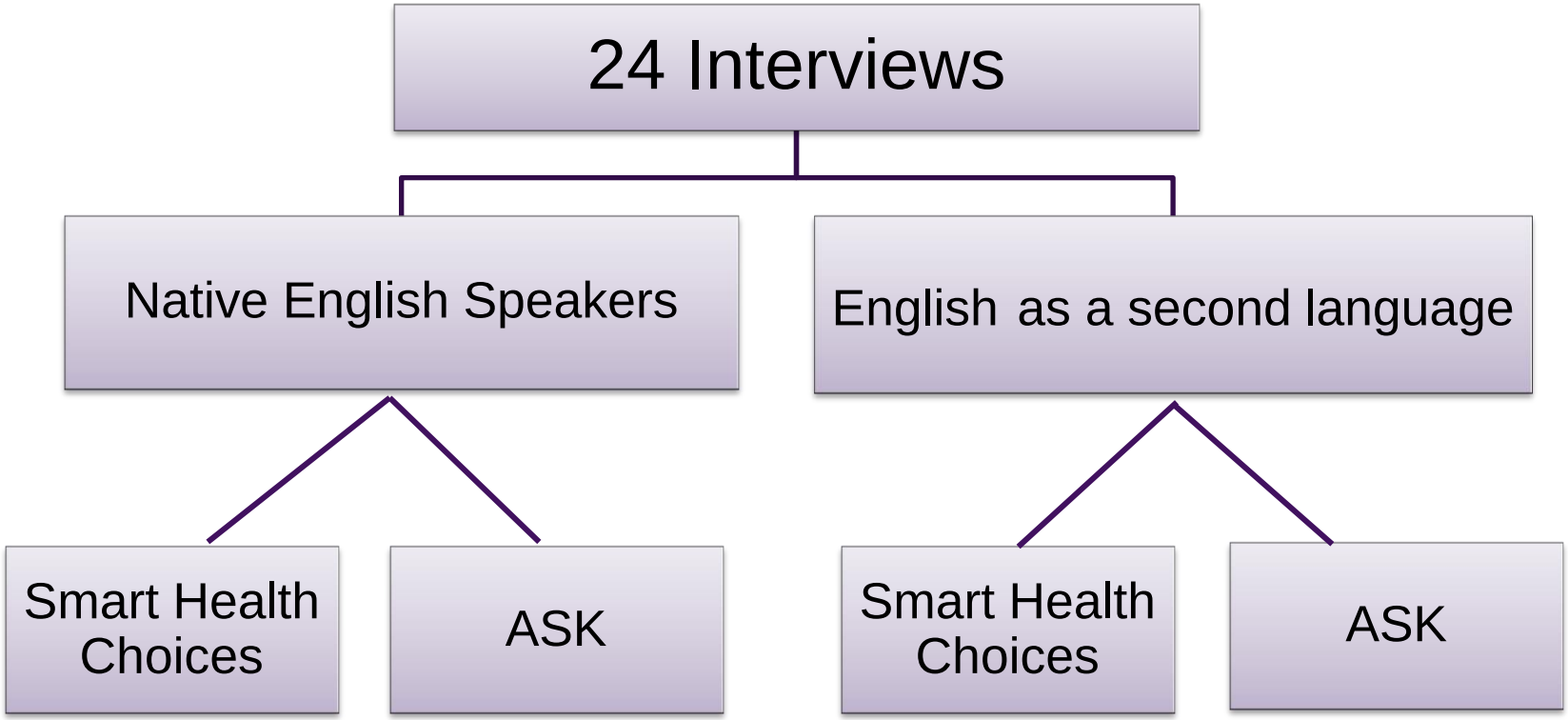


1. What are my options? (Including wait and watch)
2. What are the possible benefits and harms of those options?
3. How likely are each of those benefits and harms to happen to me?

ASK SHARE KNOW: Shepherd H *et al* *Patient Educ Couns* (2011).



***Smart health choices**:* Irwig, L. (2008). *Making sense of health advice*. London: Hammersmith.


24 Interviews
Native English Speakers
English as a second language
Smart Health Choices
ASK
Smart Health Choices
ASK

KEY FINDINGS

› Difficulty understanding both Ask Share Know and Smart Health Choices questions. Overall Ask Share Know found easier but additional support needed

Key misunderstandings

- Options
- Wait and watch
- Harms
- Third question

What are my opi- opi- opions?” (G201)

“Wait is …when you have to wait. And watch is when you watch TV…” (G201)

“Sorry, I don’t know this word.” (G202)

SUMMARY

3 successful interventions in area of SDM:

- Good uptake and adherence within the studies.
- Significant effect on the primary outcomes in each trial
- Careful piloting and consultation with our target audience has been highly effective.
- Published developmental work along the way
- This supports transparency in intervention development and reporting (Hoffman et al BMJ 2014 TIDieR)

MOVING FORWARD…..

- Made efforts to include our target sample in the research/ investigator team in recent projects.
- Proved difficult – people can find it intimidating, have other commitments and often drop out.
- But we are learning: setting up a panel of consumers, pay them for their time, get contributions early in design process.

Straus, Tetroe, Graham 2013
Knowledge to Action Framework

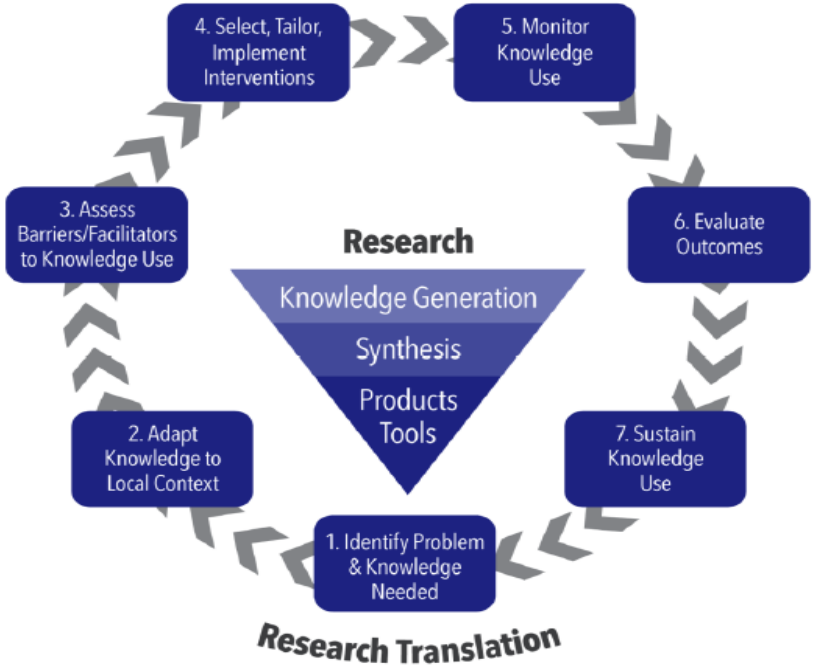
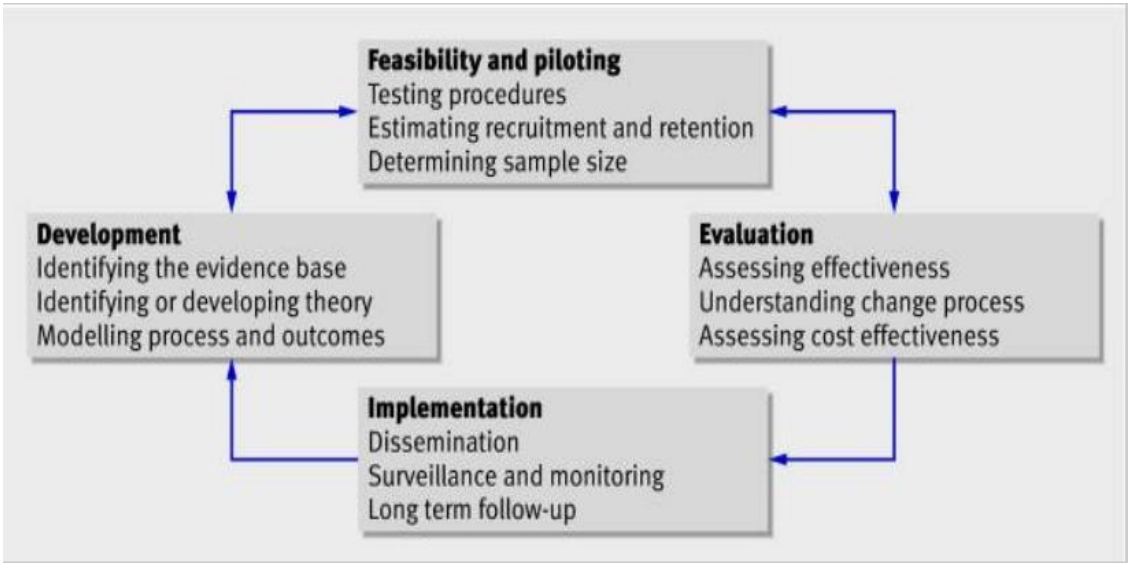


Figure 1: Model for research and research translation activities.



UK Medical Research Council
Developing and Evaluating
Complex Interventions 2008

THANK YOU

kirsten.mccaffery@sydney.edu.au

SYDNEY MEDICAL SCHOOL

Sydney School of Public Health
Screening and Test Evaluation Program
Centre for Medical Psychology & Evidence Based Decision-making

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