



The University of Sydney  
School of Psychology

# An International Randomised Trial of Skills Training in Gaining Consent to Clinical Trials and Standard Treatment from Patients with Early Breast Cancer.

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The University of Sydney





# Background

- Patients should be given the opportunity to participate in decisions *to the level that they prefer*, and give informed consent to clinical trials and standard treatments: according to the shared decision making (SDM) paradigm<sup>1</sup>
- But:
  - Patients have difficulty understanding treatment options and making an informed choice
  - Doctors find it difficult to facilitate SDM, and to present treatment options with clarity and without coercion (particularly clinical trials)
- Only 2-4% of adult cancer patients are recruited into trials, and doctor barriers account for over 50% of non-accrual.<sup>2,3</sup>
- Audiotape audits reveal that communication is not currently always ideal<sup>4</sup>



1. Gattelari M, Butow P et al. *Soc Sci Med*, 2001; 51, 1865-78
2. Saetern WB et al. *JCO* 2002;20:2109–2117.
3. Lee JY & Breaux SR. *Cancer*, 1983; 52, 1014 - 1016.
4. Tomamichel M et al. *Annals of Oncology*, 1995; 6, 363 - 369



# Background

- Consultation skills training may improve this process
- Few large scale evaluations of consultation skills training have been published
  - Most have focused on generic, or emotion-focused skills
  - Most have evaluated doctor behaviour, not patient outcomes



# Background

- Brown et al developed and piloted a consultation skills training program targeting **the discussion of treatment options**.<sup>1</sup>
  - The program was valued by doctors, and resulted in changes to doctor behaviour <sup>2</sup>
- **The current study aims** to evaluate in a multi-centre, randomised controlled trial, the impact of this consultation skills training program on doctor and patient outcomes



1. Brown R, Butow P et al, *Soc Sci Med* 2003; 58/2, 379-390.
2. Brown, R, Butow, P et al *Psycho-oncology*. (2007) 16(6), 507 - 516





# Study team

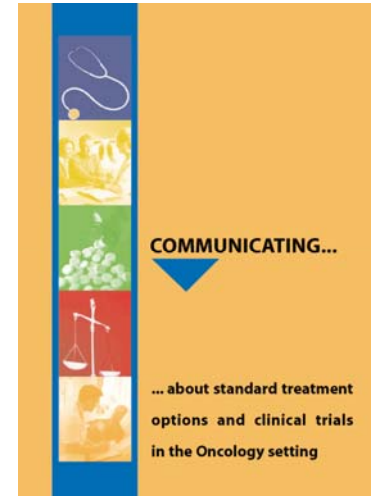
- Collaboration between the **The University of Sydney (CeMPED)** and **IBCSG** (Swiss QOL office)
- Investigators: **Phyllis Butow<sup>1</sup>, Jurg Bernhard<sup>2</sup>, Julie Aldridge<sup>3</sup>, Richard Brown<sup>1</sup>, Ilona Juraskova<sup>1</sup>, Fran Boyle<sup>1</sup>**
  1. University of Sydney: CeMPED
  2. IBCSG: Swiss QOL Office
  3. IBCSG: Statistical centre





# Training Content

- **1 day face-to-face workshop**
  - **Strategies document, based on:**
    - review of the literature
    - analysis of actual consultations
    - a consensus process, involving stakeholders
  - **Role-play** of difficult scenarios
  - **Individualised feedback** about 2 audio-taped consultations with real patients transcribed and analyzed using the Decision Analysis System for Oncology (DAS-O)<sup>1</sup>
- **A follow-up phone call 1 month later**, to resolve difficulties/concerns
- **Provision of consultation pathway** to guide discussion





# Four key concepts

1. Establishing the patient-doctor team
2. Following a consultation pathway
3. Aiding patient understanding
4. Disclosure and avoiding coercion



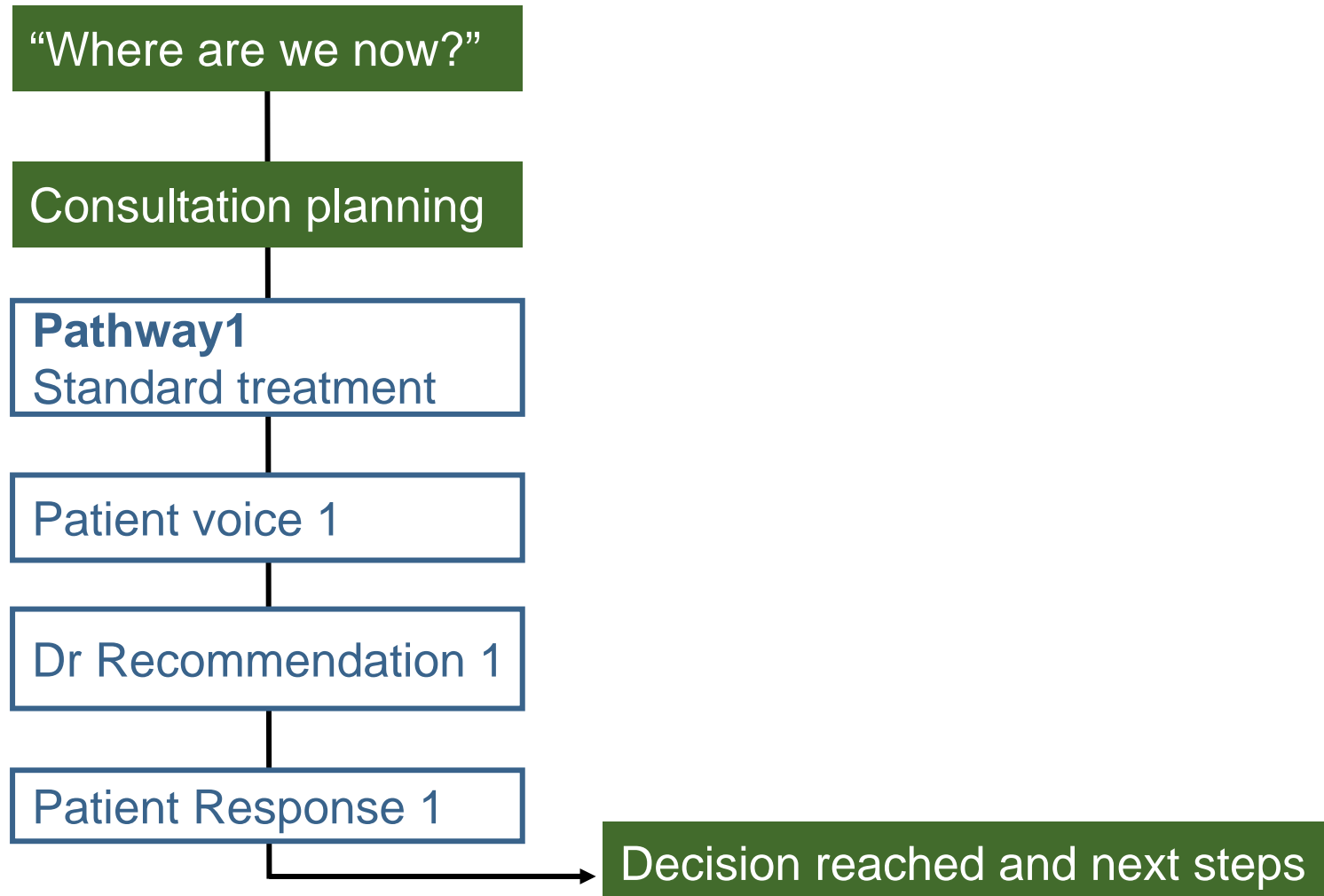
# Key concept 1: Establishing the patient-doctor team

- Introduce joint decision-making
- Check preferences for:
  - Information
  - Involvement in decision-making
- Check understanding & medical knowledge
- Invite questions and comments
- Portray the patient as active
- Explicitly offer choice



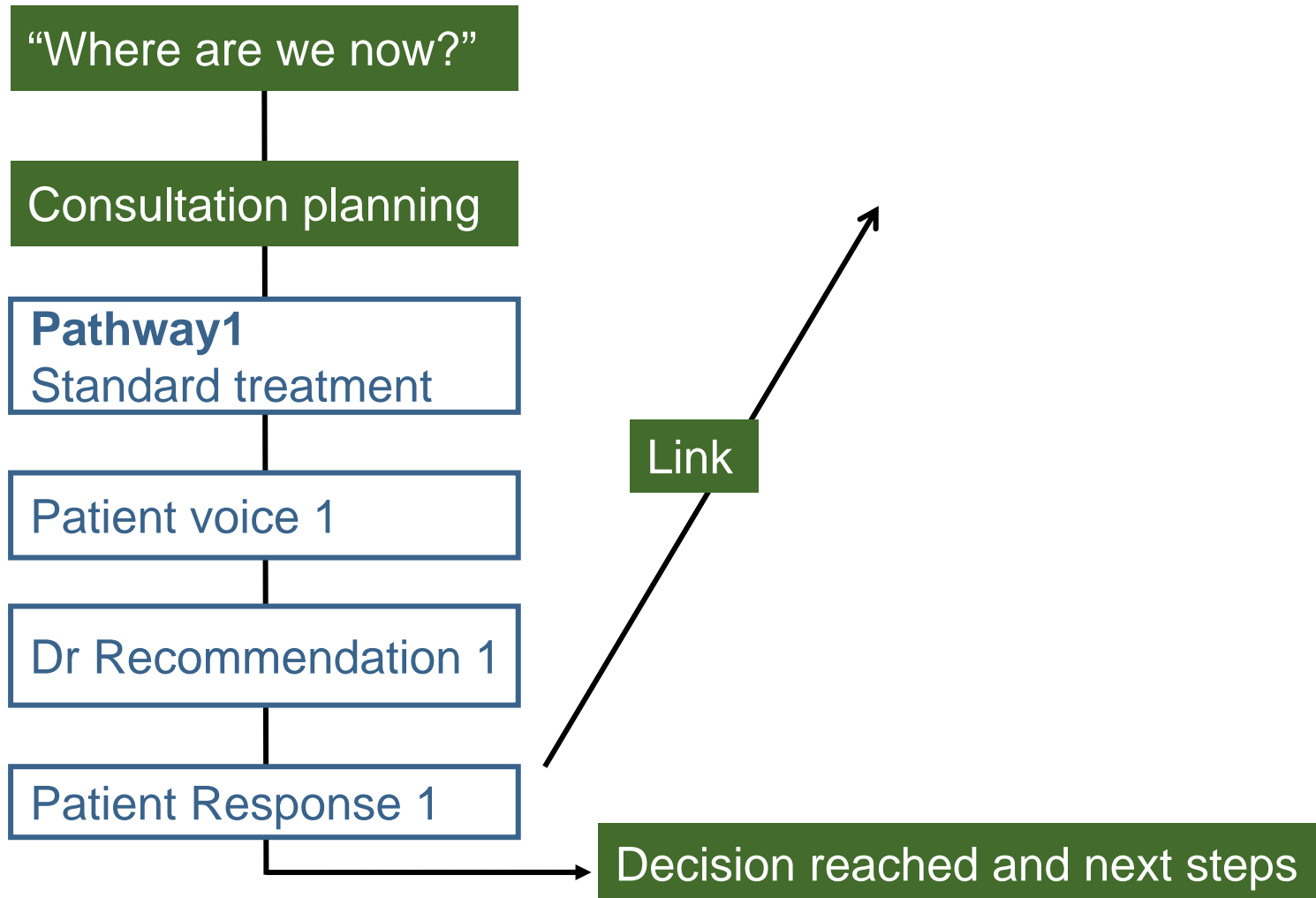
# Key Concept 2: Following a consultation pathway

*Brown et al, Soc Sci Med 2004*



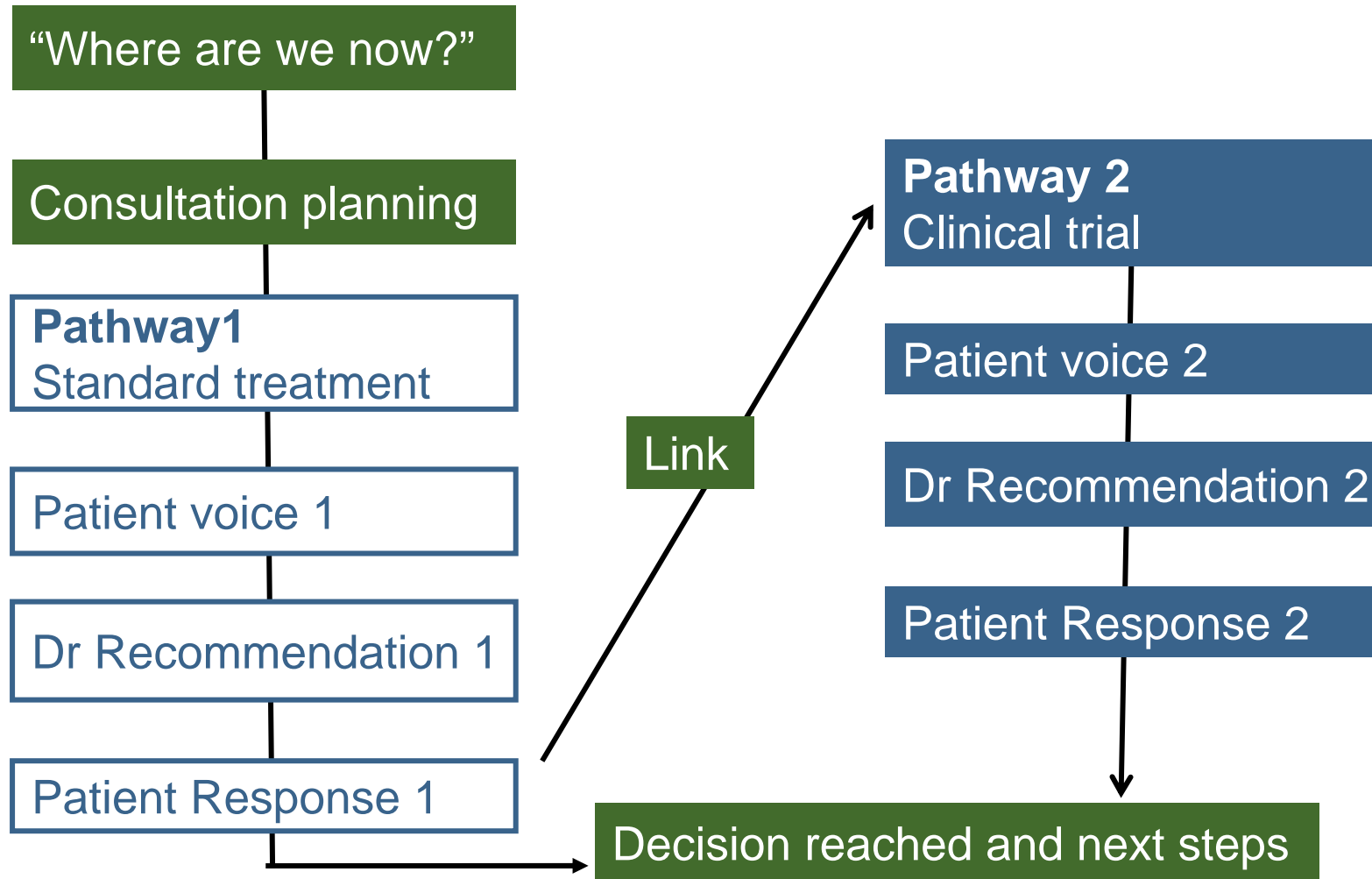
# Key Concept 2: Following a consultation pathway

*Brown et al, Soc Sci Med 2004*



# Key Concept 2: Following a consultation pathway

*Brown et al, Soc Sci Med 2004*





# Key concept 3: Aiding understanding

- Provide all relevant information
- Group and categorise information
- Use simple language; avoid jargon
- Summarise
- Order information
- Draw diagrams





# Key concept 4: Avoiding coercion and disclosing

- Avoid language which implies exclusion or inclusion as a result of treatment choice
- Spend the same time on all options
- Avoid minimising side effects of one treatment
- Avoid differential use of framing or statistics
- Encourage individual choice
- Disclose:
  - availability of trial treatment off-trial
  - other possible trials available
  - financial benefit: personal / institutional
  - career benefit



# IBCSG 33-03: Trial design

**Pre-patient-cohort:** 5-10 patients per doctor. Prospective assessment pre, 2 weeks and 4 months after consultation

## Randomization of doctors

**Communication skills training**

**No training**

Prospective assessment of doctor measures before, immediately after, and 5 months after training

**Post-patient-cohort:**  $\geq 8$  patients per doctor. Prospective assessment pre, 2 weeks and 4 months after consultation





# Primary outcome

- Patient decisional conflict
  - Patient reported outcome
  - 12-items with 3 sub-scales
    - decisional uncertainty
    - factors contributing to uncertainty
    - perceived effectiveness of decision making
  - Good test-retest reliability ( $r=0.81$ ), internal consistency, (alphas 0.78-0.92), discriminant and construct validity
  - Items:
    - *This decision was hard for me to make*
    - *I needed more advice and information about the choices*
    - *I was unsure what to do in this decision*



# Secondary patient outcomes

- Achievement of preferred level of involvement (Cassileth et al 1980)
- Satisfaction with
  - decision (Holmes-Rovner et al 1996)
  - consultation (Adapted from Roter 1977, Korsch et al 1968)
  - doctor communication (Brown et al 2001)
- Patient knowledge (Study developed)
- State anxiety (Spielberger 1983)
- Quality of life (IBCSG)



# Secondary doctor outcomes

- Communication skills
  - DAS-O <sup>1</sup> ratings of 2 audio-taped consultations in the pre-cohort and 2 in the post-cohort
- Satisfaction with
  - training
  - information provision
- Stress and burnout <sup>2</sup>
  - subscales: 1. Depersonalisation, 2. Emotional exhaustion, 3. Personal accomplishment



# Tape coding: DAS-O

- Blind coder
- What was coded?
  - Establishing dr/pt team (21 behaviours)
  - Following consultation pathway (12 phases)
  - Information about standard treatment ( 6 items)
  - Information about clinical trial (14 items)
  - Clarity ( 7 items)
  - Disclosure and coercion ( 8 items)
- Presence or absence + Subjective quality score (basic /advanced)
- Inter-& intra- rater reliability: kappa = 0.54



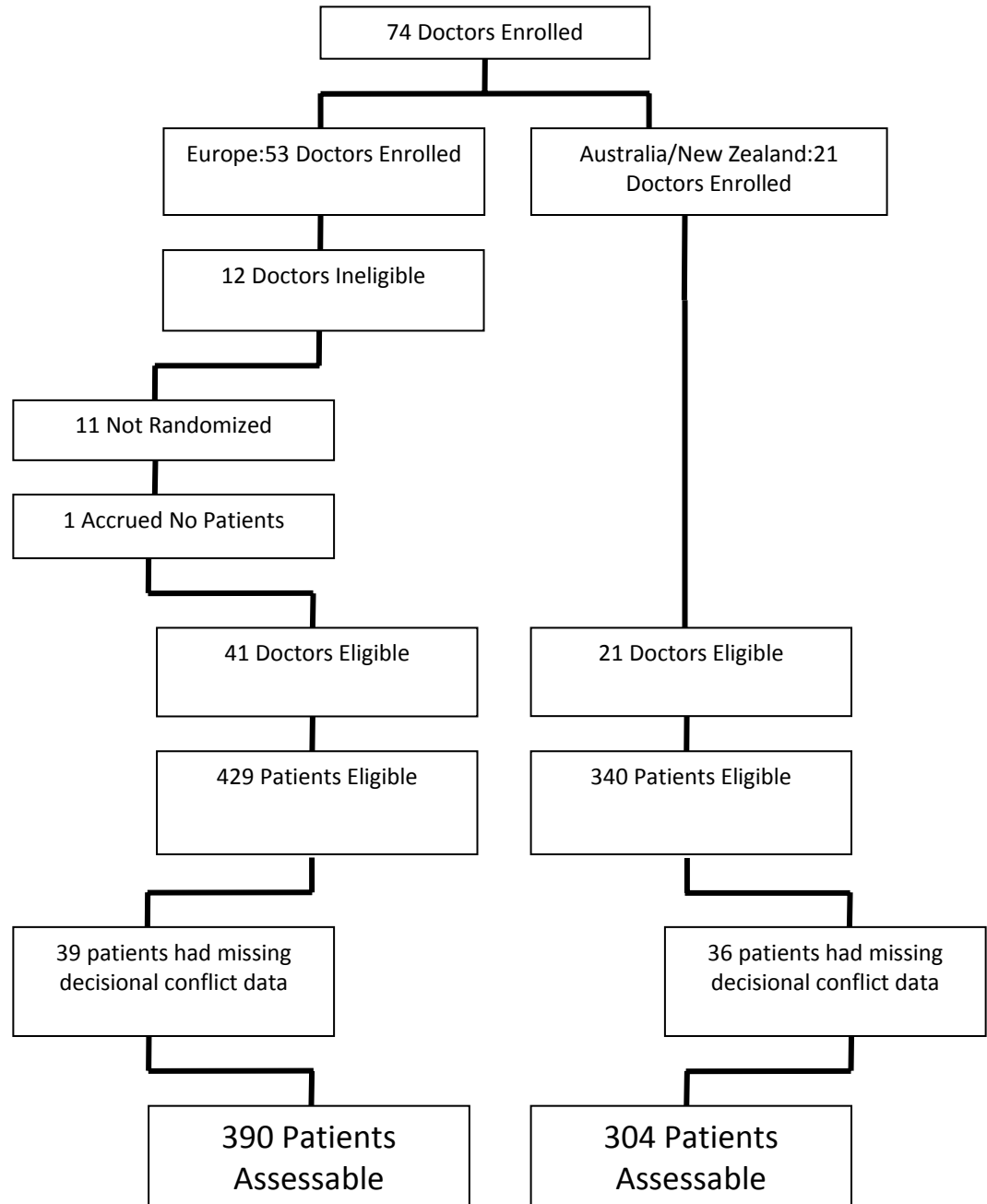
# Statistical analysis

- **Primary objective:** to assess the impact of the training on patient decisional conflict (DCS) two weeks post- consultation
- **Protocol:** target accrual of 44 doctors (22 per group) to detect a 3 point difference in DCS between the two groups with 90% power,  $\alpha=0.05$ , 10 patients per doctor
- **Interim analysis (2006):** based on 19 doctors from ANZ (average of 8 patients each), ICC of 0.05, and  $S^2$  (variance within doctors plus variation among doctors) of 48.8, we needed *19 doctors from SGA* (8 patients each) to detect a 3 point difference in DCS with 90% power
- **Mixed model:** data at the patient level, doctor as a random effect, to compare the difference in DCS between the rand. groups for each of the language cohorts

$$(T_{post} - T_{pre}) - (C_{post} - C_{pre})$$

# Results:

## Recruitment & retention





## Doctor baseline characteristics

|                     | Switzerland/Germany/Austria (n=41) |           |          |           | Australia/New Zealand (n=21) |           |          |           |
|---------------------|------------------------------------|-----------|----------|-----------|------------------------------|-----------|----------|-----------|
|                     | Control                            |           | Training |           | Control                      |           | Training |           |
|                     | N                                  | %         | N        | %         | N                            | %         | N        | %         |
| n                   | 20                                 | 100       | 21       | 100       | 11                           | 100       | 10       | 100       |
| Age, median (range) | 33                                 | (27 - 44) | 34       | (24 - 48) | 47                           | (33 - 58) | 44       | (38 - 62) |
| <b>Gender</b>       |                                    |           |          |           |                              |           |          |           |
| Male                | 7                                  | 35        | 8        | 38        | 6                            | 55        | 5        | 50        |
| Female              | 13                                 | 65        | 13       | 62        | 5                            | 45        | 5        | 50        |
| <b>Specialty</b>    |                                    |           |          |           |                              |           |          |           |
| Medical Oncology    | 6                                  | 30        | 5        | 24        | 6                            | 55        | 6        | 60        |
| Radiology           | -                                  | -         | -        | -         | 3                            | 27        | 3        | 30        |
| Surgeon             | 2                                  | 10        | 2        | 10        | 2                            | 18        | 1        | 10        |
| Gynaecologist       | 12                                 | 60        | 14       | 67        | -                            | -         | -        | -         |



## Doctor baseline characteristics

|   | Switzerland/Germany/Austria (n=41) |           |          |          | Australia/New Zealand (n=21) |          |          |          |
|---|------------------------------------|-----------|----------|----------|------------------------------|----------|----------|----------|
|   | Control                            |           | Training |          | Control                      |          | Training |          |
|   | N                                  | %         | N        | %        | N                            | %        | N        | %        |
| n   | 20                                 | 100       | 21       | 100      | 11                           | 100      | 10       | 100      |
| <b>Institution</b>  |                                    |           |          |          |                              |          |          |          |
| Public  | 20                                 | 100       | 20       | 95       | 7                            | 64       | 7        | 70       |
| Private   | -                                  | -         | 1        | 5        | -                            | -        | -        | -        |
| Both  | -                                  | -         | -        | -        | 4                            | 36       | 3        | 30       |
| <b>Previous training in communication skills</b>  | 6                                  | 30        | 4        | 19       | 5                            | 45       | 6        | 60       |
| <b>Previous years of practice, median (range)</b>   | 6                                  | (1 - 18)  | 6        | (1 - 24) | 16                           | (2 - 35) | 20.5     | (8 - 37) |
| <b>Average no of patients per doctor recruited to any trial over 6 mnths median (range)</b> | 15                                 | (5 - 200) | 15       | (3 - 55) | 15                           | (5 - 50) | 8        | (3 - 20) |





## Patient baseline characteristics

|                     | Switzerland/Germany/Austria (n=429) |           |          |           | Australia/New Zealand (n=340) |           |          |           |
|---------------------|-------------------------------------|-----------|----------|-----------|-------------------------------|-----------|----------|-----------|
|                     | Control                             |           | Training |           | Control                       |           | Training |           |
|                     | N                                   | %         | N        | %         | N                             | %         | N        | %         |
| n                   | 214                                 | 100       | 215      | 100       | 171                           | 100       | 169      | 100       |
| Age, median (range) | 58                                  | (24 - 85) | 58       | (31 - 88) | 50.5                          | (27 - 81) | 53       | (30 - 83) |
| Tumor size, median  | 2                                   |           | 2        |           | 1.9                           |           | 2        |           |
| <b>Nodal Status</b> |                                     |           |          |           |                               |           |          |           |
| Missing             | 3                                   | 1         | 8        | 4         | 2                             | 1         | 7        | 4         |
| Negative            | 138                                 | 64        | 129      | 60        | 100                           | 58        | 96       | 57        |
| Positive            | 73                                  | 34        | 78       | 36        | 69                            | 40        | 66       | 39        |



## Patient baseline characteristics

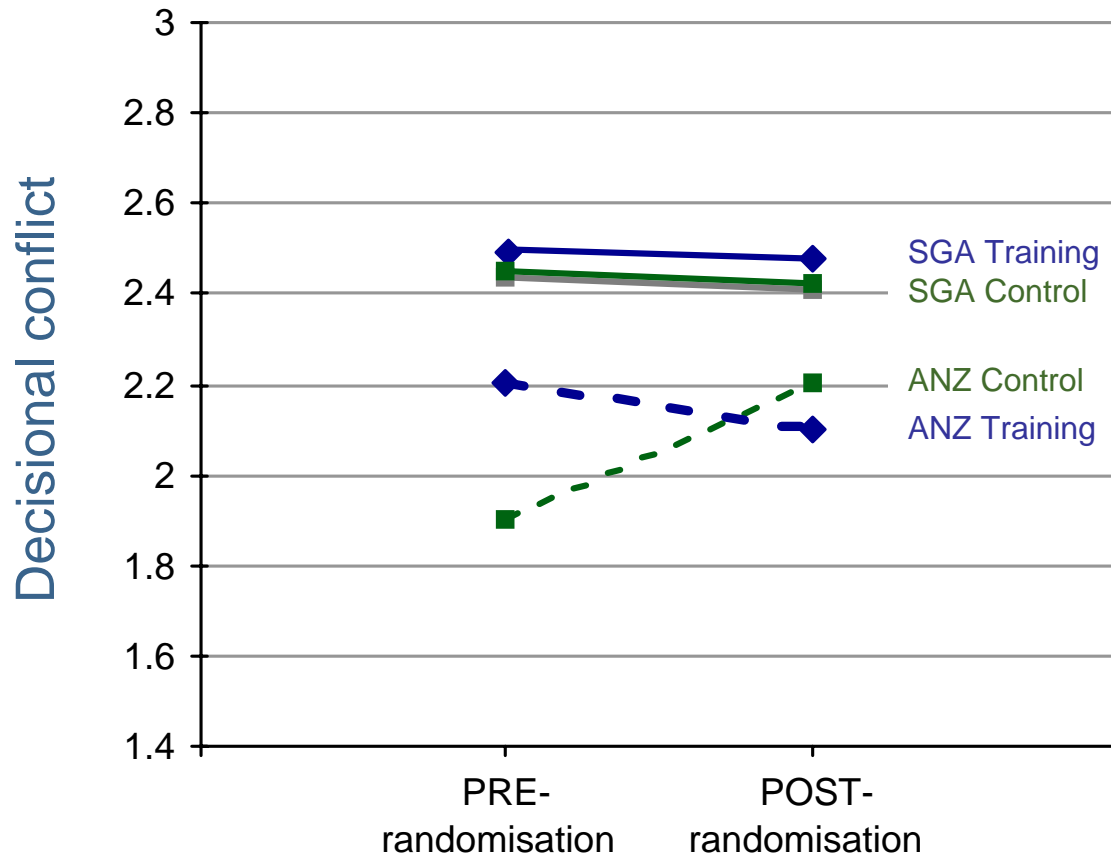
|                         | Switzerland/Germany/Austria (n=429) |     |          |     | Australia/New Zealand (n=340) |     |          |     |
|-------------------------|-------------------------------------|-----|----------|-----|-------------------------------|-----|----------|-----|
|                         | Control                             |     | Training |     | Control                       |     | Training |     |
|                         | N                                   | %   | N        | %   | N                             | %   | N        | %   |
| n                       | 214                                 | 100 | 215      | 100 | 171                           | 100 | 169      | 100 |
| Grade of tumor          |                                     |     |          |     |                               |     |          |     |
| 1                       | 2                                   | 1   | 10       | 5   | 8                             | 5   | 9        | 5   |
| 2                       | 31                                  | 14  | 27       | 13  | 30                            | 18  | 38       | 22  |
| 3                       | 100                                 | 47  | 84       | 39  | 79                            | 46  | 63       | 37  |
| Missing                 | 81                                  | 38  | 94       | 44  | 54                            | 32  | 59       | 35  |
| Hormone receptor status |                                     |     |          |     |                               |     |          |     |
| Negative                | 39                                  | 18  | 39       | 18  | 36                            | 21  | 41       | 24  |
| Positive                | 165                                 | 77  | 164      | 76  | 115                           | 67  | 103      | 61  |
| Missing                 | 10                                  | 5   | 12       | 6   | 20                            | 12  | 25       | 15  |
| Medical Training        | 27                                  | 13  | 39       | 18  | 41                            | 24  | 33       | 20  |





# Primary endpoint: Patient Decisional Conflict

(scale range: 1-5; scores  $\leq 2$  indicate no conflict)



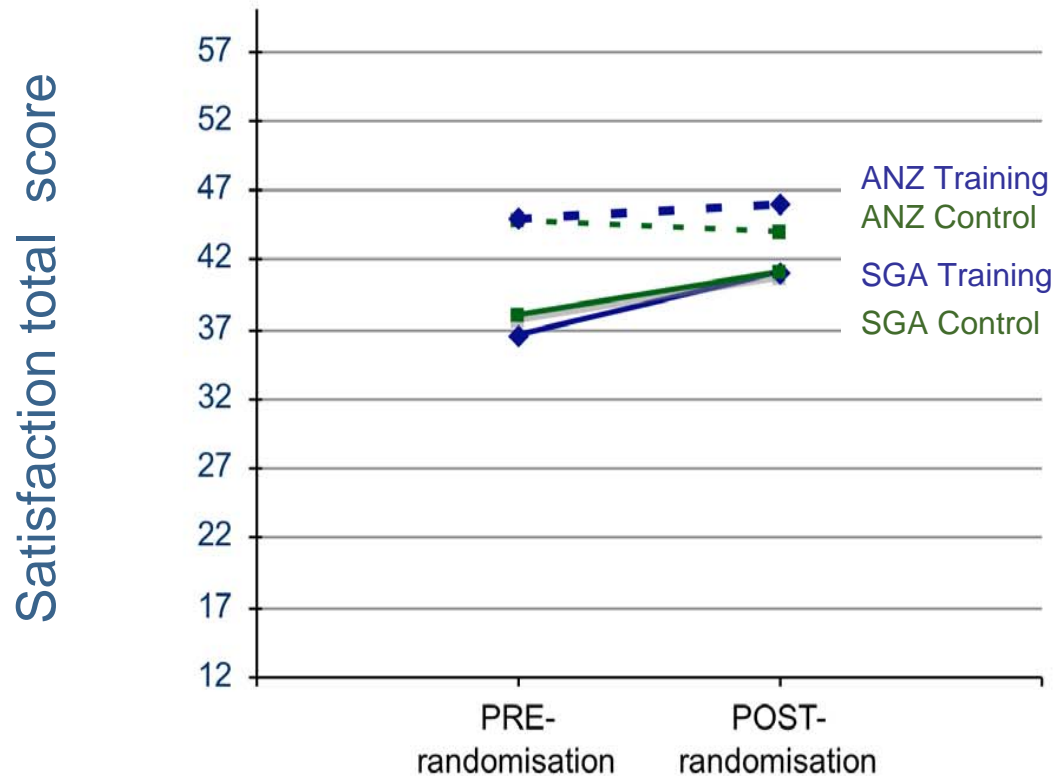
ANZ:  $p=0.001$   
SGA:  $p=0.93$





# Patient Satisfaction with Dr consultation skills

(scale range: 12-60; higher score indicates better outcome)



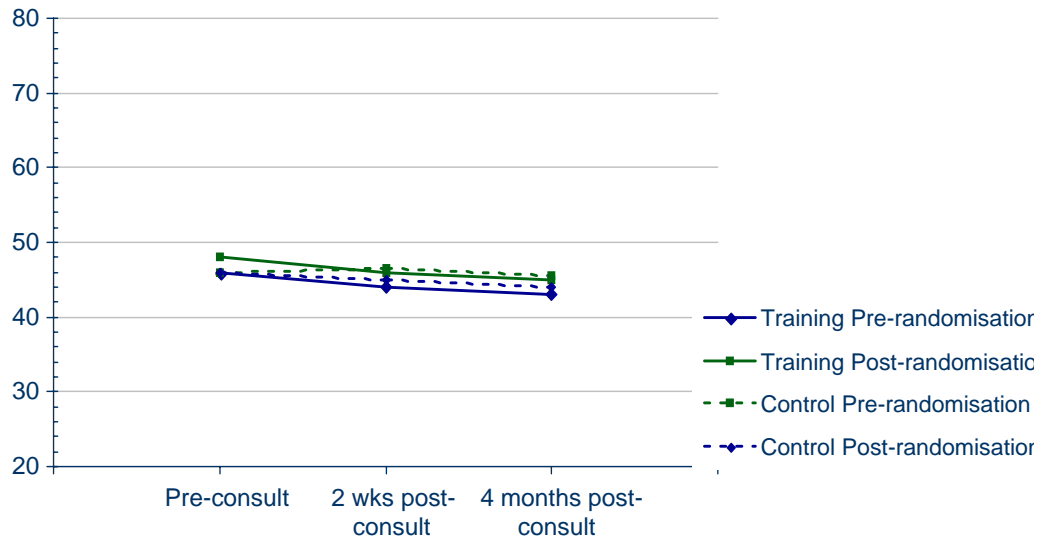
ANZ:  $p = 0.26$   
SGA:  $p = 0.08$



# Patient State Anxiety (STAI)

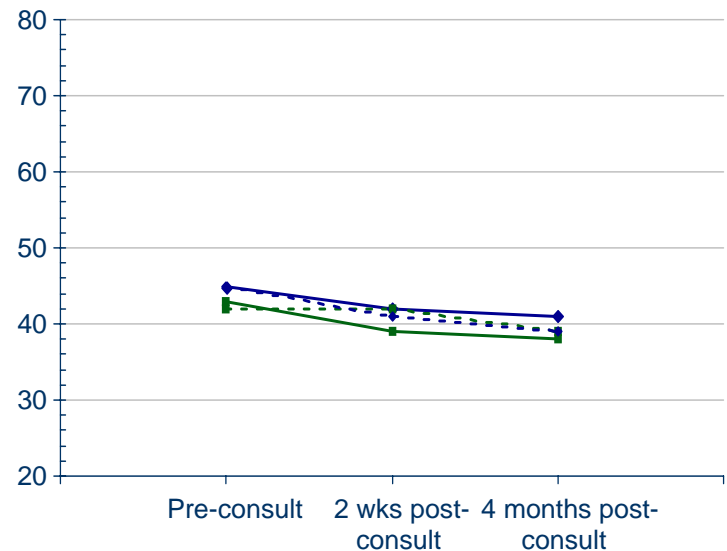
(scale range: 20-80; higher score indicates worse outcome)

## SGA (Switzerland/Germany Austria)



SGA:  $p = 0.67$

## ANZ (Australia/New Zealand)

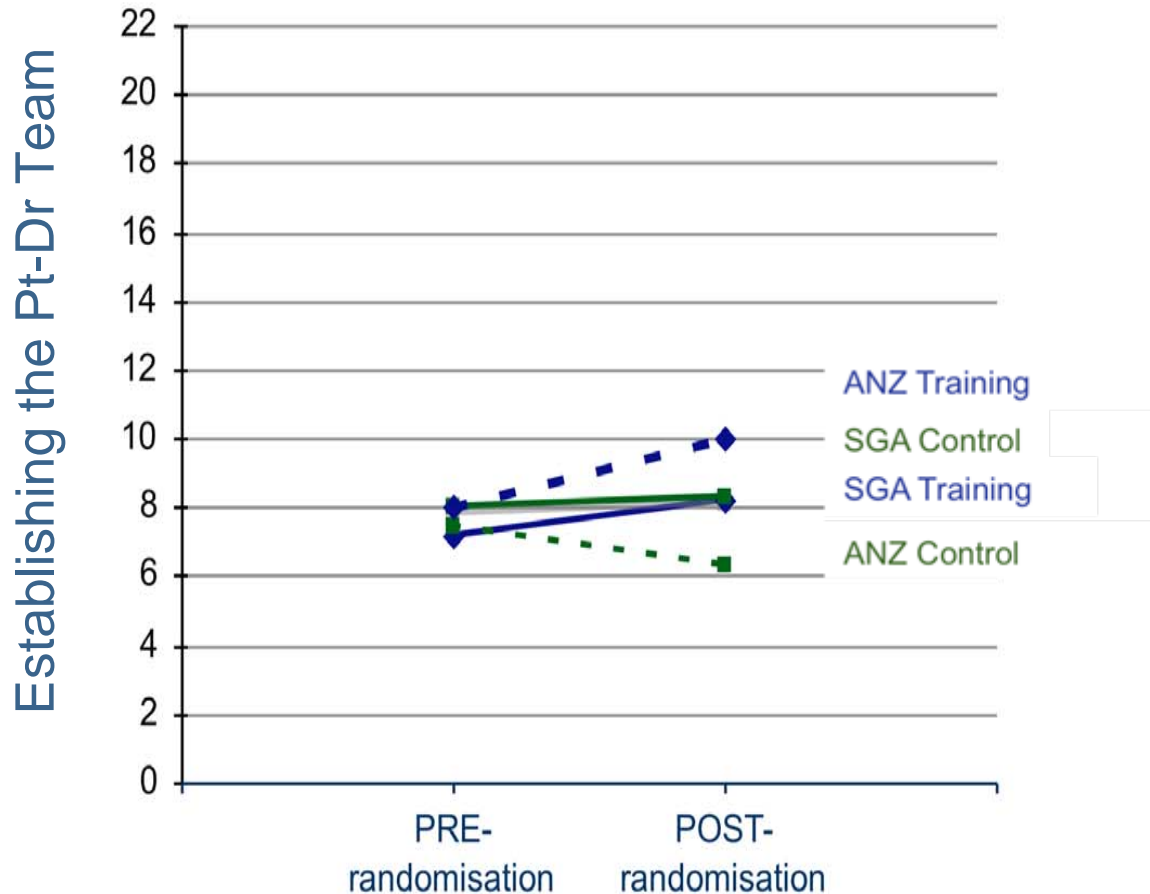


ANZ:  $p = 0.85$



# Doctor behaviour: Establishing the Patient-Dr Team

(scale range: 0-22; higher score indicates better outcome)

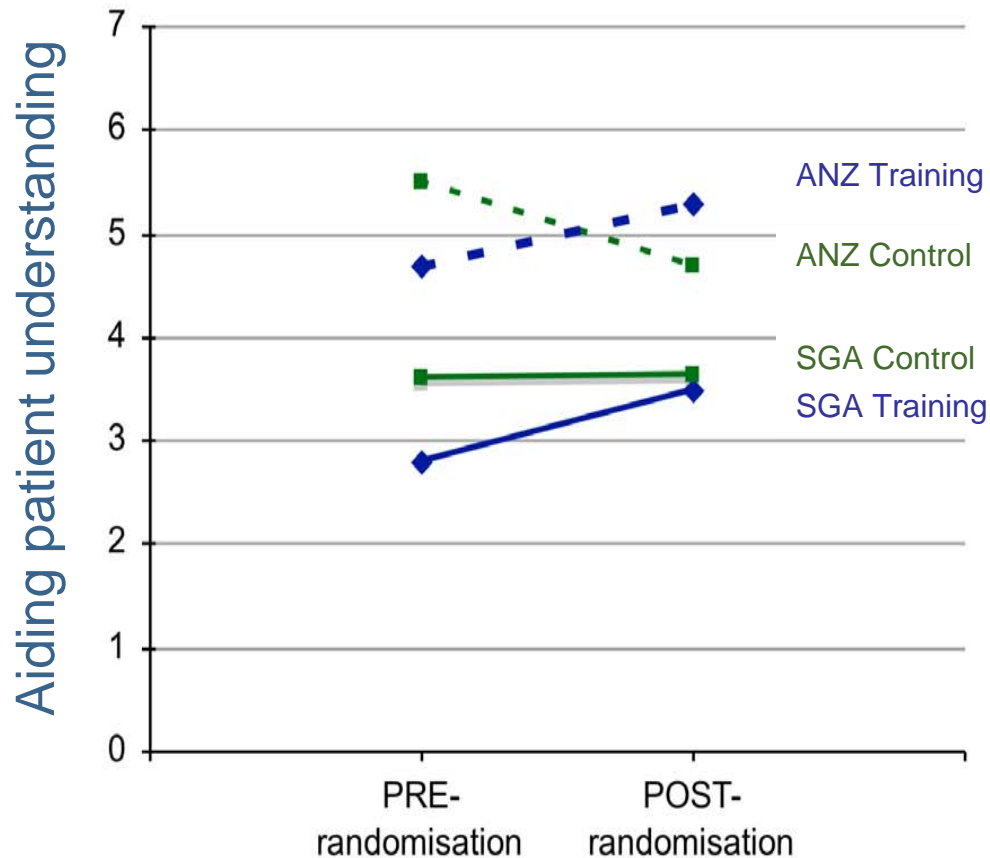


SGA:  $p = 0.71$   
ANZ:  $p = 0.03$



# Doctor behaviour: Aiding patient understanding

(scale range: 0-7; higher score indicates better outcome)

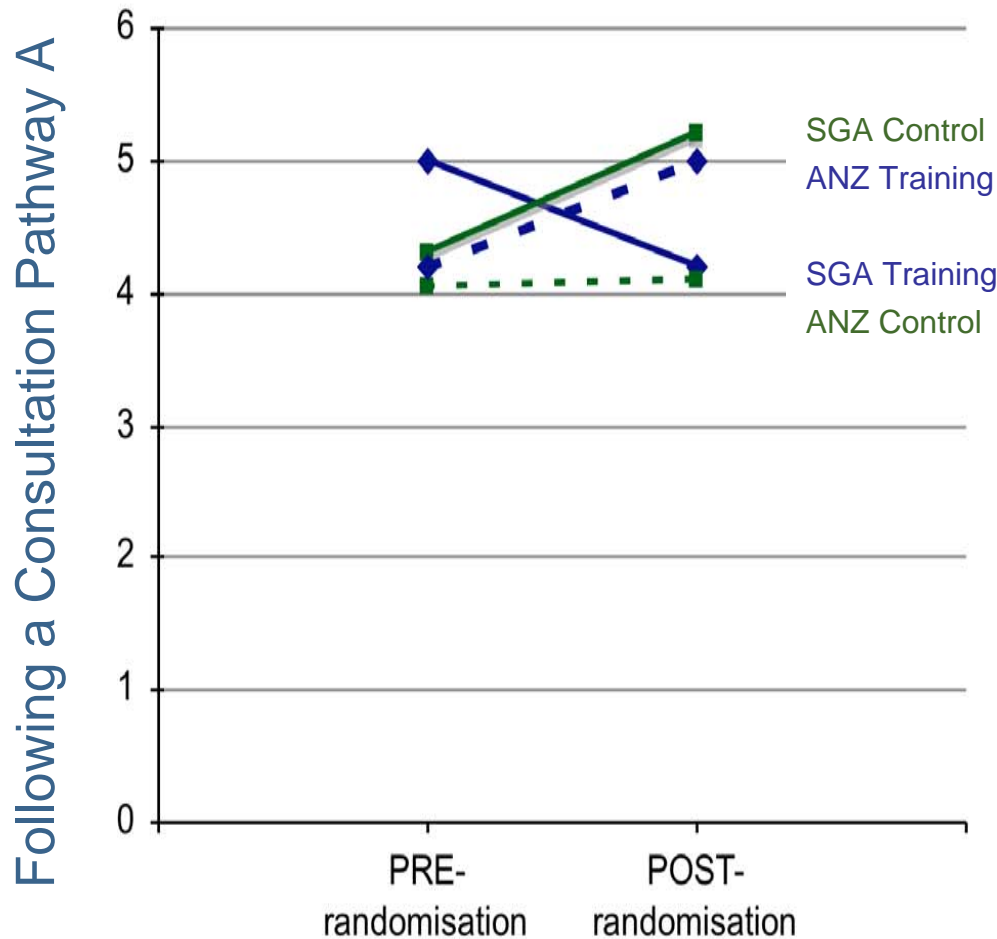


SGA:  $p=0.28$

ANZ:  $p=0.14$



# Doctor behaviour: Following consultation pathway: standard treatment (scale range: 0-6; higher score indicates better outcome)



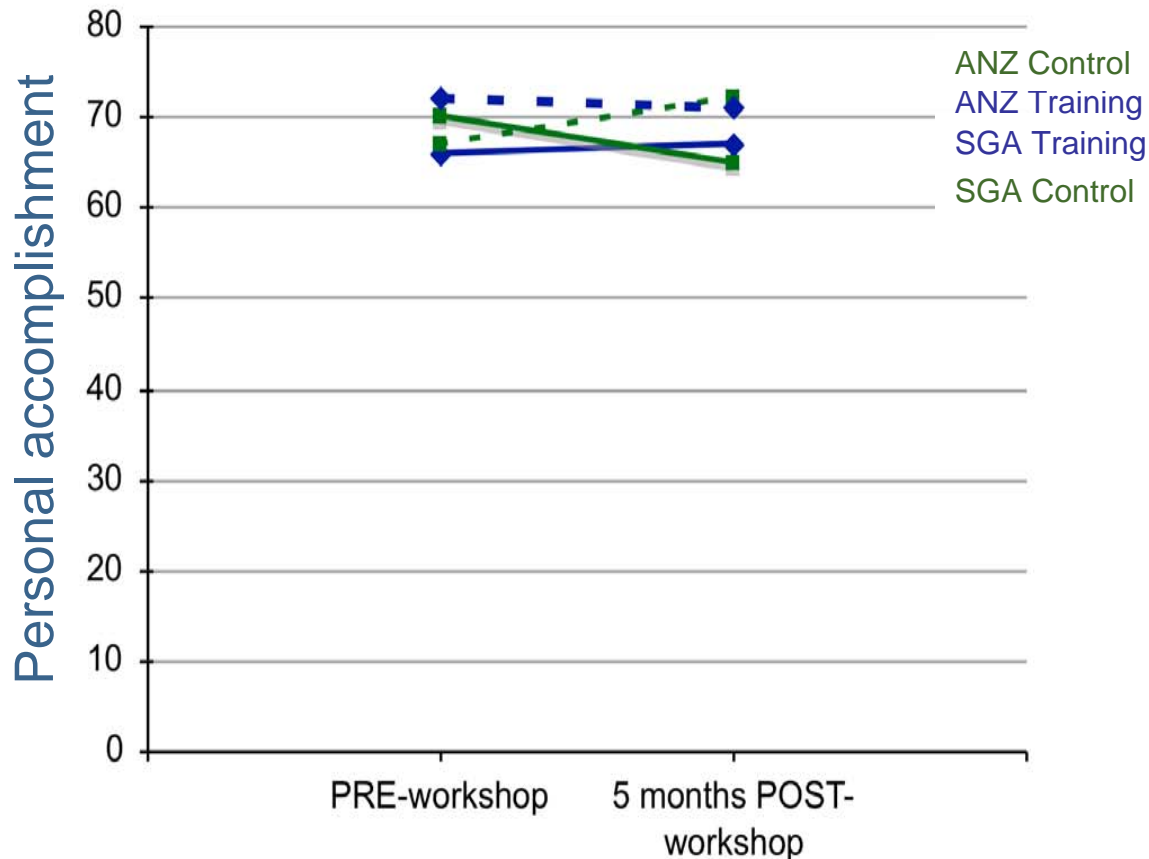
SGA:  $p=0.11$

ANZ:  $p=0.33$



# Stress and burnout: **Personal accomplishment**

(scale range: 0-80; higher score indicates worse outcome)



SGA:  $p=0.03$   
ANZ:  $p=0.10$

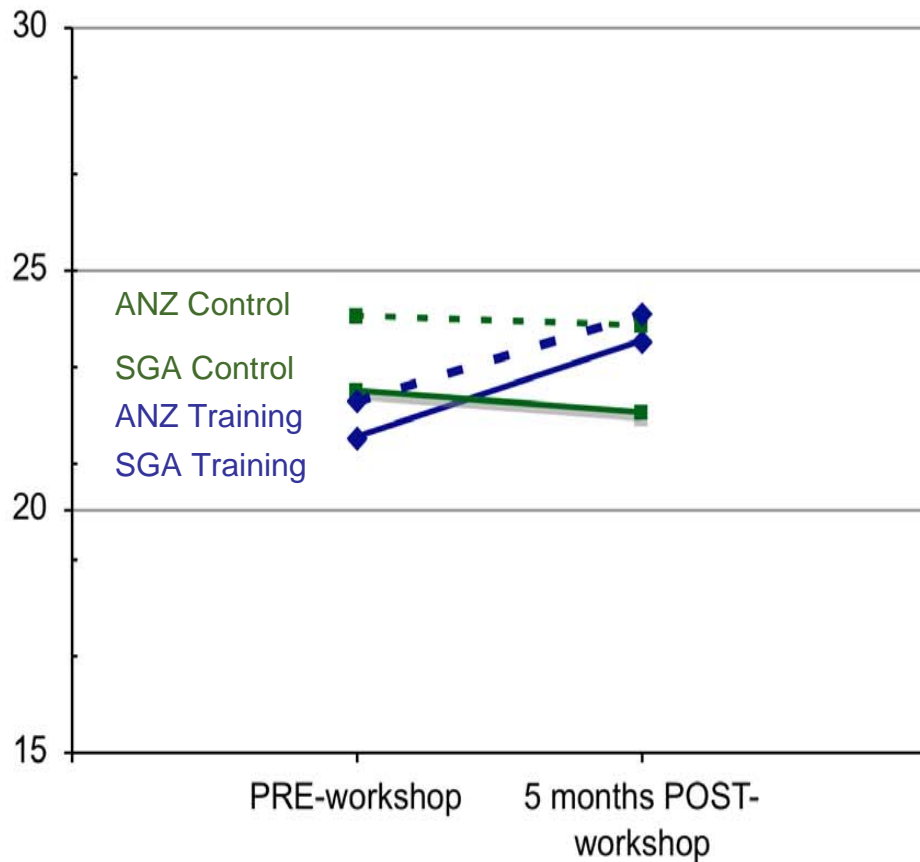
No significant differences on other stress & burnout scales (depersonalisation or emotional exhaustion)



# Doctor satisfaction with information provision

(scale range: 0-30; higher score indicates better outcome)

Satisfaction with information provision

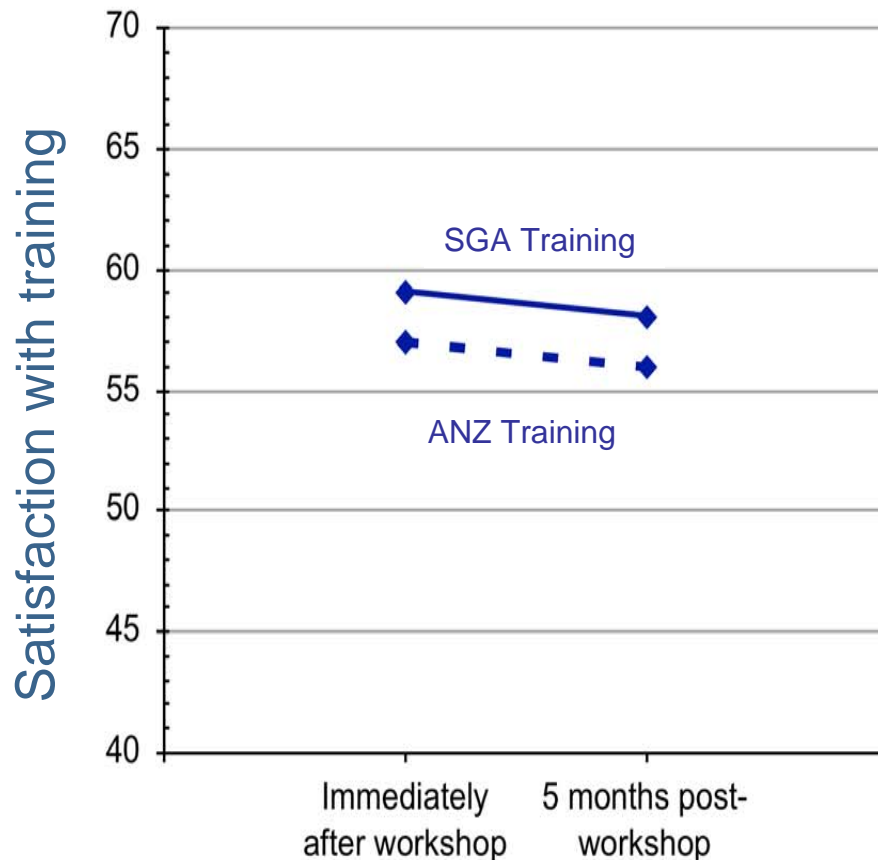


SGA:  $p=0.20$   
ANZ:  $p=0.43$



# Doctor satisfaction with training

(scale range: 0-75; higher score indicates better outcome)



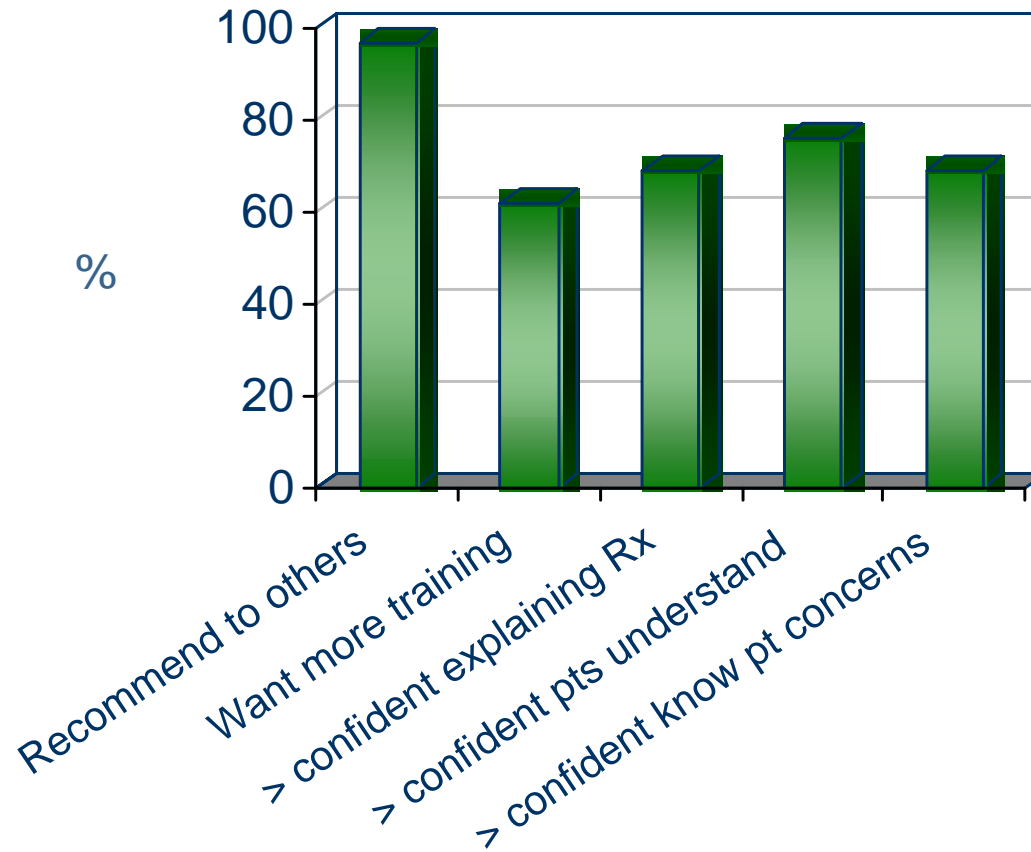


# Agreement between Dr and Pt: Was a trial discussed?

- Trial ***not discussed***
  - agreement 82% for both ANZ and SGA
  
- Trial ***discussed***
  - SGA: agreement 37% (n=82)
  - ANZ: agreement 50% (n=57)
  
  - Patients frequently thought a trial had NOT been discussed, when it HAD been discussed

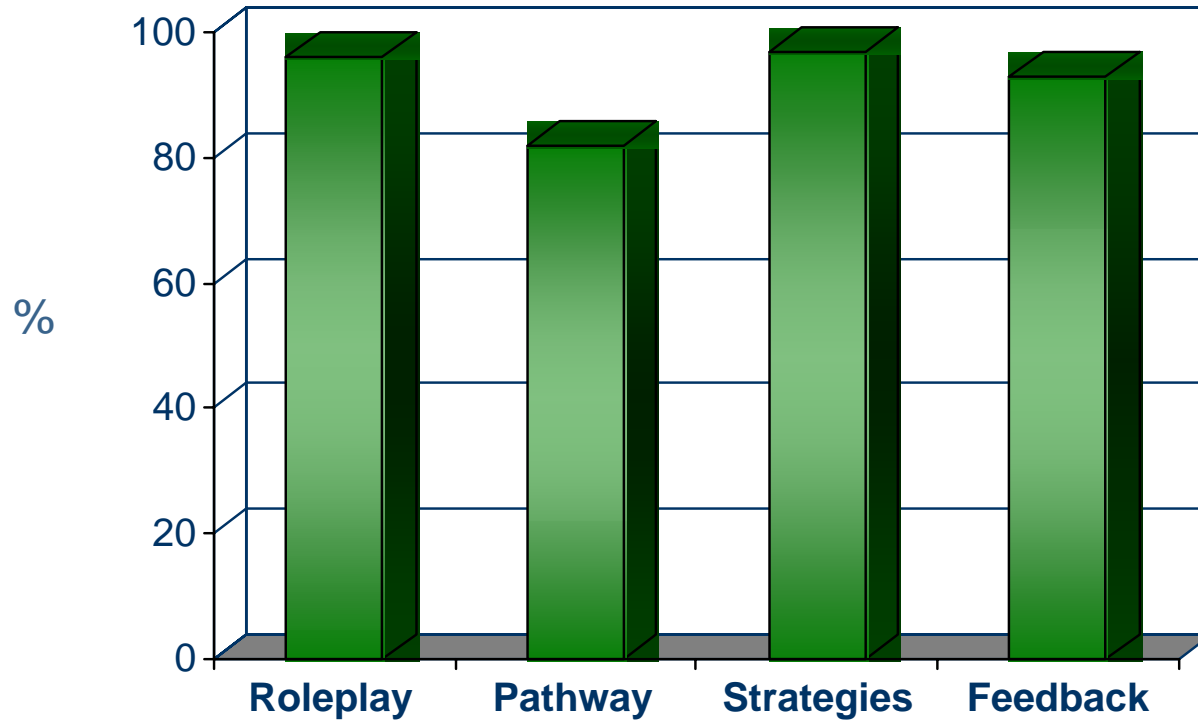


# Satisfaction with training immediately post





# Found value in...





# Discussion and Conclusions

- No overall training effect on patient or doctor endpoints
  - In ANZ arm, patients had reduced decisional conflict and doctors increased behaviours designed to establish a team approach
- Variation in patient and doctor data between SGA and ANZ centers, and between pre- and post-training cohort
- *Cross-cultural differences* need attention in conducting international trials on communication interventions
- Training not effective? Not sufficiently intensive?
- Assumptions for power calculation not appropriate?



# Discussion and Conclusions

- Patients often unaware that a trial had been discussed
- A concern for informed consent
- Shared decision making remains a challenge
- We need longer, culturally appropriate training programmes





# Thank you

This study required considerable logistic efforts.

We would like to thank the physicians who participated in the trial, the patients who took the time to complete the questionnaires, the data managers who took care of this study in the centers, and Karin Ribí, Peter Zoller, Cornelia Zuberbühler, Monika Dzidowska, Gwynneth Wong, Gina Bark and Anna-Lena Lopez for central trial coordination.

## *Acknowledgement of Funding*

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