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Title: Can consultation skills training change doctors' behaviour to increase involvement of patients in making decisions about standard treatment and clinical trials: a randomized controlled trial.

Running title: Discussing standard treatment and clinical trials

Authors: Butow P¹, PhD; Brown R², PhD; Aldridge J³,MS; Juraskova I¹, PhD; Zoller P⁴, Boyle F^{1,5}, MD, PhD; Wilson-Genderson, M² PhD & Bernhard J⁴, PhD.

Affiliations:

1. Centre for Medical Psychology and Evidence-based Decision-Making (CeMPED), University of Sydney, Australia
2. Department of Social and Behavioral Health School of Medicine, Virginia Commonwealth University Richmond, USA
3. International Breast Cancer Study Group (IBCSG) Statistical Centre, Department of Biostatistics & Computational Biology, Dana-Farber Cancer Institute, Boston USA
4. IBCSG Coordinating Center and Department of Medical Oncology, Inselspital, Bern University Hospital, Bern, Switzerland
5. Pam McLean Centre, Northern Clinical School, University of Sydney, Australia

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Address for correspondence

Phyllis Butow, School of Psychology, University of Sydney NSW 2060, AUSTRALIA

Ph: +61 2 93512859; Fax: +61 2 90365292, email: phyllis.butow@sydney.edu.au

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Abstract

Background

Informed consent is required for both standard cancer treatments and experimental cancer treatments in a clinical trial. Effective and sensitive physician-patient communication about informed consent is difficult to achieve. Our aim was to train doctors in clear, collaborative and ethical communication about informed consent, and evaluate the impact of training on the doctor behavior, stress and satisfaction.

Participants and Methods

Participants were 21 oncologists from 10 Australian/New Zealand (ANZ) centers and 41 oncologists from 10 Swiss/German/ Austrian (SGA) centers. Oncologists were randomized to participate in a 1-day workshop or not. Patients were recruited before and after the training. Doctors were asked to submit 1-2 audiotaped consultations before and after training. Doctors completed outcome measures before and after completing the post-training cohort recruitment.

Results

95 consultation interactions were audiotaped. Doctors strongly endorsed the training. ANZ intervention doctors demonstrated a significant increase in collaborative communication ($p=0.03$). There was no effect of training on other doctor behaviors. Trained doctors did not demonstrate reduced stress and burnout. Patient outcomes are presented elsewhere

Conclusions

Training can improve some aspects of the process of obtaining informed consent. Methods to increase the impact of training are required, and may include longer training and more intensive follow-up.

Keywords: Oncology, Consultation skills training, Physician Behavior, Decision-making, Clinical trials, Randomized controlled trial

Introduction

The imperative for oncologists to involve patients in treatment decision-making has intensified over the past decade, particularly in response to changes in ethical mandates about informed consent (Breitsameter, 2010; Charles & Gafni, 2010; Siminoff, 2010) and evidence that shared decision making (SDM) results in better patient outcomes (Brown et al., 2012; Fallowfield, Hall, Macguire, Baum, & A'Hern, 1994 b; Gattellari, Butow, & Tattersall, 2001).

Charles, Gafni, & Whelan (1997) have defined four components of shared decision making, namely the simultaneous involvement of doctor and patient in all phases of decision making, information exchange in both directions and by both parties, mutual deliberation on treatment options, and agreement on the treatment to implement. As theories of communication would suggest,(Albrecht, Penner, Ruckdeschel et al, 2003) effective SDM requires both the transmission of information essential to decision making and relational skill to ensure that information is tailored to patient needs.

Despite the putative benefits of SDM, many oncologists do not routinely involve patients in clinical decision making (Albrecht et al, 2003; Albrecht, Ruckdeschel, et al., 2003; Brown, Butow, Ellis, Boyle, & Tattersall, 2004; Brown, Bylund, Siminoff, & Slovin, 2010), are not negotiable when making final treatment decisions (Tomamichel et al., 1995), and rarely elicit or meet their patients' preferences for SDM (Bilodeau & Degner, 1996; Brown & Albrecht, 2010; Brown, Butow, Boyle, & Tattersall, 2007; Ford, Schofield, & Hope, 2003; Gattellari et al., 2001; Sutherland, Llewellyn-Thomas, Lockwood, & Tritchler, 1989).

Some oncologists are concerned that while SDM may be largely beneficial, for some it may be overly burdensome, lead to confusion, and raise anxiety, particularly for patients who prefer to remain passive (Kaplan, Greenfield, Gandek, Rogers, & Ware, 1996). Resolving this tension, eliciting and meeting patients decision making needs and thereby achieving SDM is a complex communication process, yet many oncologists are not equipped with the skills necessary to achieve SDM (Brown, Butow, Ellis, et al., 2004). The difficulty oncologists experience in communicating, including during decision making, has been shown to be a primary contributor to oncologists' stress and burnout (Degner, Sloan, & Venkatech, 1997). Moreover, SDM is even more ethically pressing and harder to achieve when a clinical trial is discussed (Brown RF Butow P, Butt D et al, 2004; Jenkins VA, Fallowfield L, Souhami A et al, 1999). Many trial concepts are unfamiliar to patients, additional time is required to discuss trial participation, and oncologists are under pressure to increase recruitment to trials. Thus if doctors also struggle in having trial discussions, this might have an even stronger affect on stress and burnout.

The evidence for better patient outcomes with SDM, variation in practice, the complexities and barriers to achieving SDM in both standard practice and clinical trial settings, and the negative consequences for oncologists of poor communication, all suggest that it is critical to develop, implement and evaluate targeted communication skills training to aid oncologists in these complex treatment discussions. Surprisingly, few studies have evaluated such training interventions, and these studies have mainly used pre-post designs (Brown et al., 2007; Jenkins, Fallowfield, Solis - Trapala, Landridge, & Farewell, 2005). To fill this gap, we conducted an international randomized controlled trial that examined the impact of training oncologists in

delivering clear and ethical information about standard treatment options and clinical trials, and strategies to encourage SDM.

We hypothesized that oncologists would find the training helpful, that their use of specific communication skills aligned with SDM would increase, and that oncologists' confidence in their information provision would improve. We also hypothesized that these improvements would be reflected in reduced levels of stress and burnout. Finally, we hypothesized that improved oncologist communication would result in subsequent benefits for patient outcomes. This paper reports on doctor outcomes from the training. Patient outcomes are reported elsewhere (Bernhard et al., 2011).

Participants

The International Breast Cancer Study Group (IBCSG) conducted Trial 33-03 in centers in Australia and New Zealand (referred to as ANZ) and Switzerland, Germany and Austria (referred to as SGA).

Medical, surgical, radiation and gynecological oncologists, working in major cancer centers or clinics (including private oncologists) and involved in the treatment of patients with early breast cancer, and their patients for whom adjuvant therapy for breast cancer was indicated, were eligible for this trial. The following patient criteria were additionally required: age greater than or equal to 18 years, adequate knowledge in local language (English or German), and being mentally and physically capable of participating. Doctor participation was independent of previous or concurrent participation in other communication training programs.

Recruitment

Local trial coordination was supported and monitored by a central coordinator for ANZ and SGA, respectively. Doctors in centers accruing to adjuvant breast cancer clinical trials were invited to join the trial in order to a) ensure the relevance of the intervention material to oncologists and b) increase the likelihood that we would capture consultations where clinical trials were discussed and thus be able to assess relevant skill uptake in our outcome measures. Following baseline assessment and before the scheduled training workshop, doctors were randomly assigned to the experimental (training workshop) or control (no training workshop) group, stratified by centre. Doctors in the control group were offered the training after completing trial follow-up.

Sample description and doctor characteristics

Target accrual was 44 doctors (22 per randomized group to detect a 0.25-point difference in the main *patient* outcome (decisional conflict) between the two groups with 90% power, $\alpha = 0.05$ and 10 patients per doctor (pre-randomisation and post-randomisation cohorts).

We approached large Oncology centres with active recruitment to breast cancer trials, 10 in ANZ and 10 in SGA, all of which agreed to participate. At those centres, we invited all doctors involved in breast cancer trials to participate; 53 agreed in the SGA cohort and 21 in the ANZ cohort. Unfortunately we have no data on those who refused. Twelve of the interested physicians, all from the SGA cohort, were not eligible (11 were not randomized, 1 enrolled no patients), leaving a total of 62 doctors: 41 in the SGA cohort, and 21 in the ANZ cohort. Thus a

median number of 1.5 doctors per center (range: 1-6) enrolled in ANZ centres and a median of 4 doctors per center (range: 2-6) enrolled in SGA centres. See Appendix 1 acknowledging the contribution of participating centers. At baseline, all participating doctors were asked to recruit to the study 5-10 consecutive new patients, both before and after the intervention, who were facing a treatment decision.

All participating doctors randomized to the intervention completed all aspects of the training. Fifty-three (85.5%) doctors and 158 of their patients were assessable with regard to the primary endpoint for this analysis: doctor behavior (Figure 2). In the ANZ cohort, all 21 enrolled and eligible doctors provided audiotaped consultations; of the 84 consultations requested (4 per doctor: 2 before and 2 after the intervention), 63 (75%) were audiotaped. In the SGA cohort, of the 41 enrolled and eligible doctors, 32 provided audiotaped consultations, for a total of 95 (74%) audiotaped consultations. Seven of those who did not provide an audiotape were gynaecological oncologists from one centre, where research support was low. All 62 randomized and eligible doctors had complete data for the doctor-reported secondary endpoints.

Insert Figure 2 here

The baseline characteristics of the 62 randomized doctors and 158 audiotaped patients by language cohort and randomization arm are shown in Tables 1 and 2, respectively. There were more female doctors in the SGA than in the ANZ cohort, and for both cohorts combined, 63% of doctors in the control arm were female as compared to 48% in the experimental arm however these differences failed to reach conventional levels of statistical significance. Doctors working

in radiology participated only in the ANZ cohort and those from gynecology only in the SGA cohort. The ANZ cohort was on average 10 years older than the SGA cohort of physicians.

Overall, there were no significant demographic or clinical differences between patients with audiotaped consultations who were seeing experimental versus control doctors or between those who were recruited to the pre- and post-randomization cohorts in the ANZ and SGA cohorts, respectively.

Characteristics of doctors with ($n = 53$) and without ($n = 9$) audiotapes were compared and no differences were detected for randomization arm ($\chi^2 (1) = 1.17, p > .28$), gender ($\chi^2 (1) = 1.68, p > .20$), institutional affiliation ($\chi^2 (1) = 1.56, p > .45$), nor previous training in communication ($\chi^2 (1) = 0.809, p > .35$); in all cases Fischer exact test agrees with chi-square result for lack of significance. For doctor specialty ($\chi^2 (3) = 5.61, p > .10$; Fischer exact $p < .007$) results suggest a difference in doctor specialty with regards the presence or absence of audiotapes. Inspection of the frequencies reveals that seven (7) of the nine (9) doctors without tapes were gynecologists. Physicians without tapes were also younger (mean = 32.3, s.d.=3.53) than those with tapes (mean = 39.70, s.d. = 8.82) ($t (1) = 3.02, p < .02$).

Insert Table 1 here

Insert Table 2 here

Procedure

Participating patients completed questionnaires before, 2 weeks after, and 4 months after their initial consultation. All participating doctors were asked to audiotape two of these initial consultations and submit them to the research team. At completion of this pre-training patient recruitment, doctors were asked to complete a short questionnaire eliciting demographic and

practice details, stress and burn-out, and confidence in their provision of information to patients. Following this, the doctors were randomized (see Figure 1), and experimental arm doctors completed the intervention. All doctors then recruited a further 8-10 patients to the study, again audiotaping two of these patients' initial consultations and providing them to the study team. On completing the post-randomization cohort recruitment (about 5 months after randomization), doctors were given the follow-up questionnaire assessing stress and burnout, and confidence in their information provision. In the experimental group only, doctors also rated their satisfaction with the training immediately after and 5-months following the training workshop. Institutional Review Board approval to conduct this study was obtained from all participating centers.

Insert Figure 1 here

Training intervention

The training consisted of a seven-hour interactive face-to-face workshop with a follow-up telephone call one month later. The elements of the training workshop were evidence-based, and used accepted adult learning principles (Brown, Butow, Butt, Moore, & Tattersall, 2004). Strategies taught were based on our earlier work in which a model of communicating about clinical trials and fostering SDM in oncology consultations was developed after intense multi-disciplinary review of audiotaped consent interviews, and consensus meetings (Brown, Butow, Butt, et al., 2004). Training based on this model was shown to be acceptable and effective in a phase II trial (Brown et al., 2007). The training incorporated written and oral materials that presented principles and strategies (2 hours), a video modeling ideal behavior (30 mins), role-play practice with an actor-patient and expert facilitator (4 hours), and individualized feedback

on audio-taped consultations with actual patients (30 mins). The training workshop focused on four key concepts: a) establishing a SDM framework, b) structuring information into a recommended sequence or order, c) ensuring the discussion of key information in a clear manner and d) avoiding coercive communication (Brown, Butow, Butt, et al., 2004). Example behaviours for each of these concepts are shown in Table 3.

The training workshops were held at the participating centers and conducted in the local language (English or German) by clinical psychologists with experience in interactional skills training (authors PB, JB and RB). Before the training workshop, participants in the experimental group were expected to have read the strategies document and a set of articles about shared decision-making (Charles CI, Gafni A, Whelan T, 1997; Gattellari M, Butow PN, Tattersall MHN, 2001; Brown RF et al, 2004; Brown RF, Butow PN, Ellis P et al, 2004). Baseline audiotapes were transcribed and analyzed by the research team using the Decision Analysis System for Oncology (DAS-O) (Brown, Butow, et al., 2010) developed by our team to capture essential elements of shared decision-making according to our model. For doctors in the experimental group only, confidential written feedback concerning the strengths and opportunities for improvement in SDM demonstrated on the tapes was provided during the training workshop. One month later, training workshop participants received an individual telephone call from the trainer to discuss challenges experienced when implementing strategies, and to reinforce and extend learning.

Coding of doctor behaviors in audio-taped consultations

The primary doctor outcome for the study was change in SDM behaviors demonstrated in audio-taped consultations with real patients, coded using the DAS-O coding system (Brown et al, 2010). The coder identifies the presence (1) or absence (0) of key components of SDM in three subscales:

- i) establishing a SDM framework (22 items), e.g. introducing joint decision making, inviting comments and questions, offering choice;
- ii) providing clear and unbiased information about treatment options (28 items); this subscale is comprised of items on *ordering information clearly and providing essential information* (e.g. establishing a shared understanding of the patient's situation before describing treatment options, describing the benefits and side effects of treatment options), using techniques to *aid patient understanding* (e.g. avoiding jargon, drawing diagrams), *disclosing important facts* (e.g. availability of the trial treatment off trial) and *avoiding coercion* (e.g. avoiding language implying exclusion or inclusion as a result of treatment choice);
- iii) providing essential information about clinical trials (used only when clinical trials are discussed) (14 items), e.g. explaining equipoise, randomization and the benefits and disadvantages of trial participation.

Total scores are calculated for each subscale by summing individual item scores, with higher total scores indicating that more behaviors were displayed. Two raters applied the DAS-O coding system to the consultations. To test inter- and intra-rater reliability, they re-coded 10% of each other's and 10% of their own consultations. Inter- and intra-rater reliability as measured by kappas were on average 0.54 for presence of behaviors across the three subscales. Due to the

small number of clinical trials discussed (in 34 of 158 consultations), results for the last subscale are not reported.

Oncologist Reported Outcomes

Satisfaction with the training workshop - Oncologists completed 15 study-specific items measuring satisfaction with the training workshop. Five-point Likert scales were used with anchors at 'strongly agree' and 'strongly disagree'. Raw scores were summed to produce scores ranging from 15 to 75, with higher scores indicating greater satisfaction with training.

Confidence in information provision - Oncologists completed a six item scale measuring their confidence in the amount, clarity and completeness of information they provided, their ability to involve the patient in decision making, and patients' understanding. Five-point Likert scales were used with anchors at 'strongly agree' and 'strongly disagree'. Raw scores were summed to produce a total score (6-30) with higher scores representing higher levels of satisfaction with these aspects of consultations. This scale was developed by our group and used in a previous study of communication about clinical trials (Ellis, Butow, Simes, Tattersall, & Dunn, 1999).

Doctor stress and burnout was measured using the Maslach Burnout Inventory [MBI] as used by Rameriz et al. (Ramirez, Graham, Richards, Gregory, & Cull, 1996) Separate scales measure emotional exhaustion [EE, feelings of being emotionally overextended and exhausted by one's work], depersonalization [DP, an unfeeling and impersonal response toward recipients of one's care], and personal accomplishment [PA, feelings of competence and successful achievement in one's work]. Global measures of job stress and satisfaction are derived by summing the item

scores within each category with high scores on the emotional exhaustion and depersonalization scales and low scores on the personal accomplishment scale indicating more stress.

Statistical Methods

Language cohorts were defined by location: ANZ (English) and SGA (German). Because of potential cultural differences between the SGA and ANZ centers, all results are presented separately by language.

The primary doctor outcome measure was change in doctor behavior as determined by the audiotaped consultations and the subscale total scores of the DAS-O coding system. As only 23% of the audio-recorded treatment consultations contained a clinical trial discussion, we were unable to code for systematic changes in trial discussions due to the comparative rarity of such discussions. Doctors' self-reported stress and burnout as well as satisfaction with information provision and the training, were secondary outcomes. Demographic and practice characteristics of doctors in the experimental and control groups were tabulated by language cohort.

Respectively for each language cohort, two-sided Fisher's exact test was used to compare categorical variables between randomization groups, and two-sided Wilcoxon Rank Sum test was used to compare continuous variables between randomization groups.

Analyses were conducted to examine potential differences in the change from pre- to post-randomization between the experimental and the control groups for each outcome measure. This consisted of creating random effects linear regression model (i.e., mixed effects model) for physicians with multiple patients (Laird & Ware, 1982) at the pre- and post-randomization data

collection points. These models include a random effect for physicians to account for the fact that physicians can have multiple patients (nested) in the sample (Laird & Ware, 1982). A separate regression model was created for each of the subscales on the DAS-O as well and the three indicators of stress and burnout within each language cohort. Covariates included in each model were physician age, gender and specialty. To enhance the interpretability of the change in scores over time and or differences between the randomization arms, the mean of the difference between the experimental and control groups of the pre- to post-randomization changes was defined as: $(\text{Experimental}_{\text{post}} - \text{Experimental}_{\text{pre}}) - (\text{Control}_{\text{post}} - \text{Control}_{\text{pre}})$. Effect size (ES) was calculated as the absolute value of the estimated mean difference divided by the product of the standard error and the square root of the degrees of freedom. The analyses used SAS 9.2 (SAS Institute Inc., Cary, NC, USA).

The study was powered to detect a clinically significant change in the primary patient outcome, patient decisional conflict two-weeks post-consultation. All secondary endpoints, including doctor outcomes, are exploratory in nature, and tests are not adjusted for multiple comparisons.

Results

Acceptability of training by doctors

Overall, satisfaction with the training was high. All doctors in the experimental group completed this scale. The post-randomization, median scores for satisfaction with training were 57.5 (range = 41-75) and 56.0 (range = 38 - 73) for SGA and ANZ, respectively. Qualitative feedback was positive. All but one participant would recommend the training to others, and all but one valued highly the strategies suggested in training as well as the opportunity to practice these in role-

plays. One doctor noted that “the training was very good, and I will pass this material on to my junior doctors.”

Doctor Behavior

Table 3 shows the results of mixed effects modeling exploring differences in the change of doctor behavior scores as assessed by subscales of the DAS-O between randomization groups. In the ANZ cohort, the estimated population mean of the difference for establishing the SDM framework (subscale 1 of the DAS-O) was statistically significant, indicating that after the training workshop, doctors in the experimental group within the ANZ cohort displayed more behaviors designed to establish the SDM framework than those doctors in the control group (estimated population mean difference=3.42, s.e. = 1.50, ES=0.30, p=0.03). However, the effect size was small. There was no effect for this variable for SGA doctors (estimated population mean difference=0.52, s.e. = 1.39, ES=0.04, p=0.71). Figure 3, which displays the mean scores for establishing the SDM framework by randomization group and language cohort for the pre-randomization and post-randomization patient-doctor consultations, shows that the driving force in the significance of this endpoint is from a decline in SDM in the ANZ control group in conjunction with an increase in SDM in the ANZ experimental group. There were no significant differences pre- and post-randomization in other subscales of the DAS-O, although the direction of effects was generally in the hypothesized direction.

Insert Table 3 here

Insert Figure 3 here

Confidence in information provision

There were no significant changes from pre- to post-randomization between the experimental and control groups in their confidence in their own information provision.

Stress and Burnout

Prior to randomization there were no significant differences in stress and burnout scores between the experimental and control groups in either the SGA or ANZ cohorts. Figure 4 displays the mean scores for personal accomplishment by randomization group and language cohort, pre-randomization and 5-months post-randomization. In the SGA cohort, doctors in the experimental group maintained their levels of personal accomplishment post-training, while in the control group, doctors' sense of personal accomplishment appeared to decline. Significance was driven by this decline in the control group. The estimated population mean of the difference between the experimental and the control groups for personal accomplishment indicates that those doctors in the training group had higher levels of personal accomplishment than those in the control group from pre- to post-randomization (estimate=7.17, s.e. = 3.25, ES=0.31, p=0.03 - see Figure 4). There were no significant differences of pre- and post-randomization scores between the experimental and control groups on other stress and burnout subscales.

Figure 4 about here.

Discussion

The primary aim of this research was to demonstrate the efficacy of an oncologist-focused communication skills training intervention to increase oncologist use of SDM skills during treatment decision making consultations (including clinical trials) with early breast cancer patients. Overall, the doctors reported that the training workshop was very helpful and that they

would recommend it to others. There was a significant group difference in one element (but not others) of doctors' behavior as captured by the DAS-O coding scheme: establishing an SDM framework. Doctors in both cohorts maintained or slightly increased behaviors designed to establish a SDM framework after training, while the control group declined in this behavior. It is possible that all doctors (including controls) were attempting to appear as skilled as possible in the pre-training assessment, but that control doctors relapsed into more usual behavior in the post-training assessment. The demand characteristics of this novel situation, in which they were being filmed and audited, may have increased their motivation to behave in socially desirable ways (Pringle M, Stewart-Evans C, 1990; Penner LA, Orom H, Albrecht T et al, 2007). Most oncologists know about, and are generally favorable towards, SDM (Charles and Shepherd et al papers); thus they may have had sufficient background knowledge to guide their behavior when motivated. However, with greater familiarity, these demand characteristics may have lessened for control doctors. This raises an interesting methodological point for communication trials in the future. Perhaps measuring behavior at two time points is not sufficient, and rather an averaged baseline over several assessment points is required to overcome social desirability effects.

In comparison, the experimental group was perhaps motivated to continue focusing on SDM behaviors and actually increased their skills due to training. This is in line with previous studies (for example, Edwards & Elwyn, 2004) that have demonstrated that communication skills training can improve doctors' attitudes towards and skills in SDM. Our intervention strongly endorsed SDM and provided a clear evidence base that SDM approaches improve patient and

doctor outcomes. Furthermore, the experimental doctors received specific strategies and skills training in SDM approaches, which likely increased their use of these behaviours.

Other doctor behaviours targeted by the intervention however, (information flow, clarity of information provision and lack of coercion) were not impacted. We presented to participants an optimal information flow; however this incorporated clinical trial discussions and since these were few in our sample, the impact may have been therefore reduced. The strategies taught to increase information clarity and avoid coercion were, on the other hand, general to all treatment discussions, so it is not clear why these did not improve post-training. We did notice in role-plays during the intervention workshops, that doctors struggled more with the subtle SDM skills, rather than more overt coercive and information giving elements; in focusing on SDM we may have under-emphasised coercion and information-giving in role-play practice. Perhaps these latter elements would be better practiced within more challenging scenarios.

The secondary aims were to determine the overall effect of training on oncologists' confidence in their information provision and on their levels of stress and burnout, within an experimental design. The training workshop did not improve confidence in providing clear and unbiased information. This may have been due to a ceiling effect, with most participating doctors scoring well on these subscales prior to randomization. Doctor stress and burnout were also not affected by the training workshop, although in SGA the training workshop appeared to help doctors maintain a feeling of personal accomplishment over time. In the literature, the causes of stress and burnout have been shown to be multi-factorial, with system, patient and doctor factors

contributing to burnout (Ramirez A et al, 1996). It is perhaps not surprising that targeting one factor (communication efficacy in the doctor) was not sufficient to cause an appreciable change.

Several limitations to this study need to be acknowledged. First, as only 23% of the audio-recorded treatment consultations contained a clinical trial discussion we were unable to code for systematic changes in clinical trial discussions due to the comparative rarity of such discussions. We also therefore did not obtain data on final accrual to clinical trials. Second, while we emphasized that consecutive patient recruitment was essential, we have no way of knowing that this was achieved; it is possible that doctors selected certain patients and avoided others, thus biasing their results. However, it is likely that doctors in both arms of the study would have done this; therefore we believe that group differences are unlikely to be affected. Third, while we sought an equal number of patients per doctor, there was variation in the numbers per doctor which could have impacted our results; however, the mixed modeling with doctor as a random effect addressed this issue as much as possible by accounting for the variance attributed to multiple patients per doctor. Fourth, the preponderance of oncologists with no audio tapes available were gynecologists, so the degree to which these conclusions are applicable in that specialty specifically is limited. Finally, the study was powered for patient outcomes, and it is possible that there was not sufficient power to detect important but subtle differences in doctor behavior that work together cumulatively to enhance the patient's experience.

Nonetheless, the fact that increases in or maintenance of SDM behaviors were achieved after only seven hours of training suggests that improvement in skills can be achieved at low cost with minimal time commitment for trainees. However, the improvements were neither as large nor as

consistent across measures as we had hoped for. It appears that seven hours may not be sufficient to generate large changes in behavior and doctor outcomes. The impact of the training workshop may have been greater had it been longer than 1 day, with two follow-up phone calls. Providing more opportunities for facilitated practice over a 2-3 day period may have consolidated learning. Communication skills training workshops which have been proven efficacious have been at least three days in length (Fallowfield et al, 2002; Razavi, Delvaux, & Marchal, 2002).

Unfortunately, direct comparisons of communication skills training workshops of different lengths have not been reported in the literature, and a recent review of the available evidence from high quality trials concluded that generalization beyond the specific training workshop evaluated is not possible at this stage.(Barth & Lannen, 2011) Finding a balance between practicality and efficacy is always a challenge, and many clinicians struggle to find time to attend longer workshops. Nevertheless, achievement of enduring and more extensive change may require a longer commitment. Shorter, but more frequent sessions (for example short workshops once a month, or weekly 1-hour webinars) may be an effective but still feasible way of delivering such training.

Alternatively, the training workshop may generate greater change if regarded as more salient. In Australia, the authors have been delivering training workshops in gaining informed consent to a specific clinical trial, at the trial activation meeting. Investigators report (informally) finding the training very salient, as they will be using the skills gained in a specific setting in the near future. These training workshops have proven very popular, accessible and effective, with trial

coordinators reporting increased clinician involvement and patient recruitment, and may be more effective than generic SDM workshops.

In summary, we were able to demonstrate that a 1 day consultation skills training workshop in gaining consent to standard treatment and clinical trials maintained shared decision making behaviors. Future research should explore the trade-off between length and efficacy of communication skills training.

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Table 1
Pre-randomization characteristics of 62 randomized doctors by randomization arm

	SGA				ANZ				X ² (P value)
	Control (No Training)		Experimental (Training)		Control (No Training)		Experimental (Training)		
	N		N		N		N		
n	20		21		11		10		
Gender									
Male	7		8		6		5		.043 (.835)
Female	13		13		5		5		
Specialty									
Medical	6		5		6		6		.709 (.701)
Oncology									
Radiology	-		-		3		3		
Surgeon	2		2		2		1		
Gynaecologist	12		14		-		-		
Institution									.976 (.323)
Public	20		20		7		7		
Private	-		1		-		-		
Both	-		-		4		3		
Previous training in communication skills	6		4		5		6		.200 (.655)
	med	(range)	med	(range)	med	range	med	range	F (p)
Age in years	33	(27, 44)	34	(24, 48)	47	(33, 58)	44	(38, 62)	46.83 (<.0001) ^a
Previous years of practice	6	(1, 18)	6	(1, 24)	16	(2, 35)	21	(8, 37)	1.50 (0.226)
Mean number of patients per doctor	15	(5, 200)	15	(3, 55)	15	(5, 50)	8	(3, 20)	1.21 (0.513)

recruited to
trials over 6
months*

*refers to any trial; Fischer's exact is reported for chi-square comparisons; lsmeans is reported for means test both due to small cell sizes. Note: ^a is comparing ANZ to SGA.

Table 2:

Patient characteristics by doctor's randomization arm and language cohort for those 158 patients who had audio-taped consultations

n	SGA				ANZ				Chi sq (p)
	Control (No Training)		Experimental (Training)		Control (No Training)		Experimental (Training)		
	N	%	N	%	N	%	N	%	
Nodal Status	46	100	49	100	34	100	29	100	
Missing	-	-	-	-	1	3	-	-	1.54 (.214)
Negative	32	70	27	55	20	59	15	52	
Positive	14	30	22	45	13	38	14	48	
Grade of tumour									
1	5	11	7	14	9	26	5	17	.068 (.967)
2	24	52	24	49	14	41	10	34	
3	17	37	18	37	11	32	12	41	
Missing	-	-	-	-	-	-	2	7	
Hormone receptor status									
Negative	8	17	10	20	5	15	9	31	3.425 (.180)
Positive	36	78	39	80	26	76	15	52	
Unclear	2	4	-	-	3	9	5	17	
Training in a medical field	7	15	5	10	9	26	4	14	
	med	(range)	med	(range)	med	(range)	med	(range)	F (p)
Age in years	58	(24, 84)	58	(35, 86)	51	(28, 81)	52	(34, 79)	3.45 (.07)
Tumor size (cm)	1.8	(0.4, 5)	2.3	(0.8, 12)	1.6	(0.5, 22)	2	(0.3, 9)	2.40 (0.123)

Note: Fischer's exact is reported for chi-square comparisons; lsmeans is reported for means test both due to small cell sizes.

Table 3. Sample behaviours under each key concept

Establishing the SDM framework	Structuring information	Fostering understanding	Avoiding coercion
Introduce joint decision-making	Follow a consultation pathway	Categorise information	Spend time on all treatment options
Check patient understanding	Establish joint understanding of patient situation, before introducing treatment options	Avoid jargon	Avoid minimizing the impact of any treatment
Explicitly offer choice between options	Discuss standard treatment before introducing a trial	Use diagrams, pictures and analogies	Avoid differential framing of outcomes
Portray the patient as active	Give space for patients to voice preferences	Summarise information	Encourage individual choice

Table 4

Summary of differences between experimental and control groups of doctor outcome measures* estimated using mixed models linear regression by language cohort

Establishing the shared decision making framework	SGA	0.52	1.39	-2.25	3.29	0.71
	ANZ	3.42	1.50	0.42	6.41	0.026
Providing clear and unbiased information						
Ordering information clearly	SGA	-1.13	0.69	-2.51	0.24	0.11
	ANZ	0.60	0.62	-0.63	1.83	0.33
Aiding patient understanding	SGA	0.63	0.59	-0.54	1.80	0.29
	ANZ	1.00	0.67	-0.35	2.35	0.14
Disclosure	SGA	-0.21	0.37	-0.99	0.57	0.57
	ANZ	-0.20	0.26	-0.80	0.40	0.47
Avoiding coercion	SGA	0.10	0.49	-0.87	1.07	0.84
	ANZ	0.53	0.45	-0.36	1.43	0.24
Satisfaction with information provision						
	SGA	2.06	1.60	-1.13	5.26	0.20
	ANZ	1.70	2.14	-2.60	5.99	0.43
Doctor stress and burnout						
Depersonalization	SGA	2.30	5.62	-8.96	13.56	0.68
	ANZ	-3.67	7.00	-17.74	10.40	0.60
Emotional Exhaustion	SGA	3.13	3.51	-3.92	10.18	0.38
	ANZ	4.18	4.32	-4.50	12.85	0.34

Personal Accomplishment	SGA	7.17	3.25	0.65	13.70	0.0318
	ANZ	-6.67	4.02	-14.76	1.41	0.10

*(Exp_{post} - Exp_{pre}) - (Control_{post} - Control_{pre})

**p-value is the between-group comparison of pre vs. post differences.

Note: Doctors in the experimental group only completed “Satisfaction with training” questionnaire, thus; a between-group comparison cannot be made.

Figure 1. Trial design of IBCSG 33-03

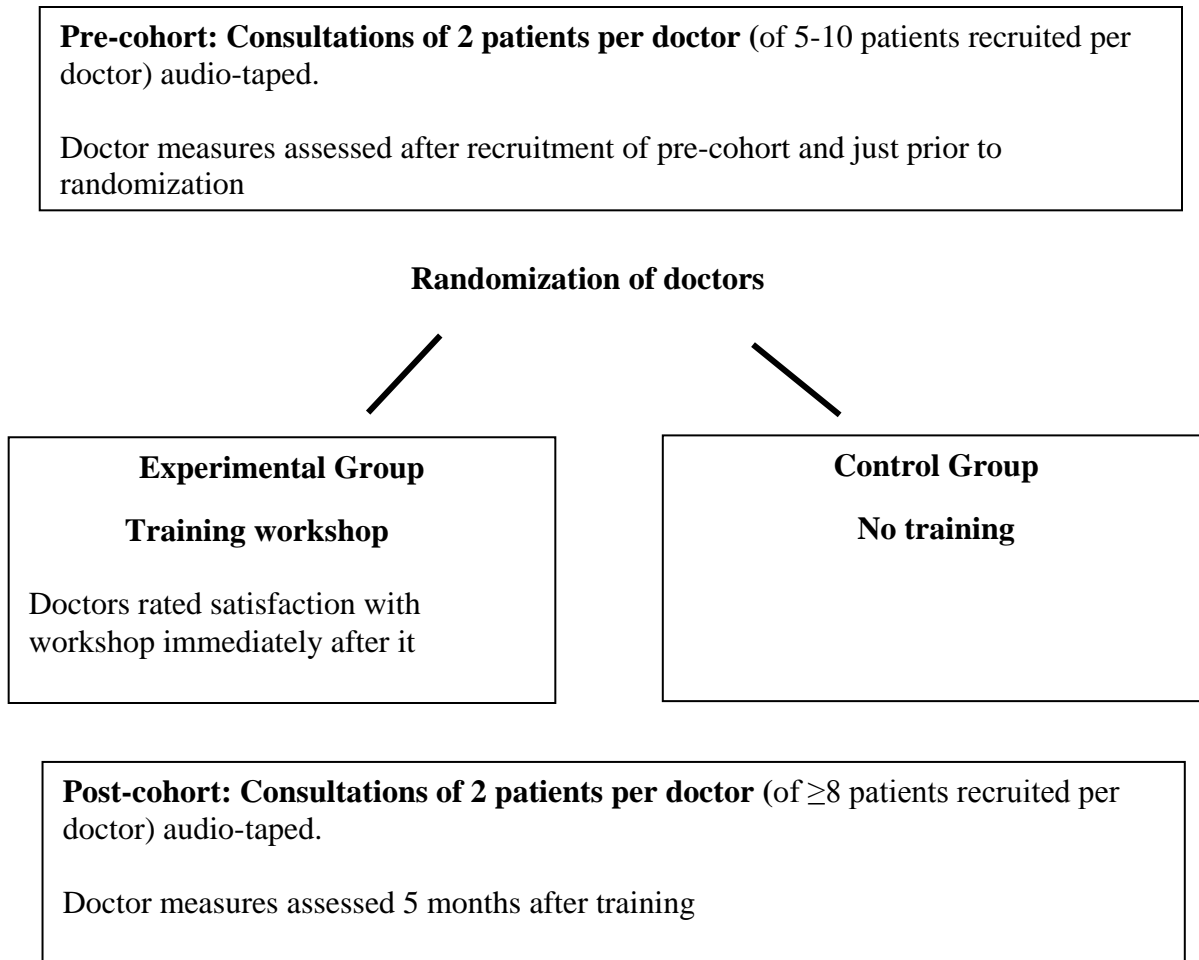


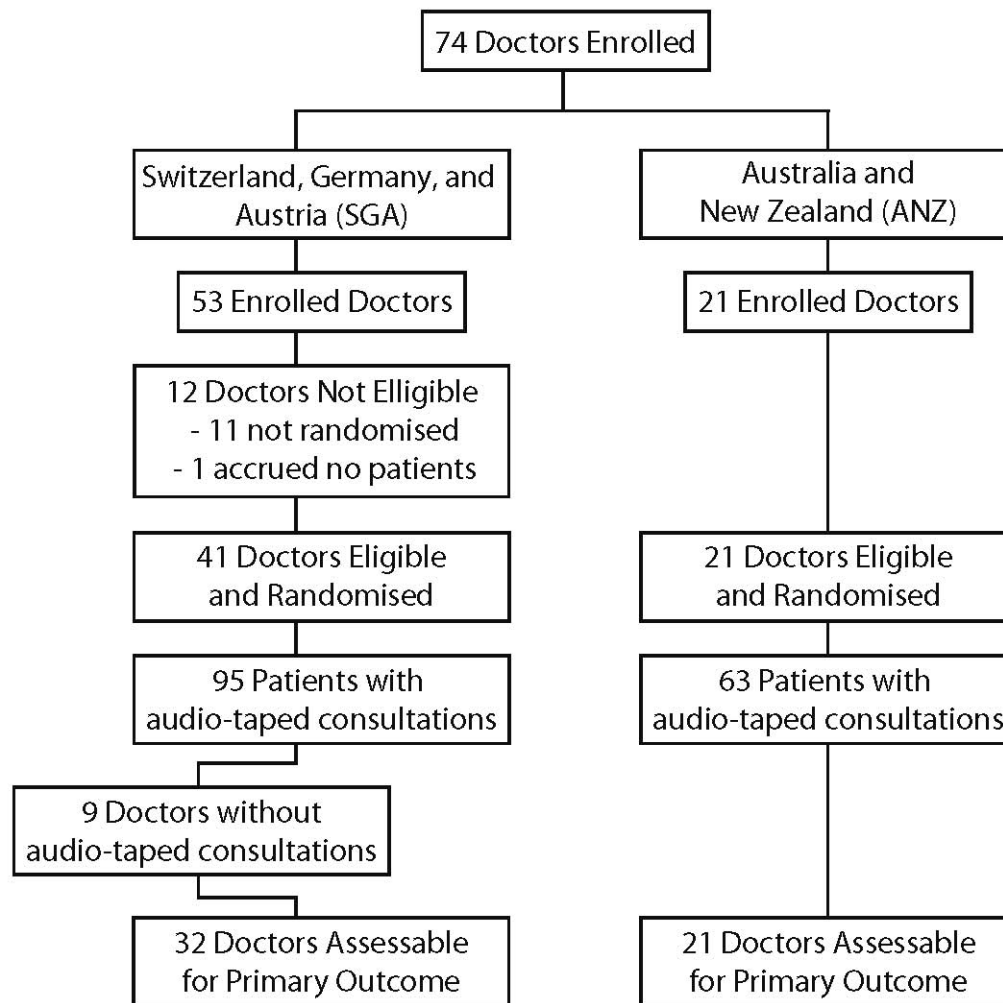
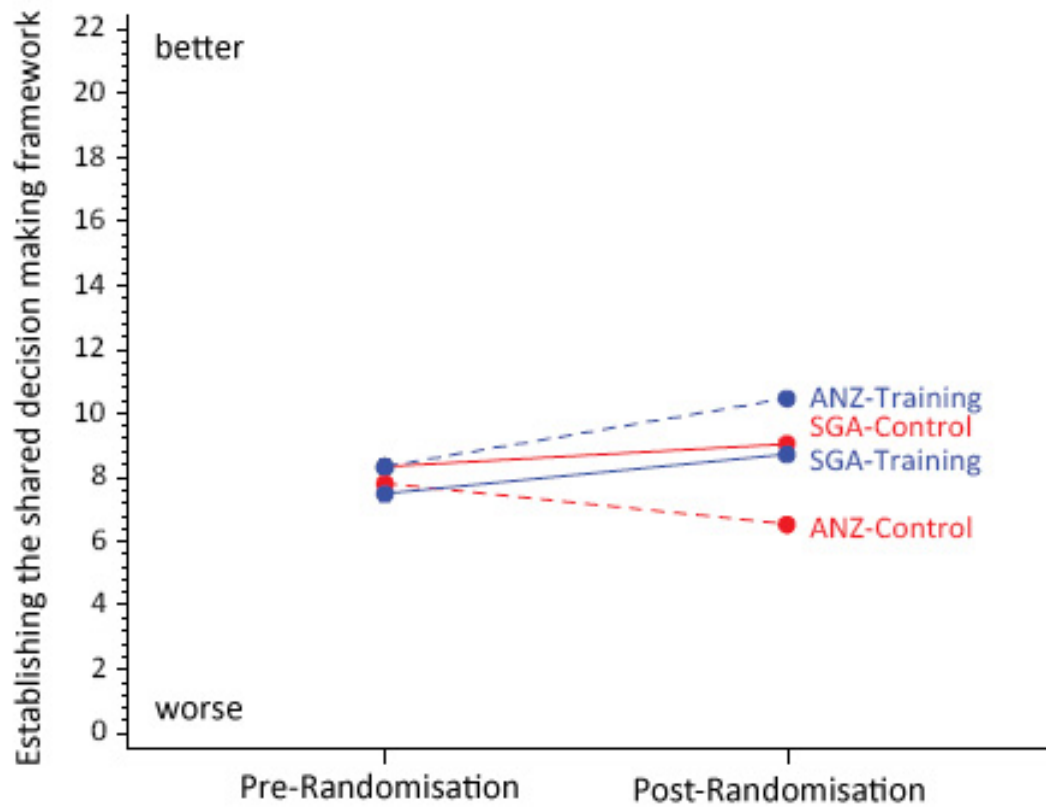
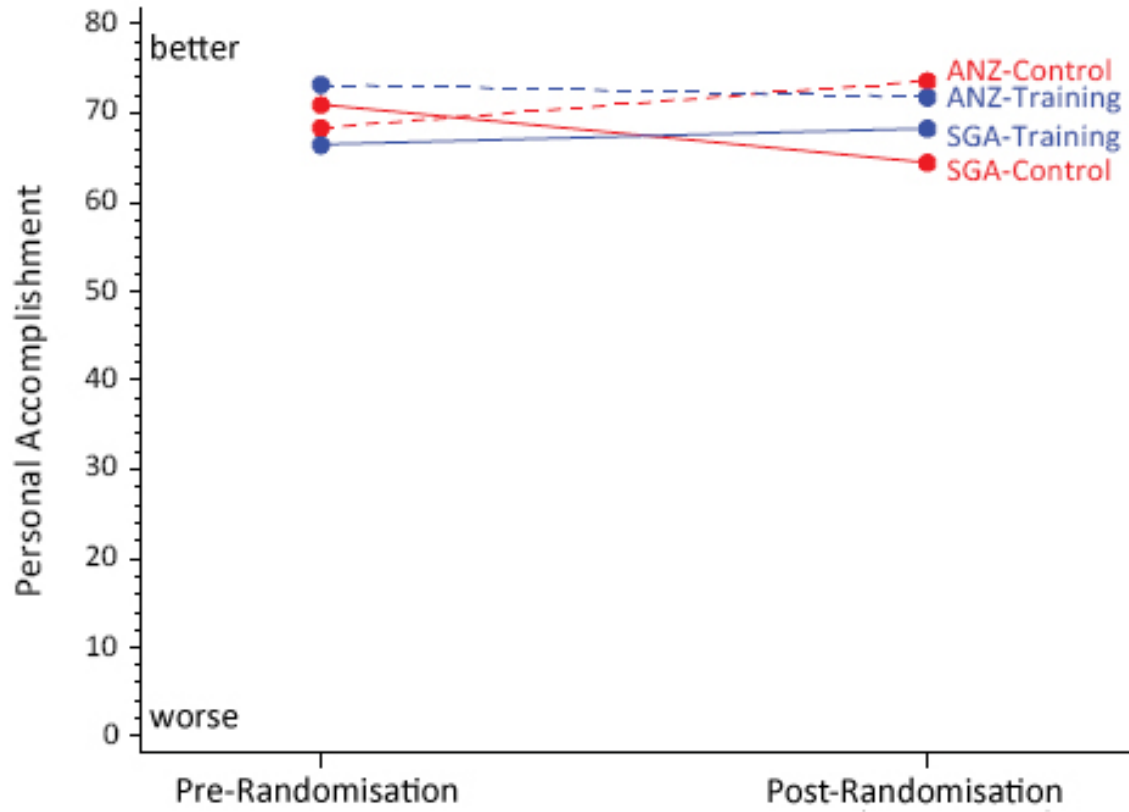
Figure 2. Consort Diagram

Figure 3.
Mean scores of establishing the shared decision making framework, by randomization group and language cohort, plotted against data collection point for 62 randomized doctors



* Note that Figures 3 and do not take into consideration the effect of multiple patients per doctor.

Figure 4.
Mean scores of doctor stress and burnout through personal accomplishment by randomization group and language cohort plotted against data collection point for 62 randomized doctors



APPENDIX OF PARTICIPATING CENTERS, DOCTORS AND LOCAL COORDINATORS

Australia

St Vincents Hospital, Melbourne: R. Snyder, W. Burns, A. Dowling, Nadia Ranieri

Maroondah Hospital, Maroondah: J. Chirgwin, Suzanne Giddings

Royal Prince Alfred Hospital, Sydney: S. Pendlebury, J. Beith, A. Hamilton, Gina Bark

Sir Charles Gairdner Hospital, Perth: C. Saunders, L. Jackson, N. Spry, F. Cameron, M. Taylor, R. Chee, Anna Davies, Philippa Kelly

Flinders Medical Center, Adelaide: B. Koczwara, Alison Richards

Westmead Hospital Sydney: V. Ahern, P. Harnett, Mary Cooper

Nepean Cancer Care Center, Penrith: N. Wilcken, Penny Murie

New Zealand

Auckland Hospital, Auckland: P. Thompson, V. Harvey, Joline Ong

Waikato Hospital, Hamilton: I. Campbell, Jenni Scarlet

Dunedin Hospital, Dunedin: D. Perez, Alison Wylie

Switzerland

Kantonsspital St. Gallen: B. Thürlimann, A. Casty, M. Hoefliger, A. Müller

Inselspital Bern: S. Aebi, M. Rabaglio, C. Baumann

Germany

Universitätsklinik Frankfurt: M. Liszka, S. Loibl, K. Schmidt, V. Gies, H. Trümper

Frauenklinik Technische Universität München: K. Miska, U. Euler, D. Paepke, K. Gauger, A. Baumgärtner

Universitätsfrauenklinik Kiel: C. Crohns, I. Meinhold-Heerlein, A. Ulrich, S. Grebe, J. Haller, A. Lüsse, J. Dürkop

Krankenhaus München Schwabing: Andrea Schulte, Alexandra von Holle, Sabine Schmid

Universitätsklinikum Jena: O. Camara, J. Hermann, A. Egbe, A. Kavallaris, H. Winzer, B. Härtwig, S. Krauspe

Austria

Wilhelminenspital Wien: H. Lass, T. Scholl, M. Brunbauer M. Riegler-Keil

Allgemeines Krankenhaus Wien: C. Singer, Y. Yücel, D. Gschwantler-Kaulich, A. Fink-Retter, D. Bikas, M. Tea Landeskrankenhaus Feldkirch: M. Knauer, R. Köberle-Wührer, P. Elke

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