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

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Abstract

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Correction added on 15 July 2014 after first online publication: The author's name was previously omitted and is now added to the list.

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 doctor behaviour, stress and satisfaction.

Participants and Methods Participants were 21 oncologists from 10 Australian/New Zealand (ANZ) centres and 41 oncologists from 10 Swiss/German/Austrian (SGA) centres. 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 Ninety-five 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 behaviours. 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.

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^{1–3} and evidence that shared decision making (SDM) results in better patient outcomes.^{4–6}

Charles *et al.*⁷ have defined four components of SDM, 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,⁸ 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,^{8–11} are not negotiable when making final treatment decisions¹² and rarely elicit or meet their patients' preferences for SDM.^{6,13–17}

Some oncologists are concerned that while SDM may be largely beneficial, for some, it may be overly burdensome and lead to confusion and raise anxiety, particularly for patients who prefer to remain passive.¹⁸ 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.¹⁰ The difficulty oncologists experience in communicating, including during decision making, has been shown to be a primary contributor to oncologists' stress and burnout.¹⁹ Moreover, SDM is even more ethically pressing and harder to achieve when a clinical trial is discussed.^{20,21} 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- and post-designs.^{15,22} 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.²³

Participants

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

Medical, surgical, radiation and gynaecological oncologists, working in major cancer centres 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 programmes.

Recruitment

Local trial coordination was supported and monitored by a central coordinator for ANZ and SGA, respectively. Doctors in centres accruing to adjuvant breast cancer clinical trials were invited to join the trial to (i) ensure the relevance of the intervention material to oncologists and (ii) 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-randomization and post-randomization 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, one 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 centre (range: 1–6) enrolled in ANZ centres and a median of four doctors per centre (range: 2–6) enrolled in SGA centres. See Appendix 1 acknowledging the contribution of participating centres. 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 behaviour (Fig. 1). In the ANZ cohort, all 21 enrolled and eligible doctors provided audio-taped consultations; of the 84 consultations requested (four per doctor: two before and two after the intervention), 63 (75%) were audio-taped. In the SGA cohort, of the 41 enrolled and eligible doctors, 32 provided audiotaped consultations, for a total of 95 (74%) audio-taped 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.

Figure 1 Consort diagram.

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 gynaecology 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 vs. 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 ($n = 9$) audio tapes were compared, and no differences were detected for randomization arm [$\chi^2 (1) = 1.17, P > 0.28$], gender [$\chi^2 (1) = 1.68, P > 0.20$] and institutional affiliation [$\chi^2 (1) = 1.56, P > 0.45$], nor previous training in communication [$\chi^2 (1) = 0.809, P > 0.35$]; in all cases, Fischer's exact test agrees with chi-square result for lack of significance. For doctor, specialty [$\chi^2 (3) = 5.61, P > 0.10$; Fischer's exact test, $P < 0.007$] 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 gynaecologists. Physicians without tapes were also

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

	SGA				ANZ				χ^2 (P-value)
	Control (no training)		Experimental (training)		Control (no training)		Experimental (training)		
	<i>N</i>		<i>N</i>		<i>N</i>		<i>N</i>		
<i>n</i>	20		21		11		10		
Gender									
Male	7		8		6		5		0.043 (0.835)
Female	13		13		5		5		
Specialty									
Medical Oncology	6		5		6		6		0.709 (0.701)
Radiology	—		—		3		3		
Surgeon	2		2		2		1		
Gynaecologist	12		14		—		—		
Institution									
Public	20		20		7		7		0.976 (0.323)
Private	—		1		—		—		
Both	—		—		4		3		
Previous training in communication skills	6		4		5		6		0.200 (0.655)
	Median	Range	Median	Range	Median	Range	Median	Range	<i>F</i> (<i>P</i>)
Age in years	33	27, 44	34	24, 48	47	33, 58	44	38, 62	46.83 (<0.0001)*
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 recruited to trials over 6 months [†]	15	5, 200	15	3, 55	15	5, 50	8	3, 20	1.21 (0.513)

*Is comparing Australian/New Zealand (ANZ) to Swiss/German/Austrian (SGA).

[†]Refers to any trial; Fischer's exact test is reported for chi-square comparisons; lsmeans is reported for means test both due to small cell sizes.

Table 2 Patient characteristics by doctor's randomization arm and language cohort for those 158 patients who had audiotaped consultations

	SGA				ANZ				
	Control (no training)		Experimental (training)		Control (no training)		Experimental (training)		
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%	χ^2 (<i>P</i>)
<i>n</i>	46	100	49	100	34	100	29	100	
Nodal status									
Missing	—	—	—	—	1	3	—	—	1.54 (0.214)
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	0.068 (0.967)
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 (0.180)
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	
	Median	Range	Median	Range	Median	Range	Median	Range	<i>F</i> (<i>P</i>)
Age in years	58	24, 84	58	35, 86	51	28, 81	52	34, 79	3.45 (0.07)
Tumour 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)

ANZ, Australian/New Zealand; SGA, Swiss/German/Austrian.

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

younger (mean = 32.3, SD = 3.53) than those with tapes (mean = 39.70, SD = 8.82) [$t(1) = 3.02$, $P < 0.02$].

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 burnout, and confidence in their provision of information to patients. Following this, the doctors were randomized (see Fig. 2), 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 centres.

Training intervention

The training consisted of a 7-h interactive face-to-face workshop with a follow-up telephone call 1 month later. The elements of the training workshop were evidence-based and used accepted adult learning principles.²⁰ Strategies

Figure 2 Trial design of IBCSG 33-03.

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	Categorize 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	Summarize information	Encourage individual choice

SDM, shared decision making.

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 multidisciplinary review of audiotaped consent interviews and consensus meetings.²⁰ Training based on this model was shown to be acceptable and effective in a phase II trial.¹⁵ The training incorporated written and oral materials that presented principles and strategies (2 h), a video modelling ideal behaviour (30 min), role-play practice with an actor-patient and expert facilitator (4 h), and individualized feedback on audiotaped consultations with actual patients (30 min). The training workshop focused on four

key concepts: (i) establishing a SDM framework, (ii) structuring information into a recommended sequence or order, (iii) ensuring the discussion of key information in a clear manner and (iv) avoiding coercive communication.²⁰ Example behaviours for each of these concepts are shown in Table 3.

The training workshops were held at the participating centres 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

SDM.^{6,7,10,20} Baseline audiotapes were transcribed and analysed by the research team using the Decision Analysis System for Oncology (DAS-O)²⁴ developed by our team to capture essential elements of SDM 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 behaviours in audiotaped consultations

The primary doctor outcome for the study was change in SDM behaviours demonstrated in audiotaped consultations with real patients, coded using the DAS-O coding system.²⁴ The coder identifies the presence (1) or absence (0) of key components of SDM in three subscales:

1. establishing a SDM framework (22 items), for example, introducing joint decision making, inviting comments and questions, offering choice;
2. 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); and
3. providing essential information about clinical trials (used only when clinical trials are discussed) (14 items), for example,

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 behaviours were displayed. Two raters applied the DAS-O coding system to the consultations. To test inter-rater reliability and intrarater reliability, they re-coded 10% of each other's and 10% of their own consultations. Inter-rater reliability and intrarater reliability as measured by kappas were on average 0.54 for the presence of behaviours 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.²⁵

Doctor stress and burnout

Doctor stress and burnout was measured using the Maslach Burnout Inventory as used by

Rameriz *et al.*²⁶ 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 centres, all results are presented separately by language.

The primary doctor outcome measure was change in doctor behaviour 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 patients²⁷ 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.²⁷ 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: $(\text{Experimental}_{\text{post}} - \text{Experimental}_{\text{pre}}) - (\text{Control}_{\text{post}} - \text{Control}_{\text{pre}})$ (Table 4). 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 2-week 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'.

Table 4 Summary of differences between experimental and control groups of doctor outcome measures* estimated using mixed models linear regression by language cohort

	Language cohort	Estimated mean difference*	Standard error	Lower 95% confidence limit	Upper 95% confidence limit	P-value†
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

ANZ, Australian/New Zealand; SGA, Swiss/German/Austrian.

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

*(Exp_{post} − Exp_{pre}) − (Control_{post} − Control_{pre}).

†P-value is the between-group comparison of pre- vs. post-differences.

Doctor behaviour

Table 4 shows the results of mixed effects modelling exploring differences in the change of doctor behaviour 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 behaviours designed to establish the SDM framework than those doctors in the control group (estimated population mean difference = 3.42, SE = 1.50, ES = 0.30, $P = 0.03$). However, the ES was small. There was no effect for this variable for SGA doctors (estimated population mean difference = 0.52, SE = 1.39, ES = 0.04, $P = 0.71$). Figure 3, which displays the mean scores for establishing the SDM framework by randomization group and lan-

guage 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 of pre- and post-randomization in other subscales of the DAS-O, although the direction of effects was generally in the hypothesized direction.

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

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 Figure 3 does 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.

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-month 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, SE = 3.25, ES = 0.31, $P = 0.03$; see Fig. 4). There were no significant differences of pre- and post-randomization scores between the experimental and control groups on other stress and burnout subscales.

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' behaviour as captured by the DAS-O coding scheme: establishing an SDM framework. Doctors in both cohorts maintained or slightly increased behaviours designed to establish a SDM framework after training, while the control group declined in this behaviour. 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 behaviour 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.^{28,29} Most oncologists know about, and are generally favourable towards, SDM;^{30,31} thus, they may have had sufficient background knowledge to guide their behaviour 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 behaviour 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 behaviours and actually increased their skills due to training. This is in line with previous studies (for example, Ref. 32) 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-emphasized 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 multifactorial, with system, patient and doctor factors contributing to burnout.²⁶ 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 modelling 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 was gynaecologists, 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 behaviour that work together cumulatively to enhance the patient's experience.

Nonetheless, the fact that increases in or maintenance of SDM behaviours were achieved after only 7 h of training suggests that improve-

ment 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 7 h may not be sufficient to generate large changes in behaviour 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- to 3-day period may have consolidated learning. Communication skills training workshops which have been proven efficacious have been at least 3 days in length.^{33,34}

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.³⁵ 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-h 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 behaviours. Future research should explore the trade-off between length and efficacy of communication skills training.

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Appendix: Appendix of Participating Centres, 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. Litzka, 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. Luesse, 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.