

Learning in practice

Discussing randomised clinical trials of cancer therapy: evaluation of a Cancer Research UK training programme

V Jenkins, L Fallowfield, I Solis-Trapala, C Langridge, V Farewell

Sussex Psychosocial
Oncology Group,
Brighton & Sussex
Medical School,
University of
Sussex, Brighton
BN1 9QG

V Jenkins
*senior research fellow
in psycho-oncology*

L Fallowfield
*professor in
psych-oncology*
C Langridge
data manager

Centro de
Investigacion en
Matematicas,
Guanajuato, Mexico
I Solis-Trapala
statistical researcher

MRC Biostatistics
Unit, Institute of
Public Health,
Cambridge
V Farewell
senior scientist

Correspondence to:
V Jenkins
val@sussex.ac.uk

BMJ 2005;330:400-3

Abstract

Objective To evaluate a training intervention aimed at improving healthcare professionals' communication with cancer patients about randomised clinical trials.

Design Before and after evaluation of training programme.

Setting Members of the National Cancer Research Network, Scottish Trials Network, and the Welsh Cancer Trials Network

Participants 101 healthcare professionals (33 clinicians and 68 research nurses).

Intervention Four modules delivered by a trained facilitator using videotapes and interactive exercises to cover general issues about discussing randomised clinical trials with patients, problems specific to adjuvant trials, trials with palliation as the goal, and trials where patients had a strong preference for one treatment arm.

Main outcome measures Before and after the intervention, participants were videotaped discussing a trial with an actor portraying a patient. These consultations were assessed for presence of information required by good clinical practice guidelines. The actor patients gave an assessment after each interview. Participants reported their self confidence about key aspects of trial discussion.

Results Analysis of the videotaped consultations showed that, after intervention, significantly more participants displayed key communication behaviours such as explaining randomisation (69 v 81, odds ratio 2.33, $P=0.033$), checking patients' understanding (11 v 31, odds ratio 3.22, $P=0.002$), and discussing standard treatment (73 v 88, odds ratio 4.75, $P=0.005$) and side effects (69 v 85, odds ratio 3.29, $P=0.006$). Participants' self confidence increased significantly ($P<0.001$) across all areas. Actor patients' ratings of participants' communication showed significant improvements for 12/15 key items.

Conclusion This intensive 8 hour intervention significantly improved participants' confidence and competence when communicating about randomised clinical trials.

Introduction

In Britain, healthcare professionals are under pressure to recruit more patients into cancer trials.¹ Few publications are available to help clinicians in their

discussions about trials with patients.² Reference is made to the importance of communication with patients, especially with regard to informed consent, but research has shown that few clinicians feel skilled in this task.³⁻⁵ More than 52% of senior clinicians attending communication skills courses and 27% of chemotherapy nurses acknowledged that providing complex information and seeking consent to clinical trials were their main communication problems, surpassing even the breaking of bad news.⁶

We designed a comprehensive educational programme to help health professionals when communicating about randomised trials. Before launching it as a national training programme, we evaluated its efficacy and acceptability with UK health professionals engaged in trial recruitment.

Participants and methods

Participants

We sent a general letter of invitation to the National Cancer Research Network, Scottish Trials Network, and the Welsh Cancer Trials Network inviting healthcare professionals to attend our training course. Although nearly all of the 33 clinicians and 68 research nurses or radiographers who took part had previously received communication skills training, many (31 clinicians and 23 nurses) had not attended a good clinical practice guideline course (see bmj.com).

Before attending our course, participants nominated a trial in which they were currently involved which would be used in their videotaped consultations.

Course contents

Our course lasted eight hours, split over two days. The course comprised interactive exercises, didactic presentations, and facilitated discussion about the videotaped scenarios in the modules. During the course, we encouraged participants to consider how they structured trial discussions with patients and how they described treatments available on and off trial and the process of randomisation, and to compare these



Further details of the conditional logistic regression used in the study are on bmj.com



This is the abridged version of an article that was posted on bmj.com on 10 February 2005: <http://bmj.com/cgi/doi/10.1136/bmj.38366.562685.8F>

with those depicted in the modules. At the end of the course participants generated a list of key points about trial discussion.

Course materials

We developed the training materials in close collaboration with experienced doctors, research nurses, trial managers, and patient groups. The training materials comprised four video modules, a CD Rom, and a comprehensive facilitator's handbook.

Module 1 provides a generic introduction to randomised clinical trials and includes comments by six patients, eight clinicians, a research nurse, and a trial manager exploring the difficulties associated with discussing trials.

Module 2 deals with the discussion of adjuvant treatment trials and contains two scenarios—a placebo controlled colorectal cancer trial and a breast cancer trial. This module also looks at handling uncertainty and dealing with uninformed and suspicious patients.

Module 3 includes two scenarios of palliative trials—a multiple myeloma trial and a trial for non-small cell lung cancer. This module promotes discussion about handling deferential patients and their more questioning relatives and giving distressed patients complex information about highly toxic treatment.

Module 4 depicts patients who may have a strong preference for a particular treatment arm and explores how to handle patients with high information needs who have collected many internet articles and newspaper cuttings—in a surgical trial for bowel cancer and a prostate cancer trial.

All four modules have linking commentary and statements by clinicians and nurses.

The facilitator handbook was developed for use by both experienced and less experienced facilitators. It contains a time-coded commentary about the issues illustrated in the accompanying videotapes and suggestions about appropriate places to stop and engage a group in discussion. It provides examples of how to structure a teaching session and a bibliography. The CD Rom contains questionnaires, handouts about the trials described in the videos, a bibliography, group exercises and presentations showing the evidence base for suggestions made.

Videotaped consultations

Before and after the course we videotaped participants conducting simulated discussions about clinical trials with patients portrayed by experienced actors well briefed about their disease and the trial being discussed. The actors were assigned one of four different characters: internet guru (who comes armed with newspaper clippings and web reports on treatments); preference (patient has already decided which treatment he or she wishes to receive); deferential; and suspicious. To enhance authenticity, we used different actors in each participant's initial and post-course discussion, but the patient characteristic and the trial remained constant.

Thirty three participants conducted two videotaped patient interviews before the course so that we could check for any practice effect in performing the interview twice.

Information item

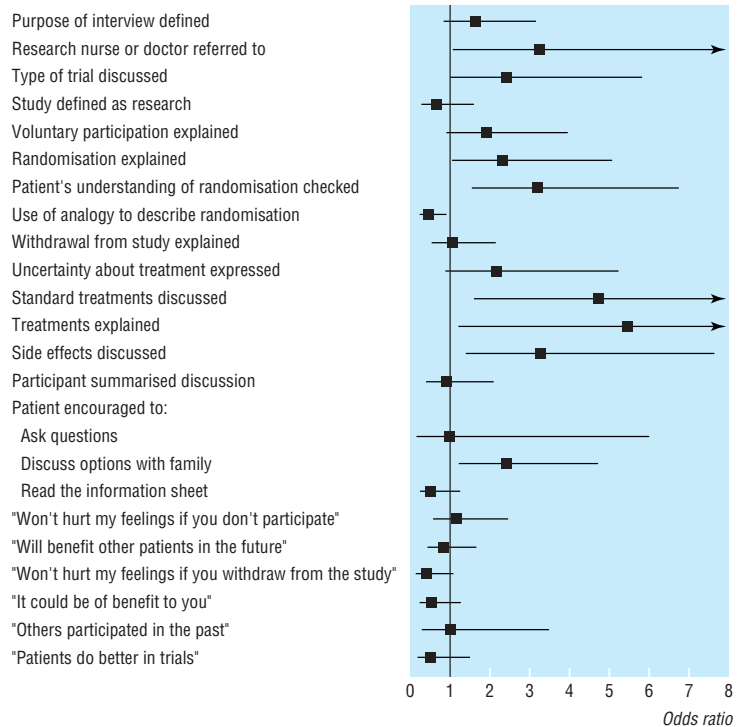


Fig 1 Odds ratios (95% confidence intervals) of improved scores after the training course for the presence of key information in participants' videotaped interviews

Assessments

Before and after the training course participants rated their self confidence on a scale from 0 (none) to 10 (very confident) about general aspects of discussing trials with patients. Items included describing randomisation, discussing different types of trials, and handling discussions with challenging patients.

Participants' videotaped interviews were objectively assessed by one of the authors, blinded as to whether they were conducted before or after the training course. Analysis involved checking for the presence of key information as stated in the good clinical practice and ethical guidelines—for example, the voluntary nature of trials, explicit use of the term randomisation, and descriptions of side effects. We also assessed specific behaviours against pre-set criteria—such as checking patients' understanding and summarising information.

After each videotaped interview, the actor "patients" completed a 15 item questionnaire about whether they had understood the explanation of randomisation, were told that participation was voluntary, and other communication issues.

Hypotheses

Our a priori hypotheses were that

- Participants' communication in key areas of discussions about clinical trials would improve after the course—that is, competence would be measurably better
- Participants would feel more confident about discussing trials and about approaching different types of patients after the course—that is, self confidence would be enhanced.

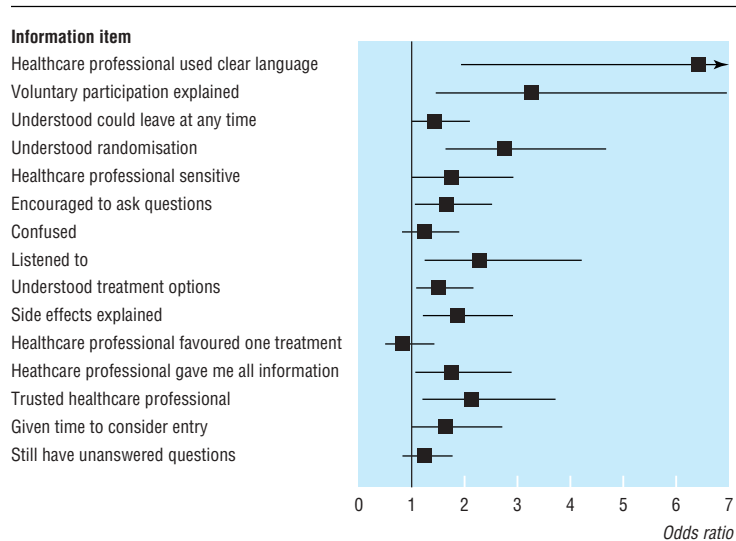


Fig 2 Odds ratios (95% confidence intervals) of improved scores after the training course for actor patients' assessments of participants' videotaped interviews

Statistical methods

We analysed the data generated from the video analysis using conditional logistic regression models in order to compare the scores reported for each participant before and after the course. We estimated odds ratios, with values > 1 indicating that a "yes" score was more likely in the interview after the course and that participants' behaviour had improved after the course.

We defined scores for the actors' questionnaire responses and an odds ratio > 1 represents a shift towards improvement after the course. The scores from the participants' confidence questionnaire were used directly, and an odds ratio > 1 indicates a shift towards higher levels of confidence after the course (see bmj.com).

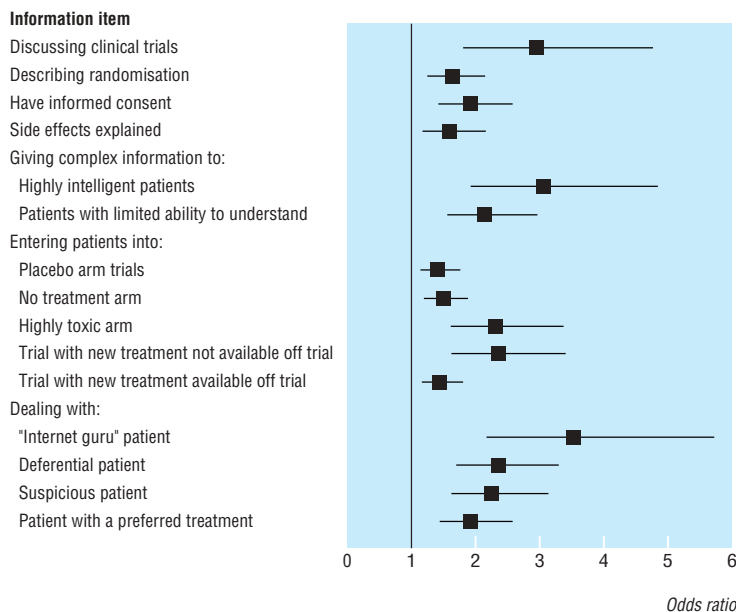


Fig 3 Odds ratios (95% confidence intervals) of improved scores after the training course for participants' self rated confidence

Results

We found no evidence of practice effects in the two videotaped interviews performed by 33 participants before the training course. Thus our final analysis for the whole sample was based on the initial interview before the course.

Video analysis—We examined rater reliability for 10% of the videotapes and found good agreement in rating of interviews conducted before and after the course ($\kappa = 0.664$ (SE 0.025)). Figure 1 shows the odds ratios for the video analysis (see bmj.com for data). After the course, more participants described the particular type of trial "very well" (81 v 91), gave clear explanations about the treatments available on and off trial (73 v 88) and their side effects (69 v 85), and explained the term randomisation (69 v 81) but used fewer analogies to do so (36 v 22). Participants also improved in checking that the patient had understood the explanation of randomisation (11 v 31) and showed some improvement in explaining the voluntary nature of the trial (71 v 81, $P = 0.08$). However, some behaviours stated in the good clinical practice guidelines, such as encouraging patients to read the trial information sheet and informing them that they could withdraw at any time, did not alter significantly (92 v 85 and 33 v 34, respectively).

Actor patients' ratings—Figure 2 shows the odds ratios for the actors' responses to their questionnaire (see bmj.com for data). For 12/15 statements the actors reported significant improvements after the training course; this occurred despite the relatively high positive baseline scores that influenced the lack of demonstrable change for three statements ("I was left confused," "The healthcare professional seemed to favour one treatment over another," "I still have unanswered questions").

For neither of these objective measures did the actor patients' sex or character type affect the pattern of participants' behaviour changes, nor was there a relation with participant type (clinician v research nurse or radiographers)

Participants' self confidence—Figure 3 shows that participants' self confidence ratings increased significantly after the training course for each statement at the $P = 0.001$ level. Despite these improvements, several aspects of trial recruitment remained challenging, including describing randomisation and time constraints. Explaining multi-arm and phase I trials, which were not portrayed in the training modules, remained problematic for most participants.

Discussion

To our knowledge this is the first evaluation of an intervention designed specifically to help health professionals provide clear information about phase III randomised trials of cancer treatments to patients and to encourage them to approach all eligible patients for recruitment. We designed our modules to stimulate and provoke constructive discussion among viewers. The course integrated different activities in order to create simultaneous rather than sequential skills development and to stimulate knowledge acquisition and awareness of how these affect patients and health professionals. This model of communication allows participants to

What is already known on this topic

Worldwide, few potentially eligible patients are approached about entry into clinical trials; healthcare professionals find discussing trials and obtaining truly informed consent difficult

Patients are often confused or unclear about the experimental nature of treatment in trials

What this study adds

A training course was designed specifically to help health professionals provide clear information about phase III randomised trials of cancer treatments to patients and to encourage them to approach all eligible patients for recruitment

The course increased participants' reported self confidence about recruiting patients into trials, and objective analyses revealed improvements in the style and content of the participants' discussions

focus on their own perceived areas of difficulty and makes the course work pertinent to their needs.⁷

We have used these types of "trigger" tapes successfully in our previous research with nurses and doctors working in oncology.^{6,7} The intervention reported here was valued highly by all participants.

The positive findings from the course included an increase in participants' reported self confidence about recruiting patients into trials, and objective analyses revealed behavioural changes in the style and content of the participants' discussions. There is strong evidence that if both competence and self confidence are improved then behavioural changes often do transfer successfully into the clinical setting and endure, even without support or consolidation courses.^{7,8}

Our training course is now being rolled out by the national cancer research networks in England and

Wales, and research to see if real patient outcomes are affected is planned.

We thank members of the NCRN Consumer Liaison Group for their generous contributions and agreement to be filmed together with Dr Rob Glynne Jones, Professor Robert Leonard, Professor Peter Selby, Professor Stephen Spiro, Professor Pierre Guillou, Dr David Bloomfield, Dr Fiona McKinna, Dr Joanne Simpson, nurse lead for the WCTN Libby Batt, trials manager Nicky Gower, and Louise Leach. Mark Mansell and Roland Brinton from Visual Image Publishing produced the series with us. Finally we thank Role Call actors, all the healthcare professionals who participated in the study, and members of Sussex Psychosocial Oncology Group who assisted in the smooth running of the courses, especially Sue Catt, Karen Nicholls, Val Shilling, Lou Atkins, Leigh Johnson, Mel Price, Tracy Woodcock, and Louise Leach.

Contributors: See bmj.com

Funding: Cancer Research UK funded the project, and AstraZeneca provided an unrestricted educational grant to help video production.

Competing interests: None declared.

Ethical approval: None required.

- 1 Department of Health. *Government response to the sixth report of the House of Commons Science and Technology Committee: session 1999/2000 cancer research—a fresh look*. London: HMSO, 2000 (Cm 4928).
- 2 Albrecht TL, Blanchard C, Ruckdeschel JC, Coover M, Strongbow R. Strategic physician communication and oncology clinical trials. *J Clin Oncol* 1999;17:3324-32.
- 3 Jenkins VA, Fallowfield LJ, Souhami A, Sawtell M. How do doctors explain randomised clinical trials to their patients? *Eur J Cancer* 1999;35:1187-93.
- 4 Pope JE, Tingey DP, Arnold JM, Hong P, Ouimet JM, Krizova A. Are subjects satisfied with the informed consent process? A survey of research participants. *J Rheumatol* 2003;30:815-24.
- 5 Donovan J, Mills N, Smith M, Brindle L, Jacoby A, Peters T, et al. Quality improvement report: Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study. Commentary: Presenting unbiased information to patients can be difficult. *BMJ* 2002;325:766-70.
- 6 Fallowfield L, Saul J, Gilligan B. Teaching senior nurses how to teach communication skills in oncology. *Cancer Nurs* 2001;24:185-91.
- 7 Fallowfield L, Jenkins V, Farewell V, Saul J, Duffy A, Eves R. Efficacy of a Cancer Research UK communication skills training model for oncologists: a randomised controlled trial. *Lancet* 2002;359:650-6.
- 8 Fallowfield L, Jenkins V, Farewell V, Solis-Trapala I. Enduring impact of communication skills training: results of a 12-month follow-up. *Br J Cancer* 2003;89:1445-9. (Accepted 10 January 2005)

doi 10.1136/bmj.38366.562685.8F

Teaching of cultural diversity in medical schools in the United Kingdom and Republic of Ireland: cross sectional questionnaire survey

Nisha Dogra, Sue Connin, Paramjit Gill, John Spencer, Margot Turner

Over the past decade, pressure to teach about cultural diversity in the medical undergraduate curriculum has increased.^{1,2} *Tomorrow's doctors* states that "students should have acquired respect for patients and colleagues that encompasses, without prejudice, diversity of background and opportunity, language, culture and way of life."¹ In this study, we used ethnicity as an example of cultural diversity, but we acknowledge the importance of other factors. We aimed to identify the extent to which cultural diversity was being taught in medical schools in the United Kingdom and Republic of Ireland.

Participants, methods, and results

We devised a study specific questionnaire that asked a series of closed questions plus some open ended questions inviting free text responses. We sent this to contacts in all medical schools in the United Kingdom and Republic of Ireland (n=31 at the time of the study). We followed up non-respondents by a further letter and emails. We entered data into SPSS and did a content analysis of the free text responses.

University of Leicester,
Greenwood
Institute of Child Health, Leicester
LE3 0QU
Nisha Dogra
senior lecturer in child and adolescent psychiatry

continued over

BMJ 2005;330:403-4

This article was posted on bmj.com on 11 January 2005: <http://bmj.com/cgi/doi/10.1136/bmj.38338.661493.AE>