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Efficacy of an Intervention to Improve Communication About Randomised Clinical Trials (RCTs) in Cancer

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ABSTRACT

Many acknowledge the difficulties discussing trials with ill and anxious patients. We report evaluation of a training programme comprised 4 modules with videotaped scenarios, interactive exercises and comprehensive handbook, designed to assist communication about RCTs in cancer. Module 1 deals with general issues surrounding the discussion and implementation of RCTs. The other 3 modules each contain 2 scenarios dealing with adjuvant trials, those with palliation as the goal and trials where patients have a preference for one treatment arm. **Methods:** 101 participants (33 clinicians and 68 research nurses) took part in the evaluation. Objective and subjective assessments were made pre (T1) and post (T2) course. Participants were videotaped discussing a trial with a simulated patient at T1 and T2. An experienced rater, blinded to time point, checked these for the presence/absence of essential information required by Good Clinical Practice Guidelines. Simulated patients completed assessments following each interview. Participants also rated self-confidence about key aspects of trial discussion. **Findings:** Significant improvements were found in communication behaviours post-course. Objective analysis of the video assessments demonstrated a positive shift showing significant changes for key behaviours such as explaining randomisation (OR 2.33, p=0.033), checking understanding (OR 3.22, P=0.002), discussing standard treatment (OR 4.75, P=0.005), and side effects (OR 3.29, P=0.006). Self-confidence increased significantly across all areas (P<0.001). Patient simulator ratings of participants' discussions about trials showed significant changes for 12/15 key items. **Conclusions:** An intensive 1.5-day programme significantly improved participants' confidence and competence when communicating about RCTs.

INTRODUCTION

Worldwide fewer than 5% of eligible patients with cancer participate in RCTs. Research has shown that few clinicians are skilled in effective communication and little is taught in medical training despite the fact that communicating with patients, relatives and colleagues will be the most repeated event in their medical career. The discussion of RCTs of cancer therapy involves a different level of communication with its own complex language. The clinician (but increasingly in the UK it is the research nurse or research coordinator) needs to fulfil many tasks such as: -

- describe standard treatment
- discuss the uncertainty about experimental treatment
- introduce the concept of the trial
- explain the process of randomisation
- introduce other terms and concepts such as double blind, placebo etc
- clarify potential benefits and harms associated
- ensure properly informed consent

Following requests from health professionals for more up to date training materials, we designed a comprehensive educational package. The primary aim was to help doctors, nurses and others improve communication with patients and their relatives about RCTs.

DEVELOPMENT OF EDUCATIONAL TRAINING PACKAGE

Materials for the training intervention were developed in close collaboration with experienced doctors, research nurses, trial managers and patient groups. The package comprised 4 video modules, a CD-ROM and a comprehensive facilitator's handbook.

Module 1 provides a generic introduction to trials and includes comments by 6 patients, 8 clinicians and 2 research nurses/data managers interspersed by interactive exercises and short didactic presentations.

Module 2 contains 2 scenarios in which adjuvant treatment trials are discussed: - VICTOR (Rofecoxib v placebo in colorectal cancer), and the IES (Exemestane v tamoxifen breast cancer trial). The module explores handling uncertainty and dealing with uninformed and suspicious patients.

Dr Rob Glynne Jones, a medical oncologist discusses the VICTOR trial with "Ron"

"Ron" has a further discussion about the VICTOR trial with the research nurse, Libby Batt

Professor Robert Leonard, a medical oncologist, discusses the IES trial with "Bronwen".

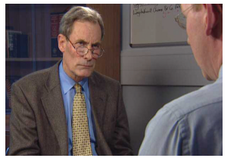
Module 3 includes 2 trials where palliation is the goal: - MYELOMA VII (multiple myeloma) and the Big Lung Trial (chemotherapy v best supportive care in non small cell lung cancer). The module permits discussion about handling deferential patients, relatives and giving distressed patients complex information with linking commentary and statements from clinicians and nurses.

Professor Peter Selby the medical oncologist discusses the MYELOMA VII trial with "Sheila".

Professor Stephen Spiro, the chest physician, discusses the Big Lung Trial with "Jack" and "Rita".

Module 4 contains 2 modules and deals with patients who may have a preference for one treatment arm or high information needs (Internet Guru) The trials chosen to illustrate these issues are: - CLASICC (conventional v laproscopic surgery for bowel cancer) and PRO7 (hormones +/- radiation therapy for prostate cancer).

Professor Pierre Guillou, a colorectal surgeon, discusses the CLASSIC trial with " Margaret"

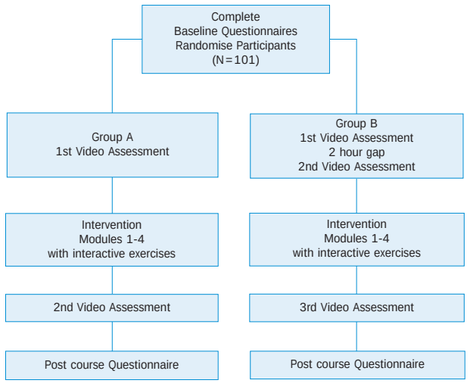


Dr David Bloomfield, a radiation oncologist, discusses the PR07 trial with "Peter"

Having developed the materials we then evaluated their efficacy during a 12-hour worhshop.

METHODS

101 healthcare professionals, 33 clinicians and 68 research nurses/fellows completed the evaluation. The majority of clinicians (94%) compared with nurses (32%) had not attended a Good Clinical Practice (GCP) guideline course.



OUTLINE OF THE EVALUATION OF THE TRAINING PACKAGE

VIDEOTAPED ASSESSMENT

Participants nominated a trial to which they were actively recruiting patients and were videotaped discussing this with a simulated patient (actor).

Almost half the group (48%) chose a trial comparing standard with a new treatment (e.g. TACT) , 22% chose to discuss a trial that had a "no extra treatment" arm (e.g.LU22) , 18% chose a trial with a placebo arm (e.g. VICTOR) , 9% a trial that had a "toxic" or high dose arm (e.g. AML12) and 3% chose a surgical trial (e.g. ALMANAC).

TACT –Standard anthracycline-based chemotherapy with fluorouracil, epirubicin and cyclophosphamide or Epirubicin and CMF versus FEC followed by sequential docetaxel as adjuvant treatment for women with early breast cancer
LU22 –Surgical resection with or without pre-operative chemotherapy in patients with operable non-small cell lung cancer.
VICTOR -Double blind, placebo-controlled trial of rofecoxib in colorectal cancer patients following potentially curative therapy.
ALMANAC -Sentinel Node Biopsy compared with standard axillary surgery in early breast cancer

The actors were instructed to display one of 4 different character types:

1. The patient who comes armed with newspaper clippings and web reports on cancer treatments (Internet Guru)
2. The patient who has already decided which treatment they wish to receive (preference)
3. The patient who defers decisions about trial participation to the nurse or clinician (deferential)
4. The patient who is uneasy about experimentation and trials (suspicious).

For pre and post workshop assessments the trial and patient characteristic remained constant. Different actors were used pre and post assessment to maintain authenticity for the healthcare professionals.

WORKSHOP CONTENT

The workshop was run over 12 hours by an experienced facilitator. Modules 1 and 2 were completed on the first afternoon and modules 3 and 4 the following morning. Participants discussed their personal trial difficulties, completed interactive exercises, and were provided with a workbook with useful references about evidence based practice. The RCT scenarios had many stop points where groups engaged in facilitated discussion.

HYPOTHESES

Our a priori hypotheses were: -

1. Health care professionals' competence when communicating about RCTs would improve following the course
2. Health care professionals will feel more confident about discussing trials and approaching patients

ASSESSMENTS

Objective:

- Analysis of pre and post workshop videotapes by an independent rater using clearly defined criteria and blind to time point of assessment
- Assessments made immediately post interview by simulated patient using standardised checklist

Subjective:

- Self rated confidence questionnaires pre and post workshop completed by participants

FINDINGS

Objective Analysis of Pre and Post Workshop Trial Discussions (Odds Ratio, P Value)

Statement	OR	P Value
Is the purpose of the interview defined?	1.67	0.118
Is the study defined explicitly as research?	0.67	0.374
Is withdrawal from study explained explicitly?	1.06	0.862
Is type of trial discussed i.e. placebo, double blind etc	2.43	0.048
Is concept of randomisation explained explicitly?	2.33	0.033
Is patient's understanding of the term checked?	3.22	0.002
Does he/she use an analogy or another expression? e.g.50: 50 to describe the randomisation process?	0.48	0.03
Was patient asked to summarise?	Fisher's	0.03
Is voluntary participation explained explicitly?	1.91	0.082
Does HCP express uncertainty about treatment decisions?	2.14	0.016
Did the HCP summarise information	0.92	0.835

Simulated Patient Assessment (Odds Ratio, P Value)

Statement	OR	P Value
The doctor used clear and understandable language	6.47	0.0018
I understood that entry into the trial is voluntary	3.29	0.002
I understood that I could leave the trial at any time	1.50	0.032
I understood the HCPs explanation of randomisation	2.81	0.001
I felt the HCP was sensitive to my concerns	1.80	0.02
I was given the opportunity to ask questions	1.70	0.013
I was left confused	1.29	0.22
I felt the HCP listened to what I had to say	2.34	0.0048
I understood the treatment options available to me	1.55	0.014
I was informed of the possible side effects of the treatments	1.91	0.0032
The HCP seemed to favour one treatment over another	0.87	0.61
I felt I was given all the information I needed to make a decision	1.8	0.017
I felt the HCP created an atmosphere of trust and support	2.18	0.0051
I felt the HCP gave me time to consider entry into the trial	1.66	0.046
I still have unanswered questions	1.24	0.26

Improvements in Self Confidence (Odds Ratio, P Value)

	OR	P
How confident are you about discussing clinical trials with patients with cancer?	3	0.001
How easy do you find describing randomisation?	1.6	0.001
How confident are you that you really do have informed consent from patients before starting treatment?	1.96	0.001
How confident are you that you tell patients about the most likely side-effects of treatment?	1.63	0.001
How comfortable are you with entering patients into placebo arm trials?	1.45	0.001
How comfortable are you with entering patients into trials which have a no treatment arm?	1.52	0.001
How comfortable are you with entering patients into a trial which has a highly toxic arm versus standard treatment?	2.35	0.001
How comfortable are you about recruiting patients into a trial comparing standard treatment versus a novel treatment or procedure which is available off trial?	1.47	0.001
How comfortable are you about recruiting patients into a trial comparing standard treatment versus a novel treatment or procedure not available off trial?	2.38	0.001
How confident are you about providing complex information about trials to the highly intelligent patient?	3.11	0.001
How confident are you about providing complex information about trials to patients who have limited ability?	2.18	0.001
How confident are you in obtaining authentic informed consent from patients who have a deferential attitude?	2.38	0.001
How confident are you when discussing trials with patients who are mistrustful and suspicious about trials?	2.28	0.001
How confident are you when dealing with patients who wish to choose their preferred treatment arm?	1.94	0.001
How confident are you in dealing with the 'internet guru'?	3.53	0.001

ROLL OUT

- Cancer Trials Networks throughout the UK are training staff using the materials
- Modules have been used successfully in other English speaking countries including Australia and North America
- Further modules to accompany series are being developed
- Plans to monitor impact of training on patient satisfaction and trial recruitment in selected centres

CONCLUSIONS

We provide clear evidence that both the confidence and competence of healthcare professionals communication about trials improves following the training intervention better communication may also help patients make properly educated decisions about trial entry

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