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Forewarned is forearmed - benefits of preparatory information on video-cassette for patients receiving chemotherapy or radiotherapy - a randomised controlled trial.

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Video directed patient information

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ABSTRACT

A series of UK and European audits have revealed that a high proportion of patients remain dissatisfied with the information they received following a diagnosis of cancer. Additional educational aids are often required to facilitate the consent process, and our previous work showed a high level of acceptability for video directed information for this purpose. In this study a multidisciplinary team of health professionals worked with patients, a documentary film company and experienced TV personalities to produce an information film. The benefits of receiving a cassette to take home following the first consultation were then evaluated in a randomised multicentre controlled study among 220 patients receiving chemotherapy or radiotherapy over a six month period.

There was a significant correlation between satisfaction and reduced treatment related anxiety overall. In the Video Group the mean HAD anxiety score was significantly lower during treatment compared to the Non Video Group (4.6 v 7.4, Chi square test p=0.001). Likewise, the mean HAD depression scores where also significantly lower in the patients prepared for the side effects of treatment with the video (2.9 v 5.3 Chi square test p=0.001). 82% felt the video was *helpful* only 5% of patients felt this extra information was *worrying*. Well designed video cassettes should be regarded as a useful additional information strategy, within routine oncology practice.

Key words Patient education, video cassettes, anxiety, depression, satisfaction.

Introduction

Although treatment options in oncology are often complex and emotive, the majority of patients want to receive sufficient information to empower them to actively participate in the decision making process[1, 2]. Only a minority of patients want to let the doctor make decisions for them without their informed input, yet patients report considerable difficulty obtaining enough reliable information[3-5]. This may explain why, in three large audits in the United Kingdom, over three quarters of the patients were dissatisfied with the information they received following a diagnosis of cancer[4-6]. Understandably, many oncology departments are aiming to improve and intensify their patient educational strategies. Whilst prolonging the verbal consultation and improving the communication skills of medical staff may achieve significant improvements in this process, educational materials have a useful role in allowing patients to continue the learning process outside the sterile, and often alien environment of the hospital clinic in the comfort of their own home, in their own time, and in the presence of friends and relatives[1].

Video technology as a source of information has been shown to be highly acceptable to patients, it is becoming relatively cheap and nearly 90% of patients now have easy access to a video player[6]. It combines vision, sound and movement, and a well made film presents a large quantity of practical information in a short period of time[7, 8]. The aims of this study were to assess patients' views with regard to the type and level of information in a carefully prepared film, and to test the hypothesis that intensifying pre-treatment preparatory information may be helpful in improving treatment associated satisfaction, anxiety and depression.

Patients and Methods

The style and level of information presented during the film used in this study was established via six focus group meetings between August 1997 - January 1998. Each group comprised of 3 doctors, 5 nurses, 1 pharmacist, 2 radiographers together with 10 patients and their relatives. This information was summarised and transcripted into a 20-minute film by a professional film company experienced in medical documentary productions. The film, entitled "Chemotherapy & Radiotherapy", was introduced and narrated by Sue Lawley and Anton Rodgers both experienced and popular TV personalities in the UK. It gave a comprehensive description of therapy and a clear indication of the associated risks. Separate sections on radiotherapy and chemotherapy (demarcated by a different coloured background and an "R" or a "C" in the corner of the screen) featured patients describing their own experiences, side effects and the methods used to alleviate them.

Local ethical committee approval was gained at Addenbrooke's Hospital, Cambridge, The Primrose Oncology Unit, Bedford and Queen Elizabeth Hospital, Kings Lynn. Two hundred and twenty patients were randomised between January and September 1998 (See figure.1). Only fifteen patients (6%) declined entry, 8 because they wished to see the film, 5 because they did not have access to a video player and three for unspecified reasons. Eligibility was broad - all patients who were > 15 years, could understand English, had a diagnosis of cancer and had completed a consultation with an Oncologist during which either chemotherapy or radiotherapy was recommended. During these consultations no parties were aware of the forthcoming randomisation - routine information was provided verbally with the aid of BACUP booklets. The

oncology research assistant approached the patient after they had completed their consultation with the Oncologist and nurse specialist. She ensured all patients had received the relevant BACUP (British Association of Cancer United Patients) booklet then following written consent, opened an opaque sealed envelope (generated independently at the trial centre). Patients were randomised (1:1) to receive or not to receive the educational video which they took home. Patients completed a Hospital Anxiety and Depression score (HAD) and a second ad hoc questionnaire at the time of randomisation (immediately after the consultation with the Oncologist) and then 3 weeks into either radiotherapy or chemotherapy. The ad hoc questionnaire recorded, the opinion of those patients, on a 1-5 scale, who received the film on the level and style of information it contained [see appendix]. A separate section measured patients' satisfaction with the information they received. Table 1 shows the demographics of all randomised patients. In the 113 (51%) patients randomly assigned to the VG there were slightly more females and initial HAD scores were slightly higher these differences were non-significant and other factors did not differ from controls.

No patient was lost to follow up before the second time point, and the data was complete except for 12 patients (10%) omitting minor data in the ad hoc questionnaire.

Statistical analysis

The data on all the questionnaires were statistically analysed independently off site by the East Anglian Cancer Intelligence Unit, Cambridge University. The Chi Squared test statistic was used to analyse categorical data, and Mann-Whitney U tests to analyse the anxiety and depression scores between groups, and the Wilcoxon signed rank test to

analyse the anxiety and depression scores within groups. To determine a relationship between anxiety and satisfaction with treatment information, in all trial patients, the Kruskall Wallis test was used. The anxiety and depression scores were presented both as means (with standard deviations and range) and as categorical data, split into the four groups – normal (scores 0-7), mild (8-10), moderate (11-14) and severe (15-21). All analyses were performed on the original HAD scores, not the grouped data.

Two hundred and forty randomisation cards were written 120 stating *Video* 120 stating *No-Video* in the Primrose Oncology research unit by the research assistant. An individual card was placed in a separate opaque envelop then sealed. The envelopes were then shuffled and placed in a tight fitting trial box. The order of the envelops for the remainder the trial was not altered. Batches of twenty were sent to the lead nurse in each trial unit for opening after written consent until completion.

All completed questionnaire were sent to the research centre for collation and then sent to the Intelligence unit at the Institute of Public Health, Cambridge University for independent analysis and statistical evaluation. No evaluation was performed at the research centre. In the Video Group (VG) all patients received a video to take home and keep on the way out of the cancer clinics, reducing the opportunity to speak to other patients. All patients in the Non Video Group (NVG) were asked if they have inadvertently watched a video (given by a friend fellow patient etc) - no patient admitted to this. The initial questionnaires were completed before randomisation and therefore no bias from the assisting nurse was possible. The second questionnaires were completed at home so again no bias was possible. The other verbal and written

information was also given to both groups of patients equally again before randomisation so no bias was possible.

Results

Ninety two of the 113 patients (82%) who watched the video felt it was *helpful or very helpful* as opposed to 14% who did not ($p<0.001$). Only 6 patients (5%) were *worried* about this extra information [Table.2]. No patient in the VG said they didn't watch it. The minimum number of times patients watched it was 1 and maximum 5 (average 2.3). Twenty percent of patients first watched the video alone, 66% with a partner, 2% with a health professional and 12% did not indicate this on the questionnaire.

Patients in the VG were substantially more satisfied or very satisfied with the information they received compared to the NVG (93% Vs 64%, Chi squared test $p<0.001$) [Table.3]. Only 1 patient in the VG was unsatisfied with the information they received (the remaining 6% being equivocal). A significant inverse correlation between treatment associated anxiety in all trial patients and satisfaction was observed (Kruskall Wallis $p<0.001$)[Table.4].

In the VG the mean anxiety HAD scores were 4.6 during treatment [table 5a]. In the NVG the mean anxiety HAD scores were 7.4 during treatment. The mean difference of 2.8 between the two groups during treatment was significant (Chi squared test $p = 0.001$). In the VG the mean depression HAD scores were 2.9 during treatment. In the NVG the mean depression HAD scores were 5.3 during treatment. The mean difference of 2.4 between the two groups during treatment was significant (Chi squared test $p = 0.001$). The percentage of patients with measurable anxiety (HAD anxiety score >7) was 22% lower in the VG (21%) than the NVG (43%) during treatmentand this

difference was also statistically significant (Chi square, p=0.001) [Table.5b]. Likewise, the percentage of patients with measurable depression (HAD depression score >7) was 20% lower in the VG (10%) than the NVG (30%) and this difference was also statistically significant (Chi square, p=0.001) [Table.5b].

Anxiety significantly decreased between the initial and treatment assessment points in the VG (mean anxiety HAD score 7.8 v 4.6, $p<0.001$). In the NVG, the was no significant difference in anxiety before or during treatment. On the other hand, there was a significant increase in treatment associated depression from the pre-treatment level in the NVG (mean depression HAD score 3.4 v 5.3, $p<0.001$), whilst it decreased in the VG (4.4 to 2.9, $p<0.001$).

Discussion

Patients cannot truly express informed consent unless they are given sufficient and appropriate information including a clear description of treatment techniques and the risk of side effects[1, 9, 10]. They also cannot be expected to educate themselves, at a time when they may be pre-occupied with their sudden change in status, may find a hospital environment alien, and may have numerous misconceptions regarding their cancer and its management[4, 5]. Some of these misconceptions stem from poorly controlled and often frankly misleading information in the media which tend to emphasize the negative aspects of conventional treatments and sensationalise preliminary results from alternative medicine or early phase one studies[1]. Health care workers are also not entirely without blame. Many outside the oncology field are unaware of major advances in radiotherapy and chemotherapy, so much of the advice given to patients may be dated and conflicting. The challenge for the producers of this educational film was to provide pro-active information, not only to improve consent and de-mystify cancer treatments for patients, but for all personnel influencing them in the treatment pathway.

This film was not designed to compete with the verbal consultation, which remains the ideal method to offer both information and support[1, 10]. Even so, there is evidence that patients' recall of the risks of treatments with a verbal consultation alone is poor and that additional materials are required to ensure true informed consent [9-11]. Improved retention of knowledge or memory recall was not included as an end point in this trial as this advantage has already been confirmed in a number of randomised trials

in a variety of settings including ambulatory day surgery[12], surgery for breast cancer[8], colonoscopy for malignant disease[13], coronary angiography [7], and genetic counselling[14]. The evidence that intensifying information provision increases patient satisfaction, however, is less well established. A measure of satisfaction was therefore an important end point for this study. A universally adaptable satisfaction questionnaire is not available for clinical trials within oncology although several ad hoc systems have been published[8, 13]. We used a simple questionnaire which was quick to complete and although not previously validated was used in a previously published multi-centre audit[6]. The results clearly demonstrated that patients given more intensive information were more satisfied. Over 90% of patients were satisfied in the VG, which was 29% better than the NVG. It is reasonable to assume therefore that the increased level of information in the VG was the key factor to improved satisfaction, as the design of the trial allowed no other factors to influence either education or satisfaction.

This trial also addressed the relationship between satisfaction with information received and psychological distress. Although, for the reasons mentioned above, it is difficult to establish validated criteria of satisfaction, the levels of satisfaction as determined by the questionnaire in this study strongly correlated with a lower psychological morbidity in the VG. This is a common observations of many health professionals but as summarised in table.4, we have confirmed this with a clear statistical significance.

The protective effect which preparatory information has on patients' psychological distress has been reported in previous randomised[10, 15-17] and observational studies[18] in a variety of medical conditions using a range of information materials. Our data confirmed these finding in a general oncology setting. These data demonstrate that patients better prepared for treatment with the video had lower levels of anxiety during treatment than at the initial pre-treatment assessment, whereas the was no difference in the NVG. This resulted in a clear significant difference in anxiety between the VG and NVG in during treatment [Table. 5b]. Data for the depression aspect of the HAD score demonstrated a different pattern. Although, patients better prepared for treatment with the video had lower levels of depression during treatment than following the initial pre-treatment assessment, in the NVG there was a significant increase in depression during treatment [Table.5b]. Using a simple scoring system with only two time points, definitive conclusions cannot be drawn from this data, but one possible explanation for the increased depression in the NVG, lies in the relationship between treatment related side effects and depression. Radiotherapy increases the risk of depression because of the well known fatigue syndrome[11]. Depression has also been linked to prolonged adverse side effects of chemotherapy including fatigue and nausea[11]. It therefore appears likely that better preparation for such side effects using the video program overcomes the risk of developing the biological symptoms of depression during treatment. Whereas in the case of anxiety, better preparation with the videotape lowers levels of anxiety which patients have already developed[11].

Why there was a slightly higher, non-significant, baseline HAD score in the initial video group [Table.1] is unknown. There were more females in this group and anxiety has been reported higher in females before hospital procedures [19]. As the initial HAD score was taken before randomisation the process of giving the video to patients could not have increased anxiety. In any case, as statistical significance was seen on analysis of the final treatment associated scores between the VG and NGV, a higher anxiety level in the initial VG group worked against achieving statistical significance not for it [Table.5a&b], and therefore, this small baseline difference could not have diluted the statistical benefit of the film. Another factor to consider in this trial was the method of assessing psychological morbidity. The HAD score has advantages because staff in trial units are familiar with the simple direct questions on one A4 page making it quick and simple to use, but there is a tendency for it to be a little non-specific to changes in anxiety and to overestimate depression if patients are anxious[20]. Several newer scoring systems are probably more specific to detect anxiety on a single sample basis[20] but at the time of the trial design the HAD score was felt the be acceptable when comparing two groups randomly allocated[22]. It may, however, be one of the contributory factors to the large differences between the two groups[20]. Therefore, although the HAD may have exaggerated the magnitude of the differences at baseline and during treatment it is unlikely to be the cause of the statistical difference.

Videocassettes have some practical advantages over other "take away" information materials by combining vision and sound which diverts the emphasis away from the written word. This is attractive for all patients but particularly those whose first

language is not English or those with reading difficulties[21, 22] which may be as high as 15% in some areas of the United Kingdom[21]. Even if patients can read, there may still be difficulties understanding the medical information in written materials[23]. As demonstrated in this trial, video cassettes can be watched alone or in the company of friends, relatives or community health workers who may not have attended the original oncology consultation. It was therefore an important aspect of this trial that all VG patients received a copy to take home. Patients were then empowered to gather information at their own pace overcoming the variation in time individuals take to understand similar issues. Not all randomised trials of video education, however, have had similarly consistent results. A randomised trial in patients undergoing colonoscopy reported increased knowledge and satisfaction but failed to demonstrate a reduction in anxiety[13]. A similar study in patients receiving genetic counselling reported similar benefits but again no reduction in anxiety[14]. Two further randomised trials, the first in patients having breast surgery and the second in patients undergoing coronary angioplasty, failed to show any improvement in satisfaction or anxiety[7, 8]. The variation in these trial results suggests that, like all educational materials, the quality of the content is paramount and how it is used is vital to success[9-11]. Involving patients in the development and showing patients recounting their personal experience undoubtedly helps. Using respected TV personalities offers the familiar face of respectability and professionalism. Above all, most studies fail to take advantage of the role which video has to play in continuing the educational process at home with their carers and friends, but instead ask patients to watch it in the unfamiliar environment of the clinic.

The film was designed to provide a broad, general background to the basics of chemotherapy and radiotherapy; the conclusions from the multidisciplinary patient editorial group had been that specific issues on disease, surgical procedures and prognosis should be addressed individually. Both sections were clearly demarcated and the high acceptability of the film indicates that a description of both chemotherapy and radiotherapy was advantageous even if they were only receiving one treatment modality (only 1 patient (1%) felt the film contained too much information - table.2). The study cohort was therefore designed to be intentionally broad, reflecting the target audience in its subsequent use.

This study has clearly confirmed that the unpleasant feeling of being inadequately informed is linked with dissatisfaction and adverse psychological consequences. Previous studies, however, have also demonstrated other practical implications for the health service. Patients with less knowledge before surgery have been shown to recover more slowly from their anaesthetic, prolonging inpatient stay[12]. Less well informed breast cancer patients require more frequent and prolonged outpatient consultations in the setting of genetic counselling[14],[11]. Self care and compliance have also been shown to be worse during subsequent radiotherapy extending the overall time course[15, 24]. All these factors increase the demands on medical staff as well as the added cost of supportive measures [10, 11]. Furthermore, failure in the provision of

relevant information is among the most common reasons for official complaints by patients and relatives[25] which can involve hours of medical and managerial time and legal expenses[26].

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In conclusion (see key messeges), these data confirm that correcting the practical uncertainties of cancer therapy improves patient satisfaction and avoids a significant component of the associated psychological distress. This study strongly supports the role of well designed practical "take-away" information materials such as the videotape *'Chemotherapy & Radiotherapy'* to support the verbal consultation and continue the educational process outside the clinic. Patient education is now a humanitarian issue and its status in the overall management of the patient requires re-prioritisation. It should be as important as the provision of tumouricidal therapies[1, 10]. Community and hospital based health workers would benefit from a choice of information materials to assist them in information provision, just as drugs are chosen for their proven effectiveness alone and in combination with other strategies.

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KEY MESSAGES

1. Removing the practical uncertainties of cancer therapy avoids a significant component of the associated psychological distress.

2. Patients are more satisfied when given additional preparatory information.

3. Satisfied patients have significantly lower levels of treatment associated anxiety.

4. The level and style of the practical information in this video cassette is highly acceptable to patients.

This paper strongly supports the role of well designed practical "take-away" information in oncology.

Table 1: Demographics of patients in the video and non-video groups

	Initial values in video group No. (%)	**Initial values in control group No (%)**
Number of patients	113 (51%)	107 (49%)
Sex		
Males	40 (43%)	52 (57%)
Females	73 (57%)	55 (43%)
Age [mean, s.d., range]	59 [14, 17-90]	63 [13, 27-94]
Chemotherapy	42 (37%)	30 (28%)
Radiotherapy	71 (63%)	77 (72%)
Breast	44 (39%)	37 (35%)
Bowel	14 (12%)	12 (11%)
Lymphoma	13 (12%)	12 (11%)
Other	42 (37%)	46 (43%)
initial HAD [anxiety]		
Normal [0-7]	56 (50%)	63 (59%)
Mild [8-10]	24 (21%)	31 (29%)
Moderate [11-14]	22 (20%)	8 (7%)
Severe [15-21]	10 (9%)	5 (5%)
initial HAD [depression]		
Normal [0-7]	87 (78%)	96 (90%)
Mild [8-10]	15 (13%)	5 (5%)
Moderate [11-14]	9 (8%)	6 (5%)
Severe [15-21]	1 (1%)	0 (0%)

Table 2: The results of the "ad hoc" questionnaire – Patients' views on the type of information given in the film

Type of information within the film	Number (%)
Worrying	6 (5%)
Not helpful	0 (0%)
Neither helpful or unhelpful	10 (9%)
Helpful	55 (49%)
Very helpful	37 (33%)
Unknown	5 (4%)

Table 3: Results of the satisfaction questionnaire video versus control groups.

	Video group **No.(%)**	**Control group** **No. (%)**
Very satisfied	61 (54%)	36 (34%)
Satisfied	44 (39%)	32 (30%)
Equivocal	4 (4%)	6 (6%)
Unsatisfied	0 (0%)	11 (10%)
Very Unsatisfied	1 (1%)	14 (13%)
Unknown	3 (2%)	8 (7%)
Total	113 (100%)	107 (100%)

P<0.001

Table 4. Demonstrates the relationship between information satisfaction and level of anxiety (in all patients).

	Normal	Mild	Moderate	Severe	Total (%)
Very satisfied	83(40%)	11 (5%)	2 (1%)	1(1%)	97 (47%)
Satisfied	54(26%)	12(6%)	7(3%)	2(1%)	75 (36%)
Equivocal	3(1%)	2(1%)	4(2%)	1(1%)	10 (5%)
Unsatisfied	0(0%)	2(1%)	5(2%)	4(2%)	11 (5%)
Very unsatisfied	5(2%)	1(1%)	6(3%)	3(1%)	15 (7%)
Total (%)	145	28	24	11	208
12 missing data	(69%)	(14%)	(11%)	(6%)	(100%)

p<0.001

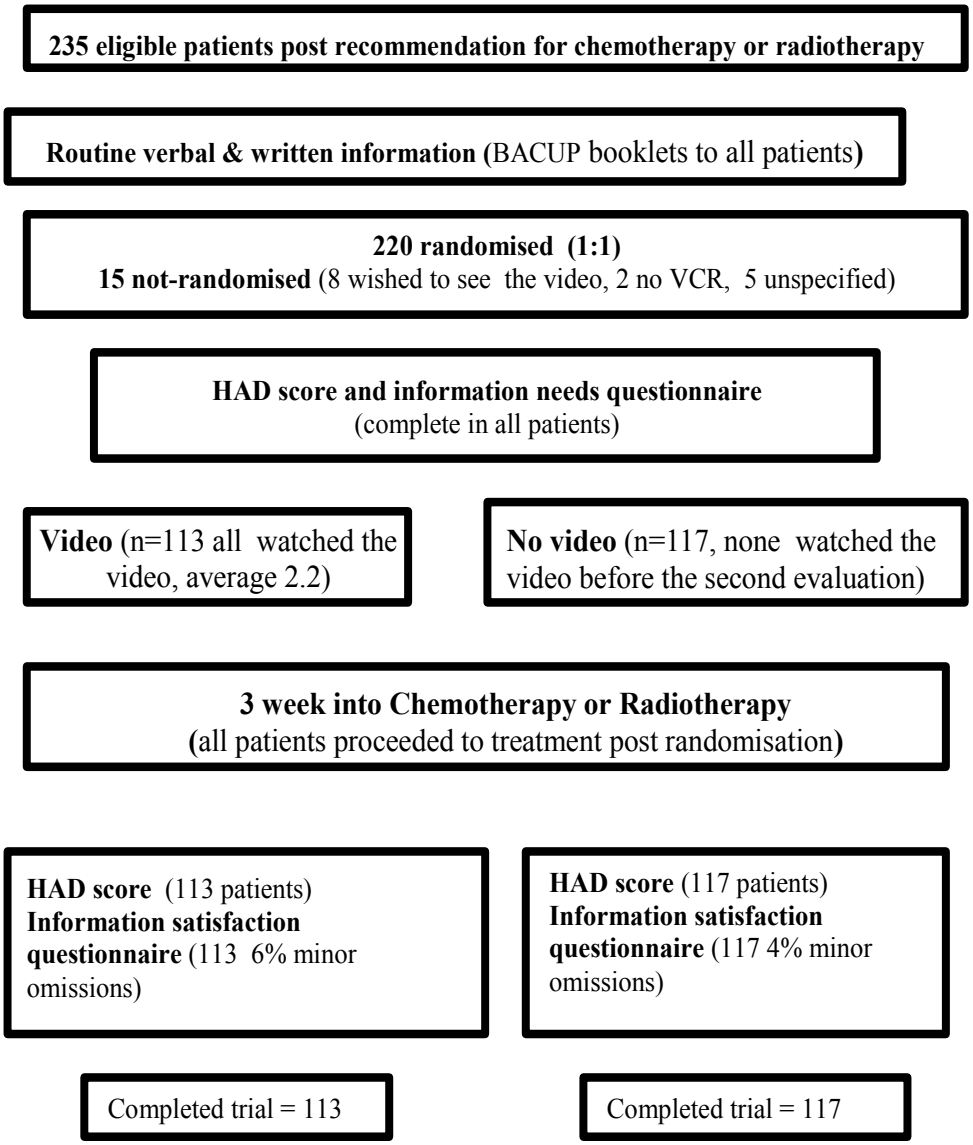
Table 5a: Difference between treatment associated anxiety and depression in the video and control groups – categorical data

HAD	Grade [score range]	Video	Control
Treatment associated Anxiety	Normal [0-7]	90 (79%)	61 (57%)
	Mild [8-10]	17 (15%)	14 (13%)
	Moderate [11-14]	4 (4%)	21 (20%)
	Severe [15-21]	2 (2%)	11 (10%)
		P<0.001	
Treatment associated Depression	Normal [0-7]	102 (90%)	75 (70%)
	Mild [8-10]	7 (6%)	18 (17%)
	Moderate [11-14]	4 (4%)	8 (7%)
	Severe [15-21]	0 (0%)	6 (6%)
		P<0.001	

Table 5b: Difference between initial and treatment associated anxiety and depression in the video and control groups – score data

Initial scores compared to scores after treatment	Video group Mean [s.d., range]	Control group Mean [s.d., range]
Anxiety		
Initial	7.8 [4.7, 0-20]	6.4 [4.0, 0-18]
Treatment associated	4.6 [3.7, 0-18] $p<0.001$	7.4 [5.2, 0-20] $p=0.104$
Depression		
Initial	4.4 [3.8, 0-15]	3.4 [2.8, 0-14]
Treatment associated	2.9 [2.9, 0-13] $p<0.001$	5.3 [4.7, 0-21] $p<0.001$

Figure.1 PATIENT FLOW CHART



APPENDIX 1 - PATIENT QUESTIONNAIRE

SATISFACTION, STYLE & LEVEL OF INFORMATION WITHIN THE FILM

How satisfied were you with the information you received about your condition and treatment.	Please tick the appropriate box
Very satisfied	
Satisfied	
Equivocal	
Unsatisfied	
Very unsatisfied	

What did you think about the type of information within the film	Please tick the appropriate box
Worrying	
Not helpful	
Neither helpful or unhelpful	
Helpful	
Very helpful	

What did you think about the level of information within the film	Please tick the appropriate box
Too weak and generalised	
Not enough	
Just the right amount	
Too much	
Misleading	

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