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**Paper:**

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**Patients report improvements in continuity of care when quality of life assessments are used routinely in oncology practice: Secondary outcomes of a randomised controlled trial**

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## **Abstract**

**Introduction and aim.** In a randomised trial investigating the effects of regular use of health-related quality of life (HRQOL) in oncology practice, we previously reported an improvement in communication (objective analysis of recorded encounters) and patient well-being. The secondary aims of the trial were to measure any impact on patient satisfaction and patients' perspectives on continuity and co-ordination of their care.

**Methods.** In a prospective trial involving 28 oncologists, 286 cancer patients were randomized to: 1) Intervention arm: regular touch-screen completion of HRQOL with feedback to physicians; 2) Attention-control arm: completion of HRQOL without feedback; 3) Control arm: no HRQOL assessment. Secondary outcomes were patients' experience of continuity of care (Medical Care Questionnaire) including "Communication" "Coordination" and "Preferences to see usual doctor" subscales, patients' satisfaction, and patients' and physicians' evaluation of the intervention. Analysis employed mixed-effects modelling, multiple regression and descriptive statistics.

**Results.** Patients in the intervention arm rated their continuity of care as better than the control group for "Communication" subscale ( $p=.03$ ). No significant effects were found for "Coordination" or "Preferences to see usual doctor". Patients' evaluation of the intervention was positive. More patients in the intervention group rated the HRQOL assessment as useful compared to the attention-control group (86% vs 29%), and reported their doctors considered daily activities, emotions and quality of life.

**Conclusion.** Regular use of HRQOL measures in oncology practice brought changes to doctor-patient communication of sufficient magnitude and importance

to be reported by patients. HRQOL data may improve care through facilitating rapport and building interpersonal relationships.

**Key words:** Patient-reported outcomes, continuity of care, communication, health-related quality of life, oncology

## INTRODUCTION

Patient-reported outcome questionnaires (PROs) are self-completed validated questionnaires designed to assess health status or health-related quality of life (HRQOL)<sup>1,2</sup>. They capture patients' experiences of symptoms and impact of disease on functioning, and can support physicians in clinical practice to monitor patient problems and facilitate patient-centred care<sup>3-5</sup>.

Systematic reviews evaluating the impact of PROs on clinical practice demonstrated a positive effect on patient-physician communication, but less consistent improvement in patient health outcomes or satisfaction<sup>6-10</sup>.

We conducted a randomised controlled trial (RCT) of regular touch-screen computer collection and feedback of HRQOL data to oncologists, confirming a positive effect on physician-patient communication (measured objectively from audio-recorded encounters) and patient well-being<sup>11</sup>. Secondary aims were to measure the impact of the intervention on patient satisfaction and perceptions of continuity and co-ordination of care. Secondary outcomes were expected to provide insight into possible mechanisms underlying the observed changes in patient well-being.

Measures of patient satisfaction in oncology are subject to ceiling effects, as patients do not rate their medical team negatively<sup>12</sup>. We found high general patient satisfaction in the pre-trial pilot and decided to investigate specific aspects of care<sup>13</sup>. Assessment of continuity and co-ordination of care was chosen, as the research was conducted in a tertiary cancer centre with care delivered by teams of physicians (5-8 doctors), and patients were often seen by different physicians.

Continuity of medical care was defined as ‘the extent to which health services are received as a coordinated and uninterrupted succession of events consistent with the patient’s medical needs’<sup>14</sup>. Continuity of clinical data and information were key components of care coordination<sup>15</sup>. HRQOL measurement can be viewed as a tool that ensures continuous flow of subjective symptoms/functioning information from the patient to the medical team<sup>16</sup>.

This article reports secondary trial outcomes (continuity of care and patient satisfaction) and patients’ and doctors’ evaluation of the intervention. We hypothesize that the use of patient-reported HRQOL data will improve “coordination” of patient information between doctors and improve “communication” about non-medical problems. These effects may result in less strong “patient preferences” to see usual doctor, as all doctors have similar patient-reported information. We expected patients to report high general satisfaction with care.

## **METHODS**

Trial methodology has been described <sup>11</sup>. Brief key information is provided.

### **Participants**

Patients attending the Medical Oncology Clinic at St James Hospital, Leeds, UK were eligible if they were commencing treatment, expected to attend at least 3-times, fluent in English and not exhibiting psychopathology. All medical oncologists and oncologists-in-training were invited. The study was approved by the institutional ethical committee. Patients and clinicians provided written informed consent.

## **Design**

A 3-arm RCT with repeated measures. Patients were randomised to: 1) Intervention arm (touch-screen HRQOL questionnaire completion and feedback of results to physicians); 2) Attention-Control arm (touch-screen HRQOL questionnaire completion, without feedback); and 3) Control arm (no measurement of HRQOL in clinic). The random assignment was unbalanced 2:1:1 and stratified by cancer site. Randomisation was carried out by telephone by the research office.

Secondary patient outcomes were measured using paper questionnaires (given to patients to complete at home and return by post) at four time-points: baseline, after 3 visits, 4 and 6 months.

## **Experimental intervention**

Intervention questionnaires were EORTC QLQ-C30<sup>17</sup> and Hospital Anxiety and Depression Scale<sup>18</sup>, completed on touch-screen computers in clinics. Graphic printouts of results were provided to physicians<sup>11</sup>.

## **Patient Outcome Measures**

**Continuity and coordination of care.** At the time of trial setup we could not find a suitable measure of patient perceptions of continuity/coordination of care delivered by multi-disciplinary teams. We developed and validated a new instrument-Medical Care Questionnaire (MCQ) in 677 cancer patients<sup>16</sup>. It has 15 items grouped in 3 subscales with good reliability: “Communication” (patient feels comfortable to discuss non-medical issues,  $\alpha=0.69$ ), “Coordination” (patient

perceptions of continuity/coordination of medical information,  $\alpha=0.84$ ) and “Patient Preferences” (to see the usual doctor,  $\alpha=0.75$ ) (Appendix 1). Scores are transformed to a 0-100 scale, high “Communication” and “Coordination” scores indicate good communication/coordination; high “Preferences” scores indicate strong preference for usual doctor.

**Satisfaction with care** was measured by two questions “How would you rate the overall quality of your medical care?” (very poor, poor, fair, good, very good, excellent), and “How well do doctors in this clinic meet your expectations?” (not at all, not so well, to some extent, very well, extremely well).

**Patients’ and physicians’ evaluation of the intervention.** Descriptive information was collected using end-of-study questionnaires for patients and doctors. Topics included: 1) patients’ experience with the touch-screen questionnaires; 2) content/relevance of the questionnaires; 3) usefulness of the intervention (willingness to use in routine care) (Appendix 2). End-of-study questionnaires were sent to patients in the intervention and attention-control arms and to doctors working in the centre at the trial closure.

### **Other measures**

K-index is as an objective measure of continuity of care, defined as:

$$\text{K-index} = (\text{Number of visits} - \text{Number of doctors}) / (\text{Number of visits} - 1)^{14,19}.$$

K-index=1, if patients see one doctor over time, and 0, if patients see different doctors each visit.

### **Statistical Analysis**



**Continuity and coordination of care.** The control and attention-control arms were each compared with the intervention arm using mixed-effects models for each MCQ subscale. Each model included the MCQ subscale change score as the outcome variable, fixed effects were baseline MCQ subscale score, study arm, time, and potential predictor covariates. Predictors were identified using univariate linear regression, with the change in MCQ subscales after three visits as the outcome variable and each covariate as the single explanatory variable. The covariates considered were patient age, gender, diagnosis, performance status, disease extent, treatment response, doctor gender (percentage females), doctor seniority (percentage consultants) and K-Index. Covariates meeting the inclusion criterion ( $p < .1$ ) were entered in the mixed-effects model.

Time was entered in the model as a continuous variable (in days). The main effect of time was assessed as a fixed effect, and nested as a random effect within patients to allow the relationship between time and outcome to vary between individuals. Mixed modelling assumes missing data is missing-at-random. The relationship between time of dropout and MCQ scores was investigated by arm in order to aid the interpretation of results under this assumption and check the robustness of the results to deviations from this assumption.

**Satisfaction with care, patients' and physicians' evaluation questionnaires** were analysed descriptively.

All analyses were on an intention to treat. Significance level was set at 5% for pre-planned analyses. The analyses were performed with SPSS Windows

Version 16.0 (SPSS Inc,Chicago, IL) and SAS version 9.1.3. (SAS Institute Inc, Cary,NC).

## RESULTS

The trial recruited between January 2000 and July 2001. All 28 **medical oncologists** working in the unit participated: 17 were male (**reflecting the male-female balance in the medical profession in UK**); median age 33.5, range 26-51 years; 22 oncologists-in-training and 6 consultants.

Patients' progress through the study is presented in Figure 1. From **419** eligible patients, 286 patients (68%) consented. The 6 month attrition rate was 35% in the intervention arm, 46% in the attention-control and 33% in the control arm, predominantly due to death (58% of drop-out cases), 87% of patients remaining on study completed the MCQ measure each time.

End of study questionnaires were returned by 91% of patients (119/131 patients in intervention/attention-control arms finishing the study); 22 oncologists, working at the centre at trial closure, completed the questionnaire.

Table 1 represents patient characteristics of the sample analysed for secondary outcomes, which were not different from those analysed for primary outcomes<sup>13</sup>.

**Continuity and coordination of care.** The results of the mixed-effects models for MCQ subscales change scores are presented in Table 2 and Figure 2.

Patients in the intervention group rated their “Communication” with doctors significantly better than the control group ( $p=.03$ ), but not different from the attention-control group ( $p =.16$ ). Investigating the MCQ scores in relation to the timing of dropout indicated that this is likely to be a conservative estimate. Patients in the intervention group dropped out when their scores were favourable, whereas patients in the attention-control/control groups dropped out when their scores were poor. The mixed-effects model assuming data is missing-at-random would underestimate the difference between the groups. The control group showed a decline in scores to month 4 followed by improvement by month 6 (Figure 2A). **This improvement can be partially explained by attrition of patients with poor scores.** Patient scores were associated with baseline MCQ “Communication” score ( $p<.0001$ ).

No significant arm effect was found for “Coordination” and “Preferences” subscales, where the change scores were dependent on baseline scores and K-Index.

**Satisfaction with care.** Between 79% and 89% of patients regardless of study arm rated their quality of care as “very good”/“excellent” (Figure 3). Between 89% and 95% of patients felt the doctors met their expectations (details not shown).

#### **Patients’ and physicians’ evaluation of the intervention.**

Patients did not feel participation in the study made their clinic visits more difficult (98%,  $n=119$ ). In the intervention arm ( $n=85$ ) 86% patients perceived the questionnaires were useful to tell the doctors how they were feeling, compared to 29% of patients in the attention-control group (no feedback,  $n=34$ ). 92% of

patients wanted to use the touch-screen intervention in routine care, 76% wanted the scores included in medical records. More patients in the intervention group than the attention-control felt the doctors considered their daily activities (65% vs 53%), emotions (87% vs 71%) and quality of life (90% vs 74%) when treating them.

From the 22 doctors responding to the end-of-study questionnaires 21 used HRQOL data “*sometimes/often*”, 12 made management changes, 15 were willing to use the data in routine care, 4 felt the study interfered with their clinical work “*sometimes/often*”. Reasons for not using the data were: forgot (12/22), no time (8/22), knew the patient (10/22), data irrelevant to patients’ problems (5/22).

## **DISCUSSION**

This pre-planned analysis examined the effects of regular use of HRQOL data in oncology practice on patients’ perceptions of continuity and satisfaction with care. Patients reported improved communication with doctors, particularly aspects of building rapport and better inter-personal relationship, making it easier to discuss emotional/personal issues. The end-of-study questionnaire showed that more patients in the intervention than the attention-control group reported HRQOL data helped them to talk to the doctors, and felt the doctors considered daily activities, emotions and quality of life. These results support primary outcomes results from audio-recorded doctor-patient communications, showing increased discussion of symptoms, emotional and physical functioning<sup>11</sup>. Similar impact on communication was found in other trials<sup>12,20-21</sup>. Our findings suggest a mechanism through which improved doctor-patient communication may lead to better patient well-being. The HRQOL data helped to focus the consultation on

topics important to the patient and facilitated discussion of non-medical issues. This impact was sufficiently large to be noticed by patients and might be expected to contribute to better emotional well-being, as observed in the trial<sup>11</sup>.

Patients expressed strong preferences to see their regular doctor, which was not influenced by the intervention. Similarly, the strongest predictor of “Coordination” of care was K-index (seeing different doctors) and the intervention did not overcome this negative effect.

Limitation of this study is the use of a new instrument of patients’ perceptions of continuity/coordination of care, making comparisons with other studies difficult. However, measuring general satisfaction again demonstrated ceiling effects and was not useful for comparison purposes<sup>12,20-23</sup>.

Non-participant rate (>30%) suggests this intervention may not be suitable for all patients, but this figure is similar to other studies with frequent data collection<sup>12</sup>. Significant attrition can be expected in advanced cancer, but the unbalanced attrition (46% in attention-control arm vs 33-35% in control and intervention arms) may influence results. We investigated possible effects of data not missing-at-random and found a trend towards underestimating arm differences, but not influencing the direction of results. Bias cannot be completely excluded, as the sample size does not allow more complex modelling for missing data.

In conclusion, this pre-planned analysis of secondary outcomes supports findings from the primary process of care outcomes showing positive effect of HRQOL data on physician-patient communication specifically focusing on continuity of

information, facilitating rapport and interpersonal relationships. Future work should target these mechanisms when implementing and training staff to use HRQOL data.

## **AUTHOR CONTRIBUTIONS**

Concepts and design: Galina Velikova, Peter J. Selby and Julia M. Brown

Financial support: Peter Selby, Galina Velikova, Julia Brown

Data acquisition: Galina Velikova, Laura Booth, Adam B. Smith, Penny Wright, Ada Keding, Clare Harley

Quality control of data and algorithms: Galina Velikova, Ada Keding, Clare Harley

Data analysis and interpretation: Ada Keding, Kim Cocks, Galina Velikova, Julia Brown

Statistical analysis: Ada Keding, Kim Cocks, Julia Brown, Galina Velikova,

Manuscript preparation: Galina Velikova, Ada Keding, Clare Harley, Penny Wright, Julia M. Brown

Manuscript editing: Clare Harley, Ada Keding, Kim Cocks, Peter J. Selby, Julia Brown, Penny Wright

Manuscript review: Galina Velikova, Ada Keding, Clare Harley, Kim Cocks, Laura Booth, Adam B. Smith, Penny Wright, Peter J. Selby, Julia M. Brown

## **CONFLICT OF INTEREST STATEMENT**

The authors indicated no potential conflict of interest.

## **ACKNOWLEDGMENTS**

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The funders had no role in the design of the trial, data collection, analysis, interpretation or writing of the report.

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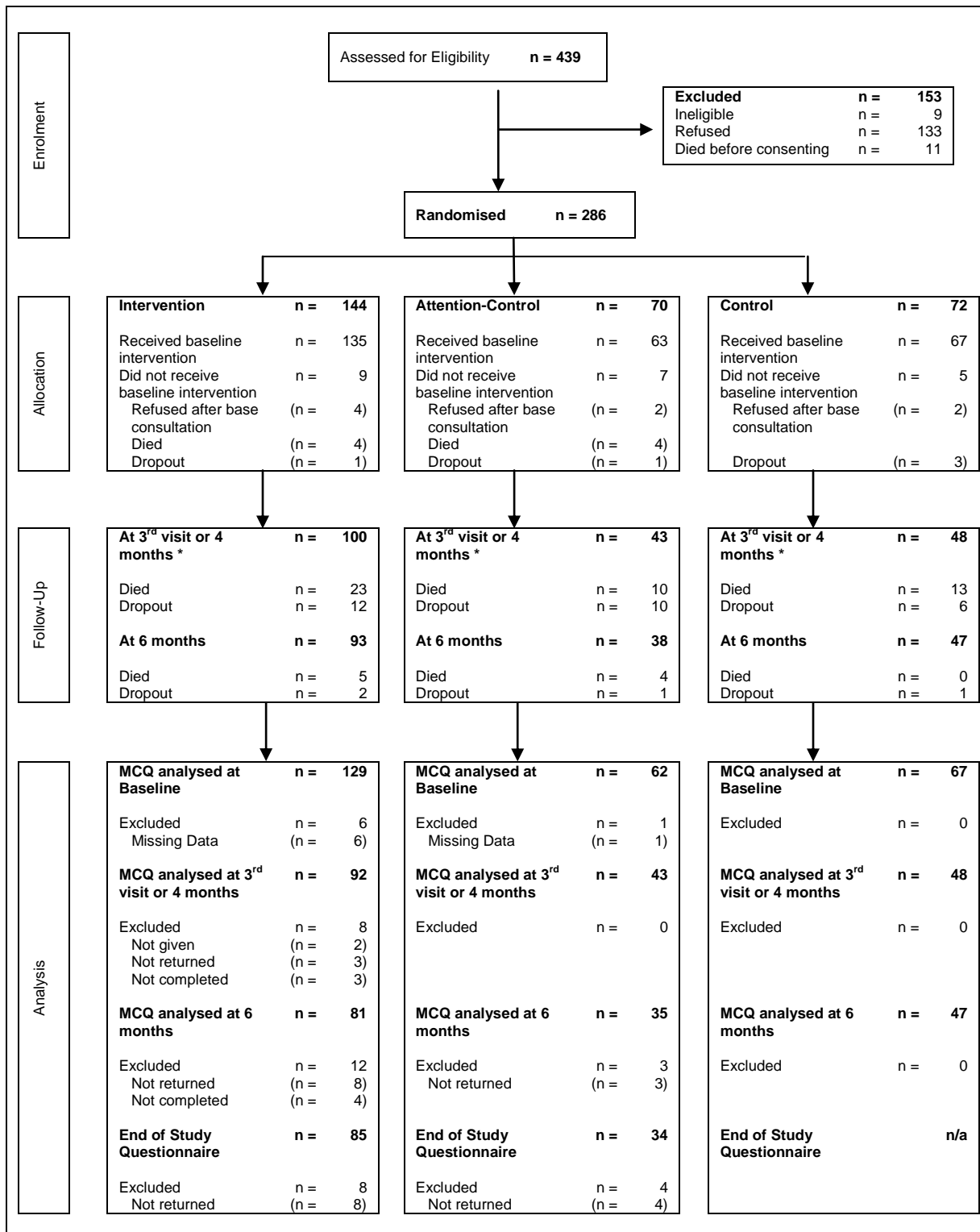
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**Figure 1 – Patient Progress through the study (CONSORT diagram)**

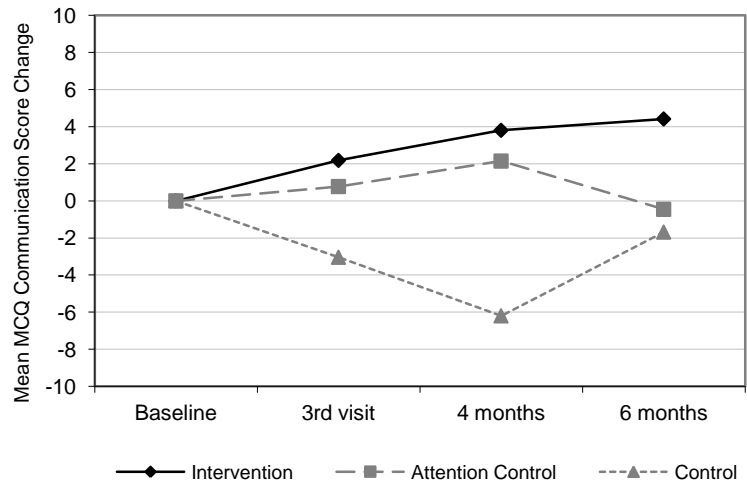


\* Figures for the 3<sup>rd</sup> visit time point and 4 months time point were combined, as patients whose 4 months point was within a month of their 3<sup>rd</sup> visit were not given the 4 month questionnaire

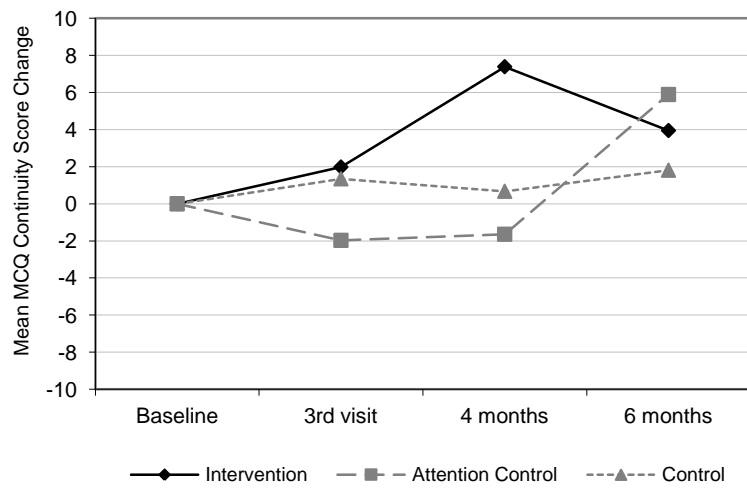
**Figure 2** – Change in Perceived Continuity of Care (Score at each time point minus score at baseline) by Study Arm over Time

- A. MCQ Communication subscale
- B. MCQ Coordination subscale
- C. MCQ Preferences subscale

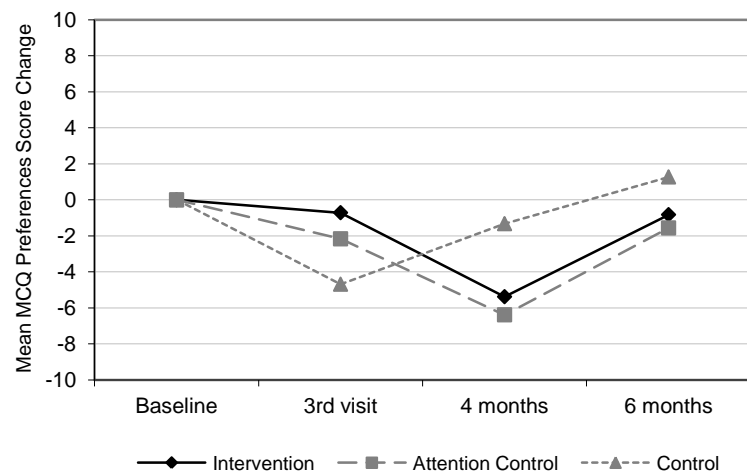
A. MCQ Communication Subscale



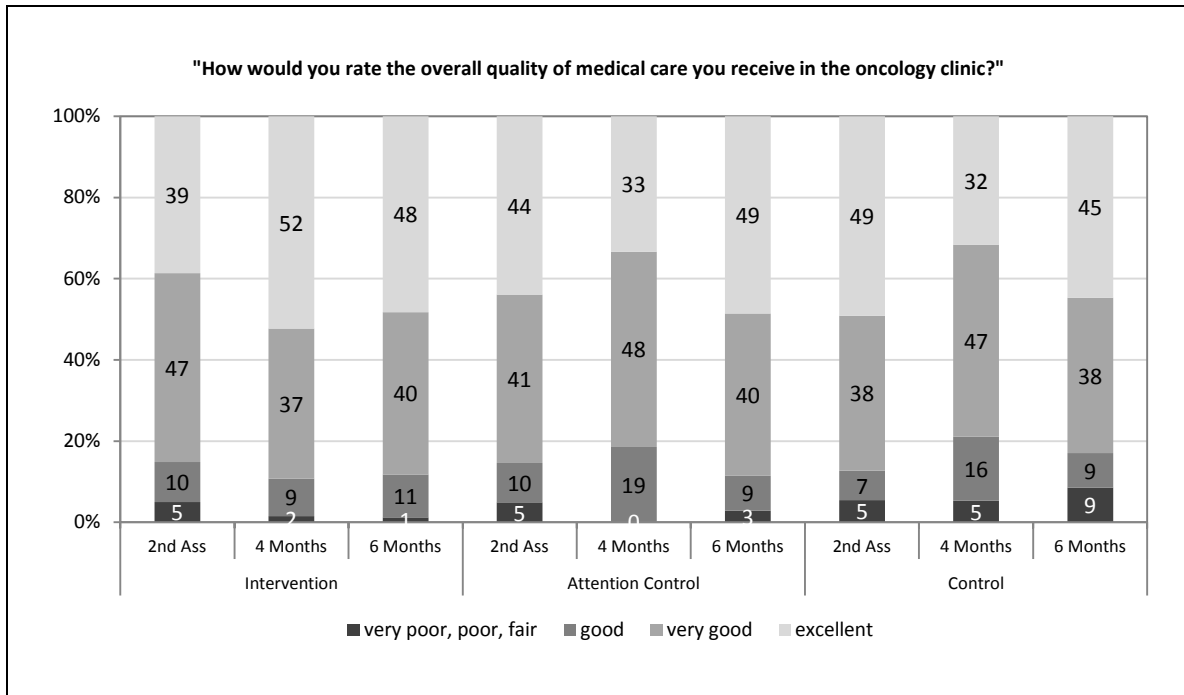
B. MCQ Coordination Subscale



C. MCQ Preferences Subscale



**Figure 3 – Proportion of Patient Ratings of Quality of Care by Study Arm over Time**



**Table 1** –Characteristics of Patients with Available MCQ data at Baseline

Characteristic	Patient Group at Baseline							
	Intervention n = 129		Attention Control n = 62		Control n = 67		Total n = 258	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
MCQ Baseline Scores								
Communication	67.5	16.93	65.3	19.06	68.5	15.57	67.2	17.10
Preferences	65.5	26.32	66.8	23.68	61.6	25.94	64.8	25.59
Coordination	63.5	20.38	61.8	19.48	61.5	21.80	62.6	20.49
Age, years	54.8	12.90	55.2	11.79	54.9	11.76	54.9	12.3
	n	%	n	%	n	%	n	%
Sex								
Female	97	75	46	74	51	76	194	75
Male	32	25	16	26	16	24	64	25
Diagnosis								
Breast cancer	26	20	11	18	11	16	48	19
Gynaecologic cancer	42	33	22	35	24	36	88	34
Renal cancer	21	16	9	15	11	16	41	16
Bladder cancer	10	8	5	8	5	7	20	8
Sarcoma	11	9	5	8	4	6	20	8
Melanoma	10	8	5	8	5	7	20	8
Other	9	7	5	8	7	10	21	8
Extent of disease								
Disease-free	2	2	2	3	0	0	4	2
Primary local disease	15	12	9	15	6	9	30	12
Local recurrence	6	5	4	6	3	4	13	5
Metastases	106	82	47	76	58	87	211	82
Performance Status								
0	25	19	5	8	9	13	39	15
1	63	49	23	37	29	43	115	45
2	29	22	26	42	24	36	79	31
3	11	9	8	13	5	7	24	9
4	1	1	0	0	0	0	1	0
Treatment								
Chemotherapy	97	75	47	76	53	79	197	76
Biological Therapy	27	21	13	21	13	19	53	21
Hormonotherapy	4	3	1	2	1	1	6	2
Observation	1	1	1	2	0	0	2	1

**Table 2** – Fixed Effects of the Mixed Effects Models for MCQ Subscales Change Score over Time

Variables	Estimate of Effect (EE)	Standard Error	95% CI	P
<b>Communication</b>				
MCQ change scores				
Intercept	35.37			
Baseline Communication MCQ	0.55	0.05	0.45 - 0.65	<.0001
Time	0.01	0.01	-0.01 - 0.03	.30
Arm				.07
Intervention v Control	4.51	2.04	0.47 - 8.56	.03
Intervention v Attention Control	3.14	2.24	-1.29 - 7.57	.16
Doctor Gender (% females)	-5.32	3.18	-11.63 - 0.98	.10
Doctor Seniority (% consultants)	-2.67	3.24	-9.09 - 3.76	.41
<b>Coordination</b>				
MCQ change scores				
Intercept	21.30			
Baseline Continuity MCQ	0.51	0.05	0.41 - 0.61	<.0001
Time	0.02	0.01	0.00 - 0.05	.03
Arm				.42
Intervention v Control	0.20	2.44	-4.64 - 5.03	.94
Intervention v Attention Control	3.36	2.64	-1.87 - 8.60	.21
Doctor Gender (% females)	-1.12	3.80	-8.65 - 6.41	.77
K-Index	21.54	4.67	12.28 - 30.80	<.0001
<b>Patient Preferences</b>				
MCQ change scores				
Intercept	7.64			
Baseline Preferences MCQ	0.76	0.05	0.66 - 0.86	<.0001
Time	0.01	0.01	-0.01 - 0.03	.39
Arm				.49
Intervention v Control	3.32	2.97	-2.57 - 9.20	.27
Intervention v Attention Control	0.09	3.23	-6.50 - 6.32	.98
Age	0.11	0.11	-0.10 - 0.32	.30