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Randomised controlled trial of a tailored information pack for patients undergoing surgery and treatment for rectal cancer

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ABSTRACT

Purpose: To evaluate the effects of a tailored information package for rectal cancer patients on satisfaction with information, anxiety and depression and readjustment.

Method: The study used a randomised control trial method. Seventy six patients undergoing surgery and treatment for rectal cancer were randomly assigned to an intervention ($n = 43$) or control group ($n = 33$). The intervention group received an information pack tailored according to their treatment plan and preferred information. The control group received the information currently given to these patients. Satisfaction with information was measured using the Patient Satisfaction with Cancer Treatment Education (PSCaTE) scale, anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS) and readjustment was measured using the Reintegration to Normal Living Index, at three time points.

Results: There was a statistically significant difference between the intervention and control group on pre and post intervention scores with patients in the intervention group expressing a higher level of satisfaction with information than those in the control group at Times 2 and 3 ($p = 0.00$ for both). The intervention group also had a significantly lower anxiety score than the control group at Time 3 ($p = 0.03$). There was no difference between depression and readjustment scores in the two groups.

Conclusion: The results support the hypothesis that a tailored information pack for patients with rectal cancer will positively affect satisfaction with information. These results will enhance the knowledge base surrounding the provision of tailored information to specific patient groups.

Introduction

Colorectal cancer is the second most common cause of cancer death in the UK with 34,000 cases annually, resulting in 16,000 deaths each year (Cancer Research UK, 2010) with rectal cancer (RC) accounting for approximately 38% of these cases. RC patients face a great deal of uncertainty as their treatment may take various routes, with at least three possible surgical outcomes, the possibility of stoma formation and adjuvant radio or chemotherapy. Consequently it can be difficult to meet the information needs of this patient group when care is provided by a multidisciplinary team (O'Connor et al., 2010). With significant recent advances in surgical techniques for RC, a gap has emerged in the information available to these patients (Broughton et al., 2004) with much of the information aimed at colorectal cancer patients generally and not specific to RC. Van Mossel et al. (2012) add that the provision of useful and timely information to colorectal cancer patients is often fragmented and inconsistent. An exploration of the information needs of RC patients carried out prior to this study indicated that the needs of this group were not adequately met (O'Connor et al., 2010).

There is evidence that satisfaction with information may lead to reduced anxiety and improved quality of life (Annunziata et al., 1998; Dunn et al., 2004; Pawar, 2005). In addition, satisfaction may be increased when information is provided in a stepwise fashion (Jefford et al., 2005; Jones et al., 2006). King et al. (2010) agree that information provision should be tailored according to patient preference adding that although the majority of patients want to know about all aspects of their treatment, some patients may ignore or avoid information as part of a coping strategy. There is a general consensus that nurses should be involved in all aspects of patient education including the development of printed resources if there is nothing suitable available (Monsivais and

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Reynolds, 2003; Demir et al., 2008). The writing of expert patient information to facilitate patients' understanding of diagnosis, treatment and management has been one of the high impact changes brought about by cancer nurse specialists (Sullivan and Elliott, 2007). With this in mind, a tailored information pack (a series of fourteen leaflets dealing with various aspects of the disease and treatment) was developed to meet the information needs of RC patients. The development of the pack was informed by the literature, and the preliminary information needs assessment as well as input from a panel of experts and patient user representatives. The newly designed pack was subsequently evaluated by focus groups of RC patients. It is crucial that the impact of information and education and their impact is evaluated using an appropriate research method (Coates, 2009).

The theoretical framework for the study was based on Knowles et al. (2005) theory of andragogy, or the education of adults, where the emphasis is on providing procedures and resources for facilitating the learners' acquisition of information and skills acoording to their readiness to learn.

Aim

The aim of this study was to evaluate the effect of a tailored information pack for RC patients on satisfaction with information. Secondary outcome measures examined the effect of the pack on anxiety and depression and reintegration to normal living.

Method

Design

This was a pragmatic trial using a parallel design with equal (1:1) allocation and repeated measures. Preparation involved liaison with Stoma Care Nurse Specialists (SCNS) and Colorectal surgeons in a number of trusts to ascertain their interest in participating. The researcher then met with the SCNSs involved to inform them about the study protocol and provide consistent training regarding how the information pack should be used.

Procedure

The study was conducted across six sites in four health care Trusts in Northern Ireland. A process evaluation of usual care across the sites established that all RC patients were referred to the SCNS for information and support following diagnosis. Data were collected using a researcher administered set of scales at three time points in a structured interview.

- Time 1: pre-intervention
- Time 2: post-intervention, after surgery prior to discharge from hospital
- Time 3: 6 months after time 2

The first three patients recruited at each site served as a pilot. Data were collected at Times 1 and 2 ensuring that the research protocol and data collection techniques were appropriate. As no changes were required at any of the sites, it was decided to continue with data collection to Time 3 with pilot participants, and to use these data in the main study. Recruitment to the pilot study and the research process therefore was the same as that for the main study, as described below and outlined in Fig. 1.

Following an initial biopsy and diagnosis of RC, patients meet the colorectal consultant to discuss further investigations and treatments. At this meeting eligible patients were informed about the study and given an invitation letter and information sheet. Patients who consented to receiving additional information were contacted by the researcher and invited to meet to discuss the study where full verbal and written information was given and written informed consent obtained. It was found at all the sites that this was also the most convenient time to collect data at Time 1, followed by an information session with the SCNS who delivered either the new information pack (intervention) or the information currently provided in usual care (control). This meeting took place in the SCNS's office on four of the sites and in a pre-assessment clinic at the other two sites. Data collection at Time 2 took place at the patients' bedside prior to discharge from hospital and at Time 3 at the office of the SCNS or by telephone if agreed with the patient.

Recruitment and randomisation

A total sample size of 76 was required to achieve 90% power to detect a difference of 20% between the mean scores of the two groups at time 2 on the satisfaction with information scale at the 5% significance level. All patients with a diagnosis of RC were considered for inclusion whilst those considered to have a prognosis of less than six months were excluded as they may not have been able to complete data collection. Randomisation was provided by an independent research secretary, using a computer generated list of random numbers. The SCNS telephoned the randomisation service for an allocation code and assignment to either intervention or control group. Blinding of the researcher as to the random allocation group of participants was used to reduce bias. Recruitment took place from January 2009 to May 2010.

Ethical considerations

Ethical approval was obtained from the Office for Research Ethics Committees, Northern Ireland (ORECNI) and research governance approval was obtained for the Trusts involved. *Registered Trial No.* ISRCTN42959693

Intervention

At their first meeting with the SCNS the intervention group received a series of leaflets from the new information pack depending on their condition, treatment plan and the information that they wished to receive. This meeting also ensured that the elements involved in the Knowles et al. (2005) Process Model used to guide this study were followed. Elements 1–4 of the model involve preparation of the learner, creating a climate conducive to learning, creating a mechanism for mutual planning and diagnosing the need for learning.

The tailored information pack consists of a series of fourteen leaflets on various aspects of disease and treatment of RC. To assist people with literacy difficulties and ensure that the content was understood, the SCNS went through a "guided tour" of the pack whereby patients were shown all of the leaflets available and received guidance in choosing information relevant to their treatment plan and condition, ensuring that they could read and understand the information. Practical demonstrations with stoma appliances in a teaching pack were also used in both intervention and control groups. This is an important consideration in preparing patients for surgery involving stoma formation (O'Connor, 2005). These steps satisfied the remaining elements of Knowles model which involve formulating learning objectives, designing a pattern of learning experiences and conducting learning experiences with suitable techniques and materials. A record of leaflets offered to each patient and which of these were accepted was kept. An index page shows all of the leaflets available to remind patients if they wish to request further information leaflets at a later stage (Fig. 2).