



Effects of a psycho-educational programme on health-related quality of life in patients treated for colorectal and anal cancer: A feasibility trial



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ABSTRACT

Purpose: Colorectal cancer (CRC) may have a negative impact on a person's quality of life. Psycho-educational interventions for patients with CRC are rarely studied.

The purpose of this feasibility trial was to evaluate the effect of a psycho-educational programme (PEP) on the health-related quality of life (HRQL) of patients treated for CRC and anal cancer.

Methods: Patients with CRC and anal cancer were randomly assigned to a PEP (n = 47) or standard treatment (n = 39). The PEP included informative lectures, discussion, and reflection. HRQL was evaluated using the SF-36 at baseline and 1, 6, and 12 months after the end of the PEP.

Results: Patients in the PEP group had significantly better *Mental Health* scores after 1 month and significantly better *Bodily Pain* scores after 6 months compared with patients who received standard care.

Conclusion: The results of this study indicate that a PEP can have a short-term effect on the mental health and bodily pain of patients treated for CRC and anal cancer when comparing with a control group. The article discusses the methodological difficulties of evaluating an intervention such as this PEP in a clinical setting.

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1. Introduction

Colorectal cancer (CRC) is a commonly diagnosed cancer with an incidence of 1.2 million cases each year (Ferlay et al., 2010). The number of CRC cases is increasing, as well as the survival rates (Chawla et al., 2013). The primary treatment is surgery, with resection of the tumour and sometimes additional adjuvant radio- and chemotherapy. A stoma is formed if the rectum is removed, or to reduce the risk for anastomosis leakage (Matthiessen et al., 2007).

Common physical side effects after CRC treatment include pain, diarrhoea, (Nikoletti et al., 2008), fatigue (Husson et al., 2015), nausea, and sexual dysfunction (Vironen et al., 2006). In addition to physical difficulties, cancer patients must face existential questions

relating to an uncertain future which is connected to the cancer diagnosis (McCaughan et al., 2012; Ohlsson-Nevo et al., 2012; Shaha et al., 2008; Wenger, 2013). Psychological distress is common among CRC patients: 14–23% have depression (Alacacioglu et al., 2010; Gray et al., 2014; Strong et al., 2007) and 20–42% have anxiety (Alacacioglu et al., 2010; Gray et al., 2014; Strong et al., 2007).

Compared with the preoperative score, the health-related quality of life (HRQL) of CRC patients has been reported to decline 1 month after surgery (Carlsson et al., 2010; Theodoropoulos et al., 2010). After 6 postoperative months, most patients' HRQL scores returned to similar levels as reported before surgery (Carlsson et al., 2010). At 2–5 years after surgery CRC patients reported a high quality of life (Arndt et al., 2006; Caravati-Jouvencaux et al., 2011; Jansen et al., 2011; Pucciarelli et al., 2008); however, individuals treated for rectal cancer have been found to suffer adverse effects from the illness and its treatment as late as 10 years after treatment (Chambers et al., 2012). Predictable factors that affect CRC patients' quality of life are fatigue, anorexia, dyspnea, and depression (Gray

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et al., 2011).

Anal cancer is a tumour of the anus and the perianal skin. The most common histological diagnosis is squamous cell carcinoma (85%) (Shridhar et al., 2015). It is a rare cancer with an estimated incidence between .2 and 1.4/100 000 worldwide (Leonard et al., 2011). Abdominoperianal resection was standard treatment before the development of chemoradiation (Shridhar et al., 2015). In this study anal cancer patients treated with radiation and abdominoperianal resection have been included as the treatment was similar to rectal cancer.

Rehabilitation programmes for cancer patients have been developed to reduce the negative impact of cancer on mental wellbeing (Galway et al., 2012; Ussher et al., 2009). Psycho-educational programmes (PEPs) constitute a common approach, in which groups of patients are provided with information about the cancer disease and how to cope in daily life. A psychologist or nurse provides support in these groups. The effectiveness of such programmes is unclear, as studies have shown conflicting results. Some studies have failed to show that PEPs effectively improve the HRQL of cancer patients (Johansson et al., 2008; Ling et al., 2012), while others have reported a positive effect on HRQL (Scott et al., 2013; Strong et al., 2008). In qualitative evaluations of PEPs, patients have expressed satisfaction that the programmes provide information and the opportunity to ask questions, and they also describe finding a new sense of belonging when they meet others with similar experiences (Docherty et al., 2008). Few randomized studies have evaluated the effect of a psychosocial group intervention on the HRQL of patients with CRC (Carmack et al., 2011; Hoon et al., 2013). Hence, the purpose of this feasibility trial was to evaluate the effect of a PEP on the HRQL of individuals treated for CRC and anal cancer.

2. Methods

2.1. Study design

This study was a prospective, longitudinal, feasibility trial that evaluated the effects of a PEP, on patients with CRC and anal cancer.

2.2. Participant selection and care

Patients treated surgically for colon, rectal, or anal cancer and expected to survive more than 2 years were recruited from a surgical clinic in a university hospital in Sweden during the 2007–2010 period. Anal cancer patients were included since the treatments with radiation and abdominoperianal resection are similar to the rectal cancer treatment.

We examined surgical code numbers from the medical records to identify eligible patients. The patients were invited to participate in the study by the first author, when they were discharged from the hospital after a resection surgery, at a return visit, or 1 month after discharge. The invitation was proffered during a personal meeting at the hospital or through a telephone call. Exclusion criteria included difficulty communicating in Swedish, known addiction problems, and recurrent CRC. Some of the patients had previously met the first author as a nurse at the ward. To avoid that the patients might have felt obliged to agree on participation, they were encouraged to read the information at home and to return the letter of consent as well as the questionnaires by mail if they wanted to be included in the study.

A total of 196 patients were eligible, and 105 consented to participate, although 86 returned the baseline assessment (Fig. 1). Patients were randomized in blocks of 20:10 patients each were randomized to the intervention group (PEP group) and the control group. The groups were assigned by drawing blank envelopes that

contained patient codes. This randomization was performed 2 weeks before the PEP started and the baseline scores were collected before randomization of the block. A total of five programmes with approximately 10 participants in each group were provided over 2.5 years. A total of 49 of the patients were randomized to the PEP. The attendance rate varied between 11 patients attended all meetings and seven patients did not attend at all (Fig. 2).

Patients in the control group received standard treatment and care. This care included a phone call from a nurse if the patient returned home early (the third day after surgery) and a return visit to the surgeon after 1 month. A hospital social worker/counsellor (HSW) introduced herself to all patients with a cancer diagnosis. If the patients wanted, they could make appointments for a session. If the ward nurses assessed a need for support they invited the HSW or encouraged the patient to make personal contact with the HSW. The participants in the control group were offered to enter a PEP after the end of the study. The study continued for 2.5 years and no patients requested to take part in the programme after the end of the study.

2.3. Intervention

The setting for the PEP was the outpatient ward of a hospital surgical clinic. The programme included seven meetings with informational lectures on the following topics: Colorectal cancer, Music and Relaxation, The Operating Theatre, The Importance of Physical Activities, The Meaning of Food, Crisis and Crisis Intervention, and Patients' Organizations (Table 1). The content of the PEP was influenced by The Family's Cancer Journey by Kristjanson and Ashcroft (1994) suggesting that "Families want information about the diagnosis, prognosis, treatment options and expected course of recovery to lessen their fears and increase their sense of predictability" (page 11). Other informational needs among both cancer patients and caregivers that guided the content of the PEP were crisis and crisis interventions (Carlsson and Strang, 1996), nutrition, pain management (Grahn and Johnson, 1990), and the cancer illness impact on the family (Eriksson and Lauri, 2000).

The session was given once a week, between 17.00 and 19.00, over seven weeks. A 60 min lecture was followed by a discussion and reflection on the topic of the day in a group with peers over 60 min. The patients were able to bring their caregivers to participate in the lectures, although patients and caregivers were separated during the subsequent group discussion. The separation in two groups enabled the patients to speak freely about their experiences and worries without being overheard by their caregiver. A registered nurse – a stoma therapist with special knowledge about colorectal cancer and anal cancer – and not part of the research team, led the discussion with the patients.

2.4. Outcome measures

The Medical Outcome Study (MOS) 36-Item Short Form Health Survey (SF-36) (Sullivan et al., 1995; Taft et al., 2001) was used to evaluate generic HRQL. The SF-36 comprises eight scales that measure *Physical Functioning*, *Role-Physical*, *Bodily Pain*, *General Health*, *Vitality*, *Social Functioning*, *Role-Emotional*, and *Mental Health*. All scales are scored from 0 to 100, with a higher score indicating better health status. Two summary scores are calculated, the *Physical Component Summary* (PCS) and the *Mental Component Summary* (MCS); these summaries reflect overall physical and mental health status (Taft et al., 2001). The summary scores are constructed and standardized in relation to the norm population (Ware, 1994). A summary score of 50 corresponds with the mean; thus, scores <50 indicate worse physical or mental health compared with the general population (Sullivan, 2002). The

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