Patient Education and Counseling 115 (2023) 107895

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.journals.elsevier.com/patient-education-and-counseling

The effect of nurse-led empowering education on nutrition impact side effects in patients with colorectal cancer undergoing chemotherapy: A randomised trial☆

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ARTICLE INFO

Keywords:
Colorectal cancer
Empowering patient education
Randomised trial
Teach-Back

ABSTRACT

Objective: This study assessed the effect of empowering education on patient-reported outcomes and morbidity.
Methods: A randomised controlled trial was conducted on adults with colorectal cancer (43 + 40). The intervention consisted of one-hour empowering patient education on nutrition impact side effects. The effect was compared with standard care. The difference between the groups was analysed pre and post intervention.
Results: The change in malnutrition-related knowledge level was higher in the intervention group compared to control group (median 0.0, IQR 1.00 vs median 0.0, IQR 0.0, $p = 0.028$). Additional contacts with outpatient clinic were fewer in intervention group (median 0.00, IQR 0.00) compared to control group (median 1.00, IQR 2.00, $p < 0.001$). We did not find a statistically significant difference in the change in activation level, risk of malnutrition and quality of life between the groups.
Conclusion: Empowering education may affect positively on patients' knowledge level related to malnutrition and reduce the number of additional contacts with health care thus reduce health care costs.
Practice implications: Empowering education may be used in patients with colorectal cancer to improve knowledge and reduce additional contacts with health care. Further research is needed on the effect of empowering education in self-care.

What is already known about the topic?

- Nutrition impact side effects are common during chemotherapy.
- Nurse-led interventions improve dietary intake and QoL in patients with cancer.
- Evidence of empowering education in nutrition impact side effects is lacking

What this paper adds?

- Description of implementation of empowering education in clinical context
- Empowering education improves knowledge and may reduce healthcare costs
- Empowering education may improve patient activation level

1. Introduction

The focus of this study lies in nurse-led empowering patient education and its potential to enhance the nutrition intake of patients with colorectal cancer (CRC). Chemotherapy (CTX) is a common treatment

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☆ Trial registration NCT04160650 (9.11.2019).
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https://doi.org/10.1016/j.pec.2023.107895
Received 15 February 2023; Received in revised form 26 June 2023; Accepted 11 July 2023
Available online 15 July 2023

for patients with high-risk stage II and III and metastatic CRC [1]. The most common CTX-related side effects are nausea, diarrhoea, dry mouth, lack of energy, drowsiness and worrying [2], which are at their most severe in the days following the treatment [3]. They can reduce nutrition intake and lead to unintentional weight loss and the risk of malnutrition [4].

Patient education on CTX related side effects' self-care is important as the care contacts are minimal. Educational nursing interventions have been promising in alleviating cancer-related side effects [5]. According to a recent study, a motivational interview reduced the incidence of fatigue and pain as well as the intensity of fatigue, but not the number of symptoms [6]. In empowering patient education (EPE), nurses support patients' expert knowledge and power and their ability to control their lives and health decisions [7]. Individual patient learning is facilitated in a respectful relationship where patients' expectations are listened to and advice is provided depending on patients' knowledge level, abilities, attitudes, and values [7,8].

In this study, one primary outcome of EPE is patient activation level, which is closely related to self-care and empowerment. Patient activation reflects the strength of self-care [9]; how ready, willing, and able a person is to manage own health [10]. Previous research suggests that those with higher levels of activation have the knowledge, skills, and confidence to manage their own care [11]. Furthermore, educational interventions tailored to pre-intervention activation levels have improved patient activation [12]. Higher activation and knowledge levels may help people to better manage their health and improve the QoL [9].

The other primary outcome of EPE is knowledge level, which is considered essential for decision-making and patient empowerment [7]. Previously, a trial of an empowering e-feedback intervention improved the knowledge level in intervention and CG, although not in the total mean between the groups in patients with breast cancer during radiotherapy [13]. Knowledge level has also had a positive effect on self-care and hospital readmission rates [14].

A secondary outcome of EPE is QoL, which is perceived as a long-term consequence of patient empowerment [15]. QoL has been estimated as average in patients with CRC and associated with the number of CTX cycles, multimorbidity and stoma [16]. The lowest score has been in emotional wellbeing and related to persistent pain and nausea. In earlier studies, the effect of educational nursing interventions on the QoL has been inconsistent [5]. A dietary intervention based on patient participation has improved the QoL and knowledge level of patients with gastric cancer, confirming the importance of patients' preferences for the effectiveness of intervention [17].

The other secondary outcome of EPE is risk of malnutrition. Nutritional interventions are recommended to manage side effects and enhance dietary intake among patients with cancer [18]. Earlier, those nutritionally at risk have benefited the most from these interventions [19]. A review exploring interventions to prevent malnutrition found three studies of nurse-led educational interventions, two of which had statistically significant effects on risk of malnutrition [20]. In hospitals, nutritional interventions are most often carried out by dietitians [21]. For example, in a study of a 6-week individualised nutritional counselling by a dietician, patients maintained an adequate nutritional status [22].

As nurses meet patients regularly during the CTX, they have an opportunity to support patients' empowerment in the self-care of nutrition impact side effects (NIS). However, nurse-led nutritional interventions are limited, and the outcomes have been merely clinical, such as patients' dietary intake [23] and nutritional status [24]. Furthermore, the effect of EPE on patient activation level, knowledge level, risk of malnutrition and QoL has not been reported in previous studies [12].

The main purpose of this study was to explore the effect of empowering patient education (EPE) in patients with CRC during CTX. The goal was to enhance the self-care of NIS. The hypothesis was that patients participating in empowering education of NIS vs standard education have higher activation and knowledge level, less risk of malnutrition and higher QoL compared to the control group (CG).

2. Methods

2.1. Design

This was a two-arm, single-centre trial with stratified randomisation with pre- and post-test measures at baseline and eight weeks after the intervention. By that time, the participants had undergone four CTX cycles, which was considered sufficient to assess the effects of the intervention.

2.2. Participants and setting

Annually approximately 4500 patients with CRC receive CTX at the University Hospital Cancer Centre. We included adults with newly diagnosed CRC who had a combination of intravenous and oral anticancer treatment. We excluded patients receiving oral chemotherapy only, with impaired physical and/or cognitive function, and not understanding Finnish. Recruitment was performed via the patient records system, by letter and by telephone. Voluntary participants were provided verbal information during the first treatment. Recruitment started in October 2019 and ended in November 2021 when the predicted sample size was reached. Due to the COVID-19 pandemic, recruitment was paused for six months in 2020.

2.3. Interventions

The effect of the empowering education on self-care of NIS was compared with standard care (Table 1). The intervention was developed using conceptual framework of Intervention Mapping by Kok 2014 [25] (Fig. S1) and Melnyk & Morrison-Beedy (2012) [26] in collaboration with a multidisciplinary research group including two nurses, a clinical nutritionist, and an oncologist. Two experts by experience participated in validation of the diary. An experienced nurse was trained for the intervention in three 3-hour sessions and the learning was verified with open-ended questions.

The face-to-face intervention lasted one hour and was carried out once. During the education, the nurse supported patients' empowerment in those self-care methods that had been successful and provided further information according to patients' expectations. In addition, the nurse supported patients' empowerment by using active listening. The nurse used baseline activation scores to tailor the education for each patient's individual activation level [28]. Understanding was verified with teach-back by asking the patients to explain in own words what they had been told [29]. If the patients were not able to teach back correctly, the nurse explained again and re-checked the understanding [30]. Patients continued monitoring the side effects until the fourth CTX cycle [31].

2.4. Data collection

At baseline we collected demographic data about education level, living and working conditions. The primary outcomes were activation level and knowledge level, and secondary outcomes were the risk of malnutrition and QoL (Table 2). Activation level was assessed with the Patient Activation Measure (PAM) [10], which measures an individual's knowledge, skills and confidence for self-care and concepts related to empowerment (patient enablement, patient activation, patient engagement and perceived control) [32] and has proved to be valid and reliable. A chart provided by the developers of the survey converts raw scores to the activation score [10,28].

The knowledge level was measured with the knowledge test (RasOma) [31] developed for this study. The relevance of item content was confirmed by a research group comprising two oncology nurses, an oncologist, a clinical nutritionist, and the researcher (LT). The face

Table 1
Content of the standard care and empowering patient education.

Standard care in control and intervention groups	Main areas of self-care: • Chemotherapy, medication • Effect of chemotherapy and medication • Chemotherapy-induced side effects' self-care • Fluid intake and varied diet • Dietary supplements Self-monitoring: • Weight • Side effects Services: • contact information of a Nurse • opportunity to consult a Clinical Nutritionist
Control group: A diary for recording nutrition impact side effects when they occurred and severity assessment on a Numeric Rating Scale (0–10)	
Intervention group: I. A diary for recording nutrition impact side effects when they occurred, severity assessment on a Numeric Rating Scale (0–10), self-care methods and reassessment of the severity. Recording knowledge expectations of side effects that may reduce food intake and their self-care.	
II. Nurse-led one-hour empowering education	1. The purpose of the education session was explained. 2. The education was tailored according to patients' baseline (M0) activation level and knowledge expectations of nutrition impact side effects and their self-care[27]. 3. Additional information (what, why, how) was provided based on patients' existing knowledge of • healthy diet • dietary changes during chemotherapy • malnutrition, its prevalence, and consequences for patients with CRC during chemotherapy • chemotherapy-induced nutrition impact side effects and their self-care after the first cycle including o oral problems o difficulty swallowing o pain o nausea, vomiting o heartburn o constipation o diarrhea o anorexia o changes in taste o cold sensitivity o pain o fatigue o worrying 4. Understanding was confirmed with teach-back.

Table 2
Outcomes and measuring instruments.

Outcome	Instrument	Scale
The patient activation level	Patient Activation Measure, PAM[10]	13 items on a 4-point Likert scale (strongly disagree–disagree–strongly agree–agree–not applicable). An individual falls into one of four levels of activation along a 100-point scale: 1 = low level; believing the patient role is important (score of ≤ 47.0), 2 = low level; having the confidence and knowledge necessary to take action (score of 47.1–55.1), 3 = moderate level; taking action to maintain and improve one's health (score of 55.2–67.0), and 4 = high level (score of ≥ 67.1); staying the course even in stressful situations.
The knowledge level	Knowledge test, RasOma[31]	15 items answered yes or no. A correct answer gives one point and an incorrect or missing answer zero points.
The risk of malnutrition	Nutritional Risk Screening, NRS2002[19]	A score of 0–7 points, patients with a total score of ≥ 3 are classified as nutritionally at risk.
The QoL	The Functional Assessment of Cancer Therapy-Colorectal, FACT-C [34]	36 items on a five-point Likert scale: physical wellbeing (0–28 points), social wellbeing (0–28 points), emotional wellbeing (0–24 points), functional wellbeing (0–28 points) and colorectal cancer subscale (0–28 points). Levels classified as low (34 points), satisfactory (34–68 points), average (68–102 points) and high (102–136 points).
The number and severity of side effects	Numeric Rating Scale (NRS)	A 11-point scale using the cut points mild (1–4 points), moderate (2–7), and severe (5–10).
The interruption, transfer, and cancellation of chemotherapy	Register data	
Morbidity (emergency room visits and contacts to outpatient clinic)	Register data	

validity of the RasOma was verified by two experts by experience. As a result, the wording of seven items was revised. The test comprises items of malnutrition, NIS and their self-care, including biophysiological (four items of malnutrition, two items of side effects) and functional (nine items of side effect self-care) knowledge dimensions [33]. The score for correct answers constitutes the level of knowledge, higher scores indicating higher level of knowledge.

In the risk of malnutrition, the Nutritional Risk Screening (NRS 2002) was used. The assessment includes impaired nutritional status, severity of disease, body mass index and age. The instrument has shown good predictive and content validity [19]. For QoL, the Functional Assessment of Cancer Therapy Scale – Colorectal (FACT-C) was used. It has been shown to have good validity and reliability [34]. Higher score means higher QoL [16]. The measurement (Version 4, Finnish 2011, copyright 1987, 1997) was acceptable if more than 50% of the items were answered in the subscale and the overall item response rate was greater than 80% [35].

Other outcome measures were the number and severity of NIS (nausea, vomiting, pain, dry or sore mouth, difficulty swallowing, heartburn, loss of appetite, alteration of taste, cold sensitivity, diarrhoea, constipation, fatigue, anxiety, worry), and morbidity, i.e., the number of emergency room (ER) visits and contacts with outpatient clinic due to NIS, and patient-related changes in treatment schedule. Patients with higher activation levels are likely to have fewer hospitalisations and ER visits compared to those with lower activation levels [36], and better nutritional status is related to better well-being and adherence to treatment schedule [22]. Data were collected from patient records for eight weeks after the intervention. The severity of NIS was self-assessed on a Numeric Rating Scale (NRS) by selecting a number that best reflects the intensity of the symptom. Higher scores indicated greater intensity. We used interference-based severity cut-points adopted from earlier studies [37].

2.5. Sample size

The sample size was calculated based on the PAM [10] to detect a seven-point mean difference between the groups, assuming standard deviation (SD) of 11 points for both groups with 80% power and significance level of 0.05. This required a sample size of 40 participants per group. The meaningful difference between the average score of individuals who engage in healthy behaviours and those who do not has been four points in the PAM [12].

2.6. *Randomisation and blinding*

Patients willing to participate were randomly assigned to intervention group (IG) and CG using the allocation ratio of 1:1 and stratified randomisation according to stage of disease and presence of stoma. An allocation sequence using blockrand package 54 in R version 3.6.1 was used [38]. For each block, the block size was randomly chosen from a set of two, four and six. An unpredictable allocation sequence was generated using sequentially numbered, opaque, sealed envelopes [39]. The researcher (LT) allocated participants to the intervention by drawing a simple random sample from each group. Blinding was not possible because participants were reminded of the educational session and nurses informed the research nurse when the patient was available.

2.7. *Statistical methods*

The main analysis compared the change between the groups at baseline and eight weeks after the intervention in primary and secondary outcomes. Prior to analysis, some background and clinical variables (employment, side effects, ER visits) were converted to 2-class variables due to small number of observations, and continuous variables (age) were converted to categorical variables to enable statistical analysis. We used 60 years as cut-off [40]. Categorical variables were described using frequencies and percentages. Continuous variables were described with means and standard deviations for normally distributed variables and with medians and interquartile ranges (IQR) for skewed-distributed variables. The differences in changes between groups in continuous outcomes were compared with two-sample t-test for normally distributed outcomes (patient activation, the QoL) and Mann-Whitney U-test for skewed-distributed outcomes (risk of malnutrition, knowledge level). A general linear model (GLM) was performed to explore the association of demographic (age, gender, education, dependents, living, working) and clinical (prevalence of cancer, number of side effects, ER visits, stoma) factors with normally distributed outcomes after adjustment for group. Bonferroni correction was used in adjustment for multiple comparisons. Mann-Whitney U-test and Kruskal-Wallis test were used to analyse the association of demographic and clinical factors with the outcomes with skewed distribution. Two-sided tests were used, and p-values less than 0.05 were considered statistically significant. Data analysis was performed using IBM SPSS 25.0 for Windows (IBM Corp., Armonk, NY).

2.8. *Ethical considerations*

The work was carried out in accordance with the code of ethics of the Declaration of Helsinki. Research ethics approval was obtained according to organisational policy from the Organisation Ethics Committee (2115/2019) prior to conducting the research. Permission to conduct the study was obtained from the organisation (83/29019). The researcher (LT) obtained written informed consent from the participants in connection with the first CTX.

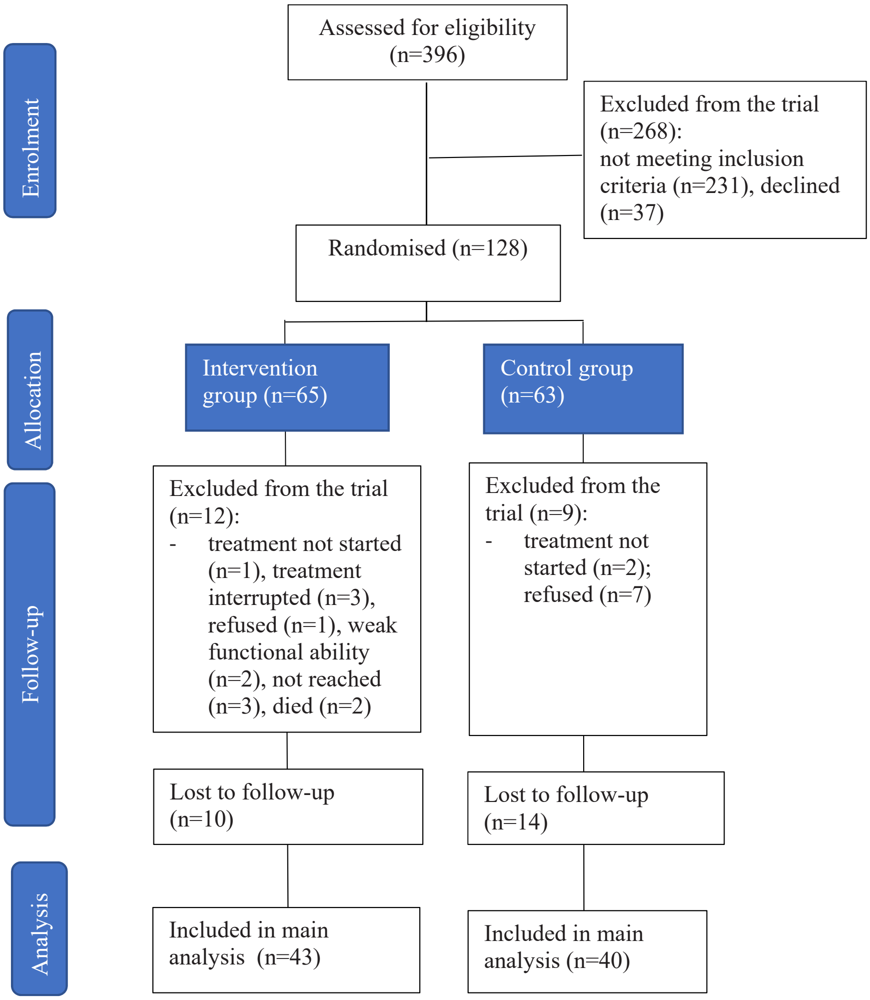

Fig. 1. Participant flow.

3. Results

3.1. Participant demographic and clinical characteristics

Of the 396 patients assessed for eligibility, 128 were eligible; 65 of them were randomly assigned to the IG and 63 to the CG. Of these patients, 43 + 40 completed both measurements (Fig. 1). The mean age of those included in the main analysis (mean 62.1, SD 9.5) and those who withdraw (60.5, SD 9.3) was not statistically significant (p=0.724). Of those included in the main analysis and withdraw, 48.2% and 33.3% were female, respectively (p=0.197).

At baseline, no statistically significant difference was found in the demographic characteristics between the groups (Table 3). Participants were mainly over 60 years of age (mean = 62, SD 9.5; 95% confidence interval 60–64; minimum 39, maximum 81), had been diagnosed with colon cancer (79% and 72.5%, respectively), and had undergone surgery (88%). About 54% of the participants had advanced cancer. As anticancer treatment, most had oxaliplatin or irinotecan with fluoropyrimidine or fluorouracil, in metastatic setting combined with bevacizumab, administered with palliative or curative intent.

3.2. Effects on activation level and knowledge level

Comparison of outcomes between the groups are presented in Table 4. At baseline, activation scores suggested moderate activation level (3) in both groups. After the intervention, a positive trend in activation scores was detected in the IG. However, the difference in the change between the groups was statistically non-significant (mean difference 4.45, 95% CI –0.19, 9.09, $p = 0.060$).

The median baseline knowledge level was 13.0 in the IG and 14.0 in the CG. No difference in the change between the groups was found in overall knowledge level after the intervention, but further analysis revealed a statistically significant difference in the change (p = 0.028) in knowledge level related to malnutrition in the IG (median 0.0, IQR 1.00) group compared to the CG (median 0.0, IQR 0.0).

Table 3
Baseline demographic and clinical characteristics of participants.

	IG (n = 43) n (%)	CG (n = 40) n (%)	*p*-value
Gender			
Female	20 (46.5)	20 (50.0)	0.751[a]
Male	23 (53.5)	20 (50.0)	
Age			
Under 60 years	16 (37.2)	17 (42.5)	0.623[a]
Over 61 years	27 (62.8)	23 (57.5)	
Educational level			
Comprehensive	7 (16.3)	5 (12.8)	0.545[a]
Secondary	10 (23.3)	6 (15.4)	
University	26 (60.5)	28 (71.8)	
Dependents			
Yes	4 (9.5)	3 (7.7)	0.769[b]
No	38 (90.5)	36 (92.3)	
Residence			
Alone	10 (23.8)	10 (25.0)	0.917[a]
With another person	22 (52.4)	22 (55.0)	
With family	10 (23.8)	8 (20.0)	
Employment			
Working	19 (45.2)	17 (42.5)	0.803[a]
Not working	23 (54.8)	23 (57.5)	
Cancer type			
Colon	34 (79.0)	29 (72.5)	0.609[b]
Rectum	9 (21.0)	11 (27.5)	
Prevalence to other organs			
Yes	22 (51.2)	15 (37.5)	0.298[a]
No	21 (48.8)	25 (62.5)	
Stoma			
Yes	8 (18.6)	8 (20.0)	0.872[b]
No	35 (81.4)	32 (80.0)	
Type of chemotherapy			
Oxaliplatin, fluoropyrimidine	35 (81.4)	34 (85.0)	0.650[a]
Irinotecan, fluoropyrimidine	5 (11.6)	2 (5.0)	
Other	3 (7.0)	4 (10.0)	

Abbreviations: [a], Chi-Square test; [b], Fisher's Exact test.

3.3. Effects on risk of malnutrition and QoL

At baseline, there was no risk of malnutrition in the IG and CG. When comparing the change in the risk of malnutrition after the intervention, no difference was found between the groups (Table 4).

At baseline, the QoL was at high level in both groups. After the intervention, QoL decreased in both groups, being at average level in the IG and remaining high level in the control group. The difference in the change was not statistically significant between the groups (Table 4).

3.4. Effects on nutrition impact side effects

The number and severity of NIS was self-monitored for eight weeks starting with the first treatment. A total of 42 (34%) participants returned the diary, 23 (51.2%) in the IG and 19 (48.8%) in the CG. Of these, 34.8% in the IG and 36.8% in the CG had 1–6 side effects, while 65.2% in the IG and 63.2% in the CG had 7–13 side effects. The difference between the groups was non-significant in terms of the number and severity of side effects. However, severe diarrhoea was more frequent in the CG compared to the IG. The most common side effects in both groups were fatigue, cold sensitivity, and nausea. The majority of the participants (83.3%) experienced moderate to severe side effects during the first cycle of CTX. The corresponding figure was 69% in the second and 66.7% in the third cycle.

3.5. Effects on morbidity and treatment changes

When exploring ER visits related to NIS, both groups had four visits during cycles 1–4 due to diarrhoea, vomiting, mouth ulcers and stomach pain. After the visits, two patients in the IG and three in the CG were admitted to hospital. When exploring side effect-related contacts with outpatient clinic, there was a statistically significant difference in the number of contacts between the IG (median 0.00, IQR 0.00) compared to CG (median 1.00, IQR 2.00, $p < 0.001$). There was statistically non-significant difference between the groups in terms of uncancelled appointments.

3.6. Association of demographic and clinical factors with outcomes

Statistically significant associations between demographic and clinical factors related to the changes in the activation level, risk of malnutrition, and QoL are reviewed at the whole data level in Appendices B–C. The increase in activation level was higher among male compared to female participants (group adjusted mean difference 4.86, 95% CI 0.32, 9.4, $p = 0.036$). A statistically significant improvement in malnutrition risk scores was seen among those living with family compared to those living alone (median –1.00, IQR 1.00 vs median 0.00, IQR 0.00, $p = 0.001$).

In the domains of QoL, social well-being improved more among those over 60 years compared to those under 60 years (median 1.00, IQR 4.50 vs median 0.00, IQR 3.33, $p = 0.044$). Furthermore, social well-being improved in those living alone compared to those who lived with family (median 2.00, IQR 3.00 vs median –1.00, IQR 2.00, $p < 0.000$) and in those living with another person compared to those who lived with family (median 0.33, IQR 4.50 vs median –1.00, IQR 2.00, $p = 0.007$). Social well-being improved in those who did not work compared to those who did work (median 1.17, IQR 5.50 vs median 0.00, IQR 2.54, $p = 0.025$) and in those who had no ER visits compared to those who had (median 1.00, IQR 4.50 vs median –1.00, IQR 1.75, $p = 0.010$).

Table 4
Comparison of outcomes between the groups.

Variable	Participants	Groups				
		IG	CG			
	Intervention / CG (n)	Mean (standard deviation) or median [inter quartile range]	Mean (standard deviation) or median [inter quartile range]	Mean difference (95% confidence interval) or median difference [95% confidence interval][c]	*p*–value	Effect size
PAM, baseline	43/40	56.7 (9.10)	59.6 (14.43)	–2.86 (–8.10, 2.37)	0.288[a]	–0.24
PAM, follow-up	43/40	60.5 (12.90)	58.9 (12.13)	1.59 (–3.89, 7.06)	0.565[a]	0.13
PAM, change	43/40	3.77 (10.42)	–0.67 (10.80)	4.45 (–0.19, 9.09)	0.060[a]	0.42
RasOma, baseline	43/39	13.00 [2.00]	14.00 [2.00]	–1.00 [–1.00, 0.00]	0.038[b]	–0.43
RasOma, follow-up	43/40	13.00 [2.00]	14.00 [2.00]	0.00 [–1.00, 0.00]	0.084[b]	–0.41
RasOma, change	43/39	0.00 [2.00]	0.00 [1.00]	0.00 [–1.00, 1.00]	0.99[b]	–0.10
NRS2002, baseline	40/40	1.00 [1.00]	2.00 [2.00]	0.00 [–1.00, 0.00]	0.089[b]	–0.51
NRS2002, follow-up	40/40	1.50 [1.00]	2.00 [1.00]	0.00 [–1.00, 0.00]	0.348[b]	–0.23
NRS2002, change	40/40	0.00 [1.00]	0.00 [1.00]	0.00 [0.00, 1.00]	0.152[b]	0.33
FACT–C, baseline	41/36	104.8 (14.2)	106.9 (17.10)	–2.14 (–9.24, 4.97)	0.551[a]	0.14
FACT–C, follow-up	41/37	100.9 (16.8)	105.9 (18.20)	–4.99 (–12.9, 2.90)	0.211[a]	–0.29
FACT-C, change	39/35	–4.03 (15.8)	–0.77 (11.60)	–3.26 (–9.7, 3.20)	0.319[a]	–0.23

Abbreviations: PAM, the Patient Activation Measure; RasOma, the knowledge test; NRS2002, the Nutritional Risk Screening; FACT–C, the Functional Assessment of Cancer Therapy–Colorectal. Effect size was calculated using Cohen's D, the mean difference / the pooled standard deviation; [a], Independent Samples T Test; [b], Mann–Whitney U Test; [c], Hodges–Lehman estimate for median difference.

4. Discussion and conclusion

4.1. Discussion

We explored the effect of empowering education on patient-reported outcomes and register data in patients with CRC during CTX. Despite the development of new types of therapies, treatment may still cause patients a number of side effects [1,3] and impair nutrition intake. Due to the toxicity of medication and the nature of the care, it is important to support patients' empowerment on NIS self-care at home.

The findings showed a positive effect of empowering patient education on activation level. Based on earlier literature, patients with higher baseline levels of activation (3−4) might have benefited from additional knowledge to support empowerment in self-care [15,28]. In this study, we mainly used the hospitals' existing educational material. We used patients' activation levels both in tailoring the education and assessing the effectiveness of the intervention. Further research is needed to utilise individuals' activation levels in patient education.

Our intervention improved patients' knowledge level in malnutrition related items, which is in line with previous research [13]. During CTX, patients may receive a wealth of information about side effects and their care, whereas education on the risk and prevention of malnutrition may not be a daily routine; instead, they are easily left for clinical nutritionists. The knowledge test covered the most common NIS in this patient group. However, only the side effects that each patient had experienced after the first CTX were discussed during the education. Furthermore, only 14% of the patients answered to the M0 questionnaire before the first outpatient visit as instructed, which might have contributed to the results of the M0 knowledge test.

The risk of malnutrition (NRS2002$\geq$3) was not present at baseline among the participants. CTX starts within 6–8 weeks after surgery when body composition changes and nutritional demand is no longer elevated [14]. Inclusion of patients not nutritionally at risk may partially explain the failure to show benefit of the intervention [19]. In this study, the number of side effects was not associated with the risk of malnutrition, unlike in previous studies [18]. Interestingly, the risk of malnutrition decreased after the intervention among those living with family. This may be due to the help of family members in a situation when a person is unable to obtain or prepare food, e.g., due to fatigue or nausea.

In contradiction with some previous studies [17], we found a negative trend in overall QoL in patients with CRC. This may indicate that the intervention had no effect on QoL or that improvements take a longer time to be detectable [4,16]. Social well-being decreased in those who were younger, living with family and working. This could be explained by long-lasting side effects [3,16]. As cancer affects the whole family, provision of emotional support can alleviate cancer-related anxiety and improve QoL [41]. The work community can be supportive, but negative behaviours may also be experienced. The main contributing factor to continuing to work has been the need to focus on looking after oneself [42]. Further research is needed on the methods by which family members and the work community can support patients with cancer during CTX.

We followed the effect of the intervention on the number and severity of side effects. In line with previous research, most of the participants had 7–13 side effects perceived as moderate or severe in the days following the CTX [2,3]. During the second and third cycles of CTX there were fewer side effects classified as moderate to severe. Unlike in previous studies [6], our intervention did not reduce the number or severity of side effects. Among those who had more side effects, the trend of QoL was downward, supporting earlier research [4]. However, it is difficult to ascertain whether the number of side effects and change in QoL were related to the intervention or due to the CTX. In this study, the patients in the IG had fewer additional contacts with the outpatient clinic compared to the control group, which is in line with previous studies [36] and could be interpreted as enhanced empowerment in self-care due to intervention. More research is needed on the effects of empowering education in patients with multiple side effects.

This study has some limitations. Firstly, the participants were recruited from the same clinic, posing a risk of diluting the effect of the intervention. However, mutual interaction with patients was sporadic. Secondly, the education sessions were not recorded to confirm the fidelity of the empowering education. However, the research nurse reported the content, duration, and the use of the teach-back method. Thirdly, the NRS2002 questionnaire was completed by the participants themselves instead of health care professionals as recommended [43]; interpretation of the responses may thus have affected the reliability of the results. The intervention could also have been more beneficial if only patients at risk of malnutrition had been included. Moreover, outcomes were self-reported by patients and assessed using same the instruments in baseline and follow-up, which may pose a risk of method bias. However, taking the patient's perspective into account in health care assessments is important, so a reasonable level of bias due to self-reported outcomes may be acceptable [44]. Fourthly, one must be cautious of generalising the number and severity of side effects to a larger population due to the low returning rate of the diaries. Finally, reinforcement sessions might have strengthened the effect of the intervention. On the other hand, implementing additional sessions could have been burdensome for patients and challenging due to limited resources.

4.2. *Conclusion*

Contrary to previous nutritional research, this study reports the effectiveness of EPE on nursing sensitive patient-reported outcomes and register data. It confirms a positive effect on patients' knowledge level. It supports self-care and reduces healthcare costs by reducing additional contacts with healthcare. A positive trend in patient activation levels warrants further research on the effect of EPE on self-care. As knowledge is essential to self-care, patients may benefit from information offered individually according to their expectations and activation levels. The findings showed that a brief empowering nursing intervention can improve knowledge level and activation level. It may reduce contacts with health care due to nutrition impact side-effects during chemotherapy treatment, thus reduce health care costs.

4.3. *Practice implications*

Empowering patient education can improve patients' knowledge level and reduce contacts with health care and thereby reduce costs. For patient education, we recommend a patient-oriented approach that takes into account patients' learning expectations and activation level.

Funding sources

This study was funded by the Helsinki University Hospital Nursing Research Centre and Cancer Centre and the University of Turku.

CRediT authorship contribution statement

Leino-Kilpi Helena: Conceptualization, Methodology, Resources, Supervision, Writing – review & editing. **Vahlberg Tero:** Data curation, Formal analysis, Writing – review & editing. **Ritmala Marita:** Writing – review & editing, Supervision, Methodology, Data curation, Conceptualization. **Tuominen Leena:** Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Mäkelä Siru:** Conceptualization, Writing – review & editing. **Nikander Pia:** Writing – review & editing.

Declaration of Competing Interest

The authors have declared that there is no conflict of interest.

Acknowledgements

We express our sincere appreciation to all participating patients, the research nurse and other staff members at the cancer clinic for their willingness to contribute to our study.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pec.2023.107895.

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