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ORIGINAL ARTICLE

Decreased symptom burden following surgery due to support from an interactive app for symptom management for patients with pancreatic and periampullary cancer

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ABSTRACT

Background: Patients with pancreatic and periampullary cancer have poor prognoses, experience multiple symptoms following surgery and sometimes lack knowledge of self-care activities. Consequently, it is vital to develop systems that support self-management, improvement of health-related quality of life and reduction of symptoms. Therefore, the aim was to evaluate the impact on health-related quality of life and self-care activity when using the Interaktor app following pancreaticoduodenectomy due to cancer.

Material and Methods: Patients in the intervention group used Interaktor up to six months after surgery. They reported symptoms daily at home and received support for self-management by continuous access to written self-care advice and to their healthcare professionals. Descriptive data from the app were collected. Health-related quality of life and self-care activity were collected before surgery, and six weeks and six months after surgery. Comparisons between the intervention group ($n = 26$) and a historical control group ($n = 33$) were made. Decline/dropout rate was 37% in the intervention group and 10% in the control group.

Results: Six weeks after surgery the intervention group rated significantly higher emotional functioning and less nausea/vomiting, pain, appetite loss, constipation, pancreatic pain, flatulence and worry about low weight. Twenty-five subscales/items showed non-statistical differences. Six months after surgery the intervention group rated significantly fewer hepatic symptoms, less worry about low weight, and higher self-care activity level. Thirty subscales/items showed non-statistical differences. The first four weeks, patients reported symptoms in a median 95% of the intended days, and for the rest of the period in median 83%.

Conclusion: The use of an app for management of patient-reported outcomes reduces symptom burdens six weeks after pancreaticoduodenectomy due to cancer. Interaktor is well accepted for patients choosing to participate and appears to facilitate supportive care needs and timely symptom management for this patient group. Future studies should also include cost-benefits and objective measures.

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Introduction

Pancreatic and periampullary cancers are relatively rare tumors but show a high mortality rate. In Sweden, 1,200 individuals are diagnosed each year, equally distributed between men and women [1]. The only hope for cure is surgical resection which can only be offered to fewer than 20% of patients [2]. Even after intentionally curative surgery and adjuvant chemotherapy the prognosis is poor, with a median survival period of 2–4 years depending on whether it is pancreatic or periampullary cancer [3,4]. Pancreaticoduodenectomy is the most common surgical procedure for these tumors. It is recognized that patients experience impaired health-related quality of life with distressing symptoms following pancreaticoduodenectomy [5,6]. Patients describe how the symptoms can lead to social isolation but also how symptoms can be managed by using medication, self-care activities, and support from friends and family [7–9]. However, it has been concluded that patients after pancreaticoduodenectomy may lack sufficient knowledge of self-care activities which requires a healthcare system with more intensive follow-up, enabling professionals to be more vigilant for symptoms [8]. Unmet supportive care needs, especially of a physical and psychological nature but also regarding information and support from the healthcare system, are prominent in patients affected by pancreatic or periampullary cancer and it is proposed that efforts should focus on changing healthcare systems so that these needs

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Supplemental data for this article can be accessed here.

are met [10]. It is emphasized that care and support for patients with cancer should focus on recovery, self-management, early recognition of signs and symptoms and routine use of patient-reported outcomes [11]. In clinical care, routine use of patient-reported outcomes can identify current concerns and impact of treatment, enhance the patient-clinician communication, promote shared decision-making, and improve patient satisfaction [12,13]. Collecting patient-reported outcomes for clinical purposes assisted by interactive web-based systems has showed several benefits for patients with cancer i.e., improved health-related quality of life, symptom management and communications with healthcare [14,15]. Patients with cancer have also reported a positive attitude to using internet interventions to enhance self-management [16]. However, to our knowledge, interactive web-based systems for collecting patient-reported outcomes and enhancing self-management have not been evaluated by patients with pancreatic or periampullary cancer.

Given the poor prognosis, impaired health-related quality of life, distressing symptoms and sometimes insufficient knowledge of self-care activities, challenges arise in supporting patients with cancer following pancreaticoduodenectomy. To address these challenges, an interactive app (Interaktor) for smart devices has been developed in which patients regularly report symptoms and receive support by continuous access to written self-care advice and their healthcare professionals. The content in the app has been developed by reviewing literature and interviewing patients and healthcare professionals [9] and has been tested for feasibility [17]. The aim of the current study was to evaluate the impact on health-related quality of life and self-care activity when using the Interaktor app following pancreaticoduodenectomy due to cancer.

Material and methods

Study design and participants

The Medical Research Council framework for developing and evaluating complex interventions formed the foundation for this project [18]. The current phase of the project had a historically-controlled, single center design. Inclusion criteria were; patients scheduled to undergo pancreaticoduodenectomy due to a suspected malignancy. Exclusion criteria were; follow-up care planned in another county, and/or unable to read Swedish. The patients were invited consecutively before surgery to participate in the study. Inclusion and data collection of the control group were made before the intervention group (Figure 1). The control group ($n = 33$) received standard care and the intervention group ($n = 26$) received standard care and the intervention. Written informed consent was obtained from all participants. Due to changes in standard care procedure during the planned study period, inclusion in the intervention group was cease earlier than planned. Ethical approval was given by the Regional Ethical Review Board in Stockholm, Sweden (Reg.no. 2011/1780-13/2).

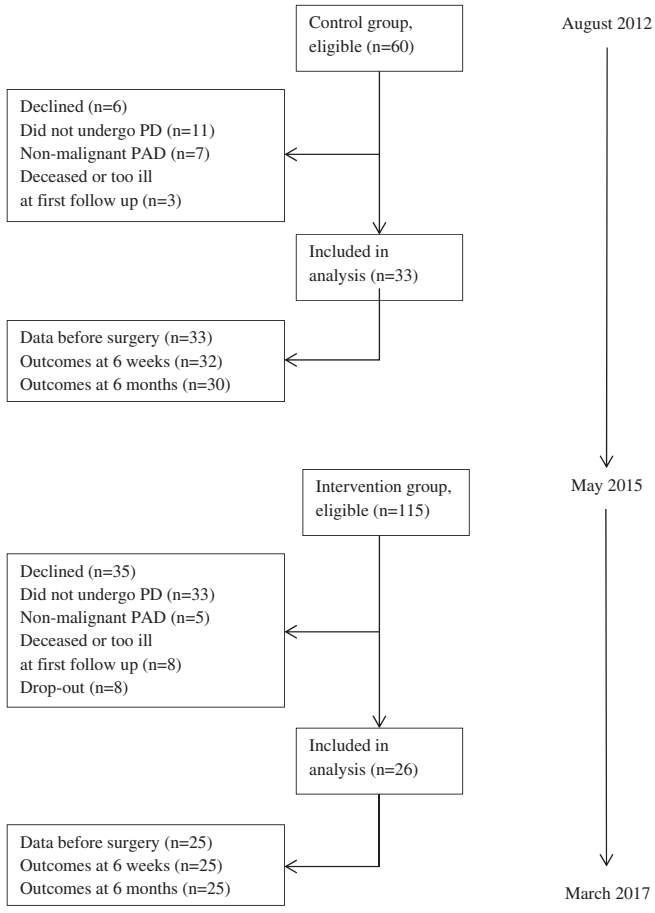

Figure 1. Flowchart of the inclusion process.

Standard care

Before surgery the patients met a surgeon, a contact nurse, a physiotherapist, an anesthesiologist and a dietician in order to gain information on the surgery and aftercare. The patients were given written folders regarding pain treatment, physiotherapy and dietary advice including information about pancreas enzyme supplements. The hospital stay was normally 2–3 weeks. If the patients had questions after discharge, they were encouraged to call their contact nurse at the surgical clinic during working hours (8 a.m. to 4 p.m. on weekdays). If in need of emergency care they were asked to contact the nearest emergency department. Patients eligible for adjuvant chemotherapy began their treatment within 10 weeks of surgery and the therapy was given at the hospital once a week for 3 of every 4 weeks for 6 months. During chemotherapy, the patients met an oncology nurse and, on some occasions, an oncologist. Between treatments the patients could call their contact nurse at the oncology clinic during working hours.

Intervention

The primary components of the Interaktor app is 1) regular assessment of self-reported symptoms, 2) connection to a monitoring web-interface, 3) risk assessment models for alerts, 4) continuous access to evidence-based self-care advice and

links to websites for more information, and 5) graphs for the patients to view the history of their symptom reporting. The pancreatic version of the app consists of 12 symptom questions and 22 areas of self-care advice, described in the feasibility study [17]. For patients receiving chemotherapy, three additional questions were added and some self-care advice was adjusted.

The patients were instructed to use Interaktor to report symptoms daily for six months, starting on the first day at home following discharge. A reminder to report was sent through the app every day. The patients were thoroughly informed both verbally and in writing that in case of an alert they would be contacted during working hours only (8 a.m. to 4 p.m. on weekdays). The nurses allocated were employed at the surgical or oncological clinic and functioned as the patients' contact nurse. The nurses were instructed to call the patients if they received a text message alert.

Data collection

Descriptive data

Data concerning age, sex, length of hospital stay, histopathology of tumor and, chemotherapy were collected from the patients' medical records. Body Mass index (BMI) were calculated the day before surgery and six weeks after surgery from the patients' medical records but could not be calculated six months after surgery due to a large amount of missing data. Data concerning living situation and educational level were self-rated by the patients. The Sense of Coherence scale (SOC-13) was used to measure individuals' ability to cope with stressful life events which is based on how comprehensive, manageable and meaningful life appears [19]. The scale is well validated and widely used and consists of 13 questions with a total score range from 13 to 91 points where a higher score indicates a higher degree of sense of coherence. Data on sense of coherence were collected since a high sense of coherence level has shown predictive validity for a good health-related quality of life [20–22] and higher self-care activity level [23].

Health-related quality of life and self-care activity

Data were collected before surgery, six weeks after surgery, and six months after surgery.

The Swedish version of the EORTC QLQ-C30 version 3.0 and the pancreas module QLQ-PAN26 were used to measure health-related quality of life. The core questionnaire is well validated and widely used and consists of 30 questions scaled in one global health status domain, five functional domains and nine symptom subscales/single items. The pancreas module is undergoing Phase IV testing and consists of 26 questions scaled in 17 symptoms and satisfaction subscales/single items. Scores for all the subscales and single-item measures range from 0 to 100 where a high score for the global and functional scales reflects a high level of quality of life/functioning, a high score for symptoms/satisfaction scales/single items reflects more symptoms/satisfaction and a high score for sexuality reflect lower sexual function [24,25].

The Appraisal of Self-Care Agency scale (ASA-A) was used to measure the engagement in self-care activities. The scale consists of 24 questions and the total score ranges from 24 to 120 points, where higher scores reflects a higher degree of self-care activity. The scale has been validated for patients performing self-care at home [23,26].

Logged data from the app

Data from the app was logged on a secure server. Logged data concerning number of reports, reported symptoms, alerts and viewed self-care advice were extracted as an Excel file.

Data analysis

One patient in the intervention group had incomplete data before surgery but completed all the other measurements and was therefore included in the analysis. The measurements aimed to be collected at six weeks after surgery was responded to in mean 49 days after surgery by the intervention group and 47 days after surgery by the control group ($p = .617$).

Statistical analysis

The items in EORTC QLQ-C30 were processed according to the EORTC scoring manual [27] and the items in EORTC QLQ-PAN26 according to CD Johnson, responsible for the pancreas module (personal communication). The items in the ASA-A-scale were processed equally to Fex and colleges [23] and the items in the SOC-13 were processed according to the manual [19].

Analyses were performed using Microsoft Excel 2010 and IBM SPSS Statistics 24. Cohen's d [28] was used to evaluated effect size and calculated by subtracting the group means and dividing the result with the pooled standard deviation giving the interpreted small effect size if $d = 0.2$, medium if $d = 0.5$ and high if $d = 0.8$. A 2-tailed statistical significance level of $p < .05$ was applied. Between-group analyses were performed using chi-square or Fisher's exact test for categorical variables and t-test for continuous variables. Variables in EORTC showing significant mean differences at six weeks and six months were run in multiple linear regression models as dependent variables with group (coded as control group = 0, intervention group = 1), chemotherapy (coded as No = 0, Yes = 1) and SOC-13 scores as independent variables using the standard method. Chemotherapy was used as an independent variable since decisions on chemotherapy may be based on patients' general condition at that time. To evaluate changes over time an ANOVA for repeated measures was analyzed separately for the intervention group and the control group.

Logged data were analyzed using descriptive statistics. Data for the first four weeks were separated from data for the rest of the reporting period. This time point approximately corresponds to the measurements at 6 weeks after surgery and also to when patients normally begin chemotherapy. Adherence to report was calculated as the number

of days a patient submitted a report divided by the number of days a patient was intended to report, and presented as a percentage.

Results

There were no significant differences between the intervention group and the control group in descriptive data (Table 1).

EORTC QLQ-C30, EORTC QLQ-PAN26 and ASA-A

Before surgery, the intervention group rated significantly less worry about low weight ($d = 0.6$, 95% CI 0.79–29.26, $p = .039$) (Table 2). At six weeks after surgery the intervention group rated significantly higher level of emotional functioning ($d = 0.9$, 95% CI–29.33 – –8.00, $p = .001$) and less nausea/vomiting ($d = 0.8$, 95% CI 6.19–30.22, $p = .004$), pain ($d = 0.5$, 95% CI 0.22–30.32, $p = .047$), appetite loss ($d = 0.8$, 95% CI 8.11–43.39, $p = .005$), constipation ($d = 0.9$, 95% CI 6.55–30.11, $p = .003$), pancreatic pain ($d = 0.8$, 95% CI 4.22–25.14, $p = .007$), flatulence ($d = 0.6$, 95% CI 1.13–30.95, $p = .035$) and worry about low weight ($d = 1.0$, 95% CI 13.49–48.67, $p = .001$) (Table 2). At six months after surgery the intervention group rated significantly fewer hepatic symptoms ($d = 0.6$, 95% CI 0.50–13.50, $p = .035$), less worry about low weight ($d = 0.6$, 95% CI 1.05 – 31.39, $p = .037$) and a higher self-care activity rate ($d = 0.6$, 95% CI 0.47 – 10.74, $p = .033$) (Table 2). Over time, the intervention group reported non-significant changes in 21 of the EORTC scales as compared to 8 for the control group (Table 2). Examples of within-group changes over time are presented in Figure 2. There were no statistically significant changes in ASA-A in any of the groups over time (Table 2).

In the multiple regression models using group, chemotherapy and sense of coherence as independent variables, the intervention group still rated significantly higher level of emotional functioning and less nausea/vomiting, pain, appetite loss, constipation, pancreatic pain, flatulence and worry about low weight at six weeks and fewer hepatic symptoms and higher self-care activity level at six months (Table 3).

Logged data in the app

In the first four weeks after discharge the intervention groups' adherence to reporting symptoms as intended was 95% in median (range 32–100%). During this period the patients reported a total 70.5 symptoms in median (range 8–157). The most commonly reported symptom was fatigue which was also reported by most patients, followed by pain and eating difficulties (Supplementary Figure S1). Alerts were triggered 3 times in median per patient (range 0–16). Self-care advice was viewed 13.5 times in median per patient (range 1–93) mostly regarding pancreatic enzyme supplements, dietary advice and pain.

The following period, after four weeks and up to six months after discharge, the intervention groups' adherence to reporting symptoms as intended was 83% in median

Table 1. Descriptive data of study participants ($n = 59$).

Descriptive data	IG ($n = 26$)	CG ($n = 33$)	p
Age, years			
Mean (SD)	67 (8,7)	66 (8,8)	.78[b]
Median (range)	67 (51-82)	66 (47-82)	
Sex, No. (%)			
Female	9 (35)	13 (39)	.79[c]
Male	17 (65)	20 (61)	
Living situation, No. (%)			
Married/living with partner	21 (81)	25 (76)	.76[c]
Living alone	5 (19)	8 (24)	
Highest education level, No. (%)			
Junior compulsory	1 (4)	5 (15)	.18[d]
Senior high school	9 (35)	15 (45)	
Postgraduate or university	15 (58)	12 (36)	
Missing data	1 (4)	1 (3)	
Length of hospital stay			
Days, Mean (SD)	12.5 (5.3)	13.4 (3.7)	.47[b]
Histopathology, No. (%)			
Pancreatic ductal adenocarcinoma	12 (46)	18 (55)	.55[d]
Periampullary cancer	12 (46)	12 (36)	
Invasive intraductal papillary mucinous neoplasm	2 (8)	1 (3)	
Invasive neuroendocrine tumor	0 (0)	2 (6)	
Chemotherapy, No. (%)			
Yes	22 (85)	22 (67)	.14[d]
No	4 (15)	11 (33)	
Body Mass Index, mean (SD)			
Before surgery	25.8 (5.6)	23.7 (3.4)	.085[b]
6 weeks after surgery	23.7 (4.9)	21.4 (3.2)	.035[b]
SOC, mean (SD)			
Before surgery	74.7 (8.5)	72.3 (12.5)	.45[b]
6 weeks after surgery	73.3 (12.5)	73.3 (11.8)	>.99[b]
6 months after surgery	75.3 (12.4)	73.2 (12.3)	.54[b]

[b]2-tailed *t*-test.
[c]Chi-square.
[d]Fisher's exact test.

Table 2. Between and within-group differences in mean scores of EORTC QLQ-C30, EORTC QLQ-PAN26 and ASA-A in the intervention group ($n = 26$) and the control group ($n = 33$).

	Before surgery			6 weeks after surgery			6 months after surgery			Over time	
	Mean (SD) IG ($n = 25$)	Mean (SD) CG ($n = 33$)	*p*	Mean (SD) IG ($n = 25$)	Mean (SD) CG ($n = 32$)	*p*	Mean (SD) IG ($n = 25$)	Mean (SD) CG ($n = 30$)	*p*	*p* IG ($n = 23$)	*p* CG ($n = 29$)
EORTC QLQ-C30											
Global health status	62.7 (21.5)	57.3 (24.4)	.39	56.9 (23.5)	49.7 (20.2)	.22	67.7 (24.0)	66.7 (18.8)	.86	**.045**	**.002**
Physical functioning	89.1 (13.9)	87.1 (14.3)	.60	73.2 (16.9)	63.3 (20.5)	.057	82.9 (18.0)	80.9 (15.0)	.65	**<.001**	**<.001**
Role functioning	57.3 (36.0)	61.1 (37.2)	.70	50.0 (35.7)	37.0 (27.3)	.12	60.0 (41.1)	71.3 (26.3)	.23	**.047**	**<.001**
Emotional functioning	75.7 (22.6)	66.3 (22.8)	.13	83.3 (19.2)	64.7 (20.5)	**.001**	86.7 (19.2)	76.9 (18.5)	.062	**<.001**	**.011**
Cognitive functioning	82.7 (21.8)	83.8 (21.8)	.84	84.7 (19.2)	80.2 (23.4)	.44	82.7 (18.9)	87.2 (15.0)	.32	.72	.19
Social functioning	73.3 (31.5)	72.4 (26.6)	.90	65.3 (28.4)	55.2 (32.6)	.22	70.7 (30.9)	78.9 (22.3)	.26	.17	**.004**
Fatigue	33.8 (21.4)	34.0 (25.8)	.97	45.8 (27.3)	58.3 (24.8)	.075	36.4 (29.5)	35.6 (18.1)	.89	.088	**<.001**
Nausea/vomiting	9.3 (18.7)	7.1 (13.2)	.59	12.0 (14.0)	30.2 (27.3)	**.004**	7.3 (12.8)	10.0 (12.1)	.43	.55	**<.001**
Pain	22.0 (23.9)	19.7 (24.1)	.72	20.7 (26.5)	35.9 (29.4)	**.047**	16.0 (22.3)	16.7 (20.5)	.91	.43	**.006**
Dyspnea	20.0 (28.9)	25.3 (28.9)	.50	18.7 (23.7)	29.2 (26.4)	.13	30.7 (30.3)	26.7 (26.8)	.61	**.018**	.67
Insomnia	30.7 (31.8)	41.4 (33.4)	.22	29.3 (30.9)	37.5 (35.7)	.37	20.0 (25.5)	30.0 (29.5)	.19	.23	.16
Appetite Loss	25.3 (26.0)	22.2 (30.8)	.69	34.7 (29.6)	60.4 (35.4)	**.005**	18.7 (25.6)	15.6 (22.7)	.64	.069	**<.001**
Constipation	12.0 (21.3)	7.1 (13.8)	.29	6.7 (13.6)	25.0 (26.8)	**.003**	5.3 (12.5)	4.4 (11.5)	.79	.18	**<.001**
Diarrhea	9.3 (22.6)	12.1 (21.8)	.64	17.3 (27.4)	24.7 (32.2)	.37	17.3 (25.7)	16.7 (25.9)	.92	.35	.077
Financial difficulties	6.7 (16.7)	8.3 (23.9)	.77	12.0 (25.2)	11.5 (23.4)	.93	14.7 (21.7)	6.7 (16.1)	.12	.12	.43
EORTC QLQ-PAN26											
Pancreatic pain	21.2 (16.1)	23.0 (20.8)	.73	21.0 (15.6)	35.7 (22.1)	**.007**	12.0 (11.3)	18.6 (17.5)	.11	**.011**	**.001**
Digestive symptoms	16.7 (25.1)	22.7 (28.8)	.41	38.7 (29.2)	53.6 (28.0)	.054	24.0 (26.8)	20.6 (20.4)	.59	**.003**	**<.001**
Altered bowel habits	11.1 (20.7)	20.7 (23.2)	.11	16.7 (20.4)	22.4 (24.2)	.35	24.7 (23.6)	25.0 (27.6)	.96	.12	.49
Hepatic	19.4 (26.3)	30.3 (34.5)	.20	1.3 (4.6)	5.7 (11.7)	.082	1.3 (4.6)	8.3 (15.6)	**.035**	**.006**	**.002**
Body Image	20.1 (26.9)	19.2 (26.4)	.90	27.3 (30.0)	43.2 (31.4)	.058	28.0 (33.2)	33.9 (31.7)	.51	.097	**.002**
Satisfaction with health care	76.7 (25.5)	68.2 (33.7)	.30	68.0 (28.4)	60.9 (26.6)	.34	63.2 (33.7)	70.6 (27.2)	.38	**.046**	.27
Sexuality	51.4 (37.7)	51.2 (40.6)	.99	63.2 (33.7)	75.0 (29.9)	.19	64.0 (32.9)	56.4 (36.8)	.44	.11	**.014**
Bloating	18.1 (32.6)	22.2 (21.5)	.56	22.7 (26.7)	33.3 (33.9)	.20	21.3 (27.0)	21.1 (30.9)	.98	.87	.27
Taste/smell alterations	29.2 (33.1)	23.2 (34.8)	.52	44.0 (31.5)	55.2 (39.4)	.25	22.7 (32.9)	23.3 (29.2)	.94	.075	**<.001**
Indigestion	14.5 (22.1)	14.6 (20.6)	.99	26.7 (27.2)	35.6 (31.5)	.27	24.0 (31.2)	17.8 (22.7)	.40	.38	**.014**
Flatulence	22.2 (30.6)	30.3 (30.5)	.33	26.7 (25.5)	42.7 (29.6)	**.035**	36.0 (31.8)	51.1 (33.6)	.095	.40	**.034**
Worry about low weight	15.3 (21.9)	30.3 (29.3)	**.039**	29.3 (30.9)	60.4 (34.3)	**.001**	16.0 (23.8)	32.2 (30.9)	**.037**	.16	**<.001**
Weak limbs	19.4 (21.8)	19.2 (25.0)	.97	34.7 (29.6)	50.0 (28.1)	.051	29.3 (30.9)	32.2 (22.3)	.69	.057	**<.001**
Dry mouth	22.2 (28.9)	27.3 (32.8)	.55	34.7 (35.3)	42.7 (34.1)	.39	20.8 (35.2)	23.3 (32.9)	.79	.37	**.009**
Side effects	14.5 (24.3)	17.8 (24.3)	.63	33.3 (27.2)	41.7 (33.9)	.32	36.0 (28.7)	36.7 (23.7)	.93	**.005**	**<.001**
Future health concern	54.7 (27.0)	60.4 (31.0)	.47	41.3 (24.1)	51.0 (25.4)	.15	36.0 (30.3)	43.3 (26.5)	.34	**.001**	**.017**
Ability to plan future	30.7 (38.4)	37.5 (33.6)	.48	37.3 (36.4)	55.2 (34.5)	.063	33.3 (33.3)	26.7 (25.4)	.40	.82	**.002**
ASA-A	IG ($n = 22$)	CG ($n = 26$)		IG ($n = 25$)	CG ($n = 31$)		IG ($n = 25$)	CG ($n = 29$)		IG ($n = 22$)	CG ($n = 20$)
	95.8 (10.3)	92.9 (11.4)	.36	96.6 (13.3)	92.4 (9.9)	.18	98.4 (9.2)	92.8 (9.5)	**.033**	.64	.56

IG = Intervention group, CG = Control group.
Bold value represent statistically significantat $p < .05$.

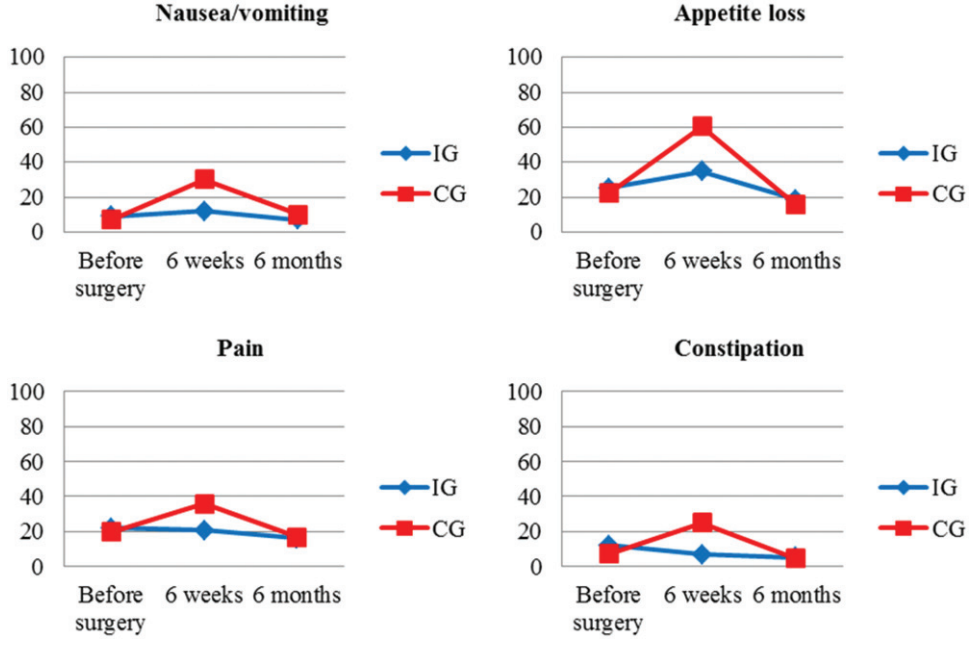

Figure 2. Within-group changes over time for symptoms in EORTC QLQ-C30 showing significant differences between groups at 6 weeks. Higher value reflects more symptoms and range 0–100. IG: Intervention group; CG: Control group.

Table 3. Multiple linear regression.

Dependent variables	Independent variables	Beta	95 % CI	*p*	Adj. *R*
Emotional functioning 6 weeks	Group	0.427	8.69 – 28.63	**<.001**	0.307
	Chemotherapy	0.001	−11.41 – 11.52	.99	
	SOC	0.401	0.32 – 1.15	**.001**	
Nausea/vomiting 6weeks	Group	−0.36	−29.53 to −4.71	**.008**	0.113
	Chemotherapy	−0.110	−20.22 – 8.33	.41	
	SOC	−0.57	−0.63 – 0.40	.66	
Pain 6 weeks	Group	−0.31	−33.01 to −2.37	**.024**	0.060
	Chemotherapy	0.205	−4.33 – 31.00	.14	
	SOC	−0.090	−0.86 – 0.42	.50	
Appetite loss 6 weeks	Group	−0.329	−40.26 to −5.95	**.009**	0.205
	Chemotherapy	−0.182	−34.15 – 5.33	.15	
	SOC	−0.251	−1.45 to −0.020	**.044**	
Constipation 6 weeks	Group	−0.452	−33.02 to −9.78	**.001**	0.197
	Chemotherapy	0.313	3.30 – 30.04	**.015**	
	SOC	−0.068	−0.62 – 0.35	.58	
Pancreatic pain 6 weeks	Group	−0.354	−25.55 to −3.74	**.009**	0.077
	Chemotherapy	−0.003	−12.70 – 12.39	.98	
	SOC	0.030	−0.40 – 0.51	.82	
Flatulence 6 weeks	Group	−0.284	−31.87 to −0.80	**.040**	0.028
	Chemotherapy	0.024	−6.29 – 19.46	.86	
	SOC	−0.048	−0.76 – 0.53	.72	
Worry about low weight 6 weeks	Group	−0.38	−44.85 to −9.82	**.003**	0.216
	Chemotherapy	−0.251	−40.55 to −0.25	**.047**	
	SOC	0.171	−0.22 – 1.25	.16	
Hepatic symptoms 6 months	Group	−0.301	−14.25 to −0.79	**.029**	0.096
	Chemotherapy	0.049	−6.49 – 9.34	.72	
	SOC	−0.258	−0.55 – 0.01	.060	
Worry about low weight 6 months	Group	−0.236	−28.83 – 1.60	.078	0.130
	Chemotherapy	−0.317	−39.07 to −3.24	**.022**	
	SOC	0.015	−0.60 – 0.67	.91	
ASA 6 m	Group	0.262	0.236 – 10.03	**.040**	0.230
	Chemotherapy	0.218	−0.87 – 10.10	.093	
	SOC	0.334	0.066 – 0.476	**.011**	

Group (Control group = 0, Intervention group = 1), Chemotherapy (No = 0, Yes = 1).
Bold value represent statistically significantat $p < .05$.

(range 21–100%). During this period the patients reported a total 96 symptoms in median (range 1–897). Most patients reported fatigue ($n = 22$), loose stool ($n = 21$), and pain ($n = 17$). Alerts were triggered 7 times in median per patient (range 0–82). Self-care advice was viewed 11 times in median per patient (range 0–119) mostly regarding fever, pancreatic enzyme supplements and pain.

Discussion

The study shows that use of an interactive app for real-time collection and management of patient-reported outcomes improved patients' symptom burdens after pancreaticoduodenectomy due to cancer. This was most prominent six weeks after surgery, specifically regarding emotional functioning and nausea/vomiting, pain, appetite loss, constipation, pancreatic pain, flatulence and worry about low weight. Using the app had moderate to high effect on those symptoms showing substantial clinical importance. At six months after surgery, most symptoms were comparable between the groups but patients using the app reported higher self-care activity level. Furthermore, within-group findings showed that patients using the app were stable over time in more functions and symptoms as compared with patients not using the app. Collecting and comparing objective data was not the focus of this study. However, collected patient characteristics show that there were no statistical differences in BMI between the groups before surgery but at six week the intervention group had higher values, corresponding to the lower levels of self-reported worry about low weight, nausea/vomiting and appetite loss. Patient-reported outcomes is essential when evaluating clinical importance and previous conclusions have been drawn that 10-points EORTC-QLQ-C30 score changes represent changes in supportive care needs for patients with cancer [29]. For most values six weeks after surgery, patients using the app reported >10-points higher scores in mean on the function scales and <10-points lower scores in mean on the symptom scales compared to the control group. Further, thresholds for clinical importance of the EORTC QLQ-C30 scale have been determined to be; >83 for physical functioning, >70 for emotional functioning, <39 for fatigue and <25 for pain [30]. Patients not using the app did not reach any of the thresholds six weeks after surgery while patients using the app did so for emotional functioning and pain. Interestingly, the patients using the app also reported values on emotional functioning, cognitive functioning, pain, dyspnea and constipation that are comparable to reports from age and sex matched persons from the Swedish population [31]. This shows the app's high clinical relevance and that the app can respond to supportive care needs for patients with pancreatic cancer.

Health-related quality of life and symptom burdens have previously been reported to be at their worst level in the six-week period after pancreaticoduodenectomy [32]. The use of the Interaktor app can provide support to decrease symptom

burdens during this stressful period. According to standard care, patients are sent home after surgery without any continuous contact with healthcare during the first few weeks at home except for being encouraged to contact healthcare when necessary. Previous studies have reported that, following surgery, patients with pancreatic cancer lack information on how to manage their illness and side-effects at home and also lack someone to discuss these issues with [7,9,10]. The patients using the Interaktor app were called by a nurse to discuss alert-generating symptoms as soon as they occurred. This happened about once a week during the first four weeks after discharge. In the later period alerts were only triggered about once a month which may be explained by the normal decrease in symptoms. Also, during that period several patients were in weekly contact with nurses at the out-clinic during chemotherapy and thereby had the opportunity to discuss symptoms and management. The Interaktor app not only enabled early contact with healthcare professionals but also offered the patients continuous access to written self-care advice. This function was used to varying degrees and advice was mostly viewed during the first few weeks at home. The patients mostly viewed advice about pancreatic enzyme supplements, diet and nutrition and pain which may explain why most improvements in symptoms at 6 weeks were gastrointestinal and pain related. Previous studies of nurse-led self-management interventions have found favorable outcomes such as early identification of symptoms and improved quality of life related to functional status [33]. The different components in Interaktor seemed to provide support to the patients to manage their symptoms and concerns. This was also shown in a sample of patients with prostate cancer reporting decreased symptom burden after radiotherapy [22] and that there was a variation of using the components of Interaktor [34]. The app facilitates early identification and management of symptoms and it is likely that the patients were encouraged to take an active role in self-care. Early identification of distressing symptoms has been evaluated as improving survival for patients undergoing treatment for cancer [35,36].

The decline and dropout rate was 37% for patients invited to use the app. Reasons was not always stated but was most commonly described as having no need, being insecure about the technology or feeling to unwell. While this affects the generalization of the findings, it also gives insight on the amount of patients who are interested in this sort of support system following pancreaticoduodenectomy. Also, patients who continued to use the app showed a very high rate of adherence throughout the study period, proving that this intervention had a concrete value for those patients that participated.

Using a design for complex interventions is a strength when developing innovations. The Medical Research Council framework proposes systematic development, careful testing and exploratory evaluation [18]. One of the strengths in the study is that when controlling for sense of coherence, previously reported to be related to health-related quality of life [20–22], the statistically significant differences remained in favor for the intervention group indicating a strong relationship between using the app and improved function and symptoms. The limitations of a historically-controlled design may be changes in patient characteristics and care regime over time. However, descriptive data were comparable between the groups and standard care routines were not changed throughout the study period. Even if the sample size in this study is small, the descriptive data shows representativeness for the patient group compared to characteristics of patients undergoing pancreaticoduodenectomy at the same clinic [37]. The limitation with the design and sample size is important to consider and affects the possibility to draw general conclusions of the app's favorable outcomes for patients undergoing pancreaticoduodenectomy. Still, for several results in this study, other studies report similar findings which strengthen our findings. Further, a moderate to high effect size was seen for most outcome variables, demonstrating effectiveness even with this small sample. The findings in the repeated measures analysis are uncertain due to a number of missing forms and must be confirmed in a larger sample. Future studies should also include cost-benefits and objective measures.

In conclusion, routine collection and management of patient-reported outcomes in clinical practice, assisted by an interactive app (Interaktor), dramatically reduced symptom burdens in the first six weeks after pancreaticoduodenectomy due to cancer. Interaktor was well accepted for those who chose to participate and facilitated supportive care needs and timely symptom management. The study contributes with important knowledge on how to support patients with poor prognoses experiencing severe symptoms.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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