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ORIGINAL ARTICLE

Patient-led follow-up reduces outpatient doctor visits and improves patient satisfaction. One-year analysis of secondary outcomes in the randomised trial Follow-Up after Rectal CAncer (FURCA)

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ABSTRACT

Background: FURCA (Follow-Up after Rectal Cancer) is a multi-centre randomised trial comparing patient-led follow-up with standard outpatient follow-up. This paper reports one-year follow-up data from the FURCA trial on selected secondary outcomes including type and number of contacts, patient-reported involvement and satisfaction with health care services during follow-up.

Material and methods: Patients with rectal cancer (stage $<$ IV) from four Danish surgical centres were randomised (1:1) into intervention (education and self-referral to project nurse) or standard follow-up (routine clinical doctor visits). The present analysis involved data on hospital contacts during the first year after surgery, patient involvement and satisfaction measured at one year, and baseline patient-reported and clinical variables.

Results: Of 512 eligible patients, 168 were allocated to patient-led follow-up (intervention) and 168 to standard follow-up (control). The total number of hospital contacts in the intervention arm did not differ significantly from the number of contacts in the control arm ($p = 0.44$). More patients had $\geq$15 contacts in the intervention arm than in the control arm ($p = 0.004$). The total number of outpatient doctor visits was significantly lower in the intervention arm ($p < 0.001$). Patients in both arms rated involvement and satisfaction high; yet patients in the intervention arm scored significantly higher on two of six items regarding involvement and all five items regarding satisfaction. Of the 168 patients in the intervention arm, 43% made direct contact (self-referral) to the project nurse, and 14 of these patients (8%) had $\geq$4 contacts. The primary reason for self-referral was bowel dysfunction.

Discussion: The findings indicate the value of a patient-led follow-up program in terms of direct access and more individually tailored intervention based on patients' needs, with most tasks being managed by nurses. Patient-led follow-up came with improved patient-perceived involvement and satisfaction; thus, it was both acceptable and favourable for the patients.

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Patient-led follow-up; patient satisfaction; rectal cancer survivors; patient involvement; hospital contacts

Background

Recent decades have seen a significant improvement in survival from rectal cancer (RC) across all stages owing to improved management [1,2]. Therefore, more patients with rectal cancer will survive with late adverse effects, including a substantial physical symptom burden and psychological distress, both of which significantly impair their quality of life (QoL) [3–6].

As of today, follow-up after RC has included calendar-scheduled outpatient clinical visits focussed on detecting recurrent or metachronous disease. The overall evidence for these follow-up programs is low according to a review of European guidelines [7] and a recently published Cochrane review of various follow-up programs across all cancer sites [7,8]. As the incidence and prevalence of late effects increase with improved survival, one may request broader aims for RC follow-up and survivorship care encompassing prevention, early detection and management of late effects [9–12]. The above-mentioned Cochrane review evaluated effects from different follow-up strategies, i.e., non-specialist-led versus

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specialist-led, and identified a need for more high-quality evidence for effects and acceptability of such strategies [13]. Patient involvement and satisfaction was not included as outcomes in that review, yet these are crucial outcomes when evaluating acceptability of alternative follow-up strategies.

Addressing this issue, a multi-centre randomised trial was launched in 2015, comparing patient-led follow-up of survivors of RC with standard outpatient follow-up (Follow-Up after Rectal CAncer – FURCA) [14]. The overall aim was to evaluate the effect on quality of life of an individually tailored follow-up program with easy access to help for those with supportive care needs and less disruption for patients with no or minor needs as an alternative to the current Danish ‘one size fits all’ strategy. Here, we report one-year follow-up data from the FURCA trial on selected secondary outcomes including type and number of contacts, patient-reported involvement and satisfaction with health care services during follow-up.

Material and methods

We developed a patient-led follow-up program and compared it to the standard follow-up program in the context of the FURCA trial with QoL and symptom burden three years after surgery as the primary outcome [14].

The patient-led follow-up was based on standardised education and thorough patient information regarding relevant symptoms and patients’ access to unrestricted self-referral to a nurse dedicated to the intervention group. Management of any problem reported was based on standardised response algorithms.

In the analysis of one-year secondary outcomes from the FURCA trial, the following hypotheses were tested:

- Patients in the intervention arm will have fewer outpatient clinical visits by doctors and more visits by nurses, yet no significant difference will appear in the total number of hospital contacts between the two allocation arms.
- Patients in the intervention arm will report a higher degree of involvement and satisfaction than will patients in the control arm.
- Intervention-arm patients with low baseline self-management (engagement in own health care) and patients with a high level of fear of cancer recurrence (FCR) at baseline will have more contacts (self-referral) than will patients with a high level of self-management and a low level of FCR

Population

Patients were recruited from four surgical centres covering one third of the Danish population as already published [14]. In brief, participants were 1:1 block randomised in blocks of 50 patients, stratified by centre, sex and treatment type (Figure 1). Patients in the control arm received standard follow-up (Figure 1), while patients in the intervention arm had no planned clinical visits except from the initial patient education, and they were informed of the computerised tomography (CT) scan results by mail or telephone, unless clinical assessment was specifically indicated.

We included patients who underwent major surgical resection with free resection margins for primary UICC stage $<$ IV rectal adenocarcinoma (ICD-0-C20.9), age $\geq$18 and fluent in Danish. We excluded patients diagnosed with metastases, synchronous cancer, cognitive deficit, and life expectancy $<$ two years as assessed by the surgeon, participation in competing follow-up studies and insufficient mastery of the Danish language. Patients were followed until date of diagnosed recurrence (local or distant), metachronous cancers, withdrawal of consent, migration out of the two participating

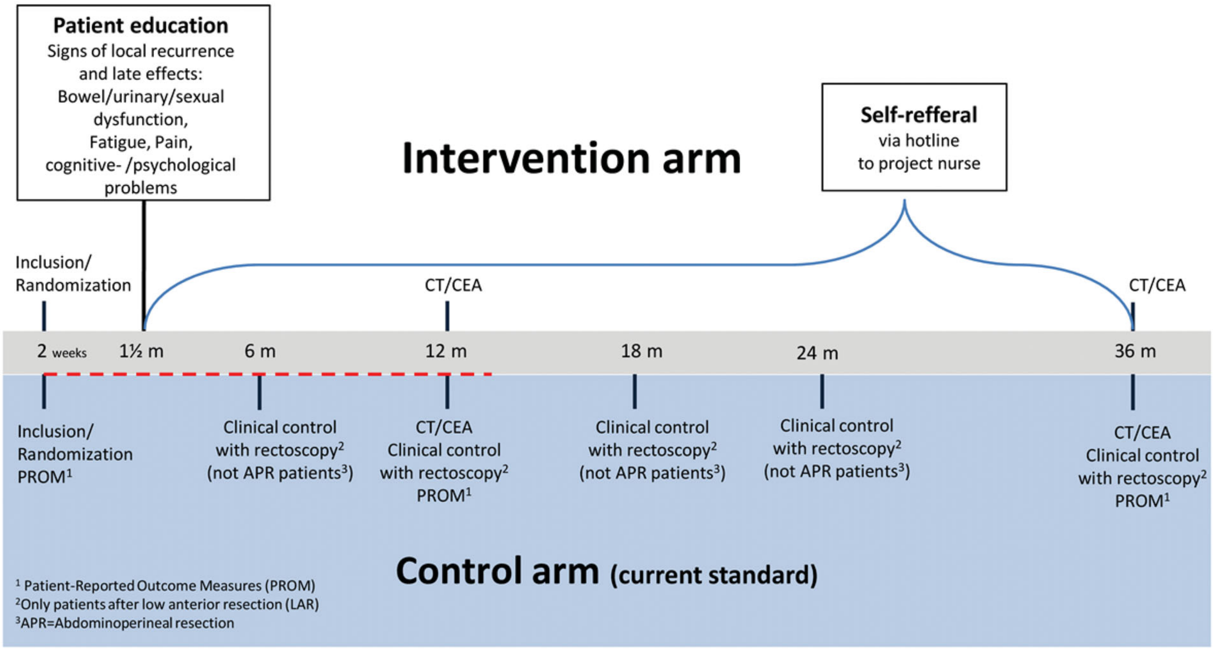

Figure 1. Design of the FURCA trial (dotted red line marks the time period for this interim analysis).

regions or death, whichever came first. Inclusion was completed by August 2018.

Data and measures

Patient data were managed by the web-based software platform 'Research Electronic Data Capture' (REDCap) [15], and filed on secure servers hosted by Aarhus University, Denmark.

Registration and categorisation of contacts

We used the following definitions for the different kinds of contacts:

Self-referrals, were patient-initiated contacts to the FURCA project nurse, either by phone or email. This option was available only for patients in the intervention arm. All self-referrals were prospectively registered in the study case report form in REDCap by the project nurse, and included date, cause and response/management.

For patients in both arms, hospital contacts in the patient's primary department during the first year were registered in a systematic audit of electronic medical records.

Routine clinical doctor-visits, included pre-scheduled 6- and 12-month visits, and did *not* include visits related to stoma reversal, vacuum assisted closure (VAC) treatment or clean colonoscopy.

Planned admissions, covered most of the planned stoma reversal procedures, dilatation of the anastomosis and admission of frail patients prior to polypectomy, etc.

Telephone contacts, covered telephone consultations with health professionals (excluding self-referrals in the intervention-arm, which were categorised separately as described above)

All contacts, included contact by telephone, mail, hospital admissions and outpatient clinic visits, and patients' self-referrals to the project nurse and the initial FURCA education session for patients in the intervention arm.

Patient-reported outcome measures (PROMs)

Patient involvement was measured with six selected items from a comprehensive questionnaire thoroughly developed by the Danish Centre for Quality (DEFACTUM) [16]. Items are rated on a numerical scale from 1 (not at all) to 10 (highly agree), and have been evaluated for their face validity, pending further psychometric validation [16]. Ratings were reported with median scores and corresponding interquartile range for each item.

Patient satisfaction with follow-up was measured with five items addressing perceived level of information and support. The items were selected from a validated questionnaire developed by the Danish Cancer Society [17]. These items were scored on a 5-point Likert scale. Item 1-3 were dichotomised into 'sufficient/almost sufficient' including the three most positive categories vs 'not sufficient/no information' including the two remaining categories. For items 4-5, the category 'No help needed' was omitted from analysis, and the remaining four options were dichotomised into 'high/some degree' vs 'insufficient/no help'

Self-management was measured with the 13-item Patient Activation Measure (PAM). PAM is rated on a 5-item Guttman-like scale, of which four levels of activation is derived, ranging from level 1 (low activation) to level 4 (high activation) The items measure critical elements for patient activation: skills, knowledge, confidence and behaviour, and PAM is considered to predict self-management behaviours. PAM is translated and validated in a Danish population [18].

Fear of cancer recurrence (FCR) was evaluated using the Fear of Cancer Recurrence Inventory (FCRI). The FCRI is a multidimensional, measure for FCR, thus matching the complexity and multidimensionality of the construct [6,19]. High scores indicate high levels of FCR. A cut-off value for clinical FCR is defined by a score of 16 or higher on the 9-item severity sub-scale [20]. The FCRI has shown sufficient psychometric properties in several languages and settings, and has been translated and validated in a Danish version [6].

Statistical analysis

Hospital contacts in the primary department during follow-up were analysed, comparing the number and types of contacts in the two allocation arms. In the intervention arm, the total number of hospital contacts included self-referrals and FURCA education sessions in addition to other contacts. A sub-analysis was conducted with two items regarding patient-perceived help and support, stratified by four contact-frequency groups.

Between-arm differences were tested for significance using the Wilcoxon rank sum test for total number of contacts and Fisher's exact test for differences in types of contacts.

For patients in the intervention arm, descriptive analyses of self-referrals in-between scheduled contacts were reported in plots and tables. Potential associations between self-referrals and covariates at baseline were examined and tested for significance using ANOVA for means and the Kruskall-Wallis test (gender, age, type of surgery, oncological treatment, optimism, self-management and fear of recurrence).

Differences and associations were considered significant if $p < 0.05$.

Ethics and data protection

Participation was conditional on informed consent, following written and oral information, delivered by the project nurse and the surgeon. The FURCA-trial is registered at the Danish Data Protection Agency, follows the ethical principles of the Helsinki Declaration and has been approved by The National Committee on Health Research Ethics. Trial registration number in clinicaltrials.gov is R97-A6511-14-S23.

Results

As illustrated in Table 1, baseline characteristics were similar in the two allocation arms, which included 336/512 (66%)

Table 1. Background variables at baseline.

	Control ($n = 168$)	Intervention ($n = 168$)	p-Value
Demographic variables			
Age at time of surgery, mean (sd)	65.6 (9.9)	65.2 (8.0)	0.70[a]
Age groups (years), n (%)			0.53[b]
<50	8 (4.8)	6 (3.6)	
50–59	37 (22.0)	38 (22.6)	
60–69	67 (39.9)	75 (44.6)	
70–79	47 (28.0)	48 (28.6)	
≥80	9 (5.4)	1 (1.0)	
Gender, – (%)			0.80[c]
Female	56 (33.3)	54 (32.1)	
Male	112 (66.7)	114 (67.9)	
Clinical variables			
Type of surgery[d], n (%)			0.48[b]
TME	76 (45.2)	66 (39.3)	
PME	31 (18.5)	40 (23.8)	
APR/Hartmann	61 (36.3)	62 (36.9)	
Stage (UICC), n (%)			0.73[b]
Stage 0	10 (6.0)	9 (5.4)	
Stage I	65 (38.7)	63 (37.5)	
Stage II	41 (24.4)	42 (25.0)	
Stage III	52 (31.0)	54 (32.1)	
Neoadjuvant oncological treatment, n (%)			0.95[b]
Yes	39 (23.6)	40 (23.8)	
No	127 (75.1)	128 (76.2)	
Missing	2 (1.2)	0 (0)	
Adjuvant oncological treatment, n (%)			0.28[c]
Yes	40 (24.0)	49 (29.2)	
No	127 (76.0)	119 (70.8)	
Patient-reported variables			
Fear of cancer recurrence (FCRI)	($n = 159$)	($n = 159$)	
Severity score, mean (sd)	48.3 (24.3)	47.9 (23.5)	0.89[a]
Clinical FCR, n (%)	41 (24.4)	30 (17.7)	0.14[c]
Patient activation measure (PAM)	($n = 144$)	($n = 142$)	0.98[b]
Level 1	14 (9.7)	9 (6.3)	
Level 2	17 (11.8)	18 (12.7)	
Level 3	77 (53.5)	84 (59.2)	
Level 4	36 (25.0)	31 (21.8)	

[a]Student's *t*-test; [b]Wilcoxon rank sum test; [c]Chi square test; [d]TME: total mesorectal excision; PME: partial mesorectal excision; APR: abdominoperineal resection.

eligible patients who accepted participation (Flowchart in Online Resource 1). Previous analysis of non-participants showed a female preponderance among non-participants who were significantly older and had a poorer performance status at the time of diagnosis [21].

Hospital contacts (n = visit counts)

The total number of hospital contacts in the intervention arm ($n = 1,451$) did not differ significantly ($p = 0.44$) from the total number of contacts in the control arm ($n = 1,229$) (Table 2). However, a significant difference was seen in the pattern of contacts ($p = 0.004$), since more patients in the intervention arm (17%) than in the control arm (7%) had ≥15 contacts (Figure 2).

Outpatient doctor visits

The total number of doctor visits was significantly lower in the intervention arm. The number of routine doctor visits was lower in the intervention arm ($n = 137$) than in the control arm ($n = 299$) ($p < 0.001$) due to the design of the study. Inversely, no significant difference in non-routine doctor visits was seen between the two arms (n control = 71, n intervention = 94, $p = 0.15$).

Outpatient nurse visits

Patients in the intervention arm had more nurse visits than had patients in the control arm due to the FURCA education session delivered by a specialist nurse. Otherwise, clinical nurse visits did not differ between the two arms (n control = 340, n intervention = 358, $p = 0.27$).

Telephone and mail contacts

Overall, the number of telephone contacts did not differ between the arms ($p = 0.59$). Fewer patients ($p = 0.01$) in the control arm than in the intervention arm had e-mail/postal contacts due to the design difference in how the one-year CT scan result was delivered.

Patient involvement and satisfaction at one year's follow-up

Patient involvement

The median score/interquartile range (IQR) in all six items was in favour of the intervention arm. For items 4 and 5, the difference was statistically significant (p-values 0.04 and 0.004, respectively) (Table 3(a)).

Patient satisfaction

For items 1-3 regarding satisfaction with received information, patients in the intervention arm were significantly more satisfied than were patients in the control arm. Likewise, the proportion of patients reporting high or some degree of relevant help and support was significantly higher in the intervention arm than in the control arm (p-values 0.028 and 0.036, respectively). The two items regarding patient-perceived help and support during follow-up were stratified by the four frequency groups for contacts, displayed in Figure 2. Sub-analysis revealed that patients in the intervention arm with many contacts reported statistically significantly improved satisfaction with help and support for physical problems, while the differences regarding help and support for emotional problems levelled out with stratification (Table 3(b)).

Patient self-referrals in the intervention arm

Number of self-referrals

Of 168 patients in the intervention arm, 95 (57%) did not contact the project nurse at all during the first year. The remaining 73 (43%) patients made altogether 169 contacts to the project nurse. Fifty-nine patients (35%) made 1-3 contacts each, while 14 patients (8%) made ≥ 4 contacts each, corresponding to a total of 72 (42%) of all self-referrals.

Table 2. Contacts in patient's primary department during 1st year of follow-up.

	Control (*n* = 168)	Intervention (*n* = 168)	*p*
Number of contacts			
Total number of contacts	1229	1451	0.44[a]
Number of contacts per patient, median (IQR)	6.5 (4–9)	6 (4–12)	
Outpatient clinical visit (doctor)			
Total number of outpatient clinical visits (doctor)	521	342	<0.001[a]
Number of visits per patient, median (IQR)	2 (2–4)	1 (0–3)	
Planned routine clinical visit			<0.001[b]
No contacts, *n* (%)	25 (16)	104 (62)	
≥1 Contact, *n* (%)	143 (84)	64 (38)	
Extra clinical visit (not routine)			0.20[b]
No contacts, *n* (%)	148 (88)	144 (86)	
≥1 Contact, *n* (%)	20 (12)	24 (14)	
Clinical visit initiated by the patient			0.33[b]
No contacts, *n* (%)	144 (86)	132 (79)	
≥1 Contact, *n* (%)	24 (14)	36 (21)	
Clinical visit related to stoma reversal (pre/post)			0.66[b]
No contacts, *n* (%)	100 (60)	109 (65)	
≥1 Contact, *n* (%)	68 (40)	59 (35)	
Clinical visit related to vacuum-assisted closure (VAC) treatment			0.62[b]
No contacts, *n* (%)	162 (96)	165 (98)	
≥1 Contact, *n* (%)	6 (4)	3 (2)	
Postoperative colonoscopy ('clean colon')			0.08[b]
No contacts, *n* (%)	142 (85)	131 (78)	
≥1 Contact, *n* (%)	26 (15)	37 (22)	
Outpatient clinical visit (nurse)			
Total number of outpatient clinical visits (nurse)	340	358	0.27[a]
Number of visits per patient, median (IQR)	2 (0–3)	1 (0–3)	
Clinical visit at stoma clinic			0.25[b]
No contacts, *n* (%)	61 (36)	78 (46)	
≥1 Contact, *n* (%)	107 (64)	90 (54)	
Clinical visit at specialist nurse clinic (bowel function specialist)			0.31[b]
No contacts, *n* (%)	160 (95)	165 (98)	
≥1 Contact, *n* (%)	8 (5)	3 (2)	
Telephone and mail consultation			–
Total number of phone/mail contacts	264	339	0.002[a]
Number of contacts per patient, median (IQR)	1 (0–2)	1 (1–2)	
Telephone consultation			0.59[b]
No contacts, *n* (%)	111 (66)	99 (59)	
≥1 Contact, *n* (%)	57 (34)	69 (41)	
E-mail/postal mail			0.01[b]
No contacts, *n* (%)	86 (51)	54 (32)	
≥1 Contact, *n* (%)	82 (49)	114 (68)	
Hospital admission			
Total number of hospital admissions	104	76	0.05[a]
Number of visits per patient, median (IQR)	0 (0-1)	0 (0-1)	
Planned admission			0.65[b]
No contacts, *n* (%)	113 (67)	122 (73)	
≥1 Contact, *n* (%)	55 (33)	46 (27)	
Acute admission			0.30[b]
No contacts, *n* (%)	141 (84)	149 (89)	
≥1 Contact, *n* (%)	27 (16)	19 (11)	
FURCA intervention			
Total number of FURCA contacts	–	336	
Number of contacts per patient, median (IQR)	–	1 (1–2)	
FURCA education			
No contacts, *n* (%)	–	1 (0.5)	
≥1 Contact, *n* (%)	–	167 (99.5)	
Self-referral FURCA (nurse), *n* (%)			
No contacts, *n* (%)	–	95 (57)	
≥1 Contact, *n* (%)	–	73 (43)	

[a] Wilcoxon rank sum test; [b] Fisher's exact test.

Impact of baseline characteristics on patients' self-referral

Patients with low baseline self-management measured by PAM did not have significantly more self-referral contacts than did patients with a high level of self-management ($p = 0.61$). Likewise, no significant difference in number of self-referrals appeared between patients with and without baseline clinical FCR (FCRI-SF score) ($p = 0.14$).

Other baseline factors (age, gender, neoadjuvant and adjuvant oncological treatment) showed no association with number of self-referrals, except from type of surgery. Patients having total mesorectal excision (TME) surgery had more self-referrals than patients undergoing other kinds of surgery did ($p = 0.001$).

Reasons for self-referrals

The primary reason for self-referral was bowel dysfunction (without stoma), with 31 unique patients making altogether

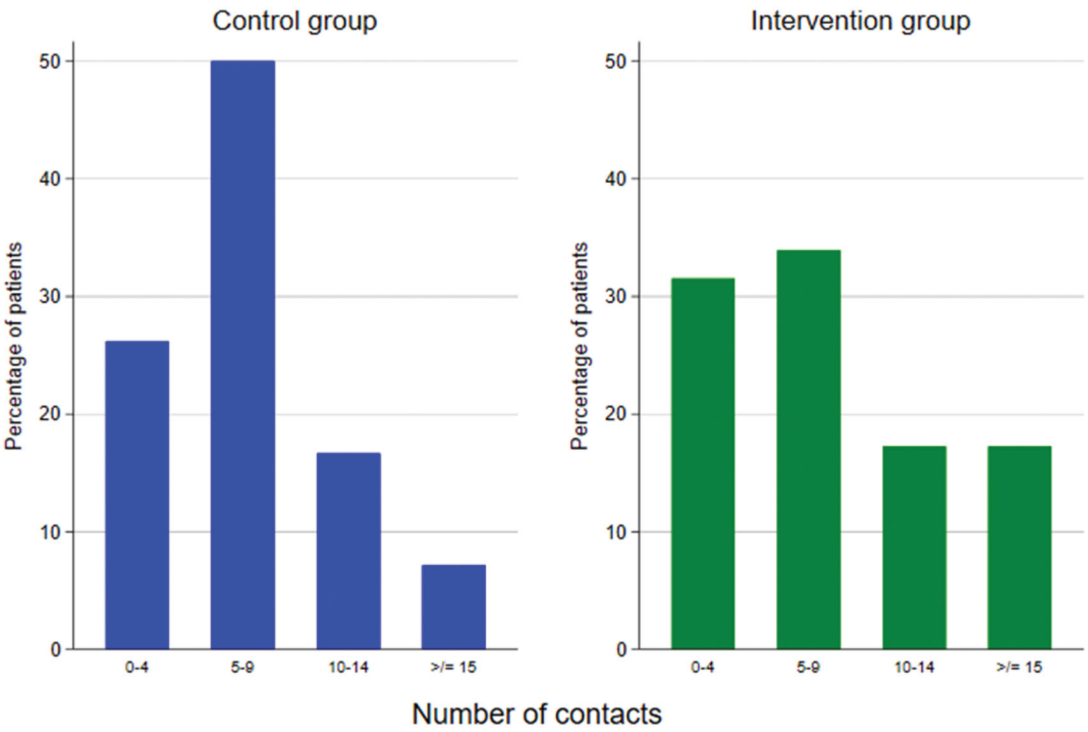

Figure 2. All contacts per allocation arm.

67 contacts during the first year. The second and third most frequent reasons were stoma problems and pain, with 14 and 10 patients being accountable for 17 and 10 self-referrals, respectively. The remaining reasons were sexual dysfunction [4], urinary dysfunction [2], fatigue [2], intestinal bleeding [3] and other physical [8] and psychological distress [4].

A considerable number of self-referrals were categorised as 'other' (63). This category comprised questions or concerns regarding logistical issues. Out of the total number of self-referrals, only eight were registered as signs of recurrence and were responded to accordingly in terms of an immediate clinical visit at a doctor's program and institution of relevant procedures. None of the eight cases led to identification of recurrent disease.

Violation of the protocol

In the control arm, 25 patients had no planned routine visit registered during the first year of follow-up. These were mainly patients with abdominoperineal resection (APR) who had no scheduled 6-months visit (per protocol) and who received the results from their 1-year CT scan per mail ($n = 12$). Some patients with TME/PME had no 6- or 12-month visit, but had other clinical visits in relation to stoma reversal or colonoscopy, replacing the routine visits ($n = 10$). Finally, three patients in the control arm ended follow-up prior to the 6 or 12-month clinical visits.

In the intervention arm, 64 patients had planned routine clinical visits registered. This was partly due to clinical decisions that a six-month check-up was necessary, i.e., for patients with post-operative complications, or because of the hospital's non-compliance with the protocol. A sub-analysis was performed in order to reveal a potential difference in satisfaction between intervention arm-patients with and without routine clinical visits. The sub-analysis revealed no significant differences, and no trend was seen towards more or less satisfaction among intervention-arm patients with routine clinical visits.

One patient in the intervention arm did not receive education due to dropout just after allocation.

Discussion

In this one-year follow-up of a randomised study comparing a patient-led follow-up strategy to traditional follow-up of patients with rectal cancer, we observed significantly fewer doctor consultations, more nurse consultations and higher involvement and satisfaction with information and support in the intervention arm than among patients in the control arm. No previous studies have evaluated the effect in a colorectal cancer population of replacement of outpatient doctor consultations with patient-initiated follow-up in a specialist nurse setting in a randomised design.

Addition of nurse-led follow-up to standard follow-up of patients with colorectal cancer has been evaluated in two randomised trials [10,22] and one observational study [11]. Jefford et al. added a SurvivorCare package (educational material, survivorship care plan, needs assessment and nurse-led end-of-treatment session and three follow-up phone calls) to standard follow-up in the intervention arm [10]. Young et al. added a supportive care intervention consisting of five scheduled, structured phone calls performed by a specialised nurse [22]. In both studies, extra nurse consultations were part of the design, yet none of them had a self-referral option [10,22].

Table 3. (a and b) Differences in patient involvement and satisfaction after at year's follow-up.

3a: Patient involvement in follow-up [16] Numerical rating scale from 1 (not at all) to 10 (highly agree)	Control	Intervention	p^a
1. I had the opportunity to talk with health professionals regarding my questions and concerns (median IQR) ($n = 261$)	8 (5–9)	8 (6–10)	0.11
2. I experienced presence and attention in consultations with health professionals (median; IQR) ($n = 264$)	8 (7–10)	9 (7–10)	0.10
3. I was taken on board when decisions were made (median; IQR) ($n = 229$)	8 (6–10)	9 (7–10)	0.16
4. Privacy and quietness have characterised my conversations with health professionals (median; IQR) ($n = 256$)	8 (7–10)	9 (8–10)	0.04
5. The health professionals have strived to understand what has been most important to me (median; IQR) ($n = 245$)	8 (6–9)	9 (8–10)	0.004
6. The health professionals have shown interest in my preferences for involving my next of kin in the follow-up (median; IQR) ($n = 228$)	8 (7–10)	9 (8–10)	0.08
3b. Patient-perceived satisfaction (information, help and support) [17] Dichotomised into 'sufficient/almost sufficient' vs. 'not sufficient/no information' (item 1–3) and 'high/some degree' vs. 'insufficient/no help' (items 4–5)			
1. How would you describe the information you received at the hospital regarding crucial symptoms that require your action? ($n = 294$) ***Sufficient/almost sufficient*** (n, %)	110 (75.9%)	133 (89.3%)	0.003
2. How would you describe the information you received at the hospital regarding where to make contact, in case of concerns and symptoms? ($n = 296$) ***Sufficient/almost sufficient*** (n, %)	119 (81.5%)	135 (90.0%)	0.04
3. How would you describe the information you received at the hospital regarding potential late effects from your disease and treatment? ($n = 295$) ***Sufficient/almost sufficient*** (n, %)	114 (78.1%)	134 (89.9%)	0.01
4. Have you received adequate help and support* during your follow-up, related to physical problems (i.e., pain and fatigue)? ($n = 208$, patients with no need were not included) ***High/some degree*** (n/%)	82 (79.6%)	95 (90.5%)	0.03
0–4 contacts	17 (77%)	22 (85%)	0.52
5–9 contacts	46 (87%)	28 (90%)	0.63
10–14 contacts	14 (74%)	23 (96%)	0.04
≥15 contacts	5 (56%)	22 (92%)	0.02
5. Have you received adequate help and support* during your follow-up, related to emotional problems (i.e., fear of cancer recurrence and depressive thoughts)? ($n = 183$, patients with no need were not included) ***High/some degree*** (n/%)	62 (66.0%)	71 (79.8%)	0.04
0–4 contacts	11 (50%)	18 (75%)	0.08
5–9 contacts	37 (73%)	23 (88%)	0.11
1–14 contacts	11 (79%)	13 (77%)	0.89
≥15 contacts	3 (43%)	17 (77%)	0.09

[a] Wilcoxon rank sum test; [b] Chi^2 significance test.

A non-randomised study by Batehup et al. introduced a model with patient-triggered follow-up, meaning fewer doctor consultations and a larger role for the clinical specialist nurse. Patients entered the model after any ongoing symptoms had been managed, and attended a one-time self-management workshop. After that, no further routine visits were arranged [11]. Two other non-randomised studies have evaluated the implementation of remote surveillance as replacement for hospital based follow-up [23,24]. Qaderi et al. offered remote surveillance to patients after at least one-year hospital-based follow-up [24], while Siddika et al. included a selected group of CRC-survivors [23]. In both studies, patients were provide with contact details of the hospital, management plan and information [23,24]

Number and pattern of hospital contacts. The total number of hospital contacts was similar in the two arms, but the proportion of doctor contacts was substantially reduced, from 42% in the control arm to 23% in the intervention arm.

The two randomised trials by Young and Jefford did not report a reduced number of doctor contacts but added nurse contacts per design [10,22]. Young et al. found a non-significant drop in readmissions and emergency room contacts in the intervention arm [22]. In the study by Batehup et al., evaluation of costs and resources showed that patient-triggered follow-up freed clinical capacity; yet at the same time, it was slightly more expensive than standard outpatient follow-up [11]. Hypothetically generated findings from the studies of remote surveillance indicated a major resource saving by replacing routine visits with patient-initiated contacts [23,24]. This supports the findings from our study, implying that patient-led follow-up might improve use of sparse health care resources.

Patient involvement and satisfaction

Patients in the intervention arm reported a higher degree of involvement and more satisfaction during follow-up, and they had fewer unmet needs. Our findings imply that the patient-led program successfully delivered a relevant intervention and that patients' individual needs were met to a higher degree.

Patient involvement

The reporting of patient-perceived involvement is limited in other studies of alternative follow-up after CRC. Qaderi et al concluded that patient-perceived involvement was not compromised in remote surveillance [24], while other studies have not reported patient involvement explicitly [10,11,22,23]. In our trial, self-management is a crucial feature, based on education and easy access to support and advice. This corresponds to basic principles in patient involvement. However, the change in contact type from outpatient visits to telephone contacts might interfere with the patients' experienced involvement, i.e., it requires extra consideration to involve next of kins in telephone consultations, and perception of presence and attention might be differently expressed in telephone vs physical consultations.

Nevertheless, perceived involvement was overall high in both arms, with median scores of 8 to 9 (with 10 being the maximum score).

Patient satisfaction

Patients in the intervention arm reported significantly higher satisfaction on all five items. Interestingly, patients with many contacts were significantly more satisfied with help and support for physical problems in the intervention arm than in the control arm. This could indicate that patients with many concerns will benefit in particular from the new follow-up program.

In Jefford *et al.*'s study of nurse-led follow-up, patients who received the SurvivorCare package were more satisfied than patients in the control group [10]. Inversely, Batehup *et al.* found no improvement in patient-experienced quality of care in patient-initiated follow-up; yet, satisfaction was in general high [11]. High patient satisfaction with remote surveillance was reported by Siddika and Qaderi, yet with no control group for comparison [23,24]. Patients' views were evaluated qualitatively in the study by Young et al. They identified three main groups with different views on the usefulness of the intervention: one group had needs covered by the standard follow-up service, one group had minimal events and few problems in their recovery, and a third group with acute or recurring concerns found the intervention useful and important to their recovery [22]. This result supports a strategy for individualised and accessible services targeting patients' different concerns and needs during follow-up.

Pattern of self-referrals in the intervention arm

Self-referral contacts were made by 73 patients (43%) in the intervention arm. Among these, only 14 patients (8%) had $\geq$ 4 self-referrals. Patients with few or no self-referrals may have had their needs for information and support covered through other contacts. Our finding supports the merits of a more tailored follow-up with an option of fewer contacts for patients with fewer needs, while patients with more needs enjoy better access to help and support. The main reasons for self-referrals were bowel dysfunction and practical issues, echoing experiences from recent years' implementation of a multi-centre screening program for late sequelae in Danish colorectal cancer clinics [25]. The findings indicate that bowel dysfunction is highly prevalent in this population. As bowel dysfunction may have severe negative impact on QoL [4] and work ability [26], and since effective treatment options are readily available in the Danish health care system, an efficient identification of these problems, and a clear strategy for referral of patients to specialised late sequelae clinics can potentially improve the QoL of a large number of rectal cancer patients.

We observed only few contacts for other reasons than bowel dysfunction. This result differs from those reported in prevalence studies of physical and psychological problems among survivors of rectal cancer [3,27,28]. It also diverges from experiences in a more recent Danish screening program for late sequelae screening [25]. In the FURCA trial, all patients in the intervention arm attended education regarding types of late sequelae and were informed about the self-referral option early in the follow-up; they received no further reminders of the broad self-referral option.

We hypothesised that patients with high self-management (high PAM score) would be more prone to make contact than would patients with a low engagement, the underlying supposition being that the active elements in the intervention were based on self-management [29]. No association was found between self-referral and a high PAM score, maybe due to a truly rejection of our hypothesis. However, a more likely explanation is that self-management is a complex domain requiring a more thorough investigation. Barlow et al. defined self-management as the individual's ability to manage symptoms, treatment, physical and psychosocial consequences from chronic illness. In this lies the individual's ability to monitor one's condition and to respond adequately to changes [30]. We believe this approach may apply to long-term cancer survivors as well. However, more in-depth studies are planned to investigate the aspects of self-management in patient-led follow-up for rectal cancer patients.

We further hypothesised that patients with a high level of FCR at baseline would have more frequent self-referrals than would patients with a low level of FCR, the underlying assumption being that patients with high FCR would have a reassurance-seeking behaviour through self-referrals. However, this hypothesis was not supported. This may be due to the highly complex and multi-dimensional nature of FCR involving multiple coping strategies for the patient, such as avoidance or internal self-assurance [31]. The aspects and details of FCR in this study population will be reported in-depth when reporting the final endpoint for the trial after 3 years' follow-up.

Strengths and limitations

The main strength of this study is its block-randomised, controlled and prospective design adjusting for potential confounding. In spite of the comprehensive nature of the intervention, altering standard follow-up to patient-led follow-up, 66% of the invited patients accepted participation. The inclusion rate in other studies testing patient-led follow-up ranges from 47% [32] to 78% [33].

Another strength of the study is the well-defined population from four treating centres covering about one third of the Danish population, which improves its representativeness across settings and demographics in the Danish healthcare system. All patient-reported outcome measures were validated.

The study does have limitations. It is an intervention study, so the population is more selected than if we had used a non-experimental design; yet, our use of wide inclusion criteria weighed against an over-selected population selection. A non-participation rate of 34% invites a risk of undifferentiated selection bias. However, the analysis of non-participants added strength and further insight into selection and representativeness, partly boding for this bias. The study found that a higher proportion of non-participants were female, significantly older and with poorer performance status at the time of diagnosis [21]. Reasons for rejection were explained by about two thirds of non-participants, most frequent causes being lack ofsurplus energy, followed by having other preferences for follow-up [21]. To prevent inequality in follow up after rectal cancer, it is important to reach all patients, not just the strongest. In another ongoing study we have recently shown that >80% of our colorectal cancer patients are willing to participate in a systematic screening for late sequelae via PROMs. Although the participation rate was negatively associated with age, as many as 74.4% of patients older than 75 years, were willing to participate [25]. However, any implementations of new follow up strategies must take into account, that a minor proportion of patients, especially the oldest, may need a tailored follow up program with pre-scheduled contacts initiated by healthcare professionals.

The FURCA trial study was launched in 2015 with three years' follow-up. Follow-up programs are being revised in Danish and international health care politics, with a tendency to decrease routine out-patient activities and focus on individualised cancer follow-up. This tendency adds to the urge of reporting the selected findings from the first year of the FURCA-trial.

In conclusion, the findings from this analysis of one-year FURCA data demonstrate the value of a patient-led follow-up program in terms of more individually tailored intervention measures where patients with needs and problems make contact and where the majority of tasks are managed by nurses. Hence, clinical resources can be allocated in smarter ways with enhanced specialised attention to patients with problems and follow-up needs, and fewer disturbing and 'empty' contacts for patients with uncomplicated survivorship. Furthermore, the patient-led follow-up came with improved patient-perceived involvement and satisfaction, thus not only being acceptable but also favourable for the patients.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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