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Effects of Survivorship Care Plans on patient reported outcomes in ovarian cancer during 2-year follow-up – The ROGY care trial

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HIGHLIGHTS

- SCPs did not increase satisfaction with information provision or care in ovarian cancer patients.
- SCPs led to a lower trust in the treatment among ovarian cancer patients.
- Our trial results suggest that patients may not benefit from an SCP as was proposed by the National Academy of Medicine.

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ABSTRACT

Objective. The aim of this study was to assess the long-term impact of an automatically generated Survivorship Care Plan (SCP) on patient reported outcomes in ovarian cancer in routine clinical practice. Outcome measures included satisfaction with information provision and care, illness perceptions and health care utilization.

Methods. In this pragmatic cluster randomized trial, twelve hospitals in the South of the Netherlands were randomized to 'SCP care' or 'usual care'. All newly diagnosed ovarian cancer patients in the 'SCP care' arm received an SCP that was automatically generated by the oncology provider, by clicking a button in the web-based Registrationsystem Oncological GYnecology (ROGY). Ovarian cancer patients ($N = 174$, mean age 63.3, SD = 11.4; all stages) completed questionnaires directly after initial treatment and after 6, 12 and 24 months.

Results. First questionnaires were returned from 61 (67%) ovarian cancer patients in the 'SCP care' arm and 113 (72%) patients in the 'usual care' arm. In the 'SCP care' arm, 66% ($N = 41$) of the patients reported receipt of an SCP. No overall differences were observed between the trial arms on satisfaction with information provision, satisfaction with care or health care utilization. Regarding illness perceptions, patients in the 'SCP care' arm had lower beliefs that the treatment would help to cure their disease (overall, 6.7 vs. 7.5, $P < 0.01$).

Conclusions. SCPs did not increase satisfaction with information provision or care in ovarian cancer patients. Our trial results suggest that ovarian cancer patients may not benefit from an SCP.

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1. Introduction

The number of cancer patients that live with or beyond cancer is increasing worldwide, due to earlier detection, rapid improvement of treatments and aging [1]. Consequently, a growing number of cancer survivors face physical and psychological challenges in life after treatment [2]. The provision of Survivorship Care Plans (SCPs), yielding patient-tailored information for cancer survivors to deal with these challenges, has been widely recommended for all cancer survivors [3]. However, evidence for informed implementation of SCPs in routine clinical practice is limited [4,5].

Three randomized controlled trials (RCTs) did not find an effect of SCPs on short or long-term satisfaction with care, quality of life or distress [6–9]. The ROGY care trial was the first RCT with a pragmatic cluster randomized design, which maximizes external validity and prevents contamination between trial arms [10]. Prior results from the ROGY care trial showed that in endometrial cancer patients, automatically generated SCPs increased the perceived amount of information received but did not improve satisfaction with information provision or care, up to one year after diagnosis [11]. In contrast to the other RCTs, the ROGY care trial found an effect on other outcomes: SCPs increased worry, emotional impact, experienced symptoms and contact with the primary care physician about their disease [11]. Based on current evidence, no definite conclusions can be drawn on the benefit of SCPs. Moreover, potential negative consequences should be considered. The ROGY care trial was designed and powered to separately evaluate the impact of SCPs in endometrial and ovarian cancer patients in order to take into account the potential moderation effect of different treatment regimens and prognosis between these two types of cancer.

In contrast to endometrial cancer, ovarian cancer is often detected at an advance stage, resulting in a poor prognosis [12]. Current 5-year survival of ovarian cancer patients is only 38–46% in developed countries [12,13]. Subsequently, information provided in an SCP (i.e. patients' cancer stage and grade, patients' treatments and long-term and late effects of the treatments) is often unfavorable and may be perceived as threatening. The initial hypotheses of the ROGY care trial was that SCPs would have a positive effect on patient reported outcomes. However, earlier findings from the ROGY care trial related to patients with endometrial cancer suggest that SCPs may also increase threatening illness perceptions. We now expect that SCPs would worsen illness perceptions in ovarian cancer patients just as they did in endometrial cancer patients.

The current study aims to assess the impact of automatically generated SCPs in the ROGY care trial on patient-reported outcomes in ovarian cancer patients up to two years after diagnosis, including satisfaction with information provision and care, illness perceptions and health care utilization.

2. Methods

2.1. Design

The pragmatic cluster randomized ROGY care trial among 221 endometrial and 174 ovarian cancer patients was conducted to assess the longitudinal impact of automatically generated SCPs on patient and health care provider reported outcomes. In the south of the Netherlands, twelve hospitals were randomly allocated to either 'usual care' or 'SCP care'. The trial was centrally approved by a Medical Research Ethics Committee, as well as by each participating center [10]. Accordingly, the current study describes the results of the impact of SCPs on patient reported outcomes in ovarian cancer patients. The impact of SCPs on health care provider reported outcomes has been described previously [14].

2.2. Participants and recruitment

All patients newly diagnosed with ovarian cancer as a primary tumor between April 2011 and March 2014 were invited to participate. Patients were excluded if they had borderline ovarian cancer, were undergoing palliative care or were unable to complete a Dutch questionnaire [10]. All eligible patients in both trial arms were included in the study shortly after initial treatment. Patients were invited to take part by means of a letter, accompanied with an informed consent form and a questionnaire, provided to the patient by their own gynecologist [10,15]. After consent, follow-up questionnaires were sent directly to the patients' home address at 6, 12, 18 and 24 months after treatment (Fig. 1). Questionnaires collected at 18 months after diagnosis did not include questions on any of the outcomes in the current study and was therefore not included in the current analysis.

2.3. Randomization and blinding

To avoid potential contamination between the trial arms, a cluster-randomized design with randomization on hospital-level was chosen. Hospitals were included if they used the registration system ROGY, which was needed to generate SCPs. To prevent imbalance between the trial arms, stratified randomization was used according to whether a hospital has a Gynecologic Oncology Center, and the annual number of endometrial and ovarian cancer patients diagnosed in each hospital. Randomization was performed via a table of random numbers, by an independent researcher blinded to the identity of the hospitals. Patients, but not oncology providers or researchers assessing the outcomes, were blinded to trial assignment [16].

2.4. SCP care versus usual care

In the hospitals that were allocated to 'usual care', standard care was provided in accordance to the Dutch follow-up guidelines. These guidelines include: verbal and written information about the period after treatment and follow-up, about signs of recurrence, and hospital contact details. In most hospitals, verbal information and the generic brochures of the Dutch Cancer Society were provided [14]. None of the hospitals provided SCPs as developed for this study.

In the hospitals that were allocated to 'SCP care', all oncology providers (gynecologist/gynecologic oncologist and oncology nurses, $N = 24$) attended an instruction evening devoted to when and how SCPs should be provided. They were instructed to provide an SCP to patients at the consultation where the results of histopathology and (adjuvant) treatment plan were discussed, mostly 7–14 days after surgery. If applicable (i.e. if there were any changes in the cancer, treatment or oncology provider), an updated version of the SCP could optionally be discussed in a follow-up consultation [17]. In addition, care providers were instructed to send a copy of the SCP to the patient's primary care physician [18]. In the Netherlands, follow-up care is provided by an oncology provider up to 5 years after diagnosis (www.oncoline.nl). Therefore, the SCP was not meant to transition the patient from oncology care to primary care, but to inform the patient about the treatments, long-term and late effects of the treatments and support services. Practical guidelines were given on the components of the SCP that should minimally be discussed with each patient during the consultation (i.e. diagnosis, prognosis, treatment(s), most important side-effects). Because of the pragmatic approach of the trial, care providers in the 'SCP care' arm were free to choose whether the gynecologist/gynecologic oncologist, or oncology nurse provided the SCP fitting their clinical practice [10].

2.5. Survivorship care plan

The SCP was based on the Dutch translation of the National Academy of Medicine (NAM) SCP template [19], adjusted to the local situation [20] by a group of gynecologists/gynecologic oncologists, oncology nurses, a radiotherapist, medical oncologist, primary care physician, and patients [10]. Texts of the SCP were based on pilot-tested patient education material from the Dutch Cancer Society. In addition, the SCP

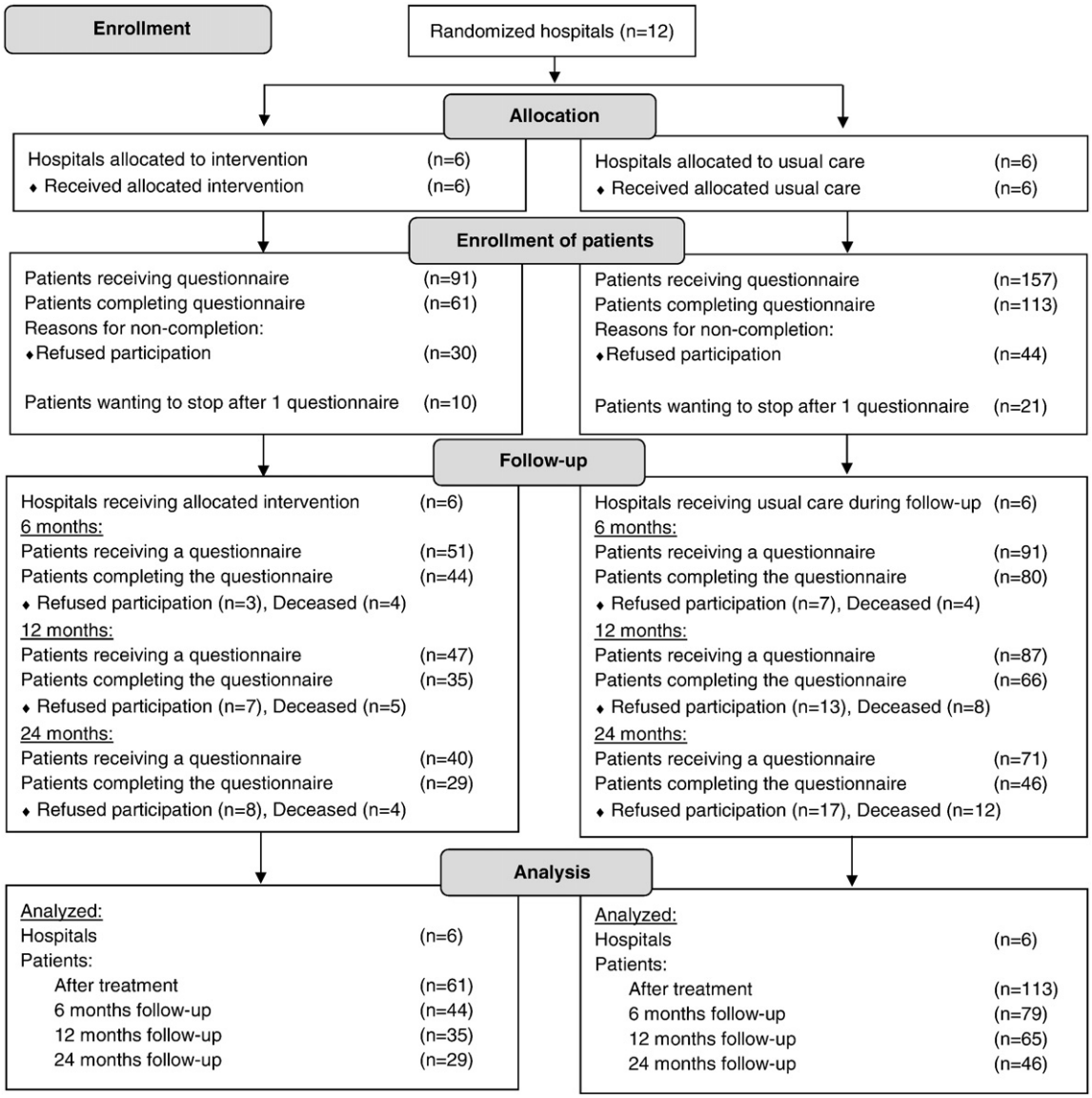

Fig. 1. CONSORT flow-diagram of ovarian cancer patient enrollment.

was pilot-tested on patients with a low/intermediate educational level to ensure that the SCP was understandable.

The SCP consisted of a tailored treatment summary including information on diagnostic tests, type of cancer, stage, grade and treatments received (type of treatment, date and medical specialist) and contact details of the hospital and medical specialists. The treatment summary contained explanatory notes of the clinical information provided and visual representations of affected organs and cancer stage of the patient. In addition, the SCP contained a tailored follow-up care plan, including detailed information on the most common short- and long-term effects of the treatments received, effects on social and sexual life, possible signs of recurrence and secondary tumors, and information on rehabilitation, psychosocial support, and supportive care services [10]. To make sure that patients were aware of receiving an SCP, the front page clearly stated "Survivorship Care Plan".

2.6. Measures

Age, socio-economic status (SES) and clinical data, such as cancer type, cancer stage and date of diagnosis, were obtained from the Netherlands Cancer Registry (NCR). The NCR routinely collects data on newly diagnosed cancer patients in all hospitals in the Netherlands [21]. SES was based on postal code of the residence area of the patient, combining aggregated individual fiscal data on the economic value of the home and household incomes [22]. SES was categorized into low, medium or high. Data obtained from the NCR were available for both participants and non-participants in the trial. Among the participants of the trial, additional socio-demographic information (i.e. marital status, employment status and comorbidities) was assessed in the first questionnaire. Marital status ('married/living together' versus 'divorced/widowed/never married') and employment status ('having a paid job' versus 'not having a paid job') were dichotomized. Comorbidity was assessed by the adapted Self-administered Comorbidity Questionnaire (SCQ), and categorized into no comorbidities, one comorbidity or more than one comorbidities [23].

Information provision was assessed with the EORTC-QLQINFO25 [24]. Scales included four multi-item subscales (information about the disease, medical tests, treatment and other care services) and four single-item scales (information about different places of care, things you can do to help yourself get well, satisfaction with the information, helpfulness of the information). All scales indicated a score between 0 (low perceived information provision) and 100 (high perceived information provision). Internal consistency of the scales (Cronbach's alphas 0.75–0.90) were good. Test-retest reliability (intraclass correlations 0.71–0.91) were good [24].

Satisfaction with care was assessed with the EORTC INPATSAT32 [25]. Scales included two multi-item scales (doctor's interpersonal skills and nurses' interpersonal skills) and two singe-items scales (exchange of information between caregivers and general satisfaction with care). All scales indicated a score between 0 (low perceived quality of care) and 100 (high perceived quality of care). Internal consistency of the scales (Cronbach's alphas 0.93–0.94) were good. Test-retest reliability (intraclass correlations 0.66–0.85) were good [25].

Illness perception was assessed with the Brief Illness Perception Questionnaire (B-IPQ) [26]. Scales included eight single-time scales regarding cognitive illness representations (how much illness affects life, how long illness will continue, how much patient has control over illness, how much treatment helps to cure illness, how many symptoms are experienced), emotional representations (how concerned patient is about illness, how much patient is affected emotionally) and comprehensiveness (how well patient understands illness). All scales indicated a score between 0 (low endorsement) and 10 (high endorsement). Test-retest reliability (Pearson correlations 0.42–0.75) was good [26].

Health care utilization was assessed by the number of visits that were made to a medical specialist or primary care physician in relation to cancer in the past 6 months.

Actual receipt of an SCP was assessed in the first questionnaire ("Did you receive a Survivorship Care Plan?"), in both trial arms. In addition, patients were asked how many times they received the SCP at 6, 12 and 24 months after treatment. If patients in the 'SCP care' arm reported SCP receipt but no SCP was generated in ROGY, they were not included in the per-protocol analysis because it was not possible to receive an SCP when not generated.

2.7. Statistical analysis

Statistical analyses were conducted using Statistical Analysis System (SAS) version 9.4. (SAS Institute, Cary, NC, 1999). Differences in characteristics of patients between the trial arms, between participants and non-participants of the trial, and between participants that completed participation and participants lost to follow-up were compared using *t*-tests for normally distributed continuous variables, Mann-Whitney *U* tests for not-normally distributed variables and chi-square tests for categorical variables.

Linear multilevel regression analysis was performed to assess the effect of SCPs on patient reported outcomes, allowing for adjustment of inter-dependency between repeated measures within patients [27] and correction for data missing at random [28,29]. A random intercept on the patient-level was included in the model to adjust for the inter-dependency between repeated measures. Based on likelihood ratio tests, neither a random intercept on the hospital-level (ICCs < 0.16) to account for the cluster-design, nor a random-slope on the patient-level (ICCs < 0.14) to account for potential dependency between the intervention and outcome variable, improved the model for any of the outcome variables and were therefore not included in the model. All a priori-selected covariates were entered into the model (i.e. age, time since diagnosis, marital status, socio-economic status, employment, comorbidities, stage, and treatment). Dependent variables were the information provision and care-, illness perceptions-, and health care utilization- scales. Additionally, we assessed whether the effect of SCPs differed for each time-point separately by adding a time-reference variable and an interaction term between trial arm and the time-reference variable to the overall model [27].

Intention-to-treat analysis (ITT) compared all patients in the 'SCP care' ($N = 61$) arm to all patients in the 'usual care' arm ($N = 113$). Per-protocol (PP) analysis compared patients in the 'SCP care' arm who reported having received an SCP at any time during follow-up and where an SCP had been generated ($N = 40$), to all patients in the usual care arm ($N = 113$).

The ROGY care trial was powered to detect a clinically meaningful difference of 0.5 SD for SCP care versus usual care on the overall primary outcomes (satisfaction with information provision and satisfaction with care). A total of 150 patients were targeted (75 per trial arm) to attain 80% power, assuming an intra-class correlation (ICC) between the hospitals of 0.005 [10].

3. Results

No differences were observed in socio-demographic or clinical baseline characteristics between the trial arms (Table 1) or between participants and non-participants of the trial (Table 2). However, patients that were lost to follow-up during the trial had a significantly higher FIGO-stage (patients with stage IV, 25% vs. 8% $P = 0.03$) (Table 2).

Questionnaires were sent to 91 patients in the SCP care arm and 157 patients in the usual care arm. Questionnaires were returned after treatment by 61 patients (67%) in the SCP care arm and 113 patients (72%) in the usual care arm. Follow-up questionnaires were received after 6 months (48% SCP care; 51% usual care), 12 months (38% SCP care; 42% usual care) and 24 months (32% SCP care; 29% usual care) (Fig. 1). Post-hoc power analysis show that for detecting a clinically meaningful difference of 0.5 SD on the outcomes, statistical power was sufficient for overall ITT analysis (96%) and for separate ITT analysis after diagnosis (88%), but lower for separate ITT analysis after 6 (75%), 18 (66%) and 24 (55%) months. For PP analysis, statistical power was sufficient for overall analysis of all time-points (89%), but low for analysis of separate time-points (77%, 63%, 52%, 44% respectively).

In the SCP care arm, 40 patients (66%) reported in the first questionnaire that they had received an SCP and 10 patients (16%) reported that they had received an updated follow-up SCP at 6, 12 or 24 months. In the usual care arm, 21 patients (18%) reported that they had received an SCP, and no patients reported receipt of an updated follow-up SCP.

ITT analysis ($N = 174$) showed no significant differences in satisfaction with information provision or satisfaction with care between patients in the SCP care arm and patients in the usual care arm overall. At 6 and 24 months after diagnosis, patients in the SCP care arm reported lower perceived information on other services (6 months: M = 29.8, SD = 23 vs. M = 38.1, SD = 25, $P = 0.02$; 24 months: M = 27.4, SD = 23 vs. M = 34.5, SD = 20, $P = 0.03$), but effect sizes were small ($r = 0.2$). In the PP analysis ($N = 153$), this difference remained only significant after 24 months (M = 27.0, SD = 23 vs. M = 34.5, SD = 20, $P = 0.048$, $r = 0.2$). Further, in ITT analysis only after 24 months, patients in the SCP care arm reported lower satisfaction with the interpersonal skills of the nurses (M = 67.8, SD = 22 vs. M = 83.1, SD = 14, $P = 0.04$, $r = 0.4$), but this difference was not significant in the PP analysis (M = 63.3, SD = 21 vs. M = 83.1, SD = 14, $P = 0.06$, $r = 0.5$) (Table 3).

In the ITT analysis overall, after diagnosis and after 6 and 12 months, patients in the SCP care arm reported lower beliefs that the treatment would help to cure the illness compared to patients in the usual care arm (overall: M = 6.9, SE = 0.2 vs. 7.5, SE = 0.3, $P < 0.01$, $r = 0.2$; after diagnosis, M = 7.2, SD = 2.3; vs. M = 7.8, SD = 1.8, $P = 0.03$, $r = 0.1$; after 6 months, M = 6.7, SD = 2.9 vs. M = 7.2, SD = 2.4, $P = 0.04$, $r = 0.1$; after 12 months: M = 6.4, SD = 2.7 vs. M = 7.2, SD = 2.5, $P < 0.01$, $r = 0.2$) (Table 3, Fig. 2). In PP analysis this finding was only significant overall (M = 7.5, SE = 0.2 vs. M = 6.9, SE = 0.3, $P < 0.01$, $r = 0.2$) and after 12 months (M = 6.6, SD = 2.6 vs. M = 7.2, SD = 2.5, $P < 0.01$, $r = 0.1$;Table 3).

In ITT analysis, patients in the 'SCP care' arm reported less visits to the medical specialist in the 6 months after treatment (M = 4.9, SD = 3.5 vs. M = 7.6, SD = 9.4, $P = 0.04$, $r = 0.2$ Table 3) In additional analysis, we also adjusted for time between first questionnaire and last treatment, to adjust for possible systematic differences in the timing of treatments between the hospitals which could explain the number of visits to the medical specialist, but results were similar (data not shown).

There were no interactions between trial arms and patients lost to follow-up for any of the outcomes, indicating that the effect of SCP care did not differ for patients who were lost to follow-up. There were

Table 1
Baseline socio-demographic and clinical characteristics of participants according to trial arm.

	Total participants ($n = 174$)	SCP care ($n = 61$)	Usual care ($n = 113$)	*P*-value*
Patients				
Age at diagnosis				
Mean (SD)	63.3 (11.4)	63.3 (11.3)	63.3 (11.4)	0.97
Age at time of first questionnaire				
Mean (SD)	64.1 (10.8)	63.6 (11.2)	64.3 (10.7)	0.67
SES, n (%)				
Low	31 (18)	13 (21)	18 (16)	0.43
Intermediate	74 (42)	22 (36)	52 (46)	
High	70 (40)	26 (43)	44 (39)	
Months since diagnosis				
Median (IQR)	2.8 (1.6–4.1)	3.0 (1.8–4.2)	2.4 (1.6–4.1)	0.31
< 1	34 (19)	8 (13)	26 (23)	0.15
1–2	57 (33)	18 (30)	39 (34)	
2–3	25 (14)	8 (13)	17 (15)	
> 3	59 (34)	27 (44)	32 (28)	
Comorbidity[1]				
None	2 (2)	2 (4)	0 (0)	0.14
1	57 (33)	21 (34)	36 (32)	
2 or more	115 (66)	38 (62)	77 (68)	
Marital status[2]				
Partner	131 (75)	48 (79)	83 (73)	0.39
No partner	44 (25)	13 (21)	31 (27)	
Employed				
Yes	51 (29)	20 (33)	31 (27)	0.44
No	124 (71)	41 (67)	83 (73)	
FIGO-stage, n (%)				
I	52 (30)	21 (34)	31 (28)	0.63
II	16 (9)	7 (11)	9 (8)	
III	74 (43)	23 (38)	51 (46)	
IV	30 (17)	10 (16)	20 (18)	
Treatment, n (%)				
Surgery	158 (91)	54 (88)	104 (93)	0.33
Chemotherapy	136 (79)	44 (72)	92 (82)	0.13
Hospital, n (%)				
1	16 (9)	16 (26)		
2	8 (5)	8 (13)		
3	5 (3)	5 (8)		
4	25 (14)	25 (41)		
5	3 (2)	3 (5)		
6	4 (2)	4 (7)		
7	37 (21)		37 (33)	
8	30 (17)		30 (26)	
9	25 (14)		25 (22)	
10	5 (3)		5 (4)	
11	4 (2)		4 (4)	
12	13 (7)		13 (11)	
Hospitals				
# Endometrial and ovarian cancer patients per year				
≤50	4 (33)	2 (33)	2 (33)	
>50	8 (67)	4 (67)	4 (67)	
Gynecologic oncology Center (Tertiary Referral Hospital)				
Yes	2 (17)	1 (17)	1 (17)	
No	10 (83)	5 (83)	5 (83)	

Note: **P*-values report comparisons between the intervention arm and the usual care arm, according to *t*-tests, Wilcoxon-Mann-Whitney test and chi-square tests. Means (M) with standard deviations (SD) were used to describe normally distributed continuous variables, medians with interquartile range (IQR) to describe not-normally distributed continuous variables, and frequencies with percentages to describe categorical variables.

[1] Comorbidities included heart disease, high blood pressure, lung disease, diabetes, ulcer or stomach disease, kidney disease, liver disease, blood disease, cancer, depression, pain and swelling in joints other than the back, osteoporosis and fractures.

[2] Marital status included: partner = married/living together; no partner = divorced/widowed/never married. The numbers may not always add up to 100, because percentages have been rounded off to whole numbers.

also no interactions between the trial arms and time for any of the outcomes, indicating that the effect of SCP care did not differ over the time points.

4. Discussion

In the present trial among ovarian cancer patients, SCPs had no beneficial effect on satisfaction with information provision and care. Instead, receiving an SCP caused less trust that the treatment would help to cure the disease. These current results are in line with earlier findings from the ROGY care trial among endometrial cancer patients [11].

Prior findings from our trial among endometrial cancer patients showed no effect of SCPs on satisfaction with information provision and care, but patients were more concerned about their illness, more affected emotionally and they experienced more symptoms [11]. In the current study among ovarian cancer patients, no effect of SCPs was found on concerns, emotional impact or symptoms experienced. This may be due to existing information provision that in most cases already explains about the poor prognosis and extensive treatment regimens generally needed for ovarian cancer. From oncology practice, we know that in endometrial cancer, treatments are often less extensive and therefore generally less information is provided. On the other hand, ovarian cancer patients who received an SCP had less trust that the treatment would help to cure the disease. This may be explained by the fact that ovarian cancer generally has a poor prognosis, and information provided in the SCP (i.e. on chance of recurrence) may not support the patients' [30] belief that she will be cured. This is negative yet realistic information that the patient otherwise would mostly not receive, as oncology providers are often reluctant to provide such information in order to prevent the patient from negative psychosocial effects. We should take in mind that for patients with an advanced cancer stage and poor prognosis, an SCP provides unfavorable information and may need to be accompanied with more extensive discussion with an oncology provider. Earlier RCTs did not focus on patient populations with advanced stages [6–8,31].

At this point, we are not sure whether less trust in the treatment is either harmful or beneficial for the patient. If patients incorrectly experience less trust in the treatment, the SCP may unnecessarily accumulate psychosocial distress. However, if less trust is according prospect, patients may be more prepared for potential negative long-term consequences of the disease, such as side effects or a recurrence. Further research is needed to assess the impact of less treatment trust on long-term quality of life, anxiety and depressive symptoms. However, it is important to keep in mind that effect sizes of illness perceptions are small; they did not reach the minimal clinically important difference threshold of 0.5 SD and may therefore be considered not clinically relevant.

In contrast to earlier findings of our trial which showed an increased amount of cancer related contact with the primary care physician in endometrial cancer patients who received an SCP, we found that ovarian cancer patients receiving an SCP reported less contact with the medical specialist in the six months after diagnosis. Possibly, ovarian cancer patients receiving an SCP have lower needs of contact with their medical specialist because questions or concerns regarding the illness are already covered in the SCP. Another explanation of this finding may be that the patients in the SCP care arm less often received chemotherapy and had therefore less contact with the medical specialist. Further, our results are based on self-reported health care use; exact registrations of hospital visits would be more reliable and may show different results. For instance, patients in the SCP care arm completed the first questionnaire a longer period of time after diagnosis compared to patients in the usual care arm. The lower self-reported health care use in the SCP care arm at 6 months after diagnosis may therefore be explained by time since treatment completion. However, we adjusted for this in our analysis and results remained similar.

Strikingly, we found that patients in the usual care arm reported a higher receipt of information on other services at 6 and 24 months after diagnosis, and higher satisfaction with the interpersonal skills of the nurses. These findings may be explained by the pragmatic approach of our trial; we did not control the existing information provision or care

Table 2
Socio-demographic and clinical variables according to (non-)participation, complete participation and lost to follow-up.

	Total participants ($N = 174$)	Non-participants ($N = 74$)	*P* value	Complete participation ($N = 75$)	Lost to follow-up ($N = 99$)	*P*-value
Age at diagnosis						
Mean (SD)	63.3 (11.4)	65.1 (12.6)	0.27	62.2 (9.9)	64.2 (12.3)	0.25
Age at time of first questionnaire						
Mean (SD)	64.1 (10.8)	Unknown		62.4 (9.9)	64.7 (12.0)	0.08
SES, n (%)						
Low	31 (18)	16 (23)	0.34	15 (22)	15 (16)	0.67
Intermediate	74 (42)	32 (46)		25 (37)	35 (38)	
High	70 (40)	21 (30)		28 (41)	41 (45)	
Marital status[1]						
Partner	131 (75)	Unknown		57 (76)	74 (74)	0.76
No partner	44 (25)	Unknown		18 (24)	26 (26)	
Employed						
Yes	51 (29)	Unknown		22 (29)	29 (29)	0.96
No	124 (71)	Unknown		53 (71)	71 (71)	
FIGO-stage, n (%)						
I	52 (30)	20 (28)	0.70	27 (36)	25 (26)	**0.03**
II	16 (9)	4 (5)		8 (11)	8 (8)	
III	74 (43)	35 (48)		34 (45)	40 (41)	
IV	30 (17)	14 (19)		6 (8)	24 (25)	
Treatment, n (%)						
Surgery	158 (91)	64 (88)	0.38	72 (96)	87 (89)	0.08
Chemotherapy	136 (79)	53 (73)	0.31	55 (73)	80 (81)	0.19
Comorbidity[2]						
None	2 (2)	Unknown		19 (26)	30 (30)	0.82
1	57 (33)	Unknown		21 (28)	27 (27)	
2 or more	115 (66)	Unknown		34 (46)	43 (43)	
Hospital, n (%)						
1	16 (9)	2 (3)	0.33	16 (21)	21 (21)	0.69
2	8 (5)	3 (4)		9 (12)	7 (7)	
3	5 (3)	2 (3)		14 (19)	16 (16)	
4	25 (14)	15 (21)		11 (15)	14 (14)	
5	3 (2)	4 (5)		3 (4)	5 (5)	
6	4 (2)	4 (5)		4 (5)	1 (1)	
7	37 (21)	10 (14)		1 (1)	4 (4)	
8	30 (17)	12 (16)		10 (13)	15 (15)	
9	25 (14)	7 (10)		1 (1)	2 (2)	
10	5 (3)	3 (4)		1 (1)	3 (3)	
11	4 (2)	3 (4)		3 (4)	10 (10)	
12	13 (7)	8 (11)		2 (3)	2 (2)	

Note: *P*-values report comparisons between participants and non-participants, and between patients that completed participation and patients lost to follow-up, according to *t*-tests and Chi-square tests. Means (M) with standard deviations (SD) were used to describe normally distributed continuous variables and frequencies with percentages to describe categorical variables. Patients with complete participation completed baseline questionnaire and all follow-up questionnaires at 6, 12 and 24 months after diagnosis; patients lost to follow-up were patients that did not complete all follow-up questionnaires.

[1] Marital status included: partner = married/living together; no partner = divorced/widowed/never married.

[2] Comorbidities included heart disease, high blood pressure, lung disease, diabetes, ulcer or stomach disease, kidney disease, liver disease, blood disease, cancer, depression, pain and swelling in joints other than the back, osteoporosis and fractures.The numbers may not always add up to 100, because percentages have been rounded off to whole numbers.

in the usual care arm. It is therefore possible that in the usual care hospitals certain aspects of information provision were perceived better compared to the intervention hospitals. Further, 18% of the patients in the usual care arm reported receipt of an SCP, although SCP provision was impossible in these hospitals [10]. Probably, these patients have perceived other information provision as an SCP.

An advantage of our pragmatic design is that oncology providers were free to choose how SCP provision was implemented, reflecting real-life clinical practice. Inevitably, this resulted in variance across the hospitals with respect to how the SCP was provided, ranging from extensively discussing the SCP with the patient to just handing one without discussion. Our trial did not aim to assess the impact of an SCP that is extensively discussed with the patient. Therefore we did not measure the extent to which the SCP was discussed with each patient. However, as shown in a recent trial among breast cancer patients, combining an SCP with a behavioral intervention using motivational interviewing techniques may actually be beneficial for patients [31]. Possibly, this would be even more beneficial in patients with advanced cancer stages as they generally have higher supportive care needs [32]. Future research is needed to assess the impact of an SCP combined with a behavioral intervention in larger samples and various cancer types.

Among the few RCTs that assessed the impact of SCPs on patient reported outcomes [6–8,31], the ROGY care trial was the first with a pragmatic cluster randomized design, which maximizes external validity and prevents contamination between trial arms [10]. Another unique feature of the trial was that SCPs could be automatically generated through the online registration system ROGY, which minimizes the time needed for SCP provision and allows for provision of updated follow-up SCPs. However, only 16% of the patients in this study reported receipt of an updated SCP. This shows that SCPs were not always updated by the oncology provider when there was a recurrence, changes in treatment or oncology provider. This is probably due to difficulties with finding time to discuss the SCP [14].

A limitation of our study is the small number of patients in our SCP care arm. This was mainly due to one large intervention hospital which, in contrast to endometrial cancer patients, did not include ovarian cancer patients in the trial. Nevertheless, our overall analysis had sufficient power to detect a minimum effect size of 0.5. However, effect sizes in our analyses turned out to be much smaller, meaning that the power of our analysis was too small to detect those small effects. Future studies aiming to detect an effect of SCPs on the outcomes used in the current analyses, should use a larger sample size. However, one may

Table 3
Effects of the intervention: overall, after diagnosis, and after 6, 12 and 24 months, for Intention to Treat analyses.

	Overall	After diagnosis ($N = 174$)			After 6 months ($N = 123$)			After 12 months ($N = 100$)			After 24 months ($N = 75$)		
	Beta (95%CI)	M (SD) SCP care	M (SD) Usual care	Beta (95%CI)	M (SD) SCP care	M (SD) Usual care	Beta (95%CI)	M (SD) SCP care	M (SD) Usual care	Beta (95%CI)	M (SD) SCP care	M (SD) Usual care	Beta (95%CI)
Information provision													
Disease	0.0 (−6.0; 6.0)	59.9 (19)	56.3 (24)	2.6 (−4.2; 9.4)	59.9 (22)	58.4 (20)	−0.8 (−8.5; 6.8)	61.2 (19)	59.1 (22)	−1.8 (−10.0; 6.4)	55.7 (21)	59.8 (25)	−5.4 (−14.2; 3.5)
Medical tests	−2.4 (−8.9; 4.1)	69.8 (23)	68.3 (24)	−0.5 (−7.9; 6.9)	69.6 (24)	71.0 (23)	−2.5 (−10.8; 5.8)	70.5 (20)	70.5 (23)	−2.0 (−11.0; 6.9)	62.8 (22)	71.0 (24)	−8.8 (−18.5; 0.9)
Treatment	−1.8 (−7.8; 4.2)	55.4 (24)	52.5 (22)	2.0 (−4.8; 8.9)	50.7 (28)	57.7 (22)	−7.2 (−15.0; 0.5)	53.7 (23)	56.4 (20)	−3.8 (−12.1; 4.5)	48.1 (24)	51.8 (20)	−2.6 (−11.6; 6.5)
Other services	−5.5 (−12.3; 1.3)	32.3 (23)	31.5 (24)	−0.6 (−8.4; 7.2)	29.8 (23)	38.1 (25)	**−10.9* (−19.7; −2.0)**	37.2 (26)	39.2 (25)	−6.7 (−16.2; 2.8)	27.4 (23)	34.5 (20)	**−11.2* (−21.5; −0.9)**
Places to go	1.6 (−6.7; 9.8)	32.2 (32)	28.2 (30)	1.8 (−8.5; 12.0)	26.8 (29)	24.4 (30)	−1.3 (−13.0; 10.4)	39.4 (37)	27.5 (33)	4.3 (−8.6; 17.1)	28.5 (32)	20.3 (26)	2.5 (−11.5;16.5)
Things to do	−0.7 (−8.9; 7.5)	49.7 (32)	39.8 (34)	8.7 (−1.4; 18.7)	37.3 (31)	39.7 (31)	−3.1 (−5.9; 12.0)	37.4 (29)	44.3 (29)	−10.0 (−22.8; 2.7)	31.0 (29)	37.0 (27)	−9.3 (−23.1; 4.6)
Satisfaction	1.8 (−5.0; 8.7)	74.7 (22)	72.2 (26)	2.3 (−5.6; 10.2)	70.7 (29)	66.7 (25)	3.1 (−5.9; 12.0)	70.6 (21)	67.2 (23)	0.2 (−9.4; 9.7)	64.4 (25)	63.7 (24)	1.9 (−8.4; 12.2)
Helpfullness	0.4 (−6.0; 6.8)	74.1 (23)	73.1 (25)	1.4 (−6.3; 9.0)	68.3 (24)	68.9 (23)	−2.0 (−10.7; 6.9)	71.9 (23)	66.1 (23)	3.2 (−6.3; 12.7)	66.7 (26)	69.8 (19)	−1.4 (−11.7; 9.0)
Satisfaction with care													
Doctor interpersonal skills	0.3 (−5.5; 6.2)	76.9 (21)	76.3 (18)	−1.0 (−7.5; 5.5)	75.6 (22)	73.9 (20)	1.3 (−5.9; 8.4)	78.6 (18)	72.2 (20)	3.3 (−4.3; 10.8)	74.3 (19)	72.1 (21)	0.2 (−8.3; 7.9)
Nurse interpersonal skills	−2.9 (−8.5; 2.8)	76.1 (21)	76.0 (19)	−1.9 (−8.2; 4.4)	72.4 (22)	73.9 (23)	−1.6 (−8.6; 5.4)	72.7 (17)	75.7 (21)	−8.9 (−20.6; 2.7)	67.8 (22)	83.1 (14)	**−12.6* (−24.8; −0.4)**
Exchange information caregiver	−1.5 (−6.8; 3.8)	67.0 (21)	66.7 (19)	−1.8 (−8.1; 4.5)	64.8 (21)	61.8 (20)	0.8 (−6.5; 8.1)	64.7 (21)	60.7 (23)	−1.3 (−9.6; 7.0)	59.2 (18)	63.2(21)	−5.6 (−14.6; 3.4)
General satisfaction with care	−0.2 (−5.3; 5.0)	78.3 (21)	76.7 (19)	−0.6 (−6.7; 5.5)	77.6 (20)	75.9 (18)	0.5 (−6.4; 7.4)	70.7 (17)	64.2 (19)	4.5 (−3.3; 12.3)	61.6 (19)	66.5 (21)	−7.0 (−15.5; 1.5)
Illness perceptions													
How much illness affects life	0.1 (−0.7; 0.8)	6.3 (2.5)	6.1 (2.6)	0.3 (−0.5; 1.1)	5.1 (2.7)	5.3 (2.7)	−0.1 (−1.0; 0.8)	5.2 (2.5)	5.3 (2.8)	−0.0 (−1.0; 1.0)	5.6 (2.5)	4.9 (2.8)	0.2 (−0.8; 1.3)
How long illness will continue	0.7 (−0.1; 1.4)	5.7 (2.5)	5.4 (2.8)	0.7 (−0.2; 1.7)	5.9 (3.3)	5.4 (3.1)	1.0 (−0.0; 2.1)	5.6 (3.0)	5.9 (3.5)	0.3 (−0.8; 1.5)	6.7 (3.3)	6.1 (3.7)	0.6 (−0.7; 1.8)
How much control over illness	−0.2 (−1.0; 0.6)	4.5 (3.1)	4.8 (2.8)	−0.4 (−1.3; 0.6)	4.7 (3.5)	4.5 (2.8)	0.2 (−0.9; 1.3)	4.0 (2.6)	4.2 (3.1)	−0.2 (−1.4; 0.9)	4.1 (3.0)	4.3 (3.1)	−0.1 (−1.4; 1.2)
How much treatment helps to cure	**−1.0** (−1.6; −0.4)**	7.2 (2.3)	7.8 (1.8)	**−0.8* (−1.6; −0.1)**	6.7 (2.9)	7.2 (2.4)	**−0.9* (−1.8; −0.1)**	6.4 (2.7)	7.2 (2.5)	**−1.4** (−2.3; −0.4)**	6.7 (2.2)	7.2 (2.3)	−0.7 (−1.8; 0.3)
How much symptoms experienced	0.1 (−0.7; 0.8)	5.3 (2.5)	5.1 (1.6)	0.5 (−0.3; 1.3)	4.0 (2.5)	4.8 (2.6)	−0.5 (−1.4; 0.4)	4.5 (2.8)	4.8 (2.8)	−0.1 (−1.1; 0.9)	4.2 (2.4)	4.8 (2.9)	0.8 (−1.8; 0.4)
How concerned about illness	0.3 (−0.5; 1.0)	6.2 (2.7)	5.8 (2.8)	0.7 (−0.1; 1.6)	5.1 (2.8)	5.6 (3.0)	−0.4 (−1.3; 0.5)	5.8 (2.7)	5.6 (3.1)	0.1 (−0.9; 1.2)	5.9 (2.5)	5.2 (2.8)	0.5 (−0.6; 1.6)
How well understand illness	−0.2 (−1.0; 0.6)	6.8 (2.7)	6.5 (2.6)	0.4 (−0.6; 1.4)	6.4 (3.2)	6.8 (2.8)	−0.5 (−1.6; 0.6)	6.0 (3.1)	6.5 (3.1)	−0.8 (−1.9; 0.4)	6.9 (3.4)	6.6 (3.1)	0.2 (−1.1; 1.5)
How much affects emotionally	0.2 (−0.6; 1.0)	5.3 (2.7)	5.1 (2.7)	0.3 (−0.5; 1.2)	4.4 (2.7)	4.8 (2.7)	−0.2 (−1.2; 0.7)	5.3 (2.5)	5.0 (3.0)	0.4 (−0.6; 1.4)	5.4 (2.6)	4.2 (2.5)	0.8 (−0.3; 2.0)
Health care utilization													
Visits medical specialist past 6 months	−1.2 (−2.5; 0.1)	7.0 (4.2)	8.5 (6.2)	−1.5 (−3.2; 0.3)	4.9 (3.5)	7.6 (9.4)	**−2.5* (−4.5; −0.4)**	3.4 (2.6)	3.6 (2.9)	0.2 (−2.0; 2.5)	2.9 (2.2)	3.2 (2.4)	−0.3 (−2.8; 2.2)
Visits primary care physician past 6 months	−0.5 (−1.2; 0.2)	3.1 (3.5)	3.6 (3.1)	−0.3 (−1.3; 0.7)	2.6 (2.6)	3.1 (3.4)	−0.4 (−1.6; 0.8)	0.9 (1.4)	2.3 (4.1)	−1.2 (−2.6; 0.2)	0.6 (1.2)	0.9 (1.4)	−0.3 (−1.8; 1.2)

Note: Linear multilevel regression analyses were performed, adjusted for age, time since diagnosis, marital status, socio-economic status, employment, comorbidities, stage, and treatment. Overall analyses report the results of the main effect of the intervention without the interaction between trial arms and time in the model. Crude means and standard deviations (SD) are reported for SCP Care and Usual Care. Unstandardized betas and confidence intervals are reported for SCP Care (ref = Usual Care). Intention To Treat analyses compared all respondents in the SCP care arm to all respondents in the usual care arm. EORTC-QLQ-INFO25 and EORTC-IN-PATSAT32 scales ranging from 0 to 100: higher scores reflect better perceived information and care received. B-IPQ scale ranging from 1 to 10: higher scores indicate more endorsement of that item. Health care utilization shows patients' reported frequency of cancer-related contact with their medical specialist or primary care physician in the past 6 months.

* $P < 0.05$.

** $P < 0.01$.

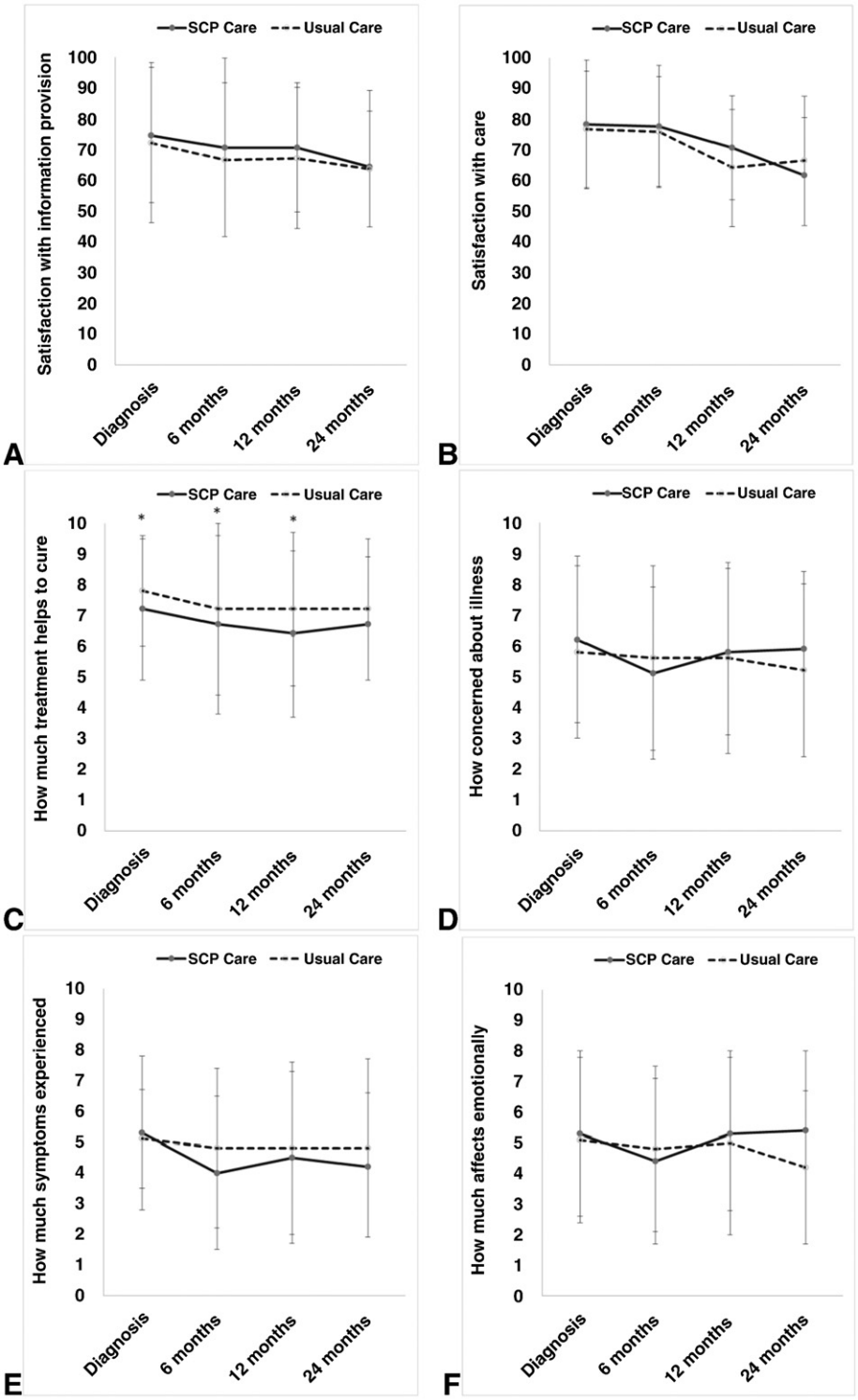

Fig. 2. Trial outcomes for satisfaction with information provision, satisfaction with care and illness perceptions over time, intention-to-treat analysis. Note: Crude means are reported. Error bars represent +1 and −1 standard deviation. *$P < 0.05$. After diagnosis, and after 6, 12 and 24 months, a total of 174, 123, 100 and 75 patients were included in analysis respectively (Table 3).

argue that detecting an effect with an effect size smaller than 0.5 is not clinically relevant.

In this study, a substantial number of patients were lost to follow-up during our two-year trial. Because of the relatively low survival in ovarian cancer, lost to follow-up was for a large part caused by death or ill-health. This resulted in a selection of patients in our follow-up analysis, who had lower cancer stages. However, the effect of the SCP was similar for patients lost to follow-up and patients who completed participation in our trial.

Further, as shown in a process evaluation of our trial [17], SCPs were generated (i.e. the oncology provider clicked the SCP button in the ROGY system) for 82% of the ovarian cancer patients. However, we found that only 66% of the ovarian cancer patients in the SCP care arm actually reported SCP receipt. Thus, for 16% of the patients we are not

sure what happened: the oncology provider did not hand over the SCP to the patient, or the patient might have forgotten her receipt of an SCP. Among endometrial cancer patients, the number of patients that reported receipt of an SCP was higher (74%), probably because most of the oncology care was provided by an oncology provider that provided the SCP in our trial (i.e. gynecologist, gynecologic oncologist or oncology nurse), while in ovarian cancer patients oncology care is for a large part provided by medical oncologists who were not instructed to provide SCPs.

Due to the pragmatic nature of the trial, not all trial participants received an SCP, reflecting real-life clinical practice. A process evaluation of our trial [17] showed that certain patients less often received an SCP (i.e. older patients and patients with a distressed personality). Current results may therefore not be fully generalizable to the full patient population. Possibly, SCPs have a higher impact on threatening illness perceptions in patients with a distressed personality, as they tend to experience more negative emotions without sharing these emotions with others [17]. Unfortunately, we could not assess if there was a selection bias in patient recruitment in the SCP care arm compared to the usual care arm, as no data was available on proportions of patients recruited versus not recruited. We did not find statistical differences in baseline characteristics between the trail arms, but our trial was not powered to detect differences in the categorical baseline variables. Possibly, patients in the SCP care arm were somewhat healthier compared to patients in the usual care arm (i.e. lower FIGO stage and less often received chemotherapy), which may have underestimated true effects of the SCPs to some extent. For instance, the impact of SCPs on illness perceptions may be worsened in unhealthier patients. However, we do not assume that we would find an effect on satisfaction with information provision or satisfaction with care, as no trend is observed in current results.

In order to assess the impact of SCPs in a situation where all patients would receive one, we conducted a per protocol analyses in addition to an intention to treat analyses. To make sure of this, we only compared the patients in the SCP care arm that reported SCP receipt, to all patients in the usual care arm. However, results did not much differ between intention to treat and per protocol analyses.

In conclusion, the present study confirms earlier findings from the ROGY care trial that SCPs did not increase satisfaction with information provision or care. Instead, SCPs led to a lower trust in the treatment among ovarian cancer patients which might reflect a more realistic perspective on the treatments effects, while among endometrial cancer patients the SCPs seemed to unnecessarily cause higher concerns, emotional impact and symptom awareness. Our trial results suggest that patients may not benefit from an SCP as was proposed by the NAM. However, the benefit of an SCP combined with a behavioral intervention needs to be further explored.

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Conflict of interest

The authors declare that they have no conflict of interest.

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