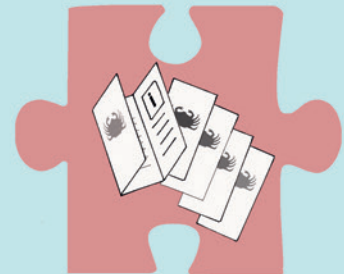
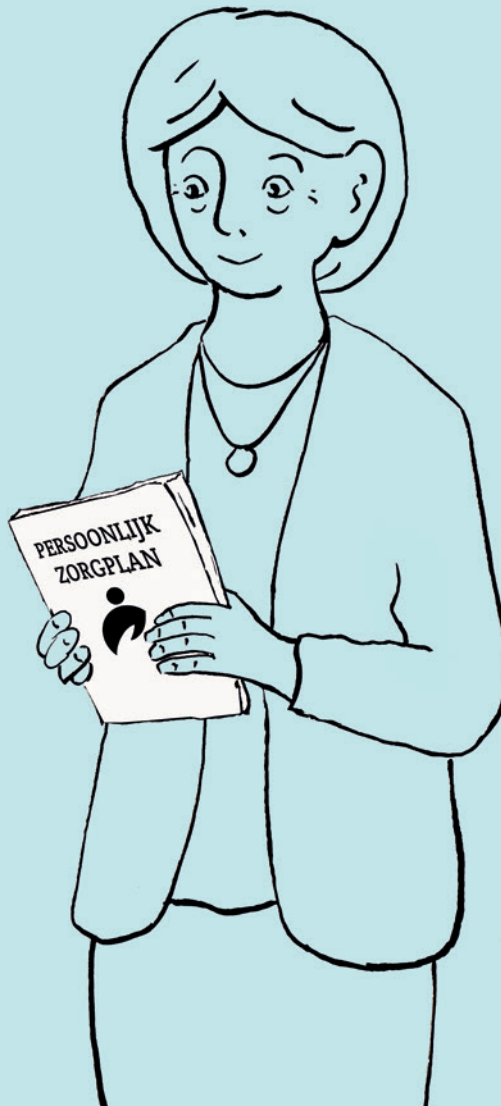


# Information provision and follow-up care in endometrial cancer: Evaluating the impact of Survivorship Care Plans on patient- and health care provider- reported outcomes

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# Information provision and follow-up care in endometrial cancer

## Evaluating the impact of Survivorship Care Plans on patient- and health care provider- reported outcomes



Kim Nicolaije



# **Information provision and follow-up care in endometrial cancer**

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# **Information provision and follow-up care in endometrial cancer**

## **Evaluating the impact of Survivorship Care Plans on patient- and health care provider- reported outcomes**

### **Proefschrift**

ter verkrijging van de graad van doctor aan Tilburg University  
op gezag van de rector magnificus, prof.dr. E.H.L. Aarts,  
in het openbaar te verdedigen ten overstaan van een door het college voor promoties  
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geboren op 23 november 1985 te Heerlen

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## CONTENTS

<b>Chapter 1</b>	General introduction	7
<b>Chapter 2</b>	Endometrial cancer survivors are unsatisfied with received information about diagnosis, treatment and follow-up: A study from the population-based PROFILES registry	19
<b>Chapter 3</b>	Follow-up practice in endometrial cancer and the association with patient and hospital characteristics: A study from the population-based PROFILES registry	41
<b>Chapter 4</b>	The impact of a cancer Survivorship Care Plan on gynecological cancer patient and health care provider reported outcomes (ROGY Care): Study protocol for a pragmatic cluster randomized controlled trial	61
<b>Chapter 5</b>	The impact of an automatically generated cancer Survivorship Care Plan on patient reported outcomes in routine clinical practice: Longitudinal outcomes of the pragmatic cluster randomized ROGY Care trial	77
<b>Chapter 6</b>	Paper Survivorship Care Plans may be less helpful for cancer patients who search for disease-related information on the Internet: Results of the ROGY Care trial	99
<b>Chapter 7</b>	Oncology providers' evaluation of the use of an automatically generated Survivorship Care Plan: Longitudinal results from the ROGY Care trial	121
<b>Chapter 8</b>	Survivorship Care Plans to inform the primary care physician: Results from the ROGY Care pragmatic cluster randomized controlled trial	143
<b>Chapter 9</b>	Summary and General discussion	161
	Nederlandse samenvatting (Dutch summary)	183
	Dankwoord (Acknowledgements)	193
	List of publications	199
	About the author	203



# Chapter 1

**General Introduction**



## GENERAL INTRODUCTION

As a result of improved early detection, improved treatments, and the ageing of the population, the number of cancer survivors is increasing rapidly in developed countries<sup>1</sup>. In The Netherlands, there were approximately 600,000 cancer survivors in 2010, and this number is estimated to grow to 900,000 in 2020<sup>2</sup>. Because many of these cancer survivors continue to live with long-term or late physical and psychosocial effects of their cancer and treatment, it is important to address their specific health care needs<sup>3,4</sup>.

The term 'cancer survivor' is defined by the American National Coalition for Cancer Survivorship (NCCS) as 'a person diagnosed with cancer from the moment of diagnosis through the balance of his or her life'<sup>5</sup>, thus referring to all individuals who have or ever had cancer. This definition was also used by the American Institute of Medicine (IOM)<sup>4</sup>. Although a later adaptation of this definition by the National Cancer Institute (NCI) also included family members, friends, and caregivers<sup>6</sup>, in this thesis the original definition of the NCCS, focusing only on the cancer survivor, is used. The term 'cancer survivor' is widely used by researchers, especially in the United States. Because this term is less often used in The Netherlands, where most health care providers prefer to use the term 'cancer patient', the terms 'cancer survivor' and 'cancer patient' are used interchangeably in this thesis.

### Growing number of endometrial cancer survivors

Endometrial cancer is the most common gynecological cancer in developed countries. The annual incidence of endometrial cancer is approximately 15-25 per 100,000 women<sup>7,8</sup>, and the incidence is growing due to increased life expectancy and risks factors such as obesity<sup>9,10</sup>. The basis of treatment for endometrial cancer is surgery, which includes hysterectomy and salpingo-oophorectomy. In selected cases, there is a place for a further surgical staging or debulking procedure, and/or appropriate adjuvant treatment (e.g., radiotherapy and/or chemotherapy)<sup>11,12</sup>. More than 75% of women with endometrial cancer are diagnosed at an early stage (i.e., FIGO stages I and II), and have a good prognosis, indicated by the overall 5-year survival rate of 80%<sup>7,8,13</sup>. Due to the increasing incidence and generally good prognosis, the number of women who have or ever had endometrial cancer is increasing<sup>9</sup>. In The Netherlands, there are currently approximately 20,000 endometrial cancer survivors<sup>14</sup>.

### Discussion about follow-up care in endometrial cancer

After primary treatment, women with endometrial cancer are monitored in routine follow-up based on periodic visits for several years after treatment. In The Netherlands,

approximately 7,000 women with endometrial cancer currently receive follow-up care<sup>14</sup>. Reasons for follow-up include early diagnosis of recurrences, in order to improve survival and/or quality of life<sup>15,16</sup>, monitoring long-term and late effects of the cancer and its treatment<sup>17</sup>, psychosocial support<sup>17,18</sup>, and information provision<sup>19-21</sup>. On the other hand, intensive follow-up schedules require considerable financial resources<sup>22-24</sup> and can increase patients' anxiety<sup>21,25</sup>. The present Dutch national guidelines recommend a period of 5 years of follow-up, with visits every 3 or 4 months during the first two years after the end of treatment, every 4 to 6 months during the third year, and annually during the fourth and fifth year, irrespective of stage and grade (<http://www.oncoline.nl>).

The frequency of follow-up visits in endometrial cancer has been a continuing area of discussion, because there is limited evidence regarding whether intensive follow-up schedules are more or less beneficial than non-intensive follow-up schedules<sup>15,26</sup>. It has been suggested that the follow-up frequency of early-stage endometrial cancer survivors may be decreased<sup>27,28</sup>, primarily because there is no survival benefit in the detection of asymptomatic recurrences at routine follow-up, compared to symptomatic recurrence or interval detection<sup>15,25</sup>. This is probably because of the relatively low recurrence rate among early stage endometrial cancer survivors (i.e., ranging from 3 to 17%)<sup>15,29,30</sup>, and because approximately 70% of recurrences present with symptoms<sup>15,25,29,31</sup> and occur within 3 years after diagnosis<sup>26,32</sup>. If the frequency of follow-up visits for endometrial cancer would be reduced, this would require adequate information provision about for instance potential symptoms of recurrences and how to monitor this.

Guidelines for follow-up in endometrial cancer lack evidence-based knowledge and vary in recommended follow-up strategies<sup>31</sup>. Previous research showed large variations in follow-up practice in endometrial cancer between different countries and institutions<sup>16,26,31,33-35</sup>. Understanding the factors associated with follow-up consumption and the preferences of endometrial cancer survivors regarding the follow-up, can help health care providers to better organize the follow-up care in endometrial cancer. However, research investigating these factors and preferences is lacking.

### **The importance of information provision**

Providing tailored information that corresponds to patients' needs is a key factor in the support for cancer survivors during follow-up care<sup>36-38</sup>. It has for instance been associated with improved satisfaction with information provision and care<sup>37</sup>, improved illness perceptions<sup>39</sup>, improved psychological adjustment<sup>40</sup>, and lower levels of anxiety

and depression<sup>36</sup>. In addition, unmet information needs have been associated with more psychological complaints, and higher levels of anxiety and depression<sup>38</sup>. Nevertheless, unmet information needs are frequently found among cancer survivors<sup>41-43</sup>.

Previous research indicates that most cancer survivors want as much information as possible<sup>43,44</sup>, but information needs differ for different patients (e.g., tumor type, gender, age, educational level, coping style)<sup>45,46</sup>. Identifying the specific information needs of endometrial cancer survivors and the factors associated can help health care providers deliver information that is better tailored to patients' specific needs. However, research investigating the specific information needs of endometrial cancer survivors during follow-up care is lacking.

### **The impact of Survivorship Care Plans**

To help the growing number of cancer survivors deal with the challenges of cancer survivorship, Survivorship Care Plans (SCPs) were recommended by both the IOM and the Dutch Health Council<sup>4,24</sup>. An SCP is a formal document that contains both a tailored treatment summary (including information on diagnostic tests, type of cancer, stage, grade, treatment, and contact details of the hospital and specialists), and a follow-up care plan (including information on possible short-term and long-term effects, effects on social and sexual life, signs of recurrence and secondary tumors, rehabilitation, psychosocial support, and supportive care services)<sup>4</sup>. SCPs are expected to meet cancer survivors' information needs, to facilitate follow-up care for cancer survivors, and to enable better communication between the health care providers involved in the follow-up care<sup>4</sup>. Based on their face validity, both the IOM and the Dutch Health council advised that SCPs should be implemented for all cancer survivors<sup>4,24</sup>. Because empirical evidence regarding the effects of implementing SCPs in routine clinical practice was lacking, the IOM also recommended research to evaluate the impact of SCPs on patient and health care provider reported outcomes<sup>4</sup>.

The quantity and quality of studies investigating the effects of SCPs on patient reported outcomes are limited<sup>47</sup>. Three randomized studies<sup>48-50</sup> did not find any differences in satisfaction with care<sup>48-50</sup>, distress<sup>48</sup>, and quality of life<sup>48</sup> between patients who did or did not receive an SCP. Although these studies provided important first insights into the impact of SCPs, there were major limitations in the study designs, including the timing of the intervention and outcomes assessment<sup>51-53</sup>. Furthermore, essential outcomes, including satisfaction with the received information, illness perceptions, and health care utilization were not investigated. In addition, it was not examined whether the effects of the SCP were different for different patients. For instance, because using the Internet

to obtain disease-related information has been associated with considerable benefits for cancer survivors<sup>54-58</sup>, it is possible that receiving an SCP has a different impact on patients who search for information about their cancer on the Internet compared to patients who do not.

Previous studies investigating the views of oncology providers (i.e., medical specialists and oncology nurses) who deliver the SCPs, have found that oncology providers' views regarding SCPs are generally positive<sup>59-64</sup>, but that they have practical concerns about implementing SCPs. In addition, substantial barriers to SCP use have been identified, including finding the time, reimbursement, personnel, and resources necessary to create SCPs<sup>59,65-69</sup>. It has therefore been proposed that automatic generation of SCPs may ease some of the burden on oncology providers<sup>61,70,71</sup>. However, oncology providers' actual experiences with automatically generated SCPs in routine clinical practice have not yet been investigated. Furthermore, little is known about how primary care physicians who receive an SCP perceive and use the SCP, and whether SCPs are a useful tool to improve the communication between primary care physicians and medical specialists.

A pragmatic cluster randomized design, assessing both patient and health care provider reported outcomes, and addressing the methodological concerns of previous studies, is needed to support informed health care decisions regarding the large-scale implementation of SCPs.

## **Aims and organization of this thesis**

The main objectives of the studies in this thesis were:

- To assess the current state of information provision and follow-up care reported by endometrial cancer survivors, and to identify possible associations with socio-demographic and clinical characteristics.
- To assess the impact of an automatically generated SCP on patient reported outcomes, and to assess health care providers' evaluation of the SCP in routine clinical practice.

This thesis started by identifying the information provision to endometrial cancer survivors. The aim of **Chapter 2** was to assess the perceived level of, and satisfaction with, information received by endometrial cancer survivors. In addition, possible associations between socio-demographic and clinical characteristics and the perceived level of and satisfaction with the received information were explored. In **Chapter 3**, we wanted to investigate to what extent endometrial cancer survivors experienced

follow-up according to the Dutch guidelines, and to identify associations between consumption of follow-up care and socio-demographic and clinical characteristics, Health-Related Quality of Life (HRQL), and worry. In addition, we wanted to evaluate patients' preferences regarding follow-up care.

The rationale and study design of the pragmatic cluster randomized ROGY Care trial are presented in **Chapter 4**. The aim of the ROGY Care trial was to assess the impact of an automatically generated SCP on patient reported outcomes and to assess health care providers' evaluation of the SCP in routine clinical practice. In **Chapter 5**, the effects of the SCP in the ROGY Care trial on endometrial cancer patients' satisfaction with information provision and care, illness perceptions, and health care utilization up to 12 months after diagnosis are presented. The aim of **Chapter 6** was to examine whether the effects of the paper SCP in the ROGY Care trial on patient reported outcomes were different for patients who searched for disease-related information on the Internet compared to patients who did not.

The aim of **Chapter 7** was to longitudinally examine the expectations and actual experiences of the oncology providers in the ROGY Care trial with the SCP, in routine clinical practice. Oncology providers' evaluation of the use of the SCP was assessed regarding the content and helpfulness, general satisfaction and motivation, use in practice and encountered barriers, and suggestions for further development. In addition, we wanted to evaluate oncology providers' preferences regarding the delivery of the SCP. In **Chapter 8**, we assessed the effects of sending an SCP to primary care physicians on the communication of primary care physicians with medical specialists and patients, and described primary care physicians' opinions regarding the SCP.

In **Chapter 9**, the main findings and methodological considerations of this thesis are discussed, and implications for clinical practice and future research are outlined.

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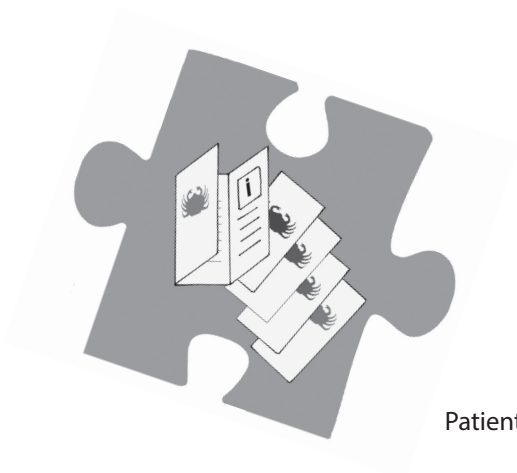
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# Chapter 2

## **Endometrial cancer survivors are unsatisfied with received information about diagnosis, treatment and follow-up: A study from the population-based PROFILES registry**

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## ABSTRACT

**Objective:** To evaluate perceived level of and satisfaction with information received by endometrial cancer survivors, and to identify associations with socio-demographic and clinical characteristics.

**Methods:** All patients diagnosed with endometrial cancer between 1999 and 2007, registered in the Eindhoven Cancer Registry, received a questionnaire including EORTC-QLQ-INFO25.

**Results:** Seventy-seven percent responded (n=742). Most patients indicated receiving quite a bit information about their disease and medical tests. However, most patients were not (54%) or a little (24%) informed about the cause of their disease, and possible side effects (36%; 27%). Especially information about additional help, rehabilitation, psychological assistance, and expected results on social and sexual life was lacking. Five percent was not or a little (36%) satisfied. Four percent found the information not or a little (35%) helpful. Fifteen percent preferred more information. Younger age, more recent diagnosis, radiotherapy, absence of comorbidities, having a partner, having received written information, and higher educational level were associated with higher perceived information receipt.

**Conclusion:** Many endometrial cancer survivors are unsatisfied with received information. Several areas of information provision are experienced as insufficient.

**Practice Implications:** More patient-tailored information is probably needed to provide optimal information. Implementation of Survivorship Care Plans might be a way to achieve this.

## INTRODUCTION

Endometrial cancer is the most frequent gynecological cancer in industrialized countries, with an incidence of 15-25 per 100,000 women per year <sup>1,2</sup>. An ageing population with more diagnoses of endometrial cancer, increased risk factors, such as obesity, diabetes, and a lower parity, and more aggressive treatments in advanced disease all have resulted in increasing numbers of endometrial cancer survivors. In 2005, there were about 17,000 endometrial cancer survivors in The Netherlands, and this number is expected to increase to 25,000 in 2015 <sup>3</sup>.

Patient information is an essential factor in the support for cancer survivors across the whole cancer trajectory. Appropriate information given to cancer survivors about their diagnosis, treatment, possible long-term and late effects and referral services can result in better informed decision making, lower levels of distress, and improved satisfaction with care and sense of control <sup>4-7</sup>. Cancer survivors who are satisfied with the information they received have a better health related quality of life, and lower levels of depression and anxiety <sup>8</sup>.

Studies suggest that most cancer patients want as much information as possible <sup>7,9,10</sup>. However, the information needs of cancer patients differ by gender, age, cultural background, educational level, cancer type, stage of disease (at diagnosis, treatment and follow-up), and coping style <sup>11,12</sup>. Understanding factors associated with information provision might help health care providers to provide more patient-centered information by giving adequate information to those who need it, at the right time <sup>13</sup>.

Previous research has shown that likelihood of cure, information on (spread of) disease, and side effects of treatment are information needs of gynecological cancer survivors <sup>14-16</sup>. In addition, previous studies suggest that gynecological cancer survivors would appreciate more information concerning how the disease and treatment affect their self-image, sexuality <sup>17</sup>, and fertility <sup>18</sup>. Identifying the specific information needs of endometrial cancer survivors might facilitate gynecologists, radiotherapists, medical oncologists, and oncology nurses in providing patient-centered information, which may contribute to improved quality of life of endometrial cancer survivors. However, until now, research investigating the specific information needs of endometrial cancer survivors is lacking.

Investigating the current state of information provision and degree of satisfaction with information provision of endometrial cancer survivors is valuable to determine whether the current information provision is sufficient, or whether improvement is necessary. The present study therefore aims to assess the perceived level of and satisfaction with information received by endometrial cancer survivors, and to identify possible associations with socio-demographic and clinical characteristics.

## **METHODS**

### **Setting and participants**

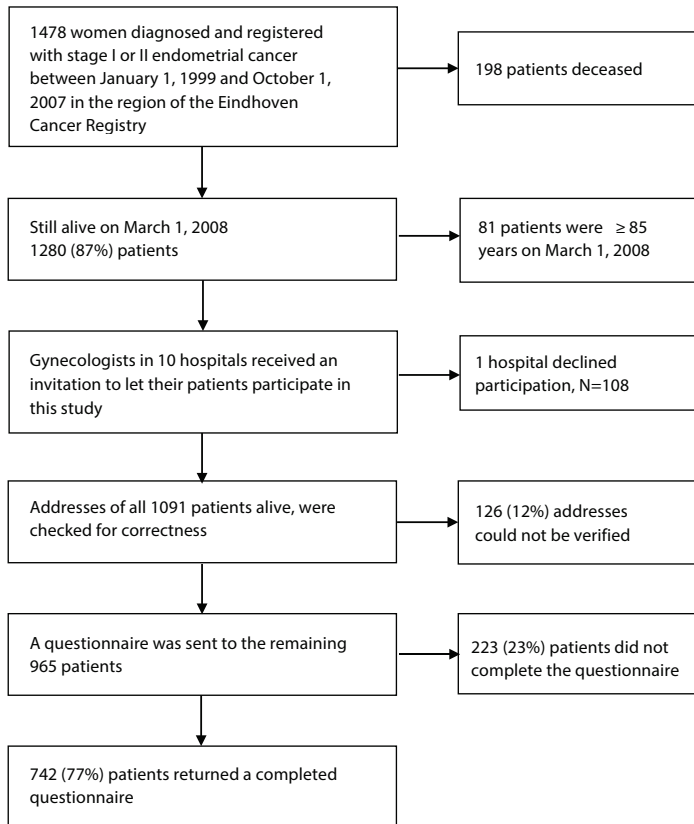
A cross-sectional study was performed among 1091 endometrial cancer survivors registered within the Eindhoven cancer registry (ECR) of the Comprehensive Cancer Center South (CCCS). The ECR records data on all patients newly diagnosed with cancer in the southern part of the Netherlands. The ECR was used to select patients diagnosed with endometrial cancer between January 1<sup>st</sup> 1999 and October 1<sup>st</sup> 2007 in 10 hospitals. All individuals (age 18-84 years) diagnosed with endometrial cancer FIGO stage I-II (classification 1988) were eligible for participation. Deceased patients were excluded by linking the ECR with the Central Bureau of Genealogy (Figure 1). Ethical approval for the study was obtained from a Medical Ethics Committee.

### **Data collection**

Data collection took place between May and July 2008 and was done within PROFILES (Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship). PROFILES is a registry for the study of the physical and psychosocial impact of cancer and its treatment from a dynamic, growing population-based cohort of both short and long-term cancer survivors. PROFILES contains a large web-based component and is linked directly to clinical data from the ECR. Details of the data collection method have been previously described<sup>19,20</sup>. Data from the PROFILES registry will be available for non-commercial scientific research, subject to study question, privacy and confidentiality restrictions, and registration ([www.profilesregistry.nl](http://www.profilesregistry.nl)).

Gynecologists sent their (former) patients a letter to inform them about the study and a questionnaire. To avoid coercion and assure anonymity, patients were asked to send the informed consent form and questionnaire back to the researchers at the Comprehensive Cancer Center South in a pre-stamped envelope. Returned questionnaires contained only a study number. By returning the completed questionnaire, patients agreed to participate and consented with linkage of the outcomes of the questionnaire to their

disease history as registered in the ECR. Patients were reassured that non-participation would not have any consequence for their follow-up care or treatment. Non-respondents were sent a reminder letter and questionnaire within 2 months.



**Figure 1.** Flow-chart of the data collection process

## Measures

### *Socio-demographic and clinical characteristics*

Clinical and patient information was obtained from the ECR<sup>21</sup> (i.e., date of birth, date of diagnosis, disease stage, and primary treatment). The questionnaire included questions on socio-demographic data (i.e., marital status, employment status, and educational level). Comorbidity at the time of survey was categorized according to the Self-administered Comorbidity Questionnaire (SCQ)<sup>22</sup>.

### **Information provision**

To evaluate the perceived level of and satisfaction with information among endometrial cancer survivors, the Dutch version of the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-INFO25 questionnaire was used<sup>23</sup>. This 25-item questionnaire incorporates four information provision subscales: perceived receipt of information about the disease (four items regarding diagnosis, spread of disease, cause(s) of disease and whether the disease is under control), medical tests (three items regarding purpose, procedures and results of tests), treatment (six items regarding medical treatment, benefits, side-effects, effects on disease symptoms, social life and sexual activity) and other care services (four items regarding additional help, rehabilitation options, managing illness at home, psychological support). The question format was as follows: "During your current disease or treatment, how much information have you received on...?" Additionally, it contains several single items on having received written information or information on CDs or tape/video and items on the satisfaction with, amount of, and helpfulness of information. The answer categories were "not at all", "a little", "quite a bit", and "very much", except for four items which have a two point yes/no scale. Furthermore, an open question was asked on what topics survivors would like to receive more or less information on. After linear transformation, all scales and items range in scores from 0 to 100, with higher scores indicating better perceived information provision. The questionnaire has been internationally validated, and internal consistency for all scales is good ( $\alpha > 0.70$ ), as is test-retest reliability (intraclass correlations  $> 0.70$ )<sup>23</sup>. A recent study also showed that the scale structure of the EORTC QLQ-INFO25 is valid<sup>24</sup>. Our data revealed Cronbach's alphas of 0.78 (disease), 0.91 (medical test), 0.85 (treatment) and 0.78 (other care services) for the four subscales respectively.

Apart from the EORTC-QLQ-INFO25 questionnaire, two single questions about the use of internet for seeking additional information were added (i.e., "Do you make use of the internet?" and "Have you used the internet to look for information about endometrial cancer?"), which could be answered with either yes or no.

### **Statistical analyses**

All statistical analyses were conducted using SPSS version 17.0 (Statistical Package for Social Sciences, Chicago, IL, USA), and p-values of  $< 0.05$  were considered statistically significant. Missing items from multi-item scales of the EORTC QLQ-INFO25 were mean-imputed if at least half of the items from the scale were answered, according to the EORTC QoL guidelines<sup>6,23,25</sup>.

Differences in socio-demographic and clinical characteristics between respondents, non-respondents, and patients with unverifiable addresses were compared using ANOVA for continuous variables and chi-square tests for categorical variables. Frequencies and percentages were used to summarize categorical data; means and standard deviations were used to summarize continuous data.

Differences between satisfied and unsatisfied survivors in perceived receipt of information, helpfulness of information, wanting more or less information, receipt of written information, and use of the internet, were compared using t-tests for continuous variables and chi-square tests for categorical variables. Patients were categorized into two groups: (a) patients who were unsatisfied or only a little satisfied, classified as unsatisfied and (b) patients who were quite satisfied or very satisfied, classified as satisfied.

ANOVA and chi-square tests were performed to investigate mean differences between socio-demographic and clinical characteristics (independent variables), and the subscales of the EORTC QLQ-INFO25 (dependent variables). For all ANOVAs, Bonferroni corrections were used.

Multivariate linear and logistic regression analyses were performed to investigate the association of socio-demographic and clinical characteristics with the subscales of the EORTC QLQ-INFO25. In the multivariate analyses, all socio-demographic and clinical variables were included. This was determined a priori<sup>26</sup>. All predictors were entered simultaneously in the regression analyses.

## RESULTS

### Patient and tumor characteristics

Of the 965 endometrial cancer survivors who were sent a questionnaire, 742 (77%) returned a completed questionnaire (Figure 1). Respondents were younger than non-respondents ( $p < 0.001$ ), with a mean age of 66.7 years (range 26.8-84.6). The mean time since diagnosis was 4.9 years (range 0.7-10.0) and most patients (93%) had stage I endometrial cancer at diagnosis. All patients were treated with surgery, followed by radiotherapy (23%) or chemotherapy (1%), if indicated (Table 1).

**Table 1.** Socio-demographic and clinical characteristics of questionnaire respondents, non-respondents and patients with unverifiable addresses

	<b>Respondents</b> N= 742	<b>Non-respondents</b> N= 223	<b>Patients with unverifiable addresses</b> N= 126	<b>p-value</b>
<b>Age at time of survey</b> (mean, SD)	66.7 (8.5)	69.4 (8.9)	66.8 (10.2)	<b>&lt;0.001</b>
<55	8%	4%	9%	<b>0.01</b>
55-69	55%	48%	58%	
≥ 70	37%	48%	33%	
<b>Years since diagnosis</b> (mean, SD)	4.9 (2.5)	5.3 (2.4)	5.1 (2.4)	0.06
<2	13%	9%	8%	0.26
2-5	41%	40%	43%	
>5	45%	51%	49%	
<b>FIGO stage at diagnosis</b>				
I	92%	92%	94%	0.89
II	8%	8%	6%	
<b>Treatment</b>				
Surgery alone	76%	77%	81%	0.42
Surgery + radiotherapy	23%	22%	17%	0.44
Surgery + chemotherapy	1%	<1%	2%	0.56
<b>Comorbidity</b>				
None	20%			
1	26%			
2 or more	54%			
<b>Marital status<sup>a</sup></b>				
Partner	70%			
No partner	27%			
<b>Educational level<sup>b</sup></b>				
High	10%			
Intermediate	63%			
Low	24%			
<b>Employed</b>				
Yes	16%			
No	85%			

Note: <sup>a</sup>Marital status included: partner = married/living together; no partner = divorced/widowed/never married. <sup>b</sup>Education levels included low = no/primary school; intermediate = lower general secondary education/vocational training; or high = pre-university education/ high vocational training/university. The numbers will not always add up to 100, because percentages have been rounded off to whole numbers.

### Perceived information provision

Most patients indicated that they received quite a bit information about their disease and medical tests (Table 2). However, most of the patients stated that they were not (54%) or only a little (24%) informed about the cause of their disease. Regarding their treatment, more than half of the patients stated that they received no (36%) or only a little (27%) information about the possible side effects. In addition, most patients indicated that they received no (34%) or only a little (27%) information about the expected results on disease symptoms. Most patients also indicated that they were not or only a little informed about the expected results of the treatment on their social life (52% and 30% respectively) and sexual life (56% and 27%). Furthermore, the majority of patients indicated that they received no or only a little information on topics related to aftercare, such as where to go for additional help (62% and 25%), rehabilitation (78% and 15%), or psychological support (80% and 14%), and how to cope with cancer at home (55% and 31%), different care locations outside the hospital (70% and 19%), or things to do to improve their health (42% and 35%; Table 2).

Fifteen percent of the patients indicated that they wished that they had received more information. Seventy-five responses were given on the open question regarding the topics survivors would like to receive more information on. Most frequently mentioned topics were the possible causes of endometrial cancer, prevention and risk of recurrence, possible side-effects of treatment, effects of treatment on their sexual life, aftercare, psychological support, and overall information on endometrial cancer. On the other hand, 6% of the patients indicated that they wished that they had received less information. Thirteen responses were given on the open question regarding the topics survivors would like to have received less information on. Most frequently mentioned topics were the effects of treatment, possible side-effects of treatment, and overall information on endometrial cancer.

Overall, 36% of the patients were just a little satisfied or unsatisfied (5%) with the information they received, and 35% found the information a little or not (4%) helpful at all. Most survivors (70%) stated that they received written information. The internet was used by 39% of the participants of which 59% had used it to search for additional information.

**Table 2.** Perceived information provision characteristics

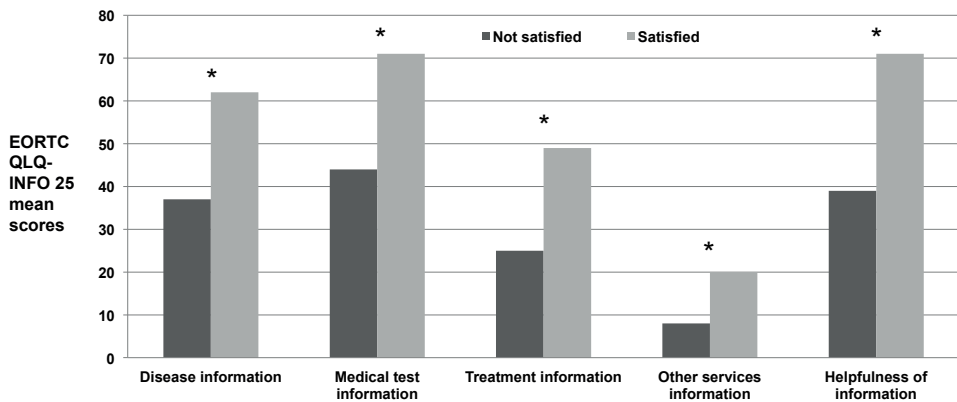
	<b>No information at all</b>	<b>A little information</b>	<b>Quite a bit information</b>	<b>Very much information</b>
<b>Disease</b>				
Diagnosis	5%	28%	47%	20%
Spread disease	13%	30%	40%	17%
Cause disease	54%	24%	14%	7%
Under control	6%	21%	45%	29%
<b>Medical tests</b>				
Purpose test	12%	26%	42%	20%
Course test	8%	29%	43%	21%
Results test	5%	24%	48%	23%
<b>Treatment</b>				
Medical treatment	15%	21%	42%	23%
Non-medical treatment	92%	5%	1%	2%
Expected result	20%	23%	41%	17%
Side effects	36%	27%	27%	10%
Expected results on disease symptoms	34%	27%	27%	12%
Expected results on social life	52%	30%	12%	6%
Expected results on sexual life	56%	27%	11%	6%
<b>Other services</b>				
Additional help	62%	25%	10%	4%
Rehabilitation	78%	15%	5%	2%
Cope with cancer at home	55%	31%	11%	3%
Psychological assistance	80%	14%	4%	2%
<b>Single items</b>				
Different care locations	70%	19%	9%	3%
Things to do to get better	42%	35%	17%	6%
	<b>Not satisfied</b>	<b>A little satisfied</b>	<b>Quite a bit satisfied</b>	<b>Very satisfied</b>
Satisfaction with information	5%	36%	42%	16%
	<b>Not helpful</b>	<b>A little helpful</b>	<b>Quite a bit helpful</b>	<b>Very helpful</b>
Helpfulness of information	4%	35%	45%	16%
	<b>Yes</b>	<b>No</b>		
Received written information	70%	30%		
Received information on video or CD-ROM	6%	94%		
Wanted more information	15%	85%		
Wanted less information	6%	94%		

Note: The numbers will not always add up to 100, because percentages have been rounded off to whole numbers.

## Satisfaction and perceived information provision

Satisfied survivors (n=396; 58%) indicated that they received more information on all subscales of the EORTC QLQ-INFO25, and found the information more useful than unsatisfied survivors (n=284; 41%) (all  $p < 0.01$ ; Figure 2).

Unsatisfied cancer survivors indicated that they received less written information (54% vs. 82%), and wanted to receive more information (27% vs. 7%; all  $p < 0.01$ ) than satisfied survivors. Some unsatisfied cancer survivors, on the other hand, indicated that they wanted to receive less information (10% vs. 3%) than satisfied survivors ( $p < 0.01$ ). There were no significant differences between unsatisfied and satisfied survivors in the use of internet for additional information (22% vs. 28%).



**Figure 2.** Differences on information provision subscale scores between survivors who are satisfied (n= 396) and not satisfied (n= 284) with the perceived information provision and helpfulness of information  
Note: \*All  $p < .001$ . EORTC-QLQ INFO25 scales 0-100: higher scores reflect better perceived information received. Not satisfied was classified by patients who were unsatisfied or only a little satisfied. Satisfied was classified by patients who were quite satisfied or very satisfied.

## Associations with perceived level of and satisfaction with information provision

In univariate analyses, younger patients indicated that they received more information about medical tests ( $p < 0.05$ ) and other care services ( $p < 0.01$ ), and wanted more information ( $p < 0.01$ ) than older patients (Table 3). Having a partner was associated with more perceived information provision about the disease ( $p < 0.01$ ), and treatment ( $p < 0.05$ ), and finding the information more helpful ( $p < 0.05$ ). Survivors who were younger, and survivors who had a partner indicated that they received more information on the expected results of their treatment on their sexual life (both

$p < 0.01$ ). Survivors who were younger, who were employed, had more comorbidities, had a higher educational level, and who used the internet for additional information indicated that they wanted to receive more information. Patients who stated that they received written information indicated that they received more information on all of the information provision subscales, were more satisfied with the information, found the information more helpful, and less often indicated that they wanted to receive more information than patients who did not receive written information (all  $p < 0.01$ ; Table 3). Patients who received less information about their disease, medical tests, and treatment, and patients who indicated to have received less useful information wanted significantly more information (all  $p < 0.05$ ). Hospital of treatment and cancer stage were not significantly associated with perceived information provision, satisfaction with information, helpfulness of information, or wanting more or less information (Table 3).

In multivariate analyses, a shorter time since diagnosis was associated with more perceived information provision about medical tests ( $p < 0.05$ ), and other care services ( $p < 0.01$ ) (Table 4).

Younger age was associated with more perceived information provision about other care services ( $p < 0.05$ ). Having undergone radiotherapy was associated with more perceived information provision about treatment ( $p < 0.01$ ). Patients who had one or more comorbidities indicated that they received less information about their disease ( $p < 0.05$ ). Having a partner was also associated with more perceived information provision about the disease ( $p < 0.05$ ). Higher educational level was associated with more perceived information provision about medical tests ( $p < 0.01$ ) and treatment ( $p < 0.01$ ). Having received written information was associated with all four of the information provision subscales (all  $p < 0.01$ ). Higher satisfaction with information provision was independently associated with absence of comorbidities ( $p < 0.01$ ), and having received written information ( $p < 0.01$ ). Cancer stage, employment status, and use of the internet for additional information were not significantly associated with perceived information provision in any of the four subscales (Table 4).

**Table 3.** ANOVA and chi-square tests evaluating the differences in mean information provision subscale scores ( $\pm$  SD) between the independent variables

	Information about disease	Information about medical tests	Information about treatment	Information about other services	Satisfaction with information	Helpfulness of information	Want more information	Want less information
	Mean (SD)							
	% Yes							
<b>Age</b>								
<55	53 (22)	64 (22)	45 (22)	26 (22)	57 (26)	60 (23)	**	4
55-69	53 (22)	61 (26)	39 (24)	14 (18)	57 (26)	58 (25)	23	5
$\geq$ 70	48 (24)	56 (29)	36 (27)	13 (19)	54 (28)	56 (27)	17	7
<b>Years since diagnosis</b>								
<2	55 (23)	**	43 (26)	19 (21)	61 (26)	59 (26)	17	7
2-5	52 (22)	62 (23)	38 (24)	15 (19)	57 (25)	58 (25)	15	4
>5	50 (23)	56 (29)	37 (25)	13 (18)	54 (29)	57 (26)	15	7
<b>Stage at diagnosis</b>								
I	51 (23)	59 (27)	38 (25)	14 (19)	57 (27)	58 (26)	15	6
II	51 (20)	62 (25)	42 (23)	17 (19)	53 (22)	56 (26)	17	6
<b>Employed</b>								
Yes	53 (22)	63 (25)	43 (24)	18 (20)	57 (26)	59 (25)	**	2
No	51 (23)	59 (27)	38 (25)	14 (18)	56 (27)	58 (26)	13	7
<b>Radiotherapy</b>								
Yes	50 (22)	60 (25)	44 (23)	13 (19)	55 (25)	57 (25)	18	7
No	52 (23)	60 (27)	37 (25)	15 (18)	57 (27)	58 (26)	15	6
<b>Comorbidity</b>								
None	56 (22)	64 (28)	42 (26)	14 (17)	67 (26)	64 (25)	**	9
1	51 (22)	60 (26)	40 (24)	16 (19)	58 (25)	59 (25)	11	3
2 or more	50 (23)	58 (27)	37 (25)	14 (19)	52 (27)	55 (26)	20	6
<b>Marital status<sup>a</sup></b>								
Partner	53 (22)	61 (26)	40 (25)	14 (19)	58 (27)	59 (25)	14	6
No partner	47 (24)	57 (28)	34 (25)	16 (19)	53 (26)	55 (26)	19	6
<b>Educational level<sup>b</sup></b>								
High	54 (20)	**	49 (24)	18 (20)	60 (24)	65 (24)	*	3
Intermediate	52 (22)	60 (26)	38 (24)	14 (19)	57 (27)	58 (25)	22	6
Low	48 (25)	55 (28)	35 (26)	15 (18)	54 (28)	56 (29)	16	8
<b>Use of internet</b>								
Yes	55 (20)	**	42 (25)	16 (19)	58 (26)	60 (25)	*	5
No	50 (23)	58 (27)	37 (25)	14 (19)	56 (27)	57 (26)	20	6
<b>Written information</b>								
Yes	55 (21)	**	42 (24)	17 (20)	62 (24)	63 (23)	**	6
No	43 (24)	51 (28)	30 (25)	10 (15)	44 (28)	45 (27)	13	5

Note: \*p<0.05; \*\*p<0.01. EORTC-QLQ INFO25 scales 0-100: high scores reflect better perceived information received. <sup>a</sup>Marital status included: partner = married/living together; no partner = divorced/widowed/never married. <sup>b</sup>Education levels included low = no/primary school; intermediate = lower general secondary education/vocational training; or high = pre-university education/ high vocational training/university.

**Table 4.** Multivariate linear and logistic regression analyses evaluating the association of independent variables with the information provision subscales

	<b>Disease</b> (Beta)	<b>Medical tests</b> (Beta)	<b>Treatment</b> (Beta)	<b>Other</b> (Beta)	<b>Satisfaction with received information</b> (Odds Ratio $\pm$ 95%CI)
<b>Age</b>	-0.25	-0.05	-0.07	-0.10*	1.00 (0.97-1.02)
<b>Years since diagnosis</b>	-0.07	-0.11*	-0.03	-0.12**	0.96 (0.89-1.03)
<b>FIGO stage</b>					
I	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>
II	0.01	0.03	-0.00	0.04	1.40 (0.71-2.76)
<b>Radiotherapy</b>					
Yes	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>
No	0.03	-0.01	-0.15**	0.03	1.21 (0.79-1.86)
<b>Comorbidity</b>					
None	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>
1	-0.13*	-0.07	-0.03	0.06	0.54 (0.31-0.92)*
2 or more	-0.11*	-0.07	-0.03	0.06	0.39 (0.24-0.63)**
<b>Marital status<sup>a</sup></b>					
Partner	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>
No partner	-0.09*	-0.04	-0.07	0.06	0.72 (0.49-1.06)
<b>Employed</b>					
No	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>
Yes	-0.03	-0.03	0.01	0.02	0.88 (0.52-1.50)
<b>Use of internet</b>					
Yes	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>
No	-0.02	-0.01	0.01	0.03	1.10 (0.72-1.67)
<b>Written information</b>					
Yes	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>
No	-0.20**	-0.18**	-0.21**	-0.17**	0.29 (0.20-0.42)**
<b>Educational level<sup>b</sup></b>					
High	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>	<i>Ref</i>
Intermediate	-0.02	-0.15*	-0.17**	-0.07	0.78 (0.43-1.39)
Low	-0.07	-0.18**	-0.17*	-0.02	0.62 (0.32-1.20)
<b>R<sup>2</sup></b>	0.08	0.08	0.32	0.25	0.16

Note: \* $p < 0.05$ ; \*\* $p < 0.01$ . <sup>a</sup>Marital status included: partner = married/living together; no partner = divorced/widowed/never married. <sup>b</sup>Education levels included low = no/primary school; intermediate = lower general secondary education/vocational training; or high = pre-university education/ high vocational training/university.

## DISCUSSION AND CONCLUSION

### Discussion

In the present study, most patients indicated that they received quite a bit information about their disease and medical tests. However, a substantial percentage of the patients stated that they were not or only a little informed about the cause of their disease, and possible side effects of their treatment. Endometrial cancer survivors received the least information on topics related to aftercare, such as what to expect in their social and sexual life, where to go for additional help, rehabilitation, or psychological support, and how to cope with cancer at home, different care locations outside the hospital, or things to do to improve their health. Moreover, issues related to aftercare were mentioned most frequently as topics that endometrial cancer survivors wanted to receive more information about. The means of the EORTC QLQ-INFO25 scores of the endometrial cancer survivors in the current study sample were lower for all of the subscales compared to two validation studies who included cancer survivors with diverse tumor types<sup>23,24</sup>.

Survivors who were not satisfied with the received information, indicated that they received less information on all information provision subscales, and found the information less helpful than satisfied survivors. Moreover, unsatisfied survivors indicated that they wanted to receive more information than satisfied survivors. Interestingly however, a small group of the unsatisfied survivors indicated that they wanted to receive less information than satisfied survivors. It is interesting to note that there was some overlap in the topics on which patients wanted to receive either more or less information. Whereas some patients indicated that they wanted to receive more information on the possible side-effects of treatment and overall information on endometrial cancer, other patients indicated that they wanted to have received less information on these topics. These findings may imply that in order to improve satisfaction with information provision, health care providers should screen their patients by asking about their specific information needs.

Factors associated with higher perceived levels of information were younger age, higher educational level, more recent diagnosis, having undergone radiotherapy, absence of comorbidities, having a partner, and having received written information. Factors associated with higher satisfaction with information were absence of comorbidities, and having received written information.

The observed association between younger age and more perceived information provision is consistent with previous research<sup>13,27</sup>. Studies have shown that older

patients tend to ask fewer questions during their visit with their physician, and might therefore receive less information<sup>28,29</sup>. Older patients are less interested in detailed information, but only want information about the most important aspects of their disease and treatment<sup>28</sup>. Furthermore, older patients have been found to have a greater reliance on information provided by their health care provider<sup>10</sup>. Doctors might also be prejudiced against older patients; some clinicians seem to provide older patients with less information<sup>30</sup>. Finally, older patients may have more difficulties processing and remembering medical information they receive than younger patients<sup>31</sup>.

Survivors with a high educational level indicated that they received more information about their medical tests and treatment than lower educated survivors. Previous studies have shown that higher educated patients want as much information on prognosis as possible<sup>32</sup>, are more likely to seek information from a greater range of sources, like the internet<sup>10</sup>, and show more perceived uncertainty<sup>33</sup>. For these reasons, higher educated survivors might ask their gynecologists for more explanation when the provided information does not yet answer their needs. It is also possible that doctors (who are higher educated themselves) are more prone to give more information to patients with a similar educational level. Higher educated patients may also be better able to understand and remember the information. To improve information provision for lower educated patients, health care providers could pay more attention to patients' health literacy levels, i.e. "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions"<sup>34</sup>, by providing information on a basic comprehension level.

Patients who were diagnosed and treated shortly before completion of the questionnaire, reported that they received more information about their medical tests and other care services. This finding might indicate that information provision has improved with time. However, it could also be ascribed to the diminishing contacts of patients with their gynecologist after the completion of treatment and follow-up<sup>35</sup>. Patients who are still under supervision of a health care provider might have a clearer picture of the information they received. It is also possible that recall bias influenced these findings. Patients may forget the information they received, because it is often complex and emotionally charged<sup>36</sup>. The mean time since diagnosis was 4.9 years, which could hinder the recall of the received information. For future research, longitudinal studies are needed to be able to assess the perceived information provision over time.

Our results also showed that patients who had undergone radiotherapy reported receiving more information about their treatment. It is very likely that patients undergoing radiotherapy also receive information from their radiotherapist. In addition, it is likely that gynecologists provide more information to these patients, as the treatment is more complex and can have more serious acute and long-term effects than surgery alone.

Patients with fewer comorbidities reported that they received more information about their disease and were more satisfied with the information. It is possible that patients with more comorbidities have more specific information needs, that are not fulfilled by the standard information provided to them. They might also have difficulties separating the information they received about their other condition(s) from the information about their cancer, or they might compare these sources of information with each other.

Patients who have a partner also indicated that they received more information about their disease. It is possible that the partner went to the consultations together with the patient, and also remembered the received information. Previous research indicates that accompanied patients are likely to benefit from the extra information that their companions remember<sup>37</sup>. The presence of companions has been found to increase patient understanding, involvement in the consultation, and decision-making<sup>38</sup>. Discussing the received information with their partner may help patients to better understand and remember the information they receive from their gynecologist.

Finally, patients who received written information indicated that they received more information, and were more satisfied with the information than patients who did not receive written information. This finding is consistent with previous studies, which have shown that providing patients with written information increases their recall, knowledge and satisfaction with information<sup>39,40</sup>.

Some limitations of the present study should be noted. Although demographic and clinical characteristics were present of the non-respondents and patients of whom the addresses could not be verified, it remains unknown why non-respondents declined to participate. In addition, the cross-sectional design limits the determination of causal associations between the study variables. Furthermore, with a mean time since diagnosis of 4.9 years, the patients in the current study can be described as (long-term) endometrial cancer survivors, who are out of the acute phase of medical treatment and decision making. The results can therefore not be generalized to patients who are in the midst of their treatment phase or shortly after treatment completion. For

future research, it would be interesting to compare the responses of these groups of patients. In addition, nothing is known about the relation with other patient-reported outcomes. For future research, it would be interesting to look at associations with other outcomes, such as psychological adjustment. Another limitation is that the EORTC QLQ-INFO25 response options (“not at all”, “a little”, “quite a bit and “very much”) do not give participants the option to respond with “somewhat” or “a moderate amount”. Patients were forced to choose between no information or a little information, and quite a bit of information or a lot of information. Some patients may have preferred a more moderate response option. Finally, the EORTC QLQ-INFO25 only measures the information patients indicated they received during their disease or treatment. It does not measure who provided the information, and when the information was provided exactly. It would be interesting to assess which aspects of information patients receive from their different health care providers (i.e., gynecologist, radiotherapist, medical oncologist, oncology nurse, general practitioner), at what point in their disease trajectory they receive the information, and whether this is associated with usefulness of and satisfaction with the information received. Moreover, as the EORTC QLQ-INFO25 assesses patient reported outcomes, it is not clear how much information was actually provided. It would therefore also be interesting to compare data on actual information provision with data from questionnaires.

## **Conclusion**

Despite the limitations noted, the present study provides important new information by showing the perceived level of and satisfaction with information received by endometrial cancer survivors, and the associations with socio-demographic and clinical characteristics. These results can help health care providers give adequate information to those who need it. The population-based sampling frame, high response rate, and large range in elapsed time since diagnosis make it possible to generalize the results to a broad range of endometrial cancer survivors.

## **Practice implications**

As the number of endometrial cancer survivors is rapidly increasing, and provision of information is one of the most important factors in the support for cancer survivors, it becomes more important to investigate the current state of information provision and satisfaction with information provision in endometrial cancer survivors.

The present study shows that endometrial cancer survivors experience several areas of information provision as insufficient, suggesting room for improvement. Health care providers often have limited time and resources. With growing evidence that well-informed patients are more satisfied with their care, and do better clinically <sup>35</sup>, efforts are needed to improve the information provision to endometrial cancer patients. The current identification of the specific information needs of endometrial cancer survivors and the factors associated with these information needs could facilitate a more patient-tailored approach of informing patients, which may contribute to improved satisfaction and quality of life of endometrial cancer survivors.

A way to achieve more patient-tailored information provision, recommended by the American Institute of Medicine <sup>41</sup> and the Dutch Health Council <sup>42</sup>, might be the implementation of a Survivorship Care Plan (SCP), which is a summary of patients' course of treatment as a formal document, including recommendations for subsequent cancer surveillance, management of late effects, and strategies for health promotion <sup>41</sup>. The present finding that endometrial cancer patients who receive written information report to have received more information, and are more satisfied with the information supports this suggestion. We are therefore currently evaluating in a randomized controlled trial (ROGY Care), whether provision of an SCP to gynecological cancer patients improves satisfaction with information, satisfaction with care, and ultimately quality of life <sup>43</sup>.

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# Chapter 3

## **Follow-up practice in endometrial cancer and the association with patient and hospital characteristics: A study from the population-based PROFILES registry**

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## ABSTRACT

**Objective:** To examine to what extent endometrial cancer survivors experienced follow-up according to the Dutch national guidelines, and to identify associations between follow-up care consumption and socio-demographic and clinical characteristics, Health-Related Quality of Life (HRQL), and worry (including fear of recurrence). Patients' preferences with the received follow-up care were also evaluated.

**Methods:** All patients diagnosed with endometrial cancer FIGO stages I-II between 1999 and 2007, registered in the Eindhoven Cancer Registry (ECR), received a questionnaire including patients' follow-up care consumption, preferences regarding the follow-up schedule, HRQL (SF36 and EORTC-QLQ-EN24), and worry (IOCv2).

**Results:** 742 (77%) endometrial cancer survivors returned a completed questionnaire. Overall, 19% reported receiving more follow-up visits than recommended by the guidelines. Overconsumption of follow-up care was lowest in follow-up year 1 (13%), and highest in follow-up years 6-10 (27%). In addition, overconsumption was associated with having a comorbid condition, a higher score on the worry subscale, and hospital of treatment. Most patients (83%) felt comfortable with their follow-up schedule. Patients in follow-up years 6-10 felt least comfortable (69%).

**Conclusion:** Follow-up frequency was higher than recommended in a large group of endometrial cancer survivors, mainly in follow-up year 6-10. Moreover, a substantial variation in follow-up practice was observed between the different hospitals. Despite limited evidence to support the use of intensive follow-up schedules, the current study suggests that intensive routine follow-up after endometrial cancer continues to be standard practice. Possibly, patients should be better informed in order to reduce overconsumption and worry.

## INTRODUCTION

Endometrial cancer is the most common gynecologic malignancy in Western countries, with an incidence of 15-25 per 100,000 women annually<sup>1,2</sup>. The majority of these women (i.e., more than 75%) are diagnosed at an early stage (i.e., FIGO stages I and II), and have an excellent prognosis, as indicated by the overall 5-year survival rate of 80% in the US and The Netherlands<sup>1-3</sup>.

After primary treatment, women with endometrial cancer are monitored in routine follow-up based on periodic visits for several years after treatment. The primary rationale for follow-up is to timely identify disease recurrence, in order to improve survival and/or quality of life<sup>4,5</sup>. In addition, follow-up may provide psychosocial support<sup>6</sup> and can be reassuring for patients<sup>7</sup>. However, intensive follow-up schedules require considerable financial resources<sup>6,8,9</sup>, and can increase patients' anxiety<sup>7</sup>.

The frequency of follow-up visits of endometrial cancer survivors has been a continuing area of discussion in the past years, due to limited evidence whether intensive follow-up schedules are more or less beneficial than non-intensive follow-up schedules<sup>4,10</sup>. The recurrence rate for early stage endometrial cancer is relatively low, ranging from 3 to 17%, depending on primary and adjuvant treatment<sup>4,11,12</sup>. Most recurrences (i.e., 70%) occur within three years after diagnosis<sup>10,13</sup>, and in patients that present with new symptoms between scheduled visits<sup>4,11,14,15</sup>. Therefore, it has been suggested that follow-up has limited clinical benefit<sup>8,16</sup>, and that the number of follow-up visits of endometrial cancer survivors, particularly those diagnosed at an early stage, might be decreased while the quality of care remains adequate<sup>17,18</sup>.

Guidelines for follow-up of endometrial cancer lack evidence-based knowledge and vary in recommended follow-up strategies<sup>14</sup>. Previous studies have shown large variations in follow-up practice in endometrial cancer between different countries and institutions<sup>5,10,14,16,19,20</sup>. However, these studies have not investigated which factors may be associated with follow-up consumption.

Understanding the factors associated with consumption of follow-up care might help health care providers to better organize the follow-up of endometrial cancer survivors. The aim of the present study was therefore to examine to what extent endometrial cancer survivors experienced follow-up according to the Dutch guidelines, and to identify associations between consumption of follow-up care and socio-demographic and clinical characteristics. As previous research has shown that treatment can have

long-term consequences on the Health-Related Quality of Life (HRQL) of endometrial cancer survivors<sup>21</sup>, and that patients with heightened anxiety levels may request more long-term follow-up<sup>22</sup>, the aim of the present study was also to identify associations between consumption of follow-up care and HRQL and worry. In addition, patients' preferences regarding the follow-up were evaluated.

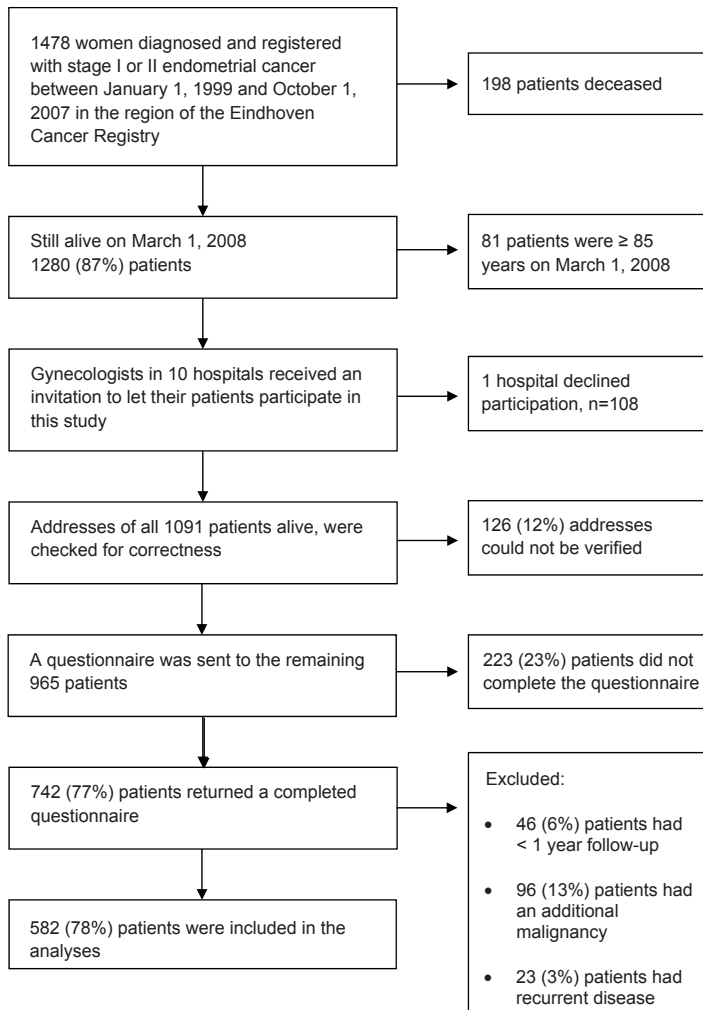
## **METHODS**

### **Setting and participants**

A cross-sectional study was performed among 1091 endometrial cancer survivors registered within the Eindhoven cancer registry (ECR) of the Comprehensive Cancer Center South (CCCS). The ECR records data on all patients newly diagnosed with cancer in the southern part of the Netherlands, an area with 10 hospitals serving 2.3 million inhabitants. The ECR was used to select patients diagnosed with endometrial cancer between January 1<sup>st</sup> 1999 and October 1<sup>st</sup> 2007 in 10 hospitals. All individuals (age 18-84 years) diagnosed with endometrial cancer FIGO stages I-II (classification 1988) were eligible for participation. Deceased patients were excluded by linking the ECR with the Central Bureau of Genealogy. In addition, patients who had less than 1 year follow-up were excluded. Patients with an additional malignancy or recurrent disease were also excluded, as this may have influenced their follow-up (Figure 1). Ethical approval for the study was obtained from a Medical Ethics Committee.

### **Data collection**

Data collection took place between May and July 2008 and was done within PROFILES (Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship). PROFILES is a registry for the study of the physical and psychosocial impact of cancer and its treatment from a dynamic, growing population-based cohort of both short and long-term cancer survivors. PROFILES contains a large web-based component and is linked directly to clinical data from the ECR. Details of the data collection method have been previously described<sup>21,23,24</sup>. Data from the PROFILES registry will be available for non-commercial scientific research, subject to study questions, privacy and confidentiality restrictions, and registration ([www.profilesregistry.nl](http://www.profilesregistry.nl)).



**Figure 1.** Flow-chart of the data collection process

Gynecologists sent their (former) patients a letter to inform them about the study and a questionnaire. To avoid coercion and assure anonymity, patients were asked to send the informed consent form and questionnaire to the Comprehensive Cancer Center South in a pre-stamped envelope. Returned questionnaires contained only a study number. Research assistants at the Comprehensive Cancer Center South separated the informed consent forms from the questionnaires before providing the questionnaires to the researchers. By returning the completed questionnaire, patients agreed to participate and consented with linkage of the outcomes of the questionnaire to their disease

history as registered in the ECR. Patients were reassured that non-participation would not have any consequence for their follow-up care or treatment. Non-respondents were sent a reminder letter and questionnaire within 2 months.

## **Measures**

### ***Socio-demographic and clinical characteristics***

Clinical and patient information was obtained from the ECR<sup>25</sup> (i.e., date of birth, date of diagnosis, disease stage, and primary treatment). Follow-up data on recurrence and metastasis were derived from chart records. Comorbidity at the time of survey was categorized according to the Self-administered Comorbidity Questionnaire (SCQ)<sup>26</sup>. Socio-Economic Status (SES) was determined by an indicator developed by Statistics Netherlands, based on individual fiscal data on the economic value of the home and household income<sup>27</sup>.

### ***Follow-up care consumption***

Follow-up care consumption was assessed by asking patients how many times they visited a medical specialist in relation to cancer in the past 12 months. Furthermore, patients were asked whether or not they currently received cancer surveillance consultations, and if so, whether a schedule was made regarding the frequency of these consultations. The answer categories were "Every 3 months", "Every 4 months", "Every 6 months", "Every year", "Every 2 years", and "No, there are no definite appointments". Finally, patients were asked whether they felt comfortable with the number of cancer surveillance consultations. The answer categories were "Yes", "No, I would like to receive consultations more often", "No, I would like to receive consultations less often", and "No, I do not want to receive any consultations".

To assess whether patients received follow-up according to the guidelines, the 2004 Dutch national guidelines on follow-up for endometrial cancer survivors were used, which recommend that follow-up consultations include a thorough history and physical examination, including a speculum and pelvic examination. The 2004 guidelines recommend a visit every 3 months during the first year, every 6 months during the second year, and every 12 months during the third, fourth and fifth year after the end of treatment, irrespective of stage and grade (<http://www.oncoline.nl>). Patients were divided according to follow-up year (i.e., follow-up year 1, year 2, years 3-5, and years 6-10). The number of cancer-related visits to a specialist in the past 12 months was compared to the number of visits recommended by the guidelines, with an upper and lower margin of 1 visit (i.e., allowing for 1 visit more or less than the guidelines). The 2004 Dutch national guidelines do not state surveillance recommendations after the

fifth year. Therefore, for years 6-10, zero visits were used (with an upper margin of 1). Follow-ups occurring more frequently were defined as overconsumption, follow-ups occurring less frequently as underconsumption.

### ***Health-Related Quality of Life***

General Health-Related Quality of Life (HRQL) was assessed with the general health scale of the validated Dutch version of the SF-36 questionnaire <sup>28</sup>. The scale was converted to a 0-100 linear scale according to standard scoring procedures, with higher scores indicating better functioning.

Disease-specific HRQL was assessed with the lymphedema scale and the gastrointestinal symptom scale of the Dutch validated European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Endometrial Cancer Module (EORTCQLQ-EN24) <sup>29</sup>. Items were rated on a 4-point Likert-scale ranging from 1 ("not at all") to 4 ("very much"). Scales were converted to a 0-100 linear scale according to standard scoring procedures, with higher scores indicating higher symptom burden.

### ***Worry***

Worry was assessed with the worry subscale of the Impact of Cancer version 2 (IOCv2) questionnaire. The IOCv2 assesses aspects of long-term cancer survivorship <sup>30</sup>. The subscale consists of 7 items regarding worries about health, the future, and recurrence of the cancer (e.g., "I worry about the cancer coming back or about getting another cancer"). Respondents indicated their level of agreement, ranging from 1 ("strongly disagree") to 5 ("strongly agree"). The subscale score is computed as the mean of the responses for the 7 items.

### **Statistical analyses**

All statistical analyses were conducted using SPSS version 17.0 (Statistical Package for Social Sciences, Chicago, IL, USA), and p-values of <0.05 were considered statistically significant.

Differences in socio-demographic and clinical characteristics between respondents, non-respondents, and patients with unverifiable addresses were compared using ANOVA for continuous variables and chi-square tests for categorical variables. Frequencies and percentages were used to summarize categorical data; means and standard deviations were used to summarize continuous data.

Multivariate logistic regression analyses were performed to investigate whether socio-demographic and clinical characteristics, HRQL and worry were associated with overconsumption of follow-up care. All socio-demographic and clinical variables, and the IOCV2 worry subscale were included in the analyses. For the SF-36 and EORTC QLQ-EN24, only the subscales that were found to be most salient in previous research<sup>21</sup> were included in the analyses (i.e., general health, lymphedema, and gastrointestinal symptoms). This was determined a priori<sup>31</sup>. All variables were entered simultaneously in the regression analyses. For continuous variables, it has been suggested to consider a meaningful magnitude of change and to report odds ratios and confidence intervals accordingly<sup>32</sup>. Therefore, for the continuous scales SF-36 and EORTC QLQ-EN24, the odds ratios and confidence intervals were calculated for a 10-unit change, as this is considered a moderate clinically meaningful difference in quality of life<sup>33</sup>. In addition, separate logistic regression analyses were performed, including only the variables that were significant in the multivariate logistic analyses, to investigate whether hospital of treatment is associated with overconsumption of follow-up care.

## RESULTS

### Study population

Of the 965 endometrial cancer survivors who were sent a questionnaire, 742 (77%) returned a completed questionnaire. Of the patients who returned a completed questionnaire, 46 (6%) patients had received less than 1 year follow-up, 96 (13%) had an additional malignancy, and 23 (3%) patients had recurrent disease and were therefore excluded (Figure 1). Respondents were younger than non-respondents ( $p < 0.001$ ), with a mean age of 66.7 years (range 26.8-84.6). Details of the characteristics of respondents, non-respondents, and patients with unverifiable addresses have been previously described<sup>21,23</sup>.

Of the participants, the mean time since diagnosis was 5.2 years (range 1.5-10.0) and most patients (93%) had stage I endometrial cancer at diagnosis. All patients were treated with surgery, followed by radiotherapy (22%) or chemotherapy (<1%). Most participants had two or more comorbidities (53%), 26% of participants had one comorbidity, and 21% had no comorbidities. The most frequent comorbid conditions were high blood pressure (42%), arthritis (36%), backache (26%), diabetes (16%), heart condition (12%), and rheumatism (10%). Characteristics of participants according to follow-up year are described in Table 1.

**Table 1.** Socio-demographic and clinical characteristics, HRQL, and worry of participants according to follow-up year

	Total (N=582)	Follow-up year 1 (N=80)	Follow-up year 2 (N=103)	Follow-up year 3-5 (N=210)	Follow-up year 6-10 (N=189)	p-value*
	N (%)					
<b>Age at time of survey</b> (Mean, SD)	66.7 (8.2)	63.4 (9.3)	65.4 (8.1)	66.3 (7.7)	69.3 (7.7)	<0.001
<b>FIGO stage</b>						
IA	88 (15)	7 (9)	15 (15)	34 (16)	32 (17)	
IB	300 (52)	37 (46)	51 (50)	105 (50)	107 (57)	
IC	155 (27)	29 (36)	28 (27)	57 (27)	41 (22)	
IIA	20 (3)	1 (1)	5 (5)	7 (3)	7 (4)	
IIB	19 (3)	6 (8)	4 (4)	7 (3)	2 (1)	0.11
<b>Histological grade</b>						
1	278 (48)	30 (38)	46 (45)	100 (48)	102 (54)	
2	224 (39)	29 (36)	42 (41)	82 (39)	71 (38)	
3	57 (10)	17 (21)	10 (10)	16 (8)	14 (7)	
Unknown	23 (4)	4 (5)	5 (5)	12 (6)	2 (1)	0.01
<b>Socio-Economic Status</b>						
Low	132 (23)	15 (19)	20 (19)	47 (23)	50 (27)	
Medium	238 (41)	38 (49)	45 (44)	84 (40)	71 (38)	
High	191 (33)	25 (32)	35 (34)	72 (35)	59 (31)	
Unknown	17 (3)	0 (0)	3 (3)	5 (2)	9 (5)	0.44
<b>Comorbidity</b>						
None	124 (21)	23 (29)	18 (18)	45 (21)	38 (20)	
1	149 (26)	20 (25)	34 (33)	51 (24)	44 (23)	
2 or more	309 (53)	37 (46)	51 (50)	114 (54)	107 (57)	0.31
	Mean (SD)					
<b>SF36 (0-100)</b>						
General health <sup>a</sup>	67 (20)	70 (19)	68 (21)	66 (21)	65 (19)	0.29
<b>EORTC-EN24 (0-100)</b>						
Lymphedema <sup>b</sup>	21 (26)	16 (22)	23 (28)	22 (27)	21 (25)	0.22
Gastrointestinal symptoms <sup>b</sup>	18 (18)	18 (19)	18 (18)	17 (19)	18 (18)	0.98
<b>IOCV2 (1-5)</b>						
Worry scale <sup>c</sup>	2.4 (0.9)	2.5 (0.9)	2.3 (1.1)	2.4 (0.9)	2.3 (0.9)	0.24

Note: \*P-values report comparisons between follow-up groups, according to ANOVA and chi-square tests. <sup>a</sup>A higher score represents a higher level of functioning. <sup>b</sup>A higher score represents a higher level of symptoms or problems. <sup>c</sup>A higher score was either represents a stronger endorsement of that content area. A dash (-) indicates that the number of patients who answered the question was 0 or 1. The numbers will not always add up to 100, because percentages have been rounded off to whole numbers.

### **Reported follow-up and satisfaction with follow-up**

Overall, 65% of participants indicated that they still received follow-up consultations at the time of questionnaire. In the first and second year, almost all survivors (93%) received follow-up consultations. In follow-up years 3-5, this was 73%, and in follow-up years 6-10, 28% ( $p < 0.001$ ; Table 2).

Within the past year, overall 37% of survivors had visited a specialist 1 to 2 times regarding their cancer. Nineteen percent reported visiting a specialist 3 to 5 times, and 3% reported more than 5 visits. Thirty percent of survivors had not visited a specialist regarding their cancer within the past year (Table 2).

In general, the majority of survivors felt comfortable with their follow-up schedule (83%). Only 2% of survivors preferred more consultations, 3% preferred less consultations, and 5% preferred no consultations at all. However, survivors in follow-up year 6-10 less often felt comfortable with their follow-up schedule (69%), and more often indicated (12%) that no consultations were preferred compared to survivors in other follow-up years ( $p < 0.001$ ; Table 2).

### **Overconsumption of follow-up care and associated factors**

Overall, 369 (63%) survivors reported to have received follow-up appointments according to the guidelines, 112 (19%) had more, and 36 (6%) had less than recommended.

Overconsumption of follow-up care was associated with follow-up year ( $p < 0.05$ ; Table 3). In follow-up year 1, only 13% of survivors had more follow-up appointments than recommended, whereas in follow-up years 6-10, more than a fourth (27%) of survivors reported overconsumption (Figure 2A). Furthermore, overconsumption was associated with having a comorbidity ( $p < 0.05$ ; Table 3) and worry ( $p < 0.01$ ; Table 3). Age, disease stage, having undergone radiotherapy, Socio-Economic Status, and general or disease-specific HRQL were not significantly associated with overconsumption of follow-up care (Table 3).

The 10 participating hospitals differed in amount of overconsumption. For instance, in hospital A, 4% of survivors reported overconsumption, whereas in hospital I, 28% reported overconsumption (Figure 2B). In additional logistic regression analyses, including hospital, follow-up year, comorbidity, and worry, overconsumption was still associated with follow-up year, comorbidity and worry. In addition, overconsumption was associated with hospital of treatment in 7 out of 9 hospitals (reference hospital A), with odds ratios ranging from 6.0 to 8.2 (95% CI 1.1-39.2; all  $p < 0.05$ ).

**Table 2.** Follow-up care consumption of participants according to follow-up year

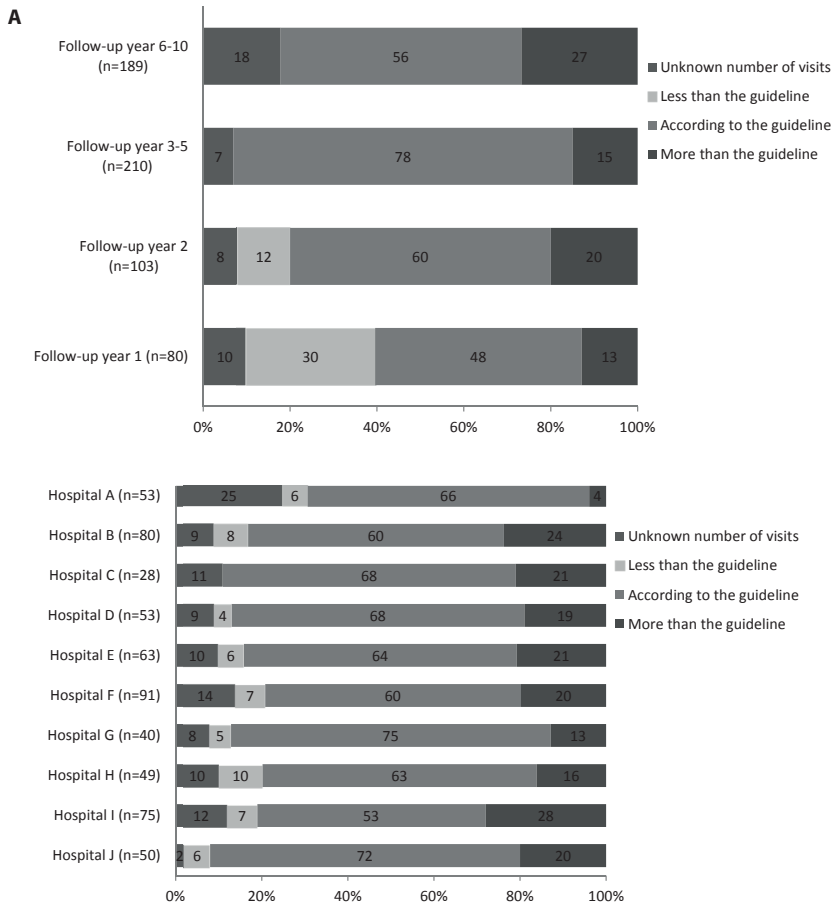
	Total (N=582)	Follow-up year 1 (N=80)	Follow-up year 2 (N=103)	Follow-up year 3-5 (N=210)	Follow-up year 6-10 (N=189)	p-value*
	N (%)					
<b>Number of cancer-related visits to a specialist in the past 12 months</b>						
0 times	172 (30)	11 (14)	12 (12)	44 (21)	105 (56)	
1-2 times	216 (37)	13 (16)	43 (42)	120 (57)	40 (21)	
3-5 times	110 (19)	38 (48)	38 (37)	27 (13)	7 (4)	
>5 times	19 (3)	10 (13)	2 (2)	4 (2)	3 (2)	<b>&lt;0.001</b>
Missing	65 (11)	8 (10)	8 (8)	15 (7)	34 (18)	
<b>Currently receiving surveillance consultations</b>						
Yes	376 (65)	74 (93)	96 (93)	153 (73)	53 (28)	
No	172 (30)	3 (4)	4 (4)	49 (23)	116 (61)	<b>&lt;0.001</b>
Missing	34 (6)	3 (4)	3 (3)	8 (4)	20 (11)	
<b>Appointments made for follow-up care<sup>a</sup></b>						
Every 3 months	32 (6)	24 (30)	4 (4)	3 (1)	1 (1)	
Every 4 months	47 (8)	22 (28)	15 (15)	9 (4)	1 (1)	
Every 6 months	160 (28)	22 (28)	56 (54)	73 (35)	9 (5)	
Every year	119 (20)	2 (3)	21 (20)	62 (30)	34 (18)	
Every 2 years	6 (1)	0 (0)	0 (0)	1 (1)	5 (3)	
No definite appointments made	28 (5)	2 (3)	0 (0)	9 (4)	17 (9)	<b>&lt;0.001</b>
Missing	190 (33)	8 (10)	7 (7)	53 (25)	122 (65)	
<b>Comfortable with follow-up schedule</b>						
Yes	480 (83)	70 (88)	95 (92)	185 (88)	130 (69)	
No, prefer more consultations	13 (2)	2 (3)	1 (1)	5 (2)	5 (3)	
No, prefer less consultations	15 (3)	4 (5)	3 (3)	6 (3)	2 (1)	
No, prefer no consultations	28 (5)	1 (1)	2 (2)	3 (1)	22 (12)	<b>&lt;0.001</b>
Missing	46 (8)	3 (4)	2 (2)	11 (5)	30 (16)	

Note: \*P-values report comparisons between follow-up groups, according to chi-square tests. <sup>a</sup>Only for patients who answered "yes" on "Currently receiving surveillance consultations". The numbers will not always add up to 100, because percentages have been rounded off to whole numbers.

**Table 3.** Descriptives, and multivariate logistic regression analyses evaluating the association between overconsumption of follow-up care and socio-demographic and clinical characteristics, HRQL, and worry

	Overconsumption (N=112)	According to guideline (N=369)	Overconsumption (vs. according to guideline) (N=481)
	N (%)		Odds Ratio $\pm$ 95%CI
<b>Age at time of survey</b>			
<60	20 (18)	71 (19)	Ref
$\geq$ 60	92 (82)	298 (81)	1.0 (0.5-1.9)
<b>Follow-up year</b>			
Year 1	10 (9)	38 (10)	Ref
Year 2	21 (19)	62 (17)	1.6 (0.6-4.3)
Years 3-5	31 (28)	164 (44)	0.9 (0.3-2.1)
Years 6-10	50 (45)	105 (29)	<b>2.5 (1.0-6.2)*</b>
<b>FIGO stage</b>			
IA	16 (14)	55 (15)	Ref
IB	56 (50)	191 (52)	1.2 (0.6-2.5)
IC	31 (28)	101 (27)	1.4 (0.5-3.4)
IIA & IIB	9 (8)	22 (6)	1.1 (0.2-4.7)
<b>Radiotherapy</b>			
Yes	31 (28)	78 (21)	Ref
No	81 (72)	291 (79)	0.7 (0.3-1.6)
<b>Comorbidity</b>			
None	10 (9)	76 (21)	Ref
1	35 (31)	90 (24)	<b>2.6 (1.1-6.1)*</b>
2 or more	67 (60)	203 (55)	1.8 (0.8-4.1)
<b>Socio-Economic Status (SES)</b>			
High	39 (35)	126 (34)	Ref
Intermediate	43 (38)	149 (41)	1.1 (0.6-2.0)
Low	26 (23)	85 (23)	1.0 (0.6-1.8)
Unknown	4 (4)	9 (2)	
Mean (SD)			
<b>SF36 (0-100)<sup>a</sup></b>			
General Health <sup>b</sup>	60 (18)	68 (20)	0.9 (0.8-1.1)
<b>EORTC-EN24 (0-100)<sup>a</sup></b>			
Lymphedema <sup>c</sup>	24 (28)	21 (26)	1.0 (0.9-1.1)
Gastrointestinal symptoms <sup>c</sup>	18 (18)	17 (18)	0.9 (0.7-1.0)
<b>IOCV2 (1-5)</b>			
Worry scale <sup>d</sup>	2.7 (0.9)	2.3 (0.8)	<b>1.7 (1.2-2.4)**</b>

Note: \* $p < 0.05$ . \*\* $p < 0.01$ . <sup>a</sup>Odds ratios and confidence intervals are reported for a 10-unit change. <sup>b</sup>A higher score represents a higher level of functioning. <sup>c</sup>A higher score represents a higher level of symptoms or problems. <sup>d</sup>A higher score represents a stronger endorsement of that content area. The numbers will not always add up to 100, because percentages have been rounded off to whole numbers.



**Figure 2.** A. Follow-up frequency of participants compared to the Dutch endometrial cancer guidelines (2004), according to follow-up year (%). B. Follow-up frequency of participants compared to the Dutch endometrial cancer guidelines (2004), according to hospital (%)

Note: The numbers will not always add up to 100, because percentages have been rounded off to whole numbers.

## DISCUSSION

In the present study, most endometrial cancer survivors reported to have received follow-up according to the national guidelines. However, there was substantial variation in follow-up practice, with both over- and underconsumption. A large group of survivors, particularly in follow-up years 6-10, reported to have received follow-up care more frequently than recommended. On the other hand, a substantial percentage of survivors in follow-up year 1 indicated that they received less follow-up visits than recommended. The overall number of survivors receiving less follow-up than recommended was

too small to do additional analyses, but in future research, it would be interesting to investigate the specific characteristics of this group of survivors.

Because the data-collection of the present study took place in 2008, survivors' reported follow-up was compared to the 2004 guidelines. Remarkably, in later revisions (2009 and 2011) more follow-up visits were recommended than the 2004 guidelines. Although the Dutch guidelines are not stringent, the data of the current study suggest that intensive routine follow-up after endometrial cancer continues to be standard practice in The Netherlands, despite limited evidence to support its use. This finding is similar to a study carried out in the United Kingdom<sup>34</sup>. More recently, the Society of Gynecologic Oncologists published guidelines regarding the surveillance of endometrial cancer<sup>35</sup>.

In general, the majority of survivors felt comfortable with their follow-up schedule. This is in line with a recent study, in which gynecological cancer patients showed a strong preference for the existing regimen of follow-up care<sup>36</sup>. In the present study however, survivors in follow-up year 6-10 less often felt comfortable with their follow-up schedule compared to patients in the other follow-up years, and more often preferred receiving no consultations at all.

The variation in overconsumption observed between participating hospitals is in line with previous studies<sup>5,10,14,16,19</sup>, reflecting the lack of compelling guidelines on regional and national levels.

Survivors with a comorbid condition more often reported visits to the specialist related to their cancer. A possible explanation is that these survivors have difficulties separating the visits regarding their comorbidity, from follow-up visits for their cancer. Specialists may also initiate more visits with these patients, due to their increased health risks. Interestingly, the presence of two or more comorbidities was not significantly associated with overconsumption of follow-up care. A possible explanation for this finding could be that patients who have more than one comorbidity visit their general practitioner (i.e., primary care provider) more often, instead of their specialist. Many common comorbidities in this study (e.g., high blood pressure, arthritis, and backache) are typically treated by a general practitioner in The Netherlands.

The observed association between overconsumption of follow-up care and worry is consistent with the previous finding that patients with heightened anxiety levels seek out health care behaviors and may therefore request more long-term follow-up<sup>22</sup>. The period following treatment is an uncertain time, and for many patients routine visits to

the hospital may be reassuring<sup>36</sup>. Our data suggest that worry does not decrease over time, not even after up to 10 years. This is in line with a recent study, which found that a third of endometrial cancer survivors remained fearful about their future health<sup>37</sup>. This fear may possibly be alleviated by adequate counseling and patient-tailored information. A previous study suggested that patients who are uncertain about how to manage their illness are at an increased risk for psychological distress<sup>38</sup>. In addition, it has been found that well-informed patients are more satisfied with their follow-up<sup>39</sup>. Sufficient information may reduce patients' worry and consequently reduce overconsumption of follow-up care. Moreover, because the majority of recurrences of endometrial cancer is symptomatic<sup>11,14</sup>, the 2009 and 2011 Dutch guidelines recommend adequate counseling about potential symptoms of recurrences of endometrial cancer. However, previous research suggests that endometrial cancer survivors do not receive adequate information regarding their risk for recurrence or how to monitor this<sup>23,37</sup>. Survivorship Care Plans, recommended by the American Institute of Medicine<sup>40</sup> and the Dutch Health Council<sup>9</sup>, can potentially address this problem. This is currently being evaluated through a multicenter RCT in gynecological cancer patients<sup>41</sup>.

Some limitations of the present study should be noted. First of all, only patients diagnosed with endometrial cancer stage I and II were included. The results can therefore not be generalized to patients with stage III or IV endometrial cancer. In addition, although demographic and clinical characteristics were known of non-respondents and patients of whom the addresses could not be verified, it remains unknown why non-respondents declined to participate. Furthermore, the cross-sectional design limits the determination of causal associations between the study variables. Another limitation of this study is the possibility of recall bias. As patients were asked to report the frequency of follow-up appointments within the last 12 months, it is possible that women who had more recent appointments remembered their appointments more accurately than those who had their last appointment a longer time ago. Age may also have affected recall, with younger patients having more accurate recall than older patients. As self-reported follow-up consumption was assessed, it is not clear how much follow-up was actually provided. It would therefore be interesting to compare data on actual follow-up provision with questionnaire data. Finally, it is unknown who provided the follow-up care (i.e., gynecologist, radiotherapist, oncology nurse), what the content of the follow-up was, and whether the consultation was initiated by the patient or health care provider.

Despite the limitations noted, the present study contributes to the ongoing discussion regarding the frequency of follow-up visits of endometrial cancer survivors by showing

the current state of follow-up, the factors associated with follow-up consumption, and patients' preferences. These results can help health care providers to critically evaluate current follow-up practices, and to better organize the follow-up care of endometrial cancer survivors. The population-based sampling frame, high response rate, and large range in elapsed time since diagnosis make it possible to generalize the results to a broad range of endometrial cancer survivors.

In conclusion, this population based study shows substantial variation in follow-up practice in endometrial cancer between different hospitals. Overconsumption is mainly found in follow-up year 6-10, and appears to be driven by follow-up year, comorbidity, worry, and hospital of treatment. More research is needed to further investigate how overconsumption in follow-up practice can be reduced in the future.

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# Chapter 4

## **The impact of a cancer Survivorship Care Plan on gynecological cancer patient and health care provider reported outcomes (ROGY Care): Study protocol for a pragmatic cluster randomized controlled trial**

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## ABSTRACT

**Background:** There is a need for improvement of information provision and post-treatment care for cancer survivors. A Survivorship Care Plan (SCP) is recommended by the American Institute of Medicine and the Dutch Health Council, which is a summary of patients' course of treatment as a formal document, and includes recommendations for subsequent cancer surveillance, management of late effects, and strategies for health promotion. Until now, evidence on the effects of implementing the SCP in clinical practice is lacking. The rationale and study design of a pragmatic cluster randomized trial, aiming to assess the impact of SCP care in routine clinical practice, is presented.

**Methods/Design:** A web-based patient registration system 'Registrationsystem Oncological GYnecology' (ROGY) is used by gynecologists in the South of the Netherlands since 2006. A personalized SCP can automatically be generated out of ROGY. In this pragmatic cluster randomized controlled trial, 12 hospitals are randomized to either 'usual care' or 'SCP care'. In patients with 'usual care', the gynecologist provides care as usual. In patients with 'SCP care', information about the tumor stage and treatment is personally discussed with the patient and a document is handed to the patient. Prospectively, all patients diagnosed with endometrial or ovarian cancer in the participating hospitals will be approached for study participation. Patients will complete questionnaires after surgery, and before additional treatment, and after 6, 12, 18 and 24 months. In addition, health care providers will be asked their opinion about implementation of SCP care. Primary outcome is defined as patient satisfaction with information provision and care. Secondary outcomes are illness perception, health-related quality of life, health care use, prevalence, course and referral rate of survivors with psychosocial distress, and health care providers' evaluation of SCP care.

**Discussion:** The ROGY Care trial will help to gain insight into the impact of SCP care on patient reported outcomes, and on the evaluation of cancer survivors and health care providers of the different elements of the SCP. Therefore, results will contribute to efforts to improve quality of care for cancer survivors.

## BACKGROUND

Due to earlier diagnoses and improved treatments, the number of cancer survivors is rapidly increasing in the Western world. In 2000, there were about 400,000 cancer survivors in The Netherlands, and this number is expected to increase to 700,000 in 2015<sup>1</sup>. Nevertheless, these cancer survivors remain at risk for adverse long-term or late effects of cancer diagnosis and treatment in many physical and psychosocial domains. Quality of life and patient reported outcomes are increasingly acknowledged to be important indicators of treatment efficacy<sup>2</sup>, especially since many new therapies only marginally improve survival rates. Furthermore, little is known about the quality of life, psychosocial well-being, and health care needs of the increasing cohort of long-term cancer survivors<sup>3</sup>. There is a need for optimizing the transition from cancer patient to cancer survivor by improving the coordination of post-treatment care for cancer survivors. In the report 'Follow-up in oncology'<sup>4</sup>, the Dutch Health Council states that the main goal of aftercare is to provide information and identify and treat the long-term effects of cancer or its therapy. Although psychosocial care is considered to be of major importance, the optimum form during aftercare remains uncertain. According to the Dutch Health Council it is necessary to encourage and give priority to research in this area.

A key factor in the support for cancer survivors is information provision. The information given to cancer survivors about their type of cancer, treatment, possible long-term and late effects and referral services can influence their illness perception and quality of life. It can result in better informed decision making, lower levels of depression and anxiety<sup>5</sup>, improved satisfaction with care, sense of control, and quality of life<sup>6</sup>. However, the number of studies that have investigated these associations is limited<sup>7</sup>. Health care providers are often still reluctant to give a full amount of information about prognoses and negative side effects of cancer and its treatment<sup>8</sup>. Although the number of studies that include long-term cancer survivors and their information needs are scarce, results from a few very recent studies suggest that most cancer survivors want more information than is provided by specialists<sup>5,9-11</sup>. These studies underline the importance of a patient-tailored approach to information provision. Providing information that is congruent with a patient's needs at that particular time is an important determinant for patient satisfaction and affects health-related quality of life (HRQoL) and anxiety and depression levels of cancer survivors<sup>12</sup>.

An approach to aftercare for cancer survivors recommended by both the American Institute of Medicine (IOM) and Health Council of the Netherlands is the Survivorship

Care Plan (SCP). An SCP provides cancer survivors completing primary care with a summary of their course of treatment as a formal document that also includes recommendations for subsequent cancer surveillance, management of late effects, and strategies for health promotion. Essential in such an SCP is detailed information provision about diagnosis and treatment of cancer, possible long-term and late effects, life-style recommendations, and available resources<sup>13</sup>. Based on its 'face validity', the IOM recommends that SCPs become standard of care, as they are likely to improve care<sup>13</sup>. The Dutch Health Council advises the implementation of SCPs for each cancer survivor in the Netherlands. The SCP is expected to be an empowering and enabling device, by facilitating better understanding and self-care by the patient. However, evidence concerning the positive and negative effects of the implementation of the SCP in daily clinical practice is lacking. As such, both the IOM and Health Council also recommend studies for the evaluation of the impact of SCPs on patient and health care provider reported outcomes. Literature suggests a patient-tailored approach to be optimal when providing prognosis or treatment summaries<sup>12</sup>. Health communication strategies, such as SCPs, may have excellent potential to meet the information needs of the increasing group of cancer survivors, and are likely to improve their quality of life<sup>9</sup>. Nevertheless, the psychological impact of these strategies on patient reported outcomes such as perceived quality of information provision, quality of care, quality of life and health care use remains unknown. As such, prospective evaluations of these strategies need to be conducted<sup>9</sup>. Therefore, it is necessary to assess the impact of SCP care in routine clinical practice before its large-scale implementation.

## **METHODS / DESIGN**

### **Objectives and hypotheses**

The aim of the proposed study is to assess the impact of SCP care on patient and health care provider reported outcomes in routine clinical practice. Primary outcomes include patients' satisfaction with information provision, and satisfaction with care. Secondary outcomes include patients' health-related quality of life, illness perception, health care use, prevalence, course and referral rate of patients with psychosocial distress, and health care providers' evaluation of the (implementation of the) SCP.

It is hypothesized that patients who receive SCP care report better satisfaction with information provision, better satisfaction with care, and more adequate illness perception than those who receive usual care. It is furthermore hypothesized that patients who receive SCP care will report a higher health care use compared to those receiving usual care<sup>14</sup>. In addition, it is expected that patients who receive the SCP will

report less anxiety, less depression or psychosocial stress and better HRQoL. However, there may be subgroups (dependent on patient characteristics, such as age, education, and personality) that will be influenced in a negative way when receiving more information than they can handle. Finally, it is hypothesized that patients who receive SCP care are more adequately referred to other health care services when they have high distress levels compared to those who receive usual care.

## Design

A pragmatic, cluster randomized controlled clinical trial (RCT) will be conducted, in which 12 hospitals will be randomized to either 'usual care' or 'SCP care'. It will be a longitudinal study, including patients immediately after initial surgery and following them for 24 months. The trial has been registered on <http://www.ClinicalTrials.gov> (NCT01185626). The description of this design follows the CONSORT recommendations for reporting on trials (<http://www.consort-statement.org>) with the extensions for pragmatic<sup>15</sup> and cluster<sup>16</sup> randomized trials.

## Study population

The RCT will be performed in a setting with gynecological patients in 12 hospitals in the South of the Netherlands. These 12 hospitals, including teaching and non-teaching hospitals, will be randomized to either 'usual care' or 'SCP care'. As defined by the US National Coalition for Cancer Survivorship (NCCS), a cancer survivor is: 'A person diagnosed with cancer from the moment of diagnosis through the balance of his or her life' (<http://canceradvocacy.org/about>). Following this definition, all endometrial and ovarian cancer survivors from the 12 participating hospitals will be included immediately after initial diagnosis and followed for 24 months. Survivors with advanced cancer or those who develop a recurrence or metastasis will not be excluded, since they are all considered to be cancer survivors according to the NCCS definition.

## Inclusion criteria

- a) Age  $\geq$  18 years (no upper age limit)
- b) Diagnosed with endometrial or ovarian cancer

## Exclusion criteria

- a) Patients with borderline ovarian cancer
- b) Patients undergoing palliative care
- c) Patients who are not able to complete a Dutch questionnaire

## Recruitment

Patients will be invited to participate in the study by their own gynecologist, after initial diagnosis. The gynecologists will send all their patients the first questionnaire, together with a letter and leaflet to inform them about the study and an informed consent form. The letter and accompanying leaflet about the study will be rather generic, stating the study's objective to investigate the quality of life of cancer survivors. Patients can fill in the informed consent form and complete the questionnaire by pencil and paper and send it back to the researchers in a pre-stamped envelope. If they prefer online completion, they can complete the questionnaire via the PROFILES (Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship) website (<http://www.profielstudie.nl>)<sup>17</sup> after secured login, for which they are provided with a link and password. To guarantee anonymity, returned questionnaires contain only a study number. If the questionnaire is not returned within 1 month, a reminder will be sent, again by the treating gynecologist. After the initial contact via the gynecologist and obtaining informed consent, the follow-up questionnaires at 6, 12, 18 and 24 months after diagnosis will be sent directly to the home address of the patient.

## Randomization

Hospitals have been pre-randomized whereby patients from a certain hospital will receive either usual care and information provision or an SCP. With this so-called pre-randomization, the conventional sequence of obtaining informed consent followed by randomization is reversed<sup>18</sup>. Pre-randomization is justified if valid evaluation of the effects of an intervention is impossible using a conventional randomized design, for example if knowledge of the intervention may lead to non-compliance or drop-out in the control group, or when the intervention is an educational program<sup>18</sup>. Pre-randomization at hospital level eliminates the problem posed by randomization at patient level in which health care providers from a hospital have to provide both types of care. By having to switch between usual care and SCP care for each patient, the health care provider could (unconsciously) influence the usual care group with that of the SCP approach by giving a patient randomized to usual care more information than was intended for usual care. Also, if usual care patients learn from other patients that they are given an SCP, it is possible that they will become dissatisfied with their usual care, even if the (dis)advantages are not well studied. This would bias the results of the study. To prevent imbalance between the treatment groups, stratified randomization was performed according to whether a hospital has a Gynecologic Oncology Center, and the annual number of endometrial and ovarian cancer patients, allowing for an even distribution of the intervention through the different participating centers.

Randomization to either usual care or SCP care at hospital level was performed with a table of random numbers by a researcher not involved in the study and blind to the identity of the hospitals. Because the health care providers administering the intervention have to know whether they have to provide either usual care or SCP care, it was not possible for them to be blinded to the group assignment. The participants on the other hand are unaware of the group assignment, as they are under the assumption that the hospital is providing usual care.

## **Intervention versus usual care**

### ***Usual care***

The health care provider (i.e., gynecologist or oncology nurse) provides care as usual. Currently, the 12 involved hospitals provide follow-up following the Dutch guidelines (<http://www.oncoline.nl>), meaning that they see their patients on given time points based on the number of years after diagnosis. Most of the participating hospitals give their patients leaflets regarding the diagnosis and treatment they receive. However none of them provide personalized printed information. All information is given during the initial treatment phase, but none of the health care providers give additional information during follow-up, except for ad-hoc referrals if needed by the patient. Most of the health care providers are not actively screening on psychosocial needs. As the usual care and information provision in these hospitals might change in time, the health care providers and patients will be asked about the type of information (e.g., brochures, DVDs, websites, personalized information) and psychosocial care they provide and receive, respectively.

### ***SCP care***

The health care provider (i.e., gynecologist or oncology nurse) provides the patient with a paper SCP after initial treatment, and discusses all the items in the SCP with the patient. To improve communication, the health care provider also sends a copy of the SCP to the patient's general practitioner. In follow-up consultations, the patient will receive an updated SCP if applicable. The health care providers involved in the SCP arm attended an instruction-evening to enhance the complete use of the SCP, by providing them with practical guidelines on how to discuss the SCP information with patients. In addition, the health care providers received a reminder, consisting of a summary of the purpose of the SCP and the study, and practical guidelines of the use of the SCP, intended to remind the health care providers to provide an SCP to their patients. As this is a pragmatic trial aiming to assess the impact of SCP care in daily clinical practice, the delivery of the intervention is allowed to vary between health care providers. The health care providers have the flexibility to discuss the SCP according to the patients' needs.

## **ROGY Survivorship Care Plan**

For the development of the SCP used in this RCT, the Dutch SCP template, which is very similar to the format that was described by the IOM<sup>13</sup>, was adjusted to the local situation as was suggested by Ganz<sup>19</sup>. A subgroup of gynecologists, oncology nurses, a radiotherapist, a medical oncologist, as well as a general practitioner and a few patients adjusted a standardized SCP to the local situation.

The paper SCP is extracted from the online registration system 'ROGY' (Registrationsystem Oncological GYnecology) and provides tailored information based on personal patient and disease data (e.g., name patient, date of birth, type of cancer, cancer stage, treatment received, providers involved). Detailed information is provided on the diagnosis, treatment, possible short-term and long-term effects of the disease and the treatment, and aftercare. In addition, the Distress Thermometer<sup>20</sup> is provided as an aid for the communication about psychosocial distress between patients and health care providers.

The SCP contains information that is tailored to the specific situation of the patient. For instance, a patient who received adjuvant radiotherapy will get information about potential long-term effects of radiotherapy and what to do if certain complaints arise. Recurrences, toxicities or other specialists involved in the patient's care will be registered in ROGY and automatically updated in the personal SCP.

The ROGY system was set up to facilitate patient registration and improve patient care by means of uniform regional multidisciplinary patient consultation. For each patient, a detailed registration is made, including information about FIGO (International Federation of Gynecology and Obstetrics) stage, grade, treatment, complications, comorbidity and follow-up. Thus, all necessary information for an SCP<sup>12</sup> is already routinely registered by all participating gynecologists, in a uniform way. By pressing a button in ROGY, which is only visible for the health care providers randomized to SCP care, it is possible to automatically generate a personalized SCP from the information available in the ROGY system. All gynecologists randomized to either usual care or SCP care use this registration system, so there will be no registration bias. Therefore, the possible quality of care improvement that comes with detailed registration is equal in both arms, and only the impact of providing SCPs will be evaluated.

## **Patient reported outcomes**

Outcomes will be assessed with standardized and validated measures shown to have acceptable psychometric properties.

### ***Satisfaction with information provision***

Satisfaction with information provision will be measured using the EORTC-INFO26<sup>21</sup> module. This questionnaire aims to evaluate the (satisfaction with) information received by cancer patients on different areas of the disease, diagnosis, treatment and care, and some qualitative aspects, for instance wishes for more information. The questionnaire contains the following scales: (a) Information about the disease; (b) Information about medical tests; (c) Information about treatment; (d) Information on other services, and single items: (a) Written information; (b) Information on CDs or tape/video; (c) Satisfaction with the amount of information; (d) Desire for more information; (e) Desire for less information; (f) Helpfulness of information. Furthermore, a more specific question will be added about whether patients have received an SCP, to control for physician compliance with the provision of SCP care.

### ***Cancer specific HRQoL***

Cancer specific HRQoL will be measured with the EORTC QLQ-C30<sup>22</sup>. Much of the content of the questionnaire is appropriate for extended monitoring of health status, including scales assessing physical, cognitive and emotional functioning, fatigue and sleep problems, and overall health and quality of life. This core instrument is supplemented by a condition-specific questionnaire module. For endometrial cancer, the EORTC-EN24<sup>23</sup> module will be used. This module assesses lymphoedema, urological symptoms, gastrointestinal symptoms, body image, sexual/vaginal symptoms, back/pelvic pain, and chemotherapy side effects. For ovarian cancer, the EORTC-OV28 module<sup>24</sup> will be used, which measures abdominal/gastrointestinal symptoms, peripheral neuropathy, other chemotherapy side-effects, hormonal/menopausal symptoms, body image, attitude to disease/treatment and sexual functioning.

### ***Satisfaction with care***

Satisfaction with care will be measured with the EORTC IN-PATSAT32<sup>25</sup>. This questionnaire was designed to assess cancer patients' perception of the quality of medical care, nursing care and care organization and services received in the hospital. The EORTC IN-PATSAT32 contains 11 multi-item and 3 single-item scales. These include the doctors' technical skills, interpersonal skills, information provision, and availability; the nurses' technical skills, interpersonal skills, information provision, and availability; the other hospital staff's interpersonal skills and information provision scale; the exchange of information single-item scale; the waiting time; the hospital access; the comfort single-item scale; and the general satisfaction single-item scale.

### ***Illness perception***

Illness perception will be measured using the Brief Illness Perception Questionnaire (B-IPQ)<sup>26</sup>. The scale has 9 items, measuring (a) cognitive representations (consequences, timeline, personal control, treatment control, identity); (b) emotional representations (concern, emotion); (c) illness comprehensibility; and (d) an open-ended response item on the 3 most important causal factors of illness.

### ***Comorbidity***

Comorbidity at the time of questionnaire completion will be assessed by the adapted Self-administered Comorbidity Questionnaire (SCQ)<sup>27</sup>. Patients will be asked to identify comorbid conditions developed in the past 12 months. The adapted SCQ lists 14 medical conditions (with the option to list up to 3 additional conditions), and assesses if the patient is treated for the comorbid condition and the perceived impact on the patients' functioning.

### ***Anxiety and depression***

Anxiety and depression will be assessed using the Hospital Anxiety and Depression Scale (HADS)<sup>28</sup>. The HADS has 14-items, with 7 items each for anxiety and depression. Each item is scored from 0 to 3, where a score of 3 represents a state corresponding to the worst anxiety or depression. The sum of these items produces two subscales ranging from 0 to 21. A score of 8 will be used as a cut-off value for both depression and anxiety<sup>28</sup>.

### ***Physical and mental fatigue***

Physical and mental fatigue will be measured using the Fatigue Assessment Scale (FAS)<sup>29</sup>, which consists of 10-items with 5 items each reflecting physical and mental fatigue. The items are scored on a 5-point response scale ranging from 1 (never) to 5 (always).

### ***Personality***

Personality will be measured with the DS14<sup>30</sup> which has 14 items ranged on a 5-point response scale ranging from 0 (false) to 4 (true). Seven of these items refer to 'Negative Affectivity' or the tendency to experience negative emotions in general (e.g., 'I am often down in the dumps or I often find myself worrying about something'). The remaining 7 items refer to the patient's level of 'Social Inhibition', or the tendency to inhibit the expression of emotion/behavior in social relationships (e.g., 'I am a closed kind of person or I often feel inhibited in social interactions'). According to previously published cut-off scores, patients were diagnosed as Type D if they scored  $\geq 10$  on both the Negative Affectivity and Social Inhibition scales.

**Health care utilization**

Health care utilization will be assessed by patients' frequency and reason (cancer-related or not) for contact with their general practitioner or medical specialist in the past 12 months. Patients will be asked whether they have been referred to other health care services.

**Additional measures**

Additional measures include demographic and socioeconomic variables such as age, education, marital status, and employment status, and clinical variables such as cancer stage at diagnosis, time after diagnosis, and initial treatment. All measures will be collected at the beginning of the trial, and at 6, 12, 18 and 24 months after diagnosis.

**Health care providers' evaluation*****Gynecologists and oncology nurses***

Gynecologists and oncology nurses in both arms will be asked their opinion about the implementation of SCP care or usual care. At the beginning of the trial and after 12 months, gynecologists and oncology nurses will be asked to fill in a short questionnaire containing questions about the type of information they provide, how satisfied they are with the information they provide, how much time they spend on their consultations on average, to what extent they expect the SCP care to have a positive effect on patients, and how motivated they are to use the SCP. In addition, at the end of patient inclusion after 12 months, all gynecologists and oncology nurses in the SCP arm are invited to participate in qualitative interviews on their opinion about (the implementation of) the SCP care.

***General practitioners***

General practitioners of patients in both arms will be asked to fill in a short questionnaire, containing questions about whether they received the SCP and whether they believe it has improved the communication between themselves and the gynecologist, and between themselves and their patient.

**Sample size**

The initial patient inclusion will be completed in approximately one year. Each year, approximately 250 endometrial and 200 ovarian cancer survivors are diagnosed in the participating hospitals. Based on previous studies<sup>31-34</sup> 337 patients (75%) are minimally expected to participate in one year. Allowing for 10% attrition, this equates about 300 patients. Assuming an average practice size, the power will be 0.98 to detect a minimum effect size of 0.5, which is considered clinically significant<sup>35</sup>. In addition, separate

analyses for endometrial and ovarian cancer survivors can be conducted: 150 patients are sufficient to detect a half standard deviation difference with a power of 0.83.

### **Statistical analysis**

Analyses will be performed adhering to the intention-to-treat principle. Descriptive statistics will be used to summarize characteristics of both hospitals and patients. Characteristics of patients (i.e., age, type of cancer, stage, treatment, socio-economic status, marital status, educational level, employment status) and hospitals (i.e., number of endometrial and ovarian cancer patients, whether a hospital is a training hospital) will be compared at baseline between the intervention and usual care group, by regression analyses.

Linear regression models will be used to analyze continuous outcome variables, and logistic models for binary outcome variables. All analyses will be adjusted for hospital, baseline values of the outcome measure, and baseline variables which differ to a clinically significant extent between groups. Differential effects of SCP care by age, type of cancer and baseline levels of the outcomes of interest will be assessed for the outcome measures by adding terms for the interaction between age, educational level, personality, type of cancer and baseline levels and care arm to the regression models.

A multilevel modeling approach <sup>36</sup> will be applied to evaluate differences between the intervention group and the control group. This approach will be used to take into account the clustering at the hospital level <sup>37</sup>. All statistical tests will be two-sided and considered significant if  $p < 0.05$ . Repeated measures analysis using generalized estimating equations will be conducted to account for the intra-patient dependency of the repeated measures <sup>38</sup>. Differences in effect of the SCP care and usual care at the different time points will also be investigated <sup>38</sup>.

Missing outcome data will be assumed to be 'missing at random' (MAR), conditional on key predictors of 'missingness' (in particular baseline values of the outcome variables of interest, and care arm). Clinically meaningful differences will be determined with Norman's 'rule of thumb', whereby a difference of  $\gg 0.5 SD$  indicates a threshold of discriminant change in health status scores of a chronic illness <sup>35</sup>.

Routinely collected data from the population-based Eindhoven Cancer Registry (ECR) and ROGY on patient and tumor characteristics will allow for the comparison of respondents, non-respondents and patients with unverifiable addresses, using t-tests for continuous variables and Chi-square analyses for categorical variables.

## **Ethical considerations**

The study protocol has been approved by the medical research ethics committees of the participating centers (Medical Research Ethics Committee reference number: NL33429.008.10). The study will be conducted according to the Declaration of Helsinki, as amended in 2008 by the World Medical Association, and all patients will be informed about the purpose, rights, and possible benefits/risks of the study. Study participation of patients is voluntary and can be cancelled at any time without provision of reasons and without any consequences. Patients can call a psychologist, an epidemiologist, or an independent general practitioner for more information about the study.

## **Data security/disclosure of original documents**

Confidentiality and anonymity of participants will be guaranteed with the assignation of a study number to each participant. As such, returned questionnaires have no names attached and will be linked to data from the ECR by study number. Therefore, it will not be possible for the researchers to track participants' names with the study numbers. The results of the patient questionnaires are not accessible to the gynecologists or other health care providers. Questionnaires are directly mailed to the study center by the patients. Returned questionnaires will be stored in a secured location for five years. Only direct members of the internal study team can access the respective files.

## **DISCUSSION**

The number of cancer survivors that are confronted with adverse long-term or late effects is rapidly increasing. These cancer survivors remain at risk for adverse long-term or late effects of cancer diagnosis and treatment, and often do not know how to interpret their physical or psychosocial problems, or where to go for support. Providing patients with an SCP may be an empowering and enabling instrument, by facilitating better understanding and self-care by the patient. However, evidence concerning the effects of the implementation of the SCP in daily clinical practice is lacking. It is therefore necessary to assess the impact of SCP care in routine clinical practice before its large-scale implementation.

If this study shows that SCP care is feasible and effective, this scientific evidence can be used to convince cancer survivors' health care providers and health insurance companies about the benefits of implementing SCP care. The results will help to gain insight into the impact of SCP care on patient reported outcomes, and on the evaluation of cancer survivors and health care providers of the different elements of the SCP. Therefore, results will contribute to efforts to improve quality of care for cancer survivors.

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# Chapter 5

## **The impact of an automatically generated cancer Survivorship Care Plan on patient reported outcomes in routine clinical practice: Longitudinal outcomes of the pragmatic cluster randomized ROGY Care trial**

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## ABSTRACT

**Purpose:** To longitudinally assess the impact of an automatically generated Survivorship Care Plan (SCP) on patient reported outcomes in routine clinical practice. Primary outcomes were patient satisfaction with information and care. Secondary outcomes included illness perceptions and health care utilization.

**Methods:** Pragmatic cluster randomized trial, in which 12 hospitals were randomized to SCP care or usual care. Newly diagnosed endometrial cancer patients completed questionnaires after diagnosis (N=221; 75% response), 6 months (N=158), and 12 months (N=147). An SCP-application was built in the web-based Registrationsystem Oncological GYnecology (ROGY). By clicking the SCP-button, a patient-tailored SCP was generated.

**Results:** In the SCP care arm, 74% received an SCP. They reported receiving more information about their treatment (M=57, SD=20 vs. M=47, SD=24, p=0.03), other services (M=35, SD=22 vs. M=25, SD=22, p=0.03), and different places of care (M=27, SD=25 vs. M=23, SD=26, p=0.04) than the usual care arm (scales: 0-100). However, there were no differences regarding satisfaction with information or care. Patients in the SCP care arm experienced more symptoms (M=3.3, SD=2.0 vs. M=2.6, SD=1.6, p=0.03), were more concerned about their illness (M=4.4, SD=2.3 vs. M=3.9, SD=2.1, p=0.03), more affected emotionally (M=4.0, SD=2.2 vs. M=3.7, SD=2.2, p=0.046), and reported more cancer-related contact with their primary care physician (M=1.8, SD=2.0 vs. M=1.1, SD=0.9, p=0.003) than the usual care arm (scale: 1-10). These effects did not differ over time.

**Conclusion:** The present trial showed no evidence of a benefit of SCPs on satisfaction with information and care. Furthermore, SCPs increased patients' concerns, emotional impact, experienced symptoms, and the amount of cancer-related contact with the primary care physician. Whether this may ultimately lead to more empowered patients needs to be investigated further.

## INTRODUCTION

The number of cancer survivors with long-term or late physical and psychosocial problems of their cancer and treatment is increasing worldwide <sup>1</sup>. Previous research underlines the need for more and improved patient-tailored information provision <sup>2,3</sup>. The Institute of Medicine (IOM) recommends the use of Survivorship Care Plans (SCPs) for all cancer survivors <sup>4</sup>, as they are expected to help survivors deal with the challenges of survivorship. However, before large-scale implementation of SCPs in routine clinical practice, potential positive and negative consequences need to be considered.

A recent review of studies of SCPs <sup>5</sup> revealed that the quantity and quality of SCP research are limited. The strength of evidence for studies examining the effect of SCPs on patient reported outcomes was low, and the majority of studies used observational designs <sup>5</sup>. Three randomized studies <sup>6,7</sup> did not find any differences in distress <sup>6</sup>, quality of life <sup>6</sup>, and satisfaction with care <sup>6-8</sup> between patients who did or did not receive an SCP. Although these studies made important first steps towards understanding SCPs' effects, there were major limitations in the study designs, including the timing of the intervention and outcomes assessment <sup>9-11</sup>. Furthermore, essential outcomes including satisfaction with the received information, illness perceptions, and health care utilization were not examined. A pragmatic cluster randomized design, including comparative clinical effectiveness <sup>12-14</sup>, addressing the methodological concerns of previous studies, is now needed to support informed health care decisions.

The aim of the pragmatic cluster randomized ROGY Care trial was to longitudinally assess the impact of an automatically generated SCP on patient reported outcomes in routine clinical practice. Primary outcomes were patients' satisfaction with information provision and care. Secondary outcomes included patients' illness perceptions and health care utilization <sup>15</sup>. It was hypothesized that patients receiving SCP care report higher satisfaction with information provision, higher satisfaction with care, more threatening illness perceptions, and higher health care utilization than patients receiving usual care <sup>15</sup>.

## METHODS

### Design and Participants

The impact of an automatically generated SCP on patient and health care provider reported outcomes was evaluated in a longitudinal pragmatic cluster randomized trial among gynecological cancer patients. Twelve hospitals in the Netherlands were

randomized to either 'SCP care' or 'usual care'. Patients were included immediately after initial surgery and followed for 24 months. The trial was centrally approved by a Medical Research Ethics Committee, as well as by each participating center <sup>15</sup>. The present study describes the primary outcomes of the trial for women newly diagnosed with endometrial cancer, up to 12 months after diagnosis. Exclusion criteria (i.e., undergoing palliative care or unable to complete a Dutch questionnaire) <sup>15</sup> were minimal to maximize generalizability <sup>16</sup>.

## **Recruitment**

All eligible patients between April 2011 and October 2012 were invited to participate, by a letter, questionnaire, and informed consent <sup>15,17</sup>. Follow-up questionnaires were sent after 6 and 12 months.

## **Randomization and Blinding**

Randomization at hospital-level was chosen to avoid potential contamination of usual care with increased information provision of SCP care. Patients were unaware of the assignment to trial arms <sup>18</sup>.

## **SCP care versus Usual care**

In the usual care arm, oncology providers (i.e., gynecologists/gynecologic oncologists, oncology nurses) gave standard care according to the Dutch follow-up guidelines (<http://www.oncoline.nl>), recommending verbal and written information about the period after treatment and follow-up, signs of recurrence, and hospital contact details. Oncology providers in the usual care arm were instructed to continue providing patient information in the way they were used to. Most oncology providers provided verbal information and generic brochures of the Dutch Cancer Society regarding the diagnosis and treatment <sup>19</sup>. None of them provided SCPs. All information was given during the initial treatment phase, but none of the oncology providers gave additional information during follow-up, except for ad-hoc referrals if indicated <sup>15</sup>.

In the SCP care arm, oncology providers were instructed to provide an SCP to patients after surgery, to provide an updated SCP during follow-up visits if there were changes in the cancer, treatment, or specialists, and to send a copy of the SCP to the patient's primary care physician. The oncology providers attended an instruction-evening and received practical guidelines on how to discuss the information in the SCP with their patients, and agreed about the minimal items that should be discussed with respect to diagnosis, treatment, and possible side-effects. Because of the pragmatic approach,

oncology providers in the SCP care hospitals were free to choose whether the gynecologist/gynecologic oncologist, and/or oncology nurse provided the SCP, fitting their clinical practice <sup>15,19</sup>.

### **Survivorship Care Plan**

The web-based 'Registrationsystem Oncological GYnecology' (ROGY) is used by all participating oncology providers in both arms since 2006. For each patient, a detailed registration is made, including tumor stage and grade, treatment, comorbidity, complications, follow-up, and specialists. For the present trial, an application was built in ROGY enabling automatic generation of an SCP combining patient and disease data, by simply pressing a button (only visible in the SCP care arm). Changes related to the cancer, treatment, or specialists were automatically updated in the SCP.

For the development of the SCP, the Dutch SCP template (based on the IOM-format) <sup>4</sup>, was adjusted to the local situation <sup>20</sup> by a subgroup of gynecologists/gynecologic oncologists, oncology nurses, a radiotherapist, medical oncologist, primary care physician, and patients <sup>15</sup>. The SCP 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, treatment, and contact details of the hospital and specialists. Moreover, the SCP contained a tailored follow-up care plan, including information on possible short-term and long-term effects, effects on social and sexual life, signs of recurrence and secondary tumors, and rehabilitation, psychosocial support, and supportive care services.

### **Measures**

Socio-demographic and clinical information was obtained from ROGY (i.e., date of birth, date of diagnosis, disease stage, primary treatment) and the questionnaire (i.e., marital status, educational level, employment status), and comorbidity by the adapted Self-administered Comorbidity Questionnaire (SCQ) <sup>21</sup>.

Satisfaction with information provision was assessed with the EORTC-QLQ INFO25 <sup>22</sup>, incorporating four information provision subscales regarding perceived receipt of information about the disease (four items), medical tests (three items), treatment (six items) and other care services (four items). Additionally, it includes 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). Scales were converted to 0-100, with higher scores indicating better perceived information provision. Internal consistency (cronbach's alphas 0.70-0.87) and test-retest reliability (intraclass correlations 0.71-0.91) are good. To check whether patients actually received an SCP, the following question was added: "Did you receive a survivorship care plan?". At 6 and 12 months, patients were also asked how many times they received the SCP.

Satisfaction with care was assessed with the EORTC IN-PATSAT32<sup>23</sup>, including two multi-item scales regarding doctors' (three items) and nurses' (three items) interpersonal skills, and two single-item scales regarding exchange of information between caregivers and general satisfaction with care. Scales were converted to 0-100, with higher scores indicating better perceived quality of care. Internal consistency (cronbach's alphas 0.67-0.96) and test-retest reliability (intraclass correlations 0.66-0.85) are good<sup>23</sup>.

Illness perception was assessed with the Brief Illness Perception Questionnaire (B-IPQ)<sup>24</sup>, consisting of eight single-item scales rated on a 0-10 linear scale, with higher scores indicating more endorsement of that item. Test-retest reliability (pearson correlations 0.42-0.75) is good<sup>24</sup>.

Health care utilization was assessed by asking how many times patients visited a medical specialist or primary care physician in relation to cancer in the past 6 months.

### **Statistical Analysis**

Statistical analyses were conducted using SPSS 19.0. Tests were two-sided and considered statistically significant if  $p < 0.05$ . Intention-to-treat analyses compared all participants in the SCP care arm to all participants in the usual care arm. Per-protocol analyses compared participants in the SCP care arm who indicated receiving an SCP in the first questionnaire to all participants in the usual care arm.

Means (M) with standard deviations (SD) were used to describe continuous variables, and frequencies with percentages to describe categorical variables. Differences in characteristics between groups were compared using t-tests for continuous and chi-square tests for categorical variables.

Linear multilevel regression analyses were performed to evaluate the differences between the SCP care arm and usual care arm. This approach was used to account for both clustering at hospital-level and intra-patient dependency of repeated measures<sup>25</sup>. Multilevel analysis corrects for missing data (assumed missing at random), by using

information from the observed outcomes to provide information about the unobserved outcomes<sup>26,27</sup>. Three levels were identified: (1) repeated measures within patients, (2) patients, (3) hospitals. The overall multi-level model included two random intercepts (i.e., hospital- and patient-level), the independent variables intervention arm (i.e., SCP care vs. usual care) and time, and the covariates age, time since diagnosis, marital status, employment, educational level, comorbidity, disease stage, and treatment. Dependent variables were the scales on information provision and care, illness perceptions, and health care utilization. For the models that did not converge, hospital was included as covariate instead of random intercept<sup>28</sup>. Because the effect of SCPs was expected to differ at different time points, it was decided a priori to also explore the results for all time points separately, by adding the interaction between trial arm and time to the overall model. Unstandardized betas (i.e., average differences between the adjusted mean outcomes of the two arms on its original scale) were presented with 95% confidence intervals.

The study was powered to detect a clinically meaningful difference of 0.5 SD for SCP care versus usual care on the overall primary outcomes. To obtain 80% power and allow for 10% attrition, 75 patients per arm were targeted<sup>15</sup>.

## RESULTS

Of the 296 eligible patients, 221 (75%) patients completed the first questionnaire. After 6 months, 158, and after 12 months, 147 patients completed the questionnaire (Figure 1). At baseline, participants were younger ( $M=67.4$ ,  $SD=8.9$ ) than non-participants ( $M=70.2$ ,  $SD=9.5$ ,  $p=0.02$ ), and more often had FIGO-stage I (87% vs. 70%,  $p<0.01$ ; Table 1). At first questionnaire completion, patients in the SCP care arm completed the questionnaire later (median=2.2 months) than patients in the usual care arm (median=1.5 months,  $p<0.01$ ; Table 2).

In the SCP care arm, at first questionnaire completion, 74% indicated actually receiving an SCP. However, 39% of patients in the usual care arm also indicated receiving an SCP. After 12 months, 30% of patients in the SCP care arm reported to have received an SCP more than once, versus 9% in the usual care arm. There were no interactions between trial arm and time for any of the outcomes, indicating that the effect of SCP care did not differ over the three time points.

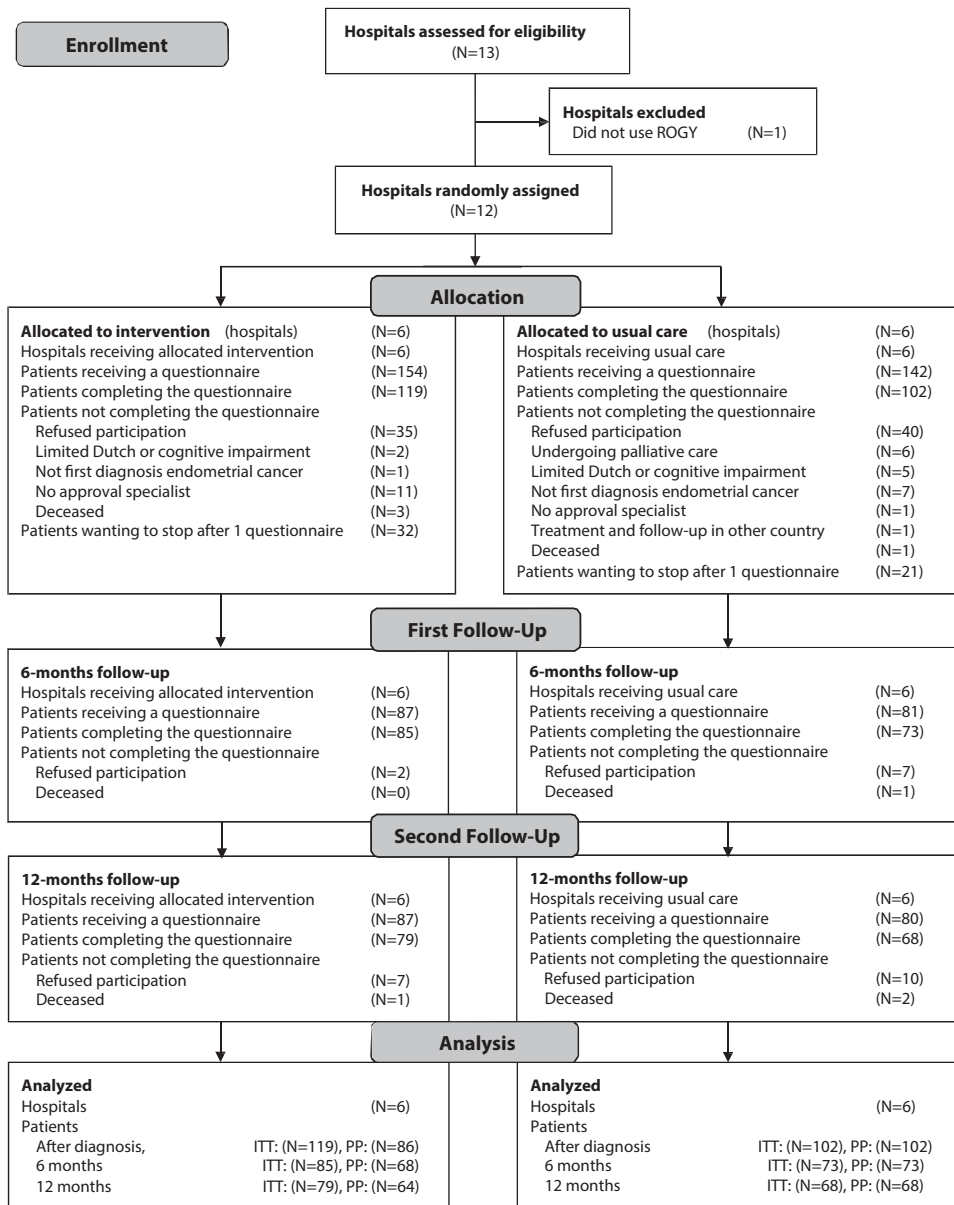
Intention-to-treat analyses at 12 months showed that patients in the SCP care arm reported receiving more information about other services than patients in the usual

care arm. Per-protocol analyses revealed three overall effects: Patients receiving SCP care reported receiving more information about treatment ( $M=57$ ,  $SD=20$  vs.  $M=47$ ,  $SD=24$ ,  $p=0.03$ ), other services ( $M=35$ ,  $SD=22$  vs.  $M=25$ ,  $SD=22$ ,  $p=0.03$ ), and different places of care ( $M=27$ ,  $SD=25$  vs.  $M=23$ ,  $SD=26$ ,  $p=0.04$ ) than patients in the usual care arm. Furthermore, patients receiving SCP care reported receiving more information about things you can do to help yourself get well at diagnosis, treatment and other services at 12 months (Table 3, Figure 2).

There were no overall effects of SCP care for any of the scales on satisfaction with care. At 12 months, in intention-to-treat analyses, patients in the SCP care arm rated the interpersonal skills of nurses lower than patients in the usual care arm. This was not found in per-protocol analyses (Table 3).

In intention-to-treat analyses, overall, patients in the SCP care arm reported that they experienced more symptoms ( $M=3.3$ ,  $SD=2.0$  vs.  $M=2.6$ ,  $SD=1.6$ ,  $p=0.03$ ), were more concerned about their illness ( $M=4.4$ ,  $SD=2.3$  vs.  $M=3.9$ ,  $SD=2.1$ ,  $p=0.03$ ), and more affected emotionally ( $M=4.0$ ,  $SD=2.2$  vs.  $M=3.7$ ,  $SD=2.2$ ,  $p=0.046$ ). Per-protocol analyses showed two overall effects: Patients receiving SCP care reported that they experienced more symptoms ( $M=3.4$ ,  $SD=2.0$  vs.  $M=2.6$ ,  $SD=1.6$ ,  $p=0.02$ ) and were more concerned about their illness ( $M=4.4$ ,  $SD=2.4$  vs.  $M=3.9$ ,  $SD=2.1$ ,  $p=0.03$ ). Furthermore, at diagnosis, patients receiving SCP care reported that they experienced more symptoms, were more concerned about their illness, and more affected emotionally. At 12 months, patients receiving SCP care reported that they were more concerned about their illness and more affected emotionally (Table 3).

Overall, patients receiving SCP care reported to have had more cancer-related contact with their primary care physician than patients in the usual care arm, both in intention-to-treat ( $M=1.8$ ,  $SD=1.9$  vs.  $M=1.2$ ,  $SD=0.9$ ,  $p=0.002$ ) and per-protocol analyses ( $M=1.8$ ,  $SD=2.0$  vs.  $M=1.1$ ,  $SD=0.9$ ,  $p=0.003$ ). (Table 3, Figure 3).



**Figure 1.** CONSORT Flow diagram of the progress of the hospitals and endometrial cancer patients through the phases of the ROGY Care trial

Note: ITT= Intention To Treat analyses, comparing all respondents in the SCP care arm to all respondents in the usual care arm. PP= Per Protocol analyses, comparing the respondents in the SCP care arm who indicated that they received an SCP in the first questionnaire to all respondents in the usual care arm.

**Table 1.** CONSORT Table of baseline socio-demographic and clinical characteristics of participants according to trial arm and of non-participants, and baseline hospital characteristics according to trial arm

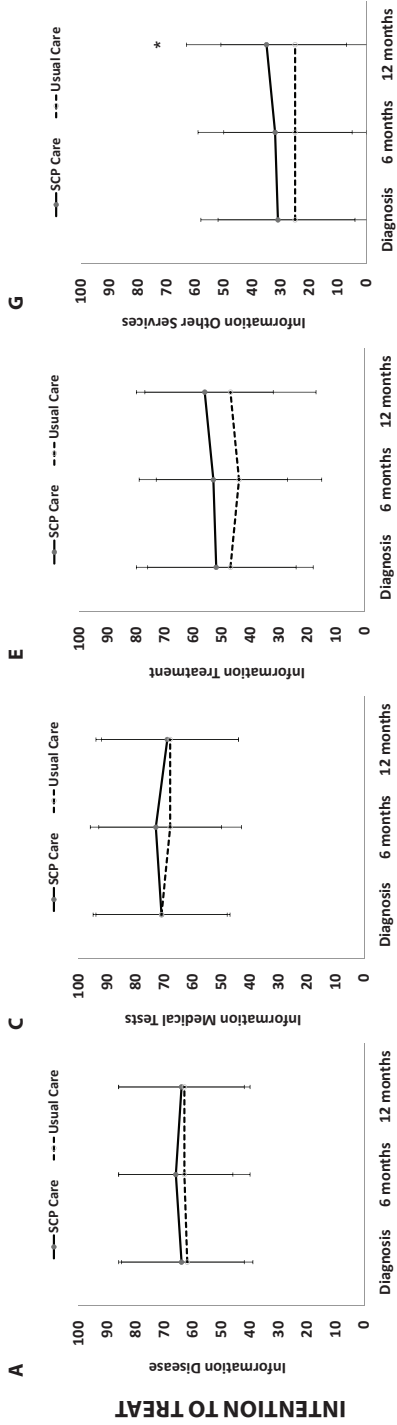
	SCP Care (N=119)	Usual Care (N=102)	p-value*	Total Participants (N=221)	Non- Participants (N=75)	p-value*
<b>Patients</b>	N (%)			N (%)		
<b>Age at diagnosis</b>						
Mean	67.1	67.7	0.65	67.4	70.2	<b>0.02</b>
SD	9.1	8.8		8.9	9.5	
<b>FIGO-stage</b>						
I	102 (86)	87 (87)	0.75	189 (87)	52 (70)	<b>&lt;0.01</b>
II	5 (4)	2 (2)		7 (3)	10 (14)	
III	8 (7)	7 (7)		15 (7)	11 (15)	
IV	3 (3)	4 (4)		7 (3)	1 (1)	
<b>Treatment</b>						
Surgery	117 (99)	97 (98)	0.46	214 (99)	72 (97)	0.45
Radiotherapy	44 (37)	37 (37)	0.99	81 (37)	34 (46)	0.19
Chemotherapy	6 (5)	12 (12)	0.06	18 (8)	7 (10)	0.76
<b>Hospital</b>						
1	22 (19)			22 (10)	4 (5)	0.61
2	12 (10)			12 (5)	7 (9)	
3	28 (24)			28 (13)	9 (12)	
4	28 (24)			28 (13)	9 (12)	
5	11 (9)			11 (5)	1 (1)	
6	18 (15)			18 (8)	5 (7)	
7		25 (25)		25 (11)	13 (17)	
8		21 (21)		21 (10)	6 (8)	
9		26 (26)		26 (12)	7 (9)	
10		12 (12)		12 (5)	4 (5)	
11		3 (3)		3 (1)	3 (4)	
12		15 (15)		15 (7)	7 (9)	
	SCP Care (N=6)	Usual Care (N=6)		Total Hospitals (N=12)		
<b>Hospitals</b>	N (%)			N (%)		
<b># endometrial and ovarian cancer patients per year</b>						
≤50	2 (33)	2 (33)		4 (33)		
>50	4 (67)	4 (67)		8 (67)		
<b>Gynecologic Oncology Center (Tertiary Referral Hospital)</b>						
Yes	1 (17)	1 (17)		2 (17)		
No	5 (83)	5 (83)		10 (83)		

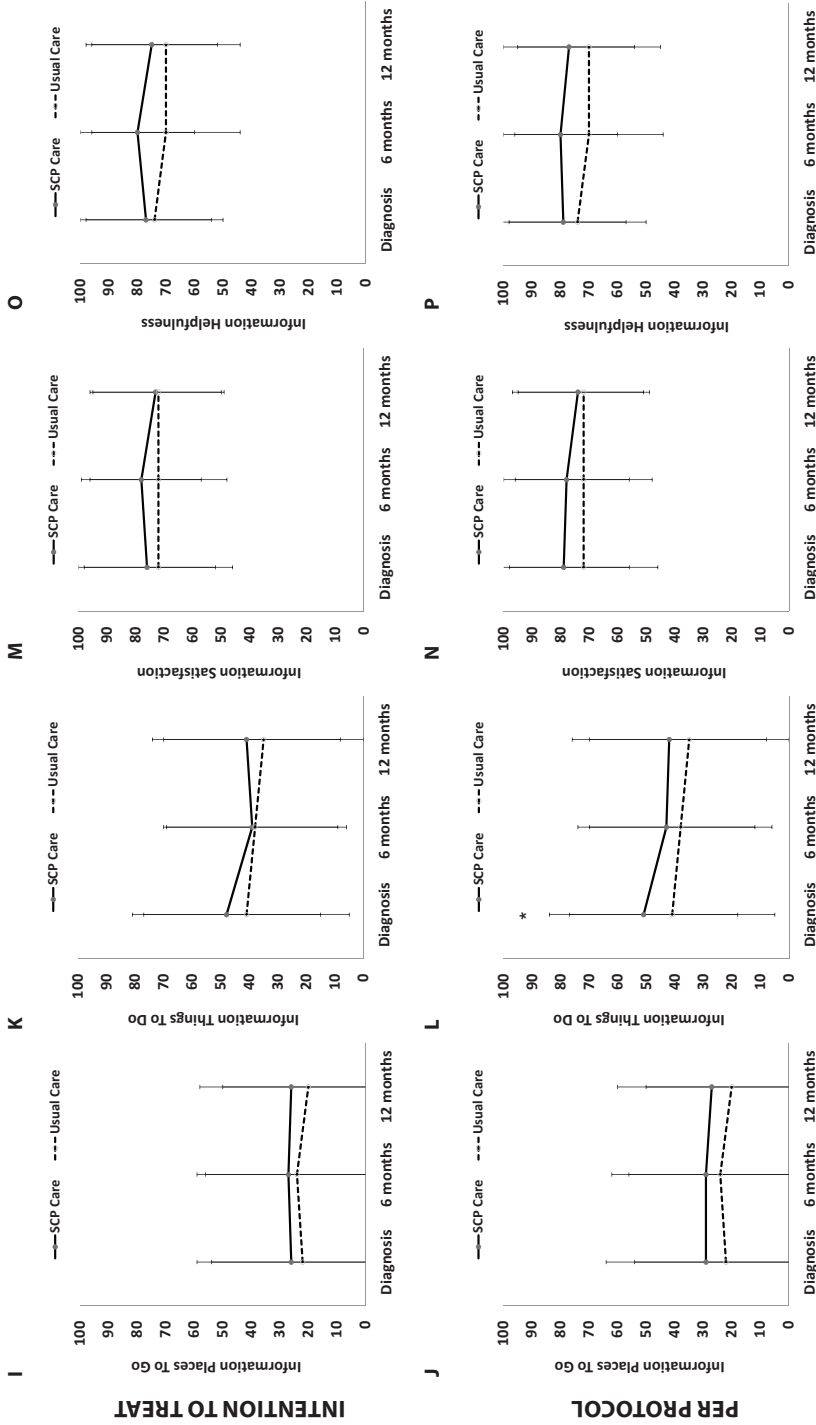
Note: \*P-values report comparisons between the intervention arm and the usual care arm, and between the trial participants and non-participants, according to t-tests and Chi-square tests. The numbers may not always add up to 100, because percentages have been rounded off to whole numbers.

**Table 2.** Socio-demographic and clinical characteristics at the first questionnaire, according to trial arm

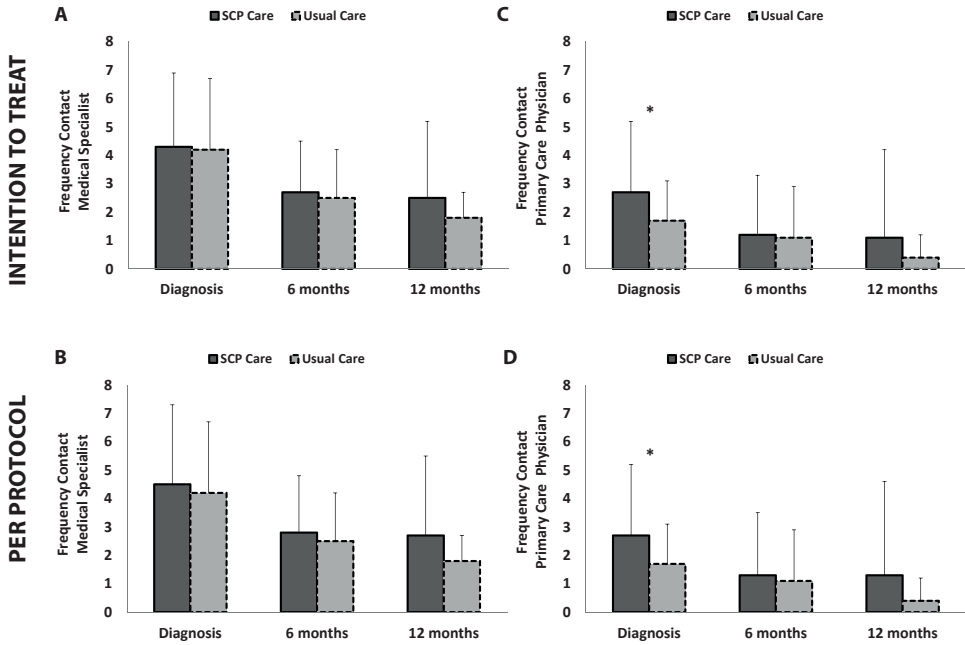
	SCP Care (N=119)	Usual Care (N=102)	p-value*	Total (N=221)
	N (%)			N (%)
<b>Age at time of survey</b>				
Mean	67.4	67.8	0.71	67.6
SD	9.1	8.9		9.0
<b>Months since diagnosis</b>				
Median	2.2	1.5	<b>&lt;0.01</b>	1.8
<1	12 (10)	24 (24)		36 (16)
1-2	40 (34)	46 (45)		86 (39)
2-3	33 (28)	20 (20)		53 (24)
>3	34 (29)	12 (12)		46 (21)
<b>Comorbidity</b>				
None	19 (17)	18 (18)	0.41	37 (17)
1	32 (28)	20 (20)		52 (24)
2 or more	64 (56)	62 (62)		126 (59)
<b>Marital status<sup>a</sup></b>				
Partner	85 (73)	76 (75)	0.74	161 (74)
No partner	31 (27)	25 (25)		56 (26)
<b>Educational level<sup>b</sup></b>				
High	17 (14)	7 (7)	0.09	24 (11)
Intermediate	71 (60)	72 (74)		143 (66)
Low	30 (25)	19 (19)		49 (23)
<b>Employed</b>				
Yes	22 (21)	15 (16)	0.40	37 (18)
No	85 (79)	79 (84)		164 (82)

Note: \*P-values report comparisons between the intervention arm and the usual care arm, according to t-tests and Chi-square tests. <sup>a</sup>Marital status included: partner = married/living together; no partner = divorced/widowed/never married. <sup>b</sup>Educational level included: low = no/primary school; intermediate = lower general secondary education/vocational training; or high = pre-university education/ high vocational training/university. The numbers may not always add up to 100, because percentages have been rounded off to whole numbers.





**Figure 2.** Trial outcomes for information provision over time for Intention To Treat and Per Protocol  
 Note: Crude means are reported for patients' scores on the EORTC-QLQ-INFO25 subscales. Error bars represent +1 and -1 standard deviation. \* p<0.05. For detailed information, see Table 3. Intention To Treat analyses compared all respondents in the SCP care arm to all respondents in the usual care arm. Per Protocol analyses compared the respondents in the SCP care arm who indicated that they received an SCP in the first questionnaire to all respondents in the usual care arm.



**Figure 3.** Patients’ reported frequency of cancer-related contact with their medical specialist and Primary Care Physician in the past 6 months, over time for Intention To Treat and Per Protocol  
 Note: Crude means are reported. Error bars represent +1 standard deviation. \*  $p < 0.01$ . For detailed information, see Table 3. Intention To Treat analyses compared all respondents in the SCP care arm to all respondents in the usual care arm. Per Protocol analyses compared the respondents in the SCP care arm who indicated that they received an SCP in the first questionnaire to all respondents in the usual care arm.

**Table 3.** Effects of the intervention: Overall, after diagnosis, and after 6 and 12 months for Intention To Treat and Per Protocol

	Overall				After diagnosis				After 6 months				After 12 months			
	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
<b>INFORMATION PROVISION</b>																
<b>Disease</b>																
Intention To Treat	2.3	-4.9 to 9.6	64 (22)	62 (23)	2.7	-5.0 to 10.4	66 (20)	63 (23)	3.3	-4.9 to 11.5	64 (22)	63 (23)	0.6	-7.7 to 8.9		
Per Protocol	3.7	-3.5 to 10.8	67 (22)	62 (23)	4.0	-3.6 to 11.6	66 (20)	63 (23)	4.5	-3.6 to 12.7	66 (22)	63 (23)	2.1	-6.1 to 10.4		
<b>Medical Tests</b>																
Intention To Treat	1.2	-5.1 to 7.5	71 (23)	71 (24)	1.2	-5.9 to 8.2	73 (23)	68 (25)	3.4	-4.4 to 11.2	69 (25)	68 (24)	-1.0	-9.0 to 6.9		
Per Protocol	3.7	-2.9 to 10.3	73 (22)	71 (24)	3.0	-4.5 to 10.5	73 (23)	68 (25)	5.9	-2.3 to 14.1	72 (24)	68 (24)	2.8	-5.5 to 11.1		
<b>Treatment</b>																
Intention To Treat	5.8	-1.2 to 12.8	52 (28)	47 (29)	4.6	-3.6 to 12.7	53 (26)	44 (29)	5.9	-3.4 to 15.1	56 (24)	47 (30)	8.1	-1.3 to 17.5		
Per Protocol	<b>8.2*</b>	0.7 to 15.8	55 (28)	47 (29)	7.2	-1.6 to 15.9	53 (25)	44 (29)	7.7	-2.0 to 17.5	59 (25)	47 (30)	<b>10.7*</b>	0.8 to 20.6		
<b>Other Services</b>																
Intention To Treat	7.9	-0.5 to 16.3	31 (27)	25 (27)	6.1	-3.0 to 15.1	32 (27)	25 (25)	7.5	-2.2 to 17.3	35 (28)	25 (26)	<b>11.6*</b>	1.7 to 21.5		
Per Protocol	<b>11.0*</b>	1.4 to 20.6	34 (28)	25 (27)	8.8	-1.4 to 19.0	33 (28)	25 (25)	9.5	-1.3 to 20.4	39 (29)	25 (26)	<b>16.0*</b>	5.0 to 27.0		
<b>Places To Go</b>																
Intention To Treat	6.1	-1.6 to 13.8	26 (33)	22 (32)	4.6	-4.9 to 14.1	27 (32)	24 (32)	7.3	-3.7 to 18.2	26 (32)	20 (30)	7.3	-3.9 to 18.5		
Per Protocol	<b>9.1*</b>	0.7 to 17.6	29 (35)	22 (32)	8.4	-2.0 to 18.8	29 (33)	24 (32)	10.6	-1.0 to 22.2	27 (33)	20 (30)	8.4	-3.5 to 20.3		
<b>Things To Do</b>																
Intention To Treat	5.0	-2.9 to 13.0	48 (33)	41 (36)	7.2	-2.7 to 17.1	39 (30)	38 (32)	3.2	-8.2 to 14.7	41 (33)	35 (35)	2.9	-8.8 to 14.6		
Per Protocol	8.5	-0.1 to 17.1	51 (33)	41 (36)	<b>11.9*</b>	1.2 to 22.6	43 (31)	38 (32)	6.8	-5.3 to 18.9	42 (34)	35 (35)	5.6	-6.8 to 18.0		
<b>Satisfaction</b>																
Intention To Treat	4.9	-2.9 to 12.8	76 (24)	72 (26)	4.9	-3.5 to 13.3	78 (21)	72 (24)	7.7	-1.3 to 16.7	73 (23)	72 (23)	1.9	-7.2 to 11.1		
Per Protocol	6.2	-1.8 to 14.1	79 (23)	72 (26)	7.2	-1.3 to 15.7	78 (22)	72 (24)	8.0	-1.1 to 17.0	74 (23)	72 (23)	2.7	-6.6 to 11.9		
<b>Helpfulness</b>																
Intention To Treat	4.3	-2.8 to 11.5	77 (23)	74 (24)	2.9	-5.0 to 10.7	80 (20)	70 (26)	7.2	-1.3 to 15.8	75 (23)	70 (26)	3.8	-4.9 to 12.4		
Per Protocol	5.9	-0.6 to 12.5	79 (22)	74 (24)	4.5	-3.2 to 12.3	80 (20)	70 (26)	8.4	-0.1 to 17.0	77 (23)	70 (25)	5.8	-2.9 to 14.5		

Table 3. Continued.

Overall	After diagnosis				After 6 months				After 12 months					
	Beta	95% CI	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	
<b>SATISFACTION WITH CARE</b>														
<b>Doctor Interpersonal Skills</b>														
Intention To Treat	-2.5	-7.3 to 2.3	77 (18)	78 (19)	-1.1	-6.5 to 4.3	79 (16)	78 (18)	-3.2	-9.2 to 2.8	75 (20)	77 (17)	-4.5	-10.6 to 1.6
Per Protocol	-1.6	-6.7 to 3.6	80 (18)	78 (19)	1.2	-4.5 to 7.0	77 (16)	78 (18)	-3.8	-10.1 to 2.5	75 (20)	77 (17)	-4.1	-10.5 to 2.3
<b>Nurse Interpersonal Skills</b>														
Intention To Treat	-2.5	-9.9 to 5.0	77 (18)	78 (19)	-1.4	-9.1 to 6.3	75 (18)	76 (18)	-2.4	-10.3 to 5.5	73 (19)	79 (19)	-9.8*	-19.2 to -0.4
Per Protocol	-2.5	-10.8 to 5.8	77 (18)	78 (19)	-1.0	-9.5 to 7.4	74 (18)	76 (18)	-3.0	-11.6 to 5.7	75 (18)	79 (19)	-9.4	-19.5 to 0.8
<b>Exchange Information Caregivers</b>														
Intention To Treat	0.3	-5.0 to 5.6	69 (16)	68 (20)	0.6	-5.2 to 6.4	67 (17)	69 (18)	-2.1	-8.5 to 4.2	69 (18)	68 (19)	2.4	-4.2 to 8.9
Per Protocol	0.8	-5.1 to 6.7	70 (17)	68 (20)	1.6	-4.7 to 7.9	67 (17)	69 (18)	-2.4	-9.1 to 4.4	70 (19)	68 (19)	3.1	-3.8 to 10.1
<b>General Satisfaction With Care</b>														
Intention To Treat	-0.5	-6.2 to 5.2	80 (16)	80 (17)	-1.5	-7.9 to 4.9	80 (17)	79 (17)	-1.8	-8.6 to 5.0	71 (18)	68 (18)	2.7	-4.3 to 9.6
Per Protocol	0.3	-4.2 to 4.9	81 (16)	80 (17)	0.3	-5.9 to 6.6	78 (17)	79 (17)	-2.8	-9.4 to 3.9	72 (18)	68 (18)	4.5	-2.4 to 11.3
<b>ILLNESS PERCEPTIONS</b>														
<b>How much illness affects life</b>														
Intention To Treat	0.5	-0.3 to 1.2	4.2 (2.4)	3.9 (2.2)	0.7	-0.2 to 1.5	3.4 (2.2)	3.4 (2.3)	0.2	-0.7 to 1.1	3.5 (2.3)	3.1 (2.3)	0.6	-0.3 to 1.5
Per Protocol	0.5	-0.3 to 1.2	4.3 (2.4)	3.9 (2.2)	0.6	-0.2 to 1.4	3.4 (2.2)	3.4 (2.3)	0.2	-0.6 to 1.1	3.5 (2.4)	3.1 (2.3)	0.6	-0.3 to 1.5
<b>How long illness will continue</b>														
Intention To Treat	0.5	-0.3 to 1.4	3.6 (2.7)	3.3 (2.2)	0.5	-0.4 to 1.4	3.4 (2.8)	3.0 (2.3)	0.2	-0.8 to 1.1	3.8 (3.2)	2.9 (2.5)	1.0	-0.0 to 1.9
Per Protocol	0.5	-0.4 to 1.4	3.7 (2.8)	3.3 (2.2)	0.5	-0.4 to 1.5	3.5 (2.9)	3.0 (2.3)	0.2	-0.9 to 1.2	3.8 (3.2)	2.9 (2.5)	1.0	-0.1 to 2.0
<b>How much control over illness</b>														
Intention To Treat	-0.4	-1.2 to 0.4	4.7 (3.0)	5.3 (3.1)	-0.6	-1.6 to 0.4	4.7 (3.3)	4.9 (3.5)	-0.6	-1.7 to 0.5	4.9 (3.0)	4.5 (3.3)	0.2	-0.9 to 1.3
Per Protocol	-0.5	-1.3 to 0.3	4.6 (3.0)	5.3 (3.1)	-0.7	-1.8 to 0.3	4.6 (3.3)	4.9 (3.5)	-0.6	-1.7 to 0.6	4.7 (3.0)	4.5 (3.3)	0.0	-1.1 to 1.2
<b>How much treatment helps illness</b>														
Intention To Treat	-0.1	-0.7 to 0.5	7.7 (2.3)	8.0 (2.1)	-0.4	-1.1 to 0.4	7.6 (2.5)	7.5 (2.7)	-0.3	-1.1 to 0.6	7.4 (2.6)	6.9 (3.0)	0.5	-0.4 to 1.4
Per Protocol	0.0	-0.6 to 0.6	7.7 (2.3)	8.0 (2.1)	-0.2	-1.0 to 0.6	7.7 (2.4)	7.5 (2.7)	-0.0	-0.9 to 0.9	7.4 (2.7)	6.9 (3.0)	0.6	-0.3 to 1.5

Table 3. Continued.

Overall	After diagnosis			After 6 months			After 12 months						
	Beta	95% CI	M (SD) SCP Usual Care	Beta	95% CI	M (SD) SCP Usual Care	Beta	95% CI	M (SD) SCP Usual Care	Beta	95% CI	M (SD) SCP Usual Care	
<b>ILLNESS PERCEPTIONS</b>													
<b>How much symptoms experienced</b>													
Intention To Treat	<b>0.8*</b>	0.1 to 1.5	3.6 (2.4)	<b>1.1*</b>	0.3 to 1.9	3.0 (2.5)	2.4 (1.8)	0.6	-0.2 to 1.5	3.0 (2.4)	2.4 (2.0)	0.6	-0.3 to 1.4
Per Protocol	<b>0.9*</b>	0.2 to 1.6	3.8 (2.5)	<b>1.2*</b>	0.4 to 2.0	3.2 (2.5)	2.4 (1.8)	0.8	-0.0 to 1.7	3.1 (2.6)	2.4 (2.0)	0.7	-0.2 to 1.6
<b>How concerned about illness</b>													
Intention To Treat	<b>0.8*</b>	0.1 to 1.6	4.9 (2.7)	<b>1.0*</b>	0.2 to 1.8	4.3 (2.8)	3.7 (2.5)	0.6	-0.3 to 1.5	4.0 (2.6)	3.3 (2.4)	0.9	0.0 to 1.8
Per Protocol	<b>0.8*</b>	0.1 to 1.5	5.0 (2.7)	<b>1.0*</b>	0.1 to 1.8	4.2 (2.7)	3.7 (2.5)	0.4	-0.4 to 1.3	4.3 (2.7)	3.3 (2.4)	<b>1.0*</b>	0.1 to 1.9
<b>How well understand illness</b>													
Intention To Treat	-0.2	-1.0 to 0.5	6.6 (2.9)	0.1	-0.8 to 1.0	6.4 (2.9)	6.7 (3.0)	-0.7	-1.7 to 0.3	6.4 (3.0)	6.5 (2.9)	-0.3	-1.3 to 0.7
Per Protocol	-0.1	-0.9 to 0.8	6.7 (2.9)	0.3	-0.7 to 1.2	6.6 (2.8)	6.7 (3.0)	-0.3	-1.4 to 0.7	6.2 (3.1)	6.5 (2.9)	-0.3	-1.4 to 0.8
<b>How much affects emotionally</b>													
Intention To Treat	<b>0.7*</b>	0.0 to 1.4	4.5 (2.6)	<b>0.9*</b>	0.1 to 1.6	3.8 (2.8)	3.5 (2.4)	0.3	-0.5 to 1.1	3.9 (2.5)	3.3 (2.4)	0.9	0.0 to 1.7
Per Protocol	0.7	-0.0 to 1.4	4.7 (2.7)	<b>0.9*</b>	0.1 to 1.7	3.8 (2.6)	3.5 (2.4)	0.3	-0.6 to 1.2	4.0 (2.5)	3.3 (2.4)	<b>0.9*</b>	0.0 to 1.8
<b>HEALTH CARE UTILIZATION</b>													
<b>Contact Medical Specialist</b>													
Intention To Treat	0.3	-0.2 to 0.7	4.3 (2.6)	0.2	-0.4 to 0.8	2.7 (1.8)	2.5 (1.7)	0.1	-0.7 to 0.9	2.5 (2.7)	1.8 (0.9)	0.5	-0.3 to 1.3
Per Protocol	0.4	-0.1 to 0.9	4.5 (2.8)	0.5	-0.2 to 1.2	2.8 (2.0)	2.5 (1.7)	0.2	-0.6 to 1.0	2.7 (2.8)	1.8 (0.9)	0.7	-0.2 to 1.5
<b>Contact Primary Care Physician</b>													
Intention To Treat	<b>0.7**</b>	0.3 to 1.2	2.7 (2.5)	<b>1.1**</b>	0.5 to 1.8	1.2 (2.1)	1.1 (1.8)	0.3	-0.5 to 1.1	1.1 (3.1)	0.4 (0.8)	0.7	-0.1 to 1.5
Per Protocol	<b>0.8**</b>	0.2 to 1.3	2.7 (2.5)	<b>1.1**</b>	0.5 to 1.8	1.3 (2.2)	1.1 (1.8)	0.4	-0.4 to 1.2	1.3 (3.3)	0.4 (0.8)	0.8	-0.0 to 1.7

Note: Linear multilevel regression analyses were performed, adjusted for age, time since diagnosis, marital status, educational level, employment, comorbidities, stage, and treatment. For the models that did not converge, hospital was included as covariate instead of random intercept. Overall analyses report the results of the main effect of the intervention without the interaction between trial arm and time in the model. Crude means and standard deviations (SD) are reported for SCP Care and Usual Care. Unstandardized betas and 95% 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. Per Protocol analyses compared the respondents in the SCP care arm who indicated that they received an SCP in the first questionnaire to all respondents in the usual care arm. EORTC-QLQ-INFO25 and EORTC-IN-PATSAT32 scales ranging from 0-100; higher scores reflect better perceived information and care received. B-IPQ scale ranging from 1-10; 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.

## DISCUSSION

The present trial showed no evidence of a benefit of SCPs on satisfaction with information provision and care. Receiving an SCP did increase the amount of information received, the degree to which the illness was perceived as threatening, and the amount of cancer-related contact with the primary care physician. These effects did not differ over time.

This is the first pragmatic cluster randomized trial examining the impact of an automatically generated SCP in routine clinical practice. Previous studies have recruited both incident and prevalent cases<sup>6,7</sup> and provided a single SCP<sup>6-8</sup>. Consequently, the timing of the SCP ranged from newly diagnosed patients to patients who were up to six years post-treatment. The current trial only recruited incident cases, and the first SCP was provided following diagnosis and surgery. Moreover, as patients' information needs may change during follow-up, a single SCP may not be sufficient. Because ROGY is dynamic, oncology providers could provide an updated SCP at every follow-up visit. In the present trial, a third of patients in the SCP care arm reported receiving an SCP more than once.

Previous studies assessed the main outcomes immediately after the consultation<sup>7</sup>, missing a major potential benefit of SCPs, namely providing patients with a personal document to take home, or up to 12 months after transfer to primary care<sup>6</sup>, missing effects that may have occurred earlier<sup>10</sup>. In the present trial, patients received the first questionnaire a few weeks after the consultation, allowing patients to review the SCP, and to discuss it with others. Moreover, follow-up questionnaires were sent at 6 and 12 months to assess SCPs' longer-term effects.

SCP care increased the amount of information received, suggesting that SCPs may be useful to provide more patient-tailored information in places where existing information provision is insufficient. However, SCP care did not show an effect on satisfaction with information provision and care. Future research is needed to investigate whether certain patients may or may not benefit from SCPs.

Patients in the SCP care arm reported to be more concerned about their illness, more affected emotionally, and to experience more symptoms. However, it is unclear whether these effects are harmful or perhaps beneficial for patients. Health care providers are often reluctant to provide information on potential late effects, because they feel it may have negative effects on psychological adjustment and increase the experience of late effects<sup>29</sup>. However, one could also argue that receiving an SCP raises patients' awareness

of cancer-related symptoms and empowers them to find the necessary support. The current outcome that patients receiving SCP care reported more cancer-related contact with their primary care physician is in line with this assumption. As follow-up care for cancer survivors is increasingly transferred to the primary care physician<sup>30-32</sup>, SCPs may be a useful tool to enable this transition.

Providing SCPs can be challenging and involves many practical barriers<sup>19,33</sup>. Nevertheless, 74% of patients in the SCP care arm reported receiving an SCP. Although implementing SCPs outside a trial setting may be more challenging, the current findings suggest that implementing SCP care in routine clinical practice is attainable. Automatically generating SCPs by abstracting the information from a registration system may be the way forward, improving some of the difficulties encountered in implementing SCPs.

It is important to consider that the clinical relevance of the found effects is uncertain, as guidelines regarding minimal clinically important differences of the included outcome measures are lacking. If a cut-off of 0.5 SD is used, no clinically relevant differences were observed for any of the outcomes.

Interestingly, more than a third of patients in the usual care arm indicated receiving an SCP. As the SCP-button was only visible in the SCP care arm, it was not possible for patients in the usual care arm to receive the SCP. Because of the pragmatic approach, oncology providers in the usual care arm were not restricted regarding their information provision. Some oncology providers in the usual care arm provided personalized information that may have been perceived as an SCP, but none of them actually provided an SCP<sup>19</sup>. As the aim of the trial was to evaluate the added value of the SCP compared to the current situation, the per protocol analyses included all patients in the usual care arm. Excluding the patients in the usual care arm who indicated receiving an SCP would result in too optimistic effects of the SCP, because the patients who received more personalized information in the usual care arm would be excluded.

Some limitations should be noted. As self-reported health care utilization was assessed, it is unclear how much health care was actually used. Also, patients in the SCP care arm completed the first questionnaire later than patients in the usual care arm. This may have been because patient inclusion was somewhat faster in the usual care arm than in the SCP care arm.

Despite these limitations, the present trial provides important new insight into the effects of SCPs in routine clinical practice. The pragmatic cluster randomized design,

limited exclusion criteria, and high response rate improve the generalizability of the findings. The results can help health care providers and policy makers make informed decisions regarding larger-scale implementation of SCPs.

### **Conclusions**

The present trial showed no evidence of a benefit of SCPs on satisfaction with information provision and care. Nevertheless, SCPs increased the amount of information received, suggesting that SCPs may be a way to provide more patient-tailored information. Furthermore, SCPs increased patients' concerns, emotional impact, experienced symptoms, and the amount of cancer-related contact with the primary care physician. Whether this may ultimately lead to more empowered patients needs to be investigated further.

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# Chapter 6

## **Paper Survivorship Care Plans may be less helpful for cancer patients who search for disease-related information on the Internet: Results of the ROGY Care trial**

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## ABSTRACT

**Background:** The Institute of Medicine recommends Survivorship Care Plans (SCPs) for all cancer survivors. However, it is unclear whether certain patient groups may or may not benefit from SCPs. SCPs are usually provided by patients' health care providers, who are patients' main source of information about their cancer. However, the Internet is also increasingly used as a source of information. Using the Internet to obtain disease-related information has been associated with considerable benefits for cancer survivors. It was therefore hypothesized that paper SCPs may be a helpful tool for patient groups who do not have access to the Internet, whereas SCPs may be of limited value for patients who already benefit from accessing information on the Internet.

**Objective:** To assess whether the effects of an automatically generated paper SCP on patients' satisfaction with information provision and care, illness perceptions, and health care utilization were moderated by (i.e., different for) disease-related Internet use.

**Methods:** In the pragmatic cluster randomized ROGY Care trial, the impact of an automatically generated SCP on gynecological cancer patient and health care provider reported outcomes is evaluated. The present study describes the results of moderation analyses of the primary patient reported outcomes. Twelve hospitals were randomized to either 'SCP care' (i.e., oncology providers provided an SCP to patients after surgery) or 'usual care' (i.e., oncology providers provided patient information in the way they were used to). An SCP-application was built in the web-based Registration system Oncological GYnecology (ROGY). By clicking the SCP-button, a patient-tailored SCP could be generated by the oncology providers in the SCP care arm. Newly diagnosed endometrial cancer patients completed questionnaires after diagnosis (N=221; 75% response), 6 months (N=158), and 12 months (N=147), including patients' satisfaction with information provision (EORTC-QLQ INFO25) and care (EORTC IN-PATSAT32), illness perceptions (B-IPQ), health care utilization (how many times patients visited a medical specialist or primary care physician in relation to cancer in the past 6 months), and disease-related Internet use (whether patients had used the Internet to look for information about cancer). Moderation of disease-related Internet use on the dependent variables was tested by linear multilevel regression analyses. When warranted, the regression analyses were stratified by the levels of disease-related Internet use.

**Results:** In total, 80 (37%) patients indicated using the Internet to obtain disease-related information. Disease-related Internet use moderated the SCP care effect on the amount of information received about the disease ( $p=0.03$ ) and medical tests

( $p=0.01$ ), helpfulness of the information ( $p=0.01$ ), and how well patients understand their illness ( $p=0.04$ ). Stratified analyses were all not statistically significant. However, there was a trend in the hypothesized direction suggesting that for the patients who do not seek disease-related information on the Internet, patients in the SCP care arm reported receiving more information about their disease (63.9 vs. 58.3) and medical tests (70.6 vs. 64.7), finding the information more helpful (76.7 vs. 67.8; scales 0-100) and understanding their illness better (6.6 vs. 6.1; scales 1-10) than the usual care arm. For patients who do seek disease-related information on the Internet, as hypothesized, patients in the SCP care arm did not report receiving more information about their disease (65.7 vs. 67.1) and medical tests (72.4 vs. 75.3), and did not find the information more helpful (78.6 vs. 76.0). In addition, they reported less understanding of their illness (6.3 vs. 7.1) than the usual care arm, which was not hypothesized.

**Conclusions:** Paper SCPs appear to improve the amount of received information about the disease and medical tests, helpfulness of the information, and understanding of the illness for patients who do not search for disease-related information on the Internet. In contrast, paper SCPs do not seem beneficial for patients who do seek disease-related information on the Internet. Future research needs to examine whether tailored online SCP dissemination may have added value for patients who use the Internet to obtain disease-related information.

## INTRODUCTION

Information provision has been demonstrated to play an essential role in the support for cancer survivors <sup>1,2</sup>. To improve patient information provision, the Institute of Medicine (IOM) recommends the use of Survivorship Care Plans (SCPs), described as personal treatment summaries and follow-up care plans, for all cancer survivors <sup>3</sup>. However, there is still an ongoing debate about the benefits of SCPs <sup>4-12</sup>.

Recent results of the pragmatic cluster randomized ROGY Care trial <sup>8</sup>, in which cancer patients were provided with an SCP on paper, showed that SCPs increased the amount of received information. However, the trial showed no evidence of a benefit of SCPs on satisfaction with information and care. Furthermore, SCPs increased patients' concerns, emotional impact, experienced symptoms, and the amount of cancer-related contact with the primary care physician. Moreover, it remains unclear whether patient characteristics may influence the effects of SCPs, and whether certain groups of patients may or may not benefit from SCPs <sup>8</sup>.

SCPs are usually provided by patients' health care providers, who are patients' main source of information about their cancer <sup>1,13</sup>. However, the Internet is also increasingly used as a source of information. Several studies have shown that a significant proportion of cancer survivors, ranging from 30-60%, is using the Internet to seek information about their cancer <sup>14-19</sup>. Especially cancer survivors who are younger <sup>15,17,19</sup>, higher educated <sup>15,17,19</sup>, male <sup>15</sup>, and have a partner <sup>19</sup> are using the Internet.

Using the Internet to obtain disease-related information has been associated with considerable benefits for cancer survivors <sup>20</sup>. For instance, it has been found that cancer survivors who use the Internet to access disease-related information feel better informed <sup>15</sup>, report receiving more information about their disease and medical tests <sup>21</sup>, find the received information more helpful <sup>21</sup>, communicate more effectively with their health care providers <sup>22</sup>, and are more actively involved in decision making <sup>23</sup>. It is therefore possible that receiving an SCP has a different impact on patients who search for information about their cancer on the Internet compared to patients who do not search for information about their cancer on the Internet.

The aim of the present analyses of the ROGY Care trial was to assess whether the effects of an automatically generated paper SCP on patients' satisfaction with information provision and care, illness perceptions, and health care utilization were moderated by (i.e., different for) disease-related Internet use. It was hypothesized that paper SCPs may

be a helpful tool to reach out to patient groups who do not have access to information on the Internet, whereas SCPs may be of limited value for patients who already benefit from accessing information on the Internet.

## **METHODS**

### **Design**

In the ROGY Care trial, the impact of an automatically generated SCP on gynecological cancer patient and health care provider reported outcomes is evaluated. In this pragmatic cluster randomized controlled trial, 12 hospitals in the Netherlands were randomized to either 'SCP care' or 'usual care'. Patients were included immediately after initial surgery and followed for 24 months. The trial was centrally approved by a Medical Research Ethics Committee, as well as by the Medical Research Ethics Committees of each participating center <sup>24</sup>, and has been registered on ClinicalTrials.gov (NCT01185626). The trial protocol <sup>24</sup>, the primary patient reported outcomes up to 12 months after diagnosis <sup>8</sup>, and the evaluation of the oncology providers <sup>25</sup> and primary care physicians <sup>26</sup> have been previously described. The present study describes the results of subgroup analyses of the primary patient reported outcomes up to 12 months after diagnosis.

### **Participants and Recruitment**

Participants were women newly diagnosed with endometrial cancer. Exclusion criteria (i.e., undergoing palliative care or unable to complete a Dutch questionnaire) <sup>24</sup> were minimal to maximize generalizability <sup>27</sup>. All eligible patients between April 2011 and October 2012 were invited to participate after initial diagnosis by their own gynecologist, by sending a letter, questionnaire, and informed consent form <sup>24,28</sup>. After the first contact via the gynecologist and obtaining informed consent, follow-up questionnaires at 6 and 12 months after diagnosis were sent directly to the home address of the patient.

### **Randomization and Blinding**

Randomization at hospital-level was chosen to avoid potential contamination of usual care with increased information provision of SCP care, and was performed with a table of random numbers by a researcher not involved in the study and blind to the identity of the hospitals. As is common in cluster randomized trials <sup>29</sup>, patients were unaware of the assignment to trial arms. Health care providers could not be blinded to trial arm assignment.

### **SCP care versus Usual care**

In the usual care arm, the oncology providers (i.e., gynecologists, gynecologic oncologists, oncology nurses) were instructed to continue providing patient information in the way they were used to: They gave standard care according to the Dutch follow-up guidelines, which recommend verbal and written information about the period after treatment and follow-up, signs of recurrence, and hospital contact details. None of the oncology providers in the usual care arm provided SCPs<sup>25</sup>.

In the SCP care arm, the oncology providers were instructed to provide an SCP to patients after surgery (i.e., during the consultation in which the final histological diagnosis was discussed), to provide an updated SCP during follow-up visits if there were changes in the cancer, treatment, or specialists, and to send a copy of the SCP to the patient's primary care physician. Because of the pragmatic approach of the trial, the delivery of the intervention was allowed to vary between hospitals and oncology providers, fitting their own clinical practice<sup>24</sup>.

### **Survivorship Care Plan**

The web-based 'Registrationsystem Oncological GYnecology' (ROGY) is used by all participating oncology providers in both arms since 2006. For each patient, a detailed registration is made in a uniform way, including tumor stage and grade, treatment, comorbidity, complications, follow-up, and information about the involved specialists (e.g., gynecologist/gynecologic oncologist, medical oncologist, radiation oncologist). For the present trial, an application was built in ROGY, enabling automatic generation of an SCP combining patient and disease data, by simply pressing a button. The ROGY system is used by all participating oncology providers in both arms, but the SCP-button is only visible for oncology providers in the SCP care arm. Any changes related to the cancer, treatment, or specialists are registered in ROGY and automatically updated in the SCP during follow-up.

For the development of the SCP, the Dutch SCP template (based on the IOM-format)<sup>3</sup>, was adjusted to the local situation <sup>30</sup> by a subgroup of gynecologists/gynecologic oncologists, oncology nurses, a radiation oncologist, medical oncologist, primary care physician, and patients <sup>24</sup>. The SCP 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, treatment, and contact details of the hospital and specialists. In addition, the SCP contained a tailored follow-up care plan, including detailed information on possible short-term and long-term effects, effects on social and sexual life, possible signs of recurrence and secondary tumors, and information on rehabilitation, psychosocial support, and supportive care services <sup>24</sup>.

## Measures

All questionnaires were assessed after initial diagnosis, and after 6 and 12 months. Socio-demographic and clinical information was obtained from ROGY (i.e., date of birth, date of diagnosis, disease stage, primary treatment) and the questionnaire (i.e., marital status, educational level - as an indicator for socioeconomic status (SES)-, employment status). Comorbidity was assessed by the adapted Self-administered Comorbidity Questionnaire (SCQ) <sup>31</sup>.

Disease-related Internet use was assessed by asking whether patients had used the Internet to look for information about cancer, which could be answered by either yes or no.

Satisfaction with information provision was assessed with the European Organization for Research and Treatment of Cancer (EORTC) QLQ-INFO25 questionnaire <sup>32</sup>. This questionnaire includes four information provision subscales: Perceived receipt of information about the disease (four items regarding diagnosis, spread of disease, cause(s) of disease and whether the disease is under control), medical tests (three items regarding purpose, procedures and results of tests), treatment (six items regarding medical treatment, benefits, side-effects, effects on disease symptoms, social life and sexual activity) and other care services (four items regarding additional help, rehabilitation options, managing illness at home, psychological support). The question format was as follows: "During your current disease or treatment, how much information have you received on...?". In addition, four single-items were included (information about different places of care, things you can do to help yourself get well, satisfaction with the information, and helpfulness of the information). The answer categories were "not at all", "a little", "quite a bit", and "very much". The scales were converted to 0-100 linear scales, with higher scores indicating better perceived information provision. Internal consistency for all scales (Cronbach's alphas 0.70-0.87) and test-retest reliability (intraclass correlations 0.71-0.91) are good <sup>32</sup>.

Satisfaction with care was assessed with two multi-item and two single-item scales of the European Organization for Research and Treatment of Cancer (EORTC) IN-PATSAT32<sup>33</sup>. This questionnaire was designed to assess cancer patients' perception of the quality of medical care, nursing care and care organization and services received in the hospital. The multi-item scales included doctors' and nurses' interpersonal skills. The single-item scales included exchange of information between caregivers and general satisfaction with care. The question format was as follows: "How would you rate...?". The answer categories were "poor", "fair", "good", "very good", and "excellent". The scales were converted to 0-100 linear scales, with higher scores indicating better perceived quality of care. Internal consistency (Cronbach's alphas 0.67-0.96) and test-retest reliability (intraclass correlations 0.66-0.85) are good<sup>33</sup>.

Illness perception was assessed with the Brief Illness Perception Questionnaire (B-IPQ)<sup>34</sup>, consisting of eight single-item scales, measuring cognitive representations (consequences, timeline, personal control, treatment control, identity), emotional representations (concern, emotion), and illness comprehensibility rated on a 0-10 linear scale, with higher scores indicating more endorsement of that item. Test-retest reliability (Pearson correlations 0.42-0.75) is good<sup>34</sup>.

Health care utilization was assessed by asking how many times patients visited a medical specialist or primary care physician in relation to cancer in the past 6 months. These questions were asked in a similar way as is done by Statistics Netherlands.

### **Statistical Analyses**

Statistical analyses were conducted using SPSS 19.0 (Statistical Package for Social Sciences, Chicago, USA). Tests were two-sided and considered significant if  $P < 0.05$ . Both intention-to-treat and per-protocol analyses were conducted. Intention-to-treat analyses compared all respondents in the SCP care arm to all respondents in the usual care arm. Per-protocol analyses compared respondents in the SCP care arm who indicated receiving an SCP in the first questionnaire to all respondents in the usual care arm. As intention-to-treat and per-protocol analyses revealed similar results, only the results of the intention-to-treat analyses are reported in the present study.

Means (M) with standard deviations (SD) were used to describe continuous variables, and frequencies with percentages to describe categorical variables. Differences in socio-demographic and clinical characteristics between respondents and non-respondents, between the SCP care arm and the usual care arm, and between patients who did or did not use the Internet to obtain information about their disease were compared using t-tests for continuous variables, and chi-square tests for categorical variables.

Moderation of disease-related Internet use on the dependent variables (i.e., 22 scales in total: 8 on information provision, 4 on satisfaction with care, 8 on illness perceptions, and 2 on health care utilization) was tested by assessing the significance of the interaction term 'Trial arm X Disease-related Internet use' in the overall linear multilevel regression model. Multilevel analysis corrects for missing data (assumed missing at random), by using information from the observed outcomes to provide information about the unobserved outcomes<sup>35,36</sup>

The model included two random intercepts (i.e., hospital- and patient-level) to account for both clustering at hospital-level and intra-patient dependency of repeated measures<sup>37</sup>, the independent variables intervention arm (i.e., SCP care vs. usual care) and time, the covariates age, time since diagnosis, marital status, employment, educational level, comorbidity, disease stage, and treatment, and the dependent variables information provision and care, illness perceptions, and health care utilization. For the models that did not converge, hospital was included as covariate instead of as random intercept<sup>38</sup>.

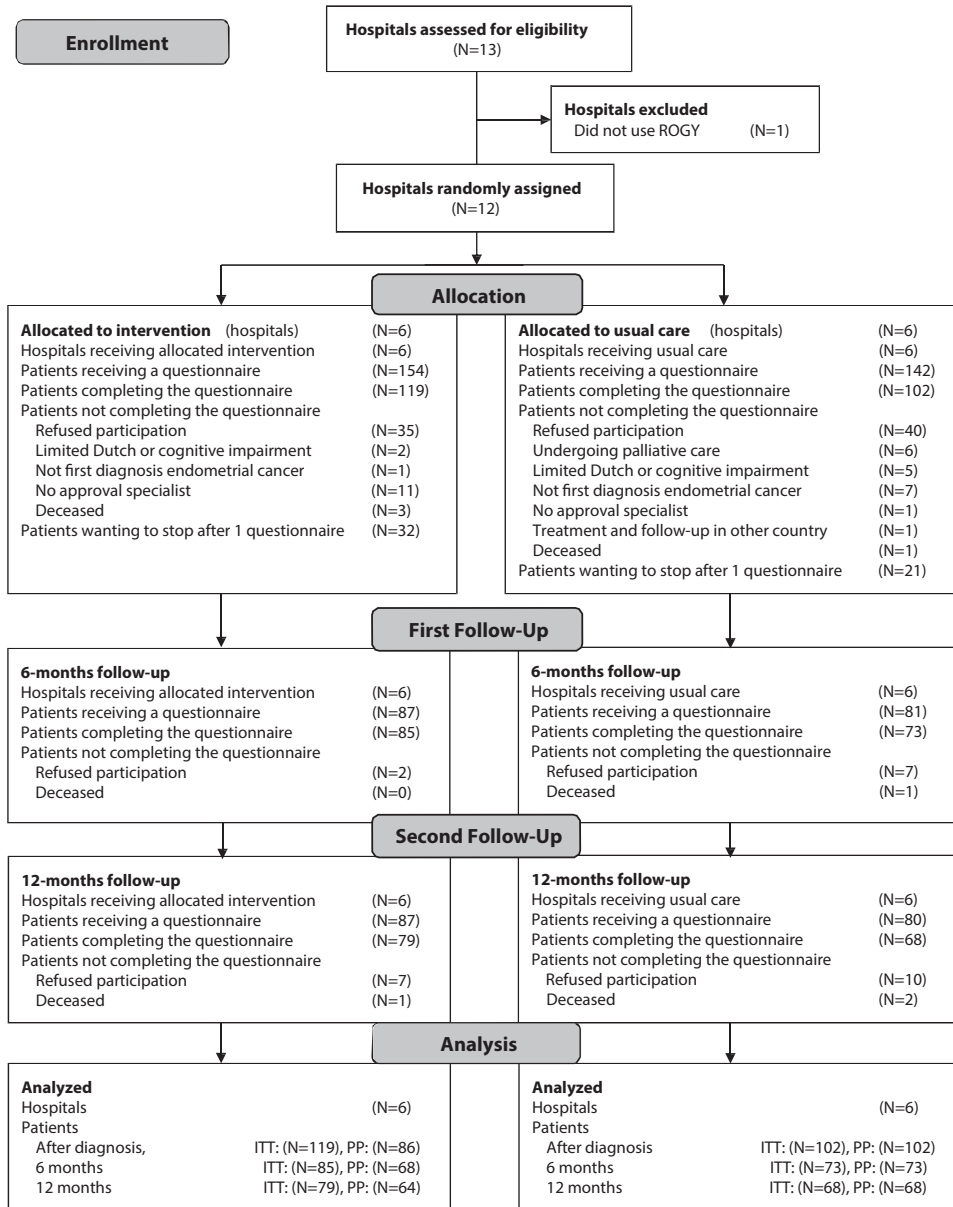
When an interaction term was significant, this was an indication that the effect of providing an SCP was different for patients who did or did not use the Internet to search for disease-related information, and that stratified analyses were warranted. For significant interaction terms, the intervention effects were re-examined in subgroups by performing the overall linear multilevel regression analyses stratified by the levels of the moderator variable (i.e., disease-related Internet use). Unstandardized betas were presented with 95% confidence intervals.

The trial was originally powered to detect a clinically meaningful difference on the overall primary outcomes of the intervention, targeting 75 patients per arm<sup>8,24</sup>. The trial was not powered to detect differences in moderation analyses or stratified analyses. These analyses can be justified because they are exploratory and because the exploration was a priori restricted to a selected moderator with a specific rationale<sup>39</sup>.

## RESULTS

### Patient characteristics

Of the 296 eligible patients, 221 (75%) patients completed the first questionnaire. After 6 months, 158 patients, and after 12 months, 147 patients completed the questionnaire (Figure 1)<sup>8</sup>.



**Figure 1.** CONSORT Flow diagram of the progress of the hospitals and endometrial cancer patients through the phases of the ROGY Care trial

Note: ITT= Intention To Treat analyses, comparing all respondents in the SCP care arm to all respondents in the usual care arm. PP= Per Protocol analyses, comparing the respondents in the SCP care arm who indicated that they received an SCP in the first questionnaire to all respondents in the usual care arm.

**Table 1.** CONSORT Table of baseline socio-demographic and clinical characteristics of participants according to trial arm and of non-participants

	SCP Care (N=119)	Usual Care (N=102)	p-value	Total Participants (N=221)	Non- Participants (N=75)	p-value
<b>Patients</b>	N (%)			N (%)		
<b>Age at diagnosis</b>						
Mean	67.1	67.7	0.65	67.4	70.2	<b>0.02</b>
SD	9.1	8.8		8.9	9.5	
<b>FIGO-stage</b>						
I	102 (86)	87 (87)	0.75	189 (87)	52 (70)	<b>&lt;0.01</b>
II	5 (4)	2 (2)		7 (3)	10 (14)	
III	8 (7)	7 (7)		15 (7)	11 (15)	
IV	3 (3)	4 (4)		7 (3)	1 (1)	
<b>Treatment</b>						
Surgery	117 (99)	97 (98)	0.46	214 (99)	72 (97)	0.45
Radiotherapy	44 (37)	37 (37)	0.99	81 (37)	34 (46)	0.19
Chemotherapy	6 (5)	12 (12)	0.06	18 (8)	7 (10)	0.76
<b>Hospital</b>						
1	22 (19)			22 (10)	4 (5)	0.61
2	12 (10)			12 (5)	7 (9)	
3	28 (24)			28 (13)	9 (12)	
4	28 (24)			28 (13)	9 (12)	
5	11 (9)			11 (5)	1 (1)	
6	18 (15)			18 (8)	5 (7)	
7		25 (25)		25 (11)	13 (17)	
8		21 (21)		21 (10)	6 (8)	
9		26 (26)		26 (12)	7 (9)	
10		12 (12)		12 (5)	4 (5)	
11		3 (3)		3 (1)	3 (4)	
12		15 (15)		15 (7)	7 (9)	

Note: P-values report comparisons between the intervention arm and the usual care arm, and between the trial participants and non-participants, according to t-tests and Chi-square tests. The numbers may not always add up to 100, because percentages have been rounded off to whole numbers.

At baseline, participants were younger ( $M=67.4$ ,  $SD=8.9$ ) than non-participants ( $M=70.2$ ,  $SD=9.5$ ,  $p=0.02$ ), and more often had FIGO-stage I (87% vs. 70%,  $p<0.01$ ; Table 1)<sup>8</sup>. In total, 80 (37%) patients indicated that they used the Internet to obtain information about their disease. This did not differ between the SCP care arm and the usual care arm (Table 2).

**Table 2.** Socio-demographic and clinical characteristics at the first questionnaire, according to trial arm

	SCP Care (N=119)	Usual Care (N=102)	p-value	Total (N=221)
	N (%)			N (%)
<b>Age at time of survey</b>				
Mean	67.4	67.8	0.71	67.6
SD	9.1	8.9		9.0
<b>Months since diagnosis</b>				
Median	2.2	1.5	<0.01	1.8
<1	12 (10)	24 (24)		36 (16)
1-2	40 (34)	46 (45)		86 (39)
2-3	33 (28)	20 (20)		53 (24)
>3	34 (29)	12 (12)		46 (21)
<b>Comorbidity</b>				
None	19 (17)	18 (18)	0.41	37 (17)
1	32 (28)	20 (20)		52 (24)
2 or more	64 (56)	62 (62)		126 (59)
<b>Marital status<sup>a</sup></b>				
Partner	85 (73)	76 (75)	0.74	161 (74)
No partner	31 (27)	25 (25)		56 (26)
<b>Educational level<sup>b</sup></b>				
High	17 (14)	7 (7)	0.09	24 (11)
Intermediate	71 (60)	72 (74)		143 (66)
Low	30 (25)	19 (19)		49 (23)
<b>Employed</b>				
Yes	22 (21)	15 (16)	0.40	37 (18)
No	85 (79)	79 (84)		164 (82)
<b>Disease-related Internet use</b>				
Yes	41 (35)	39 (39)	0.57	80 (37)
No	76 (65)	60 (61)		136 (63)

Note: P-values report comparisons between the intervention arm and the usual care arm, according to t-tests and Chi-square tests. The numbers may not always add up to 100, because percentages have been rounded off to whole numbers. <sup>a</sup>Marital status included: partner = married/living together; no partner = divorced/widowed/never married. <sup>b</sup>Educational level included: low = no/primary school; intermediate = lower general secondary education/vocational training; or high = pre-university education/ high vocational training/university.

**Table 3.** Patient characteristics at the first questionnaire, according to disease-related Internet use

	Disease-related Internet use (N=80)	No disease-related Internet use (N=136)	p-value	Total (N=216)
<b>Patients</b>	N (%)			N (%)
<b>Age at time of survey</b>				
Mean	62.8	70.3	<b>&lt;0.01</b>	67.5
SD	7.5	8.7		9.0
<b>Months since diagnosis</b>				
Median	1.6	2.0	<b>&lt;0.01</b>	1.8
<1	19 (24)	16 (12)		35 (16)
1-2	31 (39)	53 (39)		84 (39)
2-3	12 (15)	41 (30)		53 (25)
>3	18 (23)	26 (19)		44 (20)
<b>FIGO-stage</b>				
I	70 (89)	115 (86)	0.37	185 (87)
II	4 (5)	3 (2)		7 (3)
III	3 (4)	12 (9)		15 (7)
IV	2 (3)	4 (3)		6 (3)
<b>Treatment</b>				
Surgery	77 (99)	132 (99)	0.90	209 (99)
Radiotherapy	26 (33)	54 (40)	0.31	80 (38)
Chemotherapy	7 (9)	10 (8)	0.70	17 (8)
<b>Comorbidity</b>				
None	18 (23)	19 (14)	0.20	37 (18)
1	15 (19)	35 (27)		50 (24)
2 or more	45 (58)	78 (59)		123 (59)
<b>Marital status<sup>a</sup></b>				
Partner	66 (85)	92 (69)	<b>0.01</b>	158 (75)
No partner	12 (15)	42 (31)		54 (26)
<b>Educational level<sup>b</sup></b>				
High	16 (20)	7 (5)	<b>&lt;0.01</b>	23 (11)
Intermediate	59 (74)	83 (63)		142 (67)
Low	5 (6)	42 (32)		47 (22)
<b>Employed</b>				
Yes	21 (28)	16 (13)	<b>0.01</b>	37 (19)
No	54 (72)	107 (87)		161 (81)

Note: P-values report comparisons between patients reporting disease-related Internet use and patients not reporting disease-related Internet use, according to t-tests and Chi-square tests. The numbers will not always add up to 100, because percentages have been rounded off to whole numbers. <sup>a</sup>Marital status included: partner = married/living together; no partner = divorced/widowed/never married. <sup>b</sup>Educational level included: low = no/primary school; intermediate = lower general secondary education/vocational training; or high = pre-university education/ high vocational training/university.

Patients who used the Internet to obtain disease-related information were younger (62.8 years) than patients who did not use the Internet to obtain disease-related information (70.3 years; Table 3). In addition, patients who used the Internet to obtain disease-related information completed the questionnaire sooner after diagnosis (median=1.6 months vs. 2.0 months), more often had a partner (85% vs. 69%), more often had a high educational level (20% vs. 5%), and were employed more often (28% vs. 13%) than patients who did not use the Internet to obtain disease-related information.

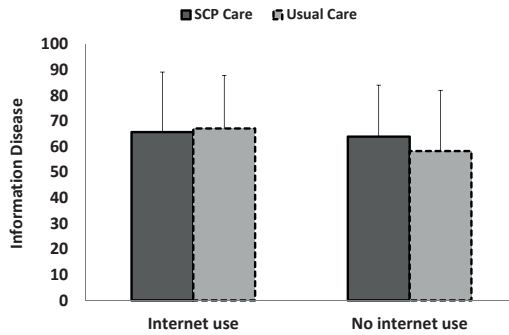
### Moderation of disease-related Internet use

Four statistically significant moderation tests were found. Disease-related Internet use moderated the intervention effect on the amount of information received about the disease ( $p=0.03$ ), the amount of information received about medical tests ( $p=0.01$ ), the helpfulness of the information ( $p=0.01$ ), and how well patients understand their illness ( $p=0.04$ ). All other interaction terms were not significant.

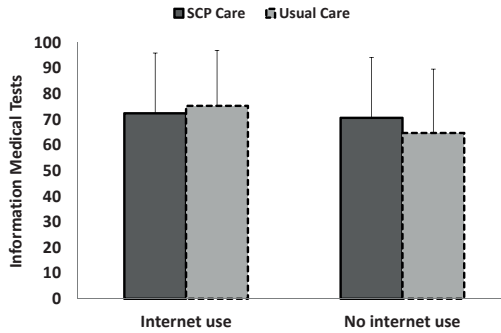
**Table 4.** Regression outcomes from the stratified analyses for the effect of SCP care on the outcomes according to disease-related Internet use.

Outcome	SCP Care Mean (SD)	Usual Care Mean (SD)	Total Mean (SD)	Beta	95% CI	p-value
<b>Information Disease<sup>a</sup></b>						
<i>Internet use</i>						
Yes	65.7 (23.4)	67.1 (20.7)	66.4 (22.1)	-1.36	-12.7 to 10.0	0.79
No	63.9 (20.1)	58.3 (23.7)	61.4 (21.9)	5.51	-3.9 to 14.9	0.22
<b>Information Medical Tests<sup>a</sup></b>						
<i>Internet use</i>						
Yes	72.4 (23.5)	75.3 (21.6)	73.9 (22.6)	-3.83	-13.5 to 5.8	0.43
No	70.6 (23.5)	64.7 (24.9)	68.0 (24.3)	4.87	-3.3 to 13.0	0.24
<b>Helpfulness Information<sup>a</sup></b>						
<i>Internet use</i>						
Yes	78.6 (21.2)	76.0 (22.0)	77.3 (21.6)	1.13	-7.4 to 9.6	0.79
No	76.7 (22.9)	67.8 (27.2)	72.9 (25.2)	6.89	-1.6 to 15.4	0.11
<b>How well understand illness<sup>b</sup></b>						
<i>Internet use</i>						
Yes	6.3 (2.8)	7.1 (2.7)	6.7 (2.8)	-0.98	-2.11 to 0.14	0.09
No	6.6 (3.0)	6.1 (3.2)	6.3 (3.1)	0.30	-0.73 to 1.33	0.56

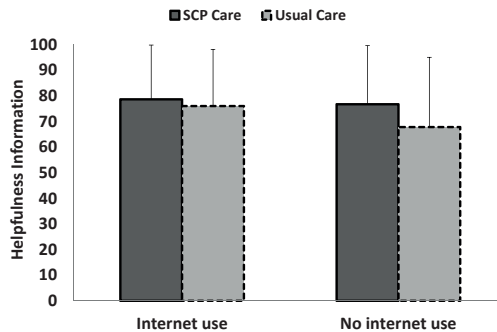
Note: Outcomes are presented only for the statistically significant interaction terms. Linear multilevel regression analyses were performed, adjusted for age, time since diagnosis, marital status, educational level, employment, comorbidities, stage, and treatment. For the models that did not converge, hospital was included as covariate instead of random intercept. Crude means and standard deviations (SD) are reported for SCP Care and Usual Care. Unstandardized betas and 95% Confidence Intervals are reported for SCP Care (ref=Usual Care). <sup>a</sup>EORTC-QLQ-INFO25 scale ranging from 0-100: higher scores reflect better perceived information received. <sup>b</sup>B-IPQ scale ranging from 1-10: higher scores indicate more endorsement of that item.



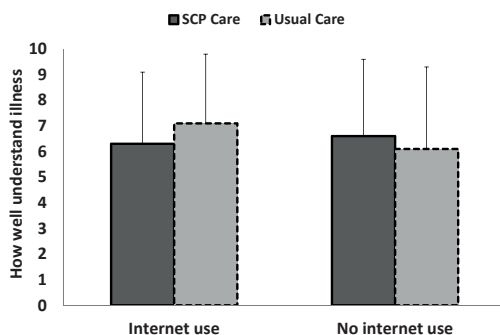
**Figure 2.** Patients’ reported amount of received information on their disease according to disease-related Internet use, for the SCP care arm and the usual care arm  
 Note: Crude means are reported. Error bars represent +1 standard deviation. EORTC-QLQ-INFO25 scale ranging from 0-100: higher scores reflect better perceived information received. For detailed information, see Table 4.



**Figure 3.** Patients’ reported amount of received information on their medical tests according to disease-related Internet use, for the SCP care arm and the usual care arm  
 Note: Crude means are reported. Error bars represent +1 standard deviation. EORTC-QLQ-INFO25 scale ranging from 0-100: higher scores reflect better perceived information received. For detailed information, see Table 4.



**Figure 4.** Patients’ reported amount of received information on the helpfulness of the information according to disease-related Internet use, for the SCP care arm and the usual care arm  
 Note: Crude means are reported. Error bars represent +1 standard deviation. EORTC-QLQ-INFO25 scale ranging from 0-100: higher scores reflect better perceived information received. For detailed information, see Table 4.



**Figure 5.** Patients' reported understanding of the illness according to disease-related Internet use, for the SCP care arm and the usual care arm

Note: Crude means are reported. Error bars represent +1 standard deviation. B-IPQ scale ranging from 1-10: higher scores indicate more endorsement of that item. For detailed information, see Table 4.

Although the stratified analyses were all not statistically significant, it appears that patients who do not seek disease-related information on the Internet may benefit from receiving an SCP, as patients in the SCP care arm reported to receive more information about their disease (63.9 vs. 58.3) and medical tests (70.6 vs. 64.7), found the information more helpful (76.7 vs. 67.8) and understood their illness better (6.6 vs. 6.1) than patients in the usual care arm (Table 4 and Figures 2-5).

On the other hand, it appears that patients who do seek disease-related information on the Internet do not benefit from receiving an SCP, as patients in the SCP care arm did not report to receive more information about their disease (65.7 vs. 67.1) and medical tests (72.4 vs. 75.3), did not find the information more helpful (78.6 vs. 76.0), and reported less understanding of their illness (6.3 vs. 7.1) than patients in the usual care arm (Table 4 and Figures 2-5).

## DISCUSSION

The results of the present secondary analyses of the ROGY Care trial suggest that paper SCPs appear to improve the amount of received information about the disease and medical tests, the helpfulness of the information, and the understanding of the illness for patients who do not search for information on the Internet themselves. In contrast, paper SCPs do not appear helpful for patients who already search for information on the Internet themselves. All other outcomes did not differ for patients who did or did not use the Internet to search for disease-related information.

Nearly two thirds of all patients in the present study did not use the Internet to search for disease-related information. These patients were older, lower educated, and less often had a partner or a job than patients who did use the Internet to search for information about their cancer. This has consistently been found in previous studies<sup>15,17,19</sup>, and has raised the concern that some patient groups do not equally benefit from the various resources available on the Internet<sup>19</sup>. As educational level is an indicator for SES<sup>40,41</sup>, patients with a higher SES search the Internet more for disease-related information than patients with a lower SES. This 'digital divide' may pose a threat to equity in health care when important information can only be or best be accessed online<sup>19</sup>. Even today, still a large group of cancer survivors does not have access to the potential benefits of the Internet. The results of the present study suggest that paper SCPs may be a useful tool to empower this patient group by improving the amount of information they receive about their disease and medical tests, the helpfulness of the information, and their understanding of their illness.

A third of all patients in the present study did use the Internet to search for disease-related information, which is consistent with previous studies<sup>14-19</sup>. The results of the present study suggest that paper SCPs may not be of added value for this patient group. A possible explanation for this finding could be that these patients already benefit from accessing information on the Internet, as using the Internet to obtain disease-related information has been associated with considerable benefits for cancer survivors<sup>20</sup>. Previous studies have found that cancer survivors who use the Internet to access disease-related information feel better informed<sup>15</sup>, report receiving more information about their disease and medical tests<sup>21</sup>, find the received information more helpful<sup>21</sup>, communicate more effectively with their health care providers<sup>22</sup>, and are more actively involved in decision making<sup>23</sup>.

It is important to take into consideration that the present study was conducted in The Netherlands, a developed country where 95% of the population has access to the Internet at home<sup>42</sup>. Furthermore, only endometrial cancer patients were included in the present study. In general, endometrial cancer patients have a lower educational level than patients with other types of cancer<sup>43</sup>, which has been found to be strongly associated with lower Internet use<sup>15,17,19</sup>. In addition, men tend to use the Internet more often than women<sup>15</sup>. Consequently, the percentage of patients who used the Internet to search for disease-related information in the present study may be an underestimation of the Internet use of cancer survivors in The Netherlands. A previous study conducted in The Netherlands in 2006, including both male and female patients with different types of cancer, found that 60% reported using the Internet by themselves<sup>15</sup>.

Surprisingly, the results of the present study suggest that paper SCPs may actually even decrease the understanding of the illness for patients who search for disease-related information on the Internet. A possible explanation could be that patients who receive an SCP and also search for information on the Internet may find information on the Internet about their illness that is conflicting with information in the SCP. This may confuse patients and may lower their understanding of the illness. It is also possible that, because these patients have access to more information, they may be more aware of aspects of their illness that they do not (completely) understand (i.e., the more you know, the more you realize how little you know). Future research needs to investigate why SCPs may not be helpful for patients who search for disease-related information on the Internet. Another possibility is that paper SCPs in their current form are not suitable for patients who search for disease-related information on the Internet. A possible way to increase the value of SCP care for patients who search for disease-related information on the Internet may be to provide these patients with access to a tailored online SCP instead of a paper SCP. Previous research showed that most patients who use the Internet prefer to get their information from reliable websites, such as the website of their hospital, and would like to have online access to their own medical file and test results <sup>15</sup>. Internet-based SCPs may be a useful way to support these patients in finding reliable information online, that is tailored to their specific situation. The results of previous studies investigating cancer patients' satisfaction with an internet-based SCP tool seem promising <sup>44-46</sup>. Future research needs to examine whether tailored online dissemination of SCPs does have added value for patients who search for cancer-related information on the Internet.

Interestingly, other effects of SCP care found in the ROGY Care trial[8], such as concerns about the illness, experienced symptoms, emotional impact, and health care utilization, did not differ for patients who did or did not use the Internet to search for disease-related information, which may limit the implications of the current study for clinical practice. However, it is important to consider that the ROGY Care trial was not originally powered to detect differences in moderation analyses or stratified analyses. Therefore, it is unclear whether insignificant outcomes in the current analyses indicate that disease-related Internet use did not moderate these outcomes or that the power was merely too small to find the effects. On the other hand, this actually makes the moderation effects that were found in the current study more convincing. Another limitation of the present study is that self-reported information provision and health care utilization were assessed, which makes it unclear how much information was actually provided and how much health care was actually used. In addition, Internet utilization was measured with a single dichotomous item. Consequently, the current study can only

make a distinction between survivors who did or did not use the Internet to search for disease-related information. It remains unknown, for instance, how many times survivors searched the Internet, what they searched for (i.e., Did they use the Internet to search for similar topics as addressed in the SCP?), or what information they found. For future research, we would recommend to use a more elaborate measure of Internet utilization that is psychometrically tested.

Despite these limitations, the present study provides important new insight into whether certain groups of patients may or may not benefit from paper SCPs in routine clinical practice. The pragmatic cluster randomized design, limited exclusion criteria, and high response rate improve the generalizability of the findings. However, at present, there is not enough evidence to recommend that patients who search for information on the Internet, or their PCPs and caregivers, should not receive a paper SCP. More research is needed to get a more nuanced understanding of the current findings before health care providers can use the information to decide whether providing a paper SCP is of added value or not. In addition, future research needs to examine whether other patient characteristics could also possibly influence the impact of SCPs.

## **Conclusions**

The results of the present secondary analyses of the ROGY Care trial suggest that paper SCPs appear to improve the amount of received information about the disease and medical tests, the helpfulness of the information, and the understanding of the illness for patients who do not search for information on the Internet themselves. In contrast, paper SCPs do not seem beneficial for patients who do search for disease-related information on the Internet. With the increasing importance of the Internet as a source of information for cancer survivors, future research needs to examine whether tailored online dissemination of SCPs may have added value for patients who use the Internet to obtain disease-related information.

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# Chapter 7

## **Oncology providers' evaluation of the use of an automatically generated cancer Survivorship Care Plan: Longitudinal results from the ROGY Care trial**

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## ABSTRACT

**Purpose:** Previous studies have merely investigated oncology providers' a priori attitudes towards SCPs. The purpose of the current study was to longitudinally evaluate oncology providers' expectations and actual experiences with the use of an automatically generated Survivorship Care Plan (SCP) in daily clinical practice.

**Methods:** Between April 2011 and October 2012, the participating oncology providers (i.e., gynecologists, gynecologic oncologists, oncology nurses) provided usual care or SCP care to 222 endometrial and 85 ovarian cancer patients included in the ROGY Care trial. All (N=43) oncology providers in both arms were requested to complete a questionnaire before and after patient inclusion regarding their expectations and evaluation of SCP care.

**Results:** Before patient inclusion, 38 (88%; 21 SCP, 17 usual care), and after patient inclusion, 35 (83%; 20 SCP, 15 usual care) oncology providers returned the questionnaire. After patient inclusion, oncology providers were generally satisfied with the SCP (M=7.1, SD=1.3, with 1=not at all - 10=very much), and motivated to keep using the SCP (M=7.9, SD=1.5). Most providers (64%) encountered barriers. Twenty-five percent felt they used more time for consultations (M=7.3 minutes, SD=4.6). However, self-reported consultation-time did not differ between before (M=21.8 minutes, SD=11.6) and after patient inclusion (M=18.7, SD=10.6;  $p=0.22$ ), or between SCP care (M=18.5, SD=10.3) and usual care (M=22.0, SD=12.2;  $p=0.21$ ).

**Conclusions:** Oncology providers using the SCP were generally satisfied and motivated to keep using the SCP. However, the findings of the current study suggest that even when the SCP can be generated automatically, oncology providers still have difficulties with finding the time to discuss the SCP with their patients.

**Implications for Cancer Survivors:** If SCP care is indeed effective, overcoming the perceived barriers is needed before large-scale implementation in order for cancer survivors to fully benefit from the potential advantages of SCPs.

## INTRODUCTION

Over the past decades, the number of cancer survivors has increased rapidly as a result of improved early detection, enhanced treatments, and ageing of the population <sup>1</sup>. In 2010, there were about 600,000 cancer survivors in the Netherlands, and this number is expected to increase to 900,000 in 2020 <sup>2</sup>, underlining the importance of addressing the specific health care needs of cancer survivors.

The Institute of Medicine (IOM) report 'From Cancer Patient to Cancer Survivor: Lost in Transition' <sup>3</sup> highlighted cancer survivors' special needs arising from the effects of the cancer and its treatment in physical and psychosocial domains. To help cancer survivors deal with the challenges of cancer survivorship, the IOM recommended the use of Survivorship Care Plans (SCPs), described as comprehensive care summaries and follow-up plans that should be written by the principal health care providers who coordinated oncology treatment <sup>3</sup>.

The process of choosing or creating the SCP template, collecting and tailoring the information, and providing the SCP to the patient can be challenging, and requires health care providers' active involvement and commitment <sup>4</sup>. Consequently, in order to achieve optimal and widely-adopted implementation of SCPs in clinical practice, it is necessary to understand the preferences and needs of the health care providers who prepare and provide the SCPs, which are primarily oncology providers (i.e., medical specialists and oncology nurses). Therefore, the IOM also recommended research to evaluate oncology providers' acceptance of SCPs and to address the barriers of the implementation of SCPs <sup>3</sup>.

Previous studies have found that, although oncology providers' opinion about SCPs is generally favorable <sup>4-9</sup>, they have pragmatic concerns about the implementation of SCPs. Substantial barriers to SCP use that have been identified are finding the time, reimbursement, personnel, and resources necessary to create SCPs <sup>4,10-14</sup>. It has therefore been suggested that automated completion of SCPs by abstracting relevant information from an electronic medical record may ease the burden on oncology providers <sup>6,15,16</sup>. Internet-based tools for online access to SCP information have been developed <sup>17,18</sup>, and appear useful for both survivors and providers <sup>18</sup>. However, actual experiences of oncology providers using automatically generated SCPs in daily clinical practice have not been investigated yet.

The ROGY Care trial assesses the impact of an automatically generated SCP, abstracted from a web-based patient registration system in daily clinical practice, in a pragmatic cluster randomized controlled trial (RCT) <sup>19</sup>. The aim of the present study was to longitudinally examine the expectations (before the intervention) and actual experiences (after the intervention) of the oncology providers in the ROGY Care trial (i.e., medical specialists and oncology nurses) with the automatically generated SCP, in daily clinical practice. Oncology providers' evaluation of the use of the SCP was assessed regarding the content and helpfulness, general satisfaction and motivation, use in practice and encountered barriers, and suggestions for further development. In addition, as previous research shows a lack of consensus about who should prepare and provide SCPs <sup>5</sup>, the present study also evaluated oncology providers' preferences regarding the delivery of the SCP.

## **METHODS**

### **Design**

In the ROGY Care trial, the impact of an automatically generated SCP on patient and health care provider (i.e., oncology providers and primary care physicians) reported outcomes is evaluated in a pragmatic cluster RCT in endometrial and ovarian cancer patients. In this trial, 12 hospitals in the South of the Netherlands were randomized to either 'SCP care' or 'usual care'. All newly diagnosed endometrial and ovarian cancer patients from the 12 participating hospitals were invited to participate in the study by their own gynecologist, after initial diagnosis. After the first contact via the gynecologist and obtaining informed consent, follow-up questionnaires at 6, 12, 18 and 24 months after diagnosis were sent directly to the home address of the patient. The ROGY Care trial has been approved by the medical research ethics committees of each participating center, and has been registered on <http://www.ClinicalTrials.gov> (NCT01185626). Details of the trial are described in a protocol paper <sup>19</sup>. The present study describes the results of the evaluation of the oncology providers (i.e., gynecologists, gynecologic oncologists (GOs), and oncology nurses).

### **Participants and recruitment**

Between April 2011 and October 2012, the participating oncology providers provided usual care or SCP care to the 222 endometrial cancer patients and 85 ovarian cancer patients that were included in the ROGY Care trial. All gynecologists, GOs, and oncology nurses participating in the trial in both arms were asked to complete a questionnaire before patient inclusion in the trial (April 2011), and after completion of the inclusion

of endometrial cancer patients (October 2012). Oncology providers were requested to return the questionnaire to the Comprehensive Cancer Center South in a pre-stamped envelope. To guarantee anonymity, returned questionnaires contained a study number only. If the questionnaire was not returned within 6 weeks, a reminder letter and questionnaire were sent. All oncology providers that completed the questionnaire, returned the questionnaire before the start of patient inclusion. None of the oncology providers participating in the study had had previous experiences with SCPs.

## **Intervention versus usual care**

### ***Usual care***

In the usual care arm, oncology providers provided standard care according to the Dutch follow-up guidelines, monitoring patients in periodic visits based on the number of years after diagnosis (<http://www.oncoline.nl>). The follow-up guidelines recommend that every patient receives verbal and written information about the period after the treatment and follow-up, about possible symptoms of recurrent disease, and about the contact details of the hospital. In addition, screening for psychosocial distress is recommended. However, the guidelines do not include the provision of an SCP. None of the oncology providers in the usual care arm provided an SCP to their patients. As the ROGY Care trial is a pragmatic trial, oncology providers in the usual care arm were asked to continue providing patient information in the way they were used to, and were not restricted regarding their information provision.

### ***SCP care***

In the SCP care arm, in addition to standard care, oncology providers provided a paper SCP to all endometrial and ovarian cancer patients after initial treatment, during the consultation in which the diagnosis was discussed. They discussed all items in the SCP with their patients. This was uniform for all patients in the trial. In follow-up visits, patients received an updated version of the SCP if necessary. Oncology providers also sent a copy of the SCP to the patient's primary care physician. In order to support the use of the SCP, oncology providers in the SCP care arm attended one instruction-evening before the start of patient inclusion, providing practical guidelines on how to discuss the information in the SCP with their patients. Moreover, consensus was reached about the minimal items that should be discussed with the patient with respect to diagnosis, treatment, and possible side-effects. In addition, oncology providers received a reminder consisting of a summary of the purpose of the SCP, and practical guidelines on the use of the SCP.

As this pragmatic trial aimed to assess the impact of SCP care in daily clinical practice, the delivery of the intervention was allowed to vary between hospitals and oncology providers. Oncology providers in the SCP care hospitals were free to choose whether the gynecologist, GO, and/or oncology nurse provided the SCP, fitting their clinical practice. In addition, they had the flexibility to discuss the SCP according to their patients' needs.

### **Survivorship Care Plan**

A web-based patient registration system 'Registrationsystem Oncological GYnecology' (ROGY) is used by all participating oncology providers in the South of the Netherlands since 2006. For each patient, a detailed registration is made in a uniform way, including information about tumor stage, grade, treatment, complications, comorbidity, and follow-up, as well as information about the specialists involved in the patient's care (e.g., gynecologist/GO, medical oncologist, radiotherapist).

An application was built in ROGY, making it possible to automatically generate a personalized SCP combining the patient and disease data in ROGY by merely pressing a button. Oncology providers have the option to either print the SCP on paper or to save it as a PDF-file (making it possible to e-mail the SCP to patients who prefer this). The ROGY system is used by all participating oncology providers in both arms, but the SCP-button is only visible for oncology providers in the SCP care arm. Changes related to the cancer, treatment, or providers are registered in ROGY and automatically updated in the SCP during follow-up.

For the development of the content of the SCP, the Dutch SCP template (based on the IOM format)<sup>3</sup>, was adjusted to the local situation before the study was initiated<sup>20</sup>. A subgroup of gynecologists/GOs, oncology nurses, a radiotherapist, a medical oncologist, a primary care physician, and patients adjusted a standardized SCP to the local situation. The oncology providers that participated in the SCP modifications also participated in the study, although not all of these providers were actually involved in providing the SCP to patients.

The SCP provides a personalized treatment summary, including detailed information on diagnostic tests, type of cancer, stage and grade, treatment, and contact details of the hospital and health care provider(s). In addition, the SCP contains a personalized follow-up care plan, including detailed information on possible short-term and long-term effects, possible effects on social and sexual life, possible signs of recurrence and second tumors, and information on rehabilitation, psychosocial support, and supportive care services. The Distress Thermometer<sup>21</sup> at the end of the SCP can be used as a screening

tool and aid for the communication about psychosocial distress. The information in the SCP is tailored to the specific situation of the patient. For instance, a patient who received adjuvant radiotherapy gets information about potential long-term effects of radiotherapy and what to do if certain complaints arise.

### **Questionnaires**

Self-administered surveys were developed to evaluate the views of the participating oncology providers regarding the use of the SCP (Appendix). The developed questionnaires were discussed with a gynecologist involved in the study for face validity, content, and relevance. To facilitate the response rate, the final versions of the questionnaires were intentionally condensed to three pages maximum, which could be completed in a few minutes.

To check whether the SCP care arm and the usual care arm did not differ before patient inclusion, the questionnaire before the start of patient inclusion asked oncology providers about the type of information and psychosocial care they provided at that time, how satisfied they were with the information they provided, and how much time they spent on their consultations on average. To assess their attitude towards SCP care before patient inclusion, the oncology providers in the SCP care arm were also asked whether they expected to need more time for their consultations because of the SCP and if so, how much more time, to what extent they expected that the SCP would affect patients positively, and how motivated they were to start using the SCP. Demographic characteristics (i.e., age, gender, and profession) were also included in the questionnaire.

For oncology providers in the usual care arm, the questionnaire after patient inclusion was identical to the questionnaire before patient inclusion. Oncology providers in the SCP care arm were in addition asked about their experiences with the SCP (e.g., content, satisfaction, motivation, use in practice, barriers, and suggestions for further development; Appendix).

### **Statistical analyses**

All statistical analyses were conducted using SPSS version 19.0 (Statistical Package for Social Sciences, Chicago, IL, USA), and p-values of  $<0.05$  were considered statistically significant. Descriptive means with standard deviations (SD) were used to describe continuous data, and frequencies with percentages were used to describe categorical data. Differences between the intervention arm and usual care arm for continuous data were tested using independent samples t-tests. For variables that were not normally

distributed, Mann-Whitney tests were used. Differences between the intervention arm and usual care arm for categorical data were tested using Chi-square tests. For variables with an expected cell-count of less than 5, Fisher's Exact tests were used. Differences between before patient inclusion and after patient inclusion were tested using paired t-tests for continuous data and McNemar tests for categorical data. The analyses comparing the differences between before and after patient inclusion included only the providers who responded both before and after patient inclusion.

## RESULTS

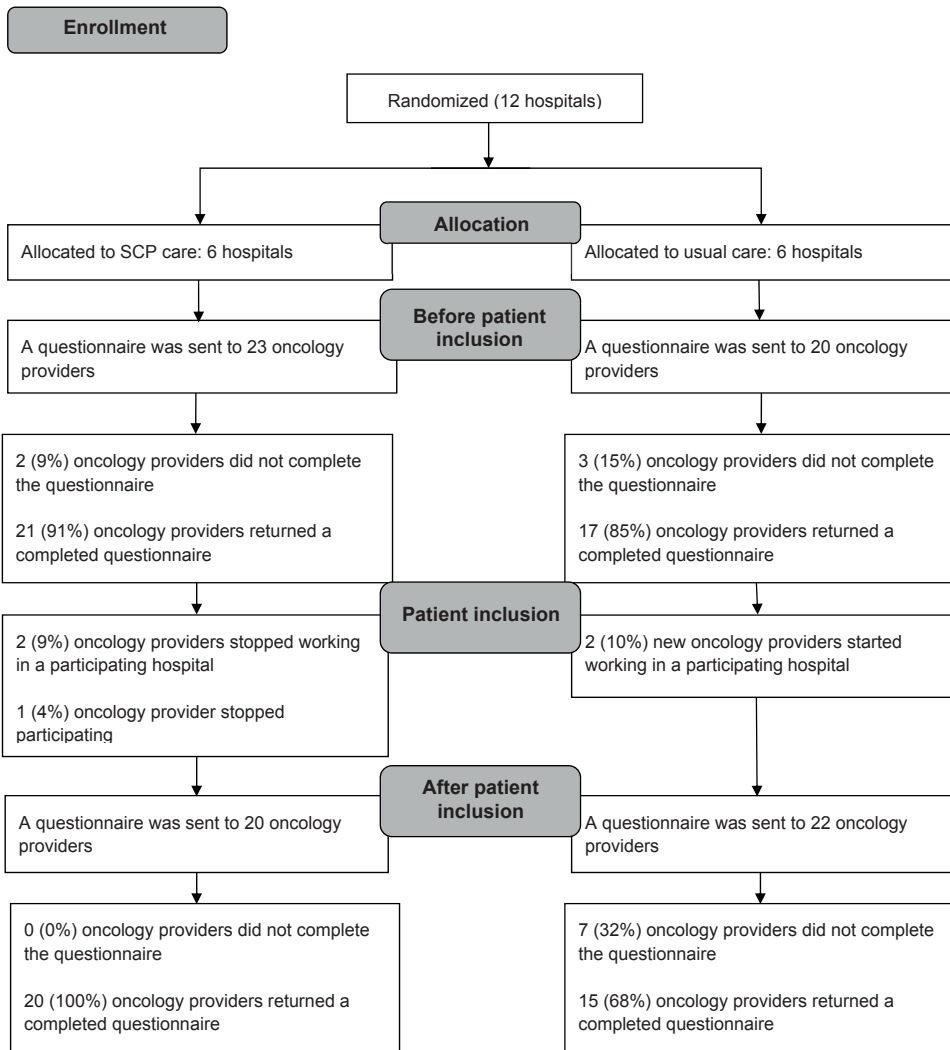
### Study sample

Before the start of patient inclusion, 38 (88%) oncology providers returned a completed questionnaire: 21 (55%) in the SCP care arm, and 17 (45%) in the usual care arm. After patient inclusion, 35 (83%) oncology providers returned a completed questionnaire: 20 (57%) in the SCP care arm, and 15 (43%) in the usual care arm (Figure 1).

The mean age of the oncology providers before patient inclusion was 47.1 years (range 34 - 64), and around two third (63%) was female. Fifty-five percent was gynecologist, 24% GO, and 21% oncology nurse. Oncology providers in the SCP care arm were similar to oncology providers in the usual care arm regarding age, gender and profession, both before and after patient inclusion (Table 1a and 1b).

### Information provision practices

Before the start of patient inclusion, oncology providers in the SCP care arm did not differ from those in the usual care arm regarding the type of information and psychosocial screening they provided, how satisfied they were with the information they provided, and the duration of an average consultation (Table 1a). Most oncology providers provided verbal information (95%) and brochures of the Dutch Cancer Society (58%). Other brochures (47%) and referral to websites (45%) were also frequently used. Screening for psychosocial distress was done by use of a screening instrument (55%) or verbally (32%). A quarter (24%) of the oncology providers reported no screening at all for psychosocial distress. Oncology providers were generally satisfied with the information they provided to their patients ( $M=7.0$ , with 1=not at all – 10=very much). The reported duration of an average consultation was 21.8 minutes (range 10 - 60).



**Figure 1.** Flow-chart of the data collection process of the oncology providers in the ROGY Care trial (CONSORT diagram)

**Table 1a.** Description of the oncology providers and information provision, *before patient inclusion*, according to intervention arm, N (%) or mean (SD)

	Total (N=38)	SCP Care (N=21)	Usual Care (N=17)	p-value*
	N (%)			
<b>Gender</b>				
Female	24 (63)	13 (62)	11 (65)	0.86
Male	14 (37)	8 (38)	6 (35)	
<b>Profession</b>				
Gynecologist	21 (55)	11 (52)	10 (59)	0.89
Gynecologic Oncologist (GO)	9 (24)	5 (24)	4 (24)	
Oncology nurse	8 (21)	5 (24)	3 (18)	
<b>Age</b> (mean, SD)	47.1 (8.1)	46.7 (8.6)	47.5 (7.5)	0.75
<b>How do you currently provide information to your patients?<sup>a</sup></b>				
Verbally <sup>b</sup>	36 (95)	20 (95)	16 (94)	0.99
Brochure Dutch Cancer Society	22 (58)	15 (71)	7 (41)	0.06
Other brochure	18 (47)	9 (43)	9 (53)	0.54
Referral to website	17 (45)	8 (38)	9 (53)	0.36
CD-ROM (Compact Disc, read only)	0 (0)	0 (0)	0 (0)	
Other	4 (11)	3 (5)	1 (6)	
<b>How satisfied are you with the information you currently provide to your patients?</b>				
(1= not at all; 10=very much); (mean, SD)	7.0 (0.8)	7.0 (0.9)	7.0 (0.8)	0.86
<b>How do you currently screen for psychosocial distress?<sup>a</sup></b>				
Screening instrument	21 (55)	11 (52)	10 (59)	0.69
Verbally <sup>b</sup>	12 (32)	6 (30)	6 (35)	0.66
I do not screen for psychosocial distress <sup>b</sup>	9 (24)	6 (30)	3 (18)	0.46
<b>How long does an average consultation take you currently?<sup>c</sup></b>				
(minutes); (mean, SD)	21.8 (11.7)	21.2 (11.4)	22.6 (12.4)	0.52

Note: \*P-values report comparisons between the intervention arm and the usual care arm, according to t-tests and Chi-square tests. <sup>a</sup>Possibility to give more than one answer. <sup>b</sup>As this variable had an expected cell-count of less than 5, Fisher's Exact tests were used. <sup>c</sup>As this variable was not normally distributed, Mann-Whitney tests were used. The numbers will not always add up to 100, because percentages have been rounded off to whole numbers and some questions allow more than one answer.

**Table 1b.** Description of the oncology providers and information provision *after patient inclusion* according to intervention arm, N (%) or mean (SD)

	Total (N=35)	SCP Care (N=20)	Usual Care (N=15)	p-value*
	N (%)			
<b>Gender</b>				
Female	21 (60)	12 (60)	9 (60)	0.99
Male	14 (40)	8 (40)	6 (40)	
<b>Profession</b>				
Gynecologist	18 (51)	12 (60)	6 (40)	0.24
Gynecologic Oncologist (GO)	11 (31)	4 (20)	7 (47)	
Oncology nurse	6 (17)	4 (20)	2 (13)	
<b>Age (mean, SD)</b>	48.2 (8.3)	47.3 (8.4)	49.4 (8.4)	0.47
<b>How do you currently provide information to your patients?<sup>a</sup></b>				
SCP <sup>b</sup>		15 (75) <sup>c</sup>		
Verbally	35 (100)	20 (100)	15 (100)	
Brochure Dutch Cancer Society	19 (54)	11 (55)	8 (53)	0.92
Other brochure	17 (49)	8 (40)	9 (60)	0.24
Referral to website	17 (49)	7 (35)	10 (67)	0.06
CD-ROM (Compact Disc, read only memory)	0 (0)	0 (0)	0 (0)	
Other	9 (26)	4 (20)	5 (33)	
<b>How satisfied are you with the information you currently provide to your patients?</b>				
(1= not at all; 10=very much); (mean, SD)	7.7 (0.9)	7.8 (0.7)	7.6 (1.1)	0.59
<b>How do you currently screen for psychosocial distress?<sup>a</sup></b>				
Screening instrument	21 (60)	11 (55)	10 (67)	0.49
Verbally <sup>d</sup>	8 (23)	7 (35)	1 (7)	0.10
I do not screen for psychosocial distress <sup>d</sup>	6 (17)	3 (15)	3 (20)	0.99
<b>How long does an average consultation take you currently?<sup>e</sup></b>				
(minutes); (mean, SD)	20.1 (11.2)	18.5 (10.3)	22.0 (12.2)	0.21

Note: \*P-values report comparisons between the intervention arm and the usual care arm, according to t-tests and Chi-square tests. <sup>a</sup>Possibility to give more than one answer. <sup>b</sup>Only for the SCP care arm. <sup>c</sup>This is not 100% because some oncology providers did not personally provide the SCP to patients. <sup>d</sup>As this variable had an expected cell-count of less than 5, Fisher's Exact tests were used. <sup>e</sup>As this variable was not normally distributed, Mann-Whitney tests were used. The numbers will not always add up to 100, because percentages have been rounded off to whole numbers and some questions allow more than one answer.

Similarly, after patient inclusion, oncology providers in the SCP care arm did not differ from oncology providers in the usual care arm regarding the type of information and psychosocial screening they provided (in addition to the SCP), how satisfied they were with the information they provided, and the duration of an average consultation (Table 1b). Oncology providers were generally satisfied with the information they provided to their patients ( $M=7.7$ , with 1=not at all – 10=very much). The reported duration of an average consultation was 20.1 minutes (range 10 - 60).

### **SCP expectations and experiences**

The expectations of oncology providers in the SCP care arm before patient inclusion were similar to their reported experiences after patient inclusion (Table 2). Both before and after patient inclusion, oncology providers were motivated to start or keep using the SCP ( $M=7.7$  and 7.9 respectively, with 1=not at all – 10=very much;  $p=0.55$ ).

Before patient inclusion, 61% of the oncology providers in the SCP care arm expected to need more time for their consultations, with an average of 7.5 minutes (range 2 - 10). After patient inclusion, 25% reported that they had actually needed more time for their consultations, with an average of 7.3 minutes (range 2 - 10). Self-reported consultation-time also did not differ before ( $M=21.8$  minutes) and after ( $M=18.7$  minutes) patient inclusion ( $p=0.22$ ). In the usual care arm, self-reported consultation-time also did not differ before ( $M=21.3$  minutes) and after ( $M=22.1$  minutes) patient inclusion ( $p=0.80$ ).

When asked to what extent they expected the SCP to affect the patient positively, oncology providers in the SCP care arm reported a 7.3 (with 1=not at all – 10=very much). After patient inclusion, when asked whether they believed the SCP had actually affected the patient positively, oncology providers reported a 7.5 ( $p=0.85$ ).

### **Evaluation of the SCP**

Overall, after patient inclusion, 70% of the oncology providers in the SCP care arm indicated that they were a provider of SCPs in their hospital (Table 3). Of these SCP providers, 43% was gynecologist, 29% GO, and 29% oncology nurse. Most oncology providers (93%) provided a paper SCP during the consultation, and 57% of the oncology providers (also) sent the SCP to their patients by mail. When asked how extensively they discussed the SCP, oncology providers reported a 5.6 (with 1=not at all – 10=very extensively).

The amount of information in the SCP was rated with a 7.0 (with 1=much too little – 10=much too much). Fourteen percent of the oncology providers indicated that they

missed information in the SCP (i.e., that they preferred certain information to be in the SCP that was not in the SCP). Suggestions were to add modules that can be switched on and off for information on possible effects on fertility and sexual life, and to add a time schedule for specific appointments. Twenty-one percent of the oncology providers indicated that they would prefer to remove certain information from the SCP. Suggestions for deletion were discrimination between curative or palliative care (as this may be too confronting), information from other specialists (e.g., radiotherapy or chemotherapy), and the TNM stage (as only the FIGO stage was discussed with their patients).

The oncology providers rated the extent to which the SCP contributed positively to the communication between themselves and the patient, and between themselves and the primary care physician with a 5.4 and a 3.0 respectively (with 1=not at all – 10=very much). In general, oncology providers rated their satisfaction with the use of the SCP with a 7.1 (with 1=not at all – 10=very much). When asked who should provide the SCP, 75% indicated the oncology nurse, 20% the gynecologist/GO, and none the primary care physician. Because of the sample size, it was not possible to examine whether the views of gynecologists, GOs, and oncology nurses differed significantly (Table 4).

**Table 2.** Comparison of SCP expectations (before patient inclusion) and actual experiences (after patient inclusion) in the SCP care arm, N (%) or mean (SD)

	Before Inclusion (N=18)	After Inclusion (N=18)	p-value*
	N (%)		
<b>How long does an average consultation take you currently?</b> (N=18; N=18) (minutes); (mean, SD)	21.8 (11.6)	18.7 (10.6)	0.22
<b>Do you expect to need/ Did you need more time for your consultations because of the SCP?</b> <sup>a</sup> (N=18; N=12)			
Yes	11 (61)	3 (25)	0.50
No	7 (39)	9 (75)	
<b>If yes, how much more time do you expect to need/ did you need for your consultations because of the SCP?</b> <sup>a,b</sup> (N=10; N=3) (minutes); (mean, SD)	7.5 (3.0)	7.3 (4.6)	0.96
<b>To what extent do you expect the SCP to/ did the SCP affect the patient positively?</b> (N=18; N=13) (1= not at all; 10=very much); (mean, SD)	7.3 (1.3)	7.5 (1.6)	0.85
<b>How motivated are you to start/ keep using the SCP?</b> (N=18; N=18) (1= not at all; 10=very much); (mean, SD)	7.7 (1.3)	7.9 (1.5)	0.55

Note: Only providers who responded both before and after inclusion were included in the analyses. \*P-values report comparisons between before patient inclusion and after patient inclusion in the SCP care arm, according to paired t-tests and McNemar tests.<sup>a</sup>Only for providers who answered "yes" on "Were you a provider of SCPs in your hospital?".<sup>b</sup>Only for providers who answered "yes" on "Do you expect to need/ Did you need more time for your consultation because of the SCP?". The numbers will not always add up to 100, because percentages have been rounded off to whole numbers. Some oncology providers did not answer all questions, and are reported as missing.

**Table 3.** Evaluation of the use of the SCP by oncology providers in the SCP care arm after patient inclusion, N (%) or mean (SD)

	<b>SCP Care</b> N=20
	N (%)
<b>Were you a provider of SCPs in your hospital?</b> (N=20)	
Yes, always	7 (35)
Yes, most of the time	2 (10)
Yes, sometimes	5 (25)
No	5 (25)
Missing	1 (5)
<b>If yes, how did you provide the SCP to patients?</b> <sup>ab</sup> (N=14)	
Personally, on paper	13 (93)
By mail	8 (57)
By e-mail	0 (0)
Missing	0 (0)
<b>How extensively did you discuss the SCP with patients?</b> <sup>a</sup>	
(N=14) (1= not at all; 10=very extensively); (mean, SD)	5.6 (1.7)
<b>What do you think about the amount of information in the SCP?</b> <sup>a</sup>	
(N=13) (1= much too little; 10=much too much); (mean, SD)	7.0 (1.4)
<b>Did you miss information in the SCP?</b> <sup>a</sup> (N=14)	
Yes <sup>c</sup>	2 (14)
No	11 (79)
Missing	1 (7)
<b>Would you prefer not to have certain information in the SCP?</b> <sup>a</sup> (N=14)	
Yes <sup>c</sup>	3 (21)
No	10 (71)
Missing	1 (7)
<b>To what extent did you succeed in providing an SCP to all eligible patients?</b> <sup>a</sup>	
(N=14) (1= not at all; 10=very well); (mean, SD)	6.9 (1.5)
<b>To what extent did you succeed in providing an SCP to all involved primary care physicians?</b> <sup>a</sup>	
(N=14) (1= not at all; 10=very well); (mean, SD)	7.5 (2.4)
<b>To what extent did the SCP contribute positively to the communication between yourself and the patient?</b> <sup>a</sup>	
(N=14) (1= not at all; 10=very much); (mean, SD)	5.4 (1.9)
<b>To what extent did the SCP contribute positively to the communication between yourself and the involved primary care physician?</b> <sup>a</sup>	
(N=14) (1= not at all; 10=very much); (mean, SD)	3.0 (1.9)

**Table 3.** *Continued.*

	<b>SCP Care</b> N=20
	N (%)
<b>Did you encounter practical problems in the use of the SCP?<sup>a</sup> (N=14)</b>	
Yes <sup>d</sup>	9 (64)
No	5 (36)
Missing	0 (0)
<b>How satisfied are you in general with the use of the SCP?<sup>b</sup></b>	
(N=14) (1= not at all; 10=very much); (mean, SD)	7.1 (1.3)

Note: <sup>a</sup>Only for providers who answered "yes" on "Were you a provider of SCPs in your hospital?". <sup>b</sup>Possibility to give more than one answer. <sup>c</sup>Specific suggestions of issues to add to or take out of the SCP are reported in the results section. <sup>d</sup>Specific practical problems that were reported are reported in the results section. The numbers will not always add up to 100, because percentages have been rounded off to whole numbers and some questions allow more than one answer. Some oncology providers did not answer all questions, and are reported as missing.

**Table 4.** Evaluation of the preference of the oncology providers in the SCP care arm after patient inclusion regarding who should provide the SCP, according to profession, N (%)

	<b>Total</b> (N=20)	<b>Gynecologist</b> (N=12)	<b>GO</b> (N=3)	<b>Oncology nurse</b> (N=4)
	N (%)			
<b>Who do you think should provide the SCP?</b>				
Gynecologist / Gynecologic Oncologist	4 (20)	1 (8)	1 (25)	2 (50)
Oncology nurse	15 (75)	11 (92)	2 (50)	2 (50)
Primary Care Physician	0 (0)	0 (0)	0 (0)	0 (0)
Missing	1 (5)	0 (0)	1 (25)	0 (0)

Note: Because of the sample size, it was not possible to examine whether the views of gynecologists, GOs, and oncology nurses differed significantly. One oncology provider did not answer all questions, and is reported as missing.

## Barriers and suggestions for improvement

Oncology providers in the SCP care arm rated the extent to which they succeeded in providing an SCP to all eligible patients with a 6.9 and to all involved primary care physicians with a 7.5 (with 1=not at all – 10=very well; Table 3). Approximately two thirds (64%) of the oncology providers indicated that they encountered practical problems in the use of the SCP. Most frequently reported practical problems were not finding an appropriate moment to discuss the SCP with the patient (56%), not completing ROGY in time for the SCP (44%), and technical issues with ROGY (11%). Other practical problems that were reported were all related to the availability of time to prepare and discuss the SCP. Suggestions for improvement of the SCP were the participation of an oncology nurse in small hospitals to ease the burden on gynecologists, to involve other specialists

in the different aspects of the SCP, to already provide an SCP before treatment, and to develop an SCP for cervical and vulvar cancer.

## DISCUSSION

In this pragmatic cluster RCT, oncology providers using an automatically generated SCP in daily clinical practice were generally satisfied with the SCP, believed the SCP affected patients positively, and were motivated to keep using the SCP. Nevertheless, oncology providers still encountered practical barriers in providing SCP care in daily clinical practice.

Previous studies have merely investigated oncology providers' a priori attitudes towards SCPs, whereas the current longitudinal study provides both expectations and actual experiences with an automatically generated SCP in daily clinical practice. Our results confirm previous findings, that oncology providers' a priori attitudes towards SCPs are generally positive<sup>4-9</sup>. In addition, the current findings indicate that these positive attitudes towards SCPs do not change after actual experience with the use of an automatically generated SCP.

Pragmatic concerns about the implementation of SCPs that were identified in previous studies were finding the time, reimbursement, personnel, and resources necessary to create SCPs<sup>4,10-14</sup>. In order to overcome these barriers, the circumstances to provide an SCP in the ROGY Care trial were designed to ease the burden on oncology providers as much as possible. By automatically abstracting all the relevant information for the SCP from the registration system ROGY, oncology providers were able to generate an SCP by merely pushing a button. Consequently, in the current study, reimbursement issues and resources necessary to create SCPs were not reported as barriers by the oncology providers. This finding suggests that an automatically generated SCP can improve some of the challenges in the process of SCP care. However, still about two thirds of the oncology providers reported that they encountered practical barriers in providing SCP care in daily clinical practice.

The most frequently reported practical barrier was finding the time to discuss the SCP. Nearly a third of the oncology providers in the SCP care arm reported the need for more time for their consultations because of the SCP. Since the oncology providers did not have to do anything other than print the SCP and discuss it with their patients, it seems that the biggest barrier in the current study was not the completion of the SCP itself, but finding the time that is needed to discuss the SCP with the patient. It is

possible that some oncology providers were better able to incorporate the discussion of the SCP into their usual provision of information than other oncology providers. It may be helpful for oncology providers from different hospitals to discuss their different approaches with each other, in order to be better able to incorporate the SCP into their own clinical practice. Interestingly, the self-reported consultation-time of the oncology providers in the SCP care arm did not differ before and after patient inclusion. Moreover, self-reported consultation-time did not differ between the SCP care arm and the usual care arm. These findings indicate that there is a difference between oncology providers' perceptions of how much time they spent on SCP care and actual reported consultation-time. It may be useful to inform oncology providers about these differences between perceived and actual reported consultation-time, in order to reduce their perceived barriers. It is important to note, however, that in the current study, consultation-time was self-reported. It may be difficult for oncology providers to correctly estimate how long an average consultation takes them. Therefore, it would be interesting for future research to also measure consultation-time objectively. In addition, as discussing the SCP after diagnosis may have consequences for the duration of follow-up consultations, it would be interesting to measure consultation-times during follow-up as well.

In the current study, 43% of the providers of SCPs was gynecologist, 29% GO, and 29% oncology nurse. Most providers indicated that oncology nurses should provide the SCP. However, their motivation for indicating this preference remains unclear. It is possible that oncology providers consider providing the information and follow-up plan in SCPs primarily as a task for oncology nurses. On the other hand, it is also possible that the current finding partly reflects the perceived time barriers. Because of the sample size, it was not possible to examine whether the views of gynecologists, GOs, and oncology nurses differed significantly. Therefore, for future research, it would be interesting to examine these possible differences.

It has been suggested that SCPs could also be a useful tool for facilitating the transition of routine follow-up care from the medical specialist to primary care, among others by improving the communication between medical specialists and primary care physicians<sup>22,23</sup>. However, in the present study, oncology providers reported to have low confidence that the SCP contributed positively to the communication between themselves and the primary care physician. For future research, it would be interesting to examine how the contribution of SCPs to the communication between medical specialists and primary care physicians can be increased. Furthermore, primary care physicians' evaluation of receiving an SCP is needed. It is important to note, however, that the SCP in the present study was not specifically tailored to the needs of primary care physicians.

Some limitations of the present study should be taken into consideration. First of all, although this RCT included oncology providers from 12 hospitals and response rates were high, the sample size of oncology providers remained relatively small. In addition, the SCPs were limited to endometrial and ovarian cancer patients. More research is needed to investigate whether including patients and care providers of other cancer types shows similar results. Moreover, although the use of a pragmatic RCT increases the external validity of the study, this may have limited the internal validity of the findings. Another limitation of this study is that the oncology provider questionnaires were not validated, which may potentially lead to a measurement bias. The development of validated measures of oncology providers' evaluation of SCPs is needed to support the research in this rapidly developing area. Furthermore, although efforts were made to reduce social desirability bias by anonymous questionnaires, respondents may have over-reported for instance their satisfaction or motivation to use the SCP. In addition, the oncology providers who were involved in the SCP modifications before the start of the study, may have reported a higher satisfaction with the content and helpfulness of the SCP.

There is a general lack of knowledge regarding the development, implementation, and outcomes of SCPs. Despite the limitations, the present study provides valuable insight into oncology providers' experiences with an automatically generated SCP in daily clinical practice. The pragmatic RCT setting, in which the delivery of the intervention was allowed to vary between hospitals and oncology providers, made it possible to evaluate experiences with the use of the SCP in daily clinical practice, improving the generalizability of the findings. In addition, the longitudinal design made it possible to examine both a priori expectations and actual experiences with the SCP.

Based on SCPs' face validity, the IOM recommended that SCPs become standard of care <sup>3</sup>. However, given the barriers to SCP use, it is necessary to assess the benefits of the use of SCPs before SCPs are more widely adopted. In a time of scarce health care resources, empirical evidence has to take the place of common sense <sup>24</sup>. Thus far, limited evidence exists regarding the efficacy of SCP's on patient reported outcomes. To date, only two randomized studies have been published examining the impact of SCPs on patient reported outcomes, in women with early-stage breast cancer <sup>25</sup>, and women with gynecologic cancer <sup>26</sup>. Both studies reported no differences between patients who did or did not receive an SCP, in distress <sup>25</sup>, quality of life <sup>25</sup>, and satisfaction with care <sup>25,26</sup>. However, additional research is needed before definitive statements can be made about the effectiveness of SCPs.

The present study is part of the larger ROGY Care trial, in which the impact of an automatically generated SCP on patient and health care provider (i.e., oncology providers and primary care physicians) reported outcomes is evaluated in a pragmatic cluster RCT in endometrial and ovarian cancer patients <sup>19</sup>. The results of this study contribute to the understanding of the effects of SCP care and to efforts to improve the quality of care for cancer survivors.

In conclusion, although oncology providers using an automatically generated SCP were generally satisfied and motivated to keep using the SCP, they still perceived practical barriers in the use of the SCP in daily clinical practice. Nevertheless, the effects of SCPs on patient reported outcomes such as satisfaction with information provision and care, health care use, and quality of life remain unclear. Before SCPs can be more widely adopted (as recommended by the IOM), additional research is needed to assess the impact of SCPs on patient reported outcomes. If SCP care is indeed effective, it is necessary to overcome the perceived barriers, in order to embed SCPs in daily clinical practice and in order for cancer survivors to fully benefit from the potential advantages of SCPs.

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**Appendix.** Questionnaires oncology providers

1. In which hospital are you employed? (CG + IG; BI + AI) => OPEN ENDED
2. What is your profession? (CG + IG; BI + AI) => Gynecologist /GO/(Oncology) nurse/Nurse-practitioner/Other, namely...
3. Gender (CG + IG; BI + AI) => Male/Female
4. Age (CG + IG; BI + AI) => ... years
5. How do you currently provide information to your patients? More than one answer possible (CG + IG; BI + AI) => SCP<sup>1</sup>/Verbally/Brochure Dutch Cancer Society/Other brochure/Referral to website/CD-ROM/Other, namely...
6. How satisfied are you with the information you currently provide to your patients? (CG + IG; BI + AI) => Not at all (1) – Very much (10)
7. How do you currently screen for psychosocial distress? More than one answer possible (CG + IG; BI + AI) => Screening instrument, namely.../I do not screen for psychosocial distress/Other, namely...
8. How long does an average consultation take you currently? (CG + IG; BI + AI) => ... minutes
9. Do you expect to need more time for your consultations because of the SCP? (IG; BI) => No/Yes, approximately ... minutes more time
10. To what extent do you expect the SCP to affect the patient positively? (IG; BI) => Not at all (1) – Very much (10)
11. How motivated are you to start using the SCP? (IG; BI) => Not at all (1) – Very much (10)
12. Were you a provider of SCPs in your hospital? (IG; AI) => Yes, always (continue with question 13)/Yes, most of the time (continue with question 13)/Yes, sometimes (continue with question 13)/No (continue with question 28)
13. What do you think about the amount of information in the SCP? (IG; AI) => Much too little (1) – Much too much (10)
14. Did you miss information in the SCP? (IG; AI) => No/Yes, namely...
15. Would you prefer not to have certain information in the SCP? (IG; AI) => No/Yes, namely...
16. To what extent do you think the SCP affects the patient positively? (IG; AI) => Not at all (1) – Very much (10)
17. How did you provide the SCP to patients? More than one answer possible (IG; AI) => Personally, on paper/Sent by mail/As PDF by e-mail/Other, namely...
18. How extensively did you discuss the SCP with patients? (IG; AI) => Not at all (1) – Very extensively (10)
19. Do you feel that you use more/less time for your consultation because of the SCP? (IG; AI) => No, stayed the same/Yes, approximately ... minutes more time/Yes, approximately ... minutes less time
20. To what extent did you succeed in providing an SCP to all eligible patients? (IG; AI) => Not at all (1) – Very well (10)
21. To what extent did the SCP contribute positively to the communication between yourself and the patient? (IG; AI) => Not at all (1) – Very much (10)
22. To what extent did you succeed in providing an SCP to all involved Primary Care Physicians? (IG; AI) => Not at all (1) – Very well (10)
23. To what extent did the SCP contribute positively to the communication between yourself and the involved Primary Care Physicians? (IG; AI) => Not at all (1) – Very much (10)
24. How satisfied are you in general with the use of the SCP? (IG; AI) => Not at all (1) – Very much (10)
25. Did you encounter practical problems in the use of the SCP? (IG; AI) => No (continue with question 27)/Yes (continue with question 26)
26. Which practical problems did you encounter in the use of the SCP? More than one answer possible (IG; AI) => ROGY was not always completed in time/The 'SCP-button' in ROGY did not always work/There was not always an appropriate moment to discuss the SCP with the patient/Other, namely...
27. Do you have any suggestions for improvements of the SCP? (IG; AI) => OPEN ENDED
28. How motivated are you to use/keep using the SCP in the future? (IG; AI) => Not at all (1) – Very much (10)
29. Who do you think should provide the SCP to the patient? (IG; AI) => Gynecologist-GO/(Oncology) nurse-Nurse practitioner/Primary Care Physician/Other, namely...
30. Do you have any comments? (CG + IG; BI + AI) => OPEN ENDED

Note: CG: Control Group; IG: Intervention Group; BI: Before Inclusion; AI: After Inclusion. <sup>1</sup>Only for the intervention group after inclusion.

# Chapter 8

## **Survivorship Care Plans to inform the primary care physician: Results from the ROGY Care pragmatic cluster randomized controlled trial**

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## ABSTRACT

**Purpose:** To assess the effects of sending a Survivorship Care Plan (SCP) to Primary Care Physicians (PCPs) on the communication of PCPs with medical specialists and patients, and to describe PCPs' opinions regarding the SCP.

**Methods:** In a pragmatic cluster randomized controlled trial, 12 hospitals were randomized to either the usual care arm, in which the PCP of endometrial and ovarian cancer patients received information as was usual in that hospital, or to the SCP-care arm, in which PCPs additionally received a copy of the patient's SCP. The PCP received a questionnaire two to three months after patient inclusion. Descriptive analyses and multilevel models were performed at the PCP-level to analyze PCP-reported outcomes.

**Results:** A questionnaire was returned by 266 PCPs (76%). One third of the PCPs in the SCP-care arm indicated having received an SCP. PCPs in the SCP-care arm were more likely to have had personal contact with the medical specialist (52% vs. 37%,  $p=0.01$ ), but were equally satisfied with the information as PCPs in the usual care arm (7.2 vs. 6.9 on a scale from 1 to 10,  $p=0.25$ ). Of all PCPs, 82% indicated that they would want to receive an SCP in the future. A quarter of the PCPs who received an SCP reported that the SCP supported contact with the patient. However, the SCP was found to be too long.

**Conclusions:** Supplying an SCP to PCPs has a potentially positive effect on the communication between the PCP and the medical specialist. The SCP should be concise and focused on PCPs' needs, such as contact information and tailored information on patient diagnosis, treatment and possible consequences.

**Implications:** In the light of transition of cancer care to PCPs, survivors may benefit from improved information provision and communication.

## INTRODUCTION

The global increase in the number of cancer survivors puts a growing pressure on our health care systems <sup>1,2</sup>. Although there is ongoing debate about the optimal model for follow-up care <sup>3</sup>, transferring routine follow-up to primary care is considered an important strategy to meet the future demand for oncology resources <sup>4-6</sup>. It has been shown not to affect timely diagnosis of recurrences, survival, patient well-being or patient satisfaction, and to considerably reduce health care costs <sup>5,7</sup>. A broader role of primary care in follow-up care requires excellent communication between medical specialists and Primary Care Physicians (PCPs), sufficient knowledge among PCPs, and a positive attitude of PCPs towards this new role <sup>8,9</sup>. This is particularly important since cancer treatment is becoming more individualized and tailored to tumor- and patient characteristics, resulting in different treatment plans and risk profiles for recurrences and late effects for patients with apparently the same type of tumor. However, so far, insight in current practice, PCPs' knowledge, and their need for information in relation to their patients with cancer is largely lacking.

Systematic information sharing, for instance by means of Survivorship Care Plans (SCPs), is viewed as valuable for facilitating the transition of routine follow-up care from the specialist to primary care <sup>9-13</sup>. The Institute of Medicine recommends that patients completing primary treatment should be provided with an SCP, containing a comprehensive care plan, including cancer type, treatment and potential consequences, timing and content of provided follow-up, recommendations for preventive practices, and the availability of psychosocial services in the community <sup>14</sup>. The report also states that an SCP should inform clinicians involved in the subsequent care of cancer survivors about treatment and signs of late effects. This suggests that in addition to benefitting the patient, SCPs may also be beneficial for PCPs' communication with medical specialists and cancer patients <sup>9</sup>. Little is known about how PCPs who receive an SCP perceive and use them, and whether SCPs are useful means to enhance the communication between PCPs and medical specialists. At present, only two small qualitative studies including 15 and 5 PCPs respectively, have been conducted evaluating the implementation and effects of an SCP for PCPs <sup>15,16</sup>. Results showed that the SCP provided new information <sup>15,16</sup> that lead to changes in patient care <sup>15</sup>. In addition, one randomized controlled trial (RCT) studied the effects of an SCP in a group of breast cancer survivors who were ready for transition from medical specialist care to follow-up care with their PCP <sup>17,18</sup>. Unfortunately, PCPs' outcomes were not studied.

The pragmatic, cluster randomized ROGY ('Registrationsystem Oncological GYnecology') Care trial evaluates the effects of an SCP in daily clinical practice on patient and health care provider (PCPs, gynecologists, oncology nurses) reported outcomes<sup>19,20</sup>. Hospitals were either randomized to SCP-care (i.e., providing SCPs to their patients and the PCPs of these patients) or usual care. Cluster randomization at hospital level was chosen in order to eliminate the possible bias posed by randomization at patient level, in which health care providers would have to switch between usual care and SCP care for each patient, and could therefore (unconsciously) influence the usual care group with that of the SCP approach.

The aims of the present study were to:

1. Compare the PCPs in the SCP-care and usual care arm regarding receipt of information from the medical specialist (i.e., receiving written information, including an SCP; receiving the information in time; satisfaction with information), and regarding the communication of the PCP with the medical specialist and the patient (i.e., having personal/telephone contact (primary outcome));
2. Describe PCPs' experiences and opinions regarding the received SCP;
3. Describe PCPs' opinions on their role in the care for cancer survivors, and their need for information and an SCP.

All outcomes were assessed at the PCP-level, not at the hospital level. We hypothesized that PCPs in the SCP-care arm would be more satisfied with the information compared to PCPs in the usual care arm, and that an SCP would improve the communication (i.e., defined as having personal contact) between the PCP with the medical specialist and patient.

## **METHODS**

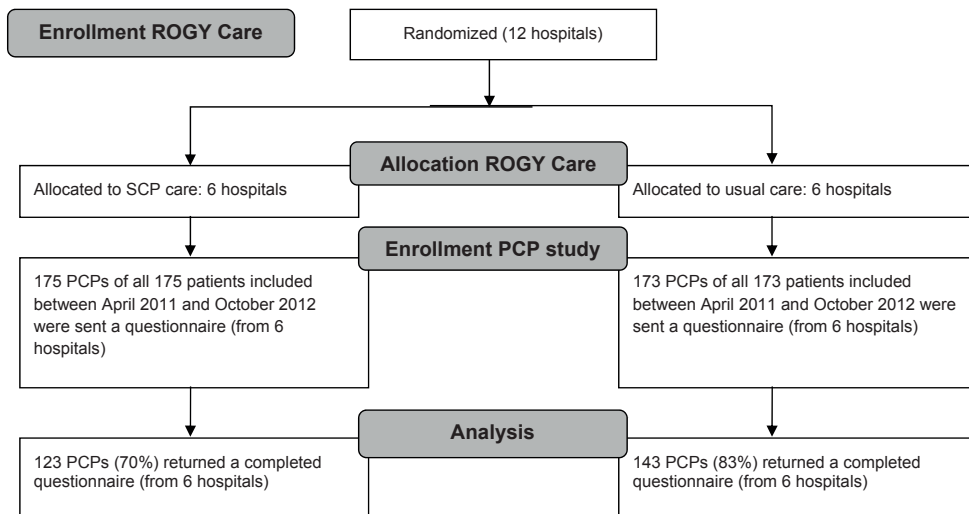
### **Design**

A pragmatic cluster RCT (ROGY Care trial) was conducted, in which 12 hospitals were randomized to either 'usual care' or 'SCP-care'. Using a cluster design prevents that health care providers from a hospital have to provide both types of care, which could lead to cross-over between both arms. Randomization was performed with a table of random numbers by a researcher not involved in the study and blind to the identity of the hospitals, and stratified according to being a Gynecologic Oncology Center, and the annual number of endometrial and ovarian cancer patients. Health care providers could not be blinded for allocation, the participants on the other hand were unaware of the group assignment, as they were under the assumption that the hospital is providing usual care (as such allocation was also concealed).

Oncology providers (i.e., medical specialists and oncology nurses) in the SCP-care arm were instructed to provide an SCP after initial surgery, not only to the patient, but to also send a copy of the SCP to the patient’s PCP. The current study reports secondary outcomes of the ROGY Care trial and evaluates the impact of an SCP on the PCP reported outcomes. More details, including the primary study aims regarding the impact of an SCP on patient reported outcomes are described in a protocol paper <sup>19</sup>. The ROGY Care trial has been approved by the medical research ethics committees of all participating centers and was registered before patient inclusion on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01185626).

### Study population and recruitment

PCPs of all eligible patients, diagnosed with endometrial or ovarian cancer between April 2011 and October 2012 in the 12 participating hospitals in the south of the Netherlands, were asked to fill out one short questionnaire (Figure 1). The twelve hospitals were both teaching and non-teaching hospitals. After initial treatment, patients were sent the first questionnaire, together with a letter and leaflet to inform them only about the questionnaire part of the study and an informed consent form for the completion of multiple questionnaires.



**Figure 1.** Flow chart of the PCP study nested within the ROGY Care trial (CONSORT diagram)

A questionnaire was sent to the PCP 2 to 3 months after patient inclusion. The questionnaire to the PCP was accompanied by a letter explaining the purpose of the study and the name of their patient asked to participate in the trial. PCPs were asked to return the questionnaire in a pre-stamped envelope. To guarantee anonymity, returned questionnaires contained a study number only. If the questionnaire was not returned within 6 weeks, a reminder letter and questionnaire were sent.

### **Survivorship Care Plan**

A web-based patient registration system 'Registrationsystem Oncological GYnecology' (ROGY) is used by gynaecologists in the south of the Netherlands since 2006. A personalized SCP can be generated automatically out of ROGY, by pushing a button. The SCP can either be printed on paper and sent to the patient's PCP by postal mail, or sent by e-mail in PDF-format. The ROGY system is used by all participating gynecologists in both arms, but the SCP-button is only visible for the gynecologists in the SCP-care arm. Consequently, only the gynecologists in the SCP-care arm were able to generate the SCP from ROGY. However, as this is a pragmatic trial, it is possible that hospitals in the usual care arm also provided their own personalized information resembling an SCP.

The SCP used in the current study was a copy of the patient version and was not specifically developed for PCPs. The SCP provides tailored information based on personal patient and disease data. The SCP provides a personalized treatment summary, including detailed information on diagnostic tests, type of cancer, stage and grade, treatment, and contact details of the hospital and health care provider(s). In addition, the SCP contains a personalized follow-up care plan, including detailed information on possible short-term and long-term effects, possible effects on social and sexual life, possible signs of recurrence and second tumors, and information on rehabilitation, psychosocial support, and supportive care services. The Distress Thermometer<sup>21</sup> at the end of the SCP can be used as a screening tool and aid for the communication about psychosocial distress.

### **Questionnaire**

A self-administered survey was developed for the purpose of this study (Appendix), since no validated questionnaire was equipped for this purpose. Based on expected effects of the SCP, the expected information needs of PCPs (obtained after consultation with PCPs when initiating the trial), and questions regarding the content of an SCP, we decided on the questionnaire outline. As a result, the questionnaire evaluated the possible impact of an SCP on the communication of the PCP with the medical specialist and the patient, and the PCP's general knowledge of and perceived role in the care for cancer patients.

The developed questionnaire was discussed with three gynecologists and a PCP for face validity, content and relevance. To facilitate a high response rate, the questionnaire was intentionally condensed to a maximum of 2 pages, which could be completed in a few minutes. Open ended questions about omission in knowledge, changes needed for a larger role of the PCP, and usefulness of the SCP, were coded and summarized.

### **Statistical analyses**

The sample of PCPs was a convenience sample and was not based on sample size calculation. Descriptive means with standard deviations (SD) and percentages were used to describe the data. Differences between the SCP-care and usual care arm were tested using t-tests and Chi-square tests for continuous and categorical data, respectively.

Three outcomes (i.e., PCPs did or did not have personal contact with a medical specialist (dichotomous; primary outcome), PCPs' satisfaction with the hospital information (continuous), and PCPs' wish to receive or not to receive an SCP in the future (dichotomous)) were evaluated in mixed-effects linear regression analysis for the continuous outcome and in mixed-effects logistic regression analyses for the dichotomous outcomes. Mixed models were used to account for the clustering of the PCPs within hospitals. Therefore, to report outcomes on the PCP-level we needed to take this clustering into account by using multilevel mixed models. We applied intention-to-treat (i.e., SCP-care vs. usual care arm) and per-protocol (i.e., receiving SCP in the SCP-care arm vs. not receiving SCP in the SCP-care arm plus usual care arm) analyses. Confounders included in the model were chosen a priori and based on literature and expected effects. The data were analyzed using Statistical Analysis System (SAS) version 9.2 (SAS Institute, Cary, NC, 1999). P-values were regarded as significant if  $p < 0.05$  and tests were two-sided.

## **RESULTS**

### **Participants**

PCPs of 348 patients were sent a questionnaire (175 SCP-care arm; 173 usual care arm) and 266 (76%) responded (Figure 1). PCPs in the SCP-care arm were similar to PCPs in the usual care arm regarding gender, working experience as a PCP, days per week active in patient care, being a teaching PCP, urbanization area, type of practice, and having had contact with the patient since the diagnosis. However, in the SCP-care arm, there were more PCPs of endometrial and less PCPs of ovarian cancer patients than in the usual care arm (Table 1).

**Table 1.** Descriptives of the study population and a description of written communication with the specialist, by SCP-care and usual care arm, N (%) or mean, Standard Deviation (SD)

	SCP-care (N=123)	Usual care (N=143)	p-value
	N (%)		
<b>Male</b>	75 (61)	103 (72)	0.07
<b>Years working as PCP</b> (mean, SD)	19 (10)	18 (9)	0.28
<b>Days per week active in patient care</b> (mean, SD)	4.2 (0.8)	4.3 (0.8)	0.29
<b>Teaching PCP</b>	44 (36)	52 (37)	0.93
<b>Urbanization area PCP practice</b>			
City	45 (37)	67 (48)	0.22
Semi-urban	52 (43)	51 (36)	
Rural	25 (20)	23 (16)	
<b>Type of practice</b>			
Solo	25 (21)	41 (30)	0.11
Duo	36 (30)	45 (33)	
Group/health centre	60 (50)	52 (38)	
<b>Had contact with patient since diagnosis</b>	111 (94)	133 (95)	0.74
<b>Type of gynaecological cancer patient</b>			
Endometrial	75 (82)	72 (66)	<b>0.01</b>
Ovarian	17 (18)	37 (34)	
<b>Written information</b>			
Survivorship Care Plan	39 (33)	22 (16)	<sup>a</sup>
Patient letter	105 (87)	124 (89)	0.55
Any written information	120 (98)	138 (98)	0.31
<b>Information in time?</b>			
No, would have preferred to receive information earlier	23 (19)	28 (20)	0.82

Note: <sup>a</sup>No p-value reported for the difference in 'receiving an SCP', since this is different by design.

### Information receipt and communication between PCP and medical specialist

One third of the PCPs in the SCP-care arm and 16% of the PCPs in the usual care arm reported receiving an SCP (Table 1). Multiple multilevel linear regression analysis showed that PCPs in the SCP-care arm and the usual care arm were equally satisfied with the information they received from the hospital ( $p=0.25$ ; intention-to-treat; Table 2; Figure 2). Consistent results were found for the per-protocol analysis ( $p=0.61$ ). PCPs in the SCP-care arm more often had personal contact with a medical specialist ( $p=0.01$ ; intention-to-treat), mostly by telephone (Table 2; Figure 2). The per-protocol analysis showed similar results ( $p=0.04$ ).

**Table 2.** Satisfaction of the PCPs with the hospital information, percentage of the PCPs who had personal contact with a medical specialist, and percentage of the PCPs who wish to receive an SCP in the future by intention-to-treat and per protocol analysis, b or Odds Ratio (OR) based on multilevel analyses

	SCP-care (N=123)	Usual care (N=143)	N	b*	OR*	95% CI*	p-value*
<b>Satisfaction with information<sup>a</sup></b>							
Intention-to-treat	7.2 (1.7)	6.9 (1.5)	241	0.24		-0.18 to 0.66	0.25
Per protocol	7.2 (1.7)	7.0 (1.6)	241	0.15		-0.43 to 0.73	0.61
<b>Personal contact with specialist<sup>b</sup></b>							
Intention-to-treat	43%	26%	243		2.49	1.29 to 4.78	<b>0.01</b>
Per protocol	47%	32%	243		2.30	1.06 to 4.99	<b>0.04</b>
<b>Wish to receive an SCP in the future<sup>c</sup></b>							
Intention-to-treat	74%	88%	196		0.37	0.12 to 1.16	0.08
Per protocol	71%	84%	196		0.59	0.20 to 1.70	0.32

Note: <sup>a</sup>Satisfaction with information: adjusted for gender, years working as PCP, type of practice, and tumor type.

<sup>b</sup>Personal contact: adjusted for gender, years working as PCP, type of practice, knowledge, and tumor type.

<sup>c</sup>Wishing to receive a SCP in the future: adjusted for gender, years working as PCP, type of practice, tumor type, knowledge, satisfaction, and larger role in the care for cancer patients. Intention-to-treat analysis: SCP-care arm/ usual care arm, Per Protocol analysis: received SCP/did not receive SCP.

### PCPs’ opinions about the SCP received

Of the PCPs in the SCP-care arm who reported receiving an SCP (N=39), 97% read the SCP totally or partially (Table 3). Almost all PCPs indicated that they received the SCP by postal mail. One quarter of the PCPs reported that the SCP provided benefit to the communication with the patient, mostly regarding the diagnosis, treatment, prognosis and psychosocial aspects. About one third of the PCPs reported that the SCP supported having contact with the patient. PCPs considered information about diagnosis, treatment and consequences as most relevant. On the open ended question regarding the use of the SCP, PCPs indicated that the SCP provided support in the consult with the patient (N=8), and that the SCP supported information provision from the hospital (N=7). Furthermore, it was reported that the SCP was too elaborate and should be more concise (N=13).

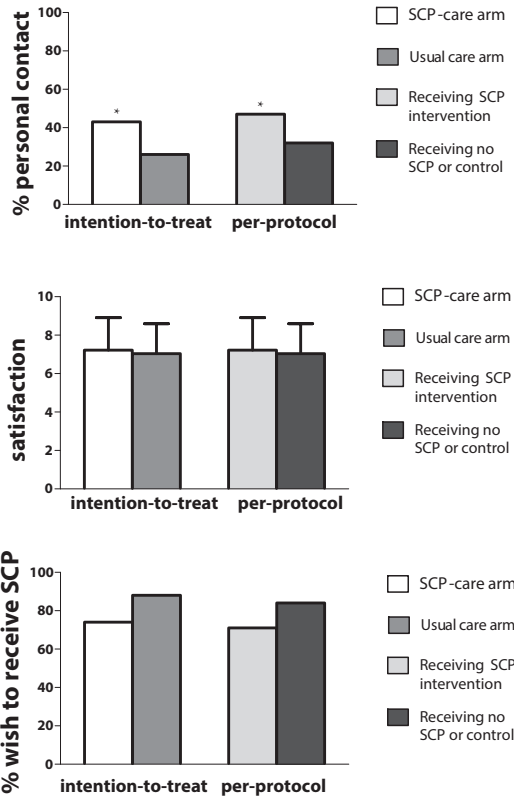
### Perceived role in cancer care and usefulness of the SCP

Of all PCPs, 82% indicated that they wished to receive an SCP in the future. No difference was observed between PCPs in the SCP-care arm and the usual care arm in wanting to receive an SCP in the future (p=0.08 intention-to-treat analysis and p=0.32 per protocol; Table 2; Figure 2). The majority of PCPs (84%) preferred to receive the SCP via the electronic medical record system for primary care and not via postal mail. About 40% of the PCPs indicated that they would like to be more involved in the care of cancer patients.

**Table 3.** PCPs' experiences and opinions regarding the SCP, as reported by PCPs in the SCP-care arm who received an SCP

	<b>SCP Care</b> (N=39)
	N (%)
<b>Provision method of SCP</b>	
Electronic	1 (3)
Postal mail	32 (97)
<b>Read SCP</b>	
Yes, totally	14 (39)
Yes, partially	21 (58)
No	1 (3)
<b>SCP of use for patient care?</b> (1 (Not at all) – 10 (very much))	
1-5	9 (26)
6, 7	18 (51)
8-10	8 (23)
<b>Did SCP provide benefit to communication with the patient?</b>	
No	27 (77)
Yes	8 (23)
More often contact	2 (6)
More/better contact about diagnosis	5 (14)
More/better contact about treatment	7 (20)
More/better contact about prognosis	7 (20)
More/better contact about psychosocial aspects	4 (11)
More/better contact about comorbidities	2 (6)
More/better contact about prevention/lifestyle	1 (3)
<b>Amount of information in SCP</b> (1 (too little) – 10 (too much)) Mean (SD)	
1-5	7.2 (1.7)
6, 7	6 (18)
8-10	12 (36)
8-10	15 (45)
<b>Which elements of the SCP are of interest to you?</b>	
Contact information specialists in hospital	17 (50)
Diagnosis information	27 (79)
Additional information diagnosis	11 (32)
Treatment information patients	28 (82)
Additional information treatment	15 (44)
Short term consequences treatment	23 (68)
Long term consequences treatment	22 (65)
Educational materials	2 (6)
Distress thermometer	2 (6)

Yet, another 17% (N=44) indicated that in order to achieve this, changes are required. Reported suggestions for changes included better and faster communication and information exchange between primary and secondary care (N=21) and proper support in time and finances (N=20). PCPs rated their knowledge to answer questions of gynecological cancer patients and to provide good care with a 6.7 on a scale from 1 (too little) to 10 (excellent).



**Figure 2.** Satisfaction of the PCPs with the hospital information, percentage of the PCPs who had personal contact with a medical specialist, and percentage of the PCPs who wish to receive an SCP in the future, by intention-to-treat and per protocol analysis

Note: Error bars represent +1 standard deviation. \*p<0.05. For detailed information, see Table 2. Intention-to-treat analysis: SCP-care arm/usual care arm, Per Protocol analysis: received SCP/did not receive SCP.

## DISCUSSION

In this pragmatic cluster randomized trial, in which automatically generated SCPs could be provided to patients and their PCPs in the SCP-care arm, still only one third of the PCPs reported to have received an SCP. The SCP improved the frequency and quality of the communication with the medical specialist and, for a quarter of the PCPs, with the patient. The SCP did not affect PCPs' satisfaction with the information. Eighty percent of all PCPs wanted to receive an SCP in the future.

The results of the current study seem to indicate that most PCPs in the SCP-care arm did not receive the SCP. However, it is also possible that PCPs either forgot that they received an SCP, or that the practice received the print version, but that it never reached the PCP. Since in the current trial, the SCP had to be sent manually by hospital staff, delivery of the SCP to the PCP might have been suboptimal. It may be enhanced by either having the patient take their SCP to the PCP themselves, or by making the delivery process automatic, for instance by integrating or linking the medical records systems of the hospital and the PCP. Remarks from our participating PCPs as well as literature supports the latter approach, as PCPs prefer an electronic version of the SCP placed in the patient's medical record<sup>16,22</sup>. As a lack of communication between the PCP and the medical specialist is considered to be an important barrier in the transfer of the responsibility for follow-up care to the PCP<sup>13</sup>, our finding that an SCP might enhance the communication between the PCP and the medical specialist is promising. Several studies have found an absence or lack of systematic information sharing among PCPs and oncologists needed to support quality survivorship care in the primary care setting<sup>12,23</sup>. In the current study, almost all PCPs reported receiving written information from the hospital. Contrary to what was hypothesized, providing an SCP did not improve satisfaction with information. Possibly, the information provided in the patient letter –received by almost 90% of the PCPs – led to sufficient satisfaction and an SCP could not add to this. In addition to enhancing the communication (i.e., having personal contact) with the medical specialist, the results of the present study indicate that for a quarter of the PCPs the SCP also added positively to the communication with the patient. However, these results might be somewhat biased, since the patients of these PCPs most likely also received their personal SCP in the hospital. It is therefore difficult to disentangle whether improved communication is associated with SCP provision to the patient, the PCP, or both. However, Shalom et al.<sup>15</sup> interviewed PCPs who received an SCP in daily clinical care, showing that 80% of the PCPs who remembered and read the SCP reported a resulting change in patient care and could provide explicit examples of this change during the interview.

Regarding the content and size of the SCP, the current results indicate that although PCPs indicated that the SCP should be more concise, most of the content was appreciated, especially contact information of the medical specialists involved and the tailored information on patient diagnosis, treatment and possible consequences. Previous studies found similar results<sup>15,16,18,24,25</sup>. In other studies, PCPs also expressed a need for information on the short-term and late effects of the treatment of their patient, on the management of these late effects<sup>15,16,24,25</sup>, and on risk for recurrence and second primary tumors<sup>25</sup>, for recommended surveillance plans<sup>16,18,26</sup>, on genetic counseling<sup>25,26</sup>, on psychosocial impact<sup>26</sup>, and on practical consequences<sup>26</sup>. In the current study, PCPs received a copy of the patient version of the SCP, which could be up to 20 pages in total. This was reported to be too elaborate. This finding is similar to recent studies, in which PCPs expressed the need for concise versions of an SCP, of about 2 to 5 pages<sup>15,16</sup>.

Several limitations regarding this study should be stated. First, only 39 PCPs in the SCP-care arm reported receiving an SCP. This has a negative impact on the effective sample size to detect differences between the two study arms. Moreover, this limited number decreased the generalizability of the opinions of the PCPs regarding the SCP. Second, gynecologists could not be blinded for study allocation, possibly increasing the tendency of these health care providers to provide better care by increasing the communication towards the PCP. A third limitation is the use of a non-validated questionnaire. As we aimed to present a one page questionnaire regarding PCPs' evaluation and because questionnaires for the purpose of this study are not readily available, we did not use a validated questionnaire. Not using a validated questionnaire might have affected our results if PCPs did not fully understand the questions or interpreted concepts, such as 'an SCP', differently. PCPs' answers might also be prone to social desirability (e.g., have you read the SCP?). The last limitation that should be noted is that a considerable part (16%) of the PCPs in the usual care arm reported receiving an SCP. As this was not possible because the SCP button was not visible in the usual care arm, this might indicate that the PCPs received a document that resembled an SCP (a possible consequence of pragmatic trials) or that the concept of an SCP was not clear, limiting the validity of the question. Despite these limitations, several strengths should be stated. The current study is the first RCT that studies the effect of an SCP to inform the PCP. An RCT makes comparison between groups possible, allowing for stronger inference than observational studies. Another strength of our study is the high response rate (76%). The pragmatic character of our cluster RCT revealed that only a minority of PCPs in the SCP-care arm received an SCP. Per protocol analyses were done to account for this.

In conclusion, supplying an SCP to PCPs has a potential positive effect on the communication of the PCP with the medical specialist and the patient, although the limited implementation prohibits drawing firm conclusions. However, the delivery of the SCP to the PCP should be facilitated better, for instance by embedding the delivery in the electronic medical record system for primary care. The SCP should be concise and focused on PCPs' needs, such as information on the health care providers involved (including contact information) and tailored information on patient diagnosis, treatment, and possible consequences. This study evaluated one single approach in enhancing the communication between the PCP and medical specialist in a situation of limited shared care. However, future research should focus on disentangling optimal approaches to improve information sharing and communication between PCPs and medical specialists.

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**Appendix. Questionnaire PCPs**

- 1a. Have you had contact with the medical specialist (e.g. gynaecologist, medical oncologist) by telephone or personally about this patient? (CG+IG) => No/Yes – if yes, Gynaecologist/Medical oncologist/Other...
- 1b. By which means did you have contact? (CG+IG) => By telephone/During the oncology meeting/Other...
2. Did you receive written information from the gynaecologist about this patient? (CG+IG) => No/Yes – if yes, Patient letter/SCP of the patient (as pdf file/by post)/Other...
3. Did you receive this information (by telephone or written) in time? (CG+IG) => No, I would have preferred receiving this information earlier/Yes/NA, continue with question 12
4. Are you satisfied with the information you received about this patient from the hospital? (CG+IG) => Not at all satisfied (1) - Totally satisfied (10)
5. Have you had contact with the patient since the cancer diagnosis? (CG+IG) => Yes/No
6. In case you received an SCP, did you read the content? (IG) => Yes, totally/Yes, partly/No, continue with question 12/NA, I did not receive an SCP, continue with question 12
- 7a. How useful is the SCP for the care of this patient? (IG) => Not useful (1) – Very useful (10)
- 7b. Why do you think the SCP is/is not useful? (IG)=> OPEN ENDED
8. Did the SCP have a positive effect on the communication between you and the patient? (IG) => No, I probably would have had similar contact with the patient without the SCP /Yes, if yes, multiple options:  
 More frequent contact  
 More frequent/better contact about the diagnosis  
 More frequent/better contact about the treatment  
 More frequent/better contact about the prognosis  
 More frequent/better contact about the psychosocial aspects  
 More frequent/better contact about the comorbidity  
 More frequent/better contact about the prevention/lifestyle
9. What do you think about the amount of information in the SCP? (IG) => Too little information (1) – Too much information (10)
10. Which elements of the SCP are important for you? (IG) => Contact information of the medical specialists in the hospital  
 Information about the diagnosis of the patient  
 In depth information about the diagnosis  
 Information about the treatment of the patient  
 In depth information about the treatment  
 Information about possible short term consequences of the treatment  
 Information about possible long term consequences of the treatment  
 Educational materials  
 The Distress Thermometer
11. What information was missing in the SCP? (IG) => OPEN ENDED
12. Would you like to receive an SCP for every patient with cancer? (CG+IG) => No/Yes, if yes, preferably by email/PCPs' electronic system/paper (by post)
13. Do you feel that you have sufficient knowledge to answer questions of patients with gynaecological cancer and provide good care? (CG+IG) => Not sufficient knowledge (1) - Excellent knowledge (10)
14. If you feel your knowledge is not sufficient, what are important omissions in your knowledge? (CG) => OPEN ENDED
15. Do you perceive a larger role in the support of patients with cancer? (CG+IG) => No/Yes/Yes, but certain changes are needed, namely: .....
16. What is your gender? (CG+IG) => Man/Woman
17. How many years of practice experience do you have? (CG+IG) => ..... Years
18. How many days per week do you see patients? (CG+IG) => ..... Days
19. Are you a trainer? (CG+IG) => Yes/No
21. Where do you work? (CG+IG) => Urban/Semi-urban/Rural
22. Do you work in a solo, duo or group practice? (CG+IG) => Solo/Duo/Group

Note: CG: Control Group; IG: Intervention Group; SCP: Survivorship Care Plan.



# Chapter 9

**Summary and General discussion**



## SUMMARY OF RESULTS

In this chapter, the main findings of the studies described in this thesis are summarized and discussed in a broader context. In addition, methodological considerations and implications for clinical practice and future research are discussed.

This thesis started by identifying the information provision to endometrial cancer survivors (**Chapter 2**). The aims were to assess the perceived level of and satisfaction with information received by endometrial cancer survivors, and to identify possible associations with socio-demographic and clinical characteristics. The population-based Eindhoven Cancer Registry was used as a sampling frame to send a questionnaire to all patients diagnosed with endometrial cancer between 1998 and 2007, and 742 (77%) patients responded. Most patients indicated that they received quite a bit of information about their disease and medical tests. However, more than half of the patients stated that they were not (54%) or only a little (24%) informed about the cause of their disease, and possible side effects of their treatment (36%; 27%). Especially information related to aftercare, such as additional help, rehabilitation, psychological assistance, and expected results on social and sexual life was lacking. A substantial percentage of the patients was not (5%) or only a little (36%) satisfied with the received information, and found the information not (4%) or only a little (35%) helpful. Younger age, more recent diagnosis, radiotherapy, absence of comorbidities, having a partner, having received written information, and higher educational level were associated with higher perceived information receipt.

Because the frequency of follow-up care of endometrial cancer survivors has been a continuing area of discussion, we wanted to investigate to what extent endometrial cancer survivors experienced follow-up according to the Dutch guidelines. In addition, we wanted to identify associations between consumption of follow-up care and socio-demographic and clinical characteristics, health-related quality of life, and worry, and to evaluate patients' preferences regarding the received follow-up care (**Chapter 3**). Analyses on the same dataset of patients diagnosed with endometrial cancer between 1998 and 2007, revealed that most patients reported to have received follow-up according to the national guidelines. However, there was substantial variation in follow-up practice, with both over- and underconsumption. A large group of survivors (19%), particularly in follow-up years 6-10 (27%), reported to have received follow-up care more frequently than recommended by the guidelines. Overconsumption was associated with having a comorbid condition, a higher score on the worry subscale, and hospital of treatment. Most patients (83%) felt comfortable with their follow-up schedule. Patients in follow-up years 6-10 felt least comfortable (69% felt comfortable).

In **Chapter 4**, the rationale and study design of the pragmatic cluster randomized ROGY Care trial were presented. Providing patients with a Survivorship Care Plan (SCP) has been recommended by the American Institute of Medicine (IOM) and the Dutch Health Council. However, evidence on the effects of implementing SCPs in routine clinical practice was lacking. The aim of the ROGY Care trial was therefore to assess the impact of an automatically generated SCP on patient reported outcomes, and to assess health care providers' evaluation of the SCP in routine clinical practice. An SCP-application was built in the web-based Registration system Oncological GYnecology (ROGY). By clicking the SCP-button, a patient-tailored SCP could automatically be generated. The study design was a pragmatic cluster randomized controlled trial, in which 12 hospitals were randomized to SCP care or usual care. All patients newly diagnosed with endometrial or ovarian cancer in the participating hospitals were approached to complete questionnaires after surgery, and after 6, 12, 18, and 24 months. In addition, health care providers were asked about their opinion about the implementation of SCP care. Primary outcomes were defined as patient satisfaction with information provision and care. Secondary outcomes were defined as illness perceptions, health care utilization, prevalence, course and referral rate of survivors with psychosocial distress, health-related quality of life, and health care providers' evaluation of SCP care.

Patient reported outcomes of the ROGY Care trial for endometrial cancer patients up to 12 months after diagnosis were examined in **Chapter 5**. Of the 296 eligible patients, 221 (75%) patients completed the first questionnaire. After 6 months, 158 (53%), and after 12 months, 147 (50%) patients completed the questionnaire. In the SCP care arm, 74% of the patients indicated receiving an SCP. Patients in the SCP care arm reported receiving more information about their treatment, other services, and different places of care than patients in the usual care arm. However, there were no differences regarding satisfaction with the received information or care. In addition, patients in the SCP care arm experienced more symptoms, were more concerned about their illness, more affected emotionally, and reported more cancer-related contact with their primary care physician than patients in the usual care arm. These effects did not differ over time.

Because the Internet is increasingly used as a source of information for cancer patients, it was examined whether the effects of an automatically generated paper SCP on patients' satisfaction with information provision and care, illness perceptions, and health care utilization were different for patients who searched for disease-related information on the Internet compared to patients who did not (**Chapter 6**). In total, 80 (37%) patients indicated that they used the Internet to obtain information about their disease. Paper SCPs appeared to improve the amount of received information about the disease

and medical tests, the helpfulness of the information, and the understanding of the illness for patients who did not search for disease-related information on the Internet themselves. In contrast, paper SCPs did not seem to be helpful for patients who already searched for disease-related information on the Internet themselves.

Providing SCPs to patients can be challenging and requires active involvement and commitment of the oncology providers (i.e., medical specialists and oncology nurses). In **Chapter 7**, we longitudinally examined the expectations (before the intervention) and actual experiences (after the intervention) of the oncology providers in the ROGY Care trial with the automatically generated SCP, in routine clinical practice. All (n=43) oncology providers in both arms were requested to complete a questionnaire before and after patient inclusion. Before patient inclusion, 38 (88%), and after patient inclusion, 35 (83%) oncology providers returned the questionnaire. After patient inclusion, the oncology providers were generally satisfied with the SCP, believed the SCP affected patients positively, and were motivated to keep using the SCP. Nevertheless, most oncology providers (64%) encountered barriers in providing SCP care in daily clinical practice. The most frequently reported practical barrier was finding the time to discuss the SCP. Twenty-five percent of the oncology providers felt they used more time for their consultations because of the SCP. However, self-reported consultation-time did not differ between before and after patient inclusion, or between SCP care and usual care.

As it has been recommended to transfer the routine follow-up care of cancer survivors from the medical specialist to the primary care physician, we wanted to investigate whether SCPs could facilitate this transition (**Chapter 8**). The aims were to assess the effects of sending an SCP to primary care physicians on the communication of primary care physicians with medical specialists and patients, and to describe primary care physicians' opinions regarding the SCP. Primary care physicians were sent a questionnaire two to three months after patient inclusion. A questionnaire was returned by 266 (76%) primary care physicians. One third of the primary care physicians in the SCP care arm indicated having received an SCP. Primary care physicians in the SCP care arm were more likely to have had personal contact with the medical specialist (52%) than primary care physicians in the usual care arm (37%). However, the SCP did not affect their satisfaction with the information. A quarter of the primary care physicians who received an SCP reported that the SCP supported their contact with the patient. Of all primary care physicians, 82% indicated that they would want to receive an SCP in the future. However, the SCP needs to be more concise.

## GENERAL DISCUSSION

Over the past decades, the number of cancer survivors has rapidly increased due to ageing of the population, and improved early detection and treatments <sup>1</sup>. In 2010, there were approximately 600,000 cancer survivors in the Netherlands, and this number is estimated to increase to 900,000 in 2020 <sup>2</sup>. Because these cancer survivors remain at risk for long-term or late effects of their cancer and its treatment in many physical and psychosocial domains, it is necessary to address their specific health care needs.

Endometrial cancer is the most frequent gynecological cancer in developed countries, with an incidence of 15-25 per 100,000 women annually <sup>3,4</sup>. The majority of these women have an excellent prognosis, indicated by the overall 5-year survival rate of 80% <sup>3-5</sup>. However, little is known about the specific health care needs of endometrial cancer survivors. Evaluating the current state of information provision and follow-up care of endometrial cancer survivors is necessary to determine whether improvements are needed.

To help the growing number of cancer survivors deal with the long-term or late physical and psychosocial effects of their cancer, Survivorship Care Plans (SCPs) have been recommended <sup>6,7</sup>. Although previous studies <sup>8-10</sup> made important first steps towards understanding the impact of SCPs, there were major limitations in the study designs <sup>11-13</sup>. A pragmatic cluster randomized trial is necessary to support informed health care decisions regarding the large-scale implementation of SCPs.

The main objectives of the studies in this thesis were:

- To assess the current state of information provision and follow-up care reported by endometrial cancer survivors, and to identify possible associations with socio-demographic and clinical characteristics.
- To assess the impact of an automatically generated SCP on patient reported outcomes, and to assess health care providers' evaluation of the SCP in routine clinical practice.

### Main findings

#### ***Information provision and follow-up care in endometrial cancer survivors***

In this thesis, it was found that endometrial cancer survivors experienced several areas of information provision as insufficient, in particular topics related to aftercare. As patient information is an essential factor in the support for cancer survivors <sup>14-17</sup>, these findings suggest that efforts are needed to improve the information provision

for endometrial cancer survivors. In addition, this thesis identified factors associated with receiving more information (i.e., younger age, more recent diagnosis, radiotherapy, absence of comorbidities, having a partner, having received written information, and higher educational level), which could facilitate a more patient-tailored approach of informing patients, such as the provision of SCPs.

A substantial variation in follow-up practice in endometrial cancer survivors between different hospitals was observed in this thesis, which is in line with previous studies<sup>18-22</sup>, and may reflect the lack of evidence-based guidelines. This thesis contributes to the ongoing debate about the organization of routine follow-up care in endometrial cancer<sup>19,23</sup>, by showing that a large group of endometrial cancer survivors, particularly in follow-up years 6-10, received follow-up care more frequently than recommended by the guidelines (i.e., overconsumption), and that these survivors felt least comfortable with their follow-up schedule. These findings suggest that a critical evaluation of current follow-up practices is required. In addition, this thesis identified factors associated with overconsumption of follow-up care (i.e., having a comorbid condition, being more worried, and hospital of treatment), which could facilitate a better organization of the follow-up care of endometrial cancer survivors.

### ***Impact of SCP care on patient reported outcomes***

No evidence of a benefit of SCPs on satisfaction with information provision and care was found in this thesis. Nevertheless, SCPs increased the amount of received information, suggesting that SCPs may be a useful way to provide more patient-tailored information in places where existing information provision is insufficient. Furthermore, SCPs increased patients' concerns, emotional impact, and experienced symptoms. However, it remains unclear whether these effects may be harmful or beneficial for patients. It is possible that providing information on potential late effects has negative effects on psychological adjustment and increases the experience of late effects<sup>24</sup>. However, it is also possible that receiving an SCP raises patients' awareness of cancer-related symptoms and empowers them to find the necessary support. Similarly, the finding in this thesis that SCPs increased patients' cancer-related contact with the primary care physician, may either indicate that SCPs unnecessarily increase health care utilization, or that SCPs empower patients to find the support they need.

In addition, the results in this thesis suggest that paper SCPs may be a useful tool to empower patients who do not search for information on the Internet, by improving the amount of information they receive about their disease and medical tests, the helpfulness of the information, and their understanding of their illness. In contrast, paper SCPs do

not seem beneficial for patients who do search for disease-related information on the Internet, suggesting that these patients already benefit from accessing information on the Internet. Health care providers could use this information to decide whether providing a paper SCP is of added value for a patient or not.

### ***Impact of SCP care on health care provider reported outcomes***

This thesis revealed that oncology providers using the SCP were generally satisfied with the SCP, believed the SCP affected patients positively, and were motivated to keep using the SCP. Automatic generation of the SCP appeared to improve some of the challenges in the process of SCP care (i.e., reimbursement issues and resources necessary to create SCPs). However, oncology providers still felt that they used more time to discuss the SCP, suggesting that before implementing SCPs in routine clinical practice, overcoming the perceived practical barriers is necessary.

The results in this thesis indicate that supplying an SCP to primary care physicians has a potentially positive effect on the communication of primary care physicians with medical specialists and patients. These findings suggest that SCPs may be useful tool to facilitate the transfer of routine follow-up care of cancer survivors from the medical specialist to the primary care physician. However, the delivery of the SCP to primary care physicians needs to be improved, for instance by embedding the delivery in the electronic medical record system for primary care. In addition, the SCP needs to be concise and focused on the specific needs of primary care physicians, such as (contact) information of the involved health care providers, and tailored information on the patient's diagnosis, treatment, and possible long-term or late effects.

### **Methodological considerations**

The studies presented in this thesis have several methodological strengths and limitations, which have been described in the previous chapters. In this section, the most important methodological considerations of the ROGY Care trial are discussed in more detail, and suggestions to advance future studies are provided.

#### ***Cluster randomized design***

In the ROGY Care trial, cluster randomization was chosen rather than individual randomization: Half of the hospitals were randomly assigned to the SCP care arm and the other half to the usual care arm. Cluster randomized trials are particularly relevant when an intervention is targeted at the clinical practice of professionals<sup>25</sup>. Randomizing individual patients to the arms would have resulted in contamination of the usual care arm with the SCP approach, because the oncology providers would have had to switch

between usual care and SCP care for each patient. Furthermore, cluster randomization at the hospital-level rather than at the provider-level was chosen, to avoid contamination of the usual care arm with the SCP approach, caused by oncology providers within the same hospital discussing their practice and sharing materials. A cluster randomized design at the hospital-level is therefore essential for the evaluation of the effectiveness of SCPs in multicenter research.

Compared to individually randomized trials, cluster randomized trials are more complex<sup>25,26</sup>. First of all, ethical considerations are more complex in cluster randomized trials<sup>26</sup>, because individual informed consent for randomization is not possible due to pre-randomization of the clusters<sup>27</sup>. In the ROGY Care trial, patients were unaware of the assignment to trial arms at the hospital-level, as they were under the impression that the hospital provided care as usual. Instead, patients gave consent to participate in a questionnaire study investigating the satisfaction with information provision and quality of life of cancer survivors. Although a strength of this design is that patients are blinded to the trial arm, which reduces possible bias, it could also be perceived as a violation of patients' individual choice<sup>28</sup>. Giving that cluster randomization was the only way to avoid contamination of the trial arms, that SCPs were not part of standard care in The Netherlands (thus no patients would be denied standard care), and that it was unknown whether SCPs would be beneficial or not, the Medical Research ethics Committees of all participating hospitals in the ROGY Care trial considered the design to be justified. When deciding to conduct a cluster randomized trial, these ethical issues need to be carefully considered. In addition, enough time should be planned to obtain Medical Research ethics Committee approval.

Secondly, cluster randomized trials require more participants to obtain equal statistical power<sup>29</sup>, because individuals within a cluster tend to be more similar to each other than to individuals in another cluster and can not be assumed to be independent<sup>25,29</sup>. This similarity is expressed by the intraclass correlation coefficient (ICC), which is 'the proportion of the total variance of the outcome that can be explained by the variation between clusters'<sup>29</sup>, ranging between 0 and 1, with a higher value representing higher similarity within a cluster<sup>25</sup>. A high ICC may lead to an overestimation of the strength of the evidence for an intervention. To calculate the sample size in a cluster randomized trial, the expected ICC of the outcome of interest needs to be assessed a priori<sup>25</sup>. The preferred way to do this is to collect own data, but if this is not available, data from the literature can also be used. In the ROGY Care trial, the expected ICC of the outcome satisfaction with information provision was calculated by using previously collected data of endometrial cancer survivors in 10 of the hospitals participating in the ROGY Care trial<sup>30</sup>.

Both the expected ICC ( $<0.005$ ) and the actual ICC in the ROGY Care trial (0.01) were low, indicating that the within-cluster variance was much greater than the between-cluster variance<sup>31</sup>. In addition to the ICC, the potential number of available clusters and the potential size of the clusters need to be assessed a priori to calculate the sample size<sup>25</sup>. Because an increase in the number of clusters (rather than an increase in the number of individuals within a cluster) increases the statistical power<sup>25</sup>, enough clusters need to be available. In the ROGY Care trial, substantial effort was put into recruiting as many hospitals that used ROGY as possible. The potential size of the clusters was assessed by calculating the annual number of endometrial and ovarian cancer diagnoses for each participating hospital in ROGY, and by estimating the expected response rate based on our previously conducted studies.

Finally, cluster randomized trials require more complex statistical analyses, because the analyses must also take into account the effect of clustering<sup>25,29</sup>. There are two main approaches to the analysis of cluster randomized trials, namely analysis at the cluster- and at the individual-level<sup>25</sup>. In analysis at the cluster-level, a summary measure is calculated for each cluster (e.g., the cluster mean)<sup>32</sup>. However, when a sufficient number of clusters (at least 10) is available, more advanced statistical techniques, such as multilevel analyses, can be used at the individual-level<sup>25</sup>. In the ROGY Care trial, multilevel regression analyses were performed at the patient-level, to account for clustering at the hospital-level<sup>33</sup>.

### ***Pragmatic approach***

In addition to the cluster randomized design, we chose for a pragmatic approach: Exclusion criteria were minimal, oncology providers in the SCP care arm were free to provide the SCP fitting their clinical practice, and oncology providers in the usual care arm were not restricted regarding their information provision. In contrast to explanatory trials, which are designed to determine the efficacy of an intervention under optimal, strongly controlled conditions, pragmatic trials are designed to determine the effectiveness of an intervention in real-life routine practice conditions<sup>34,35</sup>. The main advantage of pragmatic trials is that they maximize the applicability and generalizability of the findings. This supports the primary goal of comparative effectiveness research<sup>36</sup>, which is to generate information that can be used by health care providers and policy makers to make informed decisions regarding routine clinical settings<sup>35</sup>. This pragmatic approach is essential for the evaluation of the effectiveness of SCPs, where there is a lack of evidence that is applicable in routine clinical practice.

When conducting a pragmatic trial, there are also a number of methodological challenges that need to be considered. First of all, pragmatic trials require access to more diverse clinical settings, in order to enhance the external validity and relevance of the outcomes<sup>35</sup>. In the ROGY Care trial for instance, both teaching and non-teaching hospitals were included. In addition, because pragmatic trials include many different settings, they may require larger sample sizes and longer follow-up periods to obtain reliable and usable evidence, and may consequently be more expensive to conduct than explanatory trials<sup>34,35</sup>. Moreover, in order to generate information that is relevant and in time to influence health care decisions, it is especially important that pragmatic trials are developed in close and ongoing collaboration between the relevant stakeholders<sup>35</sup>. The ROGY Care trial was developed following recommendations of the American Institute of Medicine and the Dutch Health Council, and was designed in close and ongoing collaboration with gynecologists/gynecologic oncologists, oncology nurses, a radiotherapist, medical oncologist, primary care physician, and patients.

### ***Generalizability of the findings***

Although the pragmatic approach improved the generalizability of the ROGY Care trial, the findings may not be generalizable to all cancer survivors. Because only endometrial cancer patients were examined, it is uncertain whether similar effects of SCPs would be obtained in patients with different tumor types. Previous research indicates that perceived receipt of information and illness perceptions differ for different tumor types<sup>37</sup>, which may be explained by differences in, for instance, age, gender, and prognosis/disease severity. Future analyses of the ovarian cancer patients included in the ROGY Care trial can provide more insight into the generalizability of the findings across women with gynecological cancer. However, future studies that include patients with various tumor types are needed to evaluate whether the impact of SCPs is similar across other tumor types. In addition, it is uncertain whether the findings of the ROGY Care trial are generalizable to health care systems outside The Netherlands. Differences in clinical settings between countries, such as availability or organization, may influence the effectiveness of SCPs. Unfortunately, empirical evidence regarding how comparable different clinical settings are or how easily results of interventions can be transferred from one setting to another is lacking<sup>34</sup>. More research is needed to examine the impact of SCPs in different countries.

### ***Measurements***

The limits of what the measurements used in the ROGY Care trial can assess, need to be considered. First of all, all outcomes in the ROGY Care trial were based on self-report. While patient reported outcomes are deemed essential in the evaluation of SCPs, it

would also be valuable to collect more objective data. For instance, as the EORTC QLQ-INFO25<sup>38,39</sup> only measures the information that patients indicated to have received, it is unclear how much information was actually provided. Previous research indicates that patients often forget medical information, because the information may be difficult to understand and emotionally charged<sup>40-43</sup>. Similarly, as health care utilization was self-reported, it is unclear how much health care was really used. It may be difficult for patients to remember how often they visited their medical specialist and primary care physician in the past 6 months. For future research, it would be interesting to compare the outcomes of self-reported data to more objective data.

Furthermore, because the measurements in the ROGY Care trial were selected to evaluate the effectiveness of SCPs, the ROGY Care trial did not examine exactly how the SCPs were provided, or how the communication around the SCP delivery took place. Previous research indicates that health care providers' behavior and communication style play an important role in patients' active participation during the consultation<sup>44,45</sup>. It is therefore likely that the way oncology providers discuss the SCP with their patients during the consultation has an effect on the impact of SCP care. Future research needs to investigate how SCPs are discussed in routine clinical practice, and how different behaviors and communication styles of oncology providers may influence the impact of the SCPs, in order to improve the delivery of SCP care.

### ***Clinical relevance***

When evaluating the impact of SCPs on patient reported outcomes, it is important to not only focus on statistical significance, but to take clinical relevance into consideration as well. To determine whether differences in scores are actually perceived as beneficial by patients, evidence-based guidelines regarding the minimal clinically important difference<sup>46</sup> have been developed for several questionnaires, such as the EORTC QLQ-C30 (measuring Health-Related Quality of Life)<sup>47</sup>. However, for the EORTC QLQ-INFO25 (information provision), EORTC IN-PATSAT32 (satisfaction with care), and B-IPQ (illness perceptions), guidelines regarding minimal clinical important differences are lacking. If a cut-off of 0.5 SD is used<sup>48</sup>, no clinically relevant differences were observed in the ROGY Care trial. Therefore, at present, no definitive statements can be made regarding the clinical relevance of SCPs for patients. Future research needs to investigate how patients define a relevant change of information provision, care, and illness perceptions, in order for health care providers and policy makers to be able to properly interpret the findings.

## Implications for clinical practice and future directions

### *Follow-up care in endometrial cancer*

The organization of routine follow-up care in endometrial cancer has been a continuing area of discussion in the past years <sup>19,23</sup>, especially since the growing number of cancer survivors puts increasing pressure on our health care systems <sup>49,50</sup>. In this thesis, we observed a substantial variation in follow-up practice between different hospitals, possibly reflecting the lack of evidence-based guidelines. Overconsumption of follow-up care (i.e., receiving more follow-up than the guidelines) was mainly found among survivors in follow-up years 6-10. These survivors less often felt comfortable with their follow-up schedule compared to survivors in the other follow-up years. These findings suggest that a critical evaluation of current follow-up practices is required.

It has been suggested that the number of follow-up visits of endometrial cancer survivors may be reduced while the quality of care remains adequate <sup>51,52</sup>. A nationwide randomized controlled trial is currently conducted in The Netherlands (i.e., 'ENSURE trial', [clinicaltrials.gov: NCT02413606](https://clinicaltrials.gov/ct2/show/study/NCT02413606)), to assess patient satisfaction and cost-effectiveness of a reduced follow-up schedule for early stage endometrial cancer survivors compared to the current guidelines. If the reduced follow-up schedule results in similar patient satisfaction at lower costs, the current guidelines will be adapted and the reduced schedule can be implemented throughout the Netherlands. As this would require sufficiently informing cancer survivors about their risk for recurrence and about how they can monitor recurrences themselves, participants in the ENSURE trial will receive an SCP. In this thesis, we found that endometrial cancer survivors did not receive sufficient information about topics related to aftercare. The ROGY Care trial showed that SCPs increased the amount of received information about aftercare, suggesting that SCPs may provide more patient-tailored information when the existing information provision is insufficient, which may facilitate self-monitoring in patients. In addition, we found that SCPs increased patients' experienced symptoms and their cancer-related contact with their primary care physician. It is possible that receiving an SCP raises patients' awareness of cancer-related symptoms and empowers them to find the support they need. Future studies need to further examine whether SCPs can actually facilitate patients' self-monitoring of recurrences, or whether SCPs merely lead to unnecessary distress and overconsumption of health care. It would be interesting to assess whether the increased visits to the primary care physician are necessary to provide support for cancer-related symptoms and to refer patients with recurrences to the medical specialist, or whether the visits are mainly to reassure unnecessarily worried patients. This can for instance be done by measuring both patient- and primary care physician reported reasons for the consultations.

Transferring routine follow-up care from the medical specialist to the primary care physician has also been suggested as an important strategy to meet the growing demand for oncology resources<sup>1,53,54</sup>. This would require effective sharing of information between medical specialists, primary care physicians, and patients. The findings in this thesis that SCP care improved the frequency and quality of the communication between the medical specialist and the primary care physician, and supported the contact of primary care physicians with patients, suggest that SCPs may be a useful tool to enable this transition. In the ROGY Care trial, only one third of the primary care physicians in the SCP care arm indicated having received an SCP. It is likely that oncology providers did not send an SCP to all primary care physicians because of practical reasons, such as not finding the time or forgetting to send the SCP. In addition, even if oncology providers did send the SCP, not all primary care physicians may have paid close attention to the SCP, because it did not reach them through their usual way of communication with medical specialists (i.e., the electronic medical record system). Future research should focus on unraveling the optimal approach to improve information sharing and communication between primary care physicians, medical specialists, and patients. This could include a trial that investigates whether embedding the delivery of SCPs in the electronic medical record system for primary care, compared to sending the SCP via postal mail, improves the number of primary care physicians that receive and use the SCP, and further improves the communication between medical specialists, primary care physicians, and patients.

### ***Should SCPs be implemented for all cancer survivors?***

At present, we would not recommend to start implementing SCPs for all cancer survivors, based on several considerations. First of all, there is no substantial evidence of a benefit of SCPs. Thus far, no differences in satisfaction with care<sup>8-10</sup>, distress<sup>8</sup>, and quality of life<sup>8</sup> have been found between patients who did or did not receive an SCP. In the ROGY Care trial, receiving an SCP did increase the amount of received information, but patients did not report to be more satisfied with the received information and care. Second, at this point, no definitive statements can be made about the potential negative consequences of SCPs. In the ROGY Care trial, receiving an SCP increased the degree to which the illness was perceived as threatening and the amount of cancer-related contact with the primary care physician. It is unclear whether these consequences are beneficial, facilitating patients' self-monitoring, or harmful, leading to unnecessary distress and overconsumption of health care. Third, It is unclear whether the effects of SCPs are different for different patients groups. The first results of the ROGY Care trial suggest that outcomes of SCPs are different for patients who do or do not search the Internet for disease-related information. It is likely that there are more patient characteristics that influence the impact of SCPs. Fourth, evidence regarding the potential costs

associated with large-scale implementation of SCPs is lacking<sup>55</sup>. Finally, even if larger-scale implementation of SCPs would be warranted, practical barriers, such as time constraints, need to be addressed before SCPs can be more widely adopted. Although SCPs could be automatically generated in the ROGY Care trial, oncology providers still had difficulties finding the time to discuss the SCP with all of their patients.

On the other hand, at present, there is also not enough empirical evidence to warrant abandoning SCPs altogether. Essential gaps in the knowledge about SCPs need to be thoroughly examined in future research before conclusive statements can be made. Future analyses of the ROGY Care trial, including the outcomes at 24 months after diagnosis, and including other outcome measures (e.g., anxiety and depression), can provide more insight into some of these remaining gaps. Future studies that are now needed most, are additional pragmatic cluster randomized trials that are conducted in different countries and clinical settings, and evaluate different outcome variables, including both self-reported and objective measurements. In addition, as the effects of SCPs may be different for different patients, the samples of these trials need to be both diverse (e.g., regarding tumor type, age, gender, educational level) and large enough to be able to conduct stratified analyses. Furthermore, these trials need to include cost-effectiveness analyses to assess the costs of providing SCPs. In addition, future studies need to evaluate new ways to further decrease barriers and optimize the use of SCPs in clinical practice. Finally, it is possible that so far, no benefits of SCPs have been found, because the influences of the content, length, format, and delivery of SCPs on the outcomes of SCPs have not been examined<sup>55</sup>. Future research needs to investigate the optimal content, format, and delivery of SCPs, before it can be stated that SCPs are not beneficial for survivorship care.

### ***SCP content and length***

Previous research indicates that cancer survivors and primary care physicians have different preferences regarding the content and length of SCPs<sup>55</sup>. In general, cancer survivors prefer more detail rather than less<sup>56</sup>, and want more information on health promotion, psychosocial support, and other resources<sup>55</sup>. The results in thesis showed that primary care physicians prefer a more concise SCP that is focused on their specific needs (i.e., focusing on diagnosis, treatment, and possible consequences). Consequently, it would be problematic to create one SCP that is tailored to both the needs of patients and primary care physicians<sup>56</sup>. For that reason, it may be better to make different SCPs for patients and primary care physicians, that are tailored to their specific needs. Future research is needed to evaluate whether providing different SCPs for patients and primary care physicians is feasible in routine clinical practice.

There is a lack of consensus regarding the optimal content and length of SCPs for patients<sup>56</sup>. The SCP in the ROGY Care trial consisted of all components recommended by the IOM, thus containing both a treatment summary (including information on diagnostic tests, type of cancer, stage, grade, treatment, and contact details of the hospital and specialists), and a follow-up care plan (including information on possible short-term and long-term effects, effects on social and sexual life, signs of recurrence and secondary tumors, and rehabilitation, psychosocial support, and supportive care services). Consequently, in the ROGY Care trial, an SCP could be up to 20 pages long, depending on a patient's specific situation. However, providing this amount of information, particularly on possible side-effects and recurrence of the cancer, may also cause distress in some patients<sup>57</sup>. A study that assessed the effectiveness of a one-page SCP among Hodgkin Lymphoma survivors, found that 91% of the patients were positive about the SCP, and that the SCP did not increase patients' tension and anxiety<sup>58</sup>. It is possible that providing a shorter SCP that includes only the most important information, may have similar results regarding patients' perceived information provision as a longer SCP, while having less emotional impact on patients. In addition, a shorter SCP may minimize the required resources and may increase the use of the SCP. A suggestion for future research would be to conduct a trial that compares the impact of providing a one-page SCP, only including a treatment summary, to a longer and more detailed SCP, including both a detailed treatment summary and follow-up care plan. When evaluating the optimal content and length of SCPs, it is however important to consider that there are individual differences between cancer survivors' preferences. Whereas some patients prefer to receive as much information as possible, others prefer to receive less information<sup>56</sup>. Moreover, it may be useful for health care providers to tailor (part of) the content and length of the SCP to patients' individual needs, by asking their patients whether they would like to receive certain information or not. The Internet may provide a useful setting for tailoring the content and length of the information provision.

### ***SCP format: Paper versus online***

Although SCPs were originally designed to be printed on paper and delivered by the oncology provider<sup>6,59</sup>, it is also possible to provide patients with access to an online SCP. Online dissemination of SCPs may have several advantages over paper SCPs, such as possibly taking less time for health care providers and making it easier to exchange the SCP between health care providers. In addition, it may be easier to adapt an online SCP to patients' specific information needs, by providing patients with the option to click on more information if they want to, but not to click on information if they do not want to receive the information. Because the results of this thesis suggest that paper SCPs may not be a suitable format for patients who search for disease-related information on the

Internet, future research needs to investigate whether tailored online access to an SCP is of added value for these patients. To be of added value, this online SCP should entail more than merely providing the content of the paper SCP online. A suggestion would be to provide patients with access to a tailored online portal, where information from different sources is brought together to help these patients find reliable information and resources online. For instance, in addition to access to their own medical file and contact details of the hospital and specialists, the portal could provide access to different online sources of information that are tailored to their specific situation, and direct access to different online services that provide supportive care and psychosocial support.

On the other hand, not all patients may benefit from online dissemination of SCPs. For instance, patients who are older, lower educated, or do not have a partner or a job are less likely to use the Internet <sup>60-62</sup>. The results of this thesis indicate that paper SCPs appear to be beneficial for patients who do not search for disease-related information on the Internet. Providing an SCP that can only be accessed on the Internet may therefore alienate patient groups that actually need the support the most <sup>59</sup>. A recent review of studies of SCPs <sup>55</sup> showed that both paper and online SCPs are considered useful by cancer survivors and that some patients prefer to receive both. It is likely that patients' individual preferences regarding the format of the SCP differ. Based on the current evidence, we would propose that, ideally, health care providers tailor the SCP format to patients' preferences, by asking patients how they would like to receive the SCP: printed on paper, an account that gives access to an online SCP, or both. Future research needs to investigate whether this approach is effective and feasible in routine clinical practice.

### ***SCP timing and frequency of delivery***

In previous studies, the moment of the delivery of the SCP ranged from newly diagnosed patients to patients who were up to six years post-treatment <sup>8-10</sup>. Although the IOM recommended delivering the SCP at the end of treatment <sup>6</sup>, it may be preferable to provide the SCP directly after initial diagnosis, allowing patients to discuss the planned treatment with their oncology providers and family <sup>56</sup>. Therefore, in the ROGY Care trial, the SCP was provided directly following diagnosis and initial surgery. However, because the timing of delivery was not investigated in the ROGY Care trial, the ideal timing of providing SCPs remains unclear. Future research needs to examine the impact of the timing of the delivery of an SCP, by comparing whether providing the SCP directly after initial diagnosis leads to different outcomes than providing the SCP at the end of treatment. In addition, patients' preferences regarding the timing of the SCP delivery need to be evaluated.

Moreover, as patients' need for information may be different at different time points in the follow-up trajectory, a single SCP may not be sufficient. It has therefore been suggested to provide updates of the SCP in follow-up consultations, rather than a single, static SCP<sup>63,64</sup>. However, it was unclear whether constraints in clinical practice would limit oncology providers' ability to provide these updates<sup>59</sup>. In the ROGY Care trial, oncology providers could automatically generate an updated SCP at every follow-up visit, because any changes in disease progression, treatment, and involved specialists were continuously registered in ROGY. The results showed that a third of the patients in the SCP care arm actually received more than one SCP, suggesting that automatically generating SCP updates from a registration system may ease some of the potential barriers in clinical practice. Nevertheless, it is important to consider that, although updates of the SCP could be provided in the ROGY Care trial, patients still received nearly all of the information in the first SCP. Consequently, patients already received information about possible long-term and late effects directly after initial diagnosis. It may be better to provide the information in the SCP in different parts at different time points, so that patients only receive information that is directly relevant for them at that specific time. Thus, at initial diagnosis, patients would for instance receive the treatment summary, including information on their cancer, diagnostic tests, treatment, and contact details, whereas at the end of treatment, patients would receive the follow-up care plan, including information on possible short-term, long-term and late effects, signs of recurrence, and supportive care services. Health care providers could also tailor the timing of the information in the SCP to patients' individual needs, by asking their patients when they would like to receive certain information. Future research needs to investigate whether this approach is effective and feasible in routine clinical practice.

### ***Who should deliver the SCP?***

There is no clear consensus regarding who should develop and provide the SCP<sup>56,57,65</sup>. Previous qualitative studies have suggested primary care physicians<sup>66,67</sup>, oncology providers<sup>68</sup>, and oncology nurses<sup>69</sup>. In the ROGY Care trial, the oncology 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. The results of this thesis showed that none of the oncology providers indicated that the primary care physician should provide the SCP. In contrast, the majority of the oncology providers indicated that the oncology nurse should provide the SCP. However, because we did not ask the oncology providers about their motivation, their motives for this preference remain unclear. It is possible that oncology providers consider providing the information and follow-up plan in SCPs primarily as a task for oncology nurses. On the other hand, it is also possible that this finding partly reflects the perceived time barriers. In addition, it

remains unclear whether gynecologists/gynecologic oncologists have a different view regarding who should deliver the SCP than oncology nurses. Future research needs to examine whether oncology nurses are indeed more suitable for delivering SCPs than other providers<sup>55</sup>, and whether the outcomes of SCPs are impacted by who delivers the SCP. Furthermore, oncology providers' and patients' preferences regarding the delivery of the SCP need to be investigated in more detail. In addition, future research is needed to explore whether a more active patient involvement in obtaining the SCP may be desirable [68], for instance by referring patients to an online tool, where they can generate the SCP themselves. Previous research investigating a free online tool, that enables patients to generate their own SCP, seem promising<sup>70-72</sup>.

### **Concluding remarks**

Using SCPs to help cancer survivors deal with the long-term or late effects of their cancer was proposed by the IOM in 2006<sup>6</sup>. Nearly 10 years later, some progress has been made. This thesis provides new insight, by showing that SCPs did not increase patients' satisfaction with the received information and care, but did increase the degree to which the illness was perceived as threatening and the amount of cancer-related contact with the primary care physician. In addition, this thesis reveals that the impact of SCPs was different for patients who did or did not search for disease-related information on the Internet. Finally, this thesis shows that, although there were practical barriers, oncology providers were generally satisfied with the SCP, and that SCPs improved the communication of primary care physicians with medical specialists and patients. However, essential questions about SCPs still remain unanswered: Are SCPs beneficial for cancer survivors or not, and for which cancer survivors in particular? Are similar outcomes of SCPs found across different clinical settings and countries? What is the optimal content, length, and format of SCPs, and how feasible is this in routine clinical practice? When and by whom can SCPs best be provided? What are the costs associated with the implementation of SCPs? At present, there is not enough evidence to warrant large-scale implementation of SCPs, or to abandon SCPs altogether. Future research needs to investigate these remaining gaps in the knowledge about SCPs. At the same time, it is important to bear in mind that SCPs are not a purpose in itself, but merely a possible tool to improve the quality of information provision and follow-up care for cancer survivors. It may well be possible that tailored information can be provided to cancer survivors in more effective ways than SCPs. Future research should not forget to keep exploring the best possible way to provide cancer survivorship care.

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**Nederlandse samenvatting**

Dutch summary



## INLEIDING

### Baarmoederkanker

Baarmoederkanker is de meest voorkomende kanker van de vrouwelijke geslachtsorganen in ontwikkelde landen. In Nederland wordt per jaar bij ongeveer 1.700 vrouwen baarmoederkanker vastgesteld. Dit aantal neemt toe doordat mensen steeds ouder worden (en mensen juist op latere leeftijd vaker kanker krijgen) en door factoren die het risico op de ziekte vergroten, zoals de toename van overgewicht in de maatschappij. De meest toegepaste behandeling bij baarmoederkanker is een operatie. Dit wordt in sommige gevallen gecombineerd met bestraling en/of chemotherapie. De overlevingskansen zijn over het algemeen goed, omdat bij meer dan 75% van de vrouwen de ziekte in een vroeg stadium wordt ontdekt. Vijf jaar na de diagnose is nog 80% van de patiënten in leven. Door het groeiend aantal vrouwen dat baarmoederkanker krijgt en door de over het algemeen goede overlevingskansen, is het aantal vrouwen dat ooit de diagnose baarmoederkanker kreeg en nu nog in leven is de afgelopen jaren aanzienlijk toegenomen. Op dit moment zijn er in Nederland ongeveer 20.000 (ex-)baarmoederkankerpatiënten.

### Follow-up bij baarmoederkanker

Na de behandeling blijven vrouwen met baarmoederkanker gedurende een aantal jaar onder controle bij hun specialist volgens een vaststaand schema. Dit wordt ook wel de follow-up periode genoemd. In Nederland ontvangen ongeveer 7.000 vrouwen met baarmoederkanker routinematige follow-up controles. Redenen voor follow-up zijn onder andere (1) het vroeg vaststellen van terugkeer van de ziekte of uitzaaiingen om de overleving en/of kwaliteit van leven te verbeteren, (2) het monitoren van lange termijn en late effecten van de kanker en behandeling, (3) het bieden van psychologische steun en (4) het verstrekken van informatie. Intensieve follow-up schema's brengen echter hoge kosten met zich mee en kunnen leiden tot meer zorgen en angstgevoelens bij patiënten. De huidige Nederlandse richtlijnen adviseren een follow-up periode van 5 jaar, waarbij in de eerste 2 jaar na de behandeling iedere 3 tot 4 maanden een controle plaatsvindt, in het derde jaar iedere 4 tot 6 maanden en in het vierde en vijfde jaar jaarlijks. Er bestaat echter nog veel onduidelijkheid over het optimale follow-up schema bij baarmoederkanker, omdat er weinig bewijs is of intensieve follow-up schema's gunstiger of juist minder gunstig zijn dan minder intensieve follow-up schema's. De bestaande richtlijnen zijn niet goed onderbouwd en zijn verschillend tussen landen en instellingen. Meer inzicht in de aspecten die samenhangen met het gebruik van follow-up en de voorkeur van (ex-)baarmoederkankerpatiënten over de follow-up zou zorgverleners kunnen helpen bij het beter organiseren van follow-up controles bij baarmoederkanker.

## **Het belang van informatievoorziening**

Het verstrekken van op maat gemaakte informatie, die aansluit bij de behoefte van de patiënt, is één van de belangrijkste aspecten van de ondersteunende zorg voor (ex-)kankerpatiënten. Patiënten die goed geïnformeerd zijn kunnen bijvoorbeeld beter beslissingen nemen over hun behandeling, hebben het gevoel meer controle te hebben over hun ziekte, zijn meer tevreden over de informatievoorziening en zorg en hebben minder last van psychische klachten zoals angst en depressieve gevoelens. Uit eerder onderzoek blijkt dat de meeste (ex-)kankerpatiënten graag zo veel mogelijk informatie willen ontvangen, maar dat de informatiebehoefte afhangt van aspecten zoals het soort kanker, de leeftijd, het geslacht en het opleidingsniveau van de patiënt. Het vaststellen van de specifieke informatiebehoefte van (ex-)baarmoederkankerpatiënten en de aspecten die daarmee samenhangen, zou zorgverleners kunnen helpen bij het verstrekken van informatie die beter aansluit bij de specifieke behoeften van deze patiënten.

## **De invloed van een persoonlijk zorgplan**

Om het groeiende aantal (ex-)kankerpatiënten te ondersteunen, adviseerden zowel het Amerikaanse Institute of Medicine (IOM) en de Nederlandse Gezondheidsraad om aan iedere patiënt met kanker een persoonlijk zorgplan uit te reiken. Een persoonlijk zorgplan is een formeel document met daarin op maat gemaakte informatie over onder andere de kanker, diagnose, behandeling, contactgegevens van de betrokken zorgverleners, mogelijke korte en lange termijn effecten, tekenen van terugkeer van de kanker, revalidatiemogelijkheden en psychologische hulp. Er werd verwacht dat persoonlijke zorgplannen zouden kunnen voorzien in de informatiebehoefte van patiënten en zouden kunnen zorgen voor een betere communicatie tussen de verschillende betrokken zorgverleners tijdens de follow-up periode. Echter, wetenschappelijk bewijs voor de mogelijke effecten van het implementeren van persoonlijke zorgplannen in de dagelijkse klinische praktijk ontbrak. Om goed onderbouwde beslissingen te kunnen nemen over het wel of niet grootschalig implementeren van persoonlijke zorgplannen in de dagelijkse klinische praktijk, was het noodzakelijk om de invloed van persoonlijke zorgplannen op patiënt- en zorgverlener-gerapporteerde uitkomsten te evalueren.

## Doel van dit proefschrift

De belangrijkste doelstellingen van de in dit proefschrift beschreven studies waren:

- Het evalueren van de huidige staat van de informatievoorziening en follow-up bij (ex-)baarmoederkankerpatiënten. Daarnaast zijn associaties met patiënt-, tumor-, en behandelgegevens onderzocht.
- Het evalueren van de invloed van een automatisch gegeneerd persoonlijk zorgplan op patiënt gerapporteerde uitkomsten in de dagelijkse klinische praktijk. Daarnaast zijn de ervaringen van de betrokken zorgverleners onderzocht.

## Belangrijkste bevindingen van dit proefschrift

### *Informatievoorziening en follow-up bij (ex-)baarmoederkankerpatiënten*

In dit proefschrift ben ik begonnen met het in kaart brengen van de hoeveelheid ontvangen informatie en de tevredenheid met de ontvangen informatie bij (ex-)baarmoederkankerpatiënten (**Hoofdstuk 2**). Voor het onderzoek werden alle vrouwen die tussen 1999 en 2007 gediagnosticeerd waren met baarmoederkanker uitgenodigd om een vragenlijst in te vullen. Van de 965 (ex-)baarmoederkankerpatiënten die een uitnodiging ontvingen, vulden 742 (77%) patiënten de vragenlijst in. De meeste patiënten gaven aan dat zij redelijk veel informatie hadden ontvangen over hun ziekte en de medische onderzoeken. Echter, meer dan de helft van de patiënten gaf aan dat zij niet of slechts een beetje geïnformeerd waren over de mogelijke oorzaak van hun ziekte (78%) en de mogelijke bijwerkingen van hun behandeling (63%). Vooral informatie over de nazorg, zoals revalidatiemogelijkheden, psychologische hulp, aanvullende hulp en verwachte effecten van de behandeling op het sociale en seksuele leven, ontbrak vaak. Daarnaast was een aanzienlijk deel van de patiënten niet of slechts een beetje tevreden (41%) met de ontvangen informatie en vond de informatie niet of slechts een beetje nuttig (39%). Verder liet dit onderzoek zien dat (1) patiënten die korter geleden waren gediagnosticeerd, (2) getrouwd waren, (3) hoger opgeleid waren, (4) minder andere aandoeningen naast baarmoederkanker hadden en (5) vaker radiotherapie hadden ondergaan, aangaven meer informatie te hebben ontvangen. De resultaten van dit onderzoek suggereren dat er ruimte is voor verbetering van de informatievoorziening bij baarmoederkankerpatiënten. De in dit onderzoek vastgestelde aspecten die samenhangen met de informatievoorziening en informatiebehoeften zouden zorgverleners kunnen helpen bij het verstrekken van informatie die beter aansluit bij de specifieke behoeften van baarmoederkankerpatiënten.

Omdat er nog veel onduidelijkheid bestaat over het optimale follow-up schema bij baarmoederkanker, heb ik in **Hoofdstuk 3** geëvalueerd in welke mate (ex-) baarmoederkankerpatiënten follow-up ontvangen volgens de Nederlandse richtlijn en met welke aspecten het gebruik van follow-up samenhangt. Daarnaast is gekeken naar hoe prettig patiënten zich voelen bij hun follow-up-schema. Voor dit onderzoek is gebruik gemaakt van de eerder verzamelde gegevens van 742 vrouwen die tussen 1999 en 2007 gediagnosticeerd waren met baarmoederkanker. De meeste patiënten gaven aan dat zij follow-up hadden ontvangen volgens de landelijke richtlijn. Echter, er was sprake van grote variatie in de ontvangen follow-up, waarbij zowel overconsumptie als onderconsumptie voorkwam. In totaal had 19% van de patiënten meer follow-up afspraken gehad dan voorgeschreven in de richtlijn. Overconsumptie van follow-up was het laagst in het eerste follow-up jaar (13%) en het hoogst in de latere follow-up jaren 6-10 (27%). Patiënten die meer follow-up hadden ontvangen dan volgens de richtlijn aanbevolen, hadden vaker een andere aandoening naast baarmoederkanker en maakten zich meer zorgen over de terugkeer van hun ziekte. Daarnaast verschilde de mate van overconsumptie van follow-up in de deelnemende ziekenhuizen. Verder liet dit onderzoek zien dat de meeste patiënten (83%) zich prettig voelden bij hun follow-up schema. Echter, patiënten in de follow-up jaren 6-10 voelden zich minder vaak prettig bij hun follow-up schema (69% voelde zich prettig) en gaven vaker aan dat zij geen follow-up afspraken meer wilden ontvangen. De bevindingen van deze studie suggereren dat een kritische evaluatie van de huidige follow-up praktijk noodzakelijk is. De verkregen inzichten in de aspecten die samenhangen met het gebruik van follow-up en de voorkeur van patiënten kunnen bijdragen aan een verbetering van de organisatie van de follow-up bij baarmoederkankerpatiënten.

### ***Invloed van een persoonlijk zorgplan op patiënt gerapporteerde uitkomsten***

In **Hoofdstuk 4** werden de rationale en het studiedesign van de pragmatische cluster gerandomiseerde ROGY Care trial beschreven. Het doel van de ROGY Care trial was om de invloed van een automatisch gegenereerd persoonlijk zorgplan op patiënt gerapporteerde uitkomsten in de dagelijkse klinische praktijk te evalueren. Daarnaast wilde ik onderzoeken hoe zorgverleners het zorgplan in de dagelijkse klinische praktijk evalueren. Een zorgplan-applicatie werd gebouwd in het web-gebaseerde Registratiesysteem Oncologische Gynaecologie (ROGY). Door te klikken op de zorgplan-knop in ROGY, kon een persoonlijk op maat gemaakt zorgplan automatisch worden gegenereerd. Het studiedesign was een pragmatische cluster gerandomiseerde trial, waarin 6 ziekenhuizen het zorgplan verstrekten (zorgplan-arm) en 6 ziekenhuizen de gebruikelijke informatievoorziening aanhielden (gebruikelijke zorg-arm). Alle vrouwen die nieuw gediagnosticeerd waren met baarmoederkanker en eierstokkanker

in de deelnemende ziekenhuizen werden uitgenodigd om een vragenlijst in te vullen direct na de operatie en na 6, 12, 18 en 24 maanden. Daarnaast werden de betrokken zorgverleners gevraagd naar hun ervaringen met het zorgplan. De primaire uitkomstmaten van het onderzoek waren patiënttevredenheid met de ontvangen informatie en zorg. De secundaire uitkomstmaten waren ziekteperceptie, zorggebruik, psychosociale problemen en doorverwijzing naar aanvullende zorg, zorg-gerelateerde kwaliteit van leven en de evaluatie van het persoonlijk zorgplan door de betrokken zorgverleners.

De patiënt gerapporteerde uitkomsten van de ROGY Care trial voor baarmoederkanker patiënten tot 12 maanden na de diagnose werden onderzocht in **Hoofdstuk 5**. Van de 296 patiënten die in aanmerking kwamen voor de studie, vulden 221 (75%) patiënten de eerste vragenlijst in. Na 6 maanden vulden 158 (53%) patiënten de vragenlijst in en na 12 maanden 147 (50%) patiënten. In de zorgplan-arm gaf 74% van de patiënten aan dat zij een zorgplan ontvangen hadden. Patiënten in de zorgplan-arm gaven aan dat zij meer informatie hadden ontvangen over hun behandeling, aanvullende hulp en verschillende verzorgingslocaties dan patiënten in de gebruikelijke zorg-arm. Er waren echter geen verschillen in tevredenheid met de ontvangen informatie en zorg. Daarnaast ervoeren patiënten in de zorgplan-arm (1) meer symptomen, (2) waren zij bezorgder over hun ziekte, (3) waren zij meer emotioneel beïnvloed en (4) gaven zij aan vaker contact te hebben gehad met hun huisarts over hun kanker dan patiënten in de gebruikelijke zorg-arm. Deze effecten verschilden niet over de tijd. De bevindingen van deze studie suggereren dat persoonlijke zorgplannen de patiënttevredenheid met de ontvangen informatie en zorg niet verbeteren. Het blijft echter onduidelijk of de bevinding dat persoonlijke zorgplannen de ervaren symptomen, zorgen, emotionele impact en zorggebruik verhoogden gunstig of juist ongunstig is. Aan de ene kant is het mogelijk dat informatie in het zorgplan over mogelijke late effecten negatieve gevolgen heeft op de psychologische aanpassing aan de ziekte en het ervaren van late effecten vergroot. Aan de andere kant is het echter ook mogelijk dat het ontvangen van een persoonlijk zorgplan patiënten bewuster maakt van het feit dat bepaalde klachten gerelateerd zijn aan hun kanker en dat het zorgplan hen helpt bij het vinden van de benodigde steun.

Omdat het internet steeds meer gebruikt wordt als bron van informatie, heb ik in **Hoofdstuk 6** onderzocht of de effecten van het persoonlijk zorgplan verschilden voor patiënten die het internet gebruikten om informatie over hun ziekte te zoeken in vergelijking met patiënten die dit niet deden. In totaal gaven 80 (37%) patiënten aan dat zij het internet gebruikt hadden om informatie te zoeken over hun ziekte.

Het persoonlijk zorgplan leek de hoeveelheid ontvangen informatie over de ziekte en de medische onderzoeken, het nut van de informatie en het begrip van de ziekte te verbeteren voor patiënten die het internet niet gebruikten om informatie te zoeken over hun ziekte. Dit zou erop kunnen wijzen dat papieren zorgplannen een bruikbaar hulpmiddel kunnen zijn om patiënten die geen informatie zoeken op het internet meer inzicht en controle over hun ziekte te geven. Het zorgplan leek echter niet nuttig te zijn voor patiënten die het internet wel gebruikten om informatie te zoeken over hun ziekte. Het is mogelijk dat het papieren zorgplan in de huidige vorm niet geschikt is voor deze patiënten. Meer onderzoek is nodig om te evalueren of een op maat gemaakt online zorgplan wel een meerwaarde zou kunnen hebben voor deze patiënten.

### ***Invloed van een persoonlijk zorgplan op zorgverlener gerapporteerde uitkomsten***

Het verstrekken van persoonlijke zorgplannen aan patiënten is niet eenvoudig en vraagt om actieve betrokkenheid van de oncologische zorgverleners (medisch specialisten en oncologieverpleegkundigen). In **Hoofdstuk 7** zijn daarom de verwachtingen (vóór de interventie) en de daadwerkelijke ervaringen (na de interventie) van de oncologische zorgverleners in de ROGY Care trial met het persoonlijk zorgplan geëvalueerd. Alle 43 oncologische zorgverleners die deelnamen aan de studie werd gevraagd om een vragenlijst in te vullen, zowel vóór als na de inclusie van patiënten in de studie. Vóór de patiëntinclusie vulden 38 (88%) zorgverleners de vragenlijst in en na de patiëntinclusie 35 (83%). De zorgverleners waren over het algemeen tevreden met het zorgplan, geloofden dat het zorgplan een positieve invloed had op de patiënten en waren gemotiveerd om het zorgplan te blijven gebruiken. Daarnaast leek het automatisch genereren van het zorgplan vanuit ROGY een aantal praktische problemen te verbeteren die in eerdere studies vaak genoemd werden (zoals hoge kosten en gebrek aan benodigde materialen om het zorgplan te maken). Desondanks gaven de meeste zorgverleners aan (64%) praktische problemen te ervaren bij het verstrekken van het zorgplan. Het meest gerapporteerde probleem was het vinden van een geschikt moment om het zorgplan te bespreken. Een kwart van de zorgverleners had het gevoel meer tijd kwijt te zijn aan hun consulten vanwege het zorgplan. Deze bevindingen suggereren dat het nodig is om de ervaren praktische problemen aan te pakken voordat persoonlijke zorgplannen kunnen worden geïmplementeerd in de dagelijkse klinische praktijk.

Om de toenemende druk op de specialistische zorg te verlichten, wordt momenteel bekeken of het mogelijk is om de follow-up controles te verplaatsen van de medisch specialist naar de huisarts. In **Hoofdstuk 8** heb ik onderzocht of persoonlijke zorgplannen een faciliterende rol zouden kunnen spelen in deze transitie. Daarvoor heb ik de invloed van het versturen van een persoonlijk zorgplan aan huisartsen op

de communicatie tussen huisartsen, medisch specialisten en patiënten onderzocht. Daarnaast heb ik de mening van de huisartsen over het zorgplan geëvalueerd. Ik heb alle betrokken huisartsen 2 tot 3 maanden na de patiëntinclusie een vragenlijst gestuurd en 266 (76%) huisartsen hebben een vragenlijst ingevuld. Een derde van de huisartsen in de zorgplan-arm gaf aan een zorgplan te hebben ontvangen. Huisartsen in de zorgplan-arm gaven vaker aan dat zij persoonlijk contact hadden gehad met de medisch specialist (52%) dan huisartsen in de gebruikelijke zorg-arm (37%). Echter, het zorgplan had geen invloed op de tevredenheid met de informatie. Een kwart van de huisartsen die een zorgplan hadden ontvangen gaf aan dat het zorgplan het contact met de patiënt ondersteunde. Van alle huisartsen gaf 82% aan dat ze in de toekomst een zorgplan zouden willen ontvangen. Echter, dit zorgplan zou dan wel beknopter moeten zijn en meer moeten aansluiten bij de specifieke behoeften van huisartsen. De bevindingen van deze studie suggereren dat het versturen van een persoonlijk zorgplan aan huisartsen een positief effect zou kunnen hebben op de communicatie tussen huisartsen, medisch specialisten en patiënten, en daardoor wellicht een faciliterende rol zou kunnen spelen bij de transitie van de follow-up controles van de medisch specialist naar de huisarts. Hiervoor zijn echter verbeteringen nodig in de lengte, inhoud en wijze van het verstrekken van het zorgplan.

### **Concluderende opmerkingen**

Het gebruik van persoonlijke zorgplannen om het groeiende aantal (ex-)kankerpatiënten te ondersteunen bij de lange-termijn en late effecten van hun kanker werd voorgesteld door het Amerikaanse IOM in 2006. Bijna 10 jaar later is er enigszins vooruitgang geboekt. Dit proefschrift verschaft nieuw inzicht door aan te tonen dat persoonlijke zorgplannen de patiënttevredenheid met de ontvangen informatie en zorg niet verbeterden, maar dat ze wel de ervaren symptomen, emotionele invloed van de ziekte en het contact met de huisarts over de kanker verhoogden. Daarnaast toont dit proefschrift aan dat de invloed van persoonlijke zorgplannen verschillend was voor patiënten die het internet gebruikten om informatie over hun ziekte te zoeken in vergelijking tot patiënten die dit niet deden. Ten slotte toont dit proefschrift aan dat, hoewel er praktische problemen werden ervaren, oncologische zorgverleners over het algemeen tevreden waren met het zorgplan en dat zorgplannen de communicatie tussen huisartsen, medisch specialisten en patiënten verbeterden. Echter, essentiële vragen over persoonlijke zorgplannen blijven nog onbeantwoord: Zijn persoonlijke zorgplannen gunstig of juist ongunstig voor (ex-)kankerpatiënten en voor welke patiënten in het bijzonder? Worden vergelijkbare uitkomsten van persoonlijke zorgplannen gevonden in verschillende klinische situaties en landen? Wat is de optimale inhoud, lengte en vorm voor persoonlijke zorgplannen en hoe haalbaar is dit in de dagelijkse klinische praktijk? Wanneer en door wie kunnen

persoonlijke zorgplannen het best worden verstrekt? Welke kosten moeten worden gemaakt bij de implementatie van persoonlijke zorgplannen? Op dit moment is er niet voldoende bewijs om grootschalige implementatie van persoonlijke zorgplannen te rechtvaardigen, of om persoonlijke zorgplannen volledig af te schaffen. Toekomstig onderzoek is nodig om de overgebleven hiaten in de kennis over persoonlijke zorgplannen aan te pakken. Tegelijkertijd is het van belang om in gedachten te houden dat persoonlijke zorgplannen niet een doel op zich zijn, maar slechts een middel om de kwaliteit van de informatievoorziening en follow-up zorg voor (ex-)kankerpatiënten te verbeteren. Het is goed mogelijk dat op maat gemaakte informatie aan (ex-)kankerpatiënten kan worden verstrekt op effectievere manieren dan met persoonlijke zorgplannen. Daarom moet er in toekomstig onderzoek gezocht blijven worden naar de best mogelijke manier om ondersteunende zorg te bieden aan (ex-)kankerpatiënten.

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Kim Schellekens-Nicolaije  
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## **List of publications**



## PUBLICATIONS INCLUDED IN THIS THESIS

1. **Nicolaije KA**, Ezendam NP, Pijnenborg JM, Boll D, Vos MC, Kruitwagen RF, van de Poll-Franse LV. Paper Survivorship Care Plans may be less helpful for cancer patients who search for disease-related information on the Internet: Results of the ROGY Care trial. *Revision submitted*.
2. **Nicolaije KA**, Ezendam NP, Vos MC, Pijnenborg JM, Boll D, Boss EA, Hermans RH, Engelhart KC, Haartsen JE, Pijlman BM, van Loon-Baelemans EA, Mertens HJ, Nolting WE, van Beek JJ, Roukema JA, Zijlstra WP, Kruitwagen RF, van de Poll-Franse LV. The impact of an automatically generated cancer survivorship care plan on patient-reported outcomes in routine clinical practice: Longitudinal outcomes of the pragmatic, cluster randomized ROGY Care trial. *Journal of Clinical Oncology*, 2015; 33(31): 3550-3559.
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1. Verkissen MN, Ezendam NP, Fransen MP, Essink-Bot ML, Aarts MJ, **Nicolaije KA**, Vos MC, Husson O. The role of health literacy in perceived information provision and satisfaction among women with ovarian tumors: a study from the population-based PROFILES registry. *Patient Education and Counseling*, 2014; 95(3): 421-428.
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Kim A.H. Nicolaije was born on November 23, 1985 in Heerlen, the Netherlands. She completed secondary education at the Bernardinuscollege in Heerlen in 2004, and subsequently obtained her Bachelor's degree in Social Science (with a major in psychology and a minor in cognitive neuroscience) at University College Utrecht in 2007. She completed the Research Master program Social and Health Psychology at Utrecht University cum laude in 2010. Subsequently, she started her PhD research at Tilburg University and the Comprehensive Cancer Centre The Netherlands in 2010. Her research focused on the impact of Survivorship Care Plans on endometrial cancer patient- and health care provider- reported outcomes. Currently, she is working as a Psychology teacher at Utrecht University.

