

A survivorship care plan for breast cancer survivors: extended results of a randomized clinical trial

Annelies H. Boekhout · Elizabeth Maunsell ·
Gregory R. Pond · Jim A. Julian · Doug Coyle ·
Mark N. Levine · Eva Grunfeld · for the FUPII Trial
Investigators

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Abstract

Purpose Prevailing wisdom suggests that implementation of a survivorship care plan (SCP) will address deficits in survivorship care planning and delivery for cancer patients. Here, we present 24-month results of a randomized clinical trial on health service and patient-reported outcomes among breast cancer patients transferred to their primary care physician for follow-up care. The 24-month assessments represent the long-term benefit and sustainability of the implantation of a SCP. **Methods** In all, 408 patients with early-stage breast cancer were randomized to the SCP or control group. Patient self-completed questionnaires, supplemented with telephone interviews, during the 24-month study period assessed health service and patient-reported outcomes. The primary outcome

was cancer-specific distress. Secondary outcomes included health-related quality of life, patient satisfaction, continuity and coordination of care, and health service outcomes such as adherence to guidelines.

Results Over the course of 24 months, there were no differences between both groups in health service and patient-reported outcomes. Women from Quebec compared to those from Western Canada ($p < 0.001$), women within 2 years of completion of primary treatment compared to a longer period ($p = 0.013$), and those with a higher SF-36 mental component score compared to a lower score ($p = 0.044$) were positively associated with adherence to guidelines.

Conclusion The implementation of a SCP in the transition of survivorship care from cancer center to primary care did not

The FUPII Trial Investigators J. Wiernikowski, S. Dent, D. Rayson, D. Rheaume, G. Porter, A. Joy, S. Smith, L. Provencher, J. Sussman, S. Lupichuk, L. Paszat, K. Pritchard, A. Robidoux, J. J. Sisler

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A. H. Boekhout · E. Grunfeld
Department of Family and Community Medicine, University of
Toronto, Toronto, Ontario, Canada

A. H. Boekhout (✉)
Netherlands Cancer Institute, Antoni van Leeuwenhoek Hospital,
Plesmanlaan 121, 1066 CX Amsterdam, The Netherlands
e-mail: a.boekhout@nki.nl

E. Maunsell
Center de Recherché du CHU de Québec, Québec, Québec, Canada

E. Maunsell
Département de Médecine Sociale et Préventive, Université Laval,
Québec, Québec, Canada

G. R. Pond · J. A. Julian · M. N. Levine
Ontario Clinical Oncology Group, Hamilton, Ontario, Canada

G. R. Pond · J. A. Julian · M. N. Levine
Department of Oncology, McMaster University, Hamilton, Ontario,
Canada

D. Coyle
Department of Epidemiology and Community Medicine, University
of Ottawa, Ottawa, Ontario, Canada

E. Grunfeld
Ontario Institute for Cancer Research, Toronto, Ontario, Canada

contribute to improved health service or patient-reported outcomes in this study population. Therefore, additional research is needed before widespread implementation of a SCP in clinical practice.

Implications of Cancer Survivors The transition of survivorship care from cancer center to the primary care setting showed no negative effect on health service and patient-reported outcomes.

Keywords Breast cancer · Survivorship care plan · Randomized clinical trial

Introduction

The number of cancer survivors worldwide is steadily increasing. It has been usual practice for survivorship care to be specialist-led, usually within the cancer center where primary treatment was delivered [1]. Because of the growing prevalence of cancer survivors and their specific care needs, this traditional model of specialist and cancer center survivorship care is no longer sustainable [2].

Several different models of survivorship care have been proposed [3]. There is evidence that survivorship care can be provided by specialists, primary care physicians (PCP), nurses, or by sharing the care among a multidisciplinary team [4–6].

Cancer organizations worldwide [7] promote the use of survivorship care plans (SCPs). SCPs are purported to facilitate a seamless transition from active cancer care to survivorship care, specifically as it relates to the transition to the primary care setting [8]. Although many articles outline the potential benefits of SCPs, research on SCPs to date has been largely theoretical [8–10]. A smaller number of studies have evaluated the impact of SCPs on processes of care, health service, and patient-reported outcomes [11–13]. We conducted the first randomized clinical trial (RCT) evaluating a SCP. The objective of the RCT was to determine if a SCP for breast cancer survivors ready for transition from oncologist care to care with their own PCP improved outcomes [14]. We hypothesized that patient-reported outcomes would be positively affected by the implementation of a SCP. By delivering the SCP as teaching strategy, patients will be involved in the problem solving process, and they might be able to manage their psychosocial needs and have a sense of control over one's life. Moreover, we hypothesized that a SCP would increase recommended medical surveillance test rates and decrease rates of non-recommended testing. Results of the first planned analysis with outcomes measured at 12 months post-randomization showed that the implementation of a SCP achieved no statistically significant improvement on any of the patient-reported

or health service outcomes [20] and was not cost-effective [15]. Here, we report the final results of the trial with health service and patient-reported outcomes measured at 24 months. By evaluating health service and patient-reported outcomes, repeated observations are needed to uncover the influence of incidental behaviors or occasionally circumstances.

Methods

The setting of the RCT was specialized cancer centers throughout Canada. Details of the trial protocol and 12-month outcomes are reported elsewhere [14]. The study was approved by the ethics committees of each participating center.

Study population

Four hundred and eight patients were enrolled through nine specialized cancer centers, representing a 64 % participation rate. Eligible patients were those with early-stage breast cancer under active routine follow-up who were without recurrence or new primary cancer, having completed primary adjuvant treatment at least 3 months before entry into the study, and had a PCP to provide follow-up care. Patients were excluded if they had persistent complications of primary treatment, were previously enrolled in a study that required continued oncology follow-up, were actively observed for another primary cancer, or had a PCP who already had a patient enrolled in the study.

Design and procedures

Eligible patients were randomly assigned to PCP-led routine follow-up care without a SCP (control group) or with a SCP (intervention group) in a 1:1 ratio. Patients in both groups had a standard discharge visit with their oncologist and were informed that responsibility for continued routine follow-up care was now transferred to their PCP, and all PCPs were sent a discharge letter. In the intervention group, patients also received a 30-min educational session with a nurse, a comprehensive SCP [8] consisting the prescribed key elements including a personalized treatment summary, a patient's version of the Canadian follow-up guidelines [16], and a resource kit tailored to the patient's needs on available supportive care resources. These documents were also sent to the patient's PCP together with the full clinical practice guideline on follow-up care [17], a summary of the guideline, and a follow-up visit reminder table. Center-specific stratified randomization was performed along with stratification for time after diagnosis: <24 months after diagnosis ($n=180$) and ≥ 24 months after diagnosis ($n=228$). Patients completed

questionnaires at baseline, 3, 6, 12, 18, and 24 months, and brief telephone interviews at 9, 15, and 21 months.

Outcomes

Health service outcomes

1. Adherence to the guideline on follow-up care was assessed in each questionnaire and telephone interview. Patients were asked to record the frequency and types of follow-up visits to the PCP, the oncologist, and the frequency and types of diagnostic and screening measurements.
2. Patient knowledge of which physician was primarily responsible for follow-up care was assessed at baseline, which was the last follow-up appointment with the oncologist, and at each questionnaire.
3. Reasons for post-discharge cancer center visits were assessed in each questionnaire and telephone interview.

Patient-reported outcomes

Levels of cancer-specific distress, psychological distress, health-related quality of life, patient satisfaction, and continuity and coordination of care were assessed by the Impact of Event Scale (IES) [18, 19], the Profile of Mood States questionnaire (POMS) [20], the Physical and Mental Component SF-36 summary scales (PCS, MCS) [21, 22], the Medical Outcomes Study-Patient Satisfaction Questionnaire (MOS-PSQ) [23], and the Continuity and Coordination of Care Questionnaire (CCCQ) [24–26].

Statistical methods

The sample size calculation and the statistical methods for the primary (the change in IES total score) and secondary endpoints of patient-reported outcomes (POMS, PCS, MCS, MOS-PSQ, and CCCQ questionnaires) have been described in detail previously [14]. A linear mixed model was used to determine intervention group effects on primary and secondary patient-reported outcomes due to time from diagnosis. Mean change scores from baseline and between-group differences were calculated for all the patient-reported outcomes. Score changes of >1 point from baseline (5 % of the scale breadth) were considered as potentially clinically meaningful [27]. The adherence to the guideline was calculated according to the procedures of Hutchison et al. [23]. The number of recommended maneuvers (i.e. clinical examination and breast imaging—mammograms, breast magnetic resonance imaging

(MRI), or breast ultrasound) and the number of non-recommended maneuvers (i.e. routine imaging with bone scan, computed tomography (CT) scan, chest X-ray, abdominal ultrasound, or MRI scan) were calculated based on the clinical practice guideline [17]. Since the Canadian clinical guideline does not recommend any particular frequency of clinical breast examinations, the ASCO guideline was used [28]. The adherence score for each patient was calculated as the number of recommended maneuvers minus the number of the non-recommended maneuvers over 24 months. A multivariable logistic regression analysis was performed to determine the association of factors prognostic for adherence to the guideline (defined as at least two breast imaging tests over the 24 months). Forward stepwise selection was used to identify factors prognostic for adherence to guidelines. The frequency and reasons for post-discharge cancer center visits were compared between groups using the Fisher's exact test. The proportion of patients who correctly identified their PCP as primary responsible for follow-up care was calculated using the number of patients reporting at least one physician responsible in the denominator. The difference between groups was estimated by using the continuity-corrected Wilson score statistic. All statistical analyses were performed with SAS version 9.1 or R version 2.7.1.

Results

Patients

Of 408 women enrolled in the trial, 337 were followed ≥ 18 months after randomization and are included in this analysis (CONSORT diagram; Supplemental File 1). These patients had longer time from primary treatment to study randomization ($p=0.041$), were more likely to be married/cohabiting ($p=0.006$), and more likely to be from Quebec or Western Canada ($p=0.026$) than patients who were not followed for at least 18 months (Supplemental File 2). Baseline characteristics were balanced between the control and intervention groups (Table 1).

Health service outcomes

Adherence to guidelines

Over the 24 months, 230 patients had at least two breast imaging tests: 113 (68.9 %) in the intervention and 117 (67.6 %) in the control group ($p=0.82$). In contrast, 45 (13.5 %) women had no breast imaging tests: 19 (11.6 %) in the intervention group and 26 (15 %) in the control group ($p=0.42$). No difference between the control and intervention group was

Table 1 Baseline characteristics by group

Baseline characteristic	Control No survivorship care plan (n=173)		Intervention Survivorship care plan (n=164)	
Age: mean (SD)	61.9 (10.2)		61.1 (10.2)	
Range	38.1–87.5		35.6–87.8	
Education: n (%)				
Less than secondary	12	(6.9)	13	(7.9)
Completed secondary	46	(26.6)	46	(28.0)
Post-secondary	92	(53.2)	84	(51.2)
Unknown	23	(13.3)	21	(12.8)
Marital status: n (%)				
Single	22	(12.7)	14	(8.5)
Married/cohabiting	114	(65.9)	122	(74.4)
Widowed	17	(9.8)	14	(8.5)
Separated/divorced	20	(11.6)	14	(8.5)
Region of Canada: n (%)				
Western	50	(28.9)	48	(29.3)
Ontario	45	(26.0)	43	(26.2)
Quebec	55	(31.8)	51	(31.1)
Atlantic	23	(13.3)	22	(13.4)
Tumour grade: n (%)				
Grade 1	46	(26.6)	34	(20.7)
Grade 2	61	(35.3)	68	(41.5)
Grade 3	49	(28.3)	44	(26.8)
Unknown	17	(9.8)	18	(11.0)
Tumour size (cm): n (%)				
0 to 1.9	101	(58.4)	105	(64.0)
2 to 4.9	58	(33.5)	43	(26.2)
≥5	7	(4.1)	8	(4.9)
Unknown	7	(4.1)	8	(4.9)
Number of positive nodes: n (%)				
0	120	(69.4)	110	(67.1)
1 to 3	37	(21.4)	41	(25.0)
≥4	14	(8.1)	12	(7.3)
Unknown	2	(1.2)	1	(0.6)
Type of surgery: n (%)				
Mastectomy	42	(24.3)	47	(28.7)
Breast-conserving surgery (BCS)	131	(75.7)	117	(71.3)
Type of adjuvant treatment: n (%)				
Radiation	143	(82.7)	133	(81.1)
Chemotherapy	71	(41.0)	68	(41.5)
Hormonal therapy ^a :	130	(75.1)	113	(68.9)
Tamoxifen	95	(54.9)	94	(57.3)
Aromatase inhibitor	53	(30.6)	40	(24.4)
Months from diagnosis ^b : n, mean (range)				
<24 months	69, 11.3 (3.5, 24)		70, 12.3 (3.6, 29)	
≥24 months	104, 79.1 (3.7, 300)		94, 83.4 (11.8, 375)	
Patient-reported measures, mean (SD)				
Cancer-specific distress (IES):				
Intrusion	7.9 (7.0)		7.7 (7.5)	
Avoidance	10.5 (8.6)		11.6 (10.0)	
Total score	18.4 (13.8)		19.3 (15.7)	
Health-related quality of life (SF-36):				
Physical Component (PCS)	48.8 (8.6)		48.7 (8.4)	
Mental Component Scale (MCS)	49.7 (10.3)		51.4 (9.0)	
Patient satisfaction (PSQ):				
Total score	74.7 (18.9)		76.5 (18.8)	
Profile of Mood States questionnaire (POMS):	10.0 (14.3)		8.4 (12.3)	

IES Impact of Event Scale, MCS Mental Component Score, PCS Physical Component SF-36 Score, PSQ Patient Satisfaction Questionnaire, SD standard deviation

^a Some patients were treated with both tamoxifen and an aromatase inhibitor

^b Five patients were randomized based on incorrect stratification information. These patients are included in this summary and in all analyses

Table 2 Adherence to guidelines

	Score	No SCP (n=173) Number of patients (%)	SCP (n=164) Number of patients (%)	p value
Recommended maneuvers				
Clinical examination:				
1	1	40 (23.1)	38 (23.2)	0.84
2	2	32 (18.5)	37 (22.6)	
3 or more	3	70 (40.5)	72 (43.9)	
Breast imaging tests ^a :				
1	1	30 (17.3)	32 (19.5)	0.78
2 or more	2	117 (67.6)	113 (68.9)	
Total recommended score:				
	0	10 (5.8)	2 (1.2)	0.14 ^b
	1	10 (5.8)	14 (8.5)	
	2	31 (17.9)	22 (13.4)	
	3	36 (20.8)	36 (22.0)	
	4	32 (18.5)	30 (18.3)	
	5	54 (31.2)	60 (36.6)	
Not recommended maneuvers				
No breast imaging tests	0	26 (15.0)	19 (11.6)	0.42
No clinical examinations	1	31 (17.9)	17 (10.4)	0.061
Routine bone scan	1	31 (17.9)	24 (14.6)	0.46
Routine CT scan	1	15 (8.7)	20 (12.2)	0.37
Routine abdominal ultrasound	1	41 (23.7)	46 (28.1)	0.39
Routine MRI scan other than breast	1	18 (10.4)	18 (11.0)	1.00
Routine chest X-ray	1	51 (29.5)	62 (37.8)	0.11
Total not recommended score:				
	0	65 (37.6)	55 (33.5)	0.62 ^b
	1	54 (31.2)	61 (37.2)	
	2	33 (19.1)	26 (15.9)	
	3	17 (9.8)	15 (9.2)	
	4	4 (2.3)	6 (3.7)	
	5	0 (0.0)	1 (0.6)	
	6	0 (0.0)	0 (0.0)	
Total adherence score (median, range):		3 (–3 to 6)	3 (–2 to 6)	0.43

CT computed tomography, MRI magnetic resonance imaging, SCP survivorship care plan

^a Imaging tests: mammograms, breast ultrasounds or non-routine breast MRIs within 24 months

^b Cochran-Armitage test for trend

observed in the total adherence score (median=3, $p=0.43$) (Table 2). Education and tumor grade had a substantial proportion of patients with missing data. Neither was significant in the univariate model or the initial multivariate model based on patients with complete data. Hence, these two factors were excluded, and the forward selection process was performed using only the remaining variables. In the multivariable analyses, geographic region ($p<0.001$), time from completion of

primary treatment ($p=0.013$), and SF-36 mental component score ($p=0.044$) were prognostic for adherence with women from Quebec, those with <2 years from completion of primary treatment and those with higher SF-36 mental component scores all showing better adherence scores (Table 3).

Patient knowledge of physician primarily responsible for follow-up

At 24 months, no difference between the intervention and control groups was detected for correctly identifying their PCP as primarily responsible for follow-up; 94.0 vs. 88.4 %, $p=0.10$ and 91.7 vs. 92.0 %, $p=1.0$, respectively (data not shown).

Post-discharge cancer center visits

There were no differences in the frequency or reasons for post-discharge cancer center visits between groups. Overall, ≤ 3 % of patients returned to oncologist care for routine follow-up (Supplemental File 3).

Patient-reported outcomes

No differences between groups were observed in change from baseline to 24 months for cancer-specific distress, psychological distress, health-related quality of life, patient satisfaction, or continuity and coordination of care (Fig. 1). Within strata fluctuations (diagnosed <24 or ≥ 24 months) were small, varying between +0.31 and –0.24 (of 20 points) in the intervention group and –0.21 and +0.24 in the control group. The net between-group difference was +0.52 in patients diagnosed at <24 months and –0.48 in patients diagnosed ≥ 24 months and did not come to the one-point threshold.

Discussion

We previously reported the 12-month results of a RCT evaluating a SCP for breast cancer patients [14]. Here, we report the results extended to 24 months including the outcome of adherence to guidelines, which has not been reported previously. The 24-month assessments were needed to uncover the influence of incidental behaviors or occasionally circumstances on health service and patient-reported outcomes. Moreover, the 24-month assessments represent the long-term benefit and sustainability of the implementation of a SCP. Neither the 12- nor the 24-month analysis of this RCT supports the hypothesis that the implementation of a SCP improves adherence to guidelines, improves patient knowledge regarding which physician is primary responsible for follow-up, reduces the number of post-discharge cancer center visits, or improves patient-reported outcomes over the control condition.

Table 3 Potential prognostic factors for adherence to guidelines

Covariate/factor	Units/comparison	OR (95 % CI)	<i>p</i> value
Univariable logistic models for adherence ^a			
Months to last completed questionnaire	Per month	1.16 (0.98–1.38)	0.092
Randomization group	SCP vs. No SCP	1.06 (0.67–1.68)	0.80
Age at diagnosis	Per year	1.02 (0.99–1.04)	0.20
Age at randomization	Per year	1.02 (0.99–1.04)	0.17
Duration, diagnosis to randomization	≥2 vs. <2 years	0.71 (0.45–1.15)	0.16
Duration, from completion of primary tmt	≥2 vs. <2 years	0.73 (0.46–1.17)	0.19
Prior radiation	Yes vs. no	1.27 (0.71–2.27)	0.42
Prior hormonal therapy	Yes vs. no	1.16 (0.70–1.92)	0.57
Prior chemotherapy	Yes vs. no	0.71 (0.34–1.47)	0.35
Surgery	BCS vs. mastectomy	1.93 (1.17–3.20)	0.010
Tumor grade	Grade 3 vs. 1 or 2	0.67 (0.40–1.11)	0.12
Education: post-HS versus HS or less	Yes vs. no	0.81 (0.49–1.35)	0.42
Marital status: married/cohabiting	Yes vs. no	0.65 (0.39–1.09)	0.11
Employment status: currently employed	Yes vs. no	0.63 (0.40–1.01)	0.053
Any lost earnings	Yes vs. no	0.93 (0.34–2.54)	0.88
Incurred costs to attend clinic or PCP	Yes vs. no	1.34 (0.82–2.18)	0.24
Region of Canada	Western (reference)	1.0	<0.001
	Ontario	0.44 (0.24–0.80)	
	Quebec	3.01 (1.46–6.20)	
	Atlantic	0.44 (0.21–0.91)	
Patient reported outcomes:			
Cancer-Specific Distress (IES) Intrusion	Per 10 units	0.98 (0.71–1.34)	0.90
Cancer-Specific Distress (IES) Avoidance	Per 10 units	0.95 (0.75–1.22)	0.70
Cancer-Specific Distress (IES) Total Score	Per 10 units	0.98 (0.84–1.14)	0.75
Psychological Distress (POMS) Total Score	Per 10 units	0.92 (0.78–1.09)	0.33
Patient Satisfaction (PSQ) Gen. Satisfaction	Per 10 units	1.10 (0.98–1.24)	0.11
Patient Satisfaction (PSQ) Total Score	Per 10 units	1.04 (0.87–1.24)	0.67
Continuity of Care (CCCQ) Total Score	Per unit	0.93 (0.57–1.54)	0.78
General Health Status (SF-36) PCS	Per 10 units	0.92 (0.70–1.21)	0.54
General Health Status (SF-36) MCS	Per 10 units	1.27 (1.00–1.60)	0.046
Multivariable Logistic Model for Adherence ^a			
Region of Canada	Western (reference)	1.0	<0.001
	Ontario	0.64 (0.32–1.25)	
	Quebec	5.01 (2.24–11.2)	
	Atlantic	0.45 (0.21–0.97)	
Duration from completion of primary treatment	≥2 vs. <2 years	0.42 (0.23–0.77)	0.013
General Health Status (SF-36) MCS	Per 10 units	1.30 (1.01–1.67)	0.044

BCS breast conserving surgery, CCCQ Continuity and Coordination of Care Questionnaire, CI confidence interval, HS high school, IES Impact of Event Scale, MCS Mental Component SF-36 Score, OR odds ratio, PCP primary care physician, PCS Physical Component SF-36 Score, POMS Profile of Mood States questionnaire, PSQ Patient Satisfaction Questionnaire, SCP survivorship care plan, tmt treatment, vs. versus

^a Adherence defined as having ≥2 breast imaging tests within 24 months

Adherence to guidelines and, more particularly, the adherence to recommended breast imaging tests were evaluated in this study. The hypothesis was that a SCP would increase recommended medical surveillance test rates and decrease rates of non-recommended testing [29]. However, in this study, we found no difference in the number of recommended and non-recommended surveillance tests between both groups. Although most women in our study population had

regular follow-up visits with their PCP and regular breast imaging tests during 24-month follow-up, approximately 15 % of them had fewer than recommended breast imaging. This finding is consistent with the results of our previous population-based study showing a similar magnitude of underuse of surveillance breast imaging in breast cancer survivors, despite over 80 % being under oncologist-led follow-up care [1]. While there is no

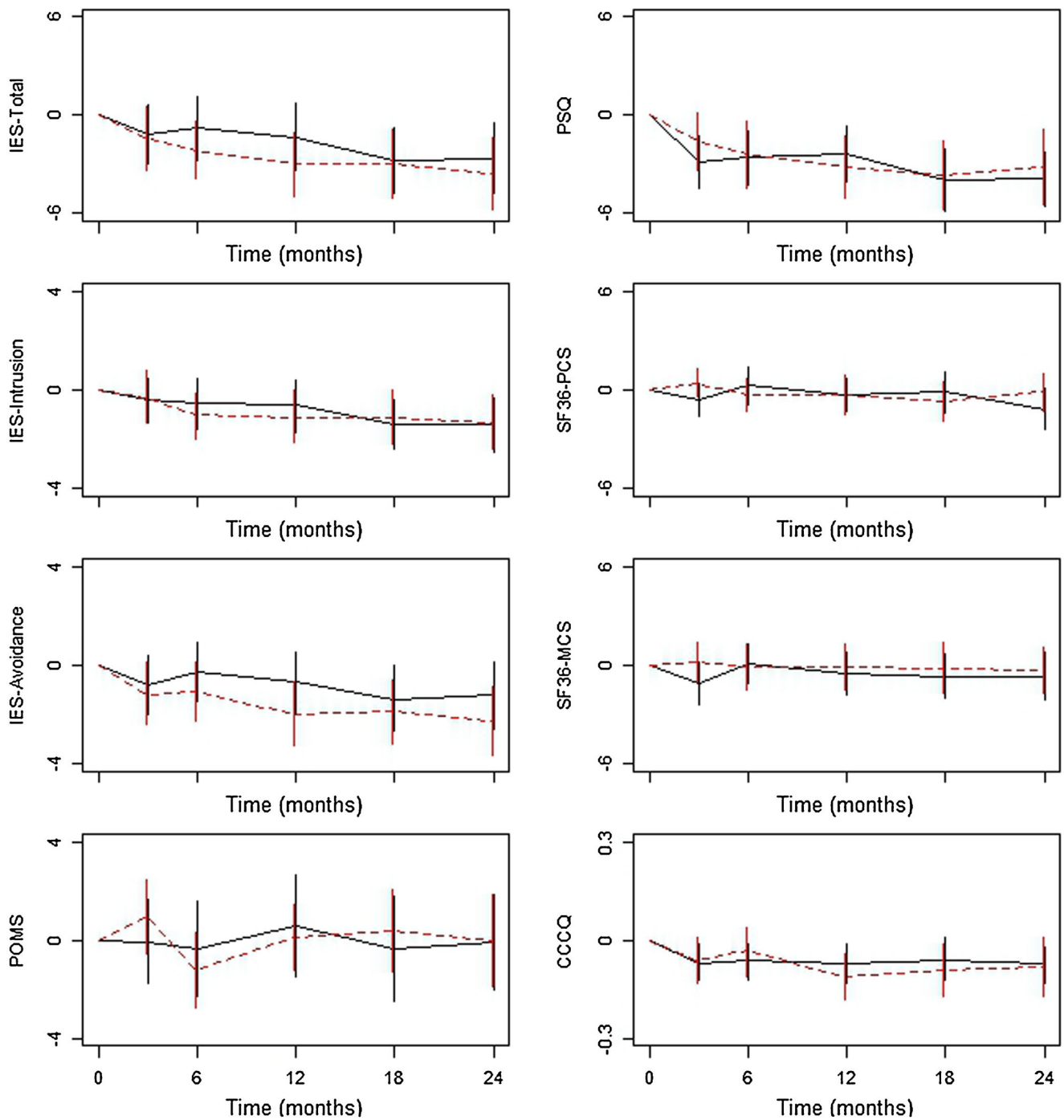


Fig. 1 Trial outcomes: change scores over time since baseline. *Red line*, survivorship care plan (SCP) group, *black line*, no SCP. *CCCQ* Continuity and Coordination of Care Questionnaire, *IES* Impact of

Events Scale, *POMS* Profile of Mood States Questionnaire, *PSQ* Patient Satisfaction Questionnaire, *PCS*, *MCS* Physical and Mental Component SF-36 summary

compelling evidence to support the frequency and intensity of follow-up visits in breast cancer patients, there is evidence to support routine breast imaging [30, 31]. Adherence rates were observed to be higher in patients from Quebec, patients within 2 years of primary treatment, and in patients with better SF-36 mental component scores.

A limitation of this study is that the adherence score is based on patient self-report. Although self-reports have been shown to be accurate [32–34], the accuracy of the data or the objectivity of patients’ responses cannot be guaranteed. Our data do not allow us to confirm whether tests were ordered for surveillance or for the evaluation of symptoms. Accordingly, there might be some misclassification of tests as routine when

they were in fact diagnostic. However, this is likely to be balanced between the intervention and control group. Moreover, questions were framed so that women could establish if the test was ordered as routine or diagnostic.

At baseline, despite being under active oncologist-led follow-up care, one third of patients considered their PCP to be the health care professional primarily responsible for their breast cancer follow-up care. This is consistent with earlier studies [35] which showed a lack of clarity in the patient's mind regarding responsibility of the involved health care providers for routine follow-up care, potentially resulting in an underuse, overuse, or inefficient use of follow-up care resources [1, 36]. However, at 24 months post-discharge, 92 % of patients in both groups were able to correctly identify their PCP as primarily responsible for follow-up. Additionally, ≤ 3 % of patients visited their oncologist for routine follow-up after transfer to the PCP, indicating that both patients and PCPs maintained their willingness to adhere to PCP-led follow-up. Similarly, there was no evidence that psychosocial variables, patient satisfaction, or continuity and coordination of care improved with the implementation of a SCP in these women. However, our study results do not inform as to whether SCPs could be beneficial for patients with high levels of psychological distress or whether the SCP will be implemented in other cancer groups. Patients in this study had relatively low scores of distress at baseline, and it is possible that breast cancer patients are relatively better informed in comparison to other cancer groups. Moreover, the IES may not have been sensitive enough to capture intervention effects in patients beyond 10 years after primary treatment. However, results were analyzed by strata, and there was no clinically meaningful effect observed related to time from diagnosis. Although, our study results are similar to those found in a randomized controlled trial of a clinic-based survivorship intervention following adjuvant therapy in breast cancer [13]. While, there were differences in study design between both studies; the patient-reported outcome measures used in these studies were similar.

In this study, patients were referred from a specialized oncology setting to a primary care setting. These study results are generalizable to practice settings where the oncologist has a "treatment ending" visit and a setting where PCPs are available and willing to accept cancer survivors. Additionally, this study does not inform as to whether SCPs could be beneficial for improvement of PCP knowledge about survivorship care, which remains an important topic for further research.

Conclusion

The implementation of a SCP in the transition of care did not contribute to improvements in adherence to guidelines, to health service, or to patient-reported outcomes. In both

intervention and control groups, there was a high level of adherence to follow-up guidelines and a small number of post-discharge cancer center visits, indicating that a standard discharge visit with the oncologist appears to achieve similar objectives as the SCP. The suggestions that a SCP may address a number of deficits in the complexity of survivorship care planning are based on a theoretic approach. Currently, several institutes are implementing survivorship care plans in clinical practice. However, results of this RCT should raise questions concerning the utility of a SCP in this patient population. The essential elements necessary for survivorship care and determination of which patients are likely to benefit should be further investigated before a costly [15] spread of implementing survivorship care plans in clinical practice.

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Conflict of interest Author Boekhout, Maunsell, Pond, Julian, Coyle, Levine, and Grunfeld declare that they have no conflicts of interest to disclose.

All procedures followed were in accordance with the ethical standards of the responsible committee of human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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