

Inpatient versus Outpatient Rehabilitation after Breast and Gynecological Cancers – A Comparative Study

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Abstract

The aim of the present study was to compare change in work status, fatigue and health related quality of life (HRQoL) from admission to 6 months after discharge among patients with breast and gynecological cancer who participated in an Inpatient Rehabilitation Program (IRP) or an Outpatient Rehabilitation Program (ORP) respectively. Women aged 18-67 years, being on sick-leave or self-reported being in need of sick-leave were included. The IRP consisted of a three weeks stay and one week booster stay at a rehabilitation center. The ORP consisted of seven weekly sessions at an academic cancer hospital. Both programs included physical exercise, patient education and group discussions. Patient-reported work status was the primary endpoint and was assessed at admission (T0) and six months after discharge (T2). Secondary endpoints were physical fatigue and HRQoL. Cochran-Armitage test for trend was used to analyze differences in change in work status between the programs. Linear regression analyses were used to analyze difference in change for the secondary endpoints. No difference in change of work status was observed between IRP and ORP from start of program (T0) to T2, as 73% improved their work status in the IRP and 76% in ORP. Fatigue and HRQoL improved substantially irrespective of programs and without differences between the programs. Outpatient rehabilitation might be as effective as inpatient rehabilitation but needs to be confirmed in a controlled study.

Keywords: Rehabilitation; Cancer survivors; Work status; Fatigue; Health related quality of life

Introduction

Many cancer survivors report reduced physical and mental work abilities after cancer treatment and need adjustments at work after treatment. Some also retire prematurely from work [1,2]. However, the reduction in the employment status among cancer survivors varies according to cancer diagnoses, treatment type- and intensity, levels of educational and occupational status [3].

In order to improve cancer survivors' work ability, health status and quality of life after cancer treatment, several rehabilitation programs have been introduced during the last decades [3-7]. The programs are mainly organized as inpatient rehabilitation programs (IRP) involving hospitalization or as outpatient rehabilitation programs (ORP) with weekly or more frequent sessions at a suitable location. The detailed content of such rehabilitation programs vary, but physical exercise, patient education and group discussions delivered by multidisciplinary teams are the major components in both types of programs. Previous

studies have examined, but not compared, the effects of IRP and ORP on work participation and health outcomes among cancer survivors [5-10]. The results from several of these studies indicate improved physical fitness and health-related quality of life in several domains [6,8,10], while one study found no change in health behavior and self-rated health after a psychosocial cancer rehabilitation [7]. To our best knowledge, programs designed specifically for cancer survivors at risk of leaving the labor market have scarcely been studied [4].

Compared to ORPs, IRPs might allow for more intensive training, a larger amount of time spent on education and more communication between the survivors themselves and between the survivors and health professionals.

In 2008, funded by a Norwegian government initiated program "Fast – Return to Work" (Fast – RTW), an ORP and an IRP were set up at two different locations in Norway. Cancer patients from the middle part of Norway were referred to an IRP, while patients from the southeast part of the country were referred to an ORP. The content of the programs was similar, but the programs differed concerning extent, duration, costs and localization. To make comparisons between

the programs possible, identical evaluation methods were selected and organised upfront at both locations. The major goal of the programs was to reduce drop-out from the work force. In order to reach this goal the programs aimed to improve the participants' health both physically, psychologically and socially.

On this background the primary aim of the present study was to compare change in work status from admission to six months after discharge among patients with breast and gynecological cancers participating in the IRP and ORP respectively. Secondary aims were to compare differences in physical fatigue and HRQoL between the participants in the two programs. Our hypothesis was that the proportion of patients who improved their work status would be greater among those participating in the IRP than among those participating in the ORP due to the higher intensity of the former program.

Material and Methods

Study design and inclusion criteria

This paper includes data on the participants from the two programs collected prospectively. Due to the similarity between the two programs regarding major goals, content and participant characteristics, we judged a comparison between the two programs to be of special relevance given the afore-mentioned scarcity of studies on rehabilitation programs specifically designed for cancer patients at risk of leaving the labor market. An identical collection of data capturing the major goals of the programs were therefore organized by the authors and set up at start of the programs.

Participants working full-time entered the programs because they perceived themselves as in potential need of sick-leave. The others were on part time- or full sick-leave after cancer treatment (Table 1). Participants attending the IRP were recruited by primary care physicians or from oncology units at hospitals in the central part of Norway. The participants in the ORP were recruited from the outpatient clinic and the radiotherapy department at the Norwegian Radium Hospital, a specialized oncology clinic at Oslo University Hospital. The primary care physicians and the oncological units were informed about the programs, but not all eligible patients were invited to participate. Hence, the study population must be regarded as a self-selected sample as many samples in rehabilitation are.

The inclusion period was from August 2008 to October 2010 and the inclusion criteria were: 1) having breast- or gynecological cancer (stage I - IV); 2) being between 18-67 years; 3) being on sick-leave or perceiving themselves in need of sick-leave at the start of the programs; 4) having completed their primary oncological treatment (except for hormone therapy) within 2 years before entering the programs; 5) being physically and mentally capable to complete the programs; and 6) having a Karnofsky performance status (KPS) above 70. KPS range from 0 to 100 where 0 = dead and 100 = no evidence of disease. KPS 70 is characterized as being able to care for self, but unable to carry on normal activity or do work [11]. Exclusion criteria were substance abuse or dependence, mental retardation and inability to understand Norwegian.

The interventions

General description for both interventions: Both interventions consisted of physical exercise, patient education and group discussions. The main goal of the physical exercise was to give the

participants an experience of being physically active and thus stimulate them to do regular physical exercise in everyday life. The patient education and group discussions focused upon: 1) cancer treatment and its side-effects; 2) physical activity; 3) nutrition; 4) economy and work situation including patient rights within the welfare system; 5) factors that can contribute to a permanent return to work for cancer patients; 6) partnership and sexuality; 7) psychological reactions in relation to cancer; and 8) distress management and coping strategies. Lectures on these topics were given by relevant health professionals and each topic was discussed in groups after the lectures. The participants could also raise other relevant topics to be discussed in these groups. Individual consultations with the professionals were given on request.

Description of the IRP: The IRP was provided by a rehabilitation centre in central Norway. All participants attended a four weeks rehabilitation program; a three weeks (15 work days) primary stay and a one week (five days) "booster stay" eight to 12 weeks thereafter. There were no criteria for attending the "booster stay". After the primary stay, the patients went home and were advised to include achieved knowledge from the primary stay in their daily life. The goal of the "booster" stay was to increase motivation to maintain physical activity during the period at home, give the participants an opportunity to discuss experiences from the period at home with peers and health professionals, to reassess individual rehabilitation goals and to perform subjective assessments and different physical exercise tests. The participants were enrolled in groups of 10 to 15 patients.

At arrival, the participants had one consultation with a nurse or a doctor in which they set the goals for their rehabilitation. Patient education sessions and/or group discussions were performed each day and covered the topics described above. The nutrition and diet education had a theoretical- and a practical part. Physical exercise was performed twice a day, and included resistance training, aerobic activities in the gym and swimming pool, Nordic walking, hiking, spinning, stretching and relaxation. Each patient trained according to an individualised program based on her initial physical exercise testing. The physical activity sessions lasted between 60 and 120 minutes. The participants were encouraged to push themselves to intensities of "somewhat exhausting" and "exhausting" (corresponding to 13 - 15 on a Borg scale) at least twice a week. The total time spent on physical exercise, patient education and group discussions for each participant was approximately 100 hours during the 4 weeks. The lectures accounted for about 15% of the time, the group discussions for about 25% and the physical activity sessions for about 60%.

Description of the ORP: ORP was delivered at an academic cancer hospital, and the participants attended once a week (5 hours each time) for seven weeks (7 days), without any subsequent "booster". ORP was delivered in groups consisting of approximately 10 participants with the same diagnosis. The content of the programs were similar for the two diagnostic groups except for some diagnosis-specific information delivered in the educational sessions.

At the start of the ORP, the participants had a consultation with a social worker in which the participants set the goals for their rehabilitation. Each day started with a one-hour lecture covering the topics described above. Each lecture was followed by a one-hour group discussion on the topic presented in the lecture. These sessions were led by a social worker and the health professional who gave the lecture. After lunch the participants performed physical activity led by a physiotherapist and a sport instructor. Activities included resistance training, Nordic walking, hiking, water gymnastic, yoga, stretching

and relaxation. The length of the physical activity sessions varied between 60 and 120 minutes. Overall, the activities were performed with moderate intensity, however adjusted individually according to results of physical tests completed at onset. During the program period the participants also attended a two-hour art therapy session lead by an occupational therapist.

The nine week program included approximately 35 hours altogether. The lectures accounted for about 25% of the scheduled time, the group discussions for about 25% and the physical activity sessions for about 50%.

Assessments

Baseline assessment was performed at the start of the programs (T0), the second assessment was performed at arrival of the booster stay among the patients attending the IRP (T1) and at the end of the program among the patients attending the ORP (T1). The final assessment was performed six months after discharge from both programs (T2). Demographic data was collected by a patient-reported questionnaire specifically designed for this study, and medical data were retrieved from the patients' medical records.

Work status

In line with the basic goal of the program, the main outcome variable was change in work status from T0 to T2. The questionnaire included a single item concerning present work status with three response alternatives: full-time work, part-time work or on sick-leave. Part-time work and sick-leave were reported in percent. Based upon the responses, the variable on work status was categorized into three groups (a) those working more at T2 ("improved work status"), (b) those working at the same extent at T2 ("similar work status") and (c) those working less at T2 ("reduced work status").

Fatigue

The fatigue questionnaire (FQ) measures two underlying constructs, mental (M-FAT) and physical fatigue (P-FAT) [12]. P-FAT was used as a secondary outcome measure. The P-FAT includes seven items and each item has four response alternatives scored 0-3. The scores are summarized with a possible score range from 0 to 21. Higher scores imply more physical fatigue. The internal consistency of the P-FAT scale (Cronbach's alpha) varied between 0.84 – 0.89 at the three assessment-points.

Health related quality of life (HRQoL)

Since the participants were off cancer treatment and in line with the content of the programs, we judged the functioning scales of the cancer specific HRQoL-questionnaire European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) [13] to capture the major content of the programs. These functioning scales assess physical functioning (PF), emotional functioning (EF), role functioning (RF) and social functioning (SF). The responses were summed into raw scale scores and then transformed to 0-100 scales according to the scoring algorithm for the EORTC QLQ-C30 [13]. Higher scores represent better functioning. A difference of 10 points or more on each scale was considered as clinically significant [14]. The internal consistencies of the EORTC subscales (PF, EF, RF and SF) varied between 0.65 – 0.88 at the different assessment points.

Statistical analyses

Non-parametric methods were applied because of the relatively small number of participants and skewed distribution of most scale scores. Crude differences between IRP and ORP at T0 were assessed with Mann-Whitney Wilcoxon test for continuous variables and Chi-square test for categorical variables. Cochran-Armitage test for assessing linear-by-linear association was used to detect difference in change of work status between IRP and ORP from T0 to T2. To adjust for the crude effect of time since diagnosis, the analyses were performed separately for those who started in the programs less than six months after diagnosis and for those participating more than six months after diagnosis. Linear regression analyses were used to test for differences in change in the secondary outcomes (P-FAT, PF, EF, RF and SF) from T0 to T1 and from T0 and T2 between IRP and ORP, adjusted for type of diagnosis and months since diagnosis. The model fit was good and the assumptions for linear regression were met. Due to multiple testing p-values < 0.01 were considered statistically significant. All statistical analyses were performed using the PASW statistical software version 18 (IBM Inc., Chicago, IL, USA).

Ethics

The studies were approved by all relevant committees of medical ethics. All participants gave written informed consent.

Results

Participation in IRP and ORP

The flow-chart in Figure 1 presents the number of patients included in the two programs (T0), completing the interventions (T1) and responding at six months follow-up (T2).

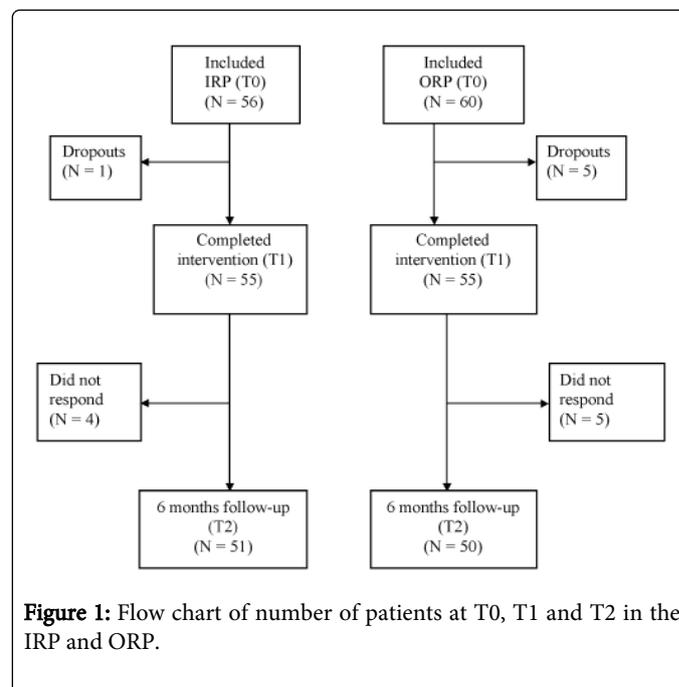


Figure 1: Flow chart of number of patients at T0, T1 and T2 in the IRP and ORP.

Ninety one percent (51 of 56 included) of the participants in the IRP and 83% (50 of 60 included) in the ORP completed all assessments. One person dropped out during the IRP due to relapse.

The reasons for drop out during the ORP were pain (n=1), relapse (n=1) and no reason given (n=3) (Figure 1).

Baseline characteristics

Median number of months since diagnosis was significantly shorter for the participants in the ORP than in the IRP (Table 1). The ORP also included a significantly higher proportion of patients with gynecological cancer (n = 27) than the IRP (n = 5). Median RF-score was significantly higher among participants in the IRP compared to the ORP at T0. For the other variables, no significant between-group differences were observed at T0 (Table 1).

Differences in change of work status between the groups from T0 to T2

Seventy three percent of those on sick-leave or working part time at T0 in the IRP improved their work status compared to 76% in the ORP (p = 0.53 for difference) (Figure 2). Among the participants on sick leave at T0, 29 of 34 participants improved their work status at T2 in the IRP and 29 of 35 participants improved their work status in the ORP (Figure 3).

Subgroup analyses showed no statistically significant differences in change of work status from T0 to T2 between the groups who entered the programs less or more than six months after diagnosis (data not shown).

Variables	IRP	ORP	p-value	
	(n = 56)	(n = 60)		
Age (years), median (range)	51 (37-66)	50 (32-67)	.34	
Months since diagnosis, median (range)	10 (4-24)	7 (3-24)	< .001	
	N (%)	N (%)		
Living with a partner				
No	17 (30)	18 (30)	.97	
Yes	39 (70)	42 (70)		
Children < 18 years living at home				
No	28 (50)	27 (45)	.59	
Yes	28 (50)	33 (55)		
Education				
Prim/second/high school	24 (44)	33 (55)	.22	
University/college	31 (56)	27 (45)		
Missing	1	0		
Work status*				
Full time	8 (14)	14 (23)	.21	
Part time	11 (20)	6 (10)		
Sick-leave	37 (66)	40 (67)		
Cancer diagnosis				

Breast cancer	51	(91)	33	(55)	< .001
Gynecological cancer	5	(9)	27	(45)	
Treatment					
Chemo. ** and rad. ** +/- surg. /horm. **	35	(62)	26	(43)	.16
Chemo. without rad. +/- surg./horm.	6	(11)	14	(23)	
Surg. ** and rad. or rad. only	11	(20)	15	(25)	
Surg. only	4	(7)	5	(8)	
Health reported functions, median (range)					
Physical fatigue	13 (6-20)		13 (5-21)		.28
Physical functioning	80 (40-100)		80 (47-100)		.55
Emotional functioning	75 (17-100)		75 (25-100)		.96
Role functioning	67 (0-100)		50 (0-100)		.004
Social functioning	67 (0-100)		67 (17-100)		0.44
*linear by linear association					

Table 1: Demographic and medical characteristics of participants in the IRP and the ORP at T0.

**chemo. = chemotherapy; rad. = radiotherapy; surg. = surgery; horm. = hormone therapy

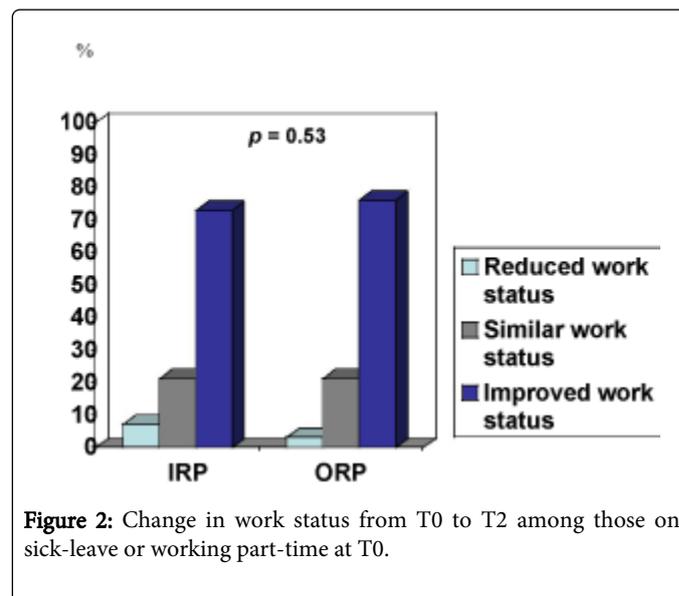


Figure 2: Change in work status from T0 to T2 among those on sick-leave or working part-time at T0.

Group differences in change of P-FAT, and functioning from T0 to T1 and from T0 to T2

Table 2 presents absolute changes in median values of P-FAT, PF, EF, RF and SF from T0 to T1 and from T0 to T2 for the two programs.

Participants in both programs improved significantly on all secondary outcomes from T0 to T2.

Linear regression analyses adjusted for type of diagnosis and months since diagnosis revealed a greater reduction in P-FAT from T0 to T1 for the participants in the IRP than in the ORP (p=0.03) (data not shown). From T0 to T2 there were no differences in P-FAT between the programs. When comparing the two programs for changes in PE, EF, RF and SF from T0 to T2 after adjustment for diagnosis and months since diagnosis, no statistically significant differences between the two programs were observed (Table 2).

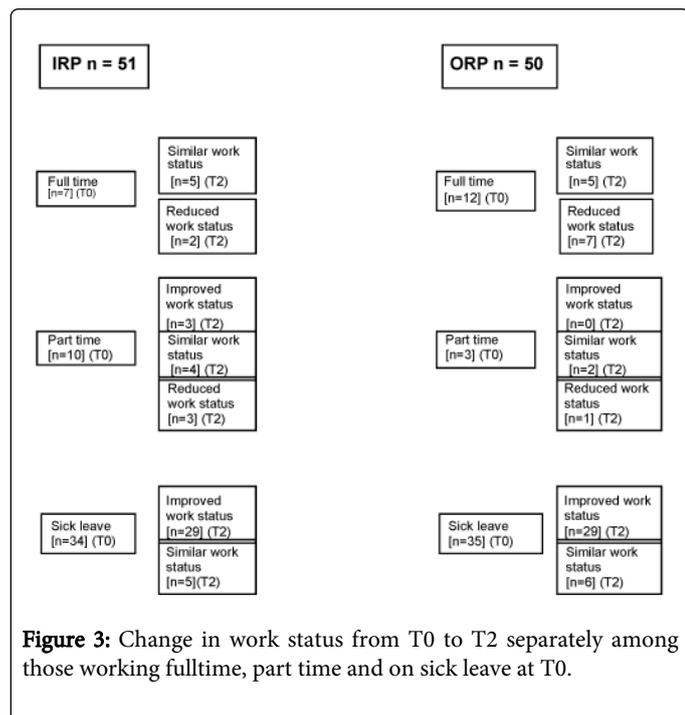


Figure 3: Change in work status from T0 to T2 separately among those working fulltime, part time and on sick leave at T0.

	IRP			ORP		
	(N = 60)			(N= 56)		
	T0	T1	T2	T1	T1	T2
Physical fatigue (0-21)*	13	8	7	13	12	9
Physical functioning (0-100) **	80	87	93	80	87	93
Emotional functioning (0-100)	75	92	83	75	83	92
Role functioning (0-100)	67	83	83	50	67	100
Social functioning (0-100)	67	83	75	67	67	83

Table 2: Median values in P-FAT, PF, EF, RF and SF among the participants in the IRP and ORP

range 0-21, higher score represent more fatigue

range 0-100, higher score represent better functioning

Discussion

We studied if change in work status differed among female cancer survivors who participated in an inpatient rehabilitation program

compared to those who attended an outpatient rehabilitation program. Participants in both programs improved their work status, but in contrast to our hypothesis, no significant difference in work status was detected between the two programs six months after discharge. Further, the participants in both programs improved on all health-related outcomes and fatigue but no differences between the programs were observed.

To our knowledge, this is the first study comparing an inpatient and an outpatient rehabilitation program for cancer survivors at risk of leaving the labor force. Finding that improvements in work status, fatigue and HRQoL, were similar after seven weekly ORP sessions and a comprehensive IRP is of both clinical and health-economic interest. On this background and the higher costs of the IRP, future studies should examine more closely which patients are in need of and should be offered comprehensive IRP.

Baseline demographic characteristics did not differ substantially between the participants in the two programs, except for a shorter time since diagnosis, more gynecological cancer and slightly poorer RF among the ORP participants. Difference in effect between the programs regarding change in work status was therefore analyzed separately for those participating in the programs less than six months after diagnosis and more than six months after diagnosis. The results from these subgroup analyses were similar, indicating no influence of effects between the programs in patients participating more or less than six months after diagnosis. Due to the low number of patients with gynecological cancer in the IRP group, we could not do subgroup analyses for patients with gynecological versus breast cancer. Since diagnosis, treatment and side-effects vary between these diagnoses, the effect of the programs might have differed between the diagnoses. We cannot exclude that the effects of the programs might differ between the diagnosis groups and this must be further examined in future studies. The strength of the study is the high compliance to the programs and the high response rate at six months follow-up. However, the participants were included from two programs at different locations and then compared. Future studies with a randomized design including a control group are therefore warranted.

The number of participants in the study is small and we do not have complete records on how many of eligible patients that were invited to participate and how many that refused to participate. It might be a chance that resourceful highly educated patients who expressed a need or wish for support during or immediately after treatment were invited more often compared to those who did not express such needs. Hence, the sample must be considered as a self-selected sample. Future large-scaled studies with a more rigorous design concerning the recruitment process are therefore warranted. Still, rehabilitation presupposes the active participation by the participants and a selection bias will therefore be a general challenge in studies of rehabilitation after cancer treatment.

Change in work status was assessed with a single item and categorized into three alternatives. Future observation studies should consider the opportunity to use measures capturing broader aspects of work ability, like the Work Ability Index [15]. The major outcome was work status and we find no reason to believe that the response to such a concrete question is biased.

At baseline the participants in both programs reported to be considerably more fatigued, and they had substantially poorer physical and emotional functioning than age-matched women from the general Norwegian population [16,17]. Six months after discharge from the

programs the scores on these patient-reported outcomes were close to what is found among women in the general Norwegian population of similar age [17].

The physical exercise component of the programs was more pronounced in the IRP than in the ORP and included physical exercise once or twice daily during the hospitalization period. This might explain the immediate reduction in fatigue reported by the participants in the IRP at T1. The present findings are in line with the results from a meta-analysis showing that physical exercise improves cancer related fatigue [18]. Physical exercise is therefore considered a core element in rehabilitation programs for cancer patients [18-20].

The main goal of this study was to compare two different programs regarding duration, extent and organization. Upfront, we hypothesized that the effect of the IRP would exceed the ORP, based on a longer duration, higher extent and a booster stay. However, we did not detect any difference in change in work status in patients participating in the IRP compared to the ORP. Given the equal effect of the two programs and the relatively higher costs of the IRP, future studies should examine more closely which patients are in need of and should be offered comprehensive IRP. For patients living far away from the rehabilitation center, those in need of medical support on a daily basis or specialized care, inpatient rehabilitation must still be considered as the favorable alternative. Further, we did not plan for analyzing the health economic aspects. IRP is more expensive than ORP and also more resource-demanding in terms of personnel. In light of the expected increase in costs for cancer care, we consider the health economic aspects to be important to include in studies and planning of future cancer rehabilitation programs.

Future prospective studies should follow patients after treatment to better understand the natural course of patient-reported health and social functioning after end of cancer treatment. By such procedure, we can better identify patients at risk for difficulties with adaptation to normal life including returning to work and adapting to a healthier life-style.

Conclusion

The present study indicates that change in work status, fatigue and HRQoL did not differ between a comprehensive inpatient rehabilitation program compared to an outpatient rehabilitation program in female cancer survivors. Future randomized clinical trials including a control group are warranted to confirm these findings. Given the different costs of two such programs, future studies should examine which subgroups of patients who have their rehabilitation needs met by ORP rather than the more costly IRP.

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