Enhancing return to work of cancer patients

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Chapter 8.

Effectiveness of a hospital-based work support intervention for cancer patients – a multi-centre randomised controlled trial

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Submitted

Abstract

Introduction

To determine the effectiveness of a hospital-based work support intervention compared to usual care for cancer patients.

Methods

Cancer patients who had been treated with curative intent and who had paid work were randomised to the intervention group (n=65) or to the control group (n=68). The intervention involves patient education and support at the hospital and the improvement of the communication between the treating physician and the occupational physician. In addition, we asked patient's occupational physician to organise a meeting with the patient and the supervisor to make a concrete gradual return-to-work plan. Outcomes at 12 months of follow-up include the rate and time until return-to-work (full or partial), quality of life, work ability, work functioning, and lost productivity costs.

Results

The return-to-work rates were 79% and 79% for the intervention group and the control group (p = 0.9) and were 86% and 83% (p = 0.6) when excluding 8 patients who died or with a life expectancy of months at follow-up. The median time from the initial sick leave to partial return to work was 194 days (range 14-435) versus 192 days (range 82-465) (p = 0.90) and the hazard ratio was 1.03 (95% CI of 0.64 – 1.6). Quality of life and work ability improved statistically over time but did not differ statistically between groups and work functioning and costs did not differ statistically between groups.

Conclusion

We found non-statistically significant differences between groups. Further research is needed to study which aspects of the intervention are useful and which elements need improvement. The intervention was highly accepted and easily implemented into usual psycho-oncological care.

Trial registration: NTR1658

Introduction

In recent years, advances in cancer screening and cancer treatment have improved the survival rates for patients with cancer. An increasing number of cancer patients are therefore able to live many years beyond the original cancer diagnosis and face new challenges upon cancer survivorship. For cancer patients of working age, returning to work is a key aspect of survivorship because it is often experienced as an important part of their recovery.[1] Furthermore, work contributes to personal, social, and economic well-being, and therefore return to work is associated with the quality of life of cancer patients.[2-4]

Unfortunately, not all cancer patients are able to return to work and many of these patients have more adverse work outcomes in comparison to the general population. For instance, the risk of unemployment is estimated to be 37% higher for cancer patients compared to non-cancer controls.[5] Furthermore, a portion of cancer patients face a decrease in income[6] and suffer from impaired work functioning compared to the general population.[7 8] Finally, the employer and the society at large are also affected due to the costs of absenteeism, disability pension, and loss of productivity.[9]

Intervention studies aimed at enhancing the return to work of cancer patients are rare, especially randomised controlled trials.[10 11] However, we developed an intervention based on previous studies that demonstrated effective results for enhancing the return to work of cancer patients,[10] and we developed this intervention together with various stakeholders involved in the return to work process of cancer patients.[12] An early intervention is most appropriate because the longer the duration of sick-leave, the more difficult return to work is to achieve.[13] For delivering an early intervention, a hospital-based intervention is most appropriate, as most cancer patients do not have contact with their employer or occupational physician during early phases of their cancer treatment and physician's advice seems to be influential.[14 15] In addition, previous studies have shown that early interventions could be most effective.[10] Furthermore, return to work should be part of the complete psycho-oncological care package and should not be dealt with in isolation.[16]

Our hypothesis is that a hospital-based intervention will enhance the return to work of cancer patients, as work is not typically addressed at the hospital.[17] Furthermore, an important and modifiable prognostic factor for the return to work of

cancer patients is self-assessed work ability,[18] which may readily be improved by providing patient education and support that addresses misconceptions concerning return to work.[19] To study the effectiveness of a hospital-based work support intervention for cancer patients, we developed a multi-centre randomised controlled trial with a follow-up period of two years.[12]

Methods

Both the design of the study and the content of the hospital-based work support intervention have been described in detail elsewhere.[12] We used the items from the CONSORT statement for improving the quality of reporting randomised trials.[20]

Patients

Cancer patients between 18 and 60 years of age who had been treated with curative intent at one of the participating hospital departments, had paid work, and who were on sick-leave were eligible to participate. Treatment with curative intent was defined as an expected 1-year survival rate of approximately 80%. We excluded patients who were not sufficiently able to speak, read, or write Dutch, had a severe mental disorder or other severe co-morbidity, and for whom the primary diagnosis of cancer had been made more than two months previously. We monitored non-response by assessing the proportion of patients who participated in comparison to all eligible patients.

The medical ethics committee of the Academic Medical Center approved the study, and the medical ethics committees of each participating hospital advised positively regarding feasibility of the study in their hospital. Patients signed informed consent forms prior to participation in the study and patients did not receive any financial reward for participation.

Hospital-based work support intervention

The hospital-based work support intervention started a few weeks after the onset of the study and was spread across a maximum of 14 months. The hospital-based work support intervention consisted of the following components: 1) delivering patient education and support at the hospital, as part of usual psycho-oncology care, 2) improving communication between the treating physician and the occupational physician, and 3)

drawing-up a concrete and gradual return-to-work plan in collaboration with the cancer patient, the occupational physician, and the employer.[12] We integrated patient education and support regarding return to work into the usual psycho-oncological care in the form of 4 meetings that lasted 15 minutes each. This care was delivered by an oncology nurse or medical social worker (hereafter referred to as nurse). A least one letter was sent to the occupational physician to enhance communication. We also asked the occupational physicians to organise a meeting between the patient and the employer to draw-up a return-to-work plan. The key aspects of the hospital-based work support intervention included patient education and support at the hospital and the provision of information to the occupational physician. In the Netherlands, patients must provide their consent to allow medical information to be sent from a treating physician to an occupational physician. Therefore, we were only able to inform the occupational physicians of patients who provided this form of consent.

Study design

This study was designed as a multi-centre randomised controlled trial with a follow-up period of two years. Here we report the results of the first follow-up year. Six hospitals in the Netherlands participated in the study.

The treating physician or nurse informed the cancer patients of the study a few weeks after their diagnosis and determined patient eligibility by assessing the inclusion and exclusion criteria. The research team contacted patients who were eligible and willing to participate and enrolled these patients in the study. After the patients had filled in the baseline questionnaire, one of us [ST] allocated the eligible patients to the intervention or to the control group using the computerised randomisation programme ALEA.[21] The allocation ratio was set as equal in the programme. Stratified randomisation was applied for two important prognostic factors for return to work;[22] age (< 50 or ≥ 50) and cancer diagnosis (i.e. hospital department). Minimisation was applied to equalise group sizes. The patient date of each consecutive patient were entered in the programme and according to the conditions mentioned above the programme randomly assigned the patients to the intervention or the control group. The allocation was irrevocable and was not changed during the study nor during the

analysis. Patients and nurses were immediately informed of the allocation as it was impossible to conceal allocation for this intervention.

Questionnaires were administrated to the patients at baseline and at 6 and 12 months of follow-up. The follow-up questionnaires were mailed to the patients' homes with a postage-paid envelope enclosed. Both the questionnaire data and the information from the nurses who delivered the intervention were gathered for the economic evaluation. Outcome measures and cancer treatment were assessed at all time points. Socio-demographic factors and prognostic factors for time until return to work were assessed at baseline only. The use of concurrent interventions was only assessed at follow-up.

Measurements

The primary outcomes were return to work and quality of life. The intervention was considered effective if patients in the intervention group had a significantly shorter time to return to work (in days) than patients in the control group, provided that their quality of life had not significantly deteriorated.

Return to work was measured both as the rate of return to work at one year of follow-up and as the number of calendar days between the first day of sick leave and the first day at work (either part-time or full-time) that was sustained for at least 4 weeks. Quality of life was assessed with the Short Form-36 (SF-36),[23] which included all subscales and a Visual Analogue Scale (VAS). Secondary outcomes included work ability, work functioning, and costs. Work ability was assessed using the first question of the Work Ability Index (WAI).[24] Impaired work functioning was assessed with the Work Limitation Questionnaire (WLQ),[25] which could only be filled in if a patient had (partly) returned to work.

We conducted the economic evaluation from a societal perspective. We included lost productivity costs and work adjustments costs for both groups and costs to deliver the intervention for the intervention group. Productivity loss was determined by multiplying the cumulative net number of hours on sick leave by the estimated price of productivity loss based on age and gender.[26] We assumed that when a patient partially returned to work, his/her productivity was 100% during the hours of partial work resumption. We calculated productivity losses using both the human capital approach

and the friction costs approach.[26] For the human capital approach, all hours on sick leave were included for 100%. For the friction costs approach, all hours on sick leave with a maximum of 167 days were included for 80%.[26] Costs to deliver the intervention were determined by combining the training costs and the costs to deliver the intervention. Training costs consisted of trainer costs, study material costs, and attendance costs for the nurses. Costs to deliver the intervention consisted of the mean hour of investment multiplied by the average nurse wage and subsequently multiplied by 42% overhead costs,[26] and the mean hour of investment of the secretary for sending of the letters to the occupational physician, as well as the printing costs for the informational leaflet. As the letter from the treating physician to the occupational physician was a copy of the letter to the general practitioner, no additional costs for the treating physician to produce these letters were taken into account.

The socio-demographic factors measured at baseline included the number of days between the first day of sick leave and enrolment in the study, marital status, time since diagnosis, breadwinner status, position at work, shift work, years in current position, years of paid employment, income, importance of work (VAS), and company size.

Prognostic factors for time to return to work of the cancer patients included[18 22] age, gender, education, diagnosis, cancer treatment, number of working hours according to contract, physical workload (Questionnaire of Perception and Judgement of Work (VBBA)),[27] fatigue (Multidimensional Fatigue Inventory (MFI)),[28] depression (Centre for Epidemiologic Studies for Depression Scale (CES-D)),[29] co-morbidity, self-efficacy (general self-efficacy scale (ALCOS)),[30] and clinical characteristics (i.e. diagnosis and treatment). Finally, the use of concurrent interventions aimed at enhancing patients' return to work was monitored.

Sample size

The calculation of the patient sample size was based on two earlier studies focused on return to work in cancer patients.[22 31] Based on the return-to-work rates in these studies, we assumed a relative risk of not returning to work of 0.53 for individuals in the intervention group versus those receiving usual care.[12] With a power of 80% and two-sided significance level of $p < 0.05$, the sample size required was 109 patients in each group.[32] Assuming that 20% of the initial patients would be lost to follow-up, 270

patients should have been recruited to gather 246 patients at 12 months of follow-up. To account for at least 10% missing data at baseline, 300 patients sought to be included in the study.

Statistical analysis

Data entry was verified by means of a 20% double data entry and a 100% double data check regarding the rate and time of patients until return to work. Participants who did and did not want to participate were analysed on age using Student's t-test. All analyses were performed according to the intention-to-treat principle, which meant that all patients were included in the analysis. However, we censored patients who dropped out of the study. Therefore, differences between patients who dropped out or completed the study were analysed according to their baseline quality of life scores.

All data were analysed by means of descriptive statics using PASW version 18. The baseline data were assessed to evaluate whether there was an imbalance between the intervention group and the control group using Student's t-test for continuous variables and the $\chi 2$ test for categorical variables. Differences between the use of concurrent interventions were assessed with the $\chi 2$ test. We considered a p-value ≤ 0.05 to be statistically significant.

We calculated relative risks and 95% confidence interval for returning to work (full and partial) at 12 months of follow-up for the intervention group versus the control group. The median time until return to work was analysed with a Kaplan-Meier survival analysis, and differences between groups were tested with the log rank test. In addition, the Cox proportional hazard model of survival analysis was applied to estimate hazard ratios and the corresponding 95% confidence intervals for the time until return to work (full and partial) with a hazard ratio < 1 indicating a longer time to return to work. Improvements in the subsequent primary outcome of quality of life and the secondary outcomes of work ability and work functioning between groups were examined using a longitudinal multilevel analysis. Mean costs between the groups were analysed using Student's t-test.

Results

Cancer patients who were diagnosed at one of the participating hospital departments between May 2009 and December 2010 and who were eligible and willing to participate were enrolled in the study. The enrolment of new patients ended in December 2010 to enable the inclusion of patient follow-up data within the time constraints of the study. Based on the participation data of patients from three hospital departments, non-response was analysed. A total of 755 of the 855 cancer patients who were treated at one of these three participating hospital departments were excluded; 611 did not meet the eligibility criteria primarily because they were too old, 119 declined participation, 25 were excluded for other reasons, and this led to an overall response rate of 47% (Figure 1). Thirty-three cancer patients were included from the remaining hospital departments. As a result, 133 cancer patients were included in the study; 65 were assigned to the intervention group and 68 were assigned to the control group. Patients who participated and those who did not participate did not differ statistically in terms of age ($p = 0.2$).

At baseline, all 133 patients provided complete data on the primary outcome, whereas 132 (99%) patients provided complete data on the secondary outcomes (Figure 1). The response rate at 12 months of follow-up was 128 (96%) for the outcome of return to work and was 108 (81%) for the outcome of quality of life and secondary outcomes. The reason why patients did not return the questionnaire included cancer recurrence (4 patients; 3%), decline (6; 5%) or were unknown 11 (8%), while 4 (3%) patients died within the 12-months follow-up period (Figure 1).

Table 1 summarises the socio-demographic characteristics of this patient population, as well as the prognostic factors that were measured at baseline. Patients were on average 47.5 ± 7.9 years old and 99% of the patients were female. Breast cancer was the most common diagnosis (62%), which was followed by cancer diagnosis of the female reproductive system (34%). Surgery was the most common treatment modality (97%), being followed by chemotherapy (67%), and radiotherapy (58%). The duration of cancer treatment was 4.5 ± 2.3 months for patients in the intervention group and 4.5 ± 2.0 for patients in the control group.

No statistically significant differences between the intervention group and the control group on any of the socio-demographic or prognostic characteristics measured

at baseline or any medical characteristics measured at follow-up were identified (Table 1).

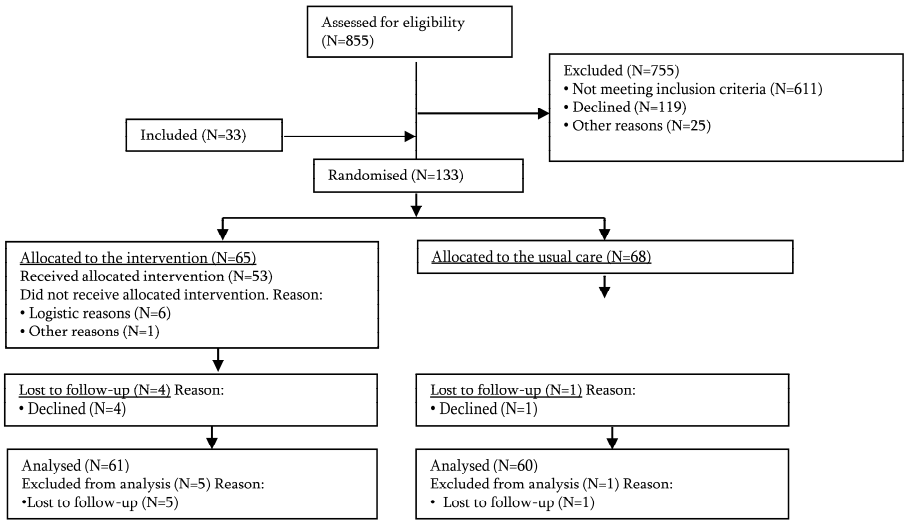

Figure 1. Patient flow.

Hospital-based work support intervention

No harm or unintended effects were reported by patients as a result of participating in the intervention. Seven patients (12%) assigned to the intervention group did not receive the patient education and support from the nurse, because these patients did not receive cancer treatment in the participating hospital department. Nine (14%) patients assigned to the intervention group did not provide consent to send medical information to their occupational physician. The reason for why these patients did not provide this type of consent included the following: not returning the consent form (56%), intervention ended before consent was asked due to cancer recurrence (22%), and not having an occupational physician (22%). For all patients who provided this type of consent, at least one letter from the treating physician was sent to the occupational physician. In five cases (10%), the patients' occupational physician organised a meeting between the patient, his/her supervisor, and him/herself to draw-up a return-to-work plan.

Table 1. Patient characteristics at baseline and cancer treatment at follow-up.

Patient characteristics		**Intervention group** *(N=65)*	**Control group** *(N=68)*	**P-value** **
Socio-demographic characteristics*				
Age *(years)* ¥		47.5 ± 8.2	47.6 ± 7.8	0.92
Gender (*% female)*		99%	100%	0.31
Marital status *(% married or living with partner)*		79%	69%	0.20
Breadwinner position *(% sole or shared)*		65%	56%	0.36
Education level *(%)*	Low	11%	16%	0.53
	Intermediate	59%	51%	
	High	30%	33%	
Clinical characteristics*				
Diagnosis *(%)*	Breast cancer	64%	60%	0.82
	Cervix cancer	23%	22%	
	Ovarian cancer	5%	10%	
	Vulva cancer	3%	3%	
	Other	5%	5%	
Number of co-morbidities *(%)*	0	45%	54%	0.09
	1	22%	31%	
	≥ 2	33%	15%	
Surgery *(%)*		99%	96%	0.78
Chemotherapy *(%)*		66%	71%	0.84
Radiotherapy *(%)*		60%	58%	0.67
Work-related characteristics*				
Type of occupation *(%)*	Health care / education	38%	37%	0.69
	Administrative	9%	9%	
	Sales	5%	12%	
	Other	48%	42%	
Type of work *(% mainly physically work)*		32%	40%	0.38
Physical workload *(0-28)***		4.7 ± 3.6	5.7 ± 4.4	0.18
Time since sick listed *(days)*		26.5 ± 35.1	15.0 ± 53.2	0.15
Importance of work *(0-100)***		58.7 ± 23.1	51.5 ± 28.3	0.11
Shift work *(% shift work)*		26%	19%	0.36
Type of contract *(%)*	Permanent	89%	84%	0.17
	Temporary	11%	9%	
	Self-employed	0%	4%	
	Other	0%	3%	
Overall work ability (WAI) *(0-10)****		5.3 ± 3.0	5.3 ± 3.1	0.94
Work ability physical workload (WAI) *(0-5)****		3.5 ± 1.1	3.3 ± 1.2	0.24
Work ability mental workload (WAI) *(0-5)****		3.0 ± 1.06	3.1 ± 1.0	0.68

Table 1. *(Continued).*

Health-related characteristics*				
QOL *(SF-36)***	Physical functioning *(0-100)*	75.4 ± 28.2	72.8 ± 27.7	0.59
	Role-physical *(0-100)*	47.6 ± 44.1	50.4 ± 42.6	0.71
	Bodily pain *(0-100)*	69.2 ± 29.7	69.1 ± 22.5	0.98
	General health *(0-100)*	61.2 ± 20.6	60.5 ± 17.9	0.81
	Vitality *(0-100)*	60.2 ± 21.1	56.8 ± 17.0	0.30
	Social functioning *(0-100)*	70.4 ± 23.4	68.5 ± 22.4	0.63
	Role-emotional *(0-100)*	49.2 ± 43.7	51.7 ± 41.1	0.74
	Mental health *(0-100)*	65.0 ± 16.6	63.9 ± 15.7	0.69
Quality of life (VAS) *(0-100)*		59.7 ± 21.7	60.6 ± 20.5	0.81
Fatigue *(MFI)****	General fatigue *(0-20)*	12.4 ± 4.9	13.1 ± 4.3	0.37
Depression *(CES-D)****	Sum score *(0-60)*	14.1 ± 9.3	13.5 ± 7.7	0.67
Self-efficacy *(ALCOS)****	Sum score *(0-80)*	66.5 ± 8.6	66.2 ± 7.6	0.83

* Continuous variables: mean ± standard deviation; nominal and ordinal variables percentages. ¥ Age at the time of randomisation. ** Student's t-test for continuous variables; $\chi 2$ test for ordinal and nominal variables. ***Higher scores represent higher level of physical work load, importance of work, work ability, functioning/well-being/quality of life, fatigue, feelings of depression, and self-efficacy.

The median number of contacts made between the nurse and the patient was 4 (range 1-4) and the median duration of each meeting was 23 minutes (range 7-60). Eight (12%) patients assigned to the control group reported having received patient education or support regarding their return to work from their nurse.

Use of concurrent interventions

Fifteen patients assigned to the intervention group, as compared to 15 patients in the control group, used a work-related concurrent intervention. The concurrent interventions for the both groups consisted of rehabilitation (8 and 8 respectively), psychologist (3 and 4), and other components (5 and 4). The number and type of the applied concurrent interventions did not differ significantly between groups.

Primary outcome – return to work and quality of life

The return-to-work rate (full or partial) of all 128 randomised patients at 12 months of follow-up was 79% for the intervention group and 79% for the control group (p = 0.97), and these rates were 86% and 83%, respectively (p = 0.61), when patients who died within the follow-up period or those with a life expectancy of only a few months were

excluded. The relative risk of returning to work (full or partial) for the intervention group versus the control group was 1.03 (95% CI 0.84 – 1.2). Of the patients who did not return to work (intervention versus control group); 2 versus 2 died within the follow-up period, 3 versus 1 had a life expectancy of a few months, 4 versus 5 lost their jobs, 2 versus 5 experienced adverse side-effects such that return to work was not (yet) possible, and 2 versus 0 demonstrated other reasons for not being able to return to work.

The median time from the initial sick leave until partial return to work was 194 days (range 14-435) for the intervention group and 192 days (range 82-465) for the control group (log rank test; p = 0.90). The median time from the initial sick leave until full return to work was 283 days (range 25-394) for the intervention group and 239 days (range 77-454) for the control group (log rank test; p = 0.52). Figure 2 summarises the Kaplan-Meier survival analyses for the two groups on partial and full return to work. The hazard ratio for partial return to work was 1.03 (95% CI 0.64 – 1.6) for the intervention group versus the control group and was 0.88 (95% CI 0.53 – 1.5) for these groups regarding full return to work.

Quality of life, which was measured both using the subscales of the SF-36 and a VAS showed statistically significant improvements over time (p ranged between 0.014 to ≤ 0.001) that did not differ statistically significant between groups (p ranged between 0.15 to 0.99) (Table 2).

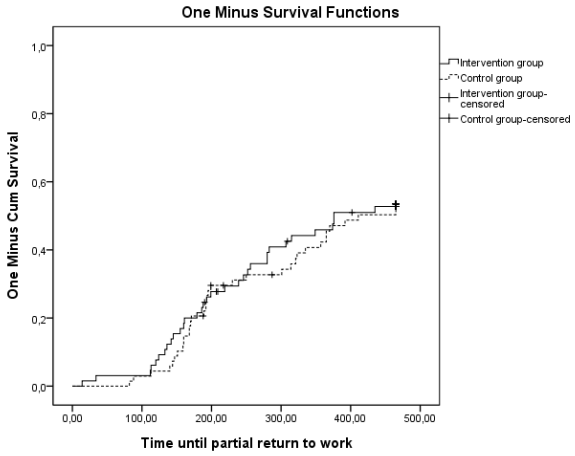

Figure 2a. Kaplan-Meier survival analyses for time until partial return to work.

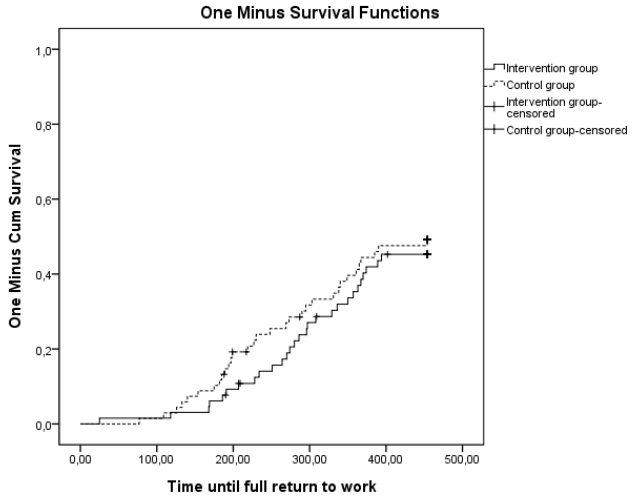

Figure 2b. Kaplan-Meier survival analyses for time until full return to work.

Secondary outcomes – work ability, work productivity, and costs

Work ability, as measured using the first question of the WAI, is shown for both groups over time in Table 2. Work ability improved statistically significant over time ($p < 0.001$) but did not differ statistically significant between groups ($p = 0.58$). Of the patients who resumed work at 6 months of follow-up or at 12 months of follow-up, work functioning was measured using the WLQ and is shown in Table 2 for both groups. Work functioning did not improve significantly over time ($p = 0.3$) and did not differ significantly between groups ($p = 0.48$).

Table 3 shows that the intervention costs were 119 Euros per patient in the intervention group. The mean (± SD) lost productivity cost according to the human capital approach was 41.393 (± 39.269) Euros in the intervention group and 38.968 (± 38.399) Euros in the control group. The mean (± SD) lost productivity cost according to the friction costs approach was 14.030 (± 3.614) Euros in the intervention group and 13.529 (± 3.313) Euros in the control group. The mean work accommodations cost was 2.975 and 3.025 Euros in the intervention group and control group, respectively. These costs did not differ statistically between groups.

Table 2. Quality of life, work ability, and work functioning.

		Group	Baseline	6 months follow-up	12 months follow-up	P-value**
Quality of life* *(SF-36; 0-100)*	Physical functioning	Intervention group	76 ± 28	71 ± 21	81 ± 16	0.95
		Control group	73 ± 28	70 ± 22	79 ± 20	
	Role-physical	Intervention group	48 ± 44	29 ± 40	47 ± 40	0.46
		Control group	50 ± 43	31 ±37	61 ± 41	
	Vitality	Intervention group	60 ± 21	51 ± 20	59 ±19	0.60
		Control group	57 ± 17	51 ± 16	56 ±16	
	General health	Intervention group	61 ± 21	54 ± 18	64 ±17	0.15
		Control group	61 ±18	59 ±18	70 ± 19	
	Social functioning	Intervention group	70 ± 23	66 ± 24	75 ± 20	0.46
		Control group	68 ± 22	66 ± 22	78 ± 20	
	Role-emotional	Intervention group	49 ± 44	53 ± 45	64 ± 42	0.71
		Control group	52 ± 41	64 ± 44	71 ± 40	
	Mental health	Intervention group	65 ± 17	71 ± 16	77 ± 15	0.32
		Control group	64 ± 16	70 ± 16	72 ± 15	
	Pain	Intervention group	69 ± 30	67 ± 25	75 ± 21	0.99
		Control group	70 ± 23	69 ± 20	76 ± 17	
Overall work productivity* (WLQ; *0-100) (N=100)*		Intervention group	NA	34 ± 19	29 ± 15	0.68
		Control group	NA	30 ± 14	27 ± 16	
Quality of life* (VAS; *0-100)*		Intervention group	60 ± 22	62 ± 23	73 ± 17	0.26
		Control group	61 ± 21	67 ± 18	70 ± 17	
Overall work ability* (WAI; *0-10)*		Intervention group	5 ± 3	4 ± 3	6 ± 2	0.59
		Control group	5 ± 3	5 ± 3	7 ± 2	

Mean ± sd; *Higher scores represent a higher level of functioning/well-being/quality of life, work ability, and work functioning. **P-value represents the interaction effect of time and group.

Table 3. Economic evaluation.

Costs of the work-directed intervention in Euros		
Description		**Costs (€)**
Training costs	1 trainer, time investment 24 hours, 50 Euros per hour	1200
	Study material, refreshments	125
	Attendance costs nurses, 11 nurses, 30 Euros per hours, 4 hours	1320
Total training costs per patient in the intervention group		41
Hospital-based work support intervention	Mean hour of investment of nurse was 1.2 hour, 43 Euros per hour	66
	Mean hour of investment of secretary was 0.16 hour, 30 Euros per hour	5
	Informational leaflet	7
Total intervention costs per patient in the intervention group		78
Total costs per patient in the intervention group		119

Table 3. *(Continued).*

Costs differences between groups in Euros					
	N	**Intervention group**	**Control group**	**Mean difference**	**P-value**
Productivity loss net HCA *(Mean (±SD) Euros)*	128	41393 (± 39269)	38968 (± 38399)	-2425	0.72
Productivity loss net FCA *(Mean (±SD) Euros)*	128	14030 (± 3614)	13529 (± 3313)	-438	0.48
Work adjustments *(Mean (±SD) Euros)*	3*	2975	3025 (± 71)	50	0.67
Hospital-based work support intervention *(Mean Euros)*	128	119	0	-119	NA

Abbreviations: HCA Human Capital Approach; FCA Friction Costs Approach; NA: not applicable; SD: standard deviation. *Only three patients had work adjustments that were not related to productivity.

Discussion

The objective of this study was to determine the effect of a hospital-based work support intervention for cancer patients, as compared to usual care on return to work and quality of life. In general, return-to-work rates were high and both the primary and secondary outcomes did not differ statistically between groups.

Strengths and limitations

One strength of our study was the innovative approach that was used to address the adverse work outcomes of cancer patients. Few studies have addressed this important subject by developing an intervention that is primarily aimed at enhancing the return to work of cancer patients.[10 11] Another strength of this study was the development of an intervention that was based on interventions that seemed effective for enhancing the return to work of cancer patients.[10] Furthermore, an additionally strength of this study was the use of a low-cost intervention that could be implemented without substantially increasing the time required, which is important because of the burden on cancer care. In addition, this intervention was easily adapted to the existing variation in usual psycho-oncological care, which yields high external validity.

One limitation of our study was the inability to include sufficient patients, according to our predetermined power analysis. This power analysis was based on two previous studies, which led us to assume a 17% increase in return-to-work rate due to

the intervention and a control group return-to-work rate of 64%.[12] Unfortunately, both the assumption of the 17% increase in return-to-work rate due to the intervention and the control group rate were too optimistic, as the rate of return to work in the intervention group was 86% and that of the control group was 83%. Therefore, we were not able to evaluate our findings with sufficient power, which led to greater uncertainty in the results.

Interpretation of findings

We found that the intervention was easily accepted in usual psycho-oncological care and we found that patients were notably satisfied with the intervention.[33] For those reasons, addressing the return to work of cancer patients is highly relevant for usual psycho-oncological care. However, we found similar return-to-work outcomes and quality of life scores for both groups. There are several possible explanations for the lack of statistically significant difference between groups, which can be sought in the intervention content and the study design.

Intervention content

The basic assumption behind the intervention was that return to work would increase by means of improved self-assessed work ability as a result of patient education and support that addressed misconceptions about cancer and work. We found that self-assessed work ability increased significantly over time but did not differ significantly between groups. It is possible that addressing these misconceptions could have required a more intense intervention or that the training we provided to the nurses was not sufficient. We do not know precisely which misconceptions impede return to work and which should be addressed. On the other hand, this later possibility was indicated as a number of nurses mentioned that they were not completely convinced of their competence to deliver the return-to-work advice. It may be that our half-day training course was too short to enable nurses to gain the knowledge required to adequately address patients' misconceptions about return to work adequately. For these reasons, it is possible that certain misconceptions regarding cancer and work could have persisted and may have resulted in the absence of an intervention effect.

In addition, we experienced difficulties in involving the occupational physician and the employer for the intervention. The involvement of the occupational physician and the employer appeared to be important,[34] and it is possible that the absence of an intervention effect was caused by the lack of involvement of the occupational physician and the supervisor.

Study design – methodological considerations

Another potential explanation for the non-statistically significant findings may be related to study design. Several sources of potential bias may have influenced our findings. To start with, the contrast between groups may have been reduced in several ways. The quality of usual care regarding work advice was probably higher in hospital departments that were willing and able to participate at the onset of the study compared to those that were not willing or able to participate, as nurses who worked in hospital departments that participated recognised the importance of work for cancer patients prior to the study. Furthermore, we attempted to reduce contamination between groups by separating the nurses who delivered the intervention from those who delivered usual care. However, this separation was not possible in all cases, and therefore contamination occurred to a larger extent. Next, the contrast between groups may have been reduced due to the fact that all cancer patients were informed about the general aim of the study (i.e. information bias) and because the recognition that work is an important aspect for many cancer patients has changed considerably during the time between the development of the intervention and the end of the study.[35] Both aspects may have led to a greater awareness in the usual care group regarding the idea that return to work is a subject that should receive attention. Furthermore, this awareness may have led to the use of concurrent interventions, such as (vocational) rehabilitation. Finally, the contrast between groups may have been reduced due to a patient selection bias; patients participating in this study may already be of the opinion that work is an important subject that should receive attention. In sum, the contrast between groups may have been reduced in several ways, and each of these may have caused an underestimation of the effect of the intervention.

Recall may have been introduced through the assessment of assessing the outcomes over a time interval of six months. We selected this extended time interval to

ease patient burden regarding the completion of the questionnaires. However, this time interval may have been too long to assess return to work reliably. However, measurement error is expected to be the same between the intervention group and the control group. Therefore, it is not likely that this error significantly affected the outcome to a great extent but it may have influenced external validity.

For the primary outcome of quality of life and the secondary outcomes of work ability and impaired work functioning, patients who dropped out of the study differed statistically from those who completed the study on some of the baseline quality of life subscales of the SF-36 (data not shown), as the patients who dropped out had worse quality of life scores. However, the baseline values of the non-completers did not differ statistically between groups. These results indicate that our findings on the effect of the intervention may not have been biased by selective loss to follow-up, but these results also may indicate an overestimation of work ability and quality of life outcomes in these patients compared to the entire population.

In accordance with the intention to treat analysis we included in the survival analysis patients who died within the follow-up period as censored. However, an assumption in survival analysis is that when a patient is censored, the change that a patient will be able to achieve the outcome is still 50%,[36 37] which is not the case in this situation. However, on a population of 133 patients, we do not expect that the 4 patients who were equally divided between the intervention group and control group, influenced the findings significantly.

Comparison with other studies

There have been a few trials that have studied interventions similar to the assessed intervention in the current study. The Cochrane review by De Boer et al identified 18 studies of which 3 evaluated a comparable intervention.[10] Of these three studies, only one was a randomised controlled trial that found a return-to-work rate of 89% and 83% for the intervention and usual care groups, respectively.[38] The remaining two interventions were controlled trials that reported favourable effects of the intervention compared to usual care. However, these studies were of moderate quality.[10] The results of our study are in line with the results of these above-mentioned studies, that only

small effects of such an intervention are to be expected. Further research is needed to study the possibility effectiveness of an improved intervention.

There are some observational studies that showed that the treating physician's advice about return to work influenced work resumption considerably either with a shorter or with a longer return to work.[14 15] However, our study shows that apparently this is an overestimation that is not reproduced in an experimental study.

It is generally acknowledged, that the variation in time to return to work is large; certain patients are never on sick-leave and work throughout treatment, whereas others are never able to return to work. These variations were confirmed by this study, some patients had already fully returned to work before the intervention had started, and others preferred to receive additional support because they were not able to work at the time of follow-up. We found an overall high return-to-work rate, as compared to the study by Spelten et al[22] that used the same inclusion criteria. As their study was conducted approximately 10 years ago, our findings may be an indication for an improved ability to return to work after cancer treatment, which may be caused by the increasing attention for return to work in curative care.[35] On the other hand, a higher return-to-work rate could also be a side-effect of a selective population that participated.

Recommendations for further research and practice

In terms of recommendations for clinical practice, this study revealed that psycho-oncological care can address the return to work of cancer patients early in their treatment, as well as follow-up, as the intervention was appreciated by patients and was perceived as useful and feasible by the nurses.[33] As we found similar work outcomes between the intervention group and the control group, an important recommendation for further research is to study if an improved intervention leads to shorter time to return to work. It may be possible that addressing misconceptions about cancer and work was more difficult than originally estimated. Therefore, it may that interventions need to be more intense, or that the training we provided to the nurses was not sufficient. Both aspects should receive more attention in future research. As it appeared that the involvement of the occupational physician and the supervisor was difficult, the intervention requires improvement on this aspect. One of the possible ways to do this

would be to develop a web-based system or a system of coded emails instead of letters to decrease the barrier to communication.

Due to the large range in time to return to work, it seems important to identify patients who have a higher risk of getting adverse work outcomes based on a clinical prediction rule. Therefore, a recommendation for further research is, to develop such a clinical prediction rule for work outcomes and to evaluate it for the accuracy in identifying patients with a higher risk of adverse work outcomes. Furthermore, apart from identifying patients with a higher risk, it is also important to tailor the level of the intervention to meet the needs of the patients, so called stepped care.

We found that the contrast between groups was reduced, due to the study design. Therefore, another recommendation for further research would be to consider alternative study designs, such as a cluster randomised controlled trial.[39]

In conclusion, we found high return-to-work rates and improved quality of life scores in both the intervention and the control group but there is still considerable uncertainty about the effects of the intervention. Further research is needed to study which aspects of the intervention are useful and which elements need improvement. The intervention was easily accepted into usual psycho-oncological care.

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