Enhancing return to work of cancer patients

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ENHANCING RETURN TO WORK OF CANCER PATIENTS

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Chapter 1.

General introduction

The impact of a cancer diagnosis on a person's life

Cancer is a generic term that comprises many heterogeneous diseases, with different treatment modalities, survival rates, and variable impacts on the health and life of patients.[1] On the other hand, there are many similarities between cancer types, such as the receipt of a sudden and unexpected diagnosis, the fact that it is a life-threatening disease, the time consuming and disabling treatment, and the fear of recurrence.[1] For these reasons, cancer patients are often studied as an entity.

Thanks to excellent doctors and researchers, cancer is no longer a fatal disease for many patients. In the Netherlands, the five-year survival rate increased from approximately 46% in 1989-1993 to approximately 59% in 2003-2007.[2] The cancer survival rate has increased as a result of advanced treatment and as a result of screening and earlier and better diagnosis.[2] In addition, advanced treatment has most often led to a smaller impact on functioning than in the past, and in several cancer types, the quality of life of patients has improved considerably.[2]

Currently, the most common treatment modalities are surgery, chemotherapy, and radiotherapy, or a combination of these three, depending on the cancer diagnosis and the patient's characteristics.[1] The duration of cancer treatment ranges from days to more than a year after the initial diagnosis, depending on the type and number of treatment modalities.[1] In case of a tumour susceptible to hormones, treatment is usually prolonged by years with hormone therapy.[1]

Although the quality of life of cancer patients has improved in the past few decades, many patients still experience long-term physical and psychological complaints. These complaints include, for example, decreased physical function,[3] fatigue,[4] distress,[5] concentration problems, and depression.[6] These symptoms may last from months to years after the end of treatment[7] and may have a negative effect on all aspects of a cancer patient's quality of life.[8] Therefore, for many patients, cancer has become a chronic disease that leads to poorer overall health and lower quality of life in comparison with the general population.[9] [10] Furthermore, apart from long-term physical and psychological complaints, other factors such as having paid employment, the amount of social support, and the current income level are associated with the quality of life of cancer patients.[11] [12]

Receiving a cancer diagnosis is, for many patients a life-changing event[13] that often results in an evaluation of their various roles in life. As a consequence, some patients set new priorities while others want to return to 'normal' as soon as possible. In addition, some cancer patients are forced to make adjustments to their lives due to long-term physical or psychological complaints.

The importance of work for cancer patients

Cancer may result in a re-evaluation of the role of work in patients' lives.[14-18] As a result, some cancer patients decide to stop working and retire early while others decide to keep working. A decision to retire early is made, for instance, due to health problems[19] or economic self-sufficiency,[20] whereas a decision to keep working may include a goal of returning to 'normal'.[21] Unfortunately, some patients are forced to stop working as a consequence of a cancer diagnosis or due to the long-term side effects (e.g. concentration problems, fatigue) in combination with a patient's work demands.[22]

Various studies have noted that cancer patients attribute great meaning to work.[18,21] For example, cancer patients report positive outcomes of having paid work; work provides social inclusion,[17 23] reduces financial problems,[18 23] is associated with the quality of life of cancer patients, [12 24] and shapes life after treatment.[18] Furthermore, cancer patients report a positive attitude towards work; work offers a sense of control in insecure times,[21] a sense of self-worth,[25] gives meaning to life,[17] and it takes the patient's mind off of the illness.[15 17 23] As a result, a return to work should be made possible for those patients who are able and want to do so.

The scale of studying work in cancer patients

In 2009, the number of people diagnosed with cancer (i.e. the incidence) was approximately 91.000 in the Netherlands[26] and is expected to increase to approximately 123.000 in 2020.[2] This increase is caused by the ageing of the population because the incidence of cancer is strongly related to older age.[2] In 2009 the number of people living with cancer (i.e. the prevalence) was approximately 420.000 in the Netherlands,[26] and this number is expected to increase to 666.000 in 2020,[2] an increase of 57%.

In the Netherlands, approximately 40% of the cancer patients are in the working population.[26 27] The working population is defined as all people in the 15-64 age group

of which approximately 70% has paid employment for at least twelve hours per week.[28] In 2009, the incidence of cancer in the working population was approximately 38.000.[26] It is expected that this incidence will increase in the near future.[29] Reasons for this increase in incidence include: increased survival rates for (childhood) cancer,[2] the ageing of the working population,[28] and people having to work longer before retiring. The last factor is likely to contribute the most to an increase of the incidence of cancer in the working population. This is because the incidence in the 65-69 age group was 11.666 in 2009,[26] which would have meant a 34% increase of cancer in the working population. Consequently, employees diagnosed with cancer will become more common in the workplace.

The adverse work outcomes of cancer patients

Cancer patients have a 37% higher risk of unemployment in comparison to non-cancer patients.[30] Additionally, the rate of return to work of patients ranges between 30% and 93%.[31] The variation among cancer patients is large: some are never sick-listed, whereas others are never able to return to work. In addition to work loss, some patients are confronted with lower work functioning,[32 33] lower work ability,[34 35] difficulties with managing their work,[36 37] unreasonable treatment at the workplace,[36 38] or face a decrease in income.[39 40] It is not only cancer patients experiencing these adverse work outcomes who are affected; the employer and the society are affected as well due to associated costs related to absenteeism, lower work productivity, and disability pensions.[41]

Difficulties with the return to work of cancer patients are associated with factors from various areas and are described extensively in the literature.[42] For instance, factors that have been associated with these difficulties are as follows: socio-demographic characteristics (e.g. age),[43 44] clinical characteristics (e.g. diagnosis),[12 45] work-related characteristics (e.g. work accommodations),[36 46] personal-related characteristics (e.g. work ability),[47] and the social security system (e.g. level of compensation). Stakeholders from various contexts and with various motives are involved in the return to work of cancer patients, i.e. work (e.g. the supervisor),[48-50] health care (e.g. the physician),[51 52] social security (e.g. the occupational physician),[53] and the personal environment (e.g. the family).[52] Adverse work outcomes are often measured as work loss due to ill health.

Nevertheless, other, less apparent, aspects have a significant impact as well; for example, reduced work functioning, reduced work ability, loss of earnings, loss of promotion opportunities, lower job satisfaction, or the inability to change jobs. Therefore, it is not only work loss at follow-up that is a subject of study in this thesis but also work functioning and work ability. However, measuring work functioning may be difficult[54] and as a result, tools that measure work functioning adequately are necessary. Adverse work outcomes irrevocably lead to additional costs for the society, the employer, and for a work-disabled cancer patient. In consequence, it is not only the level of work disability that is measured in this thesis but also the associated costs from a societal perspective.

This thesis focuses on paid employment only, as unemployment and unpaid work both entail a different institutional context. This thesis focuses on cancer patients who are treated with curative intent and who have a reasonable life expectancy only.

Organisation of the social security system in the Netherlands

Both the institutional and the cultural contexts of a country have an effect on adverse work outcomes,[54 55] which differs greatly among developed countries. Therefore, to be able to understand how these outcomes evolve for sick-listed employees, it is necessary to know how the social security system protects employees who have adverse work outcomes, and to know about the cultural context in which this system is embedded.

In the Netherlands, personal health insurance is not linked to an employment contract, and it is not of interest if a sickness absence is work-related or not. The Improved Gatekeepers Act covers the insurance of sick-listed employees against wage loss and is in force during the first two years of sick leave. The Act states that a sick-listed employee cannot be fired due to health reasons. Additionally, sick-listed employees receive at least 70% of their wage, but often 100%, in the first year, which the employer is obligated to pay. Both the employer and the sick-listed employee are responsible for the return to work. Sick-listed employees usually have an occupational physician who makes a disability evaluation with regard to the employee's work and health situation, and who independently advises the employer and the employee on a return to work. In the Netherlands, employees with cancer should be guided according to the evidence-based guidelines of the Dutch Association of Occupational Physicians.[56]

After two years of sick leave, an insurance physician of the Dutch Institute for Employee Benefit Schemes (UWV) assesses whether the sick-listed employee qualifies for a disability pension. This government institution is obligated to pay the disability pension. The employer can then terminate the employment contract.

In conclusion, because work is important for cancer patients and because a substantial number of the patients are confronted with adverse work outcomes, it is essential to address this problem with appropriate interventions. The subsequent sections provide a brief description of the theoretical approach, possible appropriate interventions to address this problem, and discuss how these interventions should be evaluated. Hereafter, the objective of this thesis, the research questions, and the outline of this thesis are presented.

The theoretical approach to adverse work outcomes of cancer patients

Various models exist to describe adverse work outcomes originating from a health deficit, depending on the area of research and the objective.[57] Because a person's health is not directly related to the level of adverse work outcomes but is influenced by the personal (e.g. coping) and the environmental context (e.g. work demands) and involves various stakeholders,[42 57] most models address the complexity of adverse work outcomes. It is important to understand these factors and understand each stakeholder to comprehend the underlying mechanism of this problem. This is important for the development of interventions and the identification of patients at the highest risk of being confronted with adverse work outcomes.

In this thesis, two models have been used as theoretical approaches to address adverse work outcomes affecting cancer patients: the International Classification of Functioning (ICF) of the World Health Organization (WHO)[58] and the shared-care model for cancer survivor care.[59] First, the International Classification of Functioning (ICF) of the World Health Organization (WHO) is used as a theoretical approach of adverse work outcomes of cancer patients because this model elaborates on the clinical characteristics and addresses these outcomes from the patient perspective.[58] This is considered important, because clinical characteristics such as the cancer diagnosis, treatment, and long-term side effects are significant prognostic factors for adverse work

outcomes of patients.[42] [45] In addition to clinical characteristics, the ICF provides clarification for the finding that both personal factors (e.g. self-assessed work ability), and environmental factors (e.g. work demands) are important prognostic for whether patients return to work.

Second, because the adverse work outcomes are considered as one aspect of cancer survivor care, this problem should not be dealt with in isolation but should be integrated into cancer care and occupational health care. Therefore, the shared-care model for cancer survivor care is used as a theoretical approach for hospital-based integrated care.[59] This model is adapted to study adverse work outcomes, the occupational health care setting, and to addresses adverse work outcomes in an early phase while improving the communication between the hospital and the occupational physician. The studies described in this thesis verify whether this model of hospital-based integrated care can be adapted to adverse work outcomes and the occupational health care setting.

Interventions to reduce adverse work outcomes of cancer patients: hospital-based integrated care

As mentioned, the degree to which someone is confronted with adverse work outcomes is a complex phenomenon that is influenced by various factors and involves various stakeholders. For this reason, interventions aimed at reducing the occurrence of such event for cancer patients should intervene multiple factors, stakeholders, or a combination of these.

Health outcomes are related to the adverse work outcomes of cancer patients. For that reason, interventions aimed at improving cancer treatment or aimed at managing the adverse side-effects of cancer treatment may have the potential to reduce these outcomes. Furthermore, cancer care that is focused on work as well, may be beneficial. For example, physicians' advice about work is correlated with the return to work by patients.[51] Therefore, providing work advice as part of cancer care may be useful. On the other hand, a personal factor such as self-assessed work ability is an important prognostic factor for a return to work, irrespective of clinical characteristics.[47] For this reason, interventions addressing misconceptions about work ability may be beneficial.[60] The work environment is another important factor that significantly influences the

adverse work outcomes of cancer patients. Thus, interventions aimed at facilitating workplace accommodations and improving guidance by occupational physicians or the employer may be effective as well.[53]

Apart from designing interventions to reduce adverse work outcomes in cancer patients, studying both the effectiveness of such an intervention and the intervention implementation process itself, in a study with high methodological quality is also important. By studying the effectiveness of an intervention, one is able to decide whether it reduced adverse work outcomes. By studying the intervention implementation process, one is able to conclude if the intervention was implemented as intended, which is important when interpreting the findings of an intervention; should the intervention itself be optimised or its implementation?

Currently the 'gold standard' for determining the effectiveness of an intervention is a randomised controlled trial[61] in which patients are allocated randomly to an intervention group or to a control group. At the end of the study, the intervention group is compared to the control group on the basis of outcomes defined a priori. Effectiveness is established if the intervention group demonstrates a statistically significant improvement on one of these outcomes compared to the control group.

As mentioned previously, adverse work outcomes are often measured as work loss due to ill health. Therefore, the primary outcome of an intervention that aimed at reducing adverse work outcomes among cancer patients should measure the time from sick leave to return to work. However, a return to work cannot be at the expense of quality of life. Therefore, an intervention should be considered effective if patients assigned to the intervention group have a return to work significantly faster than patients assigned to the control group (usual care) and if, at the same time, their quality of life does not significantly deteriorate.

Less apparent aspects of adverse work outcomes have a significant impact as well; along with a return to work, work functioning and work ability should also be measured outcomes. One commonly used measurement tool of impaired work functioning due to ill health is the Work Limitation Questionnaire (WLQ).[62] However, two reviews on the measurement properties of questionnaires that measure work functioning due to ill health noted that the measurement error of the WLQ has not been determined.[63] [64] The measurement error is an important property of a

questionnaire when using it to quantify the outcome of an intervention. To be able to use the WLQ as an outcome measure, both the measurement error and the measurement properties of the Dutch translation of the WLQ should be determined in a population of cancer patients.

Objective of the thesis and research questions

In conclusion, since the survival rates of cancer have increased considerably in recent years, the majority of cancer patients face new challenges upon cancer survivorship. For patients of working age, one key factor of cancer survivorship is work, as work provides personal and economic value. Unfortunately, previous studies indicated that cancer patients are more often confronted with adverse work outcomes when compared with the general working population. For this reason, it is important to design comprehensive interventions to reduce adverse work outcomes among cancer patients. Such hospital-based work support intervention should be evaluated in studies with high methodological quality, including effectiveness analysis as well as a process evaluation. Furthermore, as the psychometric properties of the WLQ, a commonly used questionnaire that measures impaired work functioning, are currently unknown for Dutch cancer patients, this should be subject of study as well.

In line with this rationale, the main objective of this thesis is to gain more knowledge on how to reduce the adverse work outcomes of cancer patients. The following research questions are put forward:

1. What are important aspects in the design of a hospital-based work support intervention for cancer patients with the aim of enhancing the return to work and quality of life?
2. What are the measurement properties of the Dutch translation of the Work Limitation Questionnaire (WLQ) among cancer patients?
3. How is the process of a hospital-based work support intervention for cancer patients evaluated?
4. What is the effectiveness of a hospital-based work support intervention compared to usual care for cancer patients on return to work and quality of life?

Outline of the thesis

Chapter 2 presents a systematic review on the content of interventions focusing on the return to work of cancer patients as well as on the assessment of the efficacy of these interventions on the return to work. **Chapter 3**, a qualitative study, describes cancer patients' experiences with their return to work. In **Chapter 4**, a validation study of the Dutch translation of the Work Limitation Questionnaire (WLQ) among cancer patients is presented. **Chapter 5** provides a description of the development of a hospital-based work support intervention for cancer patients as well as a study design to evaluate the effectiveness of the intervention. **Chapter 6**, **7**, and **8** address the evaluation of a hospital-based work support intervention for cancer patients: **Chapter 6**, a case study, illustrates its application; **Chapter 7** provides a process evaluation; and **Chapter 8** presents the effectiveness on return to work and quality of life, work ability, work functioning, and costs (e.g. lost productivity costs). This thesis ends with a general discussion in **Chapter 9**, in which the main findings of the studies described in this thesis are summarised and interpreted. In addition, the context in which these studies were conducted is illustrated. This general discussion ends with recommendations for further research and practice.

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Chapter 2.

Return-to-work interventions integrated into cancer care: a systematic review

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Abstract

Objectives

The purpose of this study was to review the literature on the content of interventions focusing on return to work, employment status, or work retention in patients with cancer. Furthermore, the effect of the interventions on return to work was assessed in studies reporting return to work.

Methods

A literature search was conducted using the databases MEDLINE, PsycINFO, EMBASE, and CINAHL. Articles that described a work-directed intervention focusing on return to work, employment status, or work retention in patients with cancer were included. The content of the work-directed part of the interventions was assessed based on two criteria for content analysis: 1) Does the setting fit the shared care model of cancer survivor care? 2) Does the intervention target work ability and physical workload? For studies reporting return-to-work outcomes, the return-to-work rates were assessed. For studies that used a control group the ORs and the 95% CIs were calculated.

Results

Twenty-three articles describing 19 interventions met the inclusion criteria. Seven studies reported return-to-work outcomes of which four used a control group. Only three interventions aimed primarily at enhancing return to work or employment status. The most frequently reported work-directed components were encouragement, education or advice about work or work-related subjects (68%), vocational or occupational training (21%), or work accommodations (11%). One intervention fit the shared care model of cancer survivor care and five interventions enhanced work ability or decreased physical workload. The rate of return to work ranged from 37% to 89%. In one of the four controlled studies the intervention increased return to work significantly and in the other studies the results were insignificant.

Conclusions

Only few interventions are primarily aimed at enhancing return to work in patients with cancer and most do not fit the shared care model involving integrated cancer care.

Future studies should be developed with well-structured work-directed components that should be evaluated in randomised controlled trials.

Introduction

Survival rates of cancer have increased in recent years as a result of screening, earlier and better diagnosis, and advanced treatment.[1] It is generally assumed that the incidence of cancer in the working population in Western countries will increase due to the ageing of the working population and the trend that people have to work longer until their retirement.[2] As a consequence, patients with cancer and cancer survivors will become more common in the workplace. One of the aspects of quality of life is the preservation of work or return to work,[3] which is decreased in cancer survivors as compared to cancer-free controls. Loss of work may result in a lower quality of life, lower self-esteem, and financial losses.[4] In contrast, working gives a sense of normalcy, distraction, and is seen as an important part of recovery by cancer survivors.[5 6] Not being able to work is not only a loss for cancer survivors, but also for the employer and society at large due to absenteeism and lost productivity.[7]

Earlier research showed that not all cancer survivors who were working prior to their diagnosis do return to work. In their review, Spelten et al found a mean return-to-work rate of 62% (ranging from 30% to 93%).[8] Furthermore, cancer survivors who do (partly) return to work still have a greater level of work limitations and suffer from loss of productivity in comparison with the general population.[9-11] In addition, some patients with cancer experience job discrimination, hostility in the workplace, lack of emotional and practical support from managers and from occupational health services, and become involved in disputes on terms of employment.[7 12-14]

Interventions to support cancer survivors in solving these work-related problems are needed. The International Classification of Functioning (ICF) offers a theoretical framework for developing interventions, whereas three opportunities for interventions are provided: 1) improving body structure and functioning, 2) improving environment-related factors, and 3) improving person-related factors.[15 16] Better treatment of cancer and management of cancer-related problems such as fatigue will improve body structure and functioning, with a subsequent improvement in disabilities and work functioning. Interventions to adapt the work environment and interventions to

improve person-related factors such as thoughts and expectations regarding return to work will have a potential for preventing long term disability as well.[7 8 17] Cancer treatment is well studied, however, work-directed interventions to improve work functioning are not. A review, studying the effects of interventions in breast patients with cancer with return to work as an outcome found only four studies of low methodological quality.[18] More information on the characteristics of work-directed interventions, for all patients with cancer, is needed to further develop interventions that can help patients with cancer with their return to work.

Therefore, the aim of this study was to review the literature on the content of interventions focusing on return to work, employment status, or work retention in patients with cancer. Furthermore, the effect of the interventions on return to work was assessed in studies reporting return-to-work outcomes.

Methods

A review protocol has been made in which the search strategy, article selection, and data extraction were taken into account. The Preferred Reporting Items for Systematic Reviews (PRISMA statement) have been used as formal systematic review guidelines.[19]

Search strategy

The following databases were searched: MEDLINE (PubMed), PsycINFO (ERL Webspirs/Ovid), EMBASE (Ovid), and CINAHL (EBSCO), with no restriction on language or on publication year but restricted to human studies (until October 2008). The following main medical subject headings were used: neoplasms AND intervention studies AND (vocational) rehabilitation. These medical subject headings were completed with text words and synonyms for neoplasms, work-directed terms, and intervention studies. To exclude irrelevant articles on occupational exposure, occupational diseases, and palliative care, the search strategy was refined by introducing a number of medical subject headings as 'not-terms' (see Appendix for the search strategy for PubMed).

Article selection

Articles were included if the following criteria were met: 1) patients were diagnosed with cancer at age ≥ 18 years, 2) description of an intervention aiming at the improvement of return to work, employment status, or work retention through improvement of work-environment-related or person-related factors. Articles describing an intervention that were exclusively focused on improvement of body structure or functions were excluded. Article selection was performed in three steps. In the first step, articles were independently selected by two authors (ST and AdB) based on title and abstract. In the second step, full articles were retrieved and included if the inclusion criteria were met. Articles in a language other than English, Dutch, or German were translated by an expert. In the third step, the reference lists of the selected articles and of the selected reviews were hand-searched for additional references, and experts were asked to recommend relevant articles. In cases of disagreement, a third author (MF) decided if the article met the inclusion criteria.

Data extraction

The data were extracted by one author (ST) onto a pre-designed data extraction form and checked by another (AdB or JV). In cases of disagreement, a third author (MF) decided which data were correct.

Criteria for content analysis

The content of the work-directed components of the interventions were assessed based on two criteria for content analysis. The first criterion considered if the setting in which the intervention was carried out fitted the shared care model for survivor healthcare.[20] According to this model, the oncologist provides cancer therapy in the early phase and the primary care physician takes over survivorship care after 1 or 2 years. They communicate with each other during all times and transfer knowledge periodically. For countries where an occupational physician is involved, we assumed a similar role for them as for the primary care physician. The model addresses both return to work in an early phase and improved communication which is beneficial for return to work.[21]

The second criterion was if the intervention included measures to improve self-perceived work ability and adapt physical workload which are the most important amenable prognostic factors for return to work in patients with cancer.[17 22]

Effect of the interventions on return to work

For those studies that reported return-to-work outcomes the characteristics of the study design and return-to-work outcomes were extracted. The return-to-work outcome was based on the number of patients who worked at the start of the study and who were employed but not on sick leave at follow-up. Furthermore, the ORs and 95% CIs for not returning to work were calculated if a study used a control group. These data are presented as forest plot using the software implemented in the software programme RevMan5.[23]

Methodological quality assessment

The methodological quality of the articles, which included return-to-work outcomes, was assessed using the Methodological Index for Non-Randomised Studies (MINORS).[24] The MINORS consists of 12 items of which each item can receive a score of 0 - 2 points, resulting in a maximum score of 24 points. Four of these items are only applicable in case of an article which used a control group. The quality assessment was conducted by two authors independently (ST and AdB). In cases of disagreement, a third author (MF) decided which score was correct.

Results

The search yielded 4606 articles and after excluding for doubles, 4158 articles were identified (Figure 1). Based on title and abstract, 4029 articles were excluded mostly because the intervention was not focused on return to work, employment status, or work retention or because the article did not involve an intervention. Of the 129 remaining articles, 20 articles were included after reading the full text. The other 109 articles were excluded because in 75 articles the intervention was not focused on return to work, employment status, or work retention; in 30 articles there was no intervention; and in five articles the content of the intervention was not described or the intervention did not contain a work-directed component. Three additional articles were

identified through the references of the selected articles and selected articles from experts. The references of 10 selected reviews did not reveal new articles. This resulted in 23 articles that were included in this review.[5 25-46] Two interventions were reported twice,[31 32 44 45] and one intervention was reported three times,[25-27] resulting in the description of the content of 19 different interventions.[5 25 28-31 33-43 45 46] Furthermore, of the 23 articles, seven studies reported return-to-work outcomes[25 26 28 32 37 38 41] of which four used a control group.[25 26 28 38]

Study and patient characteristics

Table 1 summarises the author(s), publication year, country, and patient characteristics of the 23 included articles. Ten articles (43%) were published more than 15 years ago while 10 articles (43%) were published in the last five years. The included articles were conducted in the USA (39%), Scandinavia (26%), the Netherlands (22%), Germany (9%), and the UK (4%). Female patients with cancer were studied most, with seven articles (30%) composed exclusively for patients with breast cancer, and in another nine articles (39%), breast cancer was the most common diagnosis. Furthermore, one article (4%) was composed exclusively for male patients with cancer aiming at patients with prostate cancer. Three articles (13%) included non-metastatic patients only, and one article (4%) included both metastatic as non-metastatic patients. Of the remaining 19 articles (83%) the disease status was either unknown or another kind of eligibility criterion was used, such as life expectancy. The mean age of the patients in the included articles was 48 ± 6 years.

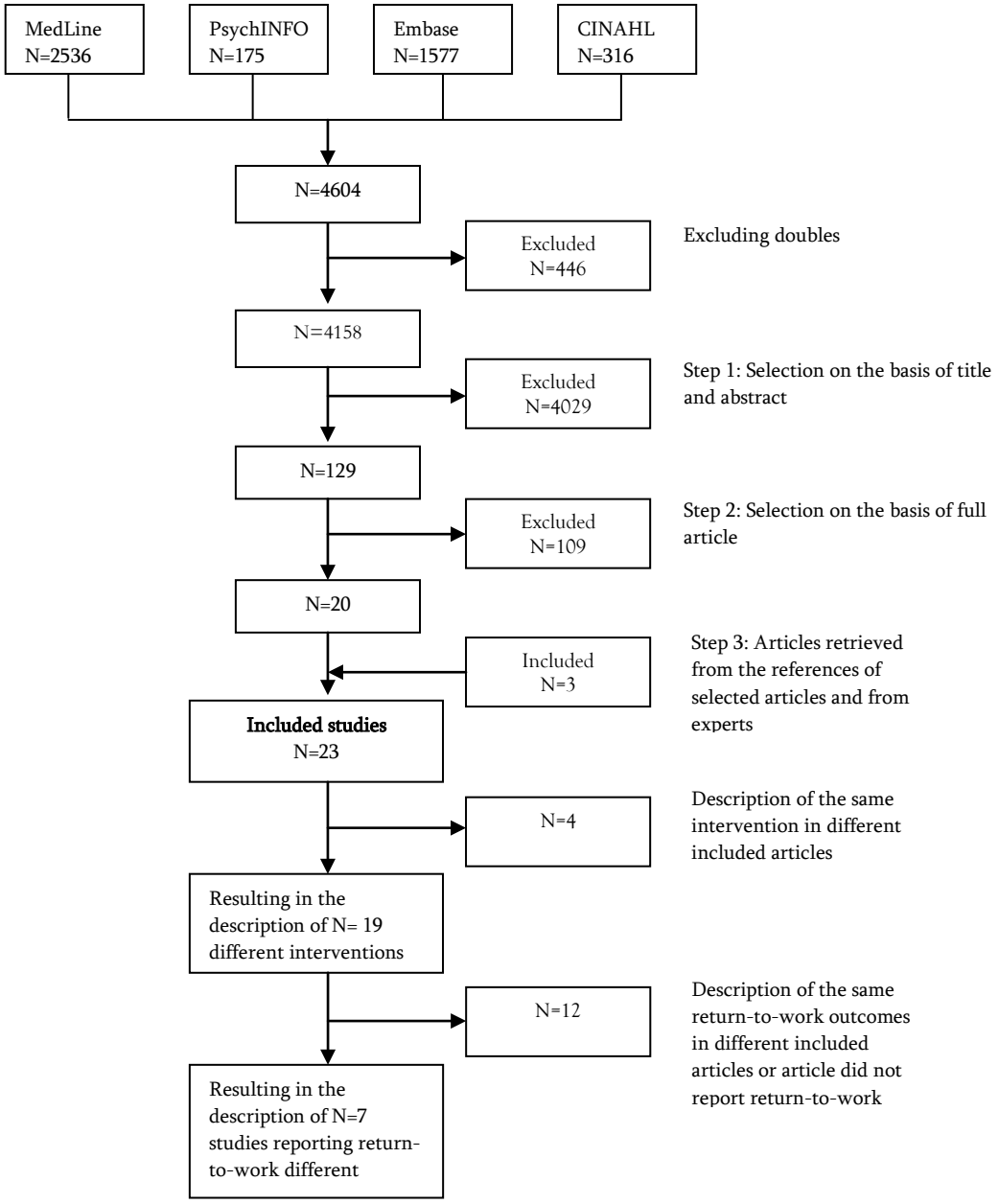

Figure 1. Article selection.

Table 1. Study and patient characteristics.

Author(s)	Publication year	Country	Diagnosis is	Patient characteristics[1]			
				Intervention group[2]		*Control group*[3]	
				Sample size, partition female	*Age (mean±sd, range)*	*Sample size, partition female*	*Age (mean ± sd, range)*
Capone et al[28]	1980	USA	Primary malignancy of the female genital organs	56, 100%	NR[4], 20-80	41, 100%	20-80
Maguire et al[38]	1983	UK	Breast cancer	75, 100%	NR	77, 100%	NR
Clark and Landis[5]	1989	USA	Breast cancer	NA	NA	NA	NA
Mellette[39]	1989	USA	Mixed	NA	NA	NA	NA
Leitsmann et al[37]	1991	Germany	Primary malignancy of the female genital organs or breast cancer	363, 100%	NR, 18-60	NA	NA
Zampini and Ostroff[46]	1993	USA	Mixed	714, 77%	NR, 20-59	NA	NA
Berglund et al[25-27]	1993	Sweden	Mixed (mainly breast cancer 83%)	30, 99%	53.2±NR, NR	30, 99%	54.2±NR
	1994a,b		Mixed (mainly breast cancer 80%)	98, 96%	52.5±NR, NR	101, 97%	53.9±NR
Rinehart[42]	1994	USA	Breast cancer	NA	NA	NA	NA
Sherer et al[43]	1997	USA	Primary malignant brain tumour	13, 38%	34.3±10.0, 23-52	NA	NA
Fismen et al[31 32]	2000, 2007	Norway	Breast cancer	50, 100%	49.0±NR, 31-66	NA	NA
Van Weert et al[44]	2004	The Netherlands	Mixed (mainly breast cancer 68%)	37, 84%	52.8±6.2, 43-67	NA	NA
	2005		Mixed (mainly breast cancer 59%)	81, 84%	51.6±9.3, NR	NA	NA
Cimprich et al[30 45]	2005	USA	Breast cancer	25, 100%	48.0±8, 34-66	NA	NA
Heim and Schwerte[33]	2006	Germany	Prostate cancer	NA	NA	NA	NA
Korstjens et al[35]	2006	The Netherlands	Mixed (mainly breast cancer 54%)	658, 78%	50.6±9.5, 18-75	NA	NA
Nieuwenhuijsen et al[41]	2006	The Netherlands	Mixed (mainly breast cancer 50%)	26, 73%	45.8±6.5, NR	NA	NA
Meneses et al[40]	2007	USA	Breast cancer	129, 100%	54.5±11.6,NR[5]	NA	NA
Høybye et al[34]	2008	Denmark	Mixed (mainly breast cancer 55%)	2174, 84%	55±NR, 35-76	NA	NA

Table 1. *(Continued).*

Korstjens et al[36]	2008	The Netherlands	Mixed (mainly breast cancer 57%)	Group 1: 71, 80%	49.9±11.3, NR	NA	NA
				Group 2: 76, 87%	47.8±10.5, NR	NA	NA
Chan et al[29]	2008	USA	Mixed	1201, 53%	40.1±14.1, NR	NA	NA

1. Patient characteristics of the intervention group or control group at baseline before the start of the intervention, unless stated otherwise.
2. NA: not applicable because intervention description only.
3. NA: not applicable because no control group or no return-to-work outcome variables reported
4. NR: not recorded.
5. Mean age of the control + intervention group.

Content of the interventions

Table 2 summarises the characteristics of the 19 interventions and the content of the work-directed part of the intervention. Only three interventions (16%) focussed primarily on improving work outcomes. Of these, two (11%) focused on return to work,[5 41] and one (5%) on employment status.[29] Of the other interventions, 15 (79%) aimed more broadly at improving quality of life and/or general functioning,[25 30 31 33-40 42 43 45 46] and one (5%) aimed at improving psychosocial symptoms.[28] Six interventions (32%) were at least partly carried out in an inpatient setting,[28 33 38 39 42 43] while 13 interventions (68%) were carried out in an outpatient setting. The start of the rehabilitation programme varied from before treatment,[28] to several years after diagnosis.[43] In six interventions (32%) follow-up care was provided by telephone or face to face.[5 31 38 40 42 43] One programme (5%) was entirely carried out in groups,[25] eight programs (42%) were carried out entirely on an individual basis,[5 28 29 38-42] and 10 interventions (53%) were carried out both individually and in groups.[30 31 33-37 43 45 46]

All interventions consisted of more than one component. Thirteen interventions (68%) were a combination of counselling and education, usually carried out by a nurse, a social worker, or a psychologist.[5 25 31 34-38 40 42 43 45 46] Six interventions (32%) had an additional component of physical exercise, usually carried out by a physical therapist.[25 31 34-36]

Table 2. Characteristics of the work-directed part of the interventions.

Author(s)	Start/end intervention, duration	Inpatient/outpatient/ setting	Description of the interventions	Discipline of trainers or counsellors
Capone et al[28]	1 session prior to initial treatment last session prior to discharge	Inpatient, gynaecologic	Efforts were made to encourage early return to usual social functions.	Psychologist
Maguire et al[38]	Within a few days after surgery, follow-up every 2 months unless patient adapted well	Inpatient, surgical unit/outpatient, at home	Monitor their progress concerning among others return to work. Patients were encouraged to return to work.	Specialist nurse
Clark and Landis[5]	At the time of diagnosis	Outpatient	a. Prevention-anticipatory guidance: potential problems are identified, strategies are selected to clarify misconceptions and debunk myths related to cancer, evaluate organisational policies and practices that may discriminate against patients with cancer and modify negative attitudes toward patients with cancer in the workplace. Attention should be paid to the other members of the organization.	Management team, occupational health team, and co-workers
			b. Restoration-rehabilitation counselling: assessment of cancer treatment and job requirements, satisfaction with work and work situation, desire to work during or after treatment. Develop a strategy for information sharing about the cancer experience with co-workers. A comprehensive work-re-entry plan is made (i.e. temporary work reassignment, rescheduling, retraining for another job, exploration for career options, flexible work schedules, job sharing).	Occupational health nurse, management personnel of the company and health care providers of the community
			c. Support-health maintenance and counselling: counselling regarding safety measures, regular follow-up in the early phase of re-entry process. Informing about insurance benefits, disability and rehabilitation benefits of employment.	Occupational health nurse
Mellette[39]	At the time of diagnosis	Inpatient, hospital/outpatient in the clinic or at home	To facilitate patients' return to work, the speech pathologist or rehabilitation counsellor calls or visits their employer.	Rehabilitation counsellor or speech pathologist

Table 2. *(Continued).*

Leitsmann et al[37]	Particularly in the first 2 years after diagnosis, after primary treatment	Outpatient, hospital	a. Work was among others a topic of the group sessions. Advice about work was linked to the group sessions. Semi-structured interviews preceding the group sessions were organised in order to facilitate the decision process about reintegration into working life.	Mainly done by a psychologist
			b. Work which corresponds with the needs of rehabilitation (e.g. reduction working hours) and change of job can be arranged in collaboration with social worker, general practitioner, company, and specialist.	Social worker, general practitioner, company, and specialist
Zampini and Ostroff [46]	After completion treatment	Outpatient, office building	a. Education - seminars and workshops: e.g. employability and legal rights, career development, job search skills.	Invited speaker, staff member with expertise in insurance and employment, consultants from the psychiatry services, social worker, and volunteer
			b. Counselling support: e.g. career decisions.	
Berglund et al[25]	Within 2 months after post-operative treatment with radio- and/or chemotherapy, during 7 weeks	Outpatient, hospital or centre separate from the hospital	Coping: by role playing of common situations when returning to work whereas the following situations were included: how to handle problem situations; people asking too much or too little or having peculiar attitudes towards cancer.	Psychologist, oncology nurse
Rinehart[42]	After surgery	Inpatient, hospital/ outpatient, at home, by phone, physician's office	To provide tips about handling issues such as related to their job.	Trained volunteer (peer model) who is matched to the patient by age, and type of surgery
Sherer et al[43]	On average 75.4 ± 87.9 months since diagnosis, during on average 2.6 ± 1.9 months	Inpatient Rehabilitation clinic	a. Initial evaluation of functioning (e.g. work site observation).	Psychologist, speech/language pathologist, occupational therapist, and vocational specialist
		Outpatient community-based setting	b. Volunteer job placement, performing duties similar to the patient's desired eventual vocational goal. Additional interventions if necessary.	

Table 2. *(Continued).*

Sherer et al[43]			c. Patients were assisted with returning to their desired independence or productive activities (i.e. writing a resume, organising a job search, facilitate patients use of compensatory strategy, periodic follow-up to maintain therapeutic gains). d. Therapists visit the job site to facilitate the patient's use of compensatory strategies and to recommend any alternations of the site or job duties needed to ensure the patient's optimal performance.	
Fismen et al[31]	After end medical treatment, during 4 months	Outpatient, rehabilitation centre and at home	Relationship with colleagues was among others a topic of the cognitive group discussions.	Nurse, oncologist
Van Weert et al[44]	Median time since end treatment 7.1 months, during 6 weeks	Outpatient, rehabilitation centre	Information: reduce uncertainty due to lack of knowledge of the disease by providing information with respect to cancer-related subjects such as work.	Several health care professionals
Van Weert et al[45]	Median time since end of treatment 11.3 ± 13.2 months, during 15 weeks			
Cimprich et al[30]	Following completion treatment, during 7 weeks	Outpatient	Group sessions dealing with psychological well being and transitioning successfully work: sharing the challenges of return to work and discussions on strategies and resources to facilitate a smooth return to work. Participants select specific goals and identify needed skills based on their own concerns.	Oncology nurse practitioner, and health educator
Heim and Schwerte[33]	NR	Inpatient/ outpatient	Vocational rehabilitation: gradual return to work with limited working hours, group sessions with theme work, workplace training on vocational aid (i.e. technical work aid, training course, reintegration aid).	Several health care professionals
Korstjens et al[35]	Time since end of treatment 1.3 ± 2.0 years, during 3 months	Outpatient, rehabilitation centre	Psycho-education: providing support in coping with cancer and enhancing self-confidence and autonomy. Discussion on subjects such as returning to work.	Oncology nurse, psychologist, social worker, and dietary advisor

Table 2. *(Continued).*

Nieuwen-huijsen et al[41]	Range 3-202 (median 45) days after the initial radiation therapy	Outpatient, hospital	a. The researcher sends 2 letters from the radiologist to the occupational physician with information about diagnosis, treatment plan, and outcome of the treatment.	Researchers
			b. The educational leaflet with practical guidelines (10 steps of advice – e.g. make return-to-work plan) was given to the patients to enhance return to work and was sent to the occupational physician.	Radiotherapy oncologist
Meneses et al[40]	Within 1 year of diagnosis, at least 1 month after surgery, during 6 months	Outpatient	Face to face education and support session with topics such as work.	Oncology nurse
Høybye et al[34]	Completed primary treatment, during 6 days	Outpatient, mediaeval castle	Lectures and patient group work on themes such as working life.	Several health care professionals
Korstjens et al[36]	Time since end treatment 1.3 ± 1.7 years, during 12 weeks	Outpatient, rehabilitation centre or hospital	Cognitive-behavioural training: interactive psycho-education and self-management skills training. Patients learn to apply self-management skills in striving for personal goals such as work.	Psychologist, nurse, physiotherapist, and social worker
Chan et al[29]	NR	State vocational rehabilitation services	Assessment, diagnosis and treatment of impairments, vocational rehabilitation counselling and guidance, college or university training, occupational/vocational training, on-the-job training, basic academic remedial or literacy training, job readiness training, disability-related augmentative skills training, miscellaneous training, job search assistance, job placement assistance, on-the-job supports, transportation services, maintenance services, rehabilitation technology, reader services, interpreter services, personal attendant services, technical assistance services, information and referral services and other services.	Rehabilitation counsellor

Content of the work- directed components of the interventions

The work-directed components are divided according to the ICF model into person-directed intervention components and environment-directed intervention components. Since some interventions have more than one work-directed component, the total number exceeded the 19 interventions.

Person-directed intervention components

In 13 interventions (68%), the work-directed component consisted of encouragement, education such as educational leaflet, counselling or advice about work or work-related subjects, or topical discussion of work in a group session.[5 28 30 33-35 37 38 40-42 45 45 46] In three interventions (16%), the intervention engaged the participants more by means of coping skills training, discussing the relationship with co-workers, and the learning of applying self-management skills in striving for personal goals such as work.[25 31 36]

Environment-directed intervention components

The environment-directed intervention components consisted of one intervention each of work which correspond with the needs of rehabilitation and of change of job,[37] gradual return to work with limited work hours, and of workplace training/vocational aid,[33] the sending of two letters from the treating physician to the occupational physician in order to enhance communication,[41] and the speech pathologist or rehabilitation counsellor calls or visits the employer of the patients.[39] In 13 interventions (68%),[25 28 30 31 34-38 40 42 45 46] job demands were not taken into account and in 12 of these (63%)[25 28 30 31 34-36 38 40 42 45 46] neither the workplace, nor the employer, nor the occupational physician, were part of the intervention.

Combination of intervention components

Three interventions (16%) consisted of a combination of person-directed and environment-directed intervention components. Clark and Landis conceived an intervention that consisted of prevention-anticipatory guidance such as strategies are selected to clarify misconceptions and myths related to cancer, restoration-rehabilitation counselling such as a comprehensive work re-entry plan, and support-health maintenance consisting of for instance regular follow-up in the early phase of

the re-entry process.[5] The intervention of Chan et al consisted of state vocational rehabilitation services consisting of for instance vocational rehabilitation counselling, occupational/vocational training or job search assistance.[29] The intervention of Sherer et al consisted of work site observation, volunteer job placement, assistance with returning to desired independence or productive activities, and therapist visits to the job site.[43]

Content analysis

Shared care model

One intervention (5%) fitted the shared care model completly,[41] while eight interventions (42%) partly met this criterion. Of these, four interventions (21%) were integrated into normal cancer care, but, transition to a primary care physician or occupational physician did not take place.[28 38 39 42] Four interventions (21%) were not integrated into normal cancer care but the transfer to the occupational physician or primary care physician did take place.[5 29 37 43] The nine other interventions (47%) did not match the shared care model,[25 30 31 34-36 40 45 46] and for one intervention (5%), it was impossible to determine.[33]

Work ability

In six interventions (32%), work ability was directly addressed by specific activities as coping skills training, vocational rehabilitation counselling and guidance or behavioural problem-solving therapy,[25 29 36] by developing a strategy for information sharing about the cancer experience with co-workers, by discussing the relationship with co-workers,[5 31] or by assisting patients with returning to their desired productivity activities.[43] Work ability was in 13 interventions (68%), only indirectly addressed by addressing work in group sessions or by encouraging and giving advice, or information about return to work or work-related subjects.[5 28 30 33-35 37 38 40-42 45 46] Work ability was not addressed in one intervention (5%).[39]

Physical workload

In two interventions (11%), physical workload was the focus of the work-directed component of the intervention and was done by making a return-to-work plan.[5 41] Physical workload was addressed, in one intervention each by facilitating patients' use

of a compensatory strategy,[43] by change of job,[37] by vocational aid,[33] by retraining for another job,[5] [33] by assessing job requirements,[5] or by training, on-the-job training/support, and disability-related augmentative skills training.[29] The physical workload was not addressed in 13 interventions (68%).[25 28 30 31 34-36 38-40 42 45 46]

Effect of the interventions on return to work

Table 3 summarises the effect of the interventions on return to work for the seven studies reporting return-to-work outcomes.[25 26 28 32 37 38 41] The rate of return to work at follow-up in the intervention group ranged from 37% to 89% with a median of 76%. The return-to-work rates were collected by questionnaire (66%),[25 26 32] semi-structured interviews (22%),[28 38 41] or hospital reports (11%).[37] Three studies were uncontrolled prospective cohort studies.[32 37 41] Four studies used a control group[25 26 28 38] of which only one used randomisation to assign the intervention.[26] One study showed an OR significantly lower than 1,[38] indicating that the intervention improved return to work (Figure 2). The other three studies were insignificant.[25 26 28] The methodological quality score of the seven studies that measured return-to-work outcomes was 15 (ranging from 9 to 18) of the possible maximum of 24. Prospective calculation of the study size (100%), adequate control group (57%), and adequate statistical analysis (57%) were mostly lacking.

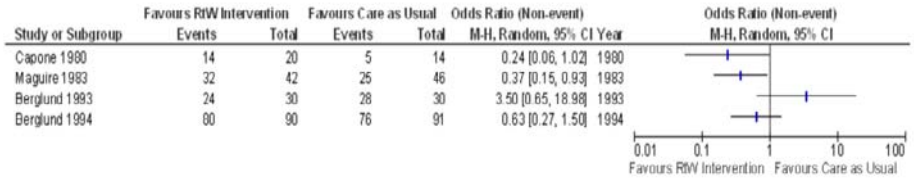

Figure 2. Forest plot of Ors and 95% CIs for not returning to work of the four studies that reported return-to-work outcomes and that used a control group.

Table 3. The effect of the interventions on return to work of the seven studies reporting return to work.

Author(s)	Study design	Assignment to control group	Measurement instrument	Follow-up	Return-to-work rate at follow-up[1]		Odds ratio [95% CI]	Quality score (range from 0-24)
					Intervention group N(%)	*Control group N(%)*		
Capone et al[28]	Controlled trial	Availability before primary treatment	Availability before primary treatment.	12 months post treatment/completion intervention	14 (70%)	5 (36%)	0.24 [0.06,1.02]	16
Maguire et al[38]	Controlled trial	Date of treatment	Semi-structured interview	12 to 18 months post treatment	32 (76%)	25 (54%)	0.37 [0.15,0.93]	18
Leitsmann et al[37]	Prospective cohort study	NA	Hospital report	5-years after start intervention	135 (37%)	NA	NA	9
Berglund et al[25]	Controlled trial	The refusal of the intervention but agreement to be monitored	Questionnaire	12 months after completion intervention	24 (80%)	28 (93%)	3.50 [0.65,18.98]	16
Berglund et al[26]	Controlled trial	Randomisation	Questionnaire	12 months after completion intervention	80 (89%)	76 (83%)	0.63[0.27,1,50]	18
Fismen et al[32]	Prospective cohort study	NA	Questionnaire	5-years after completion intervention	19 (56%)	NA	NA	10
Nieuwenhuisen et al[41]	Prospective cohort study	NA	Semi-structured interview	12 months after completion intervention	23 (89%)	NA	NA	13

1. The number of patients differs from Table 1 due the fact that not all patients were employed before the start of the study or due to missing values.

Discussion

The aim of this study was to review the literature on the content of interventions focusing on return to work, employment status, or work retention in patients with cancer by intervening with a work-directed intervention on environment-related and/or person-related factors. Furthermore, the effect of the interventions on return to work was assessed in studies reporting return to work. The extensive search strategy yielded 23 articles which met the inclusion criteria in which 19 interventions were described. Seven studies reported the effect of the intervention on return-to-work outcomes. The most frequently reported work-directed components of the included interventions consisted of encouragement, education or advice about work or work related subjects (68%), vocational or occupational training (21%), or work accommodations (11%). One intervention (5%) fit the shared care model of cancer survivor care and five interventions (26%) specifically addressed work ability or physical workload. The rate of return-to-work ranged from 37% to 89%. In one of the four controlled studies the intervention increased return to work significantly and in the other studies the results were insignificant.

Strengths/limitations

To our knowledge, this is the first review which systematically searched the literature for interventions focusing on enhancing return to work, employment status, or work retention for patients with cancer. A strength of this study is the extensive search of all relevant scientific databases and the lack of restrictions on publication year or language. Extending the review beyond the outcomes has the advantage that we can learn from the description of interventions which components are deemed effective by researchers or care providers. A limitation of this study is that the review has been restricted to work-directed interventions. It was, therefore, impossible to make inferences concerning the content and effect of interventions on return to work for cancer- or treatment-related complaints such as fatigue, distress, or speech problems.

Content of the work-directed components of the interventions

The content of the work-directed components varied widely, which indicates that a clear concept of work-directed interventions is lacking. The work-directed component

was, in most interventions, small part and was not a structured part of the intervention, indicating that enhancing return to work, employment status, or work retention was not an important objective. Work-directed interventions in musculoskeletal disorders are more common. Here, there seem to be clearer ideas of which components the work-directed intervention should contain,[47] such as the cognitive behavioural approach in graded activity,[48 49] or ergonomic approaches.[50]

The majority of the interventions did not fit the shared care model for survivor health care because these interventions were either not carried out in the hospital in the first phase, were not carried out by the occupational physician or the primary care physician in the second phase, or communication and transfer of knowledge was not established. Therefore, new strategies to integrate return-to-work support in the current normal cancer care with active communication between providers needs to be developed. For patients with chronic rheumatic disease, such strategies have been developed and could be used as a model.[51]

The majority of the interventions did not address work ability or physical workload. In 11 interventions work ability was addressed by giving 'simple' advice or counselling which could lead both to an improvement (e.g. patients who had had advice about return to work from their physician returned to work more often) or deterioration (e.g. physician advising absence from work significantly increased sickness absence) of return to work.[52 53] Vocational rehabilitation programmes in low back pain have taught us that education is less effective than problem solving therapy added to graded activity.[54] Problem-solving therapy addresses illness perceptions, which seem to be one of the causes of long sick leave in other chronic illnesses.[15] This 'simple' advice has been given in seven interventions during a group session. A drawback of group sessions is that the constitution of the group determines the significance of discussing return-to-work problems.[55] This means that it is important to discuss work issues at the individual level and preferably with a cognitive behavioural component such has been done in the study of Korstjens et al or Nieuwenhuijsen et al.[36 41] Furthermore, making a plan for employment and individual counselling/structural guidance in the study of Chan et al or making a comprehensive work re-entry plan in the study of Clark en Landis seems suitable as well.[5 29] Physical workload was addressed by organising work accommodations. It is known that perceived workplace accommodations are an

important factor for return to work and that employers, in general, are willing to carry them out for patients with cancer.[56] The occupational physician seems the best suited person to implement these workplace accommodations.[57] In more than half of the interventions, neither the workplace, nor the employer, or the occupational physicians were part of the intervention. However, patients with cancer do need social support from their workplace, especially practical support from the supervisors and from their occupational health service.[14]

Effect of the interventions on return to work

The seven studies reporting return-to-work outcomes were of poor methodological quality; only one study was a randomised controlled trial. Due to large differences between studies concerning the content of the interventions, study population, and study design it was not possible to pool data. Therefore, it was not possible to make an overall conclusion of the effect of the interventions on return to work. However, the intervention of Maguire et al and Capone et al can be compared considering the setting, the start and the content of the intervention and both ORs reveal positive effects for the intervention group.[28] [37] Even though these studies were non-randomised low-quality trials this indicates that work-directed interventions have the potential to improve work outcomes in cancers patients. The only controlled trial that did favour the control group, however insignificant, was the study of Berglund et al in which assignment to care as usual was based on the refusal to participate in the intervention but agreement to be monitored.[25] Apparently the participants judged correctly that their changes of return to work were so good that they did not need the intervention.

Implications for research

There is a need for improvement of interventions that support patients with cancer in their return to work. Improvement can be made by incorporating the shared care model and better addressing important prognostic factors such as self-reported work ability and physical workload. The small amount of information currently available suggests that successful interventions of this sort are feasible and potentially effective. The next step is to determine the effectiveness of such intervention on return to work in lager randomised controlled trials.

Funding

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What this paper adds box

- Return to work is seen by cancer survivors as an important part of recovery. However, the risk of becoming unemployed is 37% higher for cancer survivors in comparison with healthy controls.
- Most work-directed interventions are not primarily aimed at enhancing return to work or employment of patients with cancer.
- Most frequently reported work-directed components of the included studies are: occupational training, encouragement, work advice, work accommodations, or education.
- Very few work-directed interventions have studied the effect on return to work.
- Future studies should be designed to include well structured work-directed components and should have high methodological quality.

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Appendix

Search strategy for PubMed

("neoplasms"[MeSH Terms] OR cancer*[Text Word] OR neoplasm*[Text Word] OR carcinoma*[Text Word] OR oncolog*[Text Word] OR leukemia*[Text Word] OR sarcoma*[Text Word] OR lymphoma*[Text Word] OR melanoma*[Text Word] OR radiotherapy[Text Word] OR chemotherapy[Text Word])
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Chapter 3.

Breast cancer survivors' view of factors that influence the return-to-work process – a qualitative study

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Abstract

Objectives

Accumulating evidence suggests that most employed breast cancer survivors are able to return to work but often experience difficulties in the process. The objective of this study was to identify: 1) factors experienced as barriers to and facilitators of return-to-work (RTW) process, 2) which factors were important during initial and post RTW, and 3) possible solutions to RTW problems.

Methods

Twelve breast cancer survivors participated in semi-structured interviews. Interviews were thematically analysed using MAXQDA, software for qualitative data analysis. We used the World Health Organization's International Classification of Functioning, Disability, and Health as a conceptual framework.

Results

Participants experienced many barriers to and facilitators of RTW. In line with previous studies, we found that the work environmental factors, such as support from a supervisor, importance of work, and physical or psychological side-effects (such as fatigability), influenced RTW. In addition, we found that barriers included temperament and personality functions, 'job lock', and societal attitudes, while facilitators comprised taking care of one's health, skills/coping, and support from family and healthcare professionals. During initial RTW phase, physical or psychological side-effects hampered work resumption, while during post RTW phase, a lack of understanding from the work environment was problematic. Participants mentioned that guidance from healthcare professionals and information for supervisors and colleagues should be improved.

Conclusions

To enhance RTW among breast cancer survivors, interventions should focus on barriers and facilitators for individuals at different time points in the RTW process. Better guidance from healthcare professionals and information for supervisors and colleagues could also enhance the process.

Introduction

Accumulating evidence suggests that most employed breast cancer survivors are able to return to work[1-3] but often experience difficulties managing their work, for instance due to physical (e.g. arm function) or cognitive work limitations (e.g. concentration, fatigue), or unreasonable treatment at the workplace (e.g. feelings of discriminated against, unsupportive work environment).[4-6] It is important to understand the difficulties cancer survivors experience in order to develop interventions to better support them in their resumption of work.

Using regression analysis based on self-report questionnaires or administrative data, many previous studies have shown that several factors can enhance or hinder the return to work (RTW) of cancer survivors.[3 7-11] However, the difficulties of managing work depend on a complex interaction of individual and environmental factors, and the social security system,[4 12] and these difficulties may change during the course of the disease. This underlying context may not be identified by outcomes based on questionnaires or administrative data. Furthermore, RTW is often defined in quantitative studies as a singular event, but it can also be viewed as a process which different factors influence RTW in different phases, such as the initial and the post RTW phase.[13] Therefore, qualitative research of the initial and the post RTW processes may be a better method for studying this problem. In the international literature, a number of studies have applied this qualitative research method by analysing breast cancer survivors' experiences with the RTW process.[6]

This study aims to add to these previous qualitative studies by: 1) identifying factors that have been experienced as barriers to or facilitators of the initial and post RTW process, 2) classifying these factors according to the World Health Organisation's International Classification of Functioning, Disability and Health (ICF),[14] and 3) asking cancer survivors for possible solutions to their RTW problems. The ICF is a framework to describe health and disability and their impact on functioning. The ICF consists of the following domains: disease/disorder, body function, body structure, activity/participation, and personal and environmental factors.[14] We chose the ICF as a conceptual framework for this study because it allows a comprehensive analysis of the factors influencing RTW.

RTW of sick-listed employees is influenced by the institutional context of the social security system of a country. In the Netherlands, the employee cannot be fired due to his/her illness during the first two years of sickness absence and receives at least 70% of their wage, which is paid by the employer. Both the employer and the employee have responsibilities for the RTW process.

Methods

The study was designed to be qualitative, using semi-structured interviews. We used the items of the consolidated criteria for reporting qualitative research (COREQ) for improving the quality of reporting qualitative research.[15] We sought ethical approval for this study from the Medical Ethics Committee of the Academic Medical Center, who judged that ethical approval was not required. All interviews were held between May and July 2010.

Participant selection

Cancer survivors were eligible to participate if they were: 1) primarily diagnosed with breast cancer, 2) between 18 and 65 years of age, 3) working at the time of diagnosis, and 4) fluent in Dutch. We refer to cancer survivors as individuals who have been diagnosed with cancer and are still living. Cancer survivors were recruited via a notice that was posted on the websites of three Dutch cancer patient organisations, where cancer survivors could register for participation. Thereafter, the interviewer contacted them by telephone to check eligibility and explain the aim and the content of the study. The first ten consecutive breast cancer survivors who registered were enrolled in the study. Thereafter, a sampling approach was conducted with several breast cancer survivors who registered but were not yet enrolled in the study in order to capture various experiences and working situations. This sampling approach was conducted based on the type of contract and RTW phase.

Interview procedure

Before the start of the face-to-face interview, each participant was explained the purpose of the study, the position of the interviewer, and the fact that information was handled confidentially. Each participant signed an informed consent form before the

start of the interview. All interviews were audio-recorded. Participants were asked to fill in a questionnaire to assess participant (e.g. age), disease (e.g. treatment type), and work-related characteristics (e.g. occupation, importance of work measured on a visual analogue scale) and to prepare participants for the topics of the interview (e.g. facilitators of and barriers to RTW).

Semi-structured interviews were centered on a topic list. The topic list was generated on the basis of the literature and expertise of the research team and was pilot test with an experienced interviewer and with a cancer survivor. The topic list consisted of four items: 1) understanding the diagnosis, treatment, and work situation (pre-diagnosis and current), 2) identifying the factors that were barriers to and facilitators of the initial and post RTW process, 3) identifying if factors that were retrieved non-systematically from the literature[4 12 16-19] were experienced as barriers to or facilitators of RTW if not already mentioned during the interview, and 4) identifying possible solutions to RTW problems. The interviewer started with open-ended questions and subsequently asked more specific in-depth questions. Participants were encouraged to explain in detail how they experienced each factor. The interviewer summarised all mentioned factors so that participants could indicate if something was misunderstood or missing. All participants were interviewed once only, face-to-face, without anyone else present because that might have biased the participants' viewpoint or inhibited the discussion. The interviews were carried out at a place the participant preferred. All interviews were carried out by the first author, who is a female PhD student currently working on the topic of cancer survivors and RTW. The interviewer did not have a direct relationship with the participants and did not represent an organisation or a healthcare profession involved in the cancer care or RTW care of cancer survivors.

Analysis

The interviews were transcribed verbatim. Neither the transcripts nor analysis of the transcripts were returned to participants for comments or feedback. One of the authors analysed the factors that were mentioned during the interview after each interview to record if new factors were mentioned. We stopped interviewing when no new factors

were mentioned. The transcripts were coded using the MAXQDA (Verbi GmbH, Marburg, Germany) qualitative data analysis software package.

First, the transcripts were read to become familiar with the content of the interviews. Then, they were open-coded in the same order as the interviews were held. The goal of open-coding was to identify all important aspects of the text that answered the research question. The labels of the open codes represented the text as closely as possible. In addition, these open codes were classified into barriers and facilitators and generally classified in the context of the ICF (i.e. health-related, personal, and environmental). Finally, the open codes were classified according to the ICF (i.e. disease/disorder, body functions/body structure, activity/participation, personal factors, and environmental factors) using the core set for breast cancer[20] and vocational rehabilitation[21 22] as a starting point. These factors are predetermined by the ICF unless such a factor could not be identified (e.g. personal factors). Each core set consists of a set of ICF factors that are relevant to a specific condition and were formulated by experts. Furthermore, we used the classification of work-related factors as described by Minis et al.[23] In accordance with the ICF, we categorised unchangeable temperament and personality functions as body functions and changeable temperament and personality functions as personal factors. Finally, we identified which factors were considered by participants as the key barriers to or facilitators of their RTW.

In a separate analysis, factors that were important during the initial and post RTW process and possible solutions to barriers were identified and labelled. Initial RTW was defined as the period from diagnosis until returning to work. Post RTW was defined as the period from initial to sustainable RTW. To improve inter-observer reliability, another researcher coded two interviews independently and discussed the results until consensus was reached. Furthermore, before each step in the analysis took place, all authors discussed the content in order to reach consensus. Factors that did not affect RTW but did affect, for example, work productivity or quality of work life were not taken into consideration.

Results

All the breast cancer survivors who registered were eligible to participate. The interviewer contacted them by telephone to explain the content of the study, after

which all the breast cancer survivors agreed to participate after this telephonic contact. After 12 interviews, no new factors were retrieved from the interviews. Nine interviews took place at the participant's homes, two at the hospital, and one at the participant's workplace. During the interviews, no one else was present, except the spouse of participant E during the last 20 minutes. The duration of the interviews ranged from 40 - 75 minutes.

Participant characteristics

The mean age of participants was 42 (standard deviation (SD) 7) years at the time of the interview. Participants had different social backgrounds and educational levels but had the same Dutch cultural background.

Disease-related characteristics

Primary diagnosis of breast cancer was made on average two years before the interview (Table 1). Two participants had a relapse of breast cancer and were diagnosed with metastatic cancer. All participants underwent surgery, ten received chemotherapy, nine radiotherapy, and six hormone treatment. At the time of the interview, six participants were still receiving treatment, while the others had ended treatment between nine months and four years prior.

Work-related characteristics

The participants had different types of occupations and contracts before diagnosis and at the time of the interview (Table 2). Five participants had altered their occupation after cancer diagnosis either due to altered work interest or because it was not possible to carry out their former occupation due to job loss or side-effects of cancer treatment (e.g. fatigue, cognitive problems). Two participants had an improved work situation, and six had a poorer work situation, two of whom had the prospect of improvement in the near future. Six participants were (partly) on paid sick leave or (partly) on disability pension at the time of the interview. Participants rated the importance of work on a visual analogue scale of 0 - 100 with a median of 66 (range 10 - 85). Three participants were solely the breadwinner, six participants contributed equally with their husband to the family income, and in three cases the husband was the breadwinner.

Table 1. Disease-related characteristics of the participants.

Partici-pant	**Age at interview**	**Age at diagnosis**	**Cancer diagnosis**	**Treatment**						**End of treatment**	
				Surgery	*Chemo-therapy*	*Radio-therapy*	*Hormone*	*Other*	*Duration of treatment*	*No*	*Yes*
										Treatment type	*Time since end treatment - interview*
A	31	28	Breast	+	+		+		6 months and 2 years of hormone treatment	Hormone	
B	50	47	Breast	+	+	+			7 months		2 years and 3 months
C	51	43	Breast	+	+	+			Not recorded	Chemo-therapy	
		48	Local relapse		+	+		Herceptin/ Hyper-thermia	Not recorded		
		50	Lung metastasis		+				2 months		
D	51	44	Breast	+		+	+		3 months and 5 years of hormone treatment		9 months
E	44	40	Breast	+	+	+	+	Herceptin/ Ova-riectomy	7 months and 2 years of hormone treatment		2 years
F	38	36	Breast	+	+	+			13 months		1 year and 6 months

Table 1. *(Continued).*

G	41	40	Breast	+	+	+			5 months	Chemo-therapy/ hormone	
H	47	44	Breast	+	+	+	+	Herceptin/ Ova-riectomy	12 months and 3 years of hormone treatment	Hormone	
I	37	28	Breast	+	+		+		Not recorded	Hormone	
		36	Lung, liver, bone metastasis		+		+		6 months		
J	46	42	Breast	+	+	+			8 months		4 years
K	36	35	Breast	+		+			4 months		1 year and 2 months
L	34	34	Breast	+	+		+		7 months	Chemo-therapy/ hormone	

Return-to-work process

All participants had a different complex pattern of RTW. The time from initial sick leave to sustainable RTW ranged from months to years. Two participants were in the initial phase, and ten participants were in the post RTW phase (Table 2). For those participants who reached the sustainable RTW phase, an average RTW process could be divided into three phases: 1) during diagnosis and initial treatment, completely sick-listed for some time; 2) during chemotherapy and/or radiotherapy, completely sick-listed but working on a flexible basis (hours, workplace, tasks) and with fewer responsibilities and reduced expectations of supervisor/colleagues (i.e. phase 1 and 2 initial RTW), and 3) after radiotherapy or chemotherapy, gradual RTW, involving an increase in working hours, tasks, and responsibilities and gradually reducing paid sick leave (i.e. post RTW). This pattern did not apply to four of the ten participants who were in their post RTW phase: one participant did not work through treatment, two participants had a new episode of sick leave after they had returned to work, and one participant was on disability pension due to cancer recurrence after she had returned to work (Table 2).

Factors that influence return to work

Of the 12 participants, 9 experienced many barriers in their RTW process, involving all ICF domains (Table 3). In contrast, only two participants reported no or minor problems and one participant reported that her work ability was improved due to her cancer experience. Participants mentioned key barriers in all domains, whereas key facilitators were found in environmental factors only (Table 3). In addition, all participants were very motivated to resume work and all participants disclosed that they had cancer to their supervisor and colleagues.

Table 2. Work-related characteristics of the participants.

Partici-pant	Work status before diagnosis					Work status at time of interview				Sick listed at time of interview	Return-to-work characteristics	Altered work situation
	Occupation	*Contract*	*Years worked*	*Work hours*	*Shift work*	*Occupation*	*Contract*	*Work hours*	*Shift work*			
A	Supervisor call centre	Temporary (1-6-2008)	0.5	32	Yes	Re-integration counselor	Temporary (01-07-2011)	36	No	No	Worked through treatment	Improved occupation, working hours
B	Specialist nurse	Permanent	30	32	Yes	Specialist nurse	Permanent /partly disability pension	24	No	50% since last week	New episode of sick leave	Worsened working hours, work content
C	Project manager	Permanent	4	24	No	Counsellor	Disability pension/ freelance	Variable	No	Disability pension	Worked through treatment. New episode of sick leave	Worsened job loss
D	Coach	Freelance	5	Variable	Yes	Counsellor	Self-employed	24	Yes	No	Worked through treatment	Improved flexible working hours
E	Supermarket employee	Permanent	12	24	No	Cashier	Permanent	24	Yes	No	Worked through treatment	Worsened work content, shift work, policy of company

Table 2. *(Continued).*

F	Communication specialist	Permanent	8	40	No	Communication specialist	Permanent	40	No	No	Worked through treatment	Same
G	Project manager	Permanent	9	34	No	Project manager	Permanent	34	No	100% since diagnosis	Initial RTW phase Working through treatment	Worsened working hours
H	Sales manager	Permanent	2	32	No	Sales manager	Permanent	32	No	No	Worked through treatment	Same
I	Senior policy officer	Permanent	3.5	36	Yes	Senior policy officer	Permanent	36	No	40% since last diagnosis	Worked through treatment. New episode of sick leave	Worsened Working hours
J	Manager hospital	Permanent	1.5	36	No	Policy officer	Permanent	24	No	No	Work through treatment	Worsened working hours, occupation
K	Project manager	Permanent	3	32	No	Project manager	Permanent	32	No	33% since 3 months	Worked through treatment. New episode of sick leave	Worsened working hours
L	Taxi driver	Temporary (1-11-2010)	3	10	No	Taxi driver	Temporary (1-11-2010)	10	No	100% since diagnosis	Initial RTW phase. Did not returned to work	Worsened job loss

Disease/disorder and body function, body structure

Barriers to RTW include the disease itself, treatment, a slow or insufficient recovery over time, and having another co-morbidity. Participants mentioned slow or insufficient recovery over time as being caused by physical (e.g. lymphoedema) and/or psychological side-effects (e.g. concentration). As participant B recalled when trying to unlock a medicine cabinet at work:

'During early return to work, it was also the confusion in my head, I was standing in front of the medicine cupboard, and then it already started with the login codes, they did not come to mind, I had to get the medicine.'

Furthermore, temperament and personality functions, such as feeling guilty, feeling responsible or overly loyal, or having unrealistic expectations, were mentioned as barriers.

On the positive side, a recovery of breast cancer treatment, absence of long-term side-effects, being confident and conscientious, and other positive temperament and personality functions were all mentioned as RTW facilitators. As participant A explained:

'I really wanted to show them that I am not only [name of participant] with cancer, more than that, I am not that at all anymore.'

Activity/participation

Participants indicated that negative physical and psychological side-effects restricted them at the activity and/or participation level. For example, psychosocial complaints led to difficulties focusing attention and remembering facts, whereas lymphoedema impairments led to difficulties driving a car. Participant J pointed out:

'Of course I have to do a lot of thinking [for my work]. Well, when that is disrupted in the beginning and you forget half of it, then that is another restriction.'

Participants felt that they could either not perform at their pre-diagnosis level of work functioning or that they experienced difficulties doing other activities (e.g. doing household tasks), which in turn decreased the possibilities for RTW.

At the activity and participation level, the following factors were identified as RTW facilitators: being economically self-sufficient, managing their employment (i.e. re-education, seeking employment, maintaining a job, terminating a job), and taking care of their health. Participant F recalled:

'I always tried to exercise in between [treatments](…), and you just notice that that is very good for your body but also for your mind (…). Your mind resets so to say (…) and I think that it works very positive [for your work ability].'

Personal factors

On a personal level, there were several perceived barriers to RTW. Participants mentioned that they had to fight the stigma that work was not important to them during or after treatment, that they were not able to resume work, or that their work productivity was lower in comparison to healthy subjects. These stigmas became worse when diagnosed with metastatic cancer.

Many experienced cancer as a major life event that made them re-evaluate their work lives. For some, their social and family lives became a higher priority than before diagnosis. Others re-evaluated their personal work preferences in how they wanted to work and for whom. Some experienced difficulties coping with their cancer diagnosis and the RTW process because they found it difficult to ask help from others, explain their limitations to colleagues, set boundaries, or accept their limitations. Brought on by fear of recurrence, some participants reported that they did not dare to change jobs and reported a 'job lock' because they either did not want to lose their permanent contract or employee benefits. As participant F explained:

'Well, looking for a new job scares me a bit because I have a very good employer who treats you very well when you are ill, and when you accept an employment contract somewhere else, you never get a permanent employment contract straight away and imagine it [cancer] will come back, then you are in trouble.'

Table 3. Barriers/facilitators for return-to-work classified according to the ICF.

Domain	Factor	Barrier – Facilitator +	Initial * Post ** Both ***[1]	Key Barrier – Facilitator+[2]
Disease/ disorder	Breast cancer, breast cancer treatment	-	***	
	Co-morbidity	-	***	
	(Slow or insufficient) recovery over time	-/+	**	-
	Absence side-effects of breast cancer treatment	+	**	
Body function/ body structure	Sensation of muscle stiffness	-	*	
	Having difficulties with mobility of joint functions	-	*	
	Lack of quality of sleep	-	**	
	Lack of functioning of immunological system	-	***	
	Fatigability	-	***	-
	Sensations associated with cardiovascular functions	-	*	
	Discomfort associated with menopause	-	*	
	Having difficulties with attention functions	-	*	
	Having difficulties with retrieval of memory	-	*	
	Having difficulties with pace of thought	-	*	
	Having difficulties with higher-level cognitive functions	-	*	
	Having difficulties applying knowledge	-	*	
	Having difficulties being confident	-	*	
	Conscientiousness	+	*	
	Confidence	+	***	
	Energy and drive functions	+	***	-
	Temperament and personality functions, other specified	-/+	***	-
Activity/ Partici-pation	Having difficulties focusing attention	-	*	
	Having difficulties driving	-	*	-
	Having difficulties assisting others with self-care	-	*	
	Having difficulties doing housework	-	*	-
	Looking after one's health	+	***	
	Vocational training	+	*	
	Seeking employment	+	**	
	Maintaining a job	+	***	
	Terminating a job	+	***	
	Economic self-sufficiency	+	***	
Personal factors	Struggle to fight stigmatisation	-	***	
	Altered personality, priorities, or importance of work	-/+	***	-
	(Having difficulties) coping	-/+	***	
	Job lock	-	**	
	Skills/competences	+	***	

Table 3. *(Continued).*

Environmental factors – directly related to work	Job content (physical and mental demands)	-/+	***	-
	(Lack of) support of work environment	-/+	***	-/+
	Negative/positive attitude of work environment	-/+	***	-/+
	(Lesser degree of) control of working situation	-/+	***	-/+
	Negative/positive terms of employment	-/+	***	-
Environmental factors - not directly related to work	Individual attitudes of health professionals	-	*	
	Societal attitudes	-	***	
	Invisibility of cancer, treatment, or long term side-effects	-	***	
	Support and relationships family	+	***	+
	Support and relationships friends	+	***	+
	Support and relationships personal assistants	+	*	
	Support and relationships health professionals	+/-	*	+
	Support and relationships other professionals	+	***	
	Support and relationships, other specified	+	*	
	Social security services, systems and policies	+	***	

1. Influence of each factor during initial, post, or both return-to-work phases.
2. Factors that were reported as important by participants.

Additionally many personal factors were perceived to be facilitators for RTW. Having various skills and competences were mentioned, such as being able to fall back on work expertise, and having the skills to do more than the former tasks is believed to be a facilitator. Equally, valuing the importance of work is a facilitator. All participants attributed various meanings to having paid work, including that work provides structure or distraction, it enables one to be economically self-sufficient and away from home, allows one to contribute to society, offers intellectual challenges, and represents a return to normalcy. As participant K stated:

> *'Continuing working was definitely a way for me not to go crazy so to say, my whole life is arranged like that, I have my own job, I have a home, I am very independent.'*

A final personal factor that participants felt facilitates RTW is the implementation of coping strategies to deal with cancer and work, such as accepting limitations, being able to explain limitations, disclosing diagnosis and treatment, avoidance stress, accepting being fired, and being realistic towards supervisors and colleagues regarding one's own work capacity.

Environmental factors - directly related to work

In this area, several barriers to RTW were noted. Job content including physical (e.g. physical work load) and mental demands (e.g. stressful job) can be problematic. Lack of support from colleagues, supervisors, employers, and/or occupational physicians is also a barrier; many in the work environment do not know how to deal with cancer. This results in, on the one hand, insensitive management (e.g. non-supportive work environment) or, on the other hand, over-protection. Participants noted also that they did not receive sufficient support from human resources or their company in general. In some cases, participants experienced negative attitudes about their work performance as cancer survivors or they felt the work environment overestimated their work functioning, resulting in unrealistic expectations or a lack of understanding of the long-term side-effects. Furthermore, participants indicated that disclosure of cancer can evoke feelings of discomfort among colleagues and that cancer still remains a difficult subject to discuss at the workplace.

Not having control over the working situation (e.g. the job could only be performed full-time or it is not possible to have a flexible work arrangement) is also perceived as a barrier as are negative terms of employment (e.g. freelance work, being fired due to their illness). As participant L pointed out:

'[After three temporary working contracts], I was going to get a permanent employment contract. Because I, yes, became ill and then they [employer] recognised, yes, we will just not do that (..). Well the [employer] did not want to run the risk (..) also because it was taking too long so to say before you are back at your old level again (participant L).'

On the positive side, environmental factors also play a role as facilitators of RTW. Having a job that was not physically demanding or where you can (temporarily) do undemanding tasks was viewed positively:

'I temporarily did the easy things, such as marking down the products at the shop (participant E).'

Support from subordinates, colleagues, supervisor, employer, and/or occupational physician plays a key role in RTW. Support from supervisors consists, for example, of moderating someone's over-eagerness, taking away responsibilities, expressing confidence, and thinking along with the sick-listed employee. Support from colleagues and subordinates consists of social support, expressing confidence, giving positive feedback and encouragement, and making the cancer survivor feel that she has returned to a familiar and safe place. Support from the occupational physician consists of moderating someone's over-eagerness and making a RTW plan. Related to this, participants mentioned that a positive attitude in the work environment helped them. This includes understanding, having no expectations regarding productivity, and giving the employee the freedom to plan RTW as she wants. Like many environmental factors that can a positive or negative influence depending on the situation, the upside of control over the working situation is having the ability to work from home or working flexibly (i.e. plan one's day tasks, working hours flexibly throughout the week, and taking hours off when feeling ill). This can reduce the workload, which contributes to RTW.

Likewise positive terms of employment are reported as a facilitator because participants felt their employer wanted to keep them employed, offered them a new contract, or their job was being handled ably while there were on sick leave.

Environmental factors – not directly related to work

There were many perceived RTW barriers outside of work. Individual attitudes of health professionals can be negative toward RTW; one participant mentioned that her oncological nurse had advised against returning to work in between radiotherapy and chemotherapy due to fatigue, even though she did not have fatigue complaints. Another mentioned that her occupational physician did not understand that she wanted to work during treatment, because she was able to stay at home and still receive 100% of her salary.

Societal attitudes are also important; participants described the general attitude that when you have cancer and undergo treatment, you are very ill and pitiful, and thought of as not being able to work. On the other hand, there can be a certain 'invisibility' of cancer, its treatment or long-term side-effects: some stated that side-

effects such as fatigue and cognitive and emotional problems are not often visible, which can lead to less understanding at the workplace. Consequently, participants pointed out that they struggled with finding a balance between looking ill and being labelled as a cancer patient and, at the same time, receiving understanding and support. Therefore, some participants made a conscious choice of not wearing a wig, so everyone could see that they had cancer and were ill as participant F explained:

'Certainly, when you are bald from the chemo, you look ill. On the other hand, you don't look ill because of the medicine you get against nausea, which makes you rosy-cheeked, and then everybody cries: 'oh, you look so good' and that can be pretty frustrating (…). The occupational physician once said, well (…) better don't wear a wig because then they [colleagues] will see that you are ill (…), otherwise there is a chance that you will be drawn into work too fast (participant F)'

On the positive side, environmental factors not directly related to work can also be facilitators of RTW. Support and relationships with family, friends, personal assistant, health professionals, and other breast cancer survivors are important because they provide practical support and encouragement and enable discussion about RTW and being along in a difficult situation. Participants reported mostly discussing work with their treating physician in general terms, but not in detail. Some mentioned being encouraged to go back to work or discussed a phased RTW. Other health professionals, such as an occupational physician specialised in cancer and work, a social worker, a psychologist, and a re-integration counsellor, provided worthwhile support and advice. Rehabilitation improved bodily functions (e.g. lymphoedema), which enhanced their possibilities to resume work. Finally, social security services, systems, and policies also facilitated RTW as participants noted that financial necessity, expiring sick leave pay, or the absence of a safety net forced them to resume work.

Initial return to work

The following factors that were described above were found during the initial RTW phase:

Physical and psychological side-effects: Participants mentioned that some physical and psychological side-effects, such as cognitive-related side-effects, diminished over time and were only a hindering factor during initial RTW. Therefore, having difficulty concentrating, driving, taking care of their household, and taking care of their children were only a hindering factor during initial RTW.

Temporarily altered importance of work: Participants reported that they experienced a temporary altered importance of work that diminished mostly after returning to work full-time.

Altered work relationship: Some participants reported changes in work relationships on the one hand because colleagues go on with their normal lives and on the other hand because participants mentioned that they had changed fundamentally due to their cancer experience.

Other factors: During initial RTW, some temperament and personality functions, such as lacking confidence, were named as barriers, while being conscientious was a facilitator. In addition, the ability to re-educate was a facilitator during initial RTW. Finally, the advice received by one participant to not go back to work too soon was perceived as a barrier during initial RTW and peer support from other breast cancer survivors was mentioned as a facilitator.

Post return to work

The following factors that were described above were found during the post RTW phase:

Stigma: Colleagues tend to think that when a cancer survivor returns to work full-time and is not on sick leave anymore, she is cured, fully recovered, and able to perform at her pre-diagnosis level. As a result, attention, understanding, and support gradually 'wear off'. In contrast, returning to work is seen by the participants as a process, not a singular event as their work environment may see it, and this difference in perception can lead to misunderstanding. Some participants reported having to deal with problems years after diagnosis or never being able to work at their pre-diagnosis level again. In addition, this different perception was, in some cases, reinforced by the paradoxical feeling of not wanting to be labelled as a cancer survivor and to be treated as normal but

at the same time needing some understanding and support. This complicates the need for that support that they expect from their work environment.

Slow or insufficient recovery over time: A slow or insufficient recovery over time (e.g. reduced quality of sleep, fatigue) was perceived as a barrier during post RTW.

Work-related factors: One participant reported that seeking a new job after she returned to her previous job was a facilitator during the post RTW phase. However, some participants reported a 'job lock', which was perceived as a hindering factor.

Possible solutions

Some participants were not able to formulate solutions that could have helped improve their situation, while others mainly mentioned positive factors. Consequently, this topic was only discussed with six participants. The following possible solutions to RTW problems were put forward:

Improved guidance: More guidance from supervisors/employers, occupational physicians, health professionals at the hospital, and re-integration counsellors specialised in cancer were mentioned. A participant thought that making a clear comprehensive RTW plan that includes task, hours, and responsibilities is important; in this way, all stakeholders will be informed. Another participant stated that occupational physicians should have more knowledge about cancer survivor's situation (e.g. cancer treatment, work situation) and more awareness of the differences between cancer survivors regarding side-effects. Another participant stated that life after cancer (including work life) should be discussed at the end of treatment by a doctor or a breast cancer nurse. Finally, two participants mentioned that a re-integration counsellor specialised in cancer should be added to the cancer care to provide comprehensive RTW guidance.

Improved information: Specific information for employers, human resources, and occupational physicians should be provided to enhance understanding about the possible side-effects of cancer treatment that can occur during initial diagnosis, treatment, and in the long-term. Especially, information about the fatigue fluctuation was mentioned. However, employers, human resources, and occupational physicians should also be well informed about the possibilities of returning to work during/after treatment and the fact that their work productivity can be as good as before diagnosis,

in order to diminish negative beliefs. Finally, participants mentioned that society should be informed about the fact that work can be important for cancer survivors and that they are able to resume work during or after treatment.

Discussion

The objective of this study was to identify factors experienced as barriers to and facilitators of RTW of breast cancer survivors, which factors were important during initial and post RTW phases, and possible solutions for breast cancer survivors' difficulties when returning to work. We found that participants experienced many barriers and facilitators in the RTW process, involving all ICF domains. Moreover, we found that participants mentioned key barriers in all domains, whereas key facilitators were only found in environmental factors. During initial RTW, physical and psychological side-effects hampered work resumption. In the post RTW stage, work resumption was hindered by the gradual 'wearing-off' of understanding from the work environment. Participants mentioned that guidance by an occupational physician or healthcare professional should be improved and more information for the work environment should be available.

Strengths and limitations

Because of the qualitative nature of this study, these results need to be interpreted with caution and need to be confirmed in a large and unbiased sample. The study population was a self-selected population who joined an online Dutch cancer patient organisation, which may have resulted in the population consisting of young breast cancer survivors, who worked in the service sector, and who were very keen on returning to work (i.e. our results may be biased by age, working sector, and motivation). Furthermore, a recall bias may be apparent, as initial experiences may be altered by later experiences. However, we tried to minimise this recall effect by asking participants to fill in a questionnaire before the start of the interview and by interviewing participants in different phases of their RTW process. Not all participants were able to identify possible solutions to problems they encountered. Additional studies are required, for which our results can be used as a starting point. The strengths of this study include the range of disease stages, treatment, and work situation of the population. Another strength is the

use of the ICF, making the analysis of the interviews transparent. Because we first labelled all interviews with open codes, the possibility that our analysis was prejudiced by the description of the ICF is small. In addition, the use of the ICF makes it possible in the future to compare different (chronic) health conditions with each other.

Comparison with the international literature

For some these, our results are comparable with previous qualitative studies concerning the RTW experiences of cancer survivors (e.g. support from the work environment,[4] work adaptations,[18] importance of work,[24] physical/psychological side-effects,[18] re-evaluation of their work life,[18] and financial problems[18]). However, new themes were found, including temperament and personality functions, job lock, taking care of one's health, skills/coping, societal attitudes, and the support of family and healthcare professionals.

In contrast to previous studies,[4 12 16 18] participants discussed RTW with their treating physician but did not receive detailed advice. However, they reported receiving worthwhile advice from an occupational physician specialised in cancer and work, a re-integration counsellor, a psychologist, a social worker, or a rehabilitation programme. This finding indicates that other healthcare professionals play an important role in the RTW process and that interventions carried out by those professionals may be of benefit.

Contrary to another previous study carried out in the UK,[13] we found that all participants were aware of occupational health services and that most participants received some form of support. It is likely that this discrepancy can be explained by the different social security systems of the UK and the Netherlands. Furthermore, we found, in contrast to previous studies,[6 18 25] that all participants disclosed their illness and treatment to their employer and colleagues. This difference may be explained by the fact that Dutch employees who are sick-listed due to cancer may have more confidence in their employer and the Dutch social security system, which may result in the notion that disclosing their illness may not have negative consequences. However, we found that some employers had negative illness beliefs about the duration of recovery needed and work capacity that resulted in those cases in the firing of an employee because of her illness. These negative beliefs may be enhanced by the disclosure of a cancer

survivor about the time needed to return to work. Therefore, some employers should be better informed about the possibilities for cancer survivors to resume work to diminish negative illness beliefs.[26]

Finally, in contrast to another study,[25] we found that half of the participants changed their work. This anomaly may be explained by the fact, that in comparison to that study, participants in our study were more often treated with chemotherapy and/or radiotherapy, which in general leads to more difficulties for a cancer survivor and in turn may increase the necessity to alter their work.

Implications for research and practice

Most identified factors that were experienced as barriers to RTW were potentially modifiable. Because RTW patterns differed greatly among the participants and because participants experienced very diverse barriers to and facilitators of RTW, individual guidance seems most appropriate. However, some participants mentioned receiving worthwhile peer support from other breast cancer survivors, indicating that group support may offer an extra benefit. In addition, because different barriers are experienced during the initial and the post RTW process, an intervention should target different factors at different time points. Moreover, because most breast cancer survivors reported problems during both RTW phases, an intervention should be facilitated during their whole RTW process, including some substantial time after returning to work.

As most participants mentioned environmental factors as key facilitators for RTW, improving the knowledge, understanding, and awareness in the work environment is important, for decreasing negative illness beliefs, but also for preventing a 'wearing-off effect' of support and understanding and bringing attention to the importance of work for cancer survivors.

Finally, some participants reported having difficulties coping with their situation, accepting their limitations, and dealing with their unsupportive work environment. For those cancer survivors learning how to cope with their difficulties may enhance RTW. In conclusion, to improve RTW among cancer survivors, interventions should focus on barriers and facilitators for individuals at different time points in the RTW process.

Better guidance by healthcare professionals and information for the workplace could also lead to an increased and easier RTW for cancer survivors.

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Chapter 4.

Reproducibility, validity, and responsiveness of the Work Limitation Questionnaire (WLQ) among cancer survivors

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Abstract

Objective

To determine reproducibility, validity, and responsiveness of the Work Limitation Questionnaire (WLQ) among cancer survivors.

Study design and Setting

A cohort of 53 cancer survivors completed the WLQ and other questionnaires at baseline, 4 weeks, and at 6 months follow-up, we assessed internal consistency, Intraclass Correlation Coefficient (ICC), Standard Error of Measurement (SEM), floor- and ceiling effects, and compared the WLQ with other constructs. For responsiveness, we assessed the following anchor-based measures: Minimal Important Change (MIC) versus Smallest Detectable Change (SDC) and Area Under the Curve (AUC) of Receiver Operation Characteristic (ROC).

Results

We found sufficient reproducibility at the group level but not at the individual level. There was no indication of systematic bias or proportional bias. Internal consistency and construct validity for the WLQ and its subscales were sufficient or slightly less than sufficient. There was a floor effect for one subscale but there were no ceiling effects. Responsiveness was sufficient.

Conclusion

The WLQ is reproducible, valid, and responsive for the use at group level but it is not sufficiently reproducible to be used at an individual level among cancer survivors.

Introduction

Work disability refers to the condition of a partial or total inability to work, which may lead to unemployment, (partly) disability pension, absenteeism, or lower levels of work functioning. Several studies have addressed work disability of cancer survivors by studying the unemployment risk (e.g. de Boer et al[1]) or the time to return to work (e.g. Spelten et al[2]) but only few studies have addressed work functioning of cancer survivors.

Studies that addressed work functioning of cancer survivors found that cancer survivors had a significant lower level of work functioning compared to non-cancer controls,[3-5] or compared to patients with chronic illnesses.[6] Impaired work functioning of cancer survivors may increase the risk of lower economic well being.[7] In addition, lower levels of work functioning will increase the costs for the society and the employer.

With continuing advances in cancer treatment, it is expected that employment rates will also significantly improve. This will lead to an increased importance of studying work functioning to better understand the full impact of a cancer diagnosis on work disability. Knowledge about the measurement properties of work-functioning questionnaires is essential for the use of these questionnaires as outcome measures in studies on the effectiveness of interventions, for the use as an indicator of the economic burden of work disability due to cancer, and for the development of specific interventions aimed at improving work functioning in cancer survivors.

A commonly used measure of impaired work functioning due to ill health is the Work Limitation Questionnaire (WLQ).[8] This questionnaire measures a person's functional limitation (i.e. health status) in relation to the demands of a person's physical, psychological, and social work environment.[8] The measurement properties of the English WLQ have shown moderate to good reliability and validity in various chronic health conditions[8-11] but two reviews on the measurement properties of work-functioning questionnaires have pointed out that the measurement error (reproducibility) of the WLQ has not been determined previously.[9] [10] However, the measurement error is an important measurement property of a questionnaire that is designed for evaluating interventions.[12] The measurement error and the minimal important change of a questionnaire enable the interpretation of a change score over

time. Only change scores larger than the measurement error can be seen as a real change while change scores smaller than the measurement error cannot.[12]

To be able to use the WLQ for evaluating an intervention, the measurement error of the WLQ needs to be determined both at the group and at the individual level. A questionnaire can be reproducible for the use at group level and be useful for research projects but not at the individual level to be used for measuring changes in clinical practice. Furthermore, the WLQ has recently been translated into Dutch. In order to use the Dutch translation of the WLQ among cancer survivors, the measurement properties of the WLQ need to be determined in this specific population. Therefore, the aim of this study is to determine reproducibility, validity, and responsiveness of the Dutch translation of the WLQ among cancer survivors.

Methods

We studied a cohort of Dutch cancer survivors at baseline, 4 weeks, and at 6 months follow-up.

Participants and recruitment

In this study, we refer to cancer survivors as to individuals who have been diagnosed with cancer and were recurrence free at the time of inclusion in the study. Cancer survivors were recruited via websites of cancer patient organisations, via a database of the Academic Medical Center's surgery outpatient clinic, and via the department of gynaecology. To be included, cancer survivors had to be employed, had to be working in the past two weeks, be able to read or write Dutch, and had to be without severe co-morbidity.

If a cancer survivor was eligible and willing to participate, the first questionnaire and informed consent form were sent by mail to the cancer survivors' home with a free return envelope enclosed. The follow-up questionnaires were also sent by mail. The researcher sent reminders by mail and contacted non-responders by telephone to encourage returning questionnaires. We recruited cancer survivors from January 2010 until September 2010 via websites of cancer patient organisations and during March 2011 via the database.

Ethical approval for this study was sought from the Medical Ethics Committee of the Academic Medical Center, who judged that ethical approval was not required. Participants signed informed consent forms before they filled in the first questionnaire.

Study design

A prospective cohort study with measurements at the study entry (baseline), 4 weeks, and 6 months follow-up was conducted. Data measured at baseline were used to determine distribution of the WLQ, internal consistency, construct validity, and floor and ceiling effects (Table 1). To determine reproducibility we used the data measured at baseline and at four weeks follow-up in a population that reported no change (i.e. test-retest reproducibility and level of agreement) (Table 1). The time span of 4 weeks was chosen to prevent recall bias and cancer survivors were expected to be stable. To determine responsiveness, we used data measured at baseline and at 6 months (Table 1). The time span of 6 months was chosen to increase the chance of a clinical change. Participants did not receive any intervention as part of the study in the interim period.

Measurements

Demographic variables

The following demographic variables were assessed: age, gender, marital status, education level, cancer diagnosis, cancer treatment, time since cancer diagnosis, co-morbidity, breadwinner position, type of occupation, and time since work resumption. Based on type of occupation we divided work demands in mainly mentally demanding work and mainly physically demanding work.

Table 1. Measurement properties.

Measurement property *A. Definition* *B. Purpose (evaluation, discrimination, both)* *C. Dependency of a measurement property on the characteristics of a population*	**Prerequisite** *A. Prerequisite* *B. Determination method* *C. Adequateness*	**Method** *A. Measurement point* *B. Data analysis*	***A priori* formulated criteria** *A. Measurement property* *B. Adequateness of prerequisite*
Internal consistency A. The interrelatedness among items in a scale B. Both C. Little	NA	A. Baseline B. Chronbach's alpha	A. 0.70 - 0.95 B. NA
Reproducibility - test-retest reproducibility A. The ability to distinguish participants despite measurement error B. Discrimination C. Large	A. Stable subpopulation B. Single item external anchor C. Comparing stable subgroup with unstable subgroup on time since work resumption and WLQ	A. Baseline and 4 week follow-up B. Single measures ICC_agremeent: $\sigma^2_{participants} / (\sigma^2_{participants} + \sigma^2_{time} + \sigma^2_{residual})$	A. ICC_agreement > 0.90 individual level ICC_agreement > 0.70 group level B. Stable participants have resumed work a longer time ago and less work limitations in comparison to unstable participants
Reproducibility - level of agreement A. The ability to measure the same scores on repeated measurements B. Evaluation C. Little		A. Baseline and 4 week follow-up B. SEM_agreement: $\sqrt{(\sigma^2_{time} + \sigma^2_{residual})}$ SDC_ind: 1.96 x √2 x SEM_agreement LoA: 1.96 x $SD_{differences} \pm mean_{differences}$ Systematic bias: one-sample t-test mean_differences Proportional bias: correlation between means and differences	A. Large SDC or LoA values indicate that the questionnaire is not able to measure small changes ≠ systematic bias ≠ proportional bias B. See test-retest reproducibility

Table 1. *(Continued).*

Validity - construct validity A. Ability to relate questionnaire to other related constructs B. Both C. Large	NA	A. Baseline B. Correlation between the WLQ and work- and disease-related constructs	A. > 75% of the a priori formulated hypotheses were confirmed B. NA
Validity - floor and ceiling effects A. The ability to measure the highest and lowest score B. Both C. Large	NA	A. Baseline B. Percentage of participants that had the highest and the lowest score	A. < 15% of the population had the highest or lowest score B. NA
Responsiveness A. The ability to measure changes over time despite measurement error B. Evaluation C. Large	A. Stable and improved subpopulation B. Single item external anchor C. Correlation between external anchor and change scores	A. Baseline and 6 months follow-up B. Compare the MIC to SDC_ind and SDC_group MIC based on two methods; mean change method and ROC curve method	A. SDC_ind < MIC individual level SDC_group < MIC group level B. Correlation coefficient > 0.4
		B. The AUC of a ROC-curve	A. AUC > 0.70 B. Correlation coefficient > 0.4

Abbreviations: NA = not applicable; WLQ = Work Limitation Questionnaire; ICC = Intraclass correlation coefficient; SEM = Standard Error of Measurement; SDC = Smallest Detectable Change; LoA = Limits of Agreement of Bland and Altman plot; SD = Standard deviation; MIC = Minimal Important Change; AUC = Area Under the Curve; ROC = Receiver Operating Characteristic.

The WLQ

The WLQ consists of 25 items divided into 4 different subscales, including time management demands (5 items), physical demands (6 items), mental-interpersonal demands (9 items), and output demands (5 items).[8] Time management demands address scheduling demands, physical demands address job tasks that require bodily strength, mental-interpersonal demands address job tasks that require cognitive strength and the interaction with people on-the-job, and output demands address overall work productivity. The possible responses are: 'all of the time (100%)', 'most of the time', 'half of the time (about 50%)', 'a slight bit of the time', 'none of the time (0%)', and 'does not apply to my job'. The WLQ refers to the past two weeks. Scale responses were scored from 1 to 5 and 'does not apply to my job' was scored as missing value.[8] All subscales except physical demands were reversed and all subscale responses were normalised to scores ranging from 0 (no limitations) to 100 (highest limitations). Missing values were imputed with the personal scale mean if at least 50% of the items of a subscale were known.[8]

Other instruments

To measure construct validity, we compared the WLQ scores to the scores on the following questionnaires: overall work functioning measured on a Visual Analogue Scale (VAS), Work Ability Index (WAI), overall quality of life measured on a VAS, and the Rotterdam Symptom Checklist (RSCL). VAS overall work functioning ranged from 0 (worst possible work functioning) to 100 (highest possible work functioning) and refers to the past two weeks. VAS scales have proved valid and reliable.[13] We assessed work ability with the first three questions of the WAI. The first question evaluates current work ability compared to the life time best, the second question evaluates current physical work ability in relation to the physical job demands, and the third question evaluates current mental work ability in relation to the mental job demands. Acceptable measures for reliability and validity have been determined.[14] [15] The VAS overall quality of life ranged from 0 (worst possible quality of life) to 100 (highest possible quality of life) and refers to the past week. The single item VAS overall quality of life has shown good validity and reliability.[13] The RSCL consists of the following four subscales, physical symptom distress (23 items), psychological distress (7 items), activity

level (8 items), and overall valuation of life (1 item)[16] and refers to the past week. The RSCL proved reliable and valid in assessing quality of life of cancer patients.[16]

Stability and change

We used a single item external anchor to assess stability in work functioning of participants between baseline and 4 weeks follow-up (‘*to rate work functioning compared to 4 weeks ago’)* and to assess change in work functioning of participants between baseline and 6 months follow-up (‘*to rate work functioning compared to 6 months ago’).* Both questions were assessed on a 5-point Likert scale. We considered participants stable if they reported neither having improved nor deteriorated and the remainder of participants was considered as changed. We assessed the adequateness of the external anchor by comparing the group that reported being stable to the group that reported being unstable on time since work resumption and WLQ. We assumed that the subgroup that reported being stable has resumed work a longer time ago and had better work functioning measured on the WLQ compared to the subgroup that reported being changed.

Data analysis

Data entry was verified by means of a 20% double data entry. PASW version 18 was used for all statistical analysis. For correlation coefficients, we first tested whether variables were normally distributed with the Kolmogorov-Smirnov test of normality (cut-off p-value ≤ 0.05). We used a Pearson correlation coefficient if both variables were normally distributed and a Spearman correlation coefficient otherwise.

Internal consistency

Internal consistency was defined as the interrelatedness among items in a (sub)scale (Table 1). We determined the Cronbach’s alpha for the WLQ and its subscales and we considered a Cronbach’s alpha between 0.70-0.95 sufficient.[17] Since the factor structure and unidimensionality of the subscales were determined previously[8] we did not perform (confirmatory) factor analysis.[17]

Reproducibility

Reproducibility was determined based on the baseline and four weeks follow-up data of stable participants (Table 1).

Test-retest reproducibility: Test-retest reproducibility determines how well participants can be distinguished from each other despite measurement error (Table 1).[12] We calculated test-retest reproducibility with the single measures Intraclass Correlation Coefficient (ICC) including systematic difference, so called ICC_agreement.[12] We considered an ICC of > 0.90 sufficient for the use at individual level and we considered an ICC of > 0.70 sufficient for the use at group level.[17]

Level of agreement: Level of agreement determines the agreement between repeated measurements (Table 1).[12] We measured level of agreement with the Standard Error of Measurement (SEM) including variance between measurement points, so-called systematic differences between baseline and 4 weeks follow-up (SEM_agreement).[12] The SEM_agreement is expressed on the same scale as the questionnaire (0-100). To calculate 95% confidence interval of the SEM_agreement, the SEM_agreement was converted to the Smallest Detectable Changes (SDC). The SDC is used at an individual level (i.e. SDC_ind). For the use of the SDC at group level, the SDC_ind needs to be dived by $\sqrt{n}$. No prior values that were considered sufficient for the SDC can be proposed since it is expressed on the same scale as the questionnaire. However, large SDC_ind or SDC_group values indicate respectively that the questionnaire is not able to distinguish small changes from measurement error at an individual level or at a group level.

We constructed a so-called Bland and Altman plot to establish Limits of Agreement (LoA) (Table 1).[18] We plotted the means at baseline and at 4 weeks follow-up and the differences between these measurement points as well as the 95% LoA. Change scores outside the LoA can be considered a real change and change scores that fall within the LoA cannot be distinguished from measurement error. We checked if there was a systematic bias between baseline and 4 weeks follow-up by testing with a one-sample Student's t-test if the mean differences at these time points were statistically different from zero.[19] We also checked if there was proportional bias meaning that the measurement error varies across the range of the scores by testing if the correlation

between the means at baseline and four weeks follow-up and the differences between baseline and 4 weeks follow-up was ≤ 0.4[19] (Table 1).

Validity

No 'gold standard' was available to determine validity of the WLQ. Therefore, we assessed validity of the WLQ by means of comparing the WLQ with a reference standard, so called construct validity.[20]

Construct validity: Construct validity measures the degree to which a questionnaire demonstrates a logical relation to related constructs (Table 1).[17] To determine the construct validity we assessed correlations between the WLQ and various work-oriented constructs (i.e. VAS overall work functioning, WAI) and disease-oriented constructs (i.e. VAS overall quality of life, RSCL) and formulated *a priori* 4 hypotheses based on theoretical grounding. First, we hypothesised negative correlations of > 0.8 between the WLQ and the VAS overall work functioning. Second, we hypothesised negative correlations of > 0.6 between the WLQ and current work ability (first question of the WAI), between the WLQ physical demands subscale and physical work ability (second question of the WAI), and between the WLQ mental-interpersonal demands and mental work ability (third question of the WAI). Third, we hypothesised a negative correlation of 0.40-0.60 between the WLQ and the VAS overall quality of life. Fourth, we considered a positive correlation of 0.40-0.60 sufficient between the WLQ physical demands subscale and RSCL physical symptom distress subscale and between the WLQ mental-interpersonal subscale and the RSCL psychological distress subscale.

Floor (lowest limitations) and ceiling (highest limitations) effects: Floor and ceiling effects were determined based on the percentage of participants who had the lowest score (i.e. no work limitations) and the highest score (i.e. highest work limitations) (Table 1). A percentage of < 15% of the population who had the lowest or highest score of each (sub)scale was considered sufficient.[17]

Responsiveness

Responsiveness refers to the ability of a questionnaire to detect clinically important changes over time despite measurement error (Table 1).[17] To determine responsiveness,

we used the data at baseline and at six months follow-up of improved and stable participants only, because only 6 participants indicated that they had deteriorated on work functioning. Based on the single item external anchor, three groups were distinguished: those who reported having slightly improved or improved, those who reported being stable, and those who reported having slightly deteriorated or deteriorated.

We determined responsiveness both by comparing the SDC (see level of agreement) with the Minimal Important Change (MIC) as well as by the Area Under the Curve (AUC) of a Receiver Operating Characteristics (ROC) curve. Responsiveness of the WLQ is considered sufficient if the SDC is smaller than the MIC or if the AUC value is > 0.7.[17]

To assess the MIC, we first used the mean change method. We calculated the mean change on the WLQ between baseline and 6 months follow-up as the differences in mean change of those who reported being improved and those who reported being stable.[21] We also used the ROC-curve method to assess responsiveness and the MIC because large variations between MIC values within one questionnaire have been reported depending on the method used.[21] We plotted a ROC curve with sensitivity and 1-specificity for each change score between baseline and 6 months follow-up of the WLQ. The MIC based on the ROC-curve is defined as the optimal cut-off value of sensitivity and specificity (i.e. the value at the upper left corner of the ROC curve).[17] Responsiveness is then determined as the AUC value of the plotted ROC curve.

We assessed if the external anchor was adequate by calculating the correlation between the external anchor and the mean change score between baseline and 6 months follow-up and we considered a correlation coefficient of > 0.5 sufficient.[22]

Results

The sample consisted of 53 cancer survivors. Table 2 presents the participants' characteristics at baseline. Participants were on average 46.7 ± 7.6 years old. Eighty-seven percent of the participants were female. Additionally, 84% of the participants had an occupation that consisted mainly of mentally demanding tasks. The response rate at 4 weeks follow-up was 94% (N=50) and the response rate at 6 months follow-up was 85% (N=45). Reasons for non-response were cancer recurrence (N=1), not being able to

work prior to filling in the second or third questionnaire (N=1), and were in 6 cases unknown (N=6). Variables that we used for calculating correlations were not normally distributed. Therefore, we used the Spearman's correlation coefficient in all cases.

Table 2. Participant characteristics at baseline.

Participant characteristic*		**Population N=53**	**Subpopulation of stable participants N=34**
Demographic characteristics			
Age (years)		46.7 ± 7.6	48.1 ± 6.8
Gender (% female)		87	85
Marital status (% married or living with partner)		74	71
Education level (%)	Low	8	9
	Intermediate	52	62
	High	40	29
Clinical characteristics			
Cancer diagnosis (%)	Breast cancer	49	41
	Colon cancer	28	35
	Vulva cancer	6	6
	Cervix cancer	8	6
	Other	9	12
Cancer treatment (%)	Surgery	94	91
	Chemotherapy	72	71
	Radiotherapy	56	47
	Hormone therapy	32	27
	Other	11	9
Years since cancer diagnosis (%)	<1	17	12
	1-5	56	53
	>5	27	35
Number of co-morbidities		1 (0-9)	1 (0-9)
Work-related characteristics			
Breadwinner position (% sole or shared)		79	67
Type of occupation (%)	Public health	21	21
	Administrative	15	24
	Management	13	12
	Other	51	43
Mainly mentally demanding work (%)		84	77
Mainly physically demanding work (%)		16	23
Number of working hours according to contract (1 - 40)		32 (3-40)	30 (4-40)
Years since work resumption (%)	< 0.5 year	27	15
	0.5 year – 1 year	12	12
	1 year – 3 years	29	29
	> 3 years	33	44

Distribution of the WLQ

The mean and standard deviation of the WLQ was 22.9 ± 17.2, the score for time management demands was 26.3 ± 21.7, for physical demands 14.2 ± 15.4, for mental-interpersonal demands 23.4 ± 18.7, and 26.7 ± 20.3 for output demands. Participants reported 'does not apply to my job' 5 times (2%) for time management demands, 40 times (13%) for physical demands, 10 times (2%) for mental-interpersonal demands, and once (0.4%) in output demands. No missing values were found for time management demands, 6 for physical demands, 1 for mental-interpersonal demands, and no missing values were found for output demands.

Internal consistency

The Cronbach's alpha was 0.93 for the WLQ, for time management demands 0.78, for physical demands 0.88, for mental-interpersonal demands 0.94, output demands 0.92.

Reproducibility

Of the 53 participants, 34 participants were included in the reproducibility analyses since 3 participants were lost to follow-up and 16 participants were not stable (2 improved, 11 slightly improved, and 3 slightly deteriorated). This group had a significant longer time to work resumption and a lower score on the WLQ compared to unstable participants (data not shown).

Test-retest reproducibility: The single measures ICC_agreement for the WLQ and the subscales ranged between 0.65 and 0.74 (Table 3).

Table 3. Test-retest reproducibility of stable participants (N=34).

	Baseline	**4 weeks follow-up***
WLQ (mean ± SD)	19.1 ± 13.5	20.6 ± 11.8
ICC (95% CI)	-	**0.74 (0.54 - 0.86)**
Time management demands (mean ± SD)	21.4 ± 20.6	23.4 ± 17.5
ICC (95% CI)	-	**0.71 (0.49 - 0.84)**
Physical demands (mean ± SD)	13.3 ± 13.5	14.6 ± 14.4
ICC (95% CI)	-	0.65 (0.39 - 0.81)
Mental-interpersonal demands (mean ± SD)	18.8 ± 14.0	19.6 ± 13.7
ICC (95% CI)	-	**0.72 (0.51 - 0.85)**
Output demands (mean ± SD)	21.5 ± 14.2	25.3 ± 15.8
ICC (95% CI)	-	0.69 (0.47 – 0.84)

*ICC values that met the a priori criterion are presented in bold.

Level of agreement

The SEM_agreement and the SDC_ind for the 34 stable participants were respectively 6.50 and 18.02 for the WLQ, 10.31 and 28.58 (time management demands), 8.28 and 22.95 (physical demands), 7.26 and 20.12 (mental-interpersonal demands), and 8.40 and 23.28 (output demands). The mean differences of the sum score at baseline and 4 weeks follow-up of the WLQ did not differ statistically from zero neither did the mean differences of the subscales (p-values ranged between 0.057 - 0.67). None of the correlations between the means and the differences exceed the 0.5 (range -0.07 - 0.24). In Figure 1, the means of baseline and 4 weeks follow-up and the differences between baseline and 4 weeks follow-up of the WLQ as well as the 95% LoA were shown in a Bland and Altman plot.

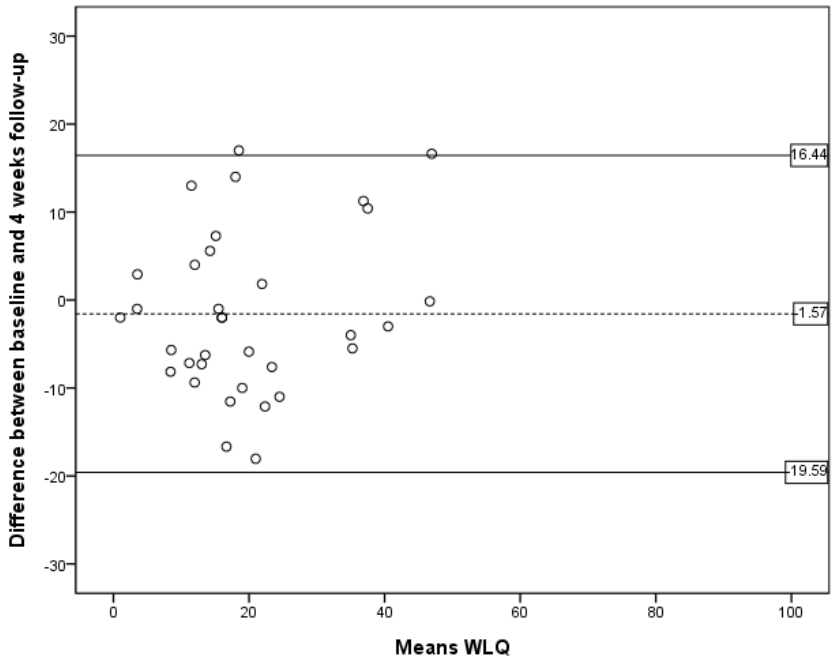

Figure 1. Bland and Altman plot of stable participants (N=34).

Validity

Correlations between the WLQ and the VAS overall work functioning ranged from -0.30 to -0.69 (Table 4), correlations between the WLQ and work ability (WAI) ranged from -0.48 to -0.77. The correlation between the WLQ subscale physical demands and physical work ability was -0.50 and the correlation between the WLQ subscale mental-interpersonal demands and mental work ability was -0.52. Correlations between the WLQ and the VAS overall quality of life ranged from -0.30 to -0.56. The correlation between the WLQ subscale physical demands and the RSCL subscale physical symptom distress was 0.45 and the correlation between the WLQ mental-interpersonal demands and the RSCL subscale psychological distress was 0.45.

Table 4. Correlation between WLQ and related constructs (N=53).

Comparable construct ***(a priori criterion)***	**WLQ**	**Spearman's correlation coefficient***	**P-value**
VAS overall work functioning (r > 0.8)	WLQ	-0.65	< 0.001
	Time management demands	-0.62	< 0.001
	Physical demands	-0.30	0.030
	Mental-interpersonal demands	-0.63	< 0.001
	Output demands	-0.69	< 0.001
Overall work ability (WAI) (r < -0.6)	WLQ	**-0.76**	< 0.001
	Time management demands	**-0.77**	< 0.001
	Physical demands	**-0.48**	< 0.001
	Mental-interpersonal demands	**-0.65**	< 0.001
	Output demands	**-0.69**	< 0.001
Physical work ability (WAI) (r < -0.6)	Physical demands	-0.50	< 0.001
Mental work ability (WAI) (r < -0.6)	Mental-interpersonal demands	-0.52	< 0.001
VAS overall quality of life (r < -0.4 – -0.6)	WLQ	**-0.49**	< 0.001
	Time management demands	**-0.56**	< 0.001
	Physical demands	-0.30	0.031
	Mental-interpersonal demands	**-0.43**	0.002
	Output demands	-0.35	0.011
Physical symptom distress scale (RSCL) (r < 0.4 – 0.6)	Physical demands	**0.45**	< 0.001
Psychological distress scale (RSCL) (r < 0.4 – 0.6)	Mental-interpersonal demands	**0.45**	< 0.001

*Correlation coefficients that met the *a priori* criterion are presented in bold.

Two participants (4%) had the lowest possible score on the WLQ, 12 participants (23%) on time management demands, 17 participants (33%) on physical demands, 6 participants (11%) on mental-interpersonal demands, and 6 participants (11%) on output demands. One participant (2%) had the highest possible score on the output demands. None of the participants had the highest possible score on the WLQ score or on any subscale.

Responsiveness

Of the 53 participants, 39 participants were included in the responsive analysis since 9 participants were lost to follow-up and 6 participants reported having deteriorated. Of these 39 participants, 19 participants reported being stable and 21 participants reported having slightly improved or improved. The MIC for improvement of the WLQ based on the mean changed method was 4.2 and the MIC for improvement of the WLQ based on the ROC-curve method was 4.0 (sensitivity 71% and specificity 31%). These MIC values did not exceed the SDC_ind (18.02) but did exceed the SDC_group (3.09) of the WLQ. The AUC-value of the ROC curve was 0.68 (Figure 2). The correlation between the external anchor and the mean change score between baseline and 6 months follow-up was 0.49.

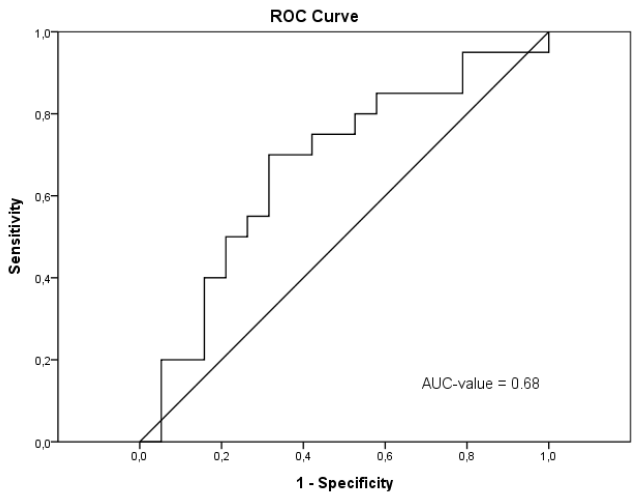

Figure 2. ROC-curve of participants who reported being stable or improved (N=39).

Discussion

We found sufficient reproducibility at the group level but not at the individual level. There was no indication of systematic bias or proportional bias. Internal consistency and construct validity for the WLQ and its subscales were sufficient or slightly less than sufficient. There was a floor effect for one subscale but there were no ceiling effects. Responsiveness was sufficient.

Strengths and limitations

The strength of our study is the determination of the measurement error (SEM) and SDC as these important characteristics of reproducibility were not determined for the original version of the WLQ in any population or any cross-cultural translation.[9 10] We determined both the SDC for clinical or individual use and for group and research use and we used several complementary methods to determine the minimal important change (MIC) for patients. Another strength is the inclusion of patients who worked less than 20 hours a week as the measurement properties for these employees were not determined in the original study by Lerner et al.[8] We were able to include a varied sample of cancer survivors that showed both stability and improvement over time, which is a prerequisite for determining reproducibility and responsiveness.

A limitation of our study is the small sample size for reproducibility analyses caused by a rather high proportion of participants who reported being unstable between baseline and 4 weeks follow-up. This is probably due to those participants who resumed work just before completing the questionnaire and whose work functioning was apparently still improving. However, we intended to determine measurement properties in a varied population because the WLQ will most likely be used in this population. Even though we used an external anchor that consisted of one item only, where the use of multiple items may be more adequate, we could show that the external anchor was adequate for both reproducibility and responsiveness analysis.

Reproducibility

Test-retest reproducibility analysis of the WLQ showed sufficient ICC values for the use at group level and almost sufficient ICC values for physical demands (0.65) and output

demands (0.69). These findings are in accordance with the original study by Lerner et al.[8] The ICC values are however insufficient for the use at individual level.

Level of agreement analysis showed large values for SEM_agreement (6.50 - 10.31) and for SDC_ind (18.02 - 28.58) compared to the range of the scale (0 - 100). The Bland and Altman plot showed equally large LoA values. The moderate level of agreement of the WLQ could be due to weakness in our study such as lack of stability of participants. We do not think that this is the case because we could show that the external anchor measured stability adequately. Taking into account recall bias we also believe that the time span of 4 weeks to measure stability was also appropriate. The lack of sufficient level of agreement could also be due to the cross-cultural adaptations but due to lack of comparable cross-cultural adaptations studies this is difficult to shown. Even though most cross-cultural adaptations affect more often the validity of a questionnaire[23] in this case, the level of agreement might be affected by differences in work culture and legalisation of sick-listed employees. In the Netherlands, employees work substantially more often part-time compared to other countries. The answer categories of the WLQ are related to a percentage of the working time, which may be more difficult to fill in when working part-time. To avoid this problem in future studies, we suggest using answer categories that are not related to time or percentage. Again another explanation could be that the properties of the scale itself led to the moderate level of agreement of the WLQ. Streiner and Norman[24] state that improving the scale design reduces the residual variance ($\sigma^2_{residual}$), which in turn leads to improved levels of agreement. That the answer categories of the WLQ can problematic is indicated by our finding that some participants mentioned that some questions were difficult to fill in. Beaton et al and Roy et al also suggested that problems with the physical demands subscale are caused by the fact that it is the only subscale that has reversed answer categories.[11 25] Therefore, we believe that reversing the answer categories of this subscale can lead to improved reproducibility. Furthermore, Walker et al suggest that problems with the subscale physical demands can be caused by the large number of 'does not apply to my job' and the consequent imputation with the scale mean while imputation with 'no limitations' may be more adequate.[26] Also in our study for more than 50% of 'does not apply to my job' answers, a participant was not consistent in reporting the same answer category at either baseline or 4 weeks follow-up (data not shown). Therefore, we suggest that when

an item does not apply to someone's job it needs to be filled in as 'no limitations' or imputed with 'no limitations' instead of the scale mean. These improvements of the scale design probably will lead to improved reproducibility.

Validity

The WLQ showed moderate to good construct validity. As expected, we found overall better construct validity for work-oriented constructs than for disease-oriented constructs. Furthermore, we found only for the VAS overall work functioning that the majority of the correlations coefficients were below what we had hypothesised. We assumed good validity for the VAS overall work functioning because VAS scales have been used in various situations and have shown good validity.[13] However, the construct validity of the VAS overall work functioning was not determined previously and it may explain the lower correlation, indicating that the VAS overall work functioning measures a slightly different work functioning construct than the WLQ. In contrast, we found the expected correlation between overall work ability (WAI) and the WLQ. This finding gives support for the work-oriented construct validity of the WLQ. We also found insufficient correlations for the subscale physical demands. This might be due to the lack of variation on this subscale in this specific population.

The floor effects and 'did not apply to my job' values that were found for the physical demands subscale are an indication that these questions are either not relevant for this population or do not address physical demands adequately. This finding has been reported previously.[8 11]

Responsiveness

Responsiveness analysis based on the AUC of the ROC-curve indicated that responsiveness of the WLQ was moderate. We found and AUC-value of 0.68 while 0.7 is considered sufficient. Roy et al found similar responsiveness results based on the AUC value (0.72) of the WLQ among patients with rheumatoid arthritis but found a higher MIC value (13) based on the ROC curve method.[25] The MIC value is influenced to a great extent by a population and should therefore be determined for each population separately.[27]

Generalizability

The scores on the RSCL were comparable to normative data of cancer survivors who were disease free for more than three years and were worse than in the general population (data not shown).[28] The WLQ-index score of our sample of 6.7 ± 5.0 was comparable to work limitations found in other studies among breast cancer survivors (5.5 ± 4.0)[3] and brain tumor survivors (5.6 ± 4.4)[4] and worse work functioning in comparison to non-cancer controls 2.8 ± 2.7.[4] Therefore, we think that our findings are generalizable to cancer survivors in general. However, in our sample there were more cancer survivors with less physically demanding jobs and a high education level. This means that the findings may not apply to cancer survivors with physically demanding jobs and low education. It would be worthwhile to study the measurement properties also in this population.

Implications for research and practice

The WLQ can be useful instrument for use in a population of cancer patients in evaluating interventions in research projects but its measurement properties should be improved for the subscale physical demands. For clinical practice, the measurement error is too large to measure change that is important to cancer patients.

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Chapter 5.

Enhancing return-to-work in cancer patients, development of an intervention and design of a randomised controlled trial

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Abstract

Background

Compared to healthy controls, cancer patients have a higher risk of unemployment, which has negative social and economic impacts on the patients and on society at large. Therefore, return-to-work of cancer patients needs to be improved by way of an intervention. The objective is to describe the development and content of a work-directed intervention to enhance return-to-work in cancer patients and to explain the study design used for evaluating the effectiveness of the intervention.

Methods/design

Development and content of the intervention

The work-directed intervention has been developed based on a systematic literature review of work-directed interventions for cancer patients, factors reported by cancer survivors as helping or hindering their return-to-work, focus group and interview data for cancer patients, health care professionals, and supervisors, and vocational rehabilitation literature. The work-directed intervention consists of: 1) 4 meetings with a nurse at the treating hospital department to start early vocational rehabilitation, 2) 1 meeting with the participant, occupational physician, and supervisor to make a return-to-work plan, and 3) letters from the treating physician to the occupational physician to enhance communication.

Study design to evaluate the intervention

The treating physician or nurse recruits patients before the start of initial treatment. Patients are eligible when they have a primary diagnosis of cancer, will be treated with curative intent, are employed at the time of diagnosis, are on sick leave, and are between 18 and 60 years old. After the patients have given informed consent and have filled out a baseline questionnaire, they are randomised to either the control group or to the intervention group and receive either care as usual or the work-directed intervention, respectively. Primary outcomes are return-to-work and quality of life. The feasibility of the intervention and direct and indirect costs will be determined. Outcomes will be assessed by a questionnaire at baseline and at 6, 12, 18, and 24 months after baseline.

Discussion

This study will provide information about the effectiveness of a work-directed intervention for cancer patients. The intention is to implement the intervention in normal care if it has been shown effective.

Trial registration: NTR1658

Background

Since the survival rates of cancer have increased considerably in recent years, the long-term side effects of cancer and cancer-related treatments may impact survivors' capabilities to regain normal lives. This implies that some forms of cancer are becoming chronic diseases entailing both poorer overall quality of life compared to the general population and disabling long-term residual symptoms, such as fatigue, depression, pain, and functional limitations.[1-3] One aspect of regaining a normal life after cancer is returning to work, which is often seen by cancer survivors as an important part of recovery.[4-6] Furthermore, the loss of work of cancer survivors is associated with lower quality of life, lower self-esteem, and worse financial situations.[7 8] Unfortunately, not all cancer survivors return-to-work. A meta-analysis showed that the risk of unemployment is 37% higher for cancer survivors compared to healthy controls;[9] cancer survivors also experience work limitations.[10 11] The employer and society at large are also affected due to absenteeism, disability pensions, and loss of productivity.[12] Furthermore, cancer survivors get little advice from their treating physicians about return-to-work issues, and they experience a lack of guidance from their general practitioners or occupational physicians as well.[13 14] Considering these negative work-related side effects for cancer survivors and the lack of attention toward these problems, there is ample room to improve return-to-work with an appropriate intervention.

A systematic review of the literature[15] concerning work-directed interventions for cancer patients showed that well-developed work-directed interventions are limited and that the methodological quality of these studies is moderate. This indicates that a new intervention needs to be developed and that its effectiveness on return-to-work and quality of life should be determined by a randomised controlled trial. Considering the financial impacts on cancer patients and society at large, the direct and indirect costs should also be taken into account.

Return-to-work is only one aspect of survivor care and it should not be dealt with in isolation. Therefore, we developed the intervention in such a way that it fits the shared-care model for cancer survivor care.[16] This model encompasses a work-directed intervention integrated into cancer care as integrated into the occupational physician or general practitioner's care, establishing active communication between these health care professionals.

Objective

The objective is to describe the development and content of a work-directed intervention to enhance return-to-work in cancer patients and to explain the study design used for evaluating the effectiveness of the intervention.

Methods/design

Development of the intervention

The development of the work-directed intervention is based on the following: 1) a systematic review concerning the content of work-directed interventions for cancer patients, 2) factors reported by cancer survivors as helping or hindering their return-to-work, 3) focus group data of cancer survivors and of supervisors regarding return-to-work after cancer, 4) vocational rehabilitation literature, and 5) semi-structured interviews with health care professionals.

First, the systematic review described the content of work-directed interventions for cancer patients on the basis of the two most important prognostic factors for return-to-work that can be directly altered by a work-directed intervention: self-perceived work ability and physical workload.[5 17] Of the 19 included studies, 18 addressed work ability and 6 addressed physical workload. The following interventions to address work ability proved to be suitable: making a return-to-work plan, individual counselling/structural guidance, and cognitive behavioural therapy, and provision of an educational leaflet. The interventions that were shown to be suitable to address physical workload were: workplace accommodations and occupational or vocational training.

Second, we incorporated factors reported by cancer survivors as helping or hindering their return-to-work. These factors were measured in a prospective cohort study of Spelten et al[18] with two-open questions: "*what or whom helped you the most*

with regard to work resumption or continuing work?" and *"what or whom hindered you the most with regard to work resumption and continuing work".*[18] Cancer survivors answered these open-ended questions at 6, 12, and 18 months after their first day of sick leave. We used the International Classification of Functioning (ICF) as a theoretical framework to categorise the answers into factors underlying work-related disability: body structure and functioning, environment-related factors, and person-related factors.[19] [20] The most frequently reported factor that aided in return-to-work in the category of body structure and functioning was general health; the most frequently reported hindering factor was fatigue. With regard to environment-related factors, managers, colleagues, and family were the most frequently reported helping factors and workload a hindering factor. For person-related factors, personality was the most frequently reported helping factor, and distrust in the manager was a hindering factor.

Third, the experiences of cancer survivors and supervisors regarding return-to-work after cancer were assessed in three focus groups.[14] A total of 7 cancer survivors and 6 supervisors participated in the focus groups. The following themes were reported by cancer survivors as being the most important: 1) contact with and support from colleagues and supervisors, 2) the occupational physician's and other physician's advice and expertise, and 3) knowledge of the long-term consequences of cancer, such as fatigue and cognitive problems. The following themes were reported by supervisors as being the most important: 1) their own role and that of the occupational physician, 2) return-to-work aspects such as work accommodations, and 3) communication with all stakeholders. The main findings of these focus groups were that support from colleagues and supervisors aids in return-to-work. Lack of knowledge and advice from occupational physicians and lack of communication between all stakeholders hinders return-to-work.[14]

Fourth, because the occupational physician is legalised to advise about the return-to-work of sick-listed employees in the Netherlands, he or she should be part of the intervention. In addition, employer participation is essential for preventing impediments. For instance, for the implementation of workplace accommodations, it is important that the employee, employer, and occupational physician agree. Furthermore, the intervention should be carried out close to the workplace and in collaboration with all stakeholders.[21]

Fifth, semi-structured interviews with a radiotherapist and four oncology nurses from four different departments in the Netherlands were held to determine the best way to integrate the intervention into usual cancer care. The health care professionals stated that the intervention should be integrated into psycho-oncological care. This seemed to be feasible based on the results of our systematic review.[15]

The interviewees' nurses stated that they lack the knowledge to provide this kind of care but that a training course would help to provide this knowledge. Furthermore, the interviewed nurses and radiotherapist believed that the intervention should be carried out individually because of variations in treatment, survival, and importance of work. In addition, the different factors reported by cancer survivors as helping or hindering their return-to-work also confirm the need to provide individual interventions. The interviewees stated that the psycho-oncological care of cancer patients varies enormously between hospital departments with respect to content, length, duration, extensiveness, and provider. These differences also hold for return-to-work, which is not addressed structurally by any of the departments. However, the interviewees believed that cancer patients need structural guidance in their return-to-work process. To achieve this guidance, they advised that meetings need to be scheduled and that communication with the occupational physician should be improved.

Content of the intervention

Incorporation of the findings described above resulted in a work-directed intervention that encompasses: 1) 4 meetings of 15 minutes each will be held at the hospital as part of the normal consulting hour to start early vocational rehabilitation. These meetings will be carried out as part of normal psycho-oncological care by an oncology nurse, social worker or nurse practitioner. In this article, we will refer to these people as the nurse. Since usual care differs between hospital departments, the organisation of these meetings may vary slightly, 2) one meeting with the participant, the occupational physician, and the supervisor will be held to make a return-to-work plan, and 3) three letters will be send to the occupational physician to enhance communication; two will be from the treating physician and one from the nurse.

1) Meetings at the hospital

The aim of the first meeting is to make a list of potential problems concerning return-to-work and to plan the intervention that best suits the individual participant. The first meeting will take place a few weeks after diagnosis, and the nurse will begin by taking a short work-anamnesis. Thereafter, the nurse will give guidance regarding the best way to inform colleagues and supervisors about the participant's illness and to keep them informed during treatment/aftercare. Furthermore, the participant will receive an informational leaflet about cancer.[22] An educational leaflet that consists of 10 steps of advice[23] will be given to the participant and will be used as a guideline for the intervention. Scheduling of the second meeting will depend on the diagnosis, treatment, and preference of the participant; it will be scheduled for a maximum of 10 months after the first meeting. The aim is to schedule this meeting two months before the participant is expected to return-to-work. This would largely occur at the end of medical treatment, because most cancer patients return-to-work thereafter.[18] However, if a participant wants to return-to-work during treatment, the second meeting will be scheduled two months before the return-to-work is expected.

The second meeting starts with a recapitulation of the topics discussed at the first meeting. Then, barriers to return-to-work will be identified, and actions to remove these barriers will be discussed. This information will be sent to the occupational physician. The identification of barriers to return-to-work and actions to remove these barriers are based on the work-anamnesis, physical, and psychosocial restrictions, coping, individual importance of work, participant preference regarding the return-to-work, and the most important prognostic factors for returning to work, such as, older age, lower education, and blue collar work.

The aim of the third and fourth meetings is to evaluate the process of return-to-work. The third meeting will be scheduled for a maximum of 2 months after the second meeting because during the actual return-to-work, different problems might arise. The barriers to return-to-work and actions to remove these barriers that were discussed in the second meeting will be evaluated. If a return-to-work plan has been made, it will be discussed. If necessary, the return-to-work plan will be altered, and extra information or advice will be provided. Possible medical or psychosocial problems will be discussed, and the patient can be referred to another professional (e.g. a psychologist) if needed.

There are two options for the fourth meeting depending on whether the participant has returned to work or not. If a participant has returned to work, the fourth meeting will be scheduled approximately 1 month after the return-to-work, and advice regarding continued employment will be provided. If the participant has not returned to work, the fourth meeting will take place a maximum of 14 months after baseline, and the contents of the third meeting will be discussed.

2) Meeting with participant's occupational physician and supervisor

The occupational physicians will be asked to schedule a meeting with the participant, the participant's supervisor, and with himself/herself to make a return-to-work plan. Medical information from the hospital regarding disease, treatment, and long-term side effects as the identified barriers to return-to-work and actions to remove these barriers that were discussed with the nurse can be used as a basis for this discussion. This meeting should be scheduled between the second and third meeting with the nurse, which would be between the second and tenth month after the first day of sick leave. The researcher will request this meeting; the request will be attached to the first letter from the treating physician to the occupational physician. A return-to-work plan will contain the following information: first day of work resumption, the number of hours the participant will work, the task(s) he/she is going to perform, and with which steps patients will increase working hours, working days and/or will do additional or different tasks.

3) Enhancing communication between treating physician and occupational physician

In the Netherlands, patients must give their consent to allow medical information to be sent from a treating physician to an occupational physician. A nurse will ask for this consent from each participant during the first meeting. If the participant gives consent, a copy of a letter from their treating physician to their primary care physician (containing general medical information such as diagnosis, prognosis, treatment plan, and outcome treatment) will be sent to their occupational physician. General information about the study (including the educational leaflet) will be attached to this letter. The identified barriers to return-to-work and actions to remove these barriers that were discussed with a nurse will be sent by a nurse to an occupational physician.

Study design to evaluate the intervention

For the description of the design of our evaluation study, we used the items of the CONSORT statement for improving the quality of reporting randomised trials.[24]

Organisation study

The study is designed as a randomised controlled trial with a follow-up of 2 years. Cancer patients are asked to participate at the hospital. The medical ethics committee of the institution, the Academic Medical Center, approved the study, and the local medical ethics committees of various participating hospitals advised positively about the local feasibility of the study. Patients will sign informed consent forms before participating in the study.

Recruitment of study population

The treating physician or nurse will inform the cancer patients about the study when they visit the hospital to discuss their treatment plans. The treating physician will check each patient's eligibility by assessing the inclusion and exclusion criteria and provide written information about the study. Then, the researcher will contact the patient by telephone to provide additional information and schedule a meeting with the patient following a visit to the hospital or at the patient's home. After the patient has signed informed consent and filled out a baseline questionnaire, he or she will be randomised to either the control group or the intervention group.

Participants

Patients are eligible to participate when they have a primary diagnosis of cancer, will be treated with curative intent, are employed at the time of diagnosis, are sick-listed, and are between 18 and 60 years old. Treatment with curative intent was defined as a 1 year survival rate of approximately 80%. The exclusion criteria are: 1) patients who are not able to speak, read or write Dutch sufficiently well, 2) patients who have a severe mental disorder or other severe co-morbidity, 3) primary diagnosis of cancer has been made more than two months ago, 4) patients who will receive primary treatment at another hospital, and 5) patients who have a primary diagnosis of testicular cancer, non-melanoma skin cancer or melanoma skin cancer. This last exclusion criterion has been

selected because, on average, these cancer patients do not experience significant problems with return-to-work; therefore, the intervention would not be useful for the majority of this patient group.[5 25]

Randomisation, blinding, and treatment allocation

The researcher will carry out randomisation using the computerised randomisation program ALEA.[26] Allocation of each patient is definite in such a way that allocation concealment is not possible. Because, patients differ significantly between the participating hospital departments in diagnosis and demographic factors, and because these aspects, as well as age, are important prognostic factors for return-to-work,[18] randomisation is stratified by the treating hospital department and age to prevent bias due to unequal randomisation. The cut-off age for stratification is 50. To equalise group sizes, minimisation is applied. If a treating hospital department has more than one nurse, participants in the intervention group will only be seen by nurses who carry out the intervention and vice versa. Participants, nurses, and researchers are not blinded to group assignment. Because all follow-up questionnaires will be filled out at home, no direct influence by the researchers is likely to occur.

Sample size

The calculation of sample size is based on two earlier studies regarding return-to-work in cancer patients. Based on the study by Spelten et al[18] with consecutive cancer patients, the expectation is that 18 months after diagnosis 36% of patients will not have returned to work[18] after care as usual in the control group. With regard to the intervention group, the expectation is that 19% of the patients will not have returned to work 18 months after diagnosis,[23] based on the study by Nieuwenhuijsen et al.[23] Due to the inclusion and exclusion criteria, a percentage of patients with relatively less severe return-to-work problems will not be included in this study and this may lead to less favourable return-to-work rates. However, our intervention is more comprehensive than in the study by Nieuwenhuijsen et al[23] and thus the expectation is that the percentages of patients that will not have returned to work will be the same as in the study by Nieuwenhuijsen et al.[23] This indicates an Odds Ratio of 0.41 of the intervention versus usual care for higher percentages of patients that are not returned to

work, which is the same as an Odds Ratio of 2.4 of the intervention versus care as usual for higher return-to-work rates. Since, the incidence of outcome is more than 10%, the Odds Ratio overestimates the magnitude of the association and therefore, we calculated the Relative Risk based on the Odds Ratio.[27] This indicates a Relative Risk of not returning to work of 0.53 of the intervention versus usual care. Based on the PS Power and Sample size Program, with a power of 80% and two-sided significance level of $p<0.05$, the sample size should be 109 patients in every arm, for a total of 216 patients.[28] Assuming that 20% of the initial patients will be lost to follow-up during the course of the study, 270 patients must be recruited to gather 246 patients at 24 months. To account for at least 10% missing data at baseline, 300 patients are intended to be included. Furthermore, a sample size of 300 will have sufficient power to be able to control for the prognostic factors in a Cox regression analysis since we assume that 5 to 10 variables will be included in the final model [17 18] and a sample size of 10 per included factor in a Cox regression analysis is considered sufficient.[29]

Contamination

In departments with more than one nurse, nurses who counsel participants in the intervention group will not counsel participants in the control group, and vice versa. Nurses who counsel participants in the intervention group are asked not to discuss the content of the intervention with nurses who counsel participants in the control group. In departments with only one nurse, this separation is not possible. However, since all nurses in the intervention group will need to extend their meeting for the intervention, and since they all need to fill out a form during each meeting, contamination between groups will be diminished. It is unlikely that employees of the same company will participate in the study; therefore, it is unlikely that participants in the control group will receive detailed information about the content of the intervention. It is possible that participants in the intervention group will discuss the content of the intervention with those in the control group at the hospital in the waiting room or during chemotherapy treatment. However, we do not consider this possibility a serious risk of contamination.

Participants will be able to use any co-intervention they wish. Since it is likely that other vocational rehabilitation programs will have a significant effect on return-to-

work, these co-interventions will be monitored by asking the participants at the end of the intervention if they have participated in any other vocational rehabilitation programs. Because the effect of other rehabilitation programs on return-to-work is unknown, these co-interventions will not be assessed.

Usual care in the Netherlands

Employees who are diagnosed with cancer should be guided according to the blueprint of evidence-based guidelines of the Dutch Association of Occupational Physicians (NVAB).[30] Furthermore, sick leave is covered in the Netherlands by the Improved Gatekeepers Act, which is in force during the first 2 years of sick leave. The act states that a sick-listed employee cannot be discharged and receives at least 70% of his/her wage. After 2 years of sickness, the sick-listed employee will be assessed for disability pension. The Improved Gatekeepers Act states that employers and sick-listed employees are responsible for work resumption, which means that both parties can be sanctioned. Furthermore, all sick-listed employees should have an occupational physician who should legally advise them about return-to-work.

Training nurses to carry out the intervention

The nurses who carry out the intervention will participate in a half-day training course. This training course consists of education about the rights and obligations of sick-listed employees according to the Improved Gatekeepers Act and education about the return-to-work problems of cancer patients. For instance, education about the return-to-work rates of cancer patients, factors that can have an impact on the return-to-work outcomes (e.g. diagnosis, type of treatment, and work ability), and the role of colleagues, supervisors, and occupational physicians. Furthermore, extensive practice is given at each meeting by means of role-playing and discussions between trainer and trainees. The training course will be given by a trained psychologist and a researcher. For evaluation, all nurses are asked to give their opinions of the training course by filling out an anonymous questionnaire at the end of the course.

Outcomes

The primary outcome parameters are return-to-work and quality of life. The secondary outcome parameters are work ability, work limitations, study feasibility, and direct/indirect costs of the intervention. The primary and secondary outcomes will be assessed at baseline and at 6, 12, 18, and 24 months after baseline. Participants will fill out the baseline questionnaires directly after signing the informed consent forms. The other questionnaires will be mailed with an enclosed free return envelope. It will take participants approximately 30 minutes to complete each questionnaire. The questionnaire has been pilot-tested with healthy subjects and cancer patients.

Effect evaluation

The study's effectiveness will be determined on the basis of the primary outcomes of return-to-work and quality of life and the secondary outcomes of work ability and work limitations, assessed at the long-term follow-up at 12 months and at the very long-term follow-up at 24 months. Prognostic factors will be taken into account in the effect analysis only if there are imbalances between the intervention group and the control group. Effectiveness will be inferred if participants in the intervention group will have a significantly shorter time to return-to-work than participants in the control group and if at the same time their quality of life does not significantly deteriorate. Return-to-work is measured both 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) sustained for at least 4 weeks and as the rate of return-to-work at follow-up. The first day of sick leave, the number of calendar days until return-to-work, and the return-to-work rates will be based on patient self-reporting on questionnaires.[23] Quality of life will be assessed with the SF-36.[31] All subscales of the SF-36 will be taken into account (physical functioning, role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and general mental health). The SF-36 has been validated in a sample of cancer patients, and normative values have been determined.[31] Work ability will be assessed with the first 3 questions of the Work Ability Index (WAI).[32] These questions concerns the evaluation of current work ability compared to their life time best and current physical and mental work ability with respect to their job demands. Acceptable measures for reliability and

validity have been determined.[33 34] Work limitations will be assessed on the basis of the Work Limitation Questionnaire, where work limitations are defined as being inversely related to productivity.[35] This questionnaire consists of four different subscales: work scheduling, physical demands, mental demands/social demands, and output demands. The English version of the Work Limitation Questionnaire has been proven valid and reliable in populations of several chronic diseases[35] and cancer survivors.[10 11 36] The validity and reliability assessments of the Dutch translation of the Work Limitation Questionnaire are currently underway for healthy controls and cancer patients.

Process evaluation

Process evaluation is divided into the following parameters: 1) feasibility of the procedure, 2) satisfaction with the intervention, 3) participant compliance with the intervention, 4) nurse adherence to the protocol, and 5) evaluation of usual care. First, feasibility of the procedure will be assessed by a researcher on the basis of a checklist at the end of the study. Second, nurse and participant satisfaction with the intervention will be assessed by a questionnaire. Third, patient compliance with the intervention will be assessed by a questionnaire. Fourth, nurse adherence to the protocol will be assessed by a researcher on the basis of reports from the nurse. Fifth, evaluation of usual care will be assessed on the basis of a questionnaire and includes organisational factors such as received support from the organisation and the occupational physician.

Economic evaluation

For the economic evaluation, the work-related costs to society, the individual cancer patient, and the employer will be taken into account, since everyone incurs costs when an individual cancer patient does not return-to-work.[37] In this way, the costs and benefits will be calculated independently of those who bear these costs and those who receive the benefits. For the intervention group, direct costs such as the costs to carry out the intervention, and indirect costs, such as absenteeism or work productivity, lost earnings, and work adjustments will be taken into account. For the control group direct costs such as the costs to carry out care as usual, and indirect costs, such as absenteeism or work productivity, lost earnings, and work adjustments will be taken into account. The direct costs will be determined by means of the average nurse wage and the amount

of time spent on each participant. The nurse will record the duration of each meeting at its completion. Indirect costs will be obtained by a questionnaire. Absenteeism will be determined by means of days on sick leave and on income and work productivity by the Work Limitation Questionnaire and on income.[35] Furthermore, lost earnings will be determined on the basis of the differences between income at baseline and income at follow-up. Work adjustments will be assessed by means of the cost of each work adjustment.

Prognostic and descriptive factors

We have taken into account as prognostic factors, all factors that were significant related to time to return-to-work in a prospective cohort study on the impact of cancer- and work-related factors on the return-to-work of cancer patients.[17] [18] Prognostic factors will be assessed by questionnaires at all time points except for diagnosis and treatment, which will be retrieved from patient files. The prognostic factors include age, gender, education, diagnosis, cancer treatment, number of working hours according to contract, physical workload as measured by the Questionnaire Perception and Judgement of Work (VBBA),[38] importance of work as measured by a Visual Analogue Scale (VAS-scale), fatigue as measured by the Multidimensional Fatigue Inventory (MFI),[39] depression as measured by the Centre for Epidemiologic Studies for Depression Scale (CES-D),[40] co-morbidity, income, self-efficacy as measured by the general self-efficacy scale (ALCOS),[41] and global quality of life as measured on a VAS-scale. The descriptive factors include the number of days between the first day of sick leave and inclusion in the study, marital status, ethnicity,[42] time since diagnosis, breadwinner status, position at work, shift work, years in current position, years of paid employment, and company size. These descriptive factors will be measured only at baseline.

Statistical analysis

Effectiveness

All analyses, which will be performed to distinguish differences between the control group and intervention group, will be performed according to the intention-to-treat principle. All baseline data and data regarding primary and secondary outcomes will be

presented using descriptive statistics. The number of days until participants' return-to-work will be analysed using the Kaplan-Meier survival method, and differences between groups will be tested with a log rank test. If necessary, the differences between the control group and the intervention group will be adjusted with a Cox regression analysis for confounders such as diagnosis and for the prognostic parameters. Longitudinal multilevel analysis will be used to examine differences between the control group and the intervention group with regard to improvement of the primary outcome of quality of life and the secondary outcomes of work ability and work limitations.

Economic evaluation

The economic evaluation will be performed according to the intention-to-treat principle. The direct and indirect costs will be summed for each participant. Mean differences in direct, indirect, and total costs will be calculated between the control group and the intervention group using bootstrapping. Incremental cost-effectiveness ratios will be calculated by assessing the ratio between the differences in costs between the groups to the differences in return-to-work rates between the groups. These ratios will be displaced in a cost-effectiveness plane, and acceptability curves will be presented.

Discussion

There is a lack of effective work-directed interventions specifically tailored to cancer patients. The aim of this study is to develop an intervention that will be carried out as a randomised controlled trial.

As a starting point for developing a new work-directed intervention, the shared care model, adjusted for the vocational rehabilitation setting, has been used. The work-directed intervention involves: 1) 4 meetings with a nurse at the treating hospital department to start early vocational rehabilitation, 2) 1 meeting with the participant, occupational physician, and supervisor to make a return-to-work plan, and 3) letters from a treating physician to an occupational physician to enhance communication. The aim of the work-directed intervention is to improve cancer patients' care and to enhance their return-to-work and quality of life.

Methodological considerations of the development and content of the intervention

Developmental considerations

In the literature, methods such as intervention mapping are often used as tools for developing new interventions. In this study, no such tools have been used; however, all of the important ingredients to develop an intervention have been employed, including the use of a model, literature, and expert knowledge. By putting this intervention into practice, the quality of vocational rehabilitation might improve due to the improved medical knowledge of an occupational physician about each patient and improved continuity of care.[43]

Content considerations

Because we used a cancer care model and interviews with health care professionals we think that we have taken practical considerations into account that will improve the intervention implementation. This resulted for example in an extra burden on participants and health care professionals that is in our view quite reasonable.

Methodological considerations of the study design

We used the items of the CONSORT statement for improving the quality of reporting randomised trials as guidance for the study protocol.[24] One drawback of our study design is that in departments with one nurse, the nurse might also give better guidance to participants in the control group leading to contamination. One way to prevent this kind of contamination is to randomise on the hospital department level, so-called cluster randomisation. In our case this had the following disadvantages. Cluster randomisation on the department level will irrevocably lead to baseline differences in patient characteristics, such as diagnosis, treatment, and age because departments deal with specific cancer patients. These baseline characteristics are the most important prognostic factors for return-to-work[17 18] and differ significantly between hospital departments in the Netherlands. Although it is possible to correct for these baseline differences afterward, bias will always be apparent. Further, nurses might invite a specific group of patients to participate in the study since they know in which group each patient will come.[44] At last, psycho-oncology care differs between hospital departments; thus, the outcome might be biased by these differences in usual care. The

drawback of our approach is of course contamination. To reduce the likelihood of contamination, nurses must fill out a process form for each patient in each meeting.

We choose not to perform a comprehensive cost effectiveness evaluation in which all direct and indirect costs, such as medical consumption are taken into account because the expectation is that the intervention has no effect on these costs. Therefore, the expectation is that these medical costs are equally divided between groups and therefore do not contribute to the cost analysis. In addition, the aim of our work-directed intervention is to improve participants' return-to-work and work productivity and to reduce absenteeism and lost earnings. Therefore, we choose to perform the economic evaluation on the basis of these work-related costs.

This study will provide information about the effectiveness of our work-directed intervention on return-to-work and quality of life. The results will be available in 2011. Furthermore, the intention is to implement the intervention in normal care if it has been shown effective.

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Chapter 6.

A hospital-based work support intervention to enhance the return to work of employees with cancer – a case study

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Abstract

The purpose of this case study was to describe how the return-to-work process evolved in an employee with cancer in the Netherlands and how a hospital-based work support intervention supported this process. The patient was a 35-year old female employee diagnosed with cervix carcinoma. After surgery, the patient experienced depression, fatigue, fear of recurrence, and low mental working capacity. Communication with the occupational physician was difficult. A social worker at the hospital provided three counselling sessions aimed to support return to work and sent letters to the occupational physician to improve the communication. The support by the social worker helped the patient to resume work gradually and the sending of information from the treating physician and social worker improved the communication with the occupational physician. This resulted in the patient being able to achieve lasting return to work. This hospital-based work support intervention was highly valued by the patient and could be an important addition to usual psycho-oncological care for employees with cancer.

Trial registration: NTR1658

Introduction

The return to work of patients diagnosed with cancer is increasingly recognised as a problem that needs more attention in both the occupational health field as in oncology. It will be even more pressing in the future as employees with cancer will become a frequent phenomenon in the workplace due the increased survival rates of cancer, the ageing of the working population, and the fact that people have to work longer before retiring.[1]

The increased survival rates of cancer imply that cancer will become a chronic disease but involve in general a lower quality of life[2] due to long-term side effects such as depression, fatigue, and distress.[3] These symptoms impact survivors' capabilities to resume their 'normal' life after cancer treatment. For employees with cancer, an important part of resuming their 'normal' life is to return to work, because work, takes one's mind off of one's illness,[4] reduces financial problems,[5] is often perceived as going 'back to normal',[6] and work is associated with the quality of life of cancer patients.[7]

Unfortunately, not all employees with cancer do return to work. In a meta-analysis, the risk of unemployment was 37% higher in cancer patients compared to healthy controls.[8] Employees with cancer also suffer from lower work productivity compared to employees without cancer.[9] [10] Furthermore, many experience difficulties with return to work, such as an insensitive work environment,[11] discrimination,[11] [12] or how to overcome symptoms such as fatigue, concentration problems, and depression.[11] [13]

To support employees with cancer upon return to work, we developed a hospital-based work support intervention with the primary aim of enhancing return to work while at least maintaining and hopefully increasing their quality of life.[14] The intervention is currently under evaluation in a multi-centre randomised controlled trial for which the medical ethics committee of the Academic Medical Center gave approval.

Return to work after an illness is a complex process facilitated or hindered by a number of factors (e.g. work ability, physical workload) that involves various stakeholders (e.g. colleagues, supervisors), and health care professionals (treating physician, occupational physician).[15] The whole process is guided by complex disability legalisation and social security that are deeply embedded in a cultural context. Elaboration and elucidation of facilitating and hindering factors will help us to better understand which mechanism operates in the return-to-work process of employees with cancer.

The institutional context of a national social security system influences the return to work of sick-listed employees. Therefore, to be able to understand how a return-to-work process evolved in an employee who was sick-listed due to cancer, it is necessary to know how the social security system protects employees with cancer that are incapacitated for work. In the Netherlands health insurance is not related to an employment contract and employees who are sick-listed have social care and financial protection. In the first two years of sick leave, the Improved Gatekeepers Act covers insurance of sick-listed employees against wage loss, which is paid by the employer and is at least 70% of their wage but often 100% during the first year of sick leave. During this first two years of sick leave, a patient cannot be dismissed for health reasons. The occupational physician will make a disability evaluation with regard to the employee's own work situation and will independently advise the employer and employee on return- to-work issues. After two years of sick leave, an independent insurance

physician will formally assess employee's ability to work. Based on this evaluation, the patient can be awarded a disability pension, which is paid by the government and the employer can then terminate the employment contract. In addition, the treating physician who treats patients in terms of a disease is strictly distinguished from the occupational physician who provides return-to-work management and strictly distinguished from the insurance physician who formally assesses disability for work.

The purpose of this case study was to describe how a return-to-work process evolved in an employee with cancer and how a hospital-based work support intervention supported this process. This case study describes a successful participant of a multi-centre randomised controlled trial (trial number: NTR1658).

Description of the multicentre randomised controlled trial

This case study describes a successful return to work of a participant of our multicentre randomised controlled trial. The intervention aims to enhance the return to work with the maintenance of quality of life in employees with cancer.[14] Eligible patients were randomised and received either usual care or the hospital-based work support intervention. Quality of life was measured with all subscales of the Short Form-36 (SF-36).[2] Secondary outcomes were work ability as measured with the Work Ability Index (WAI),[16] work limitations as measured with the Work Limitation Questionnaire (WLQ),[17] and costs. In addition, we measured fatigue with the Multidimensional Fatigue Index (MFI)[18] and depression with the Centre for Epidemiologic Studies for Depression Scale (CES-D)[19] as these are important prognostic factors for return to work.[13] Acceptable measures of validity and reliability have been reported for these questionnaires for use at group level.

Description of the hospital-based work support intervention

The hospital-based work support intervention is based on providing patient education, advice, and support at the hospital as part of psycho-oncology care, communication between stakeholders, and making a concrete gradual return-to-work plan in collaboration with all stakeholders.[14] The intervention is carried out individually. Furthermore, the time frame of the intervention is adapted to the cancer diagnosis,

treatment, the preference of the participant, and the organisation of the psycho-oncological care at the hospital department.

The first face-to-face meeting is planned a few weeks after diagnosis and the last is planned at a maximum of 14 months after its start. To improve the communication between stakeholders, two letters from the treating physician and one from the social worker are sent to the occupational physician. These letters contain medical information such as diagnosis, prognosis, treatment plan, and side-effects of treatment. In the Netherlands, patients must give their consent to allow medical information to be sent from a treating physician to an occupational physician. The social worker has asked for this consent during the first meeting. General information about the study is attached to this letter and we have asked the occupational physician to organise a meeting between supervisor, participant, and themselves to make a concrete return-to-work plan.

The case study was based upon triangulation of: social workers' reports of face-to-face meetings and contact by e-mail and telephone, participant's self-reported questionnaires filled in at baseline and at 6 and 12 months follow-up, and correspondence between the treating physician/social worker and the occupational physician.

Description of the case

Situation at first contact

Medical and personal situation

The patient was a 35-year-old female diagnosed with a cervix carcinoma stage I B1 who was referred to the department of gynaecology of the Academic Medical Center in Amsterdam, the Netherlands in December 2009. She gave written informed consent to participate in our study in January 2010, a few weeks after diagnosis and before the start of medical treatment. Additionally, she gave written informed consent to undertake and publish this case study in July 2011. As part of the ongoing study, she filled in questionnaires to assess medical, personal, work, and psychosocial characteristics [2 16 18 19] that were deemed important for return to work (Table 1).

Cancer of the cervix is a serious potential life threatening medical condition that needs extensive surgical treatment in which the womb, adjacent lymph nodes, and

sometimes the ovaries are removed. Stage 1 B1 means that the cancerous changes are confined to the cervix with little invasion and spread to the surrounding tissues, but there are no metastases. The treatment is with the intent to cure and consist of surgery and adjuvant radiotherapy if indicated by the outcome of the surgery. In addition to the usual side effects of cancer and cancer treatment such as fatigue and depression, one of the more specific side-effects of this operation is lymphoedema of the lower limbs.[20]

When one of us [ST] first met her, she presented as an independent and strong woman who attributed great meaning to her work and who was very worried about not being able to work. Her scores on the MFI, CES-D, and on the SF-36, indicated that she experienced serious fatigue, scored above the clinical cut-off score for depression[19] and did not feel well in general. She also felt limited in an emotional sense with subsequent limitations in social functioning. Her ratings of quality of life were rather low compared to a benchmark of cancer patients before the start of treatment.[2] In contrast, she did not report problems with physical functioning nor pain (Table 1). The patient reported suffering from hypoglycaemia and back, neck, and hip problems. She lived with her husband and did not have children. Both contributed to their income, which was above average.

Work situation

The patient completed intermediate vocational education and worked for 10 years. At the time of diagnosis, she worked as a planning engineer during the past 6 years for 40 hours a week with regular paid overtime. She was employed by a large company (>100 employees) on a permanent basis. When one of us [ST] first met her, she was sick-listed for 20 days. She rated her physical workload as 4 (range 0-21),[21] because some tasks required reaching and lifting heavy objects but she did not regard this as a high physical workload. The patient felt that her relationship with her supervisor and colleagues was very good. She disclosed the cancer diagnosis and treatment to them without any problems a few days after she received the diagnosis. Work was very important to her as indicated by her rating of 78 of the importance of work on a Visual Analogue Scale (VAS-scale) ranging from 0 (least important) to 100 (most important). She rated her current overall work ability as 2 on the WAI, ranging from 0 (worse) to 10 (best).[16] This assessment was especially based on a low rating of her mental work ability, which she

rated as 'low'. Her mental work ability was in line with her level of depression, low general mental health, and role limitations due to emotional problems. She did not report problems with physical work demands (Table 1).

Table 1. Outcome of self-reported questionnaires at baseline and at 6 and 12 months follow-up.

Patient characteristics	**Baseline**	**6 months**	**12 months**
Indicators for work capacity			
Overall work ability[1]	2	4	6
Work ability in relation to physical demands[2]	4	2	4
Work ability in relation to mental demands[2]	2	2	3
Overall importance of work[3]	78	100	64
Indicators for mental and physical health			
Overall quality of life[3]	49	67	62
Depression[6]	17	31	17
General fatigue[5]	16	12	13
Mental health[4]	56	48	40
Vitality[4]	50	40	35
General health[4]	35	65	60
Bodily pain[4]	90	100	77
Physical functioning[4]	100	85	95
Indicators of limitations and restrictions of participation			
Social functioning[4]	63	100	100
Role-emotional[4]	0	0	33
Role-physical[4]	0	0	75

1. Range 0-10; higher score means higher work ability
2. 5-point scale; higher score means higher work ability
3. Range 0-100; measured on VAS-scale higher score means higher quality of life
4. Subscale SF-36; range 0-100; higher score means less complaints
5. Subscale general fatigue of the Multidimensional Fatigue Inventory (MIF); range 5-25; higher score means more fatigue
6. Centre for Epidemiologic Studies for Depression Scale CES-D; range 0-60; higher score means higher level of depression

Hospital-based work support intervention

The hospital-based work support intervention was part of a multi-centre randomised controlled trial with the aim of enhancing return to work with the maintenance of quality of life in employees with cancer. In this particular case, the medical social worker [RvdB] of the Academic Medical Center carried out the hospital-based work support intervention with support from the research project. The intervention started in February 2010, and ended in August 2011 (Figure 1) and consisted of three face-to-face meetings with the social worker of 25 to 50 minutes each and a number of contacts

by telephone and e-mail. These meetings were aimed at diagnosing return-to-work problems and to support the patient with solving them. The social worker provided the patient with information about social security and legal rights. With the patient's consent, letters with medical information were sent to the occupational physician to improve the communication with the occupational physician.

Situation at follow-up

Medical and personal situation

The patient underwent major surgery in February 2010 (radical hysterectomy according to the Wertheim-Okabayashi technique) in which the cancer of the cervix was radically removed. She was admitted to the hospital for ten days. Surgery was successful and there was no indication for further treatment. As a direct side-effect of the major surgery she suffered from lymphoedema in her legs.

After 5 months of sick leave in July 2010, the patient started with an outpatient rehabilitation program for 4 months for 2 mornings a week aimed at improving her physical condition and reducing the lymphoedema in her legs (Figure 1).

In January 2011, thirteen months after diagnosis, she suffered from pain in her stomach and unaccountable blood loss. Therefore, medical examination under full anaesthetic took place to examine if the complaints were an indication of recurrence of the cancer. This examination revealed that there was no sign of recurrence.

About six months after diagnosis, the patient filled in the various questionnaires again (e.g. MFI, SF-36, CES-D, and WAI). This assessment indicated that depression and emotional limitations worsened compared to baseline (Table 1). Her level of feelings of depression was high (score = 31) and beyond the cut-off point for clinical depression (score = 17)[19] and mental health worsened. In contrast, all other indicators of health and work capacity improved, even though some only slightly (Table 1). The change score on the VAS quality of life indicated a clinically meaningful improvement[22] as well as the change score on the social functioning subscale of the SF-36.[2]

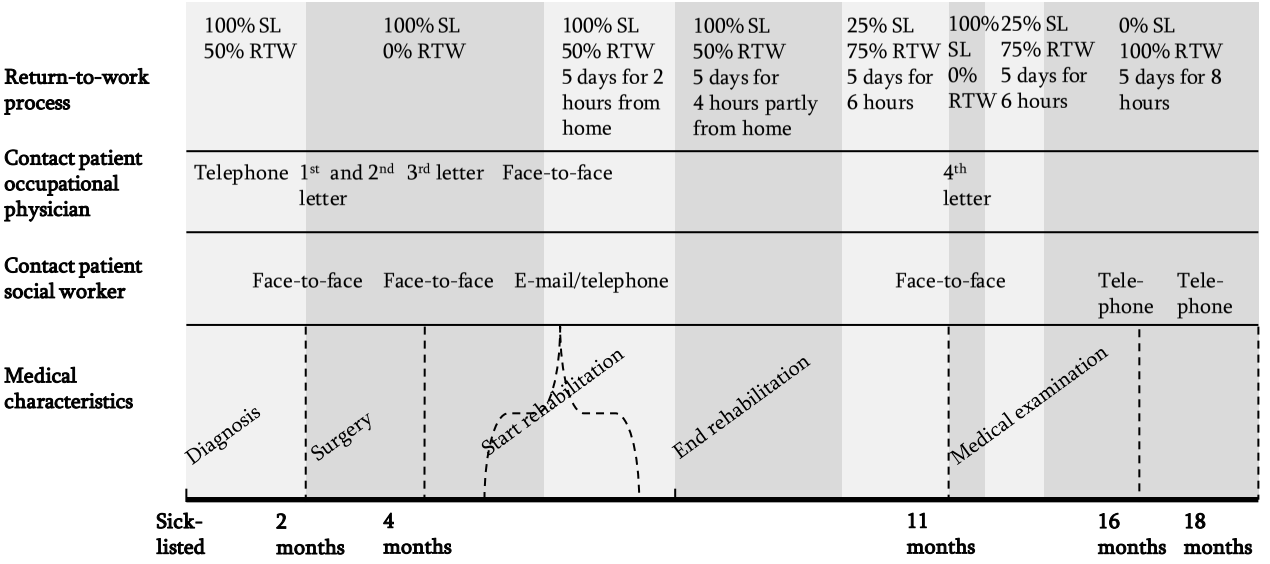

Figure 1. return-to-work process and intervention.
Abbreviations: SL = Sick-listed; RTW = return-to-work

Work situation

The patient reported sick for the first time on the 20th of December 2009 for 100% of the working time, returned to work full-time, and was not officially sick listed anymore after 14 months (Figure 1). The patient had a phased return to work. She worked before surgery although sick-listed, and after surgery she was sick-listed for 5 months in which she did not work due to physical and psychological side-effects of the cancer diagnosis and major surgery. Thereafter she had a phased return to work for 14 months including different tasks, working hours, responsibilities, workplace, and the official percentage of sick leave gradually decreased. An extra person was employed to assist her. Her work situation did show some relapses in work performance due to medical examination under full anaesthetic, fear of recurrence, problems with lymphoedema in her legs, and due to concentration and stomach problems.

The patient assessed her overall work ability at 6 months follow-up as increased compared to baseline but work ability for mental work remained low and for physical work slightly decreased (Table 1). This concurred with increased feelings of depression and not feeling up to mental work demands. Nevertheless, she found her work at 6 months follow-up even more important than at any other moments of measurement (Table 1).

Hospital-based work support intervention

The social worker met the patient for the first time when she was admitted to the hospital for surgery in February 2010. She told that work was very important and that she worked extremely long days. Although she was sick-listed, she was at work before surgery because there was so much work to do and because she appreciated the social contact. She told that she experienced a high work pressure and high mental workload because two persons should actually do her job. The social worker told her about the rights and obligations of sick-listed employees in the Netherlands and gave an informational leaflet about cancer and work.[23] In addition, the social worker discussed return to work after major surgery for a cervix carcinoma and gave an educational leaflet that consisted of 10 steps of advice, which provided support, graded activity, and goal setting for returning to work after sickness absence.[24] Even though the patient's job required a good mental and physical working capacity, the social worker assessed that

she would be able to return to work a few months after surgery because she appeared to recover well and no additional cancer treatment was needed. Therefore, the social worker and the patient agreed to meet again a few months later.

With the patient's consent, the treating physician sent a letter to her occupational physician with information about diagnosis, treatment, and side effects in February 2010 and a second letter in March 2010.

The social worker met the patient for the second time in April 2010 at the hospital department while she was still full-time on sick-listed. She told her social worker that she suffered from severe fatigue, concentration problems, that she had pain in her back, neck, and left hip, and that her physical condition was poor. She explained that her recovery did not go as well as she expected and that she had problems with resuming work: *'Due to my concentration problems, I am barely able to sit behind my computer for one or two hours and the lymphoedema in my leg gets worse after sitting for some time. Due to the pain in my back, neck, and left hip I am not able to reach and lift heavy objects.'* For that reason, the social worker advised to resume work at a very slow pace and to gradually increase work at the computer. The social worker advised not to reach or lift heavy objects. This information was also sent to the patient's occupational physician.

The patient contacted the social worker a few times by e-mail and telephone between July and October 2010 because she disagreed with her occupational physician: *'My occupational physician thinks that I am able to work for two mornings a week. Including travelling time from home to work it means that I am away from home for at least six hours. How am I supposed to do that? He did not even ask about my medical condition and I only spoke to him on the phone. He judged my abilities to work solely on the basis of the time since surgery.'* Furthermore, she feared a cancer recurrence and she was afraid of the high work pressure when returning to work.

She thought that her occupational physician did not understand her situation. The social worker advised to ask for a face-to-face appointment with the occupational physician. This turned out to be successful and misunderstanding between the patient and the occupational physician were solved. The occupational physician and the patient jointly made a gradual work resumption plan. She started from August 2010 on for 2 hours a day from home to avoid the long time for commuting. This was increased to 4

hours a day from October 2010 on, partly from home, and from November 2010 on for 6 hours a day. In the mean time an extra person was employed to assist her. The patient was relieved that her occupational physician now understood her situation.

When she was admitted to the hospital in January 2011 for a medical examination under full anaesthetic, she met the social worker for the third time. Because of a strong fear of cancer recurrence return to work was not further discussed before the results of the examination were known. A cancer recurrence would set a different perspective on return to work. Fortunately, the outcome of medical examination revealed that there was no sign of a cancer recurrence.

The patient approached her social worker by telephone in June 2011 because she still felt that her occupational physician misunderstood her limited work capacity. In addition to earlier problems, she also experienced stomach problems that led to sleeping problems. Even though the outcome of the medical examination was good, she remained afraid for a recurrence. The social worker asked the treating physician to send an extra letter to her occupational physician that described the outcome of the medical examination under anaesthetics with the intent of showing the seriousness of this medical examination and its side-effects.

During the last contact by telephone in August 2011, the social worker found that the patient sounded bright and optimistic. She said that she was happy that her supervisor accepted that she was not able to work on her pre-diagnosis level anymore and that an extra co-worker was employed who assisted her. On the other hand, she still experienced problems with lymphoedema in her legs and found it difficult to accept that she was not able to work at her pre-diagnosis level anymore.

Situation at end of follow-up

Medical and personal situation

The patient's further medical recovery was uneventful even though she experienced problems with lymphoedema in her legs.

At 12 months after diagnosis, the patient was still depressed and felt limited in her emotional functioning even though she improved since baseline and half a year follow-up. However, her levels on role limitations due to physical health, general health, social

functioning, and overall quality of life were much improved and comparable to a general population benchmark (Table 1).[2]

Work situation

Her work situation at the end of follow-up in August 2011 was good. She returned to work full-time in February 2011 and was not officially sick listed anymore. However, she was not able to work on her pre-diagnosis level, which she found difficult to accept. This was overcome by employing an extra person that assisted her.

The patient's confidence in her ability to work increased over time, which was probably reinforced by a positive experience of gradual work resumption. In addition, her levels on work productivity as measured with the Work Limitation Questionnaire[17] ranging from 0 (no limitations) to 100 (severe limitations) were 20 on time management demands, 42 on physical demands, 44 on mental-interpersonal demands, and 35 on output demands, indicated a moderate loss of work productivity especially for mental-interpersonal and physical demands which is in line with the rather low levels on work ability in relation to mental and physical work demands (Table 1).

The value the patient attached to work decreased by almost 50% at the end of follow-up, which illustrated that the experience of cancer can fundamentally change the position of work in one's life (Table 1).[25]

Evaluation of the hospital-based work support intervention

The patient evaluated the hospital-based work support intervention of the social worker on a self-reported questionnaire as very useful: '*The support, information about rights of sick-listed employees, and discussing return to work prevented me from returning to work too early'.* However, she stated that it would have been more useful for her if there had been contact with the social worker immediately after the first visit at the outpatient clinic instead of a month later. This was because she felt a lot of pressure to return to work and because at that time there was no one else who took over her job. She stated that: *'The impact of the cancer diagnosis was less than the impact of being forced to stop working. At the time of diagnosis I thought that it was not possible to stop working for at least three months'*. She found the social worker apt for this task and she appreciated that the meetings were held at the hospital. She found the

informational leaflet very useful and she rated the 10 steps of advice with an 8 on a scale from 0 (not useful) to 10 (very useful). She only found making a return-to-work plan difficult because the return-to-work plans were adjusted regularly and were not evaluated often enough.

In her opinion there was still room for improvement for her supervisor and occupational physician. She doubted the competence of the occupational physician due to a lack of knowledge of the impact of cancer on work and due to communicating by telephone only. Moreover, she felt offended by the fact that at first her occupational physician was of the opinion that the medical examinations were only unpleasant, while she feared recurrence of cancer.

Discussion

This case study described how a return-to-work process evolved in an employee with cancer and illustrated the hindrances to resume work such as depression, fear of recurrence, concentration problems, fatigue, and lymhoedema. This case study also described how a hospital-based work support intervention supported an employee with cancer in this process. It illustrated that the intervention was feasible to carry out and appreciated by the patient and that the patient achieved a lasting return to work with an increased quality of life rating.

The patient of this case study was in some aspects not a typical case. For instance, the patient was of the opinion that the impact of the cancer diagnosis was less compared to not being able to work which is not representative for employees diagnosed with cancer. The social worker thought that the patient's response was caused by her worries about the consequences of cancer for her functioning rather than the cancer diagnosis itself. In addition, the social worker thought that this was not a response to feeling unable to deal with a cancer diagnosis but that it was caused by the fact that work was very important for the patient. The patient organised her life in such a way that she spent very much time at work. In contrast, the patient was in other aspects a typical case such as the phased return to work and support form supervisor and colleagues.

This patient was at a relatively high risk of long sick leave and subsequent job loss. The following factors presented in this patient were reported in the literature to delay return to work based on prognostic research: low work ability,[26] cancer type (i.e. cervix

carcinoma I 1B),[13] depression, fatigue,[13] and low quality of vocational rehabilitation by occupational physician.[27] In addition, the male work culture is likely to have resulted in lack of support in this case, as she was not able to provide the required physical strengths. As a result, she lost her pivotal role in the company, which she had difficulties to accept. In this case the high pre-diagnosis work demands seemed to be particular hindrance for return to work but pre-diagnosis stress at work were found to increase time to return to work.[13] This could be because high pre-diagnosis work demands can increase the feeling to be needed at work and thus enhanced return to work. At the group level the enhancing and delaying effect of pre-diagnosis stressful work demands would then be cancelled out.

Even though there are many studies about prognostic factors for return to work, their clinical application is limited. What is urgently needed is to translate the findings of prognostic research into clinical prediction tool that can be used to make a clinical assessment of the risk of long term sick leave and job loss.[28] With such a prediction tool health care providers can focus on patients that most need support.

The hospital-based work support intervention was successful in supporting this patient in her return-to-work process by providing information about rights and obligations of sick-listed employees, information about cancer and work, and by providing support when and how to return to work. However, the timing of the hospital-based work support intervention was not optimal in this particular case because the patient thought that it would have been more useful for her if the hospital-based work support intervention would have started immediately after the first visit to the gynaecologist at the outpatient clinic (Figure 1). Few interventions, aimed at enhancing return to work, have been reported in the literature and hardly any have been evaluated in randomised controlled trials. [29 30] This stresses the need for developing and evaluating interventions aimed at enhancing return-to-work in employees with cancer.

In this case it turned out that difficulties with return to work were not optimally assessed because recovery seemed to go well at first and the relationship with her supervisor and her colleagues appeared good. Then the recovery process was negatively influenced by the patient's fear of cancer recurrence, fear of pre-diagnosis work pressure, and depression. It seemed that depression in this patient was to some extent

overlooked and might have needed more attention. An answer to this problem may be to screen each patient on depression and provide feedback to the social worker on patient's depression score. Depression as co-morbidity is a strong impediment to resume work in many diseases. Treatment of depression has been reported successful in patients with cancer. [31] Moreover, problems were enhanced by the miscommunication between her and her occupational physician who judged her working capacity at first only on the time that had past since surgery without taking into account her emotional and physical recovery. Even though, communication between the health care professionals was optimised by sending letters, this turned out not to be enough. The advice of the social worker to communicate face-to-face with the occupational physician was much more successful in that respect. For return-to-work interventions, it would be helpful to develop better models for communication between health care providers.

Lessons learned from this case study include the importance of a targeted yet flexible intervention, the importance of timing of the intervention, the complex process of return to work, importance of emotional recovery after a cancer diagnosis, and informing the occupational physician sufficiently about patient's situation.

In order to be able to provide a targeted but flexible intervention we should be able to screen what the most appropriate time is to intervene and what the content of the intervention for each particular employee with cancer should look like. Furthermore, in order to better deal with the complexity of a return-to-work process we need to be able to regularly evaluate the return-to-work process and regularly adjust a return-to-work plan.

Summary

In summary, this case study illustrated how a return-to-work process evolved in an employee with cancer and illustrated how a hospital-based work support intervention supported an employee in this process. The patient was a 35-year old female employee diagnosed with cervix carcinoma and resulting cancer-related symptoms of fatigue, depression, and reduced work ability. She also had difficulties with her occupational physician. A social worker at the hospital provided three counselling session aimed to support return to work as part of psycho-oncological care and improved communication with the occupational physician. The support by the social worker helped the patient to

resume work gradually and the sending of information from the treating physician and social worker improved the communication with the occupational physician. This resulted in the patient being able to achieve lasting return to work. The hospital-based work support intervention was highly valued by the patient. A hospital-based intervention aimed at supporting return to work in employees with cancer could be an important addition to usual psycho-oncological care.

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Chapter 7.

A hospital-based work support intervention to enhance the return-to-work of cancer patients – a process evaluation

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Submitted

Abstract

Introduction

The objective was to perform a process evaluation of a hospital-based work support intervention for cancer patients aimed at enhancing the return to work and quality of life. The intervention involves the delivery of patient education and support at the hospital integrated into usual psycho-oncology care and involves 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.

Methods

Eligible were cancer patients treated with curative intent and having paid work at the time of diagnosis. Data were collected from patients assigned to the intervention group (N=65) and from nurses who delivered the patient education and support at the hospital (N=4), by means of questionnaires, nurses' reports, and checklists. The following process indicators were assessed: recruitment, context, reach, intensity of the intervention delivered, intensity of the intervention received, and fidelity.

Results

A total of 47% of all eligible patients participated (reach). Nurses delivered the patient education and support in 85% of the cases according to the protocol (fidelity). In 100% of the cases at least one letter was sent to the occupational physician (fidelity). In 10% of the cases the meeting with the patient, the occupational physician, and the supervisor took place (fidelity). Patients found the intervention in general very useful (intensity of the intervention received) and nurses found the intervention useful and feasible to deliver.

Conclusion

In this study, we found that a work support intervention was easily accepted in usual psycho-oncological care but that it proved difficult to involve the occupational physician. Patients were highly satisfied and nurses found the intervention feasible.

Trial registration: NTR1658

Introduction

Due to the increased survival rates of cancer patients, a growing number of cancer patients are now be able to survive many years beyond a cancer diagnosis and thus face new challenges related to survivorship. For cancer patients of working age, one challenge is their return to work. Returning to work is important as work contributes to personal[1] and economic well-being[2] and is associated with the quality of life of cancer patients.[3 4]

Unfortunately, not all cancer patients are able to return to work successfully. A meta-analysis demonstrated that the risk of unemployment was 37% higher for cancer patients than healthy controls.[5] Moreover, interventions primarily aimed at improving cancer patients' return to work are rare, especially those that have been studied in randomised controlled trials.[6 7] Therefore, we developed an intervention on the return to work of cancer patients and quality of life.[8]

We developed this intervention based on previous studies that had employed effective interventions for enhancing the return to work of cancer patients,[6] and we developed this intervention in collaboration with various stakeholders involved in the return-to-work process of cancer patients.[8] An early intervention is most appropriate, as longer periods of sick leave often cause patients return to work to be more difficult.[9 10] For the delivery of an early intervention, a hospital-based intervention is most appropriate, as most cancer patients do not have contact with their supervisor or occupational physician during the early phases of their cancer treatment and their advice seems to be influential.[11 12]

Performing a process evaluation is important for interpreting the findings of an innovative intervention because the effectiveness partially depends on how well the intervention was implemented.[13] Consequently, process evaluation results can be used to further develop the intervention by improving the intervention itself and/or the intervention implementation. Furthermore, when interpreting the findings of a newly developed intervention, identifying for whom the findings of the intervention apply and under what conditions is also considered important.[14]

Process indicators should be measured at each level that could have an influences on the implementation process of the intervention.[14] For instance, intervention exposure occurs in this study on two levels: at the level of the cancer patients who received the

intervention, and that of the nurses who received training for delivering the intervention.

Linnan and Steckler[14] proposed the following key process indicators for studying the intervention implementation: recruitment, context, reach, intensity of the intervention delivered, intensity of the intervention received, and fidelity. In this study, we distinguish between the process indicators that address how well the intervention was delivered and received (intensity of the intervention delivered, intensity of the intervention received (exposure), and fidelity) and those that address how the intervention was appreciated by the various stakeholders (intensity of the intervention received satisfaction), to whom the findings apply (recruitment, reach), and under what conditions the findings can be applied (context). We made these distinctions because the primary aim of the trial was to identify the effectiveness of the intervention. The process indicators that address how well the intervention was delivered and received can help us to interpret our findings related to effectiveness, and we therefore considered these the most important process indicators. The remaining process indicators could be helpful when implementing the intervention for usual care on a wider scale. In summary, the objective of this study was to perform a process evaluation of a hospital-based work support intervention for cancer patients.

Methods

This process evaluation was part of a multi-centre randomised controlled trial to assess the effectiveness of a hospital-based work support intervention on the return to work of cancer patients and quality of life.[8] Patients who were willing and eligible to participate were randomised to either the intervention group and received the hospital-based work support intervention or to the control group and received care as usual.[8]

Six hospitals in the Netherlands participated in the study. The medical ethics committee of the Academic Medical Center approved of the study. The local medical ethics committee of each participating hospital advised positively about feasibility of the study in their hospital.

Patients

Patients with a primary diagnosis of cancer, who were between 18 and 60 years of age, had paid work at the time of diagnosis, were on sick leave, had been treated with curative intent, and who had been treated at one of the participating hospital departments 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 adequately able to speak, read, or write Dutch, who had a severe mental disorder or other severe co-morbidity, or those for whom the primary cancer diagnosis had been made more than two months ago. Patients signed informed consent forms prior to their inclusion in the study.

Hospital-based work support intervention

The hospital-based work support intervention began a few weeks after the patients were included in the study and was spread over a maximum of 14 months. The hospital-based intervention involves the delivery of patient education and support at the hospital integrated into usual psycho-oncology care and involves 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.[8] A nurse or social worker (hereafter called nurse) who delivered psycho-oncological care in normal cancer care delivered the patient education and support at the hospital in 4 meetings of 15 minutes each. Nurses received a half-day training course in which the intervention protocol was simulated. In addition, three letters were sent to the occupational physician to enhance the communication: two from the treating physician and one from the nurse. The key aspects of the hospital-based work support intervention were the patient education and support at the hospital and the sending of information to the occupational physician.

In the Netherlands, patients must give their consent to allow medical information to be sent from a treating physician to an occupational physician, which was requested by the nurse during the first meeting. We only informed occupational physicians about diagnosis and cancer treatment of patients who gave consent providing medical information to their occupational physician.

Study design

Data of the process indicators were collected using questionnaires, which were filled in by the nurses and patients, nurses' reports of each patient in the intervention group, and checklists that were filled in by the research team throughout the study (Table 1). Patients were asked to fill in a questionnaire 14 months after randomisation. Nurses reported on each patient assigned to the intervention group after each meeting. Nurses that delivered the intervention to at least 5 patients were asked to fill in a questionnaire after the study was completed (N=5).

Process evaluation

In accordance with the key process indicators that had been proposed by Linnan and Steckler,[14] we measured the following aspects of the study: recruitment, context, reach, intensity of the intervention delivered, intensity of the intervention received, and fidelity. The various time points for the data collection of data regarding the process indicators are shown in Figure 1.

Measurement level

Process indicators were measured at three levels (Table 1) and these included the hospital department in which the intervention was carried out, the nurse and the occupational physician who carried out the intervention, and the patients. Only patients assigned to the intervention group were included in this process evaluation, as patients assigned to the control group received care as usual only.

Table 1. Process indicators.

Process indicators *Definition*			**Measurement level**	**Measurement tool**
Recruitment *The proportion of hospitals, hospital departments, and nurses who participated in the study compared to the number of the hospitals, hospital departments, and nurses that were contacted by the research team*			Hospital department	Checklist
			Nurse	
Context *The contextual aspects (e.g. usual cancer care) that directly or indirectly affect the intervention implementation*			Hospital department	Checklist
Reach *The extent to which the target population participated in the intervention*			Cancer patients	Checklist
Intensity of the intervention delivered *The extent to which the intervention actually was delivered according to the intervention protocol*		Drop-out of hospital departments	Hospital department	Checklist
		Proportion of intervention that was delivered according to the intervention protocol	Hospital department	Nurses reports
		Drop-out of nurses	Nurse	Checklist
Intensity of the intervention received *The extent to which the intervention was actually received by the target population*	**Exposure**	Compliance with the intervention[1]	Patient	Questionnaire
		Drop-out of patients	Patient	Nurses report
	Satisfaction	Satisfaction with the training	Nurse	Questionnaire
		Perceived feasibility	Nurse	Questionnaire
		Perceived effectiveness	Nurse	Questionnaire
		Satisfaction with the intervention[1]	Patient	Questionnaire
Fidelity *The extent to which the intervention content was carried out according to the intervention protocol*		Protocol adherence	Nurse	Nurses reports
			Occupational physician	Checklist

1. Measured 14 months after a patient's start in the study.

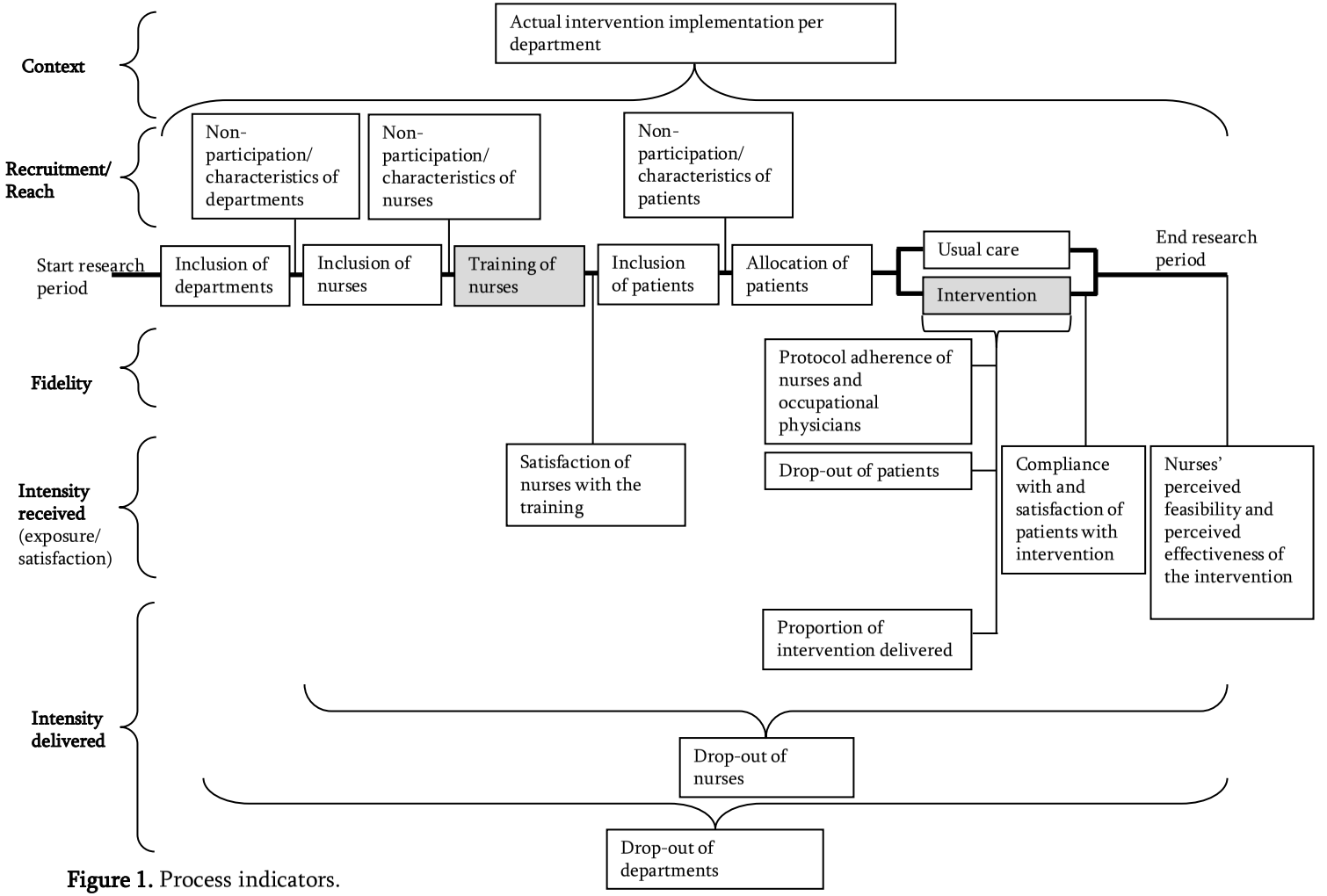

Figure 1. Process indicators.
Legend: grey denotes intervention delivery

Process indicators

Recruitment

We measured the participation (yes or no) of the hospitals, hospital departments, and nurses, as well as the reasons for non-participation. We measured recruitment as the proportion of hospitals, hospital departments, and nurses that did participate in the study compared to the total number of hospitals, hospital departments, and nurses that had been contacted by the research team.

Context

We measured intervention implementation per department to identify whether various health care contexts directly or indirectly affected intervention implementation. Two factors were considered important during the research period: the type of cancer diagnosis and the occupation of the health care professional who delivered the patient education and support at the hospital.

Reach

Reach was measured by gathering information about the participation (yes or no) of the cancer patients as well as the reasons for non-participation and was done to identify to what extent the target population participated in the study. In addition, we identified if our procedure to reach patients was feasible. Reach was expressed as the proportion of cancer patients that did participate in the study compared to all cancer patients that were found eligible to participate. Furthermore, we registered age of the cancer patients who did and did not want to participate in order to identify if our findings apply to all age groups.

Intensity of the intervention delivered

We measured the proportion of the intervention that was actually delivered compared to the intervention protocol as intensity of the intervention delivered for patients who started with the intervention. Drop-out of hospital departments and nurses was recorded. For each patient in the intervention group, intensity of the intervention delivered was measured as the number of meetings that were held, the number of meetings face-to-face, and their duration. We protocolised the delivery of 4 meetings of

at least 10 minutes each of which at least two meetings were face-to-face unless a patient reached sustainable return to work before the intervention was completed. At least one initial meeting for all patients was protocolised regardless of work resumption. In case a patient was unable to complete the intervention due to medical reasons (i.e. cancer recurrence), we considered the intervention as delivered according to the protocol.

Intensity of the intervention received (exposure)

We measured exposure to the intervention as the extent to which the intervention was received as intended by measuring whether patients complied with the advice that was provided (yes or no). For each type of advice offered, an open-ended question was directed to patients, whereby the patients could provide their source of motivation for not complying with the advice. We considered compliance with 50% of the provided advice as sufficient. In addition, patient drop-out (yes or no) and their reasons for dropping out, as well as the characteristics of the patients (e.g. educational level and income) were recorded in order to identify whether compliance applied to the entire population.

Intensity of the intervention received (satisfaction)

Satisfaction with the intervention was assessed at both the nurse and the patient level.

Nurses' satisfaction with the training: Nurses' satisfaction regarding the training they had received for delivering the intervention was measured and all questions (N=5) were open-ended questions.

Nurses' perceived feasibility of the intervention: Nurses were asked whether they thought that the intervention was applicable in practice and whether they encountered barriers when applying the intervention in practice and how to best overcome these barriers in the future. Finally, we identified the nurse satisfaction with the intervention protocol and all of these questions (N=4) were open-ended questions.

Nurses' perceived effectiveness of the intervention: Nurses were asked whether they thought the intervention was effective at enhancing the return to work of cancer patients. They were also asked which portion of the intervention they considered most

useful and which not, and for which population of cancer patients. All questions (N=14) were open-ended questions.

Patients' satisfaction with the intervention: Patient's were asked about their satisfaction with each intervention component, the timing of each intervention component, the duration of the intervention, and the competence of the nurse and the occupational physician. Furthermore, if the intervention fulfilled their expectations, the perceived burden and whether the timing of the intervention was adequate were also assessed, using 3- and 4-point Likert scales as well as open-ended questions.

Fidelity

Fidelity refers to the extent to which the intervention content was carried out according to protocol. We measured fidelity by assessing the performance of the nurses and occupational physicians based on the intervention protocol, i.e. protocol adherence. Six performance indicators were established a *priori* based on the intervention protocol. An independent researcher assessed protocol adherence by scoring each indicator as either sufficient or insufficient, or not applicable. All performance indicators were weighted equally, yielding a maximal sum score of 6.

The first two performance indicators assessed nurses' performance and were assessed based on the reports that the nurses completed after each meeting with a patient. The first performance indicator addressed whether the quality of the meetings between the nurse and the patient was adequate. The second performance indicator addressed whether the nurse delivered sufficient information to the patient. The third and fourth performance indicators assessed whether the medical information was sent to the patient's occupational physician (yes or no) and a score was assigned if this had taken place. The fifth and sixth performance indicators assessed the performance of the occupational physicians' performance on the basis of the nurses' reports. The fifth performance indicator assessed whether the occupational physician organised a meeting with the patient, patient's supervisor, and him/herself, and the sixth performance indicator assessed whether a return-to-work plan was drawn-up in collaboration with the patient, patient's supervisor, and the occupational physician.

Statistical analysis

All quantitative data were analysed with descriptive statics using PASW version 18. Differences between patients who participated and those who did not, regarding age were analysed with Student's t-test. Differences regarding educational level and income between patients who demonstrated 50% compliance with the provided advices and those who demonstrated compliance below 50% were analysed with the Mann-Whitney U test for educational level and Student's t-test for income. A p-value of ≤ 0.5 was considered statistically significant. The open-ended questions were qualitatively analysed by the first author [ST] and were checked by another independent researcher. Themes were derived from the open-ended questions and were labelled.

Results

The recruitment of hospitals and hospital departments initially occurred between September 2008 and December 2009 but the recruitment period was extended by 4 months to include as many cancer patients as possible. The onset of the study per department occurred between May 2009 (department A) and November 2010 (department H) and ended at the end of December 2010 for all hospital departments (Figure 2).

Of the 133 patients included in the study, 65 patients were assigned to the intervention group. The baseline characteristics of these 65 patients assigned to the intervention group are presented in Table 2. Patients were on average 47.5 ± 8.2 years old, and all patients but one were female. Sixty-four percent of the patients were diagnosed with a breast carcinoma, 31% were diagnosed with gynaecological forms of cancer and 5% of the patients were diagnosed with other forms of cancer.

Of the 65 patients assigned to the intervention group, 58 (89%) patients received at least one consultation with the nurse to receive patient education and support about return to work, of 54 (100%) patients at least one letter was sent to their occupational physician, and the meeting between the supervisor and the occupational physician to draw-up a return-to-work plan occurred in 5 (10%) cases. Reasons for not receiving the patient education delivered by the nurse included logistical issues related to their treatment in another hospital department (N=6) or a lack of interest (N=1) (Figure 2).

Table 2. Baseline characteristics of patients assigned to the intervention group.

Patient characteristic*		Intervention group (N=65)
Socio-demographic characteristics		
Age *(years)* ¥		47.5 ± 8.2
Gender (*% female)*		99%
Marital status *(% married or living with partner)*		79%
Breadwinner position *(% sole or shared)*		65%
Education level (*%)*	Low	11%
	Intermediate	59%
	High	30%
Clinical characteristics		
Diagnosis (*%)*	Mamma carcinoma	64%
	Cervix carcinoma	23%
	Ovarian carcinoma	5%
	Vulva carcinoma	3%
	Other	5%
Days since diagnosis		48.1 ± 35.6
Work-related characteristics		
Type of occupation (*%)*	Public health	38%
	Administrative	9%
	Sales	5%
	Other	48%
Type of work *(% mainly physically demanding work)*		32%
Time since sick listed *(days)*		26.5 ± 35.1
Number of working hours according to contract *(1-40)*		26.4 ± 8.9
Importance of work (VAS) *(0-100)***		58.7 ± 23.1
Shift work *(% shift work)*		26%
Type of contract (*%)*	Permanent	89%
	Temporary	11%
Overall work ability (WAI) *(0-10)***		5.3 ± 3.0
Work ability physical work load (WAI) *(0-5)***		3.5 ± 1.1
Work ability mental work load (WAI) *(0-5)***		3.0 ± 1.1
Health-related characteristics		
Quality of life (VAS) *(0-100)***		59.7 ± 21.7
General fatigue (MFI) *(0-20)***		12.4 ± 4.9
Depression (CES-D) *(0-60)***		14.1 ± 9.3
Self-efficacy (ALCOS) *(0-80)***		66.5 ± 8.6

* Continuous variables: mean ± sd; nominal and ordinal variables percentages.

¥ Age at the time of randomisation.

**Higher score means a higher level of importance of work, work ability, quality of life, fatigue, feelings of depression, and self-efficacy.

The response rate of the patients to the questionnaire was 75% (N=49). Reasons for not responding included cancer recurrence (N=2), study decline (N=3), or were unknown (N=11), two patients died before the intervention was completed. The nurses reports for 6 (10%) patients who received at least one nurse consultation were lost and

the nurses' response rate to the questionnaire was 80%. The research team collected reach data from three hospital departments (A, C, and E) only. The other hospital departments were not able to provide data on reach due to time constraints.
Of the 8 hospital departments that participated in the study, 2 hospital departments (G and H) did not treat patients who were assigned to the intervention group (Figure 2). Therefore, the process indicators context, intensity of the intervention received, intensity of the intervention delivered, and fidelity were only assessed in 6 hospital departments (A through F).

Recruitment

Of the 11 hospitals that were contacted by the research team, 5 hospitals did not participate in the study (Figure 2). Reasons for non-participation included, uncertainty about the benefits of providing patient education and support regarding return to work as part of psycho-oncological care (N=3), a large number of other studies conducted (N=1), and a reluctance to asks cancer patients to participate in a study about return to work soon after their cancer diagnosis (N=1). There were 6 hospitals that decided to participate, and 7 of the 15 hospital departments that were contacted by the research team decided not to participate. Reasons for hospital department non-participation included the existence of a large number of other ongoing studies (N=2), nurses being unable to deliver patient education and support about return to work due to time constraints or limited psycho-oncological care (N=2), an inability to include cancer patients prior to their initial cancer treatment (N=2), and the uncertainty about the benefits of providing patient education and support about return to work as part of psycho-oncological care (N=1). In sum, 8 departments from 6 hospitals participated in the study.

At the onset of the study, 6 of the 8 hospital departments employed only one person who could deliver psycho-oncological care as well as the intervention, although each of these individuals were willing to deliver the intervention. In the hospital departments where more than one person delivered psycho-oncological care, the supervisor of each department decided which persons would be able to deliver the intervention based on their years of experience. All nurses, who were eligible to deliver the intervention, were willing to participate.

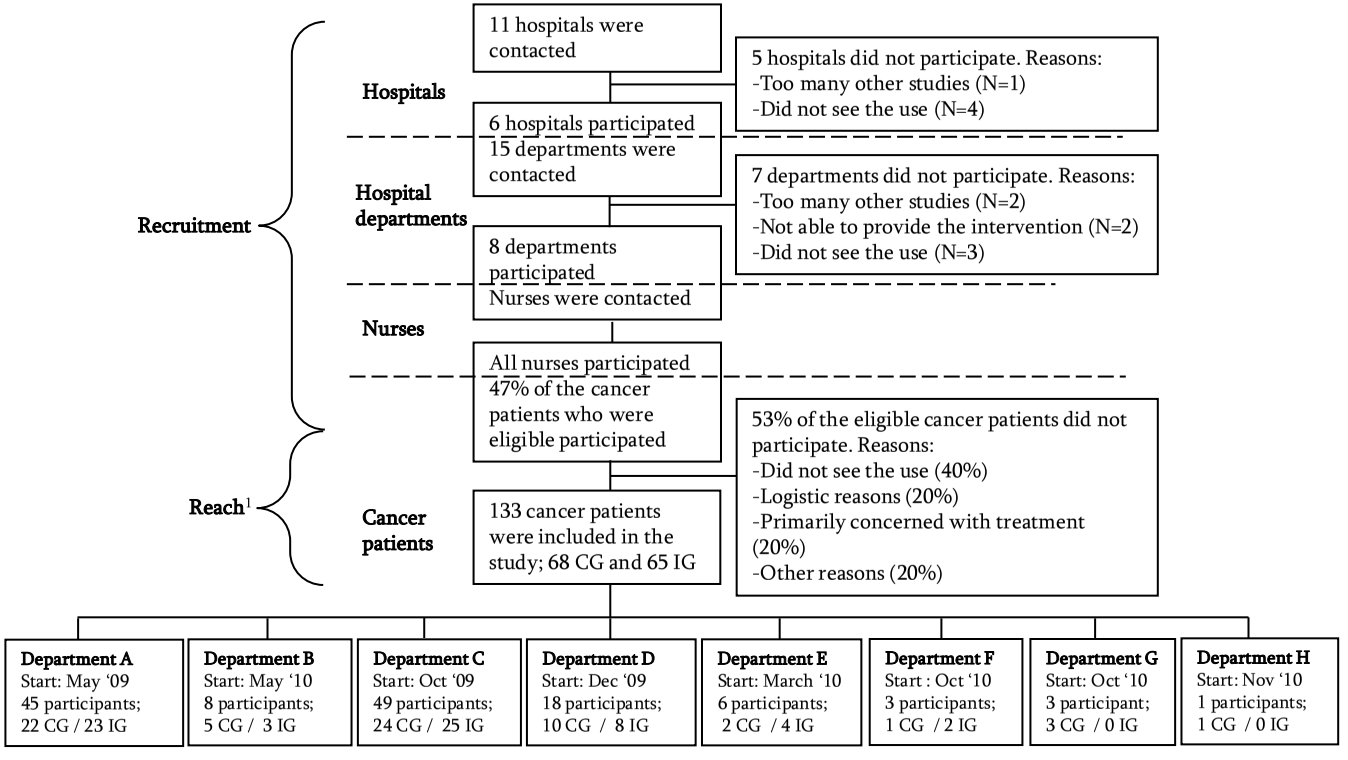

Figure 2. Recruitment and reach.
Abbreviations: CG: Control group; IG: intervention group
1. Based on three departments (A, C, E)

Context

Five hospital departments (83%) treated breast cancer patients and one department (17%) treated gynaecological cancer patients. The breast-care nurses delivered the intervention in two hospital departments (34%), an oncology nurse in one department (17%), a nurse practitioner in one department (17%), and a medical social worker in another (17%).

Reach

Based on the findings from three hospital departments (A, C, and E), an average of 47% of the eligible cancer patients participated in the study (Figure 2). Reasons for cancer patients not to participate included, not seeing a use of the intervention (40%), logistical reasons (20%), having other things on their mind (20%), or other reasons (20%). Age of the patients who did and did not participate did not differ statistically ($p = 0.2$).

Intensity of the intervention delivered

None of the 6 hospital departments dropped out of the study, although one of the nurses dropped out of the study due to a career change. This nurse's tasks related to delivering the intervention were completed by one of the other nurses, and as such, the intensity of the intervention delivered was not affected. Fifty-seven percent of the patients had 4 meetings, 66% three meetings, 76% two meetings, and 88% had at least one meeting (Table 3). In addition to these meetings, 15% of the patients had an additional meeting with their nurse to receive extra support for their return to work.

Eighty-one percent of the patients had the first meeting face-to-face, 63% had the second meeting face-to-face, 38% had the third meeting face-to-face, and 19% had the fourth meeting face-to-face (Table 3). The duration of the meetings between the nurse and the patient was on average 21 minutes and ranged between 7 and 60 minutes (Table 3). For 88% of the patients, the meetings were delivered in accordance with the intervention protocol. For 63% of the patients, the face-to-face meetings were delivered in accordance with the intervention protocol, and the duration of the meetings was in accordance with the study protocol for 97% of the patients.

Table 3. Intensity of the intervention delivered - proportion of the intervention that was delivered.

Department *Patients assigned to the intervention group of which we had nurses report*			**A - F** *(N=59)*	**According to the intervention protocol** *(% according to the protocol)*
Intensity of the intervention delivered	Number of meetings *N (%)*	4 meetings	34 (57%)	88%
		3 meetings	39 (66%)	
		2 meetings	39 (76%)	
		1 meeting	52 (88%)	
	Type of contact *N (%) meetings face-to-face*	Meeting 1	35 (81%)	63%
		Meeting 2	22 (63%)	
		Meeting 3	12 (38%)	
		Meeting 4	5 (19%)	
	Duration of meetings in minutes *Median (range)*	Meeting 1	20 (10-60)	97%
		Meeting 2	20 (9-60)	
		Meeting 3	25 (7-45)	
		Meeting 4	18 (10-60)	

Intensity of the intervention received (exposure)

Patient compliance with the advice to keep in contact with employer (79%), to keep in contact with co-workers (79%), and the advice to start with return to work before full recovery (75%) were complied with the most (Table 4). The advice to evaluate the return-to-work plan with supervisor (52%) and the advice to draw up a second return-to-work plan were complied with the least (33%).

From the open-ended questions of the patients we inferred that non-compliance with the advice to schedule a meeting with the occupational physician, to keep in contact with employer, and to keep in contact with co-workers was caused by either the fact that it was common practice (N=10) or because a patient did not have an employer anymore (N=1). In addition, the open-ended questions revealed that patients' did not comply with the advice to make a return-to-work plan for various reasons, including did not have an employer anymore (N=1), already made a return-to-work plan (N=1), or still have to make a return-to-work plan (N=1). Not complying with the advice to draw up a second return-to-work plan was caused by not seeing the use of doing it (N=3).

The education and income level of patients who demonstrated at least 50% compliance versus those who demonstrated less than 50% compliance did not differ

statistically (p = 0.3-0.8). All but one nurse received training for how to deliver the intervention and this nurse did not receive the training due to a time constraint.

Table 4. Intensity of the intervention received (exposure).

Department *Patients assigned to the intervention group who filled in the questionnaire*			**A - F** *(N=24)*
Intensity of the intervention received	Percentage advices acted upon *N (%)*	Make appointment with OP	12 (63%)
		Keep in contact with employer	19 (79%)
		Keep in contact with co-workers	19 (79%)
		Draw up return-to-work plan with supervisor and OP	16 (70%)
		Start to return to work before full recovery but with limited number of hours	18 (75%)
		Make sure that the return-to-work plan encompasses the data and number of hours of start, which days of the week will be worked, the timing of the expansion of hours, the tasks and number of hours of this expansion, and the proposed date of full return to work	14 (58%)
		Evaluate return-to-work plan with supervisor every two weeks	12 (52%)
		Draw up a second return-to-work plan that may be used if the first plan fails	8 (33%)

Abbreviations: OP = occupational physician.

Intensity of the intervention received (satisfaction)

Nurses scored the training they received with a mean score of 8 on a scale from 0 (very poor) to 10 (very good). The open-ended question responses indicated that some nurses (N=3) would have preferred to receive the training material before the start of the training and that some nurses thought the period between the training and the start of the intervention was too long (N=2).

All nurses (N=4) were satisfied with the intervention protocol and stated that it provided a clear overview of the content of the intervention. In general, nurses (N=4) believed that the intervention was feasible to carry out in practice and that the burden associated with the delivery of the intervention was manageable. Nevertheless, the following barriers for applying the intervention to practice were mentioned: 1) delivering the intervention for patients who did not receive usual psycho-oncological care, 2) delivering the intervention by telephone, and 3) integrating the intervention into usual care. For the first barrier, nurses mentioned (N=3) that the intervention was

not as feasible to deliver to patients who did not receive usual psycho-oncological care. This situation may have occurred for patients, who did not receive follow-up care at the hospital, but for the delivery of the intervention in these cases, an extra consultation was planned or meetings were held by telephone. Second, delivering the intervention by telephone was perceived as less feasible because it was time consuming to reach a patient by telephone and it was difficult to assess the patient's situation and gain the patient's trust over the telephone. Third, nurses (N=4) stated that the intervention should have been integrated into usual care according to the following adaptations: 1) meetings needed to be planned at the right time and for the proper length of time, 2) all meetings should have been face-to-face, and 3) to be able to deliver all meetings face-to-face it may mean that the intervention should be handed on to another health care professional who would be able to conduct longer follow-up consultations.

Although all nurses (N=4) believed that most patients benefited from the intervention, some nurses expected (N=2) the intervention to be only moderately effective because they felt that their advice and support may not have uniquely impacted the return to work of cancer patients, as these patients typically arrange their return to work at the workplace with their supervisor and occupational physician. However, the nurses (N=4) did consider the intervention to be useful for all cancer patients of working age.

Patient satisfaction regarding the various intervention components and their timing is shown in Table 5. Of all patients, 78% found the timing of their inclusion in the study appropriate, 80% described the duration of the intervention as adequate, and 98% of the patients found the burden related to intervention participation small or acceptable (98%). The content of the meetings with the nurses were on average perceived by 95% of the patients as useful or somewhat useful (range 88%-100%). Furthermore, on average, 84% of the patients perceived the informational leaflet and the ten steps of advice as useful or somewhat useful (range 63% - 100%). The meeting with the supervisor and the occupational physician was perceived by 88% of the patients as useful or somewhat useful. Furthermore, an average of 70% of patients perceived the timing of the various intervention components to be appropriate (range 63% - 73%), whereas the remaining patients indicated that they would have preferred these components to be delivered later.

Table 5. Intensity of the intervention received (satisfaction).

Department *Patients assigned to the intervention group who filled in the questionnaire and who reported receiving intervention component*				**A - F** *(N=45)*
Intervention	Timing being asked to participate *N (%)*		Right time	35 (78%)
			Too soon	9 (20%)
			Too late	1 (2%)
	Duration of the intervention *N (%)*		Right time	31 (80%)
			Too short	7 (18%)
			Too long	1 (3%)
	Burden to participate in the intervention *(N (%) small or acceptable)*			40 (98%)
Meetings with nurse *(N (%) useful or somewhat useful)*	Competence of the nurse *N (%) good or acceptable*			39 (93%)
	Appreciated meetings at the hospital *(N (%) yes or somewhat)*			38 (93%)
	Discuss importance of work			36 (95%)
	Discuss working trough cancer treatment			31 (97%)
	Discuss method to disclose cancer diagnosis to supervisor/colleagues			23 (92%)
	Discuss return to work			28 (88%)
	Discuss return-to-work plan			18 (100%)
	Discuss work situation at follow-up			15 (100%)
Information *(N (%) useful or somewhat useful)*	Information leaflet			37 (100%)
	Ten steps of advice	Make appointment with OP		15 (63%)
		Keep in contact with employer		18 (75%)
		Keep in contact with co-workers		18 (75%)
		Draw up return-to-work plan with supervisor and OP		22 (92%)
		Start to return to work before full recovery but with limited number of hours		21 (88%)
		Include detailed information in return-to-work plan		22 (96%)
		Provides information on the prognosis of return to work		22 (92%)
		Evaluate return-to-work plan with supervisor every two weeks		22 (92%)
		Draw up a second return-to-work plan that may be used if the first plan fails		16 (67%)
		Provides an example of a return-to-work plan		21 (88%)
Meeting with OP and supervisor	Competence of the OP *(N (%) good or acceptable)*			39 (81%)
	Competence of the supervisor *(N (%) good or acceptable)*			39 (83%)
	Useful meeting OP and supervisors *(N (%)agree or somewhat agree)*			16 (88%)
	Supervisor collaborated *(N (%) yes or somewhat)*			14 (93%)
	OP collaborated *(N (%) yes or somewhat)*			12 (86%)
	Agree with return-to-work plan *(N (%) yes or somewhat)*			12 (92%)
	Able to carry out return-to-work plan *(N (%) yes or somewhat)*			11 (85%)
Timing of the intervention components	Information leaflet *(N (%) right time)*			25 (71%)
	Ten steps of advice *(N (%) right time)*			15 (63%)
	Discus return to work with nurse *(N (%) right time)*			22 (71%)
	Meeting OP and supervisor *(N (%) right time)*			11 (73%)

Abbreviations: OP = occupational physician

Fidelity

The median sum score of the performance indicators that met the *a priori* formulated criteria was 4 and ranged between 0 and 6. The performance indicator for sending medical information to the occupational physician (100%), the indicator for satisfactory quality of the meetings between the nurse and the patient (88%), and the indicator for the delivery of sufficient information to the patients (83%) were met in most cases (Table 6). The performance indicator for the meeting between the patient, supervisor, and occupational physician to draw-up a return-to-work plan had a frequency of 10%. The reasons for why the nurses did not adhere to the protocol included its perceived usefulness or the time constraints.

Table 6. Fidelity – protocol adherence.

Department		**A - F**
Fidelity	Performance indicator *(% positive score)*	
Patients assigned to the intervention group of which we received nurses' report (N=56)	Satisfactory quality of meetings between nurse and patient	44 (88%)*
	Nurse provided sufficient information to patient	43 (83%)*
Patients assigned to the intervention group who gave consent to send medical information to OP (N=54)	Nurse sent information to OP	14 (26%)
	Medical information from treating physician to OP	54 (100%)
Patients assigned to the intervention group of which we received nurse's report and who gave consent to send medical information to OP (N=48)	Meeting between patient, supervisor, and OP	5 (10%)
	Drawing up return-to-work plan with patient, supervisor, and OP	5 (10%)

*for three patients the performance indicators were not applicable due to cancer recurrence. Abbreviations: OP = occupational physician.

Discussion

The objective of this study was to perform a process evaluation of a hospital-based work support intervention. A total of 47% of all eligible patients participated (reach) and nurses delivered patient education and support according to the protocol in 85% of the cases (fidelity). In 100% of the cases, at least one letter was sent to the occupational physician (fidelity) and in 10% of the cases, the meeting with the patient, the

occupational physician, and the supervisor took place (fidelity). We found that a hospital-based work support intervention was easily accepted into usual psycho-oncological care but that it was difficult to involve the occupational physician. Overall, patients were highly satisfied and nurses found the intervention to be feasible.

Strengths and limitations

The strength of our study was the thorough analysis of the process indicators at the department, nurse, and patient level, which was based on a previously established framework for process evaluations.[14]

One limitation of our study was that we did not include occupational physicians in the data collection process. However, the key aspects of the hospital-based intervention were both the patient education and support delivered by the nurse at the hospital, and communication with the patient's occupational physician concerning the patient's diagnosis and treatment. Because earlier research had shown that occupational physicians appreciated receiving this type of information from the hospital[15, 16] and because half of the occupational physicians in this previous study indicated that the information had influenced their rehabilitation efforts,[15] we thought that assessing these aspects in the current study was not necessary.

Another limitation of our study was the method that was used to measure fidelity. We measured fidelity by scoring performance indicators based on the self-reports of the nurses and we do not know how valid these self-reports are in comparison to independent observations. Thus, bias could have been introduced by the recording of socially desirable answers in the reports. However, independent observation may have introduced another form of bias as well, as nurses may have performed differently if they knew they were being observed. Another limitation of the study was the potential for recall bias, as the participants' compliance and satisfaction with the intervention were assessed at the end of the follow-up period. However, we could not have evaluated these aspects directly after the consultation, because this may have influenced the effect of the intervention in cases in which the patient did not receive the information during the consultation but rather received the information as during the response to the questionnaire. Finally, selection bias may also have occurred, as not all patients responded to the questionnaire. We do not know whether the reasons for not

completing the questionnaire were related to patient satisfaction or compliance with the intervention. Therefore, it is possible, that these results represent either an overestimation or underestimation.

Comparisons with the literature

Nieuwenhuijsen et al[15] studied the feasibility of an intervention for cancer patients consisting of enhanced provider communication and patient education. In comparison to this study, our study demonstrated a similar level of patient satisfaction with the ten steps of advice, whereas we found a bit lower percentage of patient compliance with the advice provided. We assume that this discrepancy was caused because some of theses advices had become common practice.

Almost 50% of the eligible patients participated in our study, which was considered an adequate result because it should be taken into account that participants had been diagnosed with cancer only a few weeks before the start of the study and therefore experienced high level of insecurity. Similar response rates were reported for the inclusion of recently diagnosed cancer patients in a life-style intervention trial.[17] For other types of patients and for other types of interventions, higher response rates have been reported. One Dutch study found a higher reach for patients with low back pain in a trial aimed at preventing work disability.[18] However, this response rate was likely overestimated because it was not based on all of the eligible patients who were invited to participate. Based on our value of reach and the opinions of patients, we can infer that work is a relevant topic for cancer patients also already early in the course of their disease. We also assume that under conditions of regular care rather than trial conditions; reach would further improve, as patients in these conditions do not have to decide about all the extras of a trial such as meeting with a researcher for informed consent and filling in questionnaires.

Other comparable trials for work support interventions among cancer and other patients have also reported the results of process evaluations.[19-21] These evaluations measured the adherence of the occupational physicians to the intervention protocol. Verbeek et al[19] reported an adherence rate that varied from 3% to 78% regarding the provision of advice to cancer patients about their return to work. Nieuwenhuijsen *et al*[21] reported that only 10% of the patients received optimal care when their absence from

work was a result of mental health problems. Rebergen et al[20] reported that, on average, the adherence of physicians was 50%, with a maximum adherence score of 20. For our intervention, the average adherence of the nurses was 85%, and this result was very good in comparison to these studies. Although these previous studies reported on the protocol adherence of the occupational physicians and we reported on protocol adherence of the nurses, both of these groups were the health care providers who delivered the work support intervention, and the results are therefore comparable.

Interpretations of findings

Our study showed that the various health care contexts (e.g. type of hospital department or type of health care professional) did not influence the intervention implementation. This finding indicates that our intervention could be successfully adapted to various health care contexts, provided that some form of psycho-oncological care is available.

The intensity of the present intervention delivered was high and was also concurrent with what we protocolised. Few drop-outs were noted, and nurses were able to extend their consultation to deliver the intervention. In contrast, the number of patients who did not start with the intervention was higher than anticipated, which was mainly caused by the fact that those patients did not receive usual psycho-oncological care from the nurses who delivered the intervention. For these patients, nurses encountered problems and either and extra consultation was required or the intervention had to be delivered completely over the telephone. Nurses considered this form of delivery to be less effective and more difficult. We believe that this situation would be remediated if the intervention could be implemented over a wider scale, which would provide usual psycho-oncological care to all patients and better integrate the intervention with patient care.

Patients and nurses were in general very satisfied with the various intervention components and found that the timing of the intervention components was appropriate. However, encouraging the occupational physicians to organise a meeting between the patient, the supervisor and him/herself in order to draw-up a return-to-work plan proved difficult, which was likely the result of not actively involving the occupational physician into the hospital-based work support intervention.

As expected, patient compliance with each type of advice provided was high. Only patients with a temporary employment contract that could not be extended were unable to comply with the delivered advices, as they no longer had an employer/occupational physician.

Implications for further research and practice

In terms of clinical practice, this study demonstrated that psycho-oncological care can address the work concerns of cancer patients at an early treatment phase as well as during follow-up, according to the reported satisfaction of patients and the nurses who provided the intervention. However, for further improvement, the nurses suggested the following adaptations: 1) meetings should be planned at the right time for the proper length of time, 2) meetings should be conducted face-to-face, and 3) to be able to deliver all meetings face-to-face it may mean that the intervention should be hand on to another health care professional who have longer follow-up consultations in usual cancer care.

Our study was mainly restricted to breast and gynaecological cancer patients. However, the nurses who delivered the intervention indicated that all cancer patients of working age would likely benefit from this type of intervention. Thus, evaluation studies of patients with other types of cancer are needed.

It proved difficult to involve the occupational physician and the supervisor in the intervention. As these individuals are relevant to return to work of cancer patients,[8 22] further research is required to increase their involvement. Due to the relatively low prevalence of cancer at the workplace and because most contacts during early phases of treatment are with health care professionals at the hospital, we believe that it would be difficult to organise a workplace-based intervention. However, methods to involve the workplace in the intervention should be extended, for example involving the occupational physician and the supervisor may be achieved by sending coded emails instead of letters to decrease the barrier to reach each other. However, the patient's privacy should be guaranteed at all times.

Because patients with a temporary employment contract could not comply with the advices provided, the intervention should be adapted for patients with this type of employment by assessing the specific needs and concerns of this population. This

approach is especially important, as patients with a temporary employment contract have a higher risk of becoming unemployed in comparison to patients with a permanent employment contract[23 24] and because the labour market is changing towards a higher frequency of temporary employment contracts.[25]

Acknowledgement

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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).

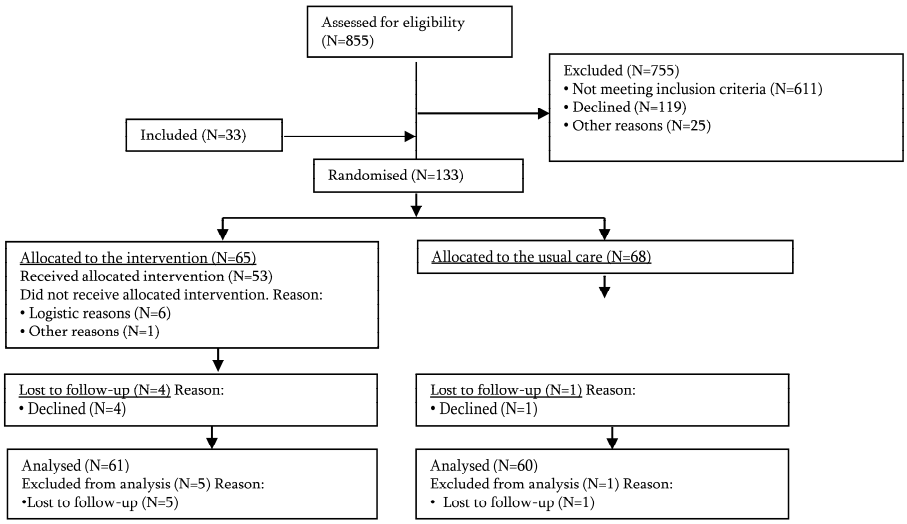

Figure 1. Patient flow.

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).

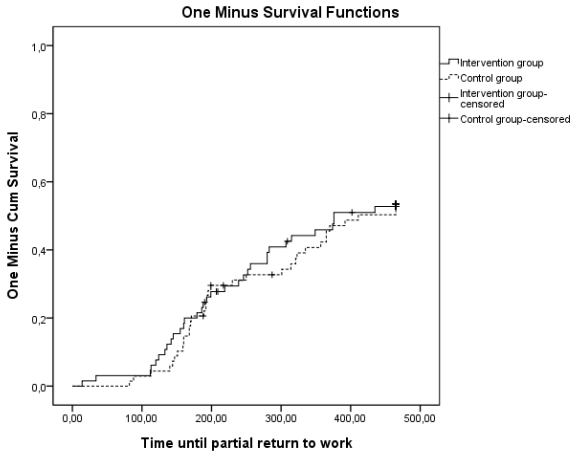

Figure 2a. Kaplan-Meier survival analyses for time until partial return to work.

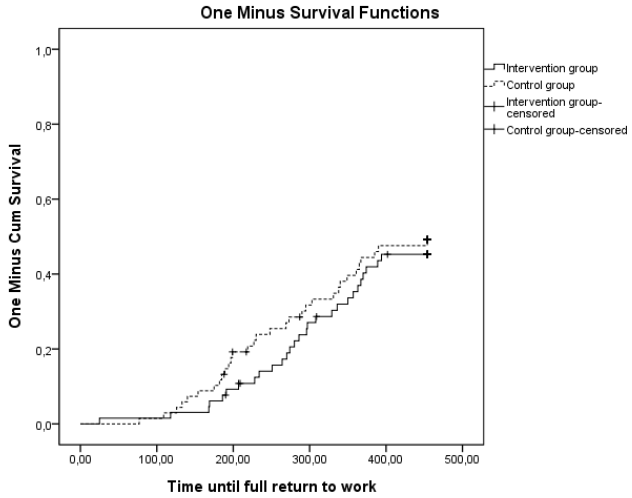

Figure 2b. Kaplan-Meier survival analyses for time until full return to work.

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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Chapter 9.

General discussion

The main objective of this thesis is to gain more knowledge on how to reduce the adverse work outcomes of cancer patients. The following research questions are put forward:

1. What are important aspects in the design of a hospital-based work support intervention for cancer patients with the aim of enhancing the return to work and quality of life?
2. What are the measurement properties of the Dutch translation of the Work Limitation Questionnaire (WLQ) among cancer patients?
3. How is the process of a hospital-based work support intervention for cancer patients evaluated?
4. What is the effectiveness of a hospital-based work support intervention compared to usual care for cancer patients on return to work and quality of life?

Main findings

Design of a hospital-based work support intervention for cancer patients

We developed an intervention for cancer patients with the primary aim of enhancing the return to work and quality of life (**Chapter 5**). Important aspects of the design of this type of intervention include the following: 1) an early hospital-based intervention that is integrated into the usual psycho-oncological care (**Chapter 2**), 2) addressing misconceptions about cancer and work (**Chapter 2**), 3) involvement of the occupational physician and the supervisor (**Chapter 3**), and 4) informing the patient's occupational physician about patient's diagnosis and cancer treatment (**Chapter 5**).

Psychometric properties of the Work Limitation Questionnaire (WLQ) among cancer survivors

To understand the full impact of a cancer diagnosis on adverse work outcomes, it is also important to understand the work functioning of cancer survivors. A commonly used measure of the impairment of work functioning due to ill health is the Work Limitation Questionnaire (WLQ), which has been translated into Dutch. However, the measurement properties of the Dutch translation of the WLQ for use in cancer survivors are currently unknown. To determine the measurement properties of the WLQ for use with cancer patients, we conducted a cohort study with three

WLQ for use with cancer patients, we conducted a cohort study with three measurement points (**Chapter 4**). We found sufficient reproducibility at the group level but not at the individual level as the minimal important change (4.0) exceeded the smallest detectable change at the group level (3.1) but not at the individual level (18.0). There was no indication of systematic bias or proportional bias. The internal consistency and construct validity for the WLQ and its subscales were sufficient or slightly less than sufficient. There was a floor effect for one subscale but there were no ceiling effects. Responsiveness was sufficient with an area under the curve of a Receiver Operating Characteristic (ROC) of 0.68. The WLQ is reproducible, valid, and responsive for the use at group level, but it is not sufficiently reproducible for clinical use among cancer survivors.

Process evaluation of a hospital-based work support intervention for cancer patients

How is the process of a hospital-based work support intervention evaluated? To answer this question, we conducted a case study (**Chapter 6**) and a process evaluation (**Chapter 7**). We conducted a case study to describe how the return-to-work process progressed in a cancer patient and how a hospital-based work support intervention supported this process (**Chapter 6)**. Furthermore, we performed a process evaluation at the level of the hospital department, nurse, and patient (**Chapter 7**). The following process evaluation outcomes were assessed: recruitment, context, reach, intensity of the intervention delivered, intensity of the intervention received, and fidelity.

The results of the case study revealed that the support delivered by the nurse helped the patient to resume work gradually and the sending of information from the treating physician and the nurse improved communication with the occupational physician. This resulted in the patient being able to achieve lasting return to work (**Chapter 6**). The results of the process evaluation showed that 47% of all eligible patients participated in the study. Nurses' meetings with the patients were conducted according to the protocol in 85% of the cases. In 100% of the cases, at least one letter was sent to the occupational physician, and in 10% of the cases a meeting took place between the patient, the occupational physician, and the supervisor. Our method, which involved asking occupational physicians to organise a meeting between the patient, the supervisor, and themselves to draw up a return to work plan, proved

difficult. Patients and nurses found the intervention in general very useful (**Chapter 7**). Nurses made the following suggestions to optimise the intervention: 1) meetings must be planned at the right time and should be allotted sufficient time, 2) meetings should be conducted face-to-face, and 3) to be able to deliver all meetings face-to-face it may mean that the intervention should be hand on to another health care professional who has longer follow-up consultations in usual cancer care.

Based on the case study and the process evaluation, we conclude that the intervention yields high acceptability to implement in usual psycho-oncological care but that it proved difficult to involve the occupational physician. Patients were highly satisfied and nurses found the intervention useful and feasible.

Effectiveness of an innovative hospital-based work support intervention for cancer patients

We studied the effectiveness of an innovative hospital-based work support intervention in a multi-centre randomised controlled trial with a follow-up of 12 months (**Chapter 8**). Cancer patients who were treated with curative intent and who had paid work participated. Patients were randomly assigned to the intervention group (N=65) or to the control group (N=68). Outcomes were the rate of and time to return to work, quality of life, work ability, work functioning, and costs (i.e. costs to deliver the intervention and lost productivity costs). The relative risk of the intervention versus usual care of the return to work rate was calculated at follow-up. The time until return to work was analysed with a Kaplan Meijer survival analysis and Cox regression analysis. Secondary outcomes were analysed with multi-level analysis.

The rate of return to full or partial work at the 12 month follow-up was 79% in the intervention group versus 79% in the control group; and 86% and 83% respectively when excluding patients who died within the follow-up period and with a life expectancy of months. The relative risk of returning to work (full or partial) in the intervention group versus the control group was 1.03 (95% confidence interval 0.84 – 1.2). The median time from initial sick leave to partial return to work was 194 days (range 14-435) in the intervention group and 192 days (range 82-465) in the control group ($p = 0.90$). The hazard ratio of partial return to work was 1.03 (95% confidence interval of 0.64 – 1.6) of the intervention group versus the control group. Quality of life

improved statistically significant over time (p ranged from 0.014 to≤ 0.001) but did not differ statistically significant between groups (p ranged from 0.15 to 0.99). Work ability and work functioning improved over time but did not differ statistically between groups. The cost of delivering the intervention was €119. Lost productivity costs did not differ between groups (€41.792 versus €40.147).

Return-to-work rates were generally high. We found non-statistically significant differences between groups, but there is still considerable uncertainty about possible effects of the intervention. Further research is needed to determine which aspects of the intervention are useful and which elements need improvement.

The context: cancer survivorship care, occupational health care, and the social security system

The approach of addressing adverse work outcomes of cancer patients by means of an early hospital-based work support intervention integrated into usual psycho-oncological care is innovative. Especially at the start of this thesis in January 2008, when few initiatives were focused primarily on ameliorating the adverse work outcomes experienced by cancer patients (Chapter 2).

From a historical perspective, this intervention was timely and innovative. It is only recently that improved cancer survival rates created a need for a focus on cancer patients' return to work. Moreover, in the past few decades, the social security system in the Netherlands has focused more on workers' disability than their ability; thus it was relatively easy to obtain a disability pension, especially in the case of a life-threatening disease such as cancer.[1 2] For this reason, cancer patients were generally less encouraged to consider returning to work. Finally, curative care and occupational health care are formally separated in the Netherlands;[2] thus treating physicians are not accustomed to addressing the return-to-work concerns of their patients. All these reasons contributed to a perspective of cancer care that was more focused on supporting patients in getting a disability pension than on helping them to return to work. The return to work of cancer patients was usually not addressed in the workplace either, because the perspective extended to the workplace where some supervisors and/or occupational physicians considered it inappropriate even to address the possibility of a return to work. Furthermore, the preceding Dutch disability Act discouraged employers

from addressing cancer patients' return to work, as a sick-listed employee could be fired after one year of sick-leave.[2]

The concept that work is important for cancer patients has gained more recognition in the time between the development of the intervention and the end of this study. For instance, the Dutch Federation of Cancer patient organisation (NFK) has made efforts to help cancer patients with their work concerns.[3-5] Their focus on work broadened from supporting patients with an adequate assessment of a cancer patient's disability pension to empowering cancer patients to return to work.[6 7] This shift in focus can also be observed in the recently published guideline for occupational physicians on cancer and work[8] and in the inclusion of work issues in a recently published guideline for cancer rehabilitation.[9]

It is interesting to consider the origins of this change. The main cause is the shift in the focus of the Dutch government from disability assessment to getting workers with disabilities back to work. Numerous legislations have been made and implemented to create incentives for employers and employees to bring employees on sick-leave back to work.[2] For instance, the requirements for getting a disability benefit have become stricter. Furthermore, the support of workers on sick-leave have become mandatory, and employers are now legally required to compensate wage loss during the first two years of sick-leave.[2] In combination with the increased rates of cancer survival, this change led to an increased interest in the work-related concerns of cancer patients. Changes in the societal and medical perceptions of what constitutes fitness for work can be observed; it is now often accepted that one can resume work gradually before full recovery is achieved,[10] that returning to work may contribute to recovery,[1 10] and that work is a relevant factor during treatment. In other words, the benefits of work for persons with a chronic illness are more often recognised.[10] Furthermore, persons with a chronic illness who remain at or return to work will become more valuable in an ageing society.

In the occupational health context, it can be observed that the labour market in European countries is shifting from permanent employment contracts to temporary employment contracts and to more precarious work in general.[11 12] In addition, the proportion of self-employed persons, who not always have access to occupational health care, is also increasing.[11] These changes are important, as these workers may be at

higher risk of experiencing adverse work outcomes.[13 14] Because of the global economic recession, many companies face financial difficulties and will cut costs, leading to termination of employment contracts. These cuts will most likely affect workers with cancer-related sick-leave more adversely than in better economic times.

In summary, the studies conducted in this thesis were performed during a time period in which the perspective of the importance of cancer patients' return to work rapidly changed. The subsequent sections will elaborate the extent to which this changing perspective may have influenced the findings of the studies in this thesis.

Methodological considerations

One adverse consequence of the intervention being innovative was that some hospital departments were not (yet) ready for this approach and chose not to participate in the intervention study (Chapter 7). For this reason, we were not able to include as many patients in our study as would have been required according to the pre-determined power analysis (Chapter 5). It was therefore not possible to test our findings with sufficient power leading to more uncertainty in the results. Return-to-work rates were generally high. We found similar return to work outcomes for both groups, but there is still considerable uncertainty about possible effects (Chapter 8). There are several possible explanations for the lack of statistically significance in these findings, which can be found in the content of the intervention and in the study design.

Intervention content

The basic assumption behind the intervention was that return to work would increase as patients' self-assessed work ability improved. This change would be effected by patient education and support addressing misconceptions about cancer and work. We found that self-assessed work ability increased significantly over time but did not differ significantly between groups. It could be that a more intense intervention is required to address misconceptions. This mechanism is supported by the experience of some nurses who did not feel convinced of their competence to deliver the return-to-work advices (Chapter 7). It may be that our half-day training course was too short to enable nurses to gain the knowledge that is required to adequately address patients' misconceptions about the return to work. On the other hand, we do not know precisely which

misconceptions impede the return to work and which should be addressed. For instance, we found that the understanding that it is useful to resume work gradually, even before one is fully recovered, was common in the usual care group as well. The prevalence of this belief might have resulted from more general changes in the perception of the importance of work for cancer patients, as noted earlier. In contrast, we also found that misconceptions about cancer and work still persist. Nurses described that one unexpected element of the patient education involved creating awareness that the social security safety net in the Netherlands has cut back in recent years and that companies may not be as loyal as anticipated. In sum, some misconceptions about cancer and work may have persisted and may have resulted in the absence of an intervention effect.

We experienced difficulties in involving the occupational physician and the employer in the intervention (Chapter 7). The involvement of the occupational physician and the supervisor appeared to be important in our qualitative study (Chapter 3). Therefore, the absence of an intervention effect may have been caused by the lack of involvement of the occupational physician and the supervisor.

Study design

Another possible explanation for the non-statistically significant findings may be found in the study design. Several forms of bias may have influenced the findings of the intervention study (Chapter 8).

The contrast between the intervention group and the control group may have been reduced in several ways. The quality of usual care regarding work advice was most likely higher in hospital departments that were willing and able to participate at the start of the study compared to hospital departments that were not willing and able to participate because nurses who worked in hospital departments that participated already recognised the importance of work for cancer patients. Next, the study design in which patients were randomised within one hospital department led to contamination between the intervention group and the control group. We tried to reduce this form of contamination between groups by separating nurses who delivered the intervention from nurses who delivered usual care, but contamination proved more persistent than had been estimated at the start of the study. Furthermore, 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 of the increased recognition of the importance of work for cancer patients. Both aspects may have led to an increased awareness in the usual care group that the return to work should receive more attention and may have led to the use of co-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 summary, the contrast between the groups may have been reduced in several ways and this shift likely caused an underestimation of the effect of the intervention versus usual care.

A bias might also have resulted from the measurement of the primary and secondary outcomes, such as the choice of questionnaires and the measurement points. The questionnaires we used to measure primary and secondary outcome, were reported to be valid[15 16] except that the validity and reliability of the Dutch translation of the Work Limitation Questionnaire (WLQ) had not previously been tested in a population of cancer patients. Therefore, we conducted a validation study of the Dutch translation of the WLQ in a population of cancer patients (Chapter 4). The results showed that the WLQ is valid to use at a group level. Furthermore, recall bias may have been introduced when we assessed the outcomes at a time interval of six months. We choose this long time interval to ease the burden on patients filling in questionnaires. However, this interval may have been too long to reliably assess return to work. The recall bias is expected to be the same between the intervention group and the control group, and would therefore not likely have affected our findings on effectiveness significantly. However, it may, fail to reliably represent the time until return to work.

Finally, the follow-up period of one year may be too short to study the primary outcome of a sustainable return to work, as the median time until full return to work was 269 and as 45% achieved full return to work at one-year follow-up. Therefore, it is possible that the findings of the study would have been different at 18 and 24 months follow-up but this is not likely as time progresses, the probability of a patient returning to work decreases and as we studied an early intervention. Therefore, we assumed that the effect would have been within the 1-year follow-up, rather than at the end of a very long-term follow-up period.

External validity: generalisability of findings and intervention implementation

As most studies conducted in this thesis were performed with female cancer patients, our findings cannot be generalised to male cancer patients because male cancer patients may face other problems upon their return to work or may attribute a different meaning to work.

The studies described in this thesis were all performed in the Netherlands, which has a unique culture in terms of occupational health care, the social security system, and cultural characteristics. It is generally acknowledged that the disability legalisation of a country especially influences the adverse work outcomes of employees on sick-leave and that disability legalisations varies widely among countries.[17] For that reason, the effect of interventions on adverse work outcomes may also vary from one country to another. However, the early hospital-based work support intervention integrated into usual psycho-oncological care can be generalised to other countries because cancer patients in other countries experiencing a lack of support about their return to work from the hospital as often as patients in the Netherlands.[18] Furthermore, as the intervention implementation appeared to be successful regarding patient education and support at the hospital and as the intervention implementation could be adapted to different local psycho-oncological care settings, we assume that it could also be adapted to the psycho-oncological care of other countries.

Implications for further research

As most of the studies in this thesis and in the literature (Chapter 2) have been conducted among breast cancer patients only, one recommendation for further research is to broaden the scope to all cancer types to verify that the findings described in this thesis apply to all cancer types. This work is especially important, because different prognostic factors influence the return to work by patients with different cancer types and because cancer diagnosis[19] and cancer treatment[20] are prognostic factors for return to work.

Along similar lines, most of the studies in this thesis and in the literature have been conducted among cancer patients with relatively good survival chances, which may be considered adequate, because the return to work may be more a cause for concern for them. However, cancer patients with less good survival chances will have

work concerns other than returning to work, such as whether they are able to or want to remain in paid work. Therefore, they may also benefit from patient education and support about these specific work concerns delivered by a nurse. Thus, another recommendation for further research is to broaden its scope to include cancer patients with less good survival chances and to elucidate their work concerns and their needs.

Most importantly, because patients and nurses appreciated the intervention, because it appeared that the intervention could be implemented in usual psycho-oncological care (Chapter 7), and because we found similar work outcomes for both groups, further research is needed to study which aspects of the intervention are useful and which elements need improvement.

Intervention content

We learned from the intervention study that it was difficult to engage the occupational physicians (Chapter 7), while the involvement of the occupational physician and the supervisor appeared to be important in our qualitative study (Chapter 3). For that reason, the intervention should be adapted such that the workplace is more involved. One possibility is to develop a web-based system or to send coded emails instead of letters to lower the barrier between the hospital and the occupational physician. However, one drawback of these systems is that patient privacy must be guaranteed at all times. Another option is to give the patient the information. For instance, patients could be given an informational leaflet about cancer and work, and they can use the leaflet as a starting point to discuss their return to work with their supervisor and/or occupational physician. In addition, an informational leaflet may provide the supervisor with general information regarding the consequences of a cancer diagnosis for work outcomes. These informational leaflets were recently developed by the Dutch Federation of Cancer patient organisations (NFK).[5] Finally, occupational physicians could be given more training on the specific needs of this population.[21]

It might be more difficult than estimated to address misconceptions about cancer and work. We do not know precisely which misconceptions impede the return to work and which should be addressed and the training that we gave to the nurses may have been insufficient. Both aspects should receive more attention in further research. Furthermore, the intervention ought to be tailored to employees with a temporary

employment contract, as patients who did not have an employer anymore stated that they could not comply with all advices (Chapter 7).

It is generally acknowledged that the variation in time until return to work is large; some patients are never on sick-leave and work through treatment, whereas others are never able to return to work. This assumption was supported by the studies included in this thesis (Chapter 8). From the intervention study (Chapter 8), it could be derived that some patients had already fully returned to work before the intervention started, while other patients would have preferred to receive much more and much longer support, as they were not able to work at follow-up. Therefore, it may be important to identify patients who have a higher risk of getting adverse work outcomes based on a clinical prediction rule. Such a clinical prediction rule for work outcomes should be developed and evaluated for accuracy in identifying patients with a higher risk of adverse work outcomes. Thereafter, health care professionals should receive training in applying the clinical prediction rule in practice.

Apart from identifying patients at a higher risk, it is also important to tailor the level of the intervention to meet the needs of the patients in a process called 'stepped care'.[22] A very rough estimation based on our intervention study can be made. To start with, very few patients need no support, as they encountered insignificant problems upon their return to work. At the next step, the majority of patients may benefit from receiving patient education and support about work. Finally, a minority of the patients need a more intensive intervention. It is not feasible for a nurse alone to deliver a much more intensive intervention as part of the nurse's normal psycho-oncological care because of the burden on the health care, which will even become more pressing in the near future as the number of cancer patients who will survive will increase.[23] The intervention for the second and third category of patients should be modelled after self-management, as self-management is a promising solution to the burden on the health care. Self-management could be more efficiently delivered through e-health, which is, for instance, the partial delivery of an intervention over the Internet. It has been suggested that e-health in combination with support from a health care professional is most effective.[24 25] Another advantage of an e-health intervention is that it can be easier tailored to the needs of the patient, as it is less structured. Such an intervention might prove the key to ending our difficulties with involving the occupational physician and

the supervisor in the intervention. Finally, the content of an e-health intervention may also be tailored to the variation in the seriousness of the cancer. The patients facing the most difficulties upon returning to work may benefit from a referral to an extra intense intervention such as an occupational physician specialised in the work concerns of cancer patients or a vocational rehabilitation coach specialised in cancer.[26]

The intervention was not specifically developed for a certain cancer type, but it was difficult to include cancer types other than breast and gynaecological cancers, frequently because of the limited psycho-oncological care of hospital departments that treated other cancer types. At these departments, there was for instance no nurse who could assist the treating physician in assessing the inclusion and exclusion criteria and informing cancer patients about the intervention study. Nurses were most often involved in breast cancer care only, as cancer care was most developed in the field of breast cancer care.[27] However, it is assumed that cancer survivorship care will improve in the near future for other cancer types,[27] which might make it easier to include other cancer types in future studies.

Intervention study design

We found that contamination took place between the intervention group and the control group. The disadvantages of a cluster randomised controlled trial (i.e. differences in baseline values) may now balance out the disadvantages of a randomised controlled trial in one department (i.e. contamination). In addition, in a cluster randomised controlled trial, it is in general easier to maintain contrast between groups, as it is not always required to inform individual patients, to which intervention arm they are assigned and what the general aim of the intervention arm is, which is likely to lead to less information bias and use of co-interventions.[28] This type of study design has been considered ethical and feasible in practice.[28]

When we developed the study design, we made the decision to assess the economic costs from a societal perspective as the society incurs costs when a cancer patient is not able to return to work. However, in addition to the societal perspective, the economic costs calculated from the perspective of a health insurance company perspective are important for this type of intervention because the hospital department bears the cost of the intervention, while the cancer patient and the employer may

receive the primary benefit (earlier and sustainable return to work). Health insurance companies are primary interested in whether interventions are effective in reducing the medical consumption as they bear the costs for the medical consumption. For that reason, if a hospital-based work support intervention appears effective, it is important to consider whether the intervention also reduces the patient medical consumption. In that case, health insurance companies might pay for the intervention, which may result in hospital departments being more likely to implement the intervention, as they will be compensated for the intervention costs.

Recommendations for practice

An important general recommendation for practice is that an individualised approach is required, as the differences between cancer patients are large in terms of both the problems experienced on return to work and the differences in the importance of work (Chapter 3 and 8). This finding holds especially for cancer patients with less good survival chances (Chapter 3). Therefore, it is important that health care professionals be made aware of these individual differences, verify the work concerns and importance of work of an individual patient, and fine-tune their support and advices to the individual patient.

Cancer survivorship care

A specific recommendation for cancer survivorship care is to be aware of the work concerns of cancer patients and to address the adverse work outcomes of cancer patients early in treatment phase, as well as at follow-up, as the intervention is appreciated by patients and perceived to be useful and feasible by nurses. Furthermore, the recent published guideline 'cancer rehabilitation' states that work should be a permanent subject of cancer rehabilitation, both during active treatment as well as at follow-up.[9] We found similar return to work outcomes for both groups but there is still considerable uncertainty about possible effects, so further research is needed to study which aspects are useful and which aspects need improvement.

Oncological rehabilitation is considered reimbursable care by the Dutch health insurance companies,[29] which should, according to the recent published rehabilitation guideline, also include interventions that address adverse work outcomes.[9] Therefore, it

would be helpful to further recognise that support for work resumption is a need of cancer patients that should be addressed by the health care system, which hospital departments should be able to reimburse by the health insurance companies if an intervention is (cost-)effective.

Occupational health care, supervisor, employer

Occupational health care professionals and the employer should be attentive to the long-term consequences of cancer treatment on work outcomes to prevent a wear-off effect on attention and support (Chapter 3). The transition from cancer patient to survivor may have all types of complications,[30] suggesting that it is important to follow someone for some time after sustainable return to work. Most patients mentioned that a gradual return to work facilitated their return to work process (Chapter 3). Therefore, another recommendation is to offer modified work duties as much as possible.

In addition to the employee with cancer being confronted with cancer, the supervisor and colleagues are confronted with cancer as well, which might make them unsure how to address their sick colleague (Chapter 3). The supervisor and colleagues may feel unsure how to address a colleague with cancer, which may be partly caused by the historical perspective on work of cancer patients as noted earlier. For those reasons, some cancer patients still experience a stigma related to cancer and work. Examples include the stigma that their work was not important for them during or after treatment, the stigma that they were not able to return to work, and/or the stigma that their work productivity was lower in comparison to healthy subjects (Chapter 3). The above concerns suggest that support of the employer/occupational health services should not be limited to the employee with cancer but should be broadened to the colleagues as well.

Cancer patients

Cancer patients are recommended to make themselves aware of the rules of the Dutch social security system, which are not fine-tuned to a specific diagnosis but similar for all persons on sick-leave regardless of the cause. Moreover, it may be beneficial for cancer patients to understand the barriers for return to work such as low self-assessed work ability or misconceptions about return to work. It will most likely be helpful to discuss

how to overcome these barriers early in the treatment process with a health care professional.

In sum, in this thesis, adverse work outcomes of cancer patients were addressed by developing a hospital-based work support intervention and by studying its effects on return to work and quality of life in a multi-centre randomised controlled trial. The importance of work for cancer patients is confirmed by the studies in this thesis. The intervention was easily accepted in usual care and patients were highly satisfied. We found high return to work rates and improved quality of life scores in both the intervention and the control groups, possible effects of the intervention need more attention. Therefore, interventions should be further developed to support cancer patients with their return to work.

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Summary

Advances in cancer screening and cancer treatment have improved the survival rates of cancer in recent years. An increasing number of cancer patients will therefore be able to live many years beyond a 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. Furthermore, work contributes to personal, social, and economic well-being and work is associated with a higher quality of life of cancer patients. Unfortunately, cancer patients have a 37% higher risk of becoming unemployed and may suffer from impaired work functioning, face a decrease in income, or may be confronted with unreasonable treatment at the workplace. Unfortunately, interventions aimed at enhancing the return to work of cancer patients are rare and work is not typically addressed as part of usual psycho-oncological care at the hospital.

The main objective of this thesis is to gain knowledge on how to reduce adverse work outcomes of cancer patients. The following research questions were put forward (**Chapter 1**):

1. What are important aspects in the design of a hospital-based work support intervention for cancer patients to enhance the return to work and quality of life?
2. What are the psychometric properties of the Dutch translation of the Work Limitation Questionnaire (WLQ) among cancer patients?
3. How is the process of a hospital-based work support intervention for cancer patients evaluated?
4. What is the effectiveness of a hospital-based work support intervention compared to usual care for cancer patients on return to work and quality of life?

Design of a hospital-based work support intervention for cancer patients

We developed an intervention for cancer patients with the primary aim of enhancing the return to work and quality of life (**Chapter 5**). Important aspects of the design of this type of intervention include the following: 1) an early hospital-based intervention that is integrated into the usual psycho-oncological care (**Chapter 2**), 2) addressing misconceptions about cancer and work (**Chapter 2**), 3) involvement of the occupational

physician and the supervisor (**Chapter 3**), and 4) informing the patient's occupational physician about patient's diagnosis and cancer treatment (**Chapter 5**).

The hospital-based work support intervention started a few weeks after inclusion in the study and was spread over a maximum of 14 months. The hospital-based work support intervention consisted of: 1) delivering patient education and support at the hospital as part of psycho-oncology care, 2) improving the communication between the treating physician and the occupational physician, 3) the advice to make a concrete and gradual return-to-work plan in collaboration with the cancer patient, the occupational physician, and the supervisor. A breast care nurse, oncological nurse, nurse practitioner, or social worker (hereafter called nurse), who delivered psycho-oncological care in normal cancer care delivered the patient education and support at the hospital in 4 meetings of 15 minutes each (both face-to-face meetings and contact by telephone). In addition, at least one letter was sent to the occupational physician to enhance the communication: two from the treating physician and one from the nurse. We asked the occupational physicians to organise a meeting between the patient and the supervisor to make a return-to-work plan. The key aspects of the hospital-based work support intervention were the patient education and support at the hospital and the sending of information to the occupational physician.

Psychometric properties of the Work Limitation Questionnaire (WLQ) among cancer survivors

To understand the full impact of a cancer diagnosis on adverse work outcomes, it is also important to understand the work functioning of cancer survivors. A commonly used measure of impaired work functioning due to ill health is the Work Limitation Questionnaire (WLQ), which has been translated into Dutch. However, the measurement properties of the Dutch translation of the WLQ among cancer survivors were unknown. Therefore, we employed a cohort study of 53 cancer survivors with three measurement points (**Chapter 4**). We found sufficient reproducibility at the group level but not at the individual level as the minimal important change (4.0) exceeded the smallest detectable change at the group level (3.1) but not at the individual level (18.0). There was no indication of systematic bias or proportional bias. The internal consistency and construct validity for the WLQ and its subscales were sufficient or

slightly less than sufficient. There was a floor effect for one subscale but there were no ceiling effects. Responsiveness was sufficient with an area under the curve of a receiver operating characteristic of 0.68. The WLQ is reproducible, valid, and responsive for the use at group level, but it is not sufficiently reproducible for clinical use among cancer survivors.

Process evaluation of a hospital-based work support intervention for cancer patients

How is the process of a hospital-based work support intervention evaluated? To answer this question, we conducted a case study (**Chapter 6**) and a process evaluation (**Chapter 7**). We conducted a case study to describe how the return-to-work process progressed in a cancer patient and how a hospital-based work support intervention supported this process (**Chapter 6)**. Furthermore, we performed a process evaluation at the level of the hospital department, nurse, and patient (**Chapter 7**). The following process evaluation outcomes were assessed: recruitment, context, reach, intensity of the intervention delivered, intensity of the intervention received, and fidelity.

The results of the case study revealed that the support delivered by the nurse helped the patient to resume work gradually and the sending of information from the treating physician and the nurse improved communication with the occupational physician. This resulted in the patient being able to achieve lasting return to work (**Chapter 6**). The results of the process evaluation showed that 47% of all eligible patients participated in the study. Nurses' meetings with the patients were conducted according to the protocol in 85% of the cases. In 100% of the cases, at least one letter was sent to the occupational physician, and in 10% of the cases a meeting took place between the patient, the occupational physician, and the supervisor. Our method, which involved asking occupational physicians to organise a meeting between the patient, the supervisor, and themselves to draw up a return to work plan, proved difficult. Patients and nurses found the intervention in general very useful (**Chapter 7**). Nurses made the following suggestions to optimise the intervention: 1) meetings must be planned at the right time and should be allotted sufficient time, 2) meetings should be conducted face-to-face, and 3) to be able to deliver all meetings face-to-face it may mean that the intervention should be hand on to another health care professional who has longer follow-up consultations in usual cancer care.

Based on the case study and the process evaluation, we conclude that the intervention yields high acceptability to implement in usual psycho-oncological care but that it proved difficult to involve the occupational physician. Patients were highly satisfied and nurses found the intervention useful and feasible.

Effectiveness of an innovative hospital-based work support intervention for cancer patients

We studied the effectiveness of an innovative hospital-based work support intervention in a multi-centre randomised controlled trial with a follow-up of 12 months (**Chapter 8**). Cancer patients who were treated with curative intent and who had paid work participated. Patients were randomly assigned to the intervention group (N=65) or to the control group (N=68). Outcomes were the rate of and time to return to work, quality of life, work ability, work functioning, and costs (i.e. costs to deliver the intervention and lost productivity costs). The relative risk of the intervention versus usual care of the return to work rate was calculated at follow-up. The time until return to work was analysed with a Kaplan Meijer survival analysis and Cox regression analysis. Secondary outcomes were analysed with multi-level analysis.

The rate of return to full or partial work at the 12 month follow-up was 79% in the intervention group versus 79% in the control group; and 86% and 83% respectively when excluding patients who died within the follow-up period and with a life expectancy of months. The relative risk of returning to work (full or partial) in the intervention group versus the control group was 1.03 (95% confidence interval 0.84 – 1.2). The median time from initial sick leave to partial return to work was 194 days (range 14-435) in the intervention group and 192 days (range 82-465) in the control group ($p = 0.90$). The hazard ratio of partial return to work was 1.03 (95% confidence interval of 0.64 – 1.6) of the intervention group versus the control group. Quality of life improved statistically significant over time (p ranged from 0.014 to$\leq$ 0.001) but did not differ statistically significant between groups (p ranged from 0.15 to 0.99). Work ability and work functioning improved over time but did not differ statistically between groups. The cost of delivering the intervention was €119. Lost productivity costs did not differ between groups (€41.792 versus €40.147).

Return-to-work rates were generally high. We found non-statistically significant findings between groups, but there is still considerable uncertainty about possible effects of the intervention. Further research is needed to determine which aspects of the intervention are useful and which elements need improvement.

Conclusion and recommendations for further research and practice

The importance of work for cancer patients is confirmed by the studies described in this thesis. Most importantly, a recommendation for further research is to study which aspects of the intervention are useful and which elements need improvement as we found similar work outcomes for both groups and there is still considerable uncertainty about possible effects.

An important generic recommendation for practice is that an individual approach is required as the differences among cancer patients are large regarding the experienced adverse work outcomes. A specific recommendation for psycho-oncological care is to be aware of the work concerns of cancer patients and to address the possibility of adverse work outcomes of a cancer patient both early in their treatment phase and at follow-up as the intervention was highly appreciated by patients and perceived useful and feasible by nurses.

Occupational health care professionals and the employer should be attentive of the long-term consequences of cancer treatment on work outcomes to prevent a wear-off effect of attention and support. Cancer patients are recommended to make themselves aware of the rules of the social security system and discuss return to work with a health care professional early in their treatment phase and at follow-up.

In conclusion, the importance of work for cancer patients is confirmed by the studies described in this thesis. Therefore, interventions should be further developed to support cancer patients with their return to work.

Samenvatting

De overlevingskansen van kanker zijn in de afgelopen jaren verbeterd. Daardoor is er ook meer aandacht gekomen voor psychosociale gevolgen van kanker zoals vermoeidheid, concentratieproblemen en neerslachtigheid. Deze kunnen grote invloed hebben op alle facetten van iemands leven. Een van deze facetten voor mensen met kanker is het hebben van betaald werk. Werk heeft sociale en persoonlijke waarde, is een mogelijkheid om te participeren in de maatschappij, biedt de mogelijkheid tot economische zelfstandigheid en draagt bij aan een hogere kwaliteit van leven. Eerder onderzoek heeft echter aangetoond dat mensen met kanker minder participeren in werk en meer problemen ervaren met het uitvoeren van hun werk in vergelijking tot de 'gezonde' populatie. Mensen met kanker ervaren vaker beperkingen met het uitvoeren van hun werk en gaan vaker achteruit wat betreft inkomen. Ook het werkloosheids-risico van mensen met kanker is wereldwijd 37% hoger. Er is echter nog relatief weinig aandacht voor deze problematiek. Werkhervatting maakt bijvoorbeeld nog geen vast onderdeel uit van de gebruikelijk psychosociale-oncologische zorg. Om die reden is het belangrijk dat interventies (d.i. een actieve, bewuste en geplande ingreep om het welzijn van individuen te verbeteren) worden ontwikkeld die mensen met kanker ondersteunen in hun werkhervatting.

Dit proefschrift richt zich op de vraag hoe arbeidsparticipatie van mensen met kanker verbeterd zou kunnen worden, en hoe beperkingen die zij ervaren met het uitvoeren van hun werk, kunnen worden verminderd. Daartoe is een interventie onder de naam '*begeleiding bij werkhervatting*' ontwikkeld en getoetst op toepasbaarheid en effectiviteit. Om dat te kunnen doen, is het echter van belang om eerst te toetsen of een vragenlijst die ervaren beperkingen met het uitvoeren van het werk, valide meet in een groep van mensen met kanker. Hiertoe hebben we onderzocht wat de meet eigenschappen zijn van een dergelijke vragenlijst in een groep van mensen met kanker.

In dit proefschrift staan vier onderzoeksvragen centraal (**Hoofdstuk 1**):

1) Welke aspecten zijn belangrijk bij het ontwerpen van een interventie die gericht is op het bevorderen van werkhervatting en kwaliteit van leven van mensen met kanker?
2) Wat zijn de psychometrische eigenschappen van een vragenlijst die ervaren beperkingen met het uitvoeren van werk meet in een groep van mensen met kanker?
3) Wat is de toepasbaarheid in de klinische praktijk van een interventie gericht op het bevorderen van werkhervatting en kwaliteit van leven van mensen met kanker?
4) Wat is het effect van een interventie gericht op het bevorderen van werkhervatting en kwaliteit van leven van mensen met kanker in vergelijking met de gebruikelijke zorg?

Ad. 1 Belangrijke aspecten voor een interventie 'Begeleiding bij werkhervatting' en de ontwikkeling ervan

Om werkhervatting en kwaliteit van leven van mensen met kanker te bevorderen is een interventie onder de naam *'Begeleiding bij werkhervatting'* ontwikkeld (**Hoofdstuk 5**). Voor het ontwikkelen van een interventie die gericht is op het bevorderen van werkhervatting, is eerst onderzocht welke aspecten voor een dergelijke interventie belangrijk zijn. Ten eerste blijkt het essentieel dat een interventie kort na de diagnose start: het wordt steeds moeilijker om het werk te hervatten naarmate het ziekteverzuim langer duurt. Om vroegtijdig aandacht aan werkhervatting te kunnen besteden, moet de interventie als onderdeel van de psychosociale-oncologische zorg in het ziekenhuis uitgevoerd worden. Patiënten hebben namelijk tijdens de eerste periode van ziekteverzuim over het algemeen weinig contact met hun bedrijfsarts en leidinggevende (**Hoofdstuk 5**). Daarnaast is het belangrijk dat er in de interventie aandacht wordt besteed aan misvattingen over werkhervatting, zoals het idee 'ik kan pas weer gaan werken als ik helemaal hersteld ben'. Dit soort misvattingen kunnen een belangrijke belemmering vormen voor het hervatten van werk (**Hoofdstuk 2**). Tot slot is het belangrijk dat de bedrijfsarts en de leidinggevende betrokken worden bij de interventie

(**Hoofdstuk 3**) en dat de bedrijfsarts geïnformeerd wordt over de diagnose en de behandeling van de patiënt (**Hoofdstuk 5**).

Op basis van deze bevindingen is de interventie *'Begeleiding bij werkhervatting'* ontwikkeld en getoetst. De interventie werd uitgevoerd als onderdeel van de gebruikelijke psychosociale-oncologische zorg in het ziekenhuis. Dit werd gedaan door een oncologieverpleegkundige, nurse practitioner, mammacareverpleegkundige of medisch maatschappelijk werker (hierna genoemd verpleegkundige). De interventie bestond uit de volgende componenten: 1) een verpleegkundige voerde vier gesprekken van elk een kwartier met de patiënt. Dat waren zowel een-op-een gesprekken als telefonische gesprekken, 2) het ziekenhuis stuurde medische informatie over diagnose en behandeling door de behandelend specialist en de verpleegkundige voor de bedrijfsarts van de patiënt, en 3) de bedrijfsarts kreeg het advies om een driegesprek te voeren met de patiënt en diens leidinggevende met als doel om een gefaseerd werkhervattingsplan op te stellen. Aangezien de interventie uitgevoerd werd in de klinische praktijk lag de nadruk van de interventie op de gesprekken in het ziekenhuis en het versturen van informatie naar de bedrijfsarts. In Nederland mag alleen informatie opgestuurd worden aan de bedrijfsarts als de patiënt hier toestemming voor geeft. Deze toestemming werd gevraagd door de verpleegkundige die de gesprekken voerde.

Ad. 2 Psychometrische eigenschappen van een vragenlijst waarmee ervaren beperkingen met het uitvoeren van het werk kan worden vastgesteld

Als gevolg van de diagnose kanker en/of de behandeling ervan kunnen mensen met kanker meer beperkingen met het uitvoeren van hun werk ervaren dan de 'gezonde' populatie. Zo is bekend dat zij meer moeite kunnen hebben om zich te kunnen concentreren op het werk. Het is belangrijk om in kaart te brengen welke beperkingen mensen met kanker in hun werk ervaren omdat op basis van deze kennis aanbevelingen gedaan zouden kunnen worden om werk-functioneren te verbeteren. Om deze werkbeperkingen in kaart te kunnen brengen is een goede vragenlijst noodzakelijk. Uit eerder onderzoek is gebleken dat de Engelse vertaling 'Beperkingen Werk' voldoet voor het meten van beperkingen met het uitvoeren van werk. Het is echter nog niet bekend of deze vragenlijst ook voldoet voor een groep mensen met kanker. Om die reden

hebben we onderzocht wat de psychometrische eigenschappen van deze vragenlijst zijn (**Hoofdstuk 4**). Hiertoe is de vragenlijst driemaal afgenomen in een groep van 53 mensen met kanker en is de vragenlijst op drie aspecten onderzocht. Ten eerste *betrouwbaarheid:* is de gemeten waarde representatief voor de werkelijke waarde? Ten tweede *validiteit*: meet de vragenlijst wat je wil meten? En ten derde *responsiviteit*: kan de vragenlijst veranderingen in de tijd betrouwbaar meten? Het onderzoek laat zien dat de vragenlijst voldoende betrouwbaar, valide en responsief is voor het gebruik in een groep van mensen met kanker. Echter, om de vragenlijst in de praktijk op een individueel niveau te kunnen gebruiken, zou de betrouwbaarheid van de vragenlijst verbeterd moeten worden.

Ad. 3 Toepasbaarheid van de interventie 'Begeleiding bij werkhervatting'

De toepasbaarheid van de interventie *'Begeleiding bij werkhervatting'* in de klinische praktijk is in twee studies onderzocht, te weten een casestudy (**Hoofdstuk 6**) en een procesevaluatie (**Hoofdstuk 7**). In de casestudy is het werkhervattingsproces beschreven van een patiënt die de '*Begeleiding bij werkhervatting'* succesvol heeft doorlopen. Daarnaast is beschreven hoe de '*Begeleiding bij werkhervatting'* de patiënt tijdens het werkhervattingsproces heeft ondersteund. In de procesevaluatie is onderzocht in hoeverre patiënten bereid waren om deel te nemen aan het onderzoek, in hoeverre de interventie volgens het protocol was uitgevoerd en in hoeverre patiënten en verpleegkundigen tevreden zijn met de interventie.

De casestudy (**Hoofdstuk 6**) beschrijft wat de verpleegkundige heeft gedaan om de patiënt te helpen het werk gefaseerd te hervatten. Ook is beschreven hoe het herstel van de patiënt verloopt en waar het mis gaat als er mogelijk een recidief dreigt en er onenigheid is met de bedrijfsarts. Uiteindelijk hervat de patiënt het werk volledig.

Uit de procesevaluatie (**Hoofdstuk 7**) blijkt dat patiënten en verpleegkundigen zeer tevreden te zijn over de interventie. Daarnaast blijkt dat 47% van alle geschikte patiënten ook daadwerkelijk deelnam aan het onderzoek. De interventie '*Begeleiding bij werkhervatting'* bleek goed uitgevoerd te worden in de klinische praktijk. In 85% van de gevallen werd de informatie en begeleiding door de verpleegkundige volgens het protocol uitgevoerd; in alle gevallen werd aan de bedrijfsarts ten minste één brief verstuurd. In slechts 10% van de gevallen vond echter het driegesprek met bedrijfsarts,

leidinggevende en patiënt plaats. Tot slot gaven de verpleegkundigen de volgende aanbevelingen om de interventie te optimaliseren: 1) het gesprek over werk kan qua tijd en duur beter gepland worden, 2) de gesprekken zouden een-op-een moeten plaatsvinden omdat dit prettiger en effectiever geacht wordt, en 3) om alle gespreken een-op-een te kunnen laten plaatsvinden zou in sommige gevallen dit aspect van zorg moeten worden overgedragen aan een zorgprofessional die de patiënt langer volgt.

Op basis van deze twee studies kan worden geconcludeerd dat de '*Begeleiding bij werkhervatting'* in de klinische praktijk geïmplementeerd zou kunnen worden, en dat patiënten en verpleegkundigen zeer tevreden zijn. We concluderen echter ook dat de werkplek en de bedrijfsarts van de patiënt moeilijk te bereiken zijn vanuit het ziekenhuis.

Ad. 4 Effectiviteit van de interventie 'Begeleiding bij werkhervatting'

In **Hoofdstuk 8** is het effect van de interventie *'Begeleiding bij werkhervatting'* vergeleken met de gebruikelijke zorg op werkhervatting en kwaliteit van leven. Het onderzoek betrof patiënten die gediagnosticeerd waren met kanker, die behandeld werden met curatieve intentie en die op het moment van diagnose betaald werk hadden. Het onderzoek is in 6 ziekenhuizen uitgevoerd en er deden in totaal 133 patiënten mee; 65 patiënten zaten in de interventiegroep en kregen de interventie '*begeleiding bij werkhervatting*'; 67 patiënten zaten in de controlegroep en kregen de gebruikelijke zorg. Van de 133 patiënten was 62% gediagnosticeerd met borstkanker, 33% had een gynaecologische vorm van kanker en 5% had een andere vorm van kanker. Aan de hand van vragenlijsten werden gedurende 12 maanden de volgende uitkomstmaten gemeten: 1) wel of geen gedeeltelijke of volledige werkhervatting, 2) het aantal dagen vanaf ziekmelding tot werkhervatting, 3) kwaliteit van leven, 4) werkvermogen, 5) ervaren beperkingen met het uitvoeren van werk (*ad 2*), en 6) kosten (zowel kosten door ziekteverzuim als kosten om de interventie uit te voeren).

De resultaten van de effectstudie zijn als volgt. Het aantal patiënten dat na 12 maanden volledig of gedeeltelijk het werk had hervat was 79% in de interventiegroep en 79% in de controlegroep. Als de patiënten die tussentijds waren overleden of een zeer korte levensverwachting hadden niet meegenomen worden in de berekening, zijn deze cijfers respectievelijk 86% en 83%. Redenen om het werk niet te hervatten waren:

9 patiënten waren hun baan kwijt, 7 patiënten hadden dusdanige klachten dat het hervatten van werk (nog) niet mogelijk was (bijv. vermoeidheid), 4 patiënten hadden een zeer slechte levensverwachting en 4 patiënten waren overleden gedurende 12 maanden. Het duurde gemiddeld 194 dagen (spreiding 14-435 dagen) in de interventiegroep en 192 dagen (spreiding 82-465 dagen) in de controlegroep voordat men het werk gedeeltelijk had hervat. Kwaliteit van leven, werkvermogen en ervaren beperkingen met het uitvoeren van werk verbeterden in de loop van de tijd maar verschilden niet tussen de groepen. Kosten voor ziekteverzuim waren gemiddeld €41.792 in de interventiegroep en €40.147 in de controlegroep. De kosten voor de uitvoering van de interventie bedroegen €119 per patiënt in de interventiegroep. Zowel in de interventiegroep als in de controlegroep was het aantal patiënten dat het werk had hervat relatief groot. We vonden geen verschillen tussen de groepen. Verder onderzoek is dan ook nodig om na te gaan welke elementen van de interventie succesvol zijn en welke elementen verbeterd moeten worden.

Conclusies en aanbevelingen

Het belang van werk voor mensen met kanker wordt bevestigd door de onderzoeken van dit proefschrift. We vonden geen verschil tussen de groep die de interventie *'begeleiding bij werkhervatting'* kreeg en de groep die de gebruikelijke zorg kreeg. Daarom is een aanbeveling voor vervolgonderzoek om na te gaan welke elementen van de interventie succesvol zouden kunnen zijn en welke elementen verbeterd moeten worden. De belangrijkste aspecten hierbij zijn nagaan hoe in de klinische praktijk een intensievere werkgerichte interventie uitgevoerd kan worden, bijvoorbeeld door zelfmanagement en hoe de training van verpleegkundigen in de uitvoer van de interventie geoptimaliseerd kan worden. Daarnaast zou gekeken moeten worden hoe de bedrijfsarts en de leidinggevende beter betrokken zouden kunnen worden bij een interventie die uitgevoerd wordt in de klinische praktijk.

De grote spreiding in de tijd tot werkhervatting geeft aan dat begeleiding bij werkhervatting maatwerk is zowel voor de psychosociale oncologie als voor de leidinggevende en de bedrijfsarts. Voor de psychosociale oncologie is een aanbeveling om aandacht te besteden aan het werk van mensen met kanker omdat dit door hen belangrijk wordt gevonden en door verpleegkundigen uitvoerbaar geacht wordt. Voor

de werkgever, leidinggevende en de bedrijfsarts is het belangrijk om bewust te zijn van de lange-termijn gevolgen van kanker. Daarnaast kan aan mensen met kanker aanbevolen worden kennis te hebben van de wet- en regelgeving rondom ziekteverzuim en al vroeg in het behandeltraject na te denken over hoe om te gaan met zijn of haar werk en dit te bespreken met een verpleegkundige in het ziekenhuis.

Tot besluit concluderen we dat het belang van werk voor mensen met kanker wordt bevestigd door de onderzoeken van dit proefschrift. Daarom is het belangrijk dat we doorgaan met het ontwikkelen van interventies die mensen met kanker ondersteunen in hun werkhervatting.

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List of publications

Articles related to this thesis

Tamminga SJ, Verbeek JH, de Boer AG, van der Bij RM, and Frings-Dresen MH. A hospital-based work support intervention to enhance the return to work of employees with cancer – a case study. Accepted for publication in a special issue of WORK on cancer and work.

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About the author

Sietske Joke Tamminga was born on the 18th of September 1982 in Hilversum, the Netherlands. She graduated from the Alberdingk Thijm College in Hilversum in 2001. Thereafter, she studied *Human Movement Sciences* at the VU University in Amsterdam, the Netherlands and graduated in 2006 with a specialisation in *the coordination, learning and development of action* and *human movement sciences and health care.* In 2011 Sietske started with the three-year part-time training programme *Work Disability Prevention* at the Dalla Lana school of public health, Toronto, Canada.

Sietske started working in 2006 as a research assistant at the EMGO-institute, VU medical center, Amsterdam, the Netherlands for various research projects concerning among others the prevention of work disability. In January 2008, Sietske went on as a PhD-student at the Coronel Institute of Occupational Health at the Academic Medical Center, Amsterdam, the Netherlands were she developed a hospital-based return to work intervention for cancer patients and studied its effectiveness in a multi-centre randomised controlled trial. The results of this project are described in this thesis. As part of her PhD-project she determined the measurement properties of the Work Limitation Questionnaire (WLQ) among a population of Dutch cancer survivors. Since November 2010 Sietske joined the works council. In addition, Sietske works as a volunteer for the Dutch Federation of Cancer patient organisations (NFK), where she is involved in education on cancer and work.

Currently, Sietske works as a researcher at the Coronel Institute of Occupational Health, Academic Medical Center, Amsterdam, the Netherlands, studying the effectiveness of an e-health intervention aimed at enhancing the return to work of cancer patients.