

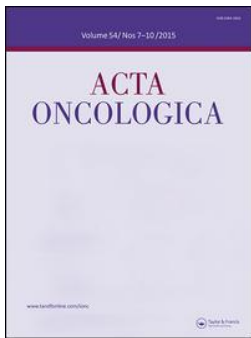
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To cite this article: M. P. van Egmond, S. F. A. Duijts, M. A. Jonker, A. J. van der Beek & J. R. Anema (2016) Effectiveness of a tailored return to work program for cancer survivors with job loss: results of a randomized controlled trial, Acta Oncologica, 55:9-10, 1210-1219, DOI: [10.1080/0284186X.2016.1213417](https://doi.org/10.1080/0284186X.2016.1213417)

To link to this article: <https://doi.org/10.1080/0284186X.2016.1213417>



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Published online: 23 Aug 2016.



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Effectiveness of a tailored return to work program for cancer survivors with job loss: results of a randomized controlled trial

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ABSTRACT

Background: Up to 53% of cancer survivors (CSs) experiences job loss during or after treatment. To support CSs with job loss in the Netherlands, a tailored return to work (RTW) program was developed. The objective of this study was to assess the effectiveness of the program on duration until sustainable RTW in CSs with job loss.

Material and methods: This study employed a two-armed (intervention/control) randomized controlled design with one-year follow-up. The primary outcome measure was duration until sustainable RTW. The secondary outcome measures were: rate of RTW, fatigue, quality of life, and participation in society. Descriptive analyses, Kaplan-Meier estimators and Cox regression analyses were conducted.

Results: Participants (N = 171) had a mean age of 48.4 years (SD = 8.6). The majority was female (69%) and breast cancer survivor (40%). The crude hazard ratio (HR) for duration until sustainable RTW was 0.86 (95% CI 0.46–1.62; p = 0.642). In the adjusted model, the intervention group had a slight, but statistically non-significant, improvement in duration until sustainable RTW compared to the control group (HR 1.16; 95% CI 0.59–2.31; p = 0.663). The program did not have any significant effects on secondary outcome measures.

Conclusion: As the tailored RTW program did not demonstrate a statistically significant effect on duration until sustainable RTW in CSs with job loss, implementation of the program in its current form is not recommended.

ARTICLE HISTORY

Received 6 May 2016
Accepted 11 July 2016

Among the many challenges in cancer survivorship are long-term or permanent physical and mental health problems, which often occur as a result of diagnosis and treatment [1,2]. For example, cancer survivors (CSs) may experience fatigue, pain and cognitive problems, long after treatment has been completed [3]. Studies have shown that these health problems may greatly affect CSs' daily functioning and quality of life [4]. Moreover, for CSs in the working age, impairments in physical and mental health may reduce chances of participation in work [5]. For example, up to 53% of CSs become unemployed, either by job loss or quitting work, in the first six years after diagnosis [6]. Moreover, across studies, CSs are 1.4 times more likely to be unemployed than healthy persons [7]. Although 64% of CSs return to work (RTW) eventually, studies show that many CSs struggle with it [6].

Furthermore, due to the increase in flexible employment in Western economies, more workers on long-term sick leave, including CSs, are vulnerable to job loss [8]. To illustrate the increase of flexible employment in the Netherlands, there was an increase of 20% in the number of persons working with a temporary contract in 2015, compared to 2008 [9].

A recent Dutch report showed that workers in temporary employment may experience job loss after being diagnosed with cancer, as Dutch employers are generally not inclined to prolong the temporary employment contracts of these workers [10]. For CSs who experience job loss, the process of RTW can be more complicated, compared to CSs who still have an employment contract, facing a large distance to the labor market, potential employer stigmatization during job interviews and no access to support from employer and colleagues [11]. Therefore, CSs who have experienced job loss may be in need for tailored RTW support.

The importance of RTW support for CSs with job loss is further stressed by insurance physicians, working at the Dutch Social Security Agency (SSA), where they provide medical consultation and assess work ability. In the Netherlands, the SSA is responsible for persons who become unemployed before or during sick leave, for example due to cancer [12]. The SSA takes over the role of the former employer in the case of job loss, by providing substituted income in the form of sickness or disability benefits. The SSA also provides RTW guidance through the services of re-integration experts, labor

experts and insurance physicians [12]. Both insurance physicians and CSs with job loss have previously reported that the SSA's usual care, including RTW guidance, is not suited to the specific RTW needs of CSs with job loss [11].

In order to meet the need for adequate RTW support in CSs with job loss, from 2011 onward, the SSA cooperated with the VU University Medical Center to develop and evaluate a tailored RTW program. From 2013 to 2015, the RTW program was offered to CSs with job loss in the Netherlands, on a national level [13]. We hypothesized that offering a tailored return to work program to CSs with job loss would lead to a significant improvement in duration until RTW in these CSs, compared to the usual care that is currently provided by the SSA. The purpose of this study was to test this hypothesis and assess the effectiveness of the tailored RTW program on duration until sustainable RTW for CSs with job loss.

Material and methods

Design

In this randomized controlled trial (RCT), the effectiveness of a tailored RTW program on duration until sustainable RTW was assessed in a population of sick-listed CSs with job loss. The RTW program was offered in a two-armed (intervention and control), non-blinded RCT, with a follow-up period of 12 months. The intervention group received the program, as well as usual care by professionals from the SSA. The control group only received the usual care from the SSA. The SSA's usual care generally consisted of a few meetings per year with an insurance physician, and potentially also a labor market or re-integration expert. The aim of these meetings was to discuss or evaluate work ability and opportunities for RTW. In that way, these meetings were somewhat comparable to meetings between a sick-listed employee and an occupational physician of his/her company. In general, usual care from the SSA does not involve any type of re-integration or supportive intervention program. As the study protocol of the RCT has been published previously, a summary of the study procedures is provided here [13]. This study has been approved by the Medical Ethical Committee of the VU University Medical Center, Amsterdam, The Netherlands. The RCT is registered in the Dutch Trial Register, registration number NTR3652.

Study population and sample size

The population of this study consisted of CSs who had experienced job loss. Most CSs in this population experienced job loss after diagnosis, because their temporary employment contract expired during/after treatment, and was not renewed. Additionally, some CSs experienced job loss before diagnosis, and were receiving unemployment benefits at time of diagnosis. After diagnosis, their unemployment benefits were changed to sickness benefits, and they became part of the population of CSs with job loss, registered at the SSA. In order to participate in this study, CSs with job loss had to be registered at the SSA as: sick-listed, receiving sickness or disability benefits due to cancer, without

employment, and of working age, i.e., 18–60 years. Specifically, CSs were selected who were on sick leave for at least 12 months and maximum 36 months. The 12-month cutoff was chosen in accordance with the Dutch social security system, in which CSs' eligibility for sickness benefits is reevaluated at 12 months. The 36-month cutoff was chosen because of limited availability of reliable data in the SSA registries, past three years of sick leave. Further, CSs had to have completed intensive cancer treatment at least six weeks before inclusion, and had to feel healthy enough to potentially participate in the RTW program (based on CSs' self-report). Additionally, the CS's general physician was contacted after inclusion in the study to verify that the CS had no comorbidities that would interfere with participation. CSs were excluded if they, among other factors, were diagnosed with metastasized cancer, were pregnant, did not speak fluent Dutch, or if they had signed up to participate in a concurrent program or study. After trial commencement, an amendment was approved by the Medical Ethical Committee of the VU University Medical Center to also include CSs with metastasized cancer in the study. This amendment was motivated by comments from CSs with metastasized cancer in the inclusion process, who were motivated and able to participate, and by advice obtained from the Dutch cancer patient movement.

Recruitment

Recruitment was organized both retrospectively and prospectively from April 2013 to January 2015. Retrospectively, all CSs who met the inclusion criteria were identified in the SSA registries, and invited to participate. Prospectively, CSs who reached the 12-month threshold were identified every other week, and invited to participate. Eligible CSs received an invitational package via postal mail. The package included an information letter, an information leaflet, a screening questionnaire with an informed consent form, a postcard, and a letter from the chief medical officer of the SSA, explaining and supporting the study, and stating that CSs were under no obligation to participate.

CSs who were not interested in participating could use the postcard to inform the researchers of their decision. On the postcard, they could provide motives for declining participation, e.g., 'I have already found a new job' or 'Due to physical problems, I am not ready to RTW yet'. Also, CSs could use the postcard to postpone the invitation to participate, i.e., they could list a new date on which they would like to be re-invited for the study. CSs who were interested to participate could complete the screening questionnaire and informed consent form, and return these to the researchers. If the CS was eligible to participate, based on the screening questionnaire, (s)he was contacted by telephone to verify if the inclusion criteria for the study were met. Also, additional information regarding the RCT was provided by phone. The CS then received the baseline questionnaire and a second informed consent form for participation in the RCT. After these forms were returned, the CS was included in the study and randomization was performed.

Randomization

After inclusion in the study, participants were randomly allocated to the intervention or the control group, using randomization software. The first step in the randomization procedure was to identify the participant's stratum, based on the employment situation prior to the participant's sick leave, as indicated in the screening questionnaire and retrieved from the SSA registry. As professionals at the SSA indicated that there could be substantial differences between participants, because of their previous employment situation, three different strata were distinguished, i.e., 1) workers whose temporary employment contract ended during sick leave; 2) temporary agency workers; and 3) unemployed workers, i.e., workers who were in-between jobs and, when diagnosed with cancer, were transferred within the SSA-system from unemployment benefits to sickness benefits. Within each stratum, participants were randomly allocated (block size: 4; ratio 1:1) to either the intervention or the control group. A researcher (KB) who was not involved in the inclusion process of participants performed the identification of the appropriate stratum and conducted the randomization procedure. The outcomes of the randomization procedure were double-checked by SD.

Tailored RTW program

The tailored RTW program consisted of an introductory interview, a 'Preparation for RTW' part, and a 'RTW' part. Throughout the entire program, participants were encouraged to actively participate in the development of a consensus-based RTW plan, as well as to participate in coaching sessions to prepare for RTW, and to explore possibilities for (therapeutic) RTW. The whole RTW program was tailored in the sense that participants could select various routes through the different parts of the program, to match the required level of RTW support. The program is presented in Figure 1.

All participants in the intervention group started the tailored RTW program with an introductory interview with a re-integration coach. In this interview, potential obstacles and possibilities for RTW were identified, and a route through the intervention program was chosen. Specifically, it was evaluated if the participant was ready to 'RTW', or if 'Preparation

for RTW' was needed. Also, participant's expectations and present activities with regard to RTW were discussed. If participants were already actively looking for jobs, they would start with the 'RTW' part (Figure 1: Route 1 in the program). In this part of the program, participants were placed in therapeutic or paid work with the support of two job hunting agencies. The two job hunting agencies who delivered the 'RTW' part employed mostly vocational therapists or personnel with a background in human resource management. They had no specific expertise with regard to cancer. The job hunting agencies had multiple locations across the Netherlands. Participants traveled to the local office nearest to them.

If the conclusion of the introductory interview was that the participant was not actively involved in RTW activities, e.g., looking for work, the participant would start with the 'Preparation for RTW' part (Route 2 in the program). This part (developing a RTW plan and coaching) was carried out by a re-integration agency, specialized in RTW coaching for CSs. The coaches from this re-integration agency also conducted the introductory interviews. These coaches were generally ex-cancer patients who had experience with cancer survivorship and job loss, and who had received training to become a specialized coach in the area of cancer and RTW. The 'Preparation for RTW' part of the program took place in the participant's home or at an office of the re-integration agency nearby.

All meetings with the re-integration coaches and job hunting agency personnel were individual face-to-face meetings. All the available routes in the intervention program are shortly described below. The full content of the tailored RTW program was previously published as part of the study protocol [13].

Route 1:

The coach and participant decided that the participant was ready to RTW. The coach then contacted the researchers to randomly assign the participant to one of the two job hunting agencies. The selected job hunting agency invited the participant for a meeting to explore job opportunities. The job hunting agency was required to find at least two suitable jobs that matched with participants work profile or wishes for RTW. Further, employment had to be offered for at least three months, and should have been either paid employment, or work with therapeutic conditions and

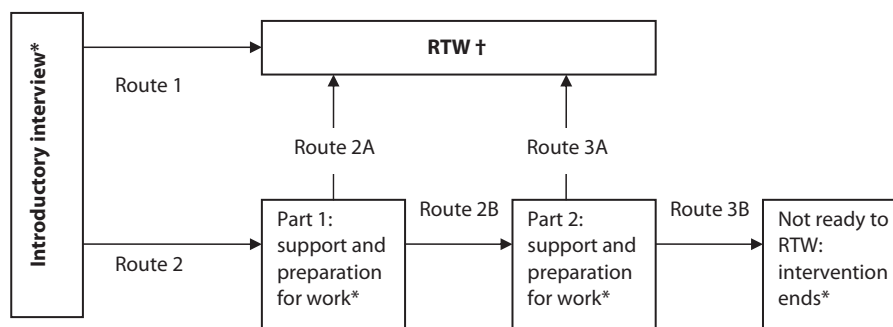


Figure 1. The tailored RTW program.

*Carried out by the re-integration coaches; †carried out by the job hunters.

ongoing benefits. According to protocol, the job hunting agencies should have found these jobs within four weeks after the first meeting with the participant. When the job hunting agency was unable to meet these requirements, the second job hunting agency involved in this study joined the search for jobs.

Route 2:

The coach and participant decided that the participant was not yet ready to start looking for a job, but that (s)he first needed preparation for RTW. In the following weeks, the participant and coach created a work profile. The work profile was based on an extensive inventory of the participants' wishes and needs for RTW, and on the participants' working experience and capabilities. Alongside this process, the participant received coaching on themes that the participant and the coach selected together. There were 12 predetermined themes available, and there was also an option to deviate from these themes if necessary. Examples of themes that were used in the coaching were: 'Fatigue and managing energy levels and RTW', 'Communication about cancer at work' and 'Stress, fluctuations in work ability and managing work, private life and recovery'. After completing the work profile and participating in four sessions of coaching, the participant and coach reevaluated whether the participant was ready to RTW (Route 2A or Route 2B).

Route 2A: The participant was ready to RTW. In this case, the coach would contact the researchers, after which a job hunter was assigned to organize a meeting with the participant and to start looking for workplaces that would fit the work profile that was created. This route is similar to Route 1 and is therefore described in more detail in the aforementioned paragraph 'Route 1'.

Route 2B: It was decided that the participant needed more preparation for RTW. Therefore, the participant received additional sessions of coaching on chosen themes. This process is essentially the same as the process described in Route 2, with the exception that the work profile was already completed at this stage. After participating in additional sessions of coaching, the coach and participant reevaluated if the participant was ready to RTW (Route 3A or Route 3B).

Route 3A: The participant was ready to RTW. In this case, the coach would contact the researchers, after which a job hunter was assigned to organize a meeting with the participant and to start looking for workplaces that would fit the work profile that was created. This route is similar to Route 1 and is therefore described in more detail in the aforementioned paragraph 'Route 1'.

Route 3B: If the participant was not ready to RTW after receiving the full 'Preparation for RTW' part of the program, the intervention program was terminated and the participant's case was referred to usual care for follow-up.

The maximum duration of the 'Preparation for RTW' part was three months. The maximum duration of the 'RTW' part was also three months. Further, one-month delay was allowed within the whole program to allow for unforeseen events, such as illnesses or holidays. Therefore, the maximum duration of the RTW program was seven months.

Outcome measures and prognostic factors

The primary outcome measure of this study was duration until sustainable RTW. This was calculated as the number of days between the day of inclusion and the first day of sustainable RTW. Sustainable RTW was defined as a period of at least 28 calendar days, during which the participant was working. Work could be paid employment, but also work resumption with ongoing benefits was considered, i.e., therapeutic work. The secondary outcome measures were: rate of RTW, defined as the proportion of participants in the intervention and the control group that returned to work, fatigue (assessed with the FACIT-Fatigue Scale (Version 4) [14]), quality of life (assessed with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C-30 version 3.0) [15]), and participation in society (assessed with the Utrecht Scale for Evaluation of Revalidation and Participation (USER-P), (three scales: frequency, restrictions, satisfaction) [16] after one year of follow-up.

Both register data and self-reported data were used to determine duration until sustainable RTW and rate of RTW in this study. Data regarding sustainable RTW in paid employment were obtained from SSA registries. In addition, data regarding sustainable RTW in therapeutic work were obtained from self-report, collected using online and paper questionnaires (depending on the participants' preference). Participants in the RCT were asked to complete extensive questionnaires at baseline (T0), after three (T1), six (T2), and 12 months (T3) follow-up.

Sample size and statistical analysis

The calculated sample size for this study was 130 participants, based on a power of $(1-\beta)=0.80$, a two-sided significance level of 0.05 (α). We aimed to include 164 participants, as we anticipated a 20% loss-to-follow-up rate during the study [13]. The entry of the self-reported data from the paper questionnaires was checked by performing a secondary data-entry of 5% of the paper questionnaires at each measurement point, i.e., T0, T1, T2 and T3. The maximum percentage of error allowed between the two data entries was 3%.

To verify the SSA-register data regarding duration until sustainable RTW in paid employment, we compared the register data with the self-reported data from the follow-up questionnaires. In case of conflicts between the register data and self-reported data, the register data were considered valid. Duration until sustainable RTW in therapeutic work was determined based on the self-reported data, as this type of employment is not registered at the SSA. In case that multiple dates of therapeutic work were reported by the participant, the date reported in the first follow-up questionnaire was used, in order to minimize recall bias. In this study, RTW in both paid employment and therapeutic work were considered as sustainable RTW. Therefore, one variable was computed based on the participants' inclusion date in the study and the first date of sustainable RTW, i.e., 'duration until sustainable RTW'. Also, this variable was used to calculate the rate of RTW in the

intervention and control group. Further, scores on validated questionnaires for non-RTW outcome measures and parameters, e.g., fatigue, quality of life, and participation in society, were calculated according to the required algorithms. No measures of imputation were used.

Descriptive analyses, t-tests and χ^2 -tests were used to describe potential differences in characteristics between the intervention and control group. All p-values reported are the results of two-sided tests. The primary outcome measure, i.e., duration until sustainable RTW, was first assessed using Kaplan-Meier estimators and the log rank test. Second, Cox regression analysis was used to estimate hazard ratios (HRs) for duration until sustainable RTW. All analyses were performed according to the intention-to-treat principle, and carried out on the level of the individual. Additionally, the per-protocol principle was applied in two separate analyses, to correct for participants in the intervention group who did not receive the intervention as intended. In the first per-protocol analysis, all persons in the intervention group who did not actually start with the RTW program were removed from analysis. In the second per-protocol analysis, all persons in the intervention group who did not receive the intervention according to protocol were removed from analysis, based on the results of a previously conducted process evaluation alongside the RCT (unpub. obs.).

The following confounders were taken into account in the analyses: age, gender, level of education, marital status, ethnicity, time between date of cancer diagnosis and inclusion in the study, and time between first day of sick leave and inclusion in the study. Also, we evaluated if significant differences in baseline characteristics between the intervention group and control group were confounders in the Cox regression analysis. The crude Cox regression model only contained the main variables of interest: duration until sustainable RTW and intervention/control group. An adjusted model was constructed by entering potential confounding variables, using a forward entry selection method. The cutoff point for relevant confounding was set at >10% change in the regression coefficient for the dependent variable, with a p-value of 0.1. Further, we evaluated effect modification by the strata in which participants were categorized, i.e., type of previous employment contract, by including interaction terms (and their corresponding main effects) into the model. In these analyses, the strata of CSs with a previous temporary contract and temporary agency contract were combined, as there were only a few participants (N = 11) with a temporary agency contract. It was tested whether the coefficient of the interaction term was significantly different from zero, at a p-value level of 0.05. Regardless of any significant confounding or effect modification, the final model was adjusted for age, gender and level of education to facilitate comparison with other studies.

Finally, regarding the secondary outcome measures, rate of RTW between the intervention and the control group was compared using a χ^2 -test. All other secondary outcome measures, i.e., fatigue, quality of life and participation in society, were analyzed using linear regression analyses and

adjusted for age, gender and level of education. SPSS 22.0 was used to perform the analyses [17].

Results

Recruitment and study population

In total, 2757 CSs were invited to participate in the study from April 2013 to January 2015. Of them, 786 survivors were interested in participation, of whom 474 met the inclusion criteria, based on the screening questionnaire. These 474 CSs were contacted by telephone, of whom 171 were eventually included in the study (Figure 2). Of these, 85 participants were randomly assigned to the tailored RTW program and 86 participants were assigned to the control group. No medical contra-indications for any of the participants were reported by their general physicians.

Also, 715 survivors responded to the initial invitation by returning the postcard. Of these, 647 declined to participate for various reasons. The remaining 68 CSs who returned a postcard, had indicated that they were interested to participate, but not at that particular point in time. These CSs received another invitation to participate in the study at the date they had indicated on the postcard. The postcard data were part of an extensive study on factors and motives associated with (non-)participation, which was published separately [18].

The mean age of the participants was 48.4 years (SD 8.6). The majority was female (69%), had children (66%), and had the Dutch nationality (95%). More than half of the participants were the principal wage earner of the household (56%). Breast cancer was the most common diagnosis in this study population (40%). On average, CSs had worked for 24.1 years (SD 10.1) before being diagnosed with cancer. The majority of participants had a clear intention to RTW at baseline (71%) (Table 1). The final questionnaires from participants were collected in March 2016.

Duration until sustainable RTW

During follow-up, 39 (22.8%) of the 171 included CSs sustainably returned to work. Of these, 21 participated in the intervention group, and 18 in the control group. In Figure 3, the Kaplan-Meier curves for duration to sustainable RTW are presented. The log rank test revealed no significant differences between the curves of the intervention group and the control group ($p = 0.642$).

The results of the Cox regression analyses are presented in Table 2. The analyses showed a crude HR for duration until sustainable RTW of 0.86 for the intervention group, compared to the control group. This indicates that participants in the intervention group took more time to sustainably RTW compared to participants in the control group, but this difference was not statistically significant [$p = 0.642$, 95% confidence interval (CI) 0.46–1.62]. Age, as well as baseline differences between the groups in levels of fatigue and CSs' active contemplation of RTW, proved to be relevant confounders in the analysis. When adjusting the model for these confounders, the intervention group had sustainably returned

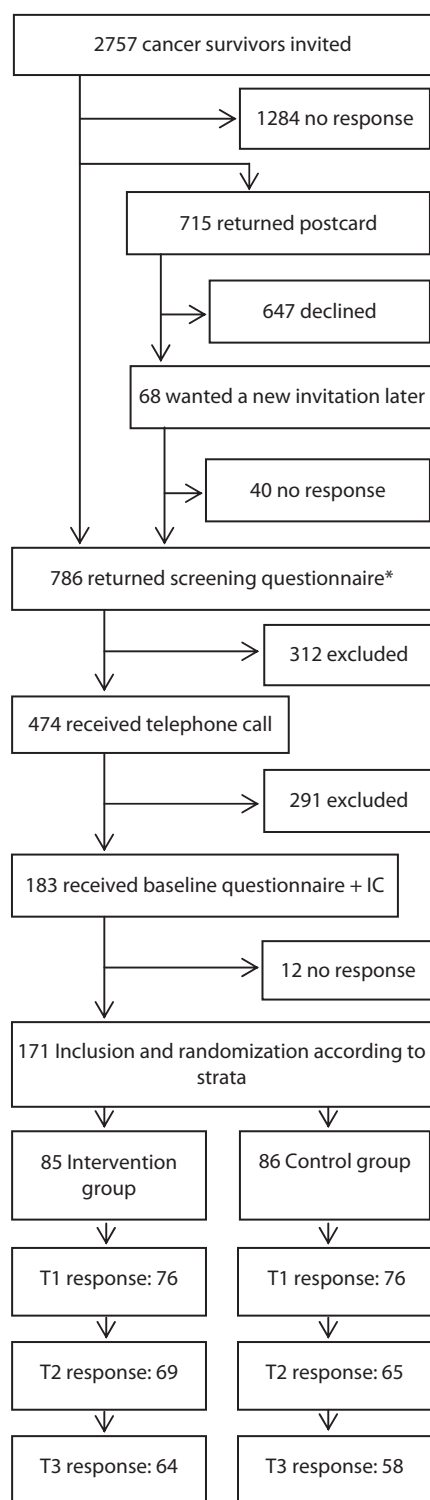


Figure 2. Participant recruitment flow diagram.

*786 CSs returned the screening questionnaire: 758 CSs returned the questionnaire after receiving the invitation, and 28 CSs returned it later on, after receiving another invitation by their own request.

to work earlier than the control group (HR 1.11; 95% CI 0.57–2.19), although this effect was far from statistically significant ($p = 0.754$). The final model was corrected for age, fatigue, active contemplation of RTW, and additionally for gender and level of education (Table 2). We found no effect modification by stratum, i.e., type of employment contract prior to job loss ($p = 0.390$).

The first per-protocol analysis, which included the control group and participants in the intervention group who had actually started participation in the program, revealed a crude HR of 0.75 (95% CI 0.38–1.47; $p = 0.401$). Adjusted for age, gender, fatigue, active contemplation of RTW, and level of education, the HR was 1.02 (95% CI 0.49–2.12; $p = 0.958$). In the second per-protocol analysis, which included the control group and participants in the intervention group who had received the whole intervention according to protocol, the crude HR was 1.32 (95% CI 0.65–2.68; $p = 0.444$), and the adjusted HR was 1.49 (95% CI 0.70–3.17; $p = 0.302$) (Figure 4). The per-protocol analyses thus revealed that participants, who received the intervention program according to protocol, had a statistically non-significant improvement in duration until sustainable RTW compared to participants in the control group.

Effect of the intervention program on rate of RTW, health-related outcomes and participation

Regarding rate of RTW, we found no significant difference in the proportion of CSs that returned to work in the control and the intervention group after one year of follow-up ($p = 0.613$). Further, the linear regression analyses showed that there were no statistically significant differences between the intervention and control group with regard to fatigue ($p = 0.538$), quality of life ($p = 0.940$), and participation in society [i.e., frequency, restrictions, and satisfaction (p -values ranged from 0.130 to 0.953)] (Table 3).

Discussion

Main findings

The hypothesis that was tested in this study was that offering a tailored return to work program to CSs with job loss would lead to a significant improvement in duration until RTW in these CSs, compared to the usual care provided by the SSA. The main finding of this study is that this hypothesis is false, i.e., we found no significant differences in duration until sustainable RTW between CSs with job loss in the intervention group, who received the tailored RTW program, and those in the control group, who received usual care. Further, there were no significant differences regarding the secondary outcome measures, i.e., rate of RTW, fatigue, quality of life, and participation in society.

Interpretation of findings

The present study offered a multidisciplinary intervention program to CSs with job loss, but found no statistically significant effect on duration until sustainable RTW. A process evaluation conducted alongside the present RCT showed that the RTW program was only moderately implemented, and that less than half of the participants in the intervention group received the program according to protocol (unpub. obs.). As the per-protocol analyses showed that CSs who had received the intervention program according to protocol had

Table 1. Characteristics of the study population.

Variable	Categories	Participants (N = 171)	Intervention group (N = 85)	Control group (N = 86)	p-Value*	
		Mean (SD)	Mean (SD)	Mean (SD)		
Age in years		48.4 (8.6)	47.9 (8.5)	48.8 (8.7)	0.492	
Total number of years working		24.1 (10.1)	23.5 (10.1)	24.6 (10.2)	0.502	
Gender		N (%)†	N (%)†	N (%)†	0.438	
	Male	53 (31.0)	24 (28.2)	29 (33.7)		
	Female	118 (69.0)	61 (71.8)	57 (66.3)		
Type of contract before sick leave					0.825	
	Temporary contract or temporary agency work	96 (56.1)	47 (55.3)	49 (57.0)		
	No contract (unemployed)	75 (43.9)	38 (44.7)	37 (43.0)		
Level of education					0.198	
	None/primary/lower vocational education	30 (17.5)	12 (14.1)	18 (20.9)		
	Secondary school	28 (16.4)	18 (21.2)	10 (11.6)		
	Vocational education/upper secondary school	60 (35.1)	32 (37.6)	28 (32.6)		
	Upper vocational education/university	53 (31.0)	23 (27.1)	30 (34.9)		
Principal wage earner					0.536	
	No	74 (43.3)	39 (45.9)	35 (41.2)		
	Yes	96 (56.1)	46 (54.1)	50 (58.8)		
Marital status					0.776	
	Living alone	36 (21.1)	17 (20.5)	19 (22.1)		
	Married	81 (47.4)	43 (51.8)	38 (44.2)		
	Living together	28 (16.4)	12 (14.5)	16 (18.6)		
	Divorced/widowed	24 (14.0)	11 (13.3)	13 (15.1)		
Having children					0.829	
	No	59 (34.5)	30 (35.3)	29 (33.7)		
	Yes	112 (65.5)	55 (64.7)	57 (66.3)		
Ethnicity					0.004	
	Dutch	163 (95.3)	77 (90.6)	86 (100)		
	Non-Dutch	8 (4.7)	8 (9.4)	0 (0.0)		
Tumor type					0.235	
	Breast	68 (39.8)	30 (44.1)	38 (55.9)		
	Lung	3 (1.8)	1 (33.3)	2 (66.7)		
	Gynecological	7 (4.1)	4 (57.1)	3 (42.9)		
	Colon	13 (7.6)	10 (76.9)	3 (23.1)		
	Gastro-intestinal	10 (5.8)	6 (60.0)	4 (40.0)		
	Head and neck	8 (4.7)	2 (25.0)	6 (75.0)		
	Prostate	3 (1.8)	2 (66.7)	1 (33.3)		
	Hematological	23 (13.5)	12 (52.5)	11 (47.8)		
	Brain	8 (4.7)	1 (12.5)	7 (87.5)		
	Other type of cancer	24 (14.0)	14 (58.3)	10 (41.7)		
	Cancer recurrence	4 (2.3)	3 (75.0)	1 (25.0)		
		No treatment	2 (1.2)	2 (100.0)		0 (0.0)
		Surgery	124 (72.5)	64 (51.6)		60 (48.4)
	Radiotherapy	84 (49.1)	32 (38.1)	52 (61.9)		
	Chemotherapy	109 (63.7)	52 (47.7)	57 (52.3)		
	Hormone therapy	47 (27.5)	19 (40.4)	28 (59.6)		
	Immunotherapy	13 (7.6)	8 (61.5)	5 (38.5)		
	Other type of treatment	13 (7.6)	7 (53.8)	6 (46.2)		
Type of previous employment contract					0.995	
	Fixed employment	49 (29.3)	25 (51.0)	24 (49.0)		
	Temporary employment	95 (56.9)	47 (49.5)	48 (50.5)		
	Temporary agency work	21 (12.6)	10 (47.6)	11 (52.4)		
	Other type of contract	2 (1.2)	1 (50.0)	1 (50.0)		
Intention to RTW					0.646	
	Uncertain or no intention to RTW	49 (28.7)	23 (46.9)	26 (53.1)		
	Clear intention to RTW	122 (71.3)	62 (50.8)	60 (49.2)		
Fatigue Health-related quality of life (levels of functioning)					0.017	
	(0–52)	33.0 (9.8)	31.2 (9.6)	34.8 (9.8)		
	Quality of life (0–100)	63.7 (17.3)	63.9 (18.1)	63.6 (16.6)		
	Physical functioning (0–100)	78.8 (14.8)	77.6 (15.1)	80.0 (14.5)		
	Emotional functioning (0–100)	64.1 (25.0)	64.4 (23.7)	63.9 (26.4)		
	Social functioning (0–100)	69.0 (26.0)	68.8 (27.4)	69.2 (24.6)		
	Cognitive functioning (0–100)	66.5 (26.9)	66.3 (25.3)	66.7 (28.5)		
	Role functioning (0–100)	63.1 (26.4)	63.5 (27.5)	62.6 (25.4)		
	Sleeping problems (0–100)	37.8 (33.8)	41.2 (33.4)	33.7 (33.9)		
	Financial problems (0–100)	40.6 (35.6)	42.4 (38.3)	38.8 (32.9)		
Participation in daily activities					0.156	
	Frequency of participation (0–100)	32.1 (8.2)	31.2 (9.0)	32.9 (7.3)		
	Restrictions in participation (0–100)	81.8 (13.8)	80.2 (14.8)	83.3 (12.6)		
	Satisfaction with participation (0–100)	63.5 (15.2)	63.5 (15.1)	63.5 (15.4)	0.994	

*p-Values are the result of t-tests and χ^2 -tests comparing the intervention and control group;

†N and calculated percentages may approach or exceed the total N and 100% because of missing values or rounding differences.

sustainably returned to work faster than the control group, although not statistically significant, it could be that implementation failure in this study contributed to the lack of significant results regarding the effectiveness of the RTW program. When comparing our results to other studies, a recent Cochrane review showed that, so far, there is moderate, but conflicting evidence that multidisciplinary interventions for CSs have a positive effect on RTW [19]. That is, a few studies in that review found a significant effect on RTW, while other studies found no effect at all. To illustrate, a study in 1983 by Maguire et al. (1983) offered a multidisciplinary program to CSs, and found significant improvement with regard to RTW [20]. Also, Van Waart et al. (2015) found a significant effect of two physical activity programs on the rate of RTW, compared to usual care in breast cancer patients receiving adjuvant chemotherapy, although RTW was not the main outcome of that study, and the study was not aimed at CSs with job loss [21]. In contrast, in other studies no effect of interventions programs on RTW was found. For instance, a recent study by Tamminga et al. (2013), which offered a hospital-based vocational intervention program to CSs,

demonstrated no effect of the intervention program on RTW compared to usual care [22]. It should be mentioned that previous studies were not aimed at CSs with job loss.

Furthermore, in studies conducted in sick-listed workers with job loss, suffering from a different health condition than cancer, the evidence regarding the effectiveness of RTW programs also seems contradictory. To illustrate, a recent study by Audhoe et al. (2016) found no effect of a multidisciplinary intervention on RTW or other work-related outcomes, such as worker participation, in sick-listed workers with psychological problems, who experienced job loss (unpub. obs.). In contrast, in a study by Vermeulen et al. (2011), in which a stepped-care participatory RTW program was offered to sick-listed workers with musculoskeletal disorders who experienced job loss, a significant effect on RTW was detected [23]. Overall, it may be concluded that there is a general lack of convincing evidence of RTW interventions in sick-listed workers who experienced job loss, both those with cancer and those with another health condition.

Further, the number of CSs that returned to work in the present study was only 22.8%. Across earlier studies in CSs, although not specifically in those with job loss, the rate of RTW was approximately 62% at one-year post diagnosis, 73% at one-and-a-half years after diagnosis and 89% at two-years post diagnosis [6]. It seems that the rate of RTW in the present study was quite low, especially given the fact that CSs in this study were already one year on sick leave at baseline. First, it should be considered that the population in the present study may have suffered from health problems that hindered their RTW. That is, CSs in this study could only participate if they received sickness or disability benefits at baseline, indicating the presence of health problems and/or disabilities in these survivors. In fact, many survivors in the present study, i.e., those who were on sick leave for 12 months, had been reevaluated for sickness benefits just before study entry. In addition, the process evaluation conducted alongside the RCT confirmed that health problems were an important reason for CSs to drop out of the intervention program (unpub. obs.). Overall, it is therefore likely that CSs in this study were suffering from health problems that may have reduced their ability to (return to) work, which

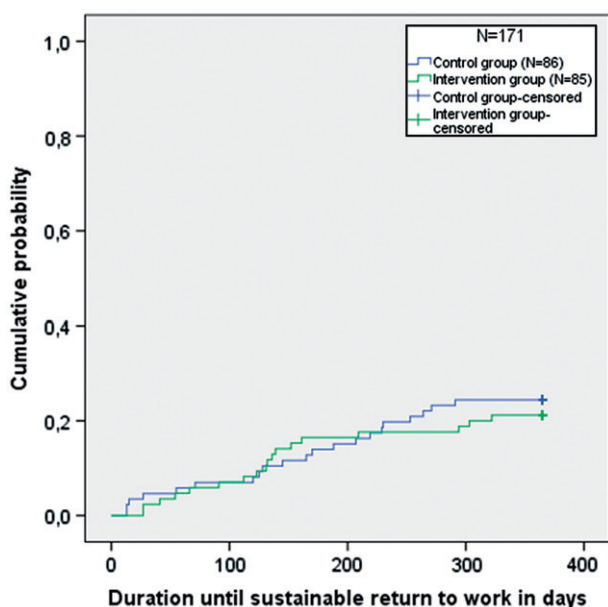


Figure 3. Kaplan-Meier curves for duration until sustainable RTW, intention-to-treat analysis.

Table 2. Results from the Cox regression analysis for duration until sustainable RTW (N = 171).

	Crude model			Adjusted model			Final model		
	HR	95% CI	p†	HR	95% CI	p†	HR	95% CI	p†
Intervention group‡	0.86	0.46–1.62	0.642	1.11	0.57–2.19	0.754	1.16	0.59–2.31	0.663
Age				0.92	0.89–0.95	<0.001	0.93	0.90–0.96	<0.001
Fatigue				1.05	1.01–1.08	0.009	1.05	1.01–1.08	0.007
Readiness to RTW contemplation phase				0.84	0.72–0.98	0.028	0.85	0.72–0.99	0.042
Gender							0.63	0.30–1.36	0.633
Level of education**									
Secondary school							0.51	0.12–2.14	0.359
Vocational education/upper secondary school							1.31	0.50–3.47	0.582
Upper vocational education/university							0.86	0.29–2.53	0.787

HR: hazard ratio.

†p-Value;

‡compared to the control group;

**compared to the reference group 'none/primary/lower vocational education'.

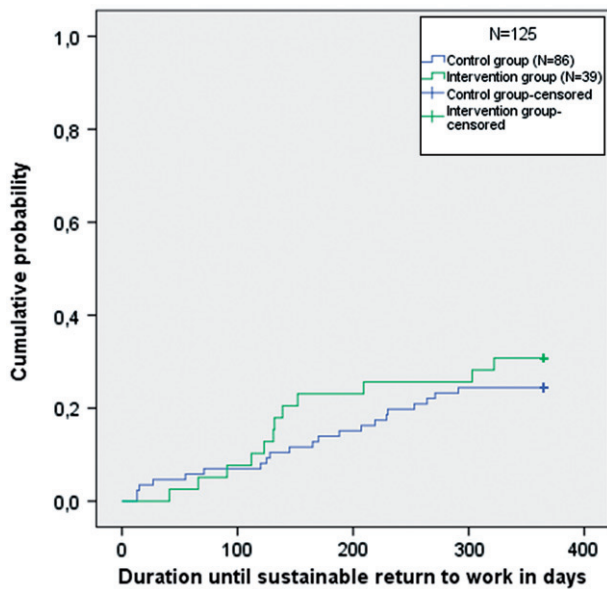


Figure 4. Kaplan-Meier curves for duration until sustainable RTW, per-protocol analysis.

Table 3. Results of the analyses on secondary outcome measures* (N = 122).

Secondary outcome measure	Beta	95% CI	p†
Fatigue	-1.253	-5.275–2.770	0.538
Quality of life	0.284	-7.117–7.684	0.940
Frequency of participation	-2.591	-5.961–0.778	0.130
Restrictions in participation	0.718	-4.695–6.131	0.793
Satisfaction with participation	0.194	-6.308–6.696	0.953

*Results for the intervention group compared to the control group, adjusted for age, gender, and level of education; †p-value.

may partly explain the low rate of RTW in the present study, compared to other studies among CSs.

Other explanations for the discrepancy in RTW rates between our study and other studies with CSs on sick leave are that previous experimental studies mostly included CSs who still had an employer [19]. As workplace- and employer-related factors, such as workplace accommodation and support from the workplace, are strongly associated with positive RTW outcomes [24], higher RTW rates may be more likely for populations of CSs with an employer, compared to a population of CSs with job loss. It should also be recognized that during the study period there was an economic recession in Europe and in the Netherlands [25], which is likely to have contributed to the low RTW rate in the present study.

Finally, the present study showed no effect of the tailored RTW program on fatigue, quality of life, and participation in society. In other RTW studies for CSs, although not specifically for CSs with job loss, the findings on health-related outcomes are, at best, ambiguous. That is, the study by Tamminga et al. (2013) found no significant effect of their RTW program on quality of life [22]. However, the study by Van Waart et al. (2015) showed improvements in physical functioning and reduction of symptoms, such as fatigue [21]. However, it should be considered that this study offered a program that was primarily aimed at improving physical fitness, and not RTW, which may make it more likely to find an

effect on physical outcomes compared to studies that have RTW as a primary aim. In conclusion, it seems that multidisciplinary intervention programs for CSs, both those with and without job loss, show conflicting results regarding RTW outcomes, as well as regarding health-related outcomes.

Strengths and limitations

The strengths of this study are that the tailored RTW program was offered in a nation-wide randomized controlled setting, and that the analysis of the primary outcome measure was based on 100% complete follow-up data, as both register data and self-reported data were used. Also, the calculated sample size required for this study was 131, and eventually 171 participants were included in the study. There are also several limitations to this study. First, only a small portion, i.e., 6% of the invited CSs eventually participated in the study. Therefore, selection bias is a real probability in this study, which limits the generalizability of our results. Another limitation is that we did not measure whether or not participants in the control group received comparable interventions as part of their usual care. Finally, our results should be interpreted in the context of a national social security system. Translation of these results to countries with a different social security context should be done cautiously.

Implications for research and practice

This study provides several key points for researchers and practitioners who are involved in the RTW process of CSs with job loss. First, given the lack of conclusive evidence of the effectiveness of RTW programs in populations of sick-listed workers with job loss, it would be worthwhile for future researchers to identify potential causes of theory, program and/or implementation failure in previous RTW studies. Specifically, researchers could compare the results of previously conducted experimental and observational RTW studies, as well as process evaluations conducted alongside previous RCTs for workers with job loss, suffering from cancer or other health conditions. Comparing studies conducted in workers within a social security context may provide new insights into potential theory and implementation failure of RTW interventions for workers who experienced job loss. This could lay the groundwork for improvements in future interventions to support RTW in workers with job loss, with cancer or with another health condition. Further, we recommend a critical evaluation of implementation methods of future intervention programs in complex settings. Specifically, procedures regarding communication and cooperation between the stakeholders involved in intervention studies for workers with job loss, such as a SSA, healthcare professionals, (future) employers, re-integration agencies and job hunting agencies, should be discussed and agreed upon before the start of an intervention program. In addition, for future studies offering RTW interventions to sick-listed workers with job loss, it would be beneficial to conduct a pilot study and/or to include a test phase in a RCT, in order to facilitate proper implementation on a larger scale later on. Practitioners could potentially be consulted in order to enhance

implementation strategies for future programs, in order to bridge the gap between research and daily practice.

Conclusion

The tailored RTW program for CSs with job loss that was offered in this study did not result in a significant improvement in duration until sustainable RTW, compared to usual care. Considering that the number of CSs with job loss is expected to increase in the future, it is essential to identify new methods of work support for these survivors. As there is still inconclusive evidence with regard to the effectiveness of current RTW programs for CSs with job loss, and for workers with other health conditions who experienced job loss, it is important to gain more knowledge on suitable intervention strategies for these populations of workers.

Acknowledgments

The authors would like to extend their gratitude to the participants in this study, to the Dutch Research Center for Insurance Medicine for funding this study, and to Re-turn, Agens and Olympia, for delivering the tailored RTW program in this study. Further, we thank K. Bonefaas-Groenewoud, A.P.J. Scholten and J. Overvliet for their contribution to this study.

Disclosure statement

The authors declare that they have no conflict of interest.

Funding

This study was supported by a grant from the Dutch Social Security Agency.

Research involving human participants

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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