Intervention to support return to work in sick-listed employees with cancer: a randomized controlled trial.

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The primary objective of this research is to obtain insight in de (cost-)efficiency of a multidisciplinary intervention focused on the improvement of return to work after sick leave of employees with cancer. Specific research questions are:- Does...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON46377

Source
ToetsingOnline

Brief title
Return to work in employees with cancer.

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Cancer, oncology

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: A Health Impact Bond aimed at job resumption among (former)cancer patients.,Amersfoortse/ASR insurance and ABN AMRO are

funding the intervention costs.

Intervention

Keyword: Cancer, Employees, Randomized, Return to work

Outcome measures

Primary outcome

The most important outcome measures of the effect study are time to return to work and quality of life. Return to work will be logged in the systems of ArboNed. In the systems of ArboNed, the registration of sickness and recovery is a dichotomous outcome measure: an employee is (partially) absent, or is completely returned to work. When an employee changes his contract during the period of absence (for example working fewer hours), this will be registered in the system.

Health related quality of life will be measured using the EuroQol 5D scale, developed by the EuroQol group (EQ-5D). The EQ-5D consists of 5 scales; Mobility, Self-care, Usual activity, Pain/Discomfort and Anxiety/Depression and a 100-point visual analogue scale. The five items cover mobility, self-care, usual activities, pain/discomfort, and anxiety/depression with three levels per item (i.e., no problem, some problems, and extreme problems). The EQ-5D is a generic instrument and has been used in cancer research in circa 200 studies.

Secondary outcome

Besides these outcome measures, some secondary outcomes will be taken into consideration. Among these are outcomes concerning the most common complaints among employees with cancer like fatigue and memory problems. We will also take

some predictive factors into consideration. For this validated questionnaires that are found appropriate for this target group and are mentioned in the guideline Cancer and work, will be used. The concepts we will be measuring are:

- Fatigue will be assessed using the Multidimensionele Vermoeidheids Index (MVI). This 20-item questionnaire is recommended in the Guideline Cancer and Work (Richtlijn Kanker en Werk).
- Expectations and experiences regarding return to work will be assessed using the Return-to-work self-efficacy questionnaire (RTWSE-10).
- Cognitive problems will be assessed using the Cognitieve symptomen checklist * work (CSC-W DV). This 21-item questionnaire is recommended in the guideline Cancer and Work Richtlijn Kanker en Werk.
- Psychological problems using the Four Dimensional Symptom Questionnaire (4DSQ).
- Data regarding healthcare costs and additional expenses will be gathered using the TIC-P questionnaire44. This questionnaire is frequently used in experimental studies to calculate the benefits of interventions and compare them to the cost of the intervention (cost-effectiveness analysis).
- Work ability will be measured using one item from the Work Ability Index .

All data about the obtaining of work and return to work will be collected through files from ArboNed at the end of the research period. All other data will be collected by questionnaires (self-reporting by the participant). This data is digitally available through the questionnaire system of ArboNed. For

participants who are unable to complete digital questionnaires, the questionnaire will be offered through telephone interviews.

Data from EuroQol and the TIC-P questionnaires can be used to perform a cost-effectiveness analysis. This will be done in a later stage of the study, if a significant effect of the intervention is found.

In addition, data about general socio-demographical characteristics, history and progression of illness and type of operation will be collected. Furthermore, a possible assessment of occupational disability (at the moment in the Netherlands after 104 week) or loss of work (for example because of the termination of a temporary contract). These factors will be included in the collection of data.

Finally, by means of short questionnnaires that consist of six items, we will measure participants* quality of life and satisfaction with the program after each session of the intervention program.

Study description

Background summary

A substantial part of the cancer patients in the Netherlands (65%) stops working partially orf completely after being diagnosed with cancer. This is mainly caused by long and/or intensive treatment and the associated residual complaints like fatigue and cognitive problems. The average leave of absence of cancer patients worldwide is 151 days. Often a distance arises during the absence period between the employee with cancer and the workplace, the employer

and the colleagues. The longer employees stay away from the workplace, the smaller the chance is that they will return to work at all. About six months after receiving the diagnosis 40% of the patients have returned to work, after eighteen months the percentage has gone up to 73%. The distance from the workplace, combined with the changing work abilities after cancer can impede return to work. This is a large scale issue in the Netherlands; approximately 225.000 people of the working age (18-65) are living with cancer. Within this group there are 40.000 new cancer diagnoses every year. Because of the flexibilization of the labor market and the increase of the retirement age, chances of employees with cancer to return to work are getting smaller. A lot of cancer patients are very motivated to work, therefore it is necessary to improve the return to work process of employees with cancer.

To achieve successful return to work, enhancement of the collaboration between the different actors in the system around the patient is crucial. These actors are especially: the employer, the occupational physician and the medical specialist. There is a presumption that the current communication between employer, occupational physician and the medical specialist is fragmented or missing at all during the course of treatment. We also know that the interventions that were executed in the past were not much focused on involving all the different actors. The professionals involved agree on the fact that a closer collaboration between the relevant actors involved in the return to work of an employee with cancer is necessary. However, there is a lack of scientific rationale or an intervention to stimulate this collaboration. In this study a new multidisciplinary intervention for return to work of employees with cancer is researched. The intervention consists of four parts: disease coping (a psychological process aimed at the coping with illness), SKILLS (the improvement of one*s personal efficacy and attitude toward work), resource management (making visible which social support sources are available to the employee) and a part on exercise. The intervention is overall focused on the connection between the work-related care and the regular healthcare and the improvement of the employability of an employee with the goal to have a successful return to work route. This study is relevant for employees with cancer, professionals like oncologists, general practitioners and occupational physicians, employers and insurance companies, investors and science.

Study objective

The primary objective of this research is to obtain insight in de (cost-)efficiency of a multidisciplinary intervention focused on the improvement of return to work after sick leave of employees with cancer.

Specific research questions are:
- Does the use of the intervention alongside the usual care of occupational care organization *ArboNed* lead to a significant improvement in a) the time until return to work and b) the quality of life of employees with cancer who are on sick leave, compared to the usual care?

- If there is a positive effect found, does it lead to cost efficiency?
- To what extent is there a positive effect on secondary outcome measures along which self-efficacy and quality of life?

Study design

In this study, a multidisciplinary intervention is added to the usual care of absenteeism, as provided by one of the major occupational care organizations in the Netherlands, which is ArboNed. We evaluate if the intervention leads to an improvement of workability and if it leads to a significant improvement of the time until return to work after absenteeism. When we find a positive effect of the intervention on workability and/or the time until return to work after absenteeism, we will analyse if this effect is also cost-effective. To research the (cost)efficacy of the intervention, we conduct a randomized control trial (RCT) among the research population *employees with cancer who are on sick leave and are being guided by ArboNed*.

SETTING
The study focuses on employees who are diagnosed with cancer, who are on sick leave and are therefore being guided by ArboNed. ArboNned, a large organization supplying work-related care in the Netherlands, has around 300 occupational physicians, divided in eighteen regional offices. About a hundred of these occupational physicians who work in de division *insured* are part of this study. All eighteen regional offices are part of this study, six of them in the control group and 12 in the intervention group.

In this study the intervention is offered to employees with cancer who are guided by one of the intervention regional offices of ArboNed. They receive the usual care as well. The results where it comes to absenteeism and return to work after absenteeism are being compared to a control group who receive only the usual care of ArboNed.

DURATION
After joining the study, participants are approximately two years part of the research group. In this period the participant will be asked to fill in three questionnaires.

Intervention

The multidisciplinary intervention is based on and fits in seamlessly with the recent authorized *Guideline cancer and work* (Richtlijn Kanker en Werk) from the Dutch union of occupational physicians (February 2017). The aim of the guideline is to *restrict unnecessary absence and inflow in disability benefits/arrangements* by *a better care for the employee with cancer* and to *increase the quality of life of the employee with cancer*. A core element of the new guideline is the *joint decision-making* with special attention for the

preference of patients. Furthermore, the occupational physicians use *stepped and matched care* within the care of an employee with cancer. This means that the employee is matched to specific interventions and aid workers bases on the severity and the clinical course of the complaints. The current intervention wants to structure and support the guideline. This means that in this intervention the occupational physician will guide the process of return to work at work and specialized aid workers will match the care. The stepped care intervention consists of the following steps:

DISEASE COPING: during this step the mental and emotional processing of having cancer is being watched. If necessary, an active intervention will take place.
RESTORATION OF CONFIDENCE: the confidence of employees with cancer toward re-integration and dealing with obstacles is being strengthened with help from the SKILLS-method
RESOURCE MANAGEMENT: in this phase * in which the employee with cancer is at work * the employee with cancer is being supported in the strengthening of his competences, autonomy and connectedness (Basic Needs).
EXERCISE: during the intervention the employee with cancer is actively stimulated to exercise with the intention to improve the physical condition as much as possible.

The course of the complaints and the illness are being followed and regularly measured during the intervention. By doing so the next step in the treatment algorithm (stepped care) can be taken in time. Following this method means both over- and undertreatment are prevented. The focus of this care from the occupational physician is mainly aimed at reducing fatigue and psychological and cognitive problems. This is because:
- Cancer related fatigue is an important symptom that forms an obstruction to return to work for employees diagnosed with cancer. The fatigue often becomes a chronical issue. For example, approximately 1/3 of the treated breast cancer patients suffer from fatigue, even though the prognoses to recovery is good. These complaints effect the quality of life, the daily functioning and the time it takes for someone to return to work.
- Cognitive problems often occur in employees with cancer who had to undergo chemotherapy (chemobrain/chemofog). Just like the fatigue, the cognitive problems can continue for a long time after treatment. Cognitive problems differ per type of cancer. Employees with a brain tumor suffer from cognitive problems in 90% of the cases, leukemia only causes cognitive problems in 20-30% of the cases and breast cancer approximately 75%.
- Psychological complaints in the form of anxiety and depression are factors that obstruct return to work and they are relatively common among employees with cancer. In a recent study about the prevalence of anxiety and depression in more than 10.000 patients with the diagnosis cancer appeared that 13% of the patients had clinical manifested depression and 19% of the patients had clinical manifested anxiety. The percentages subclinical manifested depression and anxiety were respectively 17% and 23%.

The intervention describes an innovative approach on return after work after absence as a consequence of cancer. Furthermore, this intervention is being adjusted to the different phases in curative and work-related care, i.e. the treatment-, recovery-, and re-integration phase.

The occupational physician plays the role of process consultant during the intervention. Besides that, the occupational physician will hold his regular consulting hours (which are also required by law) and he will have a multidisciplinary meeting at the end of the cancer treatment, which will be the beginning of returning to work. In the multidisciplinary meeting the employee with cancer, the manager, and the occupational physician will be present to discuss return to work. This session is repeated when the employee with cancer has been fully returned to work. The occupational physician will also consult the oncologist and they will exchange information. This happens at the beginning and at the end of the intervention.

The activities in the intervention are aimed at improving the workability and reducing fatigue, cognitive problems and psychological problems. The intervention consist of a maximum of six sessions disease coping* in which the *dual process model of coping can be used, a maximum of five sessions SKILLS and a maximum of six sessions *resource management* based on the self-determination theory of Deci & Ryan. Exercise will be a subject within every session.

DISEASE COPING
The disease coping module consist of a maximum of six sessions distributed across a maximum of 24 weeks. The aim of this module is to detect the development of depression and anxiety in an early stage of the cancer treatment and stop progression of depression and anxiety. When the first signals arise the *dual process of coping* by Stroebe and Schut is used, of course in agreement with the participant. In this method, there are two ways of coping with stress and loss. First there is the *loss-orientation*, in which coping is directly focused on the stress that arises because of the loss. Then there is the *restoration-orientation* which refers to the process in which someone tries to deal with the stress compared to a new role, identity or new tasks. This last orientation improves self-efficacy, self-confidence, independence and autonomy to arrange ones daily life in a good way. Besides that, this approach supports personal growth and the ability to learn new skills. This method is already being used for different types of grief and sadness, but it has not been used for cancer patients. The rationale of this method is that it not only teaches someone how to deal with the stress that is involved in (the treatment of) cancer, but also with aspects of loss and emotion regulation.

SKILLS
The intervention part SKILLS consists of a maximum of five session distributed across five weeks. This part is executed by the corporate social worker or a reintegration coach of Re-turn. This is decided by availability. The aim of

this part is to strengthen the confidence patients have in their return to work. Different studies in the field of work related (psychological) complaints and return to work show that trust in one*s own abilities is an important predictor for the speed of return to work. SKILLS is derived from a group approach for people with a distance to the labor market and has been applied to people seeking a job and people with a chronic condition. SKILLS is based on strengthening the confidence in one*s own abilities and dealing with setbacks. It is a very powerful and proven effective method, with long-term effects. The corporate social workers of ArboNed and the reintegration coaches of Re-turn are going to be trained in the SKILLS-protocol prior to the start of the study.

RESOURCE MANAGEMENT
The resource-management, i.e. the managing of resources in the form of Basic Needs Satisfaction is the third step off stepped care. This module is executed by Re-turn. The goal of this part of the intervention is to get employees with cancer more motivated to show healthy behavior and to persevere and expand work resumption. The Basic Need Satisfaction finds its scientific base in the Self Determination Theory by Deci & Ryan. This theory assumes that a behavioral change is more effective if patients (and therefore also employees with cancer) are more autonomously (intrinsically motivated. A meta-analysis on the application of this theory in healthcare has shown that when the psychological basic needs (competence, autonomy and relatedness) of a patient are more satisfied, the motivation to show healthy behavior (for example *working*) becomes stronger and more intrinsic.

EXERCISE
At this moment there is enough evidence that exercising has a positive effect on the quality of life of employees with cancer. Exercise reduces the fatigue that arises during and after the cancer treatment in an effective way. The most important goal of the intervention is to make sure that employees with cancer * when possible - exercise 150 minutes a week in a moderate to intensive way, distributed across 3-5 days a week. Exercising more does not seem to have an effect. Besides that, the fact that exercises based on yoga have a positive effect on the cognitive problems that can arise during the cancer treatment will be emphasized. The amount of exercise of a participant will be discussed briefly in every session.

All the sessions of the intervention will be held according to the Stress Inoculation Training method of Meichenbaum. The session begins with a conceptualization (which thoughts and experiences had an employee with cancer in certain situations), followed by discussing the right (coping) strategy to manage these thoughts and experiences. This strategy will be practiced and after that the session will be ended with an assignment for everyday life.

Study burden and risks

Participants in the control group receive usual care, and are asked to complete

three questionnaires in a two-year time period. Participants in the intervention group are also asked to complete three questionnaires and they receive usual care + the intervention. The intervention consists of 17 sessions of 1.5 hours each, offered in line with the treatment and recovery plan of the patient. The intervention components have been offered in previous settings before, but were not evaluated in scientific studies. No adverse effects are known to have come forth from these sessions. All in all, we consider the risks and burden for participants very low, particularly as many cancer patients are known to participate in additional courses or rehabilitation programs alongside usual care, with no adverse effects in general.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- be of the working age (18-65 years).
- be diagnosed with a form of cancer matching the CAS codes described below.
- have a permanent contract with an employer, or a temporary contract with an employer which will end at least six months after start of the study.
- good command of the Dutch language, orally and in writing.;CAS codes
A209: Other Neoplasm (non-specified)
B200: Hodgkin lymphoma
B201: Leukemia
B209: Malignancies of the hematopoetic and lymphoid tissues
E209: Endocrine gland neoplasm
L200: Bone metastases
L209: Bone neoplasm
L219: Neoplasm in muscle- and connective tissues
N209: Meninges neoplasm (brain tissue)
N210: Central nervous system malignancies
N219: Central nervous system neoplasms (e.g. benign tumours)
N229: Neoplasms in the autonomous and peripheral nervous system
R200: Malignancies in the lungs or in bronchial tissue
R209: Other neoplasms in the respiratory tract (non-specified)
S200: Malignancies in the gasrto-intestinal tract
S201: Liver metastasis
S209: Other neoplasms in the gastro-intestinal tract (non-specified)
U200: Kidney, bladder and urinary malignancies
U219: Neoplasms in the male reproductive system
U229: Neoplasms in the mammae

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Pregnancy.
- Severe comorbidities of physical or psychological nature that make participation from a medical perspective irresponsible (to judgement of the company doctor).
- matching one of the CAS codes described below.
- Already being signed up for a reintegration track at Re-turn or another intervention aimed at return to work at work (with an exception of recovery tracks being instated from the regular healthcare).
- Retirement within 24 months after reporting sick.
- The employee was already reported sick prior to an insurance agreement between the employer and the Amersfoorste Verzekeringen. ;CAS codes

A200: Kaposi sarcoma
C209: Non-specified neoplasms in the cardiovascular system
D200: Malignant melanoma
D201: Other malignancies in the skin and adnex (non-specified)
D209: Other neoplasms of the skin and adnex (non-specified)
H209: Ear and mastoïd neoplasms
U209: Other neoplasms in the kidney, bladder and urinary tract (non-specified)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2017
Enrollment:	211
Type:	Anticipated

Ethics review

Approved WMO Date:	12-02-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	30-05-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	18-03-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63659.028.17