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Can an early, tailored return to work management intervention focused on support to cancer patients undergoing treatment and their workplaces enhance the readiness for return to work and the return to work rate?

Submission date	**Recruitment status**	[_] Prospectively registered
08/08/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/08/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/03/2021	Cancer	

Plain English summary of protocol

Background and study aims

An increasing number of cancer survivors are of working age. Cancer is also a known cause of people withdrawing early from the labour market and also a prolonged absence from work due to sickness. Cancer survivors in lower socioeconomic groups (for example, people who do lower skilled jobs) and/or suffer from another disease (co-morbidity) are at particular risk of recurrent sickness absence, unemployment or permanent withdrawal from the labour market. Not being able to work to the same ability and unfavourable work conditions can also mean that cancer survivors of lower socioeconomic status and/or co-morbidity find returning to work more difficult. Support from supervisors and adjustments that make it possible for the cancer survivor to do their job more easily (work accommodations) may be important in preventing sickness relapses due to the job environment affecting their state of health. It is not known how important occupational rehabilitation during cancer treatment might be in helping cancer survivors return to work and, in particular, how it may help those patients of lower socioeconomic status and/or co-morbidity. This study aims to increase the likelihood of cancer survivors returning to work through a programme (intervention) of individual support offered by a job consultant connected to the oncology ward at Aarhus University Hospital.

Who can participate?

Cancer patients between 18 and 60 years of age who are living in Randers or Silkeborg municipalities in Denmark diagnosed with breast, gastro-intestinal, head and neck, testis, ovarian or cervix cancer and being treated with chemotherapy or radiotherapy. They must be permanently or temporary employed (with at least 6 months left of their contract) and possibly on sick leave.

What does the study involve?

Patients that meet the criteria for participating in the trial and living in either Randers or

Silkeborg municipalities in Denmark are placed in the intervention group. Patients that meet the criteria but live outside of these municipalities are placed in the control group. Those in the intervention group take part in an early, tailored return to work management programme that supports cancer patients as they are undergoing treatment. Those in the control group are offered the standard sick leave management programme. The return to work rates among cancer survivors in the intervention group is then compared to those in the control group. The effect of the intervention on cancer survivors of lower socioeconomic status and/or co-morbidity is also assessed.

What are the possible benefits and risks of participating?
The participants might experience psychological distress by being met with questions about work at an early stage of treatment. The intervention will not have any impact on the patients chemotherapy or radiotherapy. The participants can at all times throughout the intervention withdraw from the study.

Where is the study run from?
The patients are recruited from the Department of Oncology at the Aarhus University Hospital (Denmark), Municipal Job Centre in Silkeborg (Denmark) and the Municipal Job Centre in Randers (Denmark).

When is the study starting and how long is it expected to run for?
December 2013 to May 2015

Who is funding the study?
The Danish Cancer Society (Denmark)
The Foundation of Health Science in Central Denmark Region (Denmark)
The Health Foundation (Helsefonden) (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
In a controlled clinical trial it is studied if occupational rehabilitation of cancer patients initiated parallel to cancer treatment at the hospital enhances the readiness for return to work and the return to work rate?

Acronym
Can-Return

Study objectives
We hypothesise that an early, tailored occupational rehabilitation intervention conducted by a municipal job consultant parallel to cancer treatment at the oncology ward will increase the chance of an early return to work among cancer survivors from two municipalities compared with other cancer survivors not receiving this intervention but treated at the same hospital and receiving the standard municipal sick leave management.

Furthermore, we hypothesise that cancer survivors with low socioeconomic status and co-morbidity will benefit more from the intervention, i.e. increased chance of an early return to work, than cancer survivors having high socioeconomic status and not suffering from co-morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been notified to and registered by the Danish Data Protection Agency nr. 1-16-02-408-13. According to Danish law, questionnaire-based examinations and interview examinations shall not be notified to the Research Ethics Committee if the study does not include examination of human biological material or examination of individuals.

Primary study design
Interventional

Study design
Controlled trial conducted at a single-centre with a 12-month follow-up

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Eligible patients are newly diagnosed with breast, gastro-intestinal, head and neck, testis, ovarian or cervix cancer, and are referred to chemotherapy or radiotherapy.

Interventions
Intervention
The intervention is a new way of conducting municipal occupational rehabilitation.
The intervention aims at supporting and helping cancer patients to return to work (RTW) by a systematic assessment of the patients needs, actual resources and readiness for RTW.
The occupational rehabilitation is offered only to patients from either Randers or Silkeborg municipalities.
Two job consultants are specially trained in using elements of the Acceptance and Commitment

Therapy (ACT), the Individual Placement and Support Model (IPS), and the questionnaire Readiness for Return to Work-scale (R-RTW).
The ACT is a development of cognitive behaviour therapy, which is based on recognition of the persons values and immediate needs in the current life situation.

The goal of ACT is to increase psychological flexibility, which can be defined as the ability to contact the present moment more fully as a conscious human being, and to change or persist in behavior that support ones own values. Psychological flexibility is established through six core ACT processes: acceptance, cognitive fusion, being present, self as context, values, and committed action. Each of these areas is conceptualized as a positive psychological skill. The patients are in the dialogue with the job consultant confronted with these six core elements in order to enhance commitment and behavior change towards RTW.

The IPS is a way to systematize the actions by which the job consultant supports RTW. The model originates from helping people with severe illness to gain employment, and builds on the following key elements: integration at the workplace, paid work, individualized services, and a wide variety of ongoing support for each person. This variety of support is operationalised in a number of phases. These IPS-phases correspond to the score obtained from the R-RTW questionnaire.
The score from the R-RTW questionnaire define the phase in which the patient perceive him-/herself to be: pre-contemplation, contemplation, preparation, action, insecure maintenance, and proactive maintenance.
Hence, the use of a dialogue inspired by ACT and a systematic assessment integrated in the IPS are the tools by which the job consultant supports the patients RTW-process. Through the IPS-phases the rehabilitation plan is adjusted to patients needs, actual resources and readiness for RTW.
ACT and IPS are used throughout the intervention, which continues for one year or until RTW. Intervention includes the patients willingness to involve next of kin, work place, employer, and colleagues.

At the first meeting with the job consultant the cancer patient answers a questionnaire containing items regarding resources, co-morbidity, work ability, self-efficacy, support at work, and R-RTW.

The questions about resources have dichotomized response categories (yes or no):
Are you married?, Do you have children?, Are you pre-graduate or more/have a higher education, >3 years?, Are you employed?, Last year personal income before taxation >250.000 Dkr?, Are you white-collar or self-employed?, Are you a manager?, Do you own your home/residence?, Is Danish your native language?.

Questions about co-morbidity have four response categories (no/never, yes/present, yes /previously, if previously yes - do you have any late complications?):
Asthma, allergies, diabetes, hypertension, coronary thrombosis, angina, cerebral thrombosis, chronic obstructive pulmonary disease, osteoarthritis, arthritis, osteoporosis, cancer, migraine, minor psychiatric disorder, major psychiatric disorder, herniated disc or other back disorders, cataract, tinnitus.

One question about self-perceived work ability is answered on a 10-point scale from 1 (least chance) to 10 (highest chance):
Do you expect to have any work ability in 6 months?

Six questions about self-efficacy with four response categories (fits perfectly, fits quite well, fits a little bit, does not fit at all):
I am always able to solve difficult problems, if I try hard enough, If people work against me, I find a way of achieving what I want, It is easy for me to stick to my plans and reach my objectives, I feel confident that I can handle unexpected events, I keep calm when there are problems, as I trust in my ability to solve them, When I have a problem, I can usually find several ways of solving it, Regardless of what happens, I usually manage.

Six questions about support at work with five response categories (always, often, sometimes, seldom, never, hardly ever):
How often do you get help and support from your colleagues?. How often are your colleagues willing to listen to your problems at work?, How often do your colleagues talk with you about how well you carry out your work?
How often is your nearest superior willing to listen to your problems at work?, How often do you get help and support from your nearest superior?, How often does your nearest superior talk with you about how well you carry out your work?

Questions about readiness to return to work with five response categories (strongly disagree, disagree, neither disagree nor agree, agree, strongly agree):
Are you currently back at work? (yes/no)

For those not back at work
1. You do not think you will ever be able to go back to work
2. You have been making plans with someone from your workplace to return back to work
3. You have been thinking about making some changes that will help you go back to work
4. As far as you are concerned there is no point in thinking about returning to work
5. You have learned different ways to cope with your pain so you can return to work
6. You are actively doing things now to get back to work
7. You think you might be ready to go back to work
8. You are planning to go back to work, even if your pain is not 100% gone
9. Physically, you are starting to feel ready to go back to work
10. You have been increasing your activities at home in order to build up your strength to go back to work
11. You are getting help from others to return to work
12. You are not ready to go back to work
13. You have found strategies to make your work manageable so you can return to work
14. Mentally, you are starting to feel ready to go back to work
15. You have been wondering if there is something you could do to return to work
16. You worry about having to stop working again due to your injury
17. You have started thinking about going back to work
18. You have a date for your first day back at work
19.You wonder if you will be able to go back to work
20. You wish you had more ideas about how to get back to work
21. You would like to have some advice about how to go back to work
22. As far as you are concerned, you do not need to go back to work ever

For those back at work
1. You are trying different strategies to stay at work
2. You are doing everything you can to stay at work
3. You are getting help from others to stay at work
4. You are working hard to find ways to cope with the difficulties of being back at work
5. You have learned different ways to cope with your pain so that you can stay at work

6. You are taking steps to prevent having to go off job again due to your injury
7. You have found strategies to make your work manageable so you can stay at work
8. You are back at work but are not sure you can keep up the effort
9. You worry about having to stop working again due to your injury
10. You still find yourself struggling to stay at work due to the effects of your injury
11. You are back at work and it is going well
12. You feel you may need help in order to stay at work

Control
The control group is defined by patients with identical inclusion criteria as for the intervention group except that they live in other municipalities than Silkeborg and Randers. The control group is identified via the electronic patient records at the Aarhus University Hospital. The control group is offered the standard sick leave management within their municipal of residence. The municipal jobcentres in Denmark are responsible for paying sickness benefits and initiating occupational/vocational rehabilitation to help sick-listed persons to RTW. All employed, self-employed, temporarily employed and unemployed persons fulfilling the criteria of previous employment (120 hours within a period of 13 weeks) are eligible for sickness benefits. According to law, the employer pays sickness benefits during the first 4 weeks, afterwards the municipality refunds the employers wage expenses for a maximum of 52 weeks, within a period of 78 weeks. Medical certificates are not mandatory but can be requested by the municipal social security system and the employer. By law, the municipal sickness benefit officers at the jobcentres are obliged to conduct an interview with all sickness beneficiaries by the end of the 8th week of the sickness absence period and to assign the sick-listed into three categories. Category 1 includes persons who are likely to RTW within three months without intervention; category 2 includes persons who are unlikely to RTW within three months, but able to participate in activities facilitating RTW, like graded RTW. Category 3 includes persons who are unlikely to RTW within three months and unable to participate in RTW activities. In accordance with the law sickness benefit officers are obliged to conduct regular follow-up interviews at least every four weeks with beneficiaries in category two. Most cancer patients should be categorised as 2, but in reality they may be spared the obligatory meetings with the social security officer while receiving their treatment. In reality this leads to a short time frame in which the cancer patients are offered vocational/occupational rehabilitation, i.e. by the end of treatment to the maximum of 52 weeks of sickness benefit reimbursement.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome is RTW rates among cancer survivors in the intervention group compared with the control group. Return to work is defined by at least 4 consecutive weeks of no social transfer payments or attending a modified job called flexi job. The outcome is identified in a national register on weekly public transfer payments called the DREAM-register. Four consecutive weeks of no transfer payment is considered to be equivalent to RTW along with four consecutive weeks of transfer payment equivalent to attending in a flexi job.

Key secondary outcome(s)
The secondary outcomes are whether socioeconomic status or co-morbidity is modifying the effect of the intervention on RTW. Socioeconomic status is defined by marital status, having children, educational level, employment status, last year income, work position, whether being

in a management position, whether ones housing is owned, and ethnicity. The information is identified in Statistics Denmark. Co-morbidity is defined by the Charlson-index and identified in the medical records at Aarhus University Hospital.

Completion date
06/05/2015

Eligibility

Key inclusion criteria
1. 18-60 years of age
2. Place of residence: Silkeborg Municipality or Randers Municipality
3. Participants are permanent or temporary employed (with at least 6 months left by the time of inclusion) and possibly sick-listed at the start of the intervention.
4. Patients diagnosed with breast, gastro-intestinal, head and neck, testis, ovarian or cervix cancer.
5. Patients referred to chemotherapy or radiotherapy in the oncology ward at the Aarhus University Hospital.

The control patients have identical inclusion criteria except for place of residence.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
347

Key exclusion criteria
Patients who cannot speak or read Danish.

Date of first enrolment
06/12/2013

Date of final enrolment
06/05/2015

Locations

Countries of recruitment
Denmark

Study participating centre
P.P. Oerumsgade 9-11
Aarhus
Denmark
8000

Sponsor information

Organisation
Public Health and Quality Improvement, Central Denmark Region (Denmark)

ROR
https://ror.org/0247ay475

Funder(s)

Funder type
Charity

Funder Name
The Danish Cancer Society (Kræftens bekæmpelse) (Denmark); Reference number: R73-A4736

Funder Name
The Health Foundation (Helsefonden) (Denmark); Reference number: OHVOPYKC-304A5651505B4B45-5697

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2021	05/03/2021	Yes	No
Protocol article	protocol	29/07/2015		Yes	No