Internet-based WOrk-related cognitive Rehabilitation for Cancer survivors: a randomised controlled trial

Published: 21-11-2018
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The aim of the current study is to develop an internet-based cognitive intervention programme for occupationally active cancer survivors confronted with cognitive problems and to evaluate the (cost-)effectiveness of this programme.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON55687

Source
ToetsingOnline

Brief title
i-WORC study

Condition

- Cognitive and attention disorders and disturbances

Synonym
cognitive complaints, difficulty in thinking

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: KWF

Intervention

Keyword: cancer, cognition, rehabilitation, work

Outcome measures

Primary outcome

The primary outcome will be the accomplishment of an individually defined work-related treatment goal (Goal Attainment Scaling).

Secondary outcome

• Neuropsychological functioning will be measured using a self-administered online neuropsychological test battery, the Amsterdam Cognition Scan (ACS)

• Self-perceived cognitive problems will be assessed using the Cognitive Symptom Checklist-Work, Dutch version (CSC-W DV).

• Work ability will be assessed using the first item of the Work Ability Index (WAI),

• Work functioning among participants will be measured using the 27-item Work Role Functioning Questionnaire (WRFQ)

• Need for recovery after a workday will be assessed using the 11-item subscale of the questionnaire on Perception and Judgement of Work (VBBA)

• Health-Related Quality of Life will be measured using the SF-36

• Coping will be assessed with the 5-point Cognitive Emotion Regulation Questionnaire (CERQ)

Study description

Background summary

Cognitive problems are common in non-central nervous system (CNS) cancer survivors. These cognitive problems are perceived as an important contributor to decline in job performance and work ability. Various interventions for cancer-related cognitive impairment have been proposed, but effectiveness concerning work-related outcomes has not yet been established. Effective treatment options to alleviate the effects of cognitive decline and to improve work ability are needed for working cancer survivors and their employers.

Study objective

The aim of the current study is to develop an internet-based cognitive intervention programme for occupationally active cancer survivors confronted with cognitive problems and to evaluate the (cost-)effectiveness of this programme.

Study design

A three-armed randomized controlled trial will be conducted with six months of follow-up, including two intervention groups (i.e., basic and extensive cognitive rehabilitation programme) and one waitlist control group. Primary and secondary outcomes will be measured at baseline (T0), at three months, upon completion of the intervention (T1), and at three months post-intervention (T2).

Intervention

The extensive arm will contain a comprehensive training programme (including psycho-education, fatigue management, and cognitive strategy training) with individual guidance (blended intervention). Five to eight sessions will have to be completed in a period of 12 weeks. The basic arm will contain a brief cognitive training programme (including psycho-education and fatigue management) without individual guidance. Three to five sessions will have to be completed in a period of 12 weeks.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Although chances are very scarce, there is a possibility that patients experience serious psychological distress as a result of the cognitive rehabilitation programme. In that case, patients will be offered a consult with a psychologist or psychiatrist in the Antoni van Leeuwenhoek. The total participation time (3-8 sessions a 60 minutes plus homework a 60 minutes per session in 12 weeks; three measurement points with a completion time of 120 minutes) can be seen as a burden. We expect that the cognitive rehabilitation programme will improve work-related goals attainment,

cognitive problems and work-related outcomes.

Contacts

Public
Nederlands Kanker Instituut

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Nederlands Kanker Instituut

Plesmanlaan 121
Amsterdam 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Working age (18 - 65 years) at the time of study entry
2. Histologically confirmed cancer (all tumour types except for brain tumours).
3. Between 12 and 42 months after diagnosis.
4. Completed primary therapy including chemotherapy, targeted agents and/or immunotherapy. Patients who are still receiving hormonal therapy can be included in the trial.
5. Experience cancer/cancer treatment-related cognitive problems. Both patients with and without cognitive impairment assessed with neuropsychological tests, formally assessed with neuropsychological tests, will be included in the study.

6. Fixed or temporary employment contract (with at least six months left of their contract).
7. Being at work for a minimum of 12 working hours/week

Exclusion criteria

1. Psychiatric or neurological disorder that can interfere with current study aims.
2. Lack basic proficiency in Dutch.
3. Participating in comparable studies or programmes.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2018
Enrollment:	261
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-11-2018
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	10-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-08-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-09-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-09-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-05-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-11-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	11-02-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-03-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL66221.031.18