An online testing approach to assess cognitive problems associated with cancer and cancer treatment.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON35221

Source
ToetsingOnline

Brief title
Online cognitive testing battery for the oncology setting.

Condition

- Cognitive and attention disorders and disturbances

Synonym
cognitive deficits; memory, planning and attention problems

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: cancer treatment, cognitive assessment, neuropsychology, online

Outcome measures

Primary outcome

A subset of the participating patients (n=220) completes the following traditional neuropsychological tests:

1) Visual reaction time (FePsy); 2) WAIS III Digit Span (forward & backward); 3) Corsi Block-tapping Test; 4) Trailmaking A and B (TMT); 5) Tower of London (TOL); 6) Controlled Oral Word Association (COWA); 7) Rey Auditory Verbal Learning test, short form; 8) Grooved Pegboard; 9) Japanese and caucasian brief affect recognition test (JACBART).

Also, the newly developed neuropsychological test battery is conducted by all patients (n=385) and healthy controls (n=330). This test consists of several subtests based on the here above mentioned traditional tests.

Secondary outcome

- questionnaire on anxiety and depression: Hopkins Symptom Checklist-25
- demographics
- short questionnaire on internet usage

Study description

Background summary

In recent years there has been an increasing interest in cognitive dysfunction after cancer treatment. Several neuropsychological studies demonstrated adverse effects of chemo- and hormonal therapy in a subset of patients. A recent study by our group indicated the occurrence of neurocognitive problems. Evidence came from neuropsychological and neurophysiological research as well as from patient self reports from up until 5 years after chemotherapy. Moreover, our animal studies have shown a significant decrease in celproliferation in the rat hippocampus after a single dose intervenous administration of methotrexaat. Cognitive problems have a negative impact on the daily life of patients, can limit possibilities for work and studies and thus affect quality of live. Neuropsychological assessments offer objective measurements of functioning in specific cognitive domains, and are important for 1) cancer research: to evaluate treatments and to guide future directions; and 2) clinical patient care: to assess the disease/treatment sequelae and to guide interventions. Typical assessments are conducted by trained professionals in a face-to-face setting, using paper and pencil or computerized tests, which make them time-consuming and labor-intensive. Therefore, to date most studies conducted are relatively small. As not all cancer patients and all cognitive domains seem to be affected alike, and the trend in cancer treatment is towards more personalized - and therefore less prevalent - treatment strategies, much larger studies are needed to determine the relative cognitive toxicity of specific treatments, and to identify subgroups of patients most vulnerable for cognitive effects in a context of many confounding factors.
The past decade it has been shown that online assessment provides a good method to obtain data in large samples in a quick and cost efficient way. An online cognitive testing tool may help to rapidly acquire large data sets and could therefore proof to be of importance for the research in the field of cancer and cognition.

Study objective

The aim of the proposed project is to develop a user-friendly and standardized online neuropsychological test battery. It will be a concise test, measuring those domains which have proven to be most sensitive to the adverse effects of chemo- and hormonal therapy. These domains are: learning and memory, attention, executive functioning and information processing speed. For each domain 1 or 2 subtests will be selected.
Traditional neuropsychological tests with adequate psychometric qualities will be used as a starting point and converted to online equivalents. The online cognitive test battery is intended to be: 1) tailored to detect cognitive dysfunction associated with cancer treatment; 2) designed to optimize test performance (to get test results that show true capacity) in unmonitored settings; 3) fully tested on usability, convergent validity, context validity, and test-retest reliability; 4) sustained by customized reference data; and 5) ready for deployment in larger-scale research on cancer and cognition.
Such a testing tool will allow us to signal side-effects of (new) therapies in an early stage, monitor cognitive functioning pre- and post treatment and -

eventually- to identify patients at risk for developing cognitive problems. Subsequently, the resulting knowledge can support oncologists in choosing suitable therapies for their patients, cognitive researchers in designing interventions against cognitive impairment in cancer patients, and patients in optimizing their quality of life after cancer treatment.

Study design

This observational study is a collaboration between the department of Psychosocial Research and Epidemiology of the NKI-AVL, the Psychonomics department of the University of Amsterdam and the department of Communication Science of the VU University Amsterdam.

Study burden and risks

There are no risks associated with participation in the study. The performance of neuropsychological tests is generally considered as not too stressful. Participants will be tested twice maximum. The assessments will take place at the patient's home and/or in the Antoni van Leeuwenhoek hospital (depending on the participant group they belong to). Travel expenses and parking costs will be reimbursed.
Furthermore, since data is obtained though the internet, special attention will be paid to safe data transmission and storage. Privacy is ensured by the use of a secured MySQL database, encrypted data and a separate database for the subjects' contact details including a unique code and excluding test results.

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

Disease free cancer patients (equal gender distribution, age-range: 18-74) treated at the NKI-AVL with chemotherapy and/or hormonal therapy will be included.
Healthy partners (partner, family member or friend of the opposite sex with comparable age and education level) of patients will serve as control group to gather reference data.
Patients and heatlhy controls should have sufficient proficiency in Dutch language.

Exclusion criteria

Cancer patients: involvement of the central nervous system
Healthy controls: cancer, any neurological or psychiatric symptoms which can influence cognitive performance

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2011
Enrollment:	715
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-02-2012
Application type:	First submission
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	NL37964.031.11