Identifying neural mechanisms associated with cancer-related fatigue: a cross-sectional study in testicular cancer survivors

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Primary:o To compare effort- and/or reward-related neural activity between cancer survivors and healthy controlso To assess whether cancer-related fatigue is related to effort- and/or reward-related neural activitySecondary objectives:o To assess...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53997

Source
ToetsingOnline

Brief title
Neural mechanisms of cancer-related fatigue

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
cancer-related fatigue

Health condition

kanker-gerelateerde vermoeidheid

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Effort-based decision making, Fatigue, fMRI, Testicular cancer

Outcome measures

Primary outcome

- Task-related activity during effort-based decision making

- Self-reported fatigue

Secondary outcome

- Individual levels of high-sensitive C-reactive protein (CRP) on testing day

- Resting-state functional connectivity patterns

Study description

Background summary

Post-cancer fatigue is one of the most prevalent and debilitating side -effects of cancer and its treatment. Fatigue symptoms are part of the sickness syndrome, a set of behavioral symptoms including fatigue, depressive symptoms and reduced engagement in activities that are triggered by treatment-induced inflammation.
These symptoms are considered adaptive during chemotherapeutic treatment, but they can become maladaptive if they persist long after curative treatment. Currently, little is known on what (neural) mechanisms may underlie the persistence of cancer-related fatigue.

Fatigue is intrinsically linked to reduced motivation and alterations in effort-reward decision making. Neuroscience research has shown that effort and reward weighting are two dissociable constructs that are processed by different neuronal brain networks. Several studies suggest that repeated exposure to

inflammation (as happens during multiple cycles of chemotherapeutic treatments) can produce long lasting changes in brain function and neurochemistry, which may ultimately result in long-lasting alterations in motivational behaviours and mood. The current study will therefore use task-related fMRI during an effort-based decision-making task to elucidate the neural mechanisms of cancer-related fatigue.

To this end, we will measure fatigue-related motivational and neural changes in young males treated for testicular cancer 2-10 years after treatment. Fatigue will be measured as a two-dimensional behavioural construct involving effort and reward weighting in choices on whether or not to engage in physical activities for reward. Participants will make these choices whilst laying in an MRI-scanner. This allows us to investigate the separate neural networks for effort and reward, as well as the integration of the two. The results of this study will provide insights into behaviors and their possible neural mechanisms that contribute to persistent cancer-related fatigue.

Study objective

Primary:
o To compare effort- and/or reward-related neural activity between cancer survivors and healthy controls
o To assess whether cancer-related fatigue is related to effort- and/or reward-related neural activity

Secondary objectives:
o To assess whether effort- and/or reward-related neural activity is associated with low-grade peripheral inflammation (CRP)
o To explore resting-state functional connectivity patterns related to cancer-related fatigue and peripheral inflammation

Study design

A cross-sectional, observational design in 50 cancer survivors and 45 healthy controls

Study burden and risks

The burden consists of a phone call followed by a testing day at the Donders Institute of 2 hours. During the testing day, participants will perform one behavioural task, which will partly be done in the MRI-scanner and partly on the regular PC, and undergo a resting state scan. In addition, they will have a finger prick to determine high-sensitive CRP and perform a short working memory task. Lastly, they will fill out some online questionnaires at home (30-40 minutes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

For all participants: • Written informed consent • Male • Age between 18 and 50 yrs • Sufficient command of the Dutch language (to answer questionnaires)
For patients: • Unilateral orchiectomy • 3 or 4 cycles of BEP or EP treatment regimen

Exclusion criteria

For all participants: • Presence of acute infection or inflammation on day of testing (body temperature >38) • Current use of prescribed psychotropic, pain or anti-inflammatory drugs • (history of) long-term (> 6 months) daily use of over-the-counter NSAIDs (ibuproven, diclofenac, naproxen) (for patients: besides those used during cancer-treatment) • Current use of over-the-counter

corticosteroids, anti-histamic or anti-inflammatory drugs (participants that use corticosteroid moistures or hay-fever drugs are asked to not use it on the testing day) • Obesity (BMI>30) • (history of) metabolic disease (e.g. diabetes) • (history of) cardiovascular events • (history of) neurological or psychiatric symptoms/disease • (history of) chronic inflammatory disease (e.g. rheumatoid arthritis, Crohns disease) • (history of) hypo/hyperthyroide • (history of) chronic pain (>6 months) (for patients before diagnosis) • (history of) chronic fatigue syndrome or fibromyalgia (for patients before diagnosis) • (history of) hypogonadism/ hormonal disturbance or supletion (for patients before diagnosis) • Metal objects in or around the body • Claustrophobia • Glaucoma or increased risk for glaucoma • No presence of metastatic disease or relapse • No patients who received radiotherapy because other treatment with different side effects

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-05-2022
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	30-08-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	09-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76541.091.21