Identifying motivational alterations associated with cancer-related fatigue: a longitudinal study in testicular cancer patients

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Objectives: - To identify and compare motivational behaviour in patients during different phases of cancer treatment. - To test its associations with self-reported fatigue/depression. - To determine to what extent treatment regimen, inflammation,...

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

Summary

ID

NL-OMON49467

Source
ToetsingOnline

Brief title
Motivational aspects of cancer-related fatigue - LONG

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, inflammation, tetsicular cancer

Outcome measures

Primary outcome

• Individual weightings of effort and reward sensitivity, as measured with effort/reward weighting task

• Subjective mood ratings (including but not limited to fatigue, depressive mood, and anxiety) (All questionnaires are described below)

• Plasma cytokine concentration profiles (including but not limited to CRP, TNFα, IL-1 and IL-6)

Secondary outcome

• Cortisol Awakening Response (CAR)

• Potential health-related, stress-related, and psychosocial predictors (All questionnaires are described below)

• General neurocognitive functioning (Amsterdam Cognition Scan (ACS)) for replication of previous studies (Schagen et al 2008, Stouten-Kemperman et al 2015b)

- reward and punishment based learning

Study description

Background summary

Fatigue is one of the most prevalent and debilitating side effect of cancer treatment. It is part of the sickness syndrome, which is triggered by treatment-induced inflammation. Sickness syndrome is a set of mood and motivational alterations, including fatigue, depressive symptoms, and reduced engagement in activities. These symptoms are considered adaptive during chemotherapeutic treatment, but they can become maladaptive if they persists long after curative treatment. However, little is known about the mechanisms on how adaptive acute fatigue during treatment transitions into chronic maladaptive fatigue after treatment.

In this longitudinal study, we will measure fatigue-related motivational changes in young males receiving treatment for testicular cancer. We will measure fatigue as a two-dimensional behavioural construct involving effort and reward weighting in choices on whether or not to engage in physical activities for reward. In a previous study, we showed that an acute inflammatory challenge (i.e. lipopolysaccharide) in heathy volunteers increased the weighting of effort but not reward in these choices. Here we will compare choice behaviour between between acute (shortly after treatment completion) and chronic (>6 months after treatment completion) phases of treatment, and link them to alterations in mood dimensions (i.e. fatigue/depression). Furthermore, we will test various predictor variables of altered motivational choice including, treatment regimen, peripheral inflammation and other neuroendocrine and psychosocial predictors.

Neuroscience research has shown that effort and reward weighting in this task are two dissociable constructs that are processed by different neurochemical brain networks. If we find that acute and persistent fatigue are differentially associated with effort and/or reward weighting, than this will inform us about possible dissociable underlying mechanisms of acute and chronic cancer-related fatigue.

Study objective

Objectives:
- To identify and compare motivational behaviour in patients during different phases of cancer treatment.
- To test its associations with self-reported fatigue/depression.
- To determine to what extent treatment regimen, inflammation, endocrine markers and and psychosocial factors contribute to motivational changes (>6 months)

Study design

A longitudinal study with 70 patients diagnosed with testicular cancer that will each be tested 3 times, once before chemotherapeutic treatment (baseline), once after treatment (acute phase) and once 6 months after treatment (chronic phase). These patients are compared with 35 age, gender and education matched healthy controls.

Study burden and risks

The burden consists of 3 measurements, during which subjects will perform tasks at home. These tasks inlcude online computertasks (1,5 hours) online surveys (30-40 minutes) and an online cognitve test battery (50 minutes). In addition subjects are asked to collect 8 saliva samples at home and to visith the hospital for venapuncture. The latter visits are combined with planned visits to the treating physician at one of the study sites. Participation to the study will not affect usual care.

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

For all participants (healthy and patients):
• Written informed consent
• Male
• Age between 18 and 50 yrs
• Sufficient command of the Dutch language (to answer questionnaires)

For all patients:
• Unilateral orchiectomy
• BEP or EP treatment regimen (for sugery+chemo group)
• No patients who received radiotherapy because of non-comparable tumor-types and treatment side-effects

Exclusion criteria

For all participants (healthy and patients):
• 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 suppletion (for patients before diagnosis)

• (history of) renal failure

For all patients
• Patients who received radiotherapy because of non-comparable tumor-types and treatment side-effects

For all healthy participants
• Severe fatigue (CIS-fatigue <35)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2020
Enrollment:	105
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-01-2020

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-02-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-06-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-12-2020
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	NL71363.091.19