Downsides of Being Well-Informed: Tracking and Preventing Chemotherapy-Related Cognitive Problems in Breast-Cancer Patients

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The objective of this study is to investigate effects of different forms of patient information on chemotherapy side effects, in particular, assessing the severity and duration of the negative effects of information on chemotherapy-associated…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON40145

Source
ToetsingOnline

Brief title
Communicating chemotherapy-associated cognitive problems

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Cognitive and attention disorders and disturbances

Synonym
cognitive difficulties after chemotherapy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: breast cancer, chemotherapy, cognition, information

Outcome measures

Primary outcome

This study has two main endpoints:

1). Cognitive performance (memory, processing speed and executive function as measured with the Trail-Making Test and 15-words test).

2). Self-reported cognitive complaints (as measured with the MOS Cognitive Functioning Scale and M.D. Anderson Symptom Inventory).

Secondary outcome

Secundary study parameters will be measured with online questionnaires and are based on literature about information and stereotype threat effects and on the international standards in the research field of *cancer and cognition* (ICCTF: International Cognition and Cancer Task Force). Literature on stereotype threat and information effects (for example Nocebo effects) shows that the following concepts are important to include in this study:

Mediating processes:

- Activation of a cognition stereotype (measured with a word completion task)

- Motivation level during test

- Level of worry about performance

- Ego depletion

- Expectations of side effects

Moderating processes:

- Stigma consciousness

- Identification with the group

- Identification with the domain

- Stereotype endorsement

- Cancer specific distress

- Emotion regulation

- Information seeking behavior

- Stereotype self-relevance

Covariates:

- Pre-existing knowledge of cognitive problems after chemotherapy

- Level of general complaints

- Depression and anxiety

- Demographic variables

Study description

Background summary

A substantial group of breast cancer patients report cognitive complaints after chemotherapy. Information on chemotherapy side effects like cognitive problems

is increasingly accessible for patients, for instance on the Internet. But what are the effects of informing patients about chemotherapy treatment side effects?
Studies show that although treatment-related information may help patients make an informed decision, and take away worries and doubts, it also may have downsides. Research of our own group showed that merely informing (ex) breast cancer patients about the association between chemotherapy and cognitive deficits prior to completing a memory test and questionnaires, resulted in reduced memory ability and increased complaint reporting. An explanation for this mere information effect is derived from social psychological research on stereotype threat and priming and literature on Nocebo effects. Activation of the *chemotherapy-causes-cognitive problems-schema or stereotype* just before patients complete a memory test can thus affect the performance on this test. Now that research shows that (short term) information-effects are also present in a clinical setting, and can affect life after breast cancer treatment, it is important to investigate: 1.) What is the severity and duration of these negative effects of information or stereotype priming effects on cognitive deficits after chemotherapy? 2.) What are effective psychological interventions to diminish stereotype priming effects?

Previous studies have found evidence for short term priming effects in a clinical setting, but literature shows us that there is also reason to believe that priming effects are long lasting and can increase over time. In addition, empirical support has been found for promising, feasible and cost-effective interventions regarding stereotype priming. This leads to the expectation that similar interventions will be effective in reducing stereotype-threat effects in a breast cancer population. This project will address both issues. The main research hypotheses are that:
H1). Priming (activation of the *chemotherapy-causes-cognitive problems-schema*) patients with information about the relationship between chemotherapy and cognitive complaints prior to completing the questionnaires, will increase the reporting of cognitive complaints and decrease cognitive performance, compared with patients who did not receive this information;
H2). Patients in the intervention condition will report less cognitive complaints and increased cognitive performance than patients in the priming condition.
In addition, effects of potential moderating processes, mediating variables and effects of covariates will be explored. It is expected that priming especially affects respondents for whom the information is relevant. Priming is expected to operate via various mechanisms, such as increased worry and motivation. This study will also examine severity and duration of the stereotype priming effects.

Study objective

The objective of this study is to investigate effects of different forms of patient information on chemotherapy side effects, in particular, assessing the

severity and duration of the negative effects of information on chemotherapy-associated cognitive problems in breast cancer patients. The second goal of this project is to assess potential interventions to diminish the negative effects of informing patients on chemotherapy-associated cognitive problems.

Study design

This multicentre, randomized controlled trial assesses the severity and duration of stereotype threat effects (RQ1) and the effects of a psychological, information-based intervention in routine clinical practice (RQ2). The duration of the study will be three years and is a joint venture of the department of Psychosocial Research and Epidemiology of the NKI, the department of Medical Oncology of the AVL and the department of Business Communication Studies (Persuasive Communication) of the Raboud University Nijmegen.

At T0, Patients will be invited by their treating physician to take part in an online study *on experiences before, during and after cancer treatment* (in Dutch: *Ervaringen vóór, tijdens en na de behandeling voor kanker: een onderzoek naar patiënteninformatie*). This written introduction provided by the physician will be held constant and will be neutral with respect to specific information regarding cognitive problems following chemotherapy in order to prevent priming effects. However, we only ask health professionals to hold constant the information about the goals of this study, to prevent activation of the concept of cognitive difficulties after chemotherapy in relation to this study for all patients. We want to stress that the usual care and information on (chemotherapy) treatment side effects will be offered to all patients in this study.

In the online environment, participants will be randomly assigned to one of three experimental conditions; one third of the patients receive the introduction prior to the questionnaires and neuropsychological tests that *some patients treated with chemotherapy experience cognitive problems* (the experimental condition). One third of the patients will receive the same introduction, with the addition of reassuring information for example: *By far not all patients will experience these complaints. It is known that patients with cognitive complaints still can perform well on cognitive tests* (intervention condition). One third of the patients will receive a neutral introduction prior to the questionnaires, lacking the association between cognitive problems and chemotherapy (control condition). These experimental materials extend previous studies in this domain. Short-term, medium-term and longer-term priming and intervention effects will be assessed by asking patients to fill out several questionnaires and tests at T0 (before chemotherapy), T1 (six months after chemotherapy treatment), and T2 (twelve months after chemotherapy treatment). Each online assessment will take approximately 40 minutes to complete.

Intervention

Patients will be randomly assigned to one of three experimental conditions: the experimental condition, the intervention condition and the control condition. These groups will receive different information formats regarding side effects of chemotherapy prior to completing the questionnaires and neuropsychological tests. The experimental group will receive an introduction before completing the questionnaires stating that: *some patients treated with chemotherapy experience cognitive problems*. The intervention group will receive a comparable introduction, with the addition of reassuring and positively framed information including the following sentence: *By far not all patients will experience these complaints. It is known that patients with cognitive complaints still can perform well on cognitive tests*. This text also contains linguistic variations. The third group of patients will receive a neutral introduction to the questionnaires and tests, which does not refer to the association between cognitive problems and chemotherapy (control condition). These experimental materials extend previous studies in this domain.

We want to stress that this study does not interfere with clinical care as usual: information on treatment and treatment side effects is offered to all patients by their physician in the usual manner. Only the study specific information that is given to patients just prior to the completion of the questionnaires and neuropsychological tests varies between groups. This extra information on cognitive problems following chemotherapy provided to patients prior to the questionnaires is correct and based on the current knowledge and research outcomes regarding chemotherapy-associated cognitive problems. Conform the informed consent procedures in daily practice, information on (chemotherapy) treatment side effects, including cognitive problems, will be given by the physician in the usual manner.

Study burden and risks

This study does not include invasive procedures, will not harm patients and does not interfere with clinical care as usual: information on treatment and treatment side effects is offered to all patients by their physician in the usual manner. Only the study specific information that is given to patients just prior to the completion of the questionnaires and neuropsychological tests varies between groups. This extra information on cognitive problems following chemotherapy provided to patients prior to the questionnaires is correct and based on the current knowledge and research outcomes regarding chemotherapy-associated cognitive problems. Conform the informed consent procedures in daily practice, information on (chemotherapy) treatment side effects, including cognitive problems, will be given by the physician in the usual manner.

All participants will be asked to complete the online questionnaire (40

minutes) three times. Overall, completing online questionnaires is expected to be not too burdensome.

It is important to study late effects of chemotherapy in breast cancer patients from a descriptive and preventive standpoint, as people with (a history of) breast cancer constitute an increasingly large group in our community and the number of breast cancer survivors is growing. Cognitive complaints after chemotherapy are common in (ex) breast cancer patients.

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

- Newly diagnosed breast cancer patients (mamma carcinoma),
- (Neo-)adjuvant chemotherapy treatment,

- Age 18 years or older,
- Dutch-speaking and reading,
- Access to the Internet.

Exclusion criteria

- History of neurological and psychiatric symptoms that may influence cognitive functioning,
- History of cancer,
- Alcohol or drug abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-03-2014
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	08-07-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	19-12-2013

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-03-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-04-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-06-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-07-2014
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	NL43939.031.13