Early implicit promotion of vitality in breast cancer patients during neo-adjuvant treatment.

Published: 28-02-2019
Last updated: 20-06-2024

The objective of this study is to test the CBM eHealth app, with regard to the influence of the app on implicit fatigue self-concept and on explicitly experienced fatigue and vitality, both immediately after finishing the two-weekly training....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48196

Source
ToetsingOnline

Brief title
Improving vitality in breast cancer patients

Condition

- Other condition

Synonym
Fatigue, vitality

Health condition

vermoeidheid

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast cancer, Fatigue, Implicit processes, Vitality

Outcome measures

Primary outcome

Implicit fatigue, implicit vitality, explicit fatigue, explicit vitality.

Secondary outcome

- adherence to the app (logdata)

- user experiences of app use after the 14 days training (semi-structured

interview)

Study description

Background summary

In the ZGT adherence area, more than 400 women per year are diagnosed with breast cancer. In addition to surgery and radiotherapy, more than 60% of these patients receive a form of neoadjuvant or adjuvant system therapy. Many patients experience high stress levels during and after this multimodality treatment, which impedes them in picking up or continuing work. One of the main drivers of stress is cancer-related fatigue (Syrowatka et al., 2017). This is directly related to restrictions in labor participation (Paalman et al., 2016). More than 50% of all breast carcinoma patients experience fatigue complaints during their treatment course, with a substantial proportion retaining serious fatigue symptoms after the treatment (Fabi et al., 2017). In order to support women, there are already cancer rehabilitation programs such as "physiofit and back to balance", in which women qualify during or after completion of treatment. However, many women do not return to their level of work, such as before the start of breast cancer treatment. Besides, they are often unable to fulfill certain social roles as before, because severe fatigue complaints undermine the necessary physical and mental functioning and make predictability of participation more difficult. During the treatment process, breast cancer

patients can gradually develop a distorted fatigue self-image (= cognitive bias). Cognitive bias is unfavorable in relation to fatigue-related behavior (eg not performing physical activities or interpreting information through 'fatigue goggles') (Crombez et al., 2013; Hughes et al., 2016).

Neoadjuvant treatment programs offer the possibility to offer an early intervention (eg through eHealth training) already in the preoperative trajectory. The idea is that early in the treatment process in a low-threshold and simple way, the distortion in the direction of fatigue can be reversed and the self-image of the breast cancer patient is again modified in the direction of vitality. This simple training is called CBM (= cognitive bias modification) and has already shown beneficial effects in anxiety, depression, addiction, chronic pain and other symptoms (Mobini, Reynolds, & Mackintosh, 2013, Grafton et al., 2017, Kakoschke, Kemps, & Tiggemann, 2017). The underlying theories (dual process models) describe human behavior and feelings as the integration of deliberate reflexive processes and automated and unconscious processes. Helpful existing interventions such as self-management or rehabilitation programs mainly serve the conscious side of the symptoms and work with the help of health goals and clarification of steps and behavior to achieve it. The method proposed here (CBM) intervenes in the automated unconscious processes that determine a large proportion of health observations and health behavior. The CBM training consists of an eHealth computer game in which participants have to link concepts that directly relate to themselves (e.g., I) with words related to vitality (e.g., energetic). Participants have to link fatigue concepts (e.g., exhausted) words not related to the patient (e.g., others). The influence of this training will be explored by examining the change of implicit or explicit fatigue and vitality.

By applying a psychological conditioning task (through CBM training), which is essentially an unconscious process, in addition to the existing guidance possibilities within ZGT aimed at strengthening conscious processes, we hope to prevent the occurrence of an unfavorable distortion in the self-image and thus contribute to maintaining or improving experienced vitality in these patients. The ultimate goal of the eHealth intervention is that breast cancer patients experience more restorative capacity and vitality and can therefore deal better with their illness and treatment. This should result, among other things, in the fact that more women will be able to return to their original work setting (rather soon) than without using this technique. To align as much as possible with the wishes and needs of professionals and patients, investments were made in a User-Centered Design approach. For this, patients and professionals were interviewed to gain insight into the phenomenon of fatigue in breast cancer and how this plays a role in practice. The idea of **CBM is also presented to patients and professionals and we aim to get an impression of how and when our CBM intervention can best be presented to patients.

Study objective

The objective of this study is to test the CBM eHealth app, with regard to the influence of the app on implicit fatigue self-concept and on explicitly experienced fatigue and vitality, both immediately after finishing the two-weekly training. Furthermore, the study aims to explore the acceptance of the app among the target group. The overall goal of the study is that breast cancer patients experience more vitality and are better able to cope with their illness and the treatment.

Study design

The current study is a proof-of-concept study in which patients will use the app for 14 days (for 5 minutes per day). The outcome measures of this study are implicit fatigue, explicit fatigue, implicit vitality and implicit fatigue. The implicit measurement of fatigue and vitality consist of the Implicit Association Test (IAT) on the computer. The explicit measurements consist of three questionnaires that will be administered on the computer as well: The Checklist Individual Strengths (CIS), the Dutch vitality questionnaire (Vita-16) and the depression scale of the Hospital Anxiety and Depression Scale (HADS). Furthermore, the adherence of the intervention will be administered. During a short semi-structured interview (max. 30 minutes) after the 14-day training it will be explored how participants have experienced the use of the app and if there are point for improvement.

At baseline, the implicit fatigue self-concept will be measured to see what self-concept patients already have with regard to fatigue, and if this self-concept is already biased. Furthermore, explicitly experienced fatigue and vitality will be measured. The first training will take place during the second chemotherapy session. The reason to have the T0 measurement already before the first chemo, is to keep this measurement parallel with the T0 measurement of an ongoing observation study (METC approval already received).

The measurements and the interview will be combined with regular visits to the hospital.

Overview:
T0: Baseline measurement (before first chemotherapy session)
- Intervention, 14 days training in app - (during second chemotherapy)
T1: Post measurement (after 14 days training in app)

Intervention

The CBM training consist of an eHealth 'game' in which participants have to

link words related to 'self' (e.g. 'I') to words related to vitality (e.g. 'energetic'). They have to link fatigue related words (e.g. exhausted) to synonyms to the category 'others' (e.g. 'she').
An example of what the app will look like can be found in the research protocol.
Participants have to complete the training (5 min.) for 14 consecutive days.

Study burden and risks

Possibly more fatigue due to 5 min app trainer per day (very low risk)
CBM could have a 'reverse' (not explained in literature yet, risk perceived as very low)

Contacts

Public
Ziekenhuisgroep Twente

Geerdinksweg 141
Hengelo 7555DL
NL
Scientific
Ziekenhuisgroep Twente

Geerdinksweg 141
Hengelo 7555DL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Stadium II en III mammacarcinoom patients who will receive a neo-adjuvant treatment within ZGT.
- Patients are able to speak and read Dutch
- Patients have a smartphone / are familiar with using a smartphone

Exclusion criteria

- Patients are not familiar with a smartphone
- Patients are not able to speak/read Dutch

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	eHealth app
Registration:	No

Ethics review

Approved WMO

Date:	28-02-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	nog ter controle
CCMO	NL68528.044.18