FREE study: investigating the effectiveness of EMDR as a treatment for Fear of Cancer Recurrence among cancer survivors.

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The aim of the present study is to investigate the effectiveness of EMDR on FCR in breast and colon cancer survivors who have high levels of FCR at baseline. The effect on post-traumatic stress symptoms, quality of life, and physical symptoms will…

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

Summary

ID

NL-OMON48483

Source
ToetsingOnline

Brief title
Fear of cancer REcurrence Emdr study
FREE-study

Condition

- Other condition
- Breast neoplasms malignant and unspecified (incl nipple)
- Anxiety disorders and symptoms

Synonym
Fear of cancer recurrence/ fear of progression of cancer

Health condition

maagdarmneoplasmata maligne

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: subsidie wordt aangevraagd bij de VEN (vereniging EMDR Nederland)

Intervention

Keyword: cancer, EMDR, Fear of Cancer Recurrence FCR, Single case design

Outcome measures

Primary outcome

The primary outcome measure (Daily Questions FCR (DQ-FCR)) is an online list of 5 questions based on the FCRI-NL severity scale, adapted for daily measurement, which are answered daily during 16 weeks (14 weeks of the study and 2 weeks follow-up).

Secondary outcome

The secondary outcome measures are the total score of the Cancer Worry Scale (CWS), Fear of Cancer Recurrence Inventory-Dutch version (FCRI-NL), 1 item about quality of life of the EORTC-QLQ-C-30. The questionnaires are filled in at t1 (at start of baseline period), t2 (at the end of baseline period = at start of EMDR), t3 (at the end of EMDR = at start of post-treatment period), t4 (at the end of post-treatment period), and t5 (at the start of the follow-up period). Physical symptoms (Daily Questions Pain, Nausea, and Fatigue (DQ-PNF)) measured daily during 16 weeks (14 weeks of the study and 2 weeks follow-up) is also a secondary outcome measure.

Study description

Background summary

In recent years, improved methods of early diagnosis and better treatments of cancer have led to a growing number of survivors. One of the problems cancer survivors have to deal with is fear of cancer recurrence (FCR) which is defined as the *fear, worry, or concern relating to the possibility that cancer will come back or progresses. While mild or transient FCR has no lasting or serious consequences , excessive and continuous high FCR is found to impact screening and follow-up behaviors, mood, relationships, work, goal setting, and quality of life (QoL) and increase health care costs (Butow et al., 2017).
Previous research has shown that approximately half of cancer survivors and 70% of more vulnerable groups (eg, young breast cancer survivors) report moderate to high FCR levels while 10% experience high and disabling FCR (Butow et al., 2017).
Although excessive FCR has been found to be one of the most common unmet needs, few studies have investigated treatment options and no consensus exists on the best management strategies. The few studies that did investigate treatment for FCR focused on Cognitive Behavioral Therapy. These studies found promising results, but CBT is time and resource intensive. Therefore, there is need for treatment options that are of shorter duration and less resource intensive.
A treatment that is already being applied in clinical practice but has yet not been studied for cancer related fear is Eye Movement Desensitization and Reprocessing (EMDR).
EMDR is an evidence-based and protocoled treatment for patients with Post Traumatic Stress Disorder (PTSD) and PTSD symptomatology including fear of future catastrophes (Shapiro, 2014). In most patients fear of future catastrophes is based on past experiences. EMDR is a quick, patient and therapist friendly intervention to desensitize both the memories of past experiences as well as the representations of future catastrophes. EMDR has been shown to be effective not only as treatment for PTSD but also as treatment for a variety of anxiety disorders (e.g. fear of illness and specific phobia) (Logie & de Jongh, 2014) and somatic complaints such as post-operative pain, medically unexplained symptoms or seizure-related post-traumatic stress (Dautovic, de Roos, van Rood, Dommerholt, & Rodenburg, 2016), (van Rood & de Roos, 2009), (Maroufi, Zamani, Izadikhah, Marofi, & O'Connor, 2016).
The present multiple baseline case series design study will be the first to investigate whether EMDR may be effective for the treatment of FCR.

Study objective

The aim of the present study is to investigate the effectiveness of EMDR on FCR in breast and colon cancer survivors who have high levels of FCR at baseline. The effect on post-traumatic stress symptoms, quality of life, and

physical symptoms will be explored.
We propose a study combining the results of 10 single-case trials (5 survivors of mamma carcinoma and 5 survivors of colon carcinoma).

Study design

The design used is that of a ten times repeated multiple baseline case series. The mbcs is a well-established method when investigating the use of evidence-based psychological treatments in a new contexts. Within the research group a lot of expertise is available about this specific method. 5 survivors of mamma carcinoma and 5 survivors of colon carcinoma are randomized for baseline length (2-6 weeks). After baseline they receive EMDR (2-6 weeks), followed by a post-treatment period (2-8 weeks). The total length of the study; i.e. baseline, treatment and post-treatment is 14 weeks and equal for all patients. After 3 months there is a follow up of 2 weeks.
We hypothesize that EMDR treatment will reduce FCR in cancer survivors and that the results will be maintained at post-treatment and follow-up.. Furthermore, the effect on quality of life and physical functioning will be explored.
Combining the results of 10 single-case trials allows for the exploration of the generality of the effect across subjects and therapists. This type of research results in preliminary data about the efficacy of the treatment which can be used to design a Randomized Controlled Trial.

Intervention

The EMDR intervention consists of one preparation session of 90 minutes followed by weekly EMDR sessions of 90 minutes. Participants will receive a minimum of 2 and a maximum of 6 sessions including one preparation session. The Standard EMDR protocol is used to desensitize patients* most fearful images of past and representations of future cancer related catastrophes. The intake and EMDR will be carried out by two trained EMDR Level II therapist.

Study burden and risks

Participating in this study will not cause any (physical) harm for the participants. Participants have to travel to the hospital and commit to a limited amount of sessions (between 2 and 6 depending on the amount of intrusive images the patient has) of EMDR. There aren't any indications that EMDR treatment has negative effects, risks or side effects. Some people experience being more emotionally after EMDR treatment. This is part of the psychological process and an indicator that the treatment is working. This emotionality will become less in a couple of days. Er zijn geen nadelige effecten, risico*s of bijwerkingen te verwachten van de EMDR behandeling of van het invullen van de vragenlijsten.

Primary and secondary outcome measures are filled in online on a computer or

tablet from home. Answering the 5 questions of the DQ-FCR that form the primary outcome measure and the 3 items of the DQ-PNF that form one of the secondary measures takes approximately 2 min per day. Completion of the questionnaires (CWS, FCRI-NL and 1 item of the EORTC-QLQ-C-30) forming the other secondary outcome measures, five times during the study, takes about 20 minutes per assessment. Answering the 8 questions daily and completing the questionnaires five times may cause some discomfort because of the time investment.

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

Adult (18 - 70 years) survivors of breast cancer (female) or colon cancer (male/female) after ending treatment. Participants must be able to rapport on a daily basis on an online questionnaire, so minimal computer skills are

necessary. Participants with a low to normal score will not participate in the treatment phase of the study. Participants with a score above 13 (cut of score) on the CWS will be included for the treatment phase of the study.

Exclusion criteria

Age under 18 years or over 70 years, obvious intellectual impairment, and insufficient knowledge of the Dutch language. Patients with acute psychiatric problems such as acute psychotic disorders or suicidality will be excluded. Patients using medication that has an effect on anxiety need to be on stable medication for at least three months and keep medication unchanged during the study.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-02-2020
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	13-11-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26554
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68358.058.19
OMON	NL-OMON26554