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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26554

Source
NTR

Brief title
FREE

Health condition

survivors of mamacarcinoma and coloncarcinoma with high levels of fear of cancer recurrence (FCR)

Sponsors and support

Primary sponsor: LUMC Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: VEN Vereniging EMDR Nederland

Intervention

Outcome measures

Primary outcome

The primary outcome measure (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 effect of EMDR on the total scores of the CWS, FCRI-NL and item 30 about quality of life of the EORTC-QLQ-C30, and DQ-PNF will be investigated. Marital status, stage of disease, treatment variables, age, gender, educational level will be investigated as descriptive variables

Study description

Background summary

Rationale: 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.

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 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 context. 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 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.

Study population: Adult (18 - 70 yrs. old) survivors of mama carcinoma (female) and colon carcinoma (male/female) after ending curative treatment with a score higher than 13 on the Cancer Worry Scale (CWS) will be included after a signed informed consent. A potential subject who meets any of the following criteria will be excluded from participation in this study: Younger than 18 years, obvious intellectual impairment and insufficient knowledge of the Dutch language. Patients with other acute psychiatric problems such as acute psychotic disorders or acute suicidality will be excluded. Substance abuse and anti-anxiety medication are not an exclusion criterion unless patients are not stable in their use (i.e. constant use of the same dose during 3 months or more).

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.

Main study parameters/endpoints: 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).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 objective

Hypothesis 1: After EMDR (treatment phase) DQ-FCR severity will be significantly more decreased in comparison with the (possible) decrease after waiting (baseline phase). This decrease will be maintained during post-treatment and at follow up.

Hypothesis 2: After EMDR treatment (treatment phase) there will be a significantly larger decrease in DQ-PNF compared to a (possible) decrease after waiting (baseline phase). This decrease will still be maintained during post-treatment phase and at follow up phase.
Hypothesis 3: After EMDR treatment (treatment phase) there will be a significantly larger decrease in total scores of the CWS and FCRI-NL compared to a (possible) increase after waiting (baseline phase). This decrease will be maintained at the end of the post-treatment phase and at the end of the 3 month follow up phase.
Hypothesis 4: After EMDR treatment (treatment phase) there will be a significantly larger increase in quality of life (measured with item 30 of the EORTC-QLQ-C30) compared to a (possible) increase after waiting (baseline phase). This increase will be maintained at the end of the post-treatment phase and at the end of the 3 month follow up phase.

Study design

5

Intervention

In this study 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. The Standard EMDR protocol is used to desensitize patients' most fearful images of past and representations of future cancer related catastrophes. The procedure to desensitize feared catastrophic events follows the Standard EMDR protocol, except that the target relates to a feared catastrophic event (in this case the specific event that gives the most FCR) rather than a past one.
During EMDR, the patient is asked to focus on negative memories related to the FCR and at the same time to follow the fingers of the therapist, moving his eyes horizontally back and forth. After a set of eye movements (duration: about 30 seconds) the patient is asked what comes to his mind. What comes up becomes the focus for the next set of eye movements. This procedure is repeated until this memory no longer generates any distress.
When all negative FCR related experiences have been desensitized, the future catastrophe is the target for the EMDR procedure. In this study we will use the EMDR kit (consisting of a light, buzzers and headphone instead of the fingers of the therapist).

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following 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. A signed informed consent is necessary to participate.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: 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
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-12-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48483
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8223
CCMO	NL68358.058.19
OMON	NL-OMON48483

Study results