FORWARD: EMDR for fear of cancer recurrence

Published: 24-02-2021
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To study the feasibility and effects of EMDR on FCR.

Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON50927

Source
ToetsingOnline

Brief title
FORWARD

Condition

- Anxiety disorders and symptoms

Synonym
fear of cancer recurrence; anxiety about cancer coming back

Research involving
Human

Sponsors and support

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

Intervention

Keyword: eye movement desensitization reprocessing, fear of cancer recurrence, single-case experiment

Outcome measures

Primary outcome

During a period of twelve weeks participants are asked to daily score their level of FCR with one question via an app on their phone. The scores during the waiting list period in which no intervention is offered (phase A) will be compared to the scores in the intervention period, in which the EMDR protocol is offered plus a follow-up period (phase B). The start of phase B is randomly allocated between day 7 and 37. It is hypothesized that FCR scores are lower in phase B than phase A.

Secondary outcome

After a twelve-week study period, participants and therapists are interviewed to examine the feasibility of the used EMDR protocol. In these interviews, we will explore to what extent is EMDR experienced as helpful in reducing FCR and to what extent does FCR require additional treatment after EMDR.

Study description

Background summary

Many patients suffer from fear of cancer recurrence (FCR) after cancer treatment. Psychological treatments are generally effective in reducing FCR, but not for each patient. These methods focus less explicitly on specific catastrophic scenarios of the future or frightening memories, by which FCR often seems to be triggered and maintained. Eye Movement Desensitization Reprocessing (EMDR), has been effective in diminishing the impact of such catastrophic scenarios and frightening memories in post-traumatic stress disorder and Panic Disorder, resulting in reduced anxiety symptoms. This proof-of-principal study will examine whether EMDR has the potential to reduce FCR.

Study objective

To study the feasibility and effects of EMDR on FCR.

Study design

A mixed-method design in which quantitative data are gathered via a sequential, replicated, randomized single-case AB phase design and qualitative data are gathered with interviews. The case studies will be implemented in the routine clinical care of the Helen Dowling Institute (HDI).

Intervention

The Dutch EMDR-protocol will be used, in which the flash forward is an important feature. The *flash forward* focuses on catastrophic scenarios in the future. This protocol contains two to five weekly sessions.

Study burden and risks

Participation includes filling out a daily question on fear of recurrence. To minimize potential negative effects of a focus on anxiety, a daily question on positive enjoyment will be asked as well. Moreover, the most convenient time of answering the question in a specific time-period in the evening will be set in consultation with the participant. It is not expected that EMDR treatment gives rise to more discomfort or distress in comparison to treatment as usual. Following clinical practice, therapists will closely monitor the functioning of the participants during the treatment phase. After the study period, treatment goals will be evaluated. If FCR is diminished insufficiently or other treatment goals remain unmet, additional treatment will be offered.
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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

- Having received medical treatment for cancer; after the acute phase (i.e. no actual chemotherapy, radiation therapy or surgery)
- Suffer from fear of cancer recurrence (score of 22 or higher on Fear of Cancer Recurrence Inventory - Short Form)
- Referred to HDI for psychological care for fear of recurrence
- Being 18 years or older
- Being able to understand the Dutch language sufficiently.

Exclusion criteria

- Acute suicidal threat
- Acute psychotic disorder
- A history of severe early traumatic experiences

Study design

Design

Study type:	Interventional
Intervention model:	Other

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	7
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-02-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL76078.028.21