EMDR for Fear of Cancer Recurrence in Patients with Familial Melanoma. A waiting list control trial

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Primary Objective: The aim of the proposed study is to investigate whether EMDR is effective in lowering fear of cancer recurrence in patients with familial Melanoma. Secondary Objective(s): effectiveness of EMDR and quality of life at 3 months...

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

Summary

ID

NL-OMON55902

Source
ToetsingOnline

Brief title
FAME

Condition

- Anxiety disorders and symptoms
- Skin neoplasms malignant and unspecified

Synonym
fear of cancer recurrence, fear of melanoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EMDR, familiar melanoma, fear of cancer occurance, Fear of cancer recurrence, fear of melanoma, melanoma

Outcome measures

Primary outcome

The total score of the Cancer Worry Scale (CWS) on T2 is the primairy outcome

measure.

Secondary outcome

Secondary parameters are the effect of the EMDR treatment at 3 months follow-up

(T3), quality of life measured with the EORTC-QLQ-C30

Study description

Background summary

There are an estimated 232100 Cutaneous Melanoma (CM) cases diagnosed and 55500 (24%) reported deaths annually.1 The incidence and mortality rates of CM vary per geographic location and the highest incidence rates are reported for Caucasian populations with fair skin. Approximately 10% of patients diagnosed with CM have a positive family history for this malignancy. CDKN2A gene (p16-leiden mutation) is the major melanoma susceptibility gene explaining approximately 35% of familial cases. Patients with hereditary melanoma due to a CDKN2A mutation have an estimated 70% risk of developing melanoma and a 20% risk of pancreatic cancer. Many patients develop melanoma at an earlier age and many develop multiple melanomas. Patients with familial melanoma and their relatives are offered a screening program at the department of dermatology of the LUMC with regular follow-up visits with a dermatologist to facilitate early detection and prevention of melanoma from the age of twelve.4 Carriers of a CDKN2A mutation are additionally screened for pancreatic cancer using MRI from the age of 40.
Fear of cancer recurrence has been found to be high among patients with CM and also among patients with familial melanoma (Hinnen, Boonstra, Kukutsch, van Doorn 2020). A large group of patients indicate they need help with the uncertainty and threat of developing a new melanoma.5-7 While some amount of fear may be adaptive and bolster adequate healthcare behaviour such as UV protection and skin examination, high levels of fear have a negative impact on

patients quality of life8 and may lead to increased healthcare utilization9,10. EMDR-therapy is a standard treatment for FCR in clinical practise. Till recently the effectiveness was, however, not scientifically demonstrated. Of late, we showed that EMDR-therapy was effective in decreasing FCR in patients with mama- and colorectal carcinoma (Bruin, van Rood, Peeters, de Roos, Tanouis, Portielje, Gelderblom & Hinnen, submitted 2021) In this study with a replicated (n=8) single case experimental design, we found that EMDR had a large effect on high FCR and that 6 out of 8 patients went from high FCR to low FCR after EMDR. EMDR is an evidence-based and protocolized treatment for patients with Post Traumatic Stress Disorder (PTSD) and PTSD symptomatology including fear of future catastrophes (Balkom van et al., 2013). In most patients, fear of future catastrophes (illness recurrence or progression) is based on past experiences. EMDR is an intervention to desensitize both the memories of past experiences as well as the representations of future catastrophes. EMDR has been shown effective not only as treatment for PTSD but also for anxiety in the context of illness or medical situations (Dautovic, de Roos, van Rood, Dommerholt, & Rodenburg, 2016; van Rood & de Roos, 2009; Maroufi, Zamani, Izadikhah, Marofi, & O'Connor, 2016).

Study objective

Primary Objective: The aim of the proposed study is to investigate whether EMDR is effective in lowering fear of cancer recurrence in patients with familial Melanoma.

Secondary Objective(s): effectiveness of EMDR and quality of life at 3 months follow-up (t3)

Baseline characteristics: Marital status, age, gender, educational level, familial history of melanoma, personal history of melanoma, current disease status.

Study design

In this a non-blinded randomized trial with a waiting list patient high on fear of cancer recurrence will be included and randomly assigned to an intervention and waiting-list condition. Those assigned to the intervention condition will start EMDR-therapy immediately after enrolment. Those assigned to the waiting-list will start EMDR therapy after 6 weeks when still meeting the inclusion criteria. Therapy will consist of an intake (90 min) and a maximum of 4 EMDR sessions (90 min each).
After inclusion, baseline characteristic (sociodemographic and clinical variables) will be assessed. Moreover, before start EMDR, before every session and 6 weeks and 3 months after ending therapy FCR will be assessed.

Intervention

EMDR is a psychological intervention that has historically been applied to the treatment of Post-Traumatic Stress Disorder (PTSD), but has since then been shown to be effective 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 and 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).
With more than 25 randomized clinical trials, EMDR has been established as an evidence-based intervention for PTSD and PTSD symptomatology including physical symptoms and fear of future catastrophes (Balkom van et al., 2013).
Like PTSD, high levels of FCR are associated with intrusive thoughts and re-experiencing the event, avoidance of reminders of cancer, hypervigilance, difficulty in making future plans and increased emotional distress (Simonelli et al, 2017).

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 4 sessions. The sessions take place in a face to face appointment at the LUMC Oncology department. The Standard EMDR protocol is used to desensitize patients* most fearful images of past and representations of future cancer related catastrophes

Study burden and risks

Participating in this study will not cause any (physical) harm for the participants. Participants have to travel to the hospital commit to a limited amount of sessions (between 2 and 4 depending on the amount of intrusive images the patient has) of EMDR Primary and secondary outcome measures are filled in online on a computer or tablet from home. Completion of the questionnaires (CWS, 4 times during the study, takes about 20 minutes per assessment, 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)

Inclusion criteria

18 years or older, diagnosed with familial melanoma, melanoma in the past five years, receive regular screenings at the department of dermatology of the LUMC, report high fear of cancer recurrence and have signed an informed consent.

Exclusion criteria

obvious cognitive impairments and insufficient knowledge of the Dutch language.
unstable doses of anxiolytics
acute psychiatric disorder such as psychosis of suicidality

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-12-2023
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	05-10-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	05-11-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL79844.058.22