EMDR treatment of conditioned nausea and vomiting in cancer survivors - a pilot study

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Primary Objective: • To explore the effectiveness of EMDR therapy treatment in reducing symptoms of chemotherapy-induced conditioned nausea and vomiting in (former) patients with cancer.Secondary Objective:• To explore impact on QoL of chemotherapy-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON57194

Source
ToetsingOnline

Brief title
EMESIS

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cancer survivors, EMDR, Nausea, Vomiting

Outcome measures

Primary outcome

Difference in degree of conditioned nausea and vomiting after exposure to conditioned stimuli measured before and after EMDR therapy using the nausea profile questionnaire.

Secondary outcome

Impact on QoL of conditioned nausea and vomiting using Functional Living Index - Emesis (FLIE) questionnaire.

Study description

Background summary

Conditioned nausea and vomiting is a common side effect of anti-cancer treatment, and while strategies like antiemetics exist, their effectiveness is limited. Conditioned nausea and vomiting can possibly be addressed through Eye Movement Desensitization and Reprocessing (EMDR) therapy. EMDR therapy is a therapeutic intervention, proven to be effective in the treatment of post-traumatic stress disorder (PTSD), and promising in treating a range of other conditions. At the UMCG, EMDR therapy is used on a small scale to treat conditioned nausea with positive results, although more rigorous research is needed to fully establish its efficacy.

Study objective

Primary Objective:
• To explore the effectiveness of EMDR therapy treatment in reducing symptoms of chemotherapy-induced conditioned nausea and vomiting in (former) patients with cancer.

Secondary Objective:
• To explore impact on QoL of chemotherapy-induced conditioned nausea and

vomiting in (former) patients with cancer.

Study design

This exploratory study will focus on patients who were previously treated with chemotherapy at the Hematology, Pulmonary Oncology and Medical Oncology Departments of the UMCG. Potential participants are identified by the medical oncologists, pulmonologists, hematologists, psychologists, and dietitians of the UMCG during a regular hospital visit. They will introduce the study to the patient and will ask the potential participants permission to give them a letter from the investigators containing study details.

The study will also be promoted via Hematon region Groningen/Drenthe, the Dutch organization for patients with a hematological malignancy. In addition, an announcement will be made via a poster in the outpatient clinic waiting room at the UMCG. At last, information about the study will be posted on the medical oncology website of the UMCG. Patients can contact the study team if they wish to receive the study details. After receiving the letter, both patient groups will be called after two weeks to ask if they are willing to participate in the study.

If participants are willing to participate, they will be asked to fill in an online questionnaire via REDcap with questions regarding the conditioned stimulus, complaints after exposure to the conditioned stimulus, possible exclusion criteria, and nausea and treatment of nausea during chemotherapy treatment. Furthermore, they will fill in the Functional Living Index - Emesis (FLIE) questionnaire. An appointment will be scheduled with one of the UMCG psychologists. If patients have no questions regarding the study or the study information that was sent, they are asked to sign the informed consent. Next, the degree of conditioned nausea and vomiting will be measured by exposing the participant to the conditioned stimuli, followed by filling in the nausea profile questionnaire about the experienced nausea and vomiting (primary endpoint). Afterwards, the first EMDR therapy session is applied by the hospital psychologist. After 1-3 EMDR therapy sessions, conditioned nausea and vomiting will again be measured after exposure to the conditioned stimuli with the nausea profile questionnaire. At last, the background of the participant will be collected from the patients electronic medical file, including cancer type, type(s) of earlier treatment, duration of treatment, age, gender, medication, and medical psychiatric history. Participants who are not UMCG patients will answer these questions on paper after filling in the nausea profile questionnaire.

Intervention

In this study, EMDR therapy will be performed by psychologists of the UMCG who are trained in EMDR therapy and who have experience with patients with somatic

diseases. In the EMDR therapy protocol, the patient is guided through eight phases which incorporate dual focus of attention and alternating bilateral visual, auditory, and/or tactile stimulation (see supplement for protocol). The number of sessions varies per patient (1-3 sessions), depending on the desensitization of the conditioned stimuli. The sessions will last 60-90 minutes.
EMDR therapy has been utilized in clinical settings for decades, accumulating a substantial body of evidence supporting its safety and efficacy, even in patients with underlying psychological distress like psychosis (18). Numerous studies and meta-analyses have consistently demonstrated its effectiveness in reducing symptoms of PTSD and conditions. The standardized EMDR therapy protocol used by the UMCG psychologists, and their training ensure the safety of the participants.

Study burden and risks

Not applicable
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Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

o Previously pathologically confirmed diagnosis of cancer
o Previously treated with systemic cancer therapy
o Persistent complaints (>2 months) of conditioned nausea and/or vomiting
o Able to understand spoken and written Dutch
o 18 years or older

Exclusion criteria

o Ongoing psychiatric treatment
o EMDR therapy contraindications (dissociative disorders, personality disorders or severe somatic disorders (e.g. cardiac arrhythmias))
o Complex type 2 trauma
o Known with recent conditions / non-anti-cancer medication which can elicit nausea (e.g. pregnancy or alcohol abuses)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2024
Enrollment:	20

Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	05-12-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL87087.042.24
Other	volgt