ISRCTN52555566 https://doi.org/10.1186/ISRCTN52555566

Can a simple task help reduce intrusive memories in patients suffering from intrusions after traumatic events?

Submission date
27/10/2021

Recruitment status
No longer recruiting

Registration date
29/10/2021

Overall study status
Completed

Last Edited
17/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Some people who have experienced traumatic events (e.g. violence, accidents, or critical illness) suffer from intrusive memories. These are memories - often in the form of mental images, or films - that occur involuntarily and can cause severe distress. Intrusive memories form a core symptom of Posttraumatic Stress Disorder (PTSD), a mental condition that causes severe suffering in patients and poses a considerable social and economic burden. While a number of effective treatments for PTSD have been established, many of them require highly-trained specialists and are therefore (or for other reasons) limited in their availability. This study investigates the effect of a novel approach to reduce intrusive memories, using a simple visuospatial task after reactivation of a traumatic memory. The task is part of a commonly used test for prospective physicians (so called Test für Medizinische Studiengänge -TMS) and examines skills in spatial imagination. The effect of this intervention is compared to another intervention, in which participants will read a text and answer questions relating to the text afterwards. We hypothesize that the visuospatial intervention leads to a greater reduction of intrusions than the control condition.

Who can participate?
Adults (at least 18 years of age) who have experienced at least one traumatic event and are currently suffering from intrusive memories. Participants must have sufficient knowledge of the German language to read and understand longer texts (~25min).

What does the study involve?
Participants will have 3 study appointments over the course of 4 weeks. Throughout, they will keep an electronic "intrusion diary", in which they will record the occurrence of specific intrusive memories, which have been decided upon on the first appointment. 2 weeks after the first appointment, they will receive one of two interventions: They will either be asked to write down one of the intrusive memories and deal with a repetitive simple visuospatial task. In this task 80 items will be provided. The challenge is to rotate two cubes mentally. Those two cubes are identical but shown from different perspectives. The participants' job is to find out how to rotate the first cube to make it look like the second one. In the other condition, they will read an

article from Wikipedia, and answer some multiple-choice questions relating to the article afterwards. 2 weeks after the intervention, participants will be invited to answer some questions about the study and are asked for permission to be contacted 6 months after the end of the study for a telephone follow-up.

What are the possible benefits and risks of participating?
In case the intervention proves effective, participants would directly benefit from the reduction of intrusive memories. We expect no negative effects from the questionnaires, the visuospatial task, or reading the Wikipedia Article. Writing down the traumatic memory could possibly lead to arousal and distress. To ensure maximum safety, study sessions take place in the secure and well-monitored environment of a university hospital, and professional support from psychotherapeutically trained physicians is always available. During the study sessions, a member of the research team is always present in the room.

Where is the study run from?
LWL University Hospital Bochum (Germany), Department of Psychosomatic Medicine and Psychotherapy.

When is the study starting and how long is it expected to run for?
January 2021 to June 2023

Who is funding the study?
Application for funding from the Ruhr-University Bochum (FoRUM) is planned.

Who is the main contact?
Professor Henrik Kessler
henrik.kessler@ruhr-uni-bochum.de

Contact information

Type(s)
Scientific

Contact name
Prof Henrik Kessler

Contact details
Klinik für Psychosomatische Medizin und Psychotherapie
LWL-Universitätsklinikum Bochum
Alexandrinenstr. 1-3
Bochum
Germany
44791
+49-234-5077-3176
henrik.kessler@rub.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Investigation on a novel approach for reducing intrusions in patients after a traumatic event. A randomized, controlled interventional trial using a memory reminder and a visuospatial task.

Study objectives
Reactivation of a trauma-related memory, followed by executing a visuospatial task (a commonly used task to test skills in spatial imagination) will significantly reduce the frequency of visual intrusions of the traumatic event in the weeks following the intervention, compared to a verbal control task.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/10/2021, Ethikkommission der Fakultät für Medizin an der Ruhr-Universität Bochum (Ethics committee at the department of Medicine, Ruhr-University Bochum, Gesundheitscampus 33, Bochum, Germany; +49 (0)234 7981 6555; ethik@ruhr-uni-bochum.de), ref: 21-7268

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients suffering from intrusive memories after traumatic experiences

Interventions
Patients receive randomized either the experimental intervention (1.) or the control intervention (2.) at T1 (T0 + 2 weeks):
1. Reactivation of a trauma-related memory by writing down the memory of a specific traumatic event, followed by 25 min of executing a visuospatial task
2. Reading a Wikipedia article for 25 min and answering 8 multiple choice questions relating to the article afterwards
Participants will be followed up for 4 weeks (2 weeks preinterventional and 2 weeks postinterventional).

Randomisation is implemented electronically via the software package REDCap at the AMIB (Ruhr-Universität Bochum, Abteilung für Medizinische Informatik, Biometrie und Epidemiologie, Nina Timmesfeld) and hence occurs independently from the researchers who are in direct contact with the patients. After typing in the patient number at T1, the researcher electronically receives the intervention to be applied in this session. To compute the randomization scheme, interventions are randomly permutated and assigned to T1.

Intervention Type
Behavioural

Primary outcome measure
Frequency of intrusions per week , assessed by patients via an intrusion diary continuously for each week of the 4-week study duration; main focus is on the specific effect on the frequency of intrusions in the two weeks following the intervention. Additonally, retrospectively estimated frequency of intrusions will be assessed in a 6-month telephone follow-up.

Secondary outcome measures
Severity of PTSD-related symptoms, assessed via PTSD Checklist for DSM-5 (PCL-5) at T0 and T2.

Overall study start date
01/01/2021

Completion date
13/06/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/03/2022:

1. Age 18+ years
2. Have experienced at least 1 traumatic event (fulfilling criterion A for PTSD diagnosis according to DSM-5) which happened at least 2 months ago
3. Suffer from intrusive memories that relate to the traumatic event named in 2. Those intrusions should have occurred at least five times a week for the past 2 weeks
4. Sufficient knowledge of the German language
(These were changed before the first participant was recruited.)

Previous inclusion criteria:

1. Age 18+ years
2. Have experienced at least 1 traumatic event (fulfilling criterion A for PTSD diagnosis according to DSM-5)
3. Suffer from intrusive memories that relate to the traumatic event named in 2. Those intrusions should have occurred at least five times a week for the past 2 weeks
4. Sufficient knowledge of the German language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 per protocol

Total final enrolment
52

Key exclusion criteria
Current exclusion criteria as of 11/03/2022:

1. Acute suicidal tendency
2. Severe self-harming behavior, requiring medical care within last 6 months
3. Substance abuse (excluding nicotine) within last 6 months
4. Psychotic symptoms within last 6 months
5. Ongoing trauma therapy (i.e. specific trauma exposure techniques)
(These were changed before the first participant was recruited.)

———

Previous exclusion criteria:

1. Acute suicidal tendency
2. Severe self-harming behavior, requiring medical care within last 6 months
3. Substance abuse (excluding nicotine) within last 6 months
4. Psychotic symptoms within last 6 months

Date of first enrolment
09/12/2021

Date of final enrolment
03/11/2022

Locations

Countries of recruitment
Germany

Study participating centre
Department of Psychosomatic Medicine and Psychotherapy, LWL University Hospital Bochum
Alexandrinenstr. 1-3
Bochum
Germany
44791

Sponsor information

Organisation
LWL-Universitätsklinikum Bochum

Sponsor details
Alexandrinenstr. 1-3
Bochum
Germany
44791
+49-234-5077-3333
info-uk@lwl.org

Sponsor type
Hospital/treatment centre

Website
http://psychosomatik.lwl-uk-bochum.de/

ROR
https://ror.org/04nkkrh90

Funder(s)

Funder type
University/education

Funder Name
Ruhr-Universität Bochum

Alternative Name(s)
Ruhr University Bochum, RUB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date