

Can a simple computer game help reducing intrusive memories in patients suffering from intrusions after traumatic events?

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| Submission date 13/11/2020 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 13/11/2020 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 21/01/2025 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

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 the computer game TETRIS after reactivation of a traumatic memory. 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.

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 4 study appointments over the course of 8 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 and 4 weeks after the first appointment, respectively, they will receive one of two interventions: They will either be asked to write down one of the intrusive memories and play the computer game TETRIS for 25min afterwards. In the other condition, they will read an article from Wikipedia, and answer some multiple-choice questions relating to the article afterwards. 4 weeks after the third appointment, participants will return 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 computer game TETRIS, 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 available at all times. 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 2020 to August 2022

Who is funding the study?

Application for funding from the German Research Foundation's (DFG) Clinical Trials Programme is planned.

Who is the main contact?

Professor Henrik Kessler
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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Application of a behavioural intervention procedure including a memory reminder and a visuospatial task to reduce intrusions in patients after a traumatic event. A randomized, controlled cross-over trial.

Study objectives

Reactivation of a trauma-related memory, followed by executing a visuospatial task (computer game Tetris) 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 24/06/2020, Ethikkommission der Fakultät für Psychologie an der Ruhr-Universität Bochum (Ethics committee at the department of Psychology, Ruhr-University Bochum, Alexandrinenstr. 1-3, 44791, Bochum, Germany; +49 (0)234 7981 6555; ethik@ruhr-uni-bochum.de), ref: 20-6841

Study design

Single-center interventional randomized crossover trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients suffering from intrusive memories after traumatic experiences

Interventions

Patients receive 2 interventions in random order in the course of the study at T1 (T0 + 2 weeks) and T2 (T0 + 4 weeks):

1. Reactivation of a trauma-related memory by writing down the memory of a specific traumatic scene, followed by 25 min TETRIS gameplay
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 8 weeks.

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 and

the intervention time (T1 or T2), the researcher electronically receives the intrusion number to be targeted and the intervention to be applied in this session. To compute the randomization scheme, individual intrusions and interventions are randomly permuted and assigned to the two intervention time windows T1 and T2. With an intra-individual design (cross-over), bias resulting from inter-individual differences is eliminated.

Intervention Type

Behavioural

Primary outcome(s)

Frequency of intrusions per week, assessed by patients via an intrusion diary continuously for each week of the 8-week study duration; main focus is on the specific effect on the frequency of intrusions in the weeks following the intervention.

Key secondary outcome(s)

Severity of PTSD-related symptoms, assessed via PTSD Checklist for DSM-5 (PCL-5) at T0, T1, T2, and two weeks after T2

Completion date

01/08/2022

Eligibility

Key inclusion criteria

1. Age 18+ years
2. Have experienced a traumatic event (fulfilling criterion A for PTSD diagnosis according to DSM-5)
3. Suffer from at least 3 distinguishable intrusive scenes that may relate to one or several different traumatic events (i.e. trauma-related scenes that occur as intrusive memories). Those scenes should have occurred each at least once a week for the past 4 weeks
4. Sufficient knowledge of the German language

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key 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

16/11/2020

Date of final enrolment

01/08/2021

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

University Hospitals of the Ruhr-University of Bochum

ROR

<https://ror.org/03zcpvf19>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

LWL University Hospital, Ruhr-University Bochum

Results and Publications

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 09/04/2024 | 21/01/2025 | Yes | No |