

Posttraumatic intrusions (repetitive and distressing memories, thoughts, or images of a traumatic event) and the link to mental imagery

Submission date 13/02/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/02/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/04/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Many people experience traumatic events during their lifetime. Intrusive memories, also called intrusions, are common after traumatic events, such as sexual abuse, violence or accidents. Those memories occur spontaneously and involuntarily. The content of intrusions is often strongly linked to sensory and emotional representations. Thus, occurrence of intrusions can cause severe distress and substantial impairment of quality of life. Intrusive memories form a core symptom of Posttraumatic Stress Disorder (PTSD). While a number of effective treatments for PTSD have been established, little is known about characteristics, frequency and development of intrusive memories during PTSD treatment. This study investigates characteristics and frequency of posttraumatic intrusions over the course of a PTSD treatment at a specialized unit of a University hospital in Germany. Furthermore, correlations between PTSD symptoms and mental imagery are examined.

Who can participate?

Adults with diagnosis of PTSD according to ICD-10 who undergo day care or inpatient PTSD treatment at the Department of Psychosomatic Medicine and Psychotherapy of the LWL-University Hospital of the Ruhr-University Bochum.

What does the study involve?

Participants will have 2 study appointments over the course of the PTSD treatment (regularly 6-8 weeks). Throughout, they will keep an electronic intrusion diary, in which they will record the occurrence and characteristics of all intrusive memories on a daily basis. Near to admission, LEC-5, PCL-5, VVIQ, PSI-Q and BDI-II are assessed. At the end of treatment, PCL-5, VVIQ, PSI-Q and BDI-II are measured again. Participants are asked for permission to be contacted 3 and 6 months after the end of the study for a follow-up via telephone call.

What are the possible benefits and risks of participating?

They are no direct benefits of participating. We expect no negative effects from the

questionnaires or the intrusion diary. To ensure maximum safety, the study takes place in the secure and well-monitored environment of a University hospital, and professional support from psychotherapeutically trained physicians is always available.

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?

October 2022 to October 2024

Who is funding the study?

There is no specific grant planned from any funding agency in the public, commercial or not-for-profit sectors.

Who is the main contact?

Professor Henrik Kessler

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Intrusions&Mental Imagery 1.0

Study information

Scientific Title

Observational longitudinal examination of characteristics and frequency of posttraumatic intrusions and correlation with both visual and multi-sensory mental imagery during day-care or inpatient PTSD treatment.

Study objectives

This is an observational study interested in the phenomenology of posttraumatic intrusions. Therefore there are no statistically defined hypotheses. Nevertheless, clinical assumptions should be mentioned here. We assume that visual intrusions are the most common of all intrusive memories (average of all intrusions of all diary days). In addition, we assume that frequency and other intrusion characteristics (distress,nowness and vividness) decreases during PTSD treatment (comparison between the average of the first week and the last week of the study). Furthermore, we will analyse correlations between intrusions and mental imagery as well as correlations between PCL-5 and mental imagery. We assume that Scores in VVIQ and PSI-Q (assessed at the start of the study) are positively correlated with both frequency of intrusions during the first week of the diary and the subscales "intrusions" and "avoidance" of PCL-5 (assessed at the start of study).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/11/2022, 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: 22-7696

Study design

Single-center observational trial

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Development of posttraumatic intrusions during day-care or inpatient PTSD treatment.

Interventions

Inpatients or day-care patients suffering from PTSD record frequency and characteristics of their posttraumatic intrusions in a digital intrusion diary on a daily basis. At the start (T0) and the end of the treatment (T1), PCL-5, BDI-II, VVIQ and PSI-Q are measured. At T0, additionally LEC-5 and sociodemographics are assessed, while at T1 a feedback questionnaire about content and benefit of treatment takes place as well. Optionally, a seven-day version of the intrusion diary and PCL-5, BDI-II, VVIQ and PSI-Q are applied once more 3 and 6 months after hospital discharge (T2 and T3).

Intervention Type

Other

Primary outcome measure

Frequency and characteristics of posttraumatic intrusions during day care or inpatient PTSD treatment measured by a digital intrusion diary on a daily basis.

Secondary outcome measures

Timepoints are T0, T1 (start and end of treatment), T2, T3 (3 and 6 months after hospital discharge):

1. Severity of PTSD-related symptoms, assessed via PTSD Checklist for DSM-5 (PCL-5) at T0, T1, T2, T3.
2. Visual mental imagery, assessed via Vividness of Visual Imagery Questionnaire (VVIQ) at T0, T1, T2, T3.

3. Multi-sensory imagery, assessed via Plymouth Sensory Imagery Questionnaire (PSI-Q) at T0, T1, T2, T3.
4. Severity of depressive symptoms, assessed via Beck Depression Inventory II (BDI-II) at T0, T1, T2, T3.

Overall study start date

01/10/2022

Completion date

20/10/2024

Eligibility

Key inclusion criteria

1. Inpatient or day-care PTSD treatment at the Department of Psychosomatic Medicine and Psychotherapy of the LWL-University Hospital of the Ruhr-University Bochum.
2. Diagnosis of Posttraumatic stress disorder according to ICD-10 (F43.1).
3. Motivation and willingness to take part in the study.
4. Age between 18 and 65 years.
5. Sufficient knowledge of the German language.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

40

Total final enrolment

57

Key exclusion criteria

1. Active substance abuse (excluding nicotine).
2. Symptoms of psychosis within the last six months.
3. Acute suicidal tendencies or thoughts.
4. Non corrected vision.

Date of first enrolment

24/02/2023

Date of final enrolment

29/02/2024

Locations

Countries of recruitment

Germany

Study participating centre

Department of Psychosomatic Medicine and Psychotherapy; LWL University Hospital Bochum

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Sponsor information

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LWL-Universitätsklinikum Bochum

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Sponsor type

Hospital/treatment centre

Website

<https://www.lwl-uk-bochum.de/>

ROR

<https://ror.org/04nkkrh90>

Funder(s)

Funder type

University/education

Funder Name

Department of Psychosomatic Medicine and Psychotherapy; LWL University Hospital Bochum

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

20/03/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date