

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

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<b>Registration date</b> 15/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/04/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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  
henrik.kessler@ruhr-uni-bochum.de

## Contact information

### Type(s)

Public

### Contact name

Prof Henrik Kessler

### Contact details

Pacelliallee 4  
Fulda  
Germany  
36043  
+49 661 846591  
henrik.kessler@rub.de

### Type(s)

Scientific

### Contact name

Prof Henrik Kessler

### Contact details

Pacelliallee 4  
Fulda  
Germany  
36043  
+49 661 846591  
henrik.kessler@rub.de

### Type(s)

Principal investigator

**Contact name**

Prof Henrik Kessler

**Contact details**

Pacelliallee 4

Fulda

Germany

36043

+49 661 846591

henrik.kessler@rub.de

**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

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

### **Study type(s)**

Other

### **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(s)**

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

### **Key secondary outcome(s)**

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.

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**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**

Alexandrinenstr. 1-3

Bochum

Germany

44791

# Sponsor information

## Organisation

LWL-Universitätsklinikum Bochum

## 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

## 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