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Can the computer game TETRIS reduce symptoms of re-experiencing in patients suffering from Posttraumatic Stress Disorder?

Submission date
24/11/2016

Recruitment status
No longer recruiting

Registration date
18/01/2017

Overall study status
Completed

Last Edited
11/12/2018

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
During their lifetime, many people are exposed to traumatic events. Possible traumatic events include acts of war, emotional, physical or sexual abuse, neglect, life-threatening accidents or illnesses, or natural disasters. Some of the people who have been exposed to traumatic events develop a condition known as Posttraumatic Stress Disorder (PTSD). PTSD is characterized by recurrent unwanted re-experiencing of traumatic scenes (intrusions, in their most extreme form referred to as "flashbacks"), constantly high stress levels (hyperarousal), and avoidance of trauma-related reminders (e.g. places reminiscent of the traumatic event). A number of treatments have been developed for the treatment of PTSD. Mainly, these include different forms of talking therapies, such as trauma-focused cognitive behavioral therapy (CBT), or Eye-Movement Desensitization and Reprocessing (EMDR). However, these treatments require highly trained specialists, and are therefore limited in their availability and come with high costs. The aim of this study is to investigate the usability and effectiveness of a promising novel treatment approach. To reduce the frequency of unwanted intrusions, PTSD patients undergoing inpatient treatment will play the well-known computer game TETRIS for 25 minutes, following the reactivation of trauma-related material through generation of a written "script" of a specific traumatic scene which is being re-experienced as intrusions.

Who can participate?
Patients aged between 18 and 65 who are suffering from PTSD who are undergoing inpatient treatment.

What does the study involve?
From the beginning of their inpatient treatment, particiants are asked to keep an "intrusion diary", in which they record the occurrence of their different intrusive scenes. After a "baseline" period of 2 weeks, during which participants only fill out the diary in addition to standard inpatient treatment, they receive weekly treatment sessions, in which they are asked to write down a traumatic scene (the reactivation of traumatic material) and then play the computer

game TETRIS for 25 minutes. The treatment lasts for between five and ten weeks. Additionally, patients fill out questionnaires on a weekly basis to assess the severity of PTSD symptoms, as well as levels of depression and anxiety.

What are the possible benefits and risks of participating?
A possible benefit for participating patients may be a reduction in the number of intrusions. No negative effects are expected from keeping the intrusion diary, filling out the questionnaires, or playing the computer game TETRIS. Reactivation of trauma-related material (i.e. writing down the traumatic scenes) may lead to an increase in psychological distress. However, such a reactivation is part of many established PTSD treatments, and patients are in a secure and well-monitored environment, in which professional support is available at all times. During the reactivation/TETRIS sessions, a trained psychotherapist is present in the room to provide support if needed.

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

When is the study starting and how long is it expected to run for?
July 2014 to November 2016.

Who is funding the study?
Mercator Research Center Ruhr (MERCUR) (Germany)

Who is the main contact?
Professor Henrik Kessler
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of trauma reactivation followed by a visuospatial intervention on intrusive symptoms in patients suffering from PTSD: a feasibility study

Study objectives
Reactivation of trauma-related material followed by a visuospatial task (the computer game TETRIS) can reduce the frequency of intrusive symptoms in PTSD patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommission der Fakultät für Psychologie an der Ruhr-Universität Bochum (Ethics committee at the department of Psychology, Ruhr-University Bochum), 30/10/2014

Study design
Single-center uncontrolled open-label interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Post traumatic stress disorder (PTSD)

Interventions
After two weeks of baseline (i.e., only assessing the number of intrusions via self-record intrusion diary), patients receive intervention sessions in the presence of a therapist or research assistant. Intervention sessions are intended to take place on a weekly basis. However, due to practical reasons (e.g. overlap with regular inpatient treatment sessions, instability of patients),

actual frequency of intervention sessions may vary. These intervention sessions typically last about 1 hour, including reactivation of trauma-related material (asking participants to: "Please write down a short report of a specific traumatic scene from a third person perspective"), followed by playing TETRIS for 25 minutes. Subjective levels of arousal are assessed on a 0-10 scale before reactivation, after reactivation, and after playing TETRIS. Also, TETRIS scores are recorded. Intervention sessions are continued until the end of inpatient treatment. There is no follow-up.

Intervention Type
Behavioural

Primary outcome measure
Number of intrusions per week is measured by reviewing “intrusion diaries” kept daily by participants for the duration of their inpatient treatment (5-10 weeks).

Secondary outcome measures
1. PTSD symptom severity is measured using the Impact of Events Scale - Revised (IES-R) at baseline, and then weekly for the duration of inpatient treatment (5-10 weeks)
2. Depression is measured using the Beck Depression Inventory II (BDI-II) at baseline, and then weekly for the duration of inpatient treatment (5-10 weeks)
3. Anxiety is measured using the Beck Anxiety Inventory (BAI) at baseline, and then weekly for the duration of inpatient treatment (5-10 weeks)

Overall study start date
01/07/2014

Completion date
28/11/2016

Eligibility

Key inclusion criteria
1. Age 18-65
2. Diagnosis of PTSD (ICD-10: F43.1) assessed clinically
3. Inpatient treatment (multimodal trauma-focused psychotherapy) at study facility

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Substance abuse or dependence within last 6 months
2. Acute suicidal tendency

Date of first enrolment
16/04/2015

Date of final enrolment
09/06/2016

Locations

Countries of recruitment
Germany

Study participating centre
LWL-Universitätsklinikum Bochum
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Ruhr-Universität Bochum
Alexandrinenstr. 1-3
44791 Bochum
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Sponsor information

Organisation
LWL-Universitätsklinikum Bochum der Ruhr-Universität Bochum

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03zcpvf19

Funder(s)

Funder type
Research organisation

Funder Name
Mercator Research Center Ruhr (MERCUR)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in Spring 2017.

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Henrik Kessler (henrik.kessler@rub.de).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018		Yes	No