ISRCTN66456536 https://doi.org/10.1186/ISRCTN66456536

Electroencephalographic and peripheral physiological correlates of post-traumatic stress disorder as an efficacy indicator of a cognitive-behavioural treatment program

Submission date
27/03/2006

Recruitment status
No longer recruiting

Registration date
31/03/2006

Overall study status
Completed

Last Edited
22/04/2008

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KA 1476/3-1

Study information

Scientific Title

Study objectives
Cognitive-behavioral intervention for patients with post-traumatic stress disorder (PTSD) improves their health in comparison to wait-list control condition

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the University Ethics Committee, Dresden University in September 2001 (ref: 33 02 2001)

Study design
Interventional, randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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

Interventions
Cognitive-behavioral treatment (psychotherapy) versus wait-list control

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Clinical interview for PTSD (CAPS)

Secondary outcome measures
1. Questionnaires
2. Electroencephalogram (EEG) parameters
3. Peripheral electrophysiology

Overall study start date
01/04/2002

Completion date
31/08/2003

Eligibility

Key inclusion criteria
1. Positive diagnosis (above the threshold of standardized clinical assessment according to clinical interview - clinician-administered PTSD scale [CAPS])
2. Age 18-65 years
3. German language competency

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
Co-morbid diagnoses (e.g. bipolar disorder, current alcohol or drug abuse and cognitive impairment)

Date of first enrolment
01/04/2002

Date of final enrolment
31/08/2003

Locations

Countries of recruitment
Germany

Switzerland

Study participating centre
University of Zurich
Zurich
Switzerland
8006

Sponsor information

Organisation
German Research Foundation (Deutsche Forschungsgemeinsschaft) (DFG)

Sponsor details
Kennedyallee 40
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Germany
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Sponsor type
Research organisation

Website
http://www.dfg.de

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research organisation

Funder Name
German Research Foundation (Deutsche Forschungsgemeinsschaft) (DFG) KA 1476/3-1 to /3-3

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	06/07/2006		Yes	No