

# Association of the neuroendocrine parameters of cortisol and adrenocorticotropin hormone (ACTH) during repeated exposure therapy with long-lasting therapy outcome in patients with panic disorder and agoraphobia

<b>Submission date</b> 12/11/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/12/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/08/2019	<b>Condition category</b> 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**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

N/A

## Study information

### Scientific Title

Association of the neuroendocrine parameters of cortisol and adrenocorticotropin hormone (ACTH) during repeated exposure therapy with long-lasting therapy outcome in patients with panic disorder and agoraphobia: an observational study

### Study objectives

During exposure, patients will release higher concentrations of stress hormones compared to controls. Concentrations of stress hormones during exposure will be related to therapy outcome.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Local Ethics Committee (Ethikausschuss 1 am Campus Charité - Mitte, Berlin, Germany) approved on the 6th February 2007 (ref: EA1/199/06)

### Study design

Observational case-control study

### Primary study design

Observational

### Study type(s)

Quality of life

### Health condition(s) or problem(s) studied

Panic disorder with agoraphobia

### Interventions

Eight sessions of standardised and manualised cognitive behavioural group-therapy for panic disorder and agoraphobia plus three individual exposure therapy sessions employing flooding technique, were administered. Before, during and after exposure therapy, blood samples were drawn via an indwelling catheter from each patient.

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome(s)

1. Concentrations of cortisol and adrenocorticotropin hormone (ACTH) during exposure training
2. Panic and Agoraphobia Scale after therapy and at follow-up

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

1. Mobility Inventory for Agoraphobia after therapy and at follow-up
2. Beck Depression Inventory after therapy and at follow-up
3. Beck Anxiety Inventory after therapy and at follow-up
4. Hamilton Rating Scale for Depression after therapy and at follow-up
5. Hamilton Rating Scale for Anxiety after therapy and at follow-up
6. Clinical Global Impression after therapy and at follow-up

### **Completion date**

01/03/2008

## **Eligibility**

### **Key inclusion criteria**

1. Subject familiarised with experimental procedure and had given written informed consent
2. Diagnosis of panic disorder with agoraphobia according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM IV), at least "moderately ill"
3. Aged 18 - 75 years, either sex
4. Sufficiently able to communicate with investigator, answer questions and fill in questionnaires
5. Reachability of patient for treatment and follow-up
6. Compliance of patient
7. Undisturbed day-night rhythm

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

20

### **Key exclusion criteria**

1. Inability to give informed consent
2. Hospitalisation in a mental institution
3. Other psychiatric illnesses like schizophrenia, substance abuse or dementia
4. Acute suicidal tendency

5. Epilepsy or other illness of the central nervous system (CNS) (e.g. brain tumour, encephalitis)
6. Severe internal medical illness, e.g., severe hypertension, severe cardiac insufficiency, condition after acute myocardial infarction, cardiac arrhythmia of severity index IV or V according to Lown grade, severe dysfunction of liver or kidney, diabetes mellitus requiring insulin treatment, disturbances of haematopoiesis
7. Pregnancy or breastfeeding
8. Changes of psychopharmacological treatment within the last 8 weeks or discontinuation of psychopharmacological treatment within less than 2 weeks before beginning of the study
9. Recent interference with diurnal cycle
10. Current psychotherapeutic treatment specific for panic disorder and/or agoraphobia
11. Participation in other study within last month before beginning of the study or during the study

**Date of first enrolment**

01/03/2007

**Date of final enrolment**

01/03/2008

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

Clinic of Psychiatry and Psychotherapy

Berlin

Germany

10117

## Sponsor information

**Organisation**

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

**ROR**

<https://ror.org/001w7jn25>

## Funder(s)

**Funder type**

Government

## Funder Name

German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany) (ref: 01 GV 0612)

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/03/2011	21/08/2019	Yes	No