

# Psychotherapy study to examine whether exposure-based psychotherapy for anxiety disorders is particularly effective when endogenous cortisol levels are high

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<b>Registration date</b> 08/04/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/04/2013	<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

Exposure-based psychotherapy is the gold standard for treating anxiety disorders. Recent research has indicated that the effectiveness of exposure may be increased by cortisol administration before treatment sessions. Cortisol administration may however have unpleasant side effects. Therefore, the current study wants to investigate whether natural variation in endogenous cortisol levels can be used to improve exposure-based psychotherapy.

Our physiological status differs a lot from morning to evening. For example the cortisol level is high in the morning and then declines during the day with low levels in the evening/night. In our study we want to examine whether the endogenous variations in diurnal cortisol levels are also able to modulate therapy outcome. That is why we expect therapy in the morning (when cortisol levels are high) to have a better outcome than therapy in the evening (when endogenous cortisol levels are low). The two groups will receive the same treatment, but are randomly allocated to receiving this treatment either at 8am or at 6pm.

### Who can participate?

We wish to treat 60 patients with spider phobia. Participation is restricted to physically healthy, non smoking women who use oral contraceptives and who have a body mass index between 20 and 25.

### What does the study involve?

Participants will receive state of the art psychotherapy treatment for spider phobia. Participants will need to come for two sessions. In the first session, it will be determined if participants fulfil diagnostic criteria for spider phobia and meet criteria for study participation. The treatment is also explained in detail. The second session is the real treatment session. It will last approximately three hours and will involve confrontation with living spiders. Participants will also be required to fill in a number of questionnaires and to give saliva samples and a strand of

hair so that we can measure endogenous cortisol levels. One week and three months after the treatment session, participants come back for a behavioural approach task, which examines how close they can get to a live spider.

What are the possible risks and benefits of patients?

The study involves no risks and most participants will benefit from it. The treatment manual is well-established and known to be highly effective. People with low endogenous cortisol levels may, however, profit a little bit less than people with high cortisol levels.

Where is the study run from?

The study is run at the Saarland University (Germany). It is conducted by the Department of Psychology, Division of Clinical Psychology and Psychotherapy.

When is study starting and how long is it expected to run for?

The study started in Summer 2011 and will end when 60 patients have been treated.

Who is funding the study?

The study is exclusively funded by the Saarland University.

Who is the main contact?

Prof. Dr. Tanja Michael

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Tanja Michael

### Contact details

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## Additional identifiers

## Study information

### Scientific Title

Randomised controlled trial to determine whether the effectiveness of exposure-based psychotherapy for specific phobia is influenced by endogenous cortisol levels

### Study objectives

Patients with high endogenous levels of cortisol profit more from treatment than patients with low endogenous levels of cortisol

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethical committee of the medical association of Saarland was provided on March 17 th 2011

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

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

Treatment

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

Specific Phobia (Spider Phobia) / Psychotherapy

### **Interventions**

Comparing two treatment conditions for spider phobia.

Participants underwent a one session (three hour) exposure therapy treatment. Participants were gradually exposed to different living spiders of increasing sizes and cognitions about spiders were challenged during treatment.

The therapy session consisted of several exposure steps with increasing complexity. The therapist first demonstrated each exposure task to the patient and then asked the patient to carry out the task. Each task was repeated till a marked anxiety reduction occurred. The first step was to catch the smallest spider with a glass and a postcard. After this task was accomplished with a low anxiety level the patient was asked to touch the spider with his index finger. The third step was to let the spider walk on the patients hand. After this, the therapists instructed the patient to let the spider walk on her body. The above four steps were then repeated with another 2 spiders of gradually larger size, the largest being about 5 cm (with legs.)

The two treatment conditions differed solely in the time of interventions. Treatments in the first group were conducted at 08.00 a.m. in the morning, treatments in the second group were conducted at 06.00 p.m. in the evening. Participation included four appointments: an initial screening session to clarify study eligibility and to assess symptoms before treatment (pretreatment assessment), one three-hour-treatment session (either at 08.00 a.m. in the morning or at 06.00 p.m. in the evening), an assessment one week after the treatment session (posttreatment assessment), and a follow-up assessment 12-14 weeks after the treatment session (follow-up assessment).

### **Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Behavioural Approach Test (BAT): To test the patients fear and avoidance of living spiders participants are asked to approach a living house spider that is placed in a sealed container. The patients behaviour is rated on a scale from 0 to 12, where 0: refusal to enter the room and 12: holding the spider for at least 20 seconds.

Measured at baseline (prior to treatment), one week after treatment, and three months (12-14 weeks after treatment).

**Key secondary outcome(s)**

Fear of Spider Questionnaire (FSQ): The FSQ is a self-report questionnaire designed to measure spider phobia. It consists of 18 items that refer to a restricted time period and are rated on a seven point scale.

Measured at baseline (prior to treatment), one week after treatment, and three months (12-14 weeks after treatment).

**Completion date**

31/05/2012

**Eligibility****Key inclusion criteria**

Participation is restricted to:

1. Healthy, non-smoking women, aged 18-60
2. Using oral contraceptives
3. Body mass index between 20-25 mg<sup>2</sup>

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Lower age limit**

18 Years

**Upper age limit**

60 Years

**Sex**

Female

**Key exclusion criteria**

1. Recent history of systemic or oral cortisol therapy
2. Any axis I disorder (other than spider phobia)
3. Severe acute or chronic disease (e.g. lung or heart diseases)
4. Allergic reactions to insect bites
5. Pregnancy and lactating
5. Current pharmacological treatment or psychotherapy
6. We also require patients to refrain from physical exercise, alcohol and caffeinated drinks within 3 hours prior to therapy

**Date of first enrolment**

01/06/2011

**Date of final enrolment**

31/05/2012

## Locations

**Countries of recruitment**

Germany

**Study participating centre****Saarland University**

Saarbruecken

Germany

66123

## Sponsor information

**Organisation**

University of Saarland (Germany)

**ROR**

<https://ror.org/01jdpv68>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Saarland University (Germany)

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration