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

Submission date
20/02/2013

Recruitment status
No longer recruiting

Registration date
08/04/2013

Overall study status
Completed

Last Edited
30/04/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 than 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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).

Secondary outcome measures
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).

Overall study start date
01/06/2011

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^2

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Female

Target number of participants
Sixty

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)

Sponsor details
Universität des Saarlandes
Campus
D-66123 Saarbrücken
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Sponsor type
University/education

Website
http://www.uni-saarland.de/

ROR
https://ror.org/01jdpyv68

Funder(s)

Funder type
University/education

Funder Name
Saarland University (Germany)

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