ISRCTN12918583 https://doi.org/10.1186/ISRCTN12918583

Assessing and training fear inhibition in spider phobia via eye-movements

Submission date
23/02/2022

Recruitment status
No longer recruiting

Registration date
28/02/2022

Overall study status
Completed

Last Edited
02/09/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aim
Anxiety and fear can be characterized by a shift of attention in favor of threatening stimuli. According to the Attentional-Control-Theory, this bias is associated with a decreased inhibition of bottom-up perceptual processes. Inhibitory control can be investigated by means of the antisaccade task, in which participants are required to look into the opposite direction of a stimulus in the peripheral visual field. Higher antisaccade latencies and error rates thereby indicate inhibitory control deficits, which are considered a pathogenic factor in anxiety disorders. In line with this, previous studies have revealed an impaired antisaccade performance in participants with subclinical anxiety. However, studies investigating clinical populations are sparse.
This study has three main goals: First, we aim to compare the antisaccade performance of spider phobic patients with healthy control participants. Second, we aim to investigate associations between antisacccade performance and psychophysiological (heart rate, skin conductance level, startle response) as well as behavioral measures of fear (ratings, behavioral avoidance test) towards threatening stimuli. Third, this study aims to explore effects of an antisaccade training on inhibitory control (indexed by antisaccade performance), as well as psychophysiological and behavioral measures of fear.

Who can participate?
Patients with a specific phobia of the animal subtype (spiders) who fulfill the criteria for a specific phobia.
Healthy participants who do not fulfill the criteria for a specific phobia and do not exceed a value of 19 points in the spider phobia questionnaire (SPQ).

What does the study involve?
Participants take part in a brief screening and a diagnostic interview via telephone. If they meet the inclusion criteria, they will provide informed consent, fill in psychometric questionnaires and participate in laboratory assessments (2-3 hours for healthy controls and 3-4 hours for patients with spider phobia): First, a baseline assessment including a Behavioral Avoidance Test (BAT), a free viewing paradigm with physiological assessments (heart rate, skin conductance level, startle response), and the anti-saccade task with an eye-tracking assessment will be obtained. Second, participants are randomized into two intervention groups receiving an anti-saccade

(experimental group) or a pro-saccade training (control group). Afterwards, the post-1-assessment of the antisaccade task and the BAT are conducted.
From this point on the assessment continues only for participants with specific phobia. These switch training conditions and then participate in the post-2-assessment composed of the antisaccade task, the free viewing physiological assessment, and the BAT.

What are the possible benefits and risks of participating?
Results of this study shed light to pathogenic mechanisms involved in pathological anxiety and their modulation. As such, it may inform future research and clinical approaches of anxiety treatment. The risks of participating in the study are a short increase of anxiety, due to the anxiety-inducing stimuli, loud startle noises, and fatigue of the eyes.

Where is the study run from?
University of Siegen (Germany) and University of Münster (Germany)

When is the study starting and how long is it expected to run for?
June 2021 to December 2023

Who is funding the study?
DGPs (German Society for Psychology: Biological Psychology and Neuropsychology)
Movisens (Germany)
Innovative Medizinische Forschung (IMF) of the medical faculty of Münster (Germany)

Who is the main contact?
Dr. Kati Roesmann (Kati.Roesmann@uni-siegen.de)
Fabian Breuer M.Sc. (breuerfa@uni-muenster.de)

Contact information

Type(s)
Principal investigator

Contact name
Dr Kati Roesmann

ORCID ID
https://orcid.org/0000-0001-6940-3551

Contact details
Obergraben 23
Siegen
Germany
57072
+49 271 740-5123
Kati.Roesmann@uni-siegen.de

Additional identifiers

Study information

Scientific Title
Inhibitory control and its modification in specific phobia - An antisaccade study

Acronym
SPIN

Study objectives
H1: Phobics will show higher latencies and error rates, i.e. a poorer performance, than healthy controls in the antisaccade paradigm.
H1.1: Differences in antisaccade performance between phobics and healthy controls are higher when using phobia-related vs. neutral stimuli.
H2: Latencies and error-rates in the anti-saccade task are correlated with physiological (skin conductance response, heart rate, startle-response) and behavioral measures of fear.
H3: The anti-saccade training improves antisaccade performance (i.e., lower error rates, and shorter latencies)
H4: Changes in antisaccade performance are associated with changes in behavioral and physiological measures of fear.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/09/2021, Ethics Committee of the University of Siegen (Adolf-Reichwein-Str. 2a, NA, 57076, Germany; +49 0271 740-4819; ethikrat@uni-siegen.de), ref: ER_39/2021

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Inhibitory control in specific phobia of the animal typus (spider).

Interventions
Intervention group: Antisaccade training
Control group: Prosaccade training
Participants will be randomised into the two groups by a randomisation sheet.

Antisaccade Training: Visual stimuli (pictures of spiders) will be presented on a screen in the left or right peripheral visual field. Participants are instructed to look at the mirrored position on the screen. The duration of this training is 15 minutes including short breaks.
Prosaccade Training: Visual stimuli (pictures of neutral objects) will be presented on a screen in the left or right peripheral visual field. Participants are instructed to look at the presented stimulus. The duration of this training is 15 minutes including short breaks.

Intervention Type
Behavioural

Primary outcome(s)
Antisaccade latencies will be measured in the antisaccade task at baseline, post-1-, and - for spider phobics only - post-2-assessment. All assessments take place on one day.

Key secondary outcome(s)
Antisaccade error rates will be measured in the antisaccade task at baseline, post-1-, and - for spider phobics only - post-2-assessment. All assessments take place on one day

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. 18-65 years
2. Specific phobia (animal-subtype: spider) and healthy controls
3. Normal or corrected-to normal vision
4. Normal hearing

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Lifetime diagnosis of substance-related bipolar or psychotic disorder
2. Current psychiatric disorder or a psychiatric disorder in the past (exception for spider phobics: past mild to moderate depressive episode and/or current or past specific phobia of the animal typus)
3. Medication (Benzodiazepine, Barbiturate)
4. Neurological disorder (especially epilepsy)
5. Dementia
6. Injury of the central nervous system
7. Hearing disorder (also tinnitus anamnestic), subjective auditory hypersensitivity (like

hyperacusis)
8. Regular nicotine consumption (>5 cigarettes/day)
9. Known allergy to bites of insects or arachnids

Date of first enrolment
01/03/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Germany

Study participating centre
University of Siegen
Obergraben 23
Siegen
Germany
57072

Sponsor information

Organisation
University of Siegen

ROR
https://ror.org/02azyry73

Funder(s)

Funder type
University/education

Funder Name
Medizinische Fakultät, Westfälische Wilhelms-Universität Münster

Alternative Name(s)
Medical Faculty Münster, Medical Faculty, WWU Münster, Medizinische Fakultät Münster

Funding Body Type

Government organisation

Funding Body Subtype
Local government

Location
Germany

Funder Name
German Society for Psychology: Biological Psychology and Neuropsychology

Funder Name
Movisens

Results and Publications

Individual participant data (IPD) sharing plan
Data are available upon reasonable request.
Kati.Roesmann@uni-siegen.de, breuerfa@uni-muenster.de

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/12/2023	08/01/2024	Yes	No
Statistical Analysis Plan	A SAP on planned analyses of data obtained during the baseline assessment version 1.0	30/11/2022	09/12/2022	No	No
Statistical Analysis Plan	A SAP on planned analyses of data obtained during the intervention assessment version 1.0		12/04/2023	No	No
Statistical Analysis Plan			02/09/2024	No	No