







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

<b>Submission date</b> 23/02/2022	<b>Recruitment status</b> No longer recruiting	 Prospectively registered
<b>Registration date</b> 28/02/2022	<b>Overall study status</b> Completed	 Protocol added
<b>Last Edited</b> 08/01/2024	<b>Condition category</b> Mental and Behavioural Disorders	 SAP added
		 Results not yet added and study completed for less than 1 year
		 Raw data not yet added
		 Study completed

## Plain English Summary

### 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 antisaccade 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

<http://orcid.org/0000-0001-6940-3551>

### Contact details

Obergraben 23

Siegen

Germany

57072

+49 271 740-5123

Kati.Roesmann@uni-siegen.de

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Protocol/serial number**

Nil known

## Study information

**Scientific Title**

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

**Acronym**

SPIN

**Study hypothesis**

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

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

## Study type(s)

Other

## Participant information sheet

Not available in web format, please use contact information to request a participant information sheet

## Condition

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 measure

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.

## Secondary outcome measures

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

## Overall study start date

01/06/2021

## Overall study end date

31/12/2023

# Eligibility

## Participant 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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

60 (30 patients with spider phobia, 30 healthy control participants)

**Participant 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

**Recruitment start date**

01/03/2022

**Recruitment end date**

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

## Sponsor details

Adolf-Reichwein-Straße 2

Siegen

Germany

57076

+49 271 740-4106

tim.klucken@psychologie.uni-siegen.de

## Sponsor type

University/education

## Website

<https://www.uni-siegen.de/start/>

## 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

## Funder Name

Movisens

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

### Intention to publish date

31/12/2024

### 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?
<a href="#">Statistical Analysis Plan</a>	A SAP on planned analyses of data obtained during the baseline assessment version 1.0	30/11/2022	09/12/2022	No	No
<a href="#">Statistical Analysis Plan</a>	A SAP on planned analyses of data obtained during the intervention assessment version 1.0		12/04/2023	No	No
<a href="#">Protocol article</a>		19/12/2023	08/01/2024	Yes	No