Social safety learning in adolescents with and without clinical anxiety.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON57097

Source
ToetsingOnline

Brief title
Social safety learning

Condition

- Anxiety disorders and symptoms

Synonym
associative learning, fear

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Delfland (Delft)
Source(s) of monetary or material Support: Stichting GGZ Delfland

Intervention

Keyword: Clinical anxiety, Safety learning, Vicarious fear extinction

Outcome measures

Primary outcome

The main study parameters are conditioned response (measured by means of skin conductance response), subjective levels of distress, US expectancy ratings, anxiety symptoms and quality of life.

Secondary outcome

Other relevant study parameters are susceptibility to peer influence, pubertal development, perceptions of the observed learning model, and demographics, measured with questionnaires.

Study description

Background summary

Clinical anxiety disorders are one of the most prevalent disorders in modern society. Exposure-based cognitive behavioral therapy (CBT) has received the most empirical support for treating anxiety disorders in children and adolescents, however response rates are still only around 50%. A very important mechanism for exposure-based CBT is safety learning, in which adolescents have relatively more difficulty. Tapping into adolescent-specific ports-of-entry, such as peer influence, might therefore help enhance treatment effectiveness. In the current study, we will investigate whether peer influence might enhance adequate safety learning by comparing vicarious safety learning to non-vicarious safety learning in adolescents with and without clinical anxiety. Golkar et al. (2013) already showed first evidence that vicarious safety learning, as compared to non-vicarious safety learning, may be related to more efficient down regulation of anxiety in an adult population, hence we aim to replicate these results in two samples: typically developing and clinically anxious adolescents.

Study objective

The general aim of this project is to better understand the mechanisms involved in safety learning, specifically in adolescents with and without clinical anxiety. First, we aim to investigate differences in vicarious and non-vicarious safety learning. Second, we aim to investigate whether adolescents with clinical anxiety show delayed safety learning, compared to typically developing adolescents. Third, we aim to investigate vicarious and non-vicarious safety learning in relation to CBT treatment outcomes in the clinical anxiety group.

Study design

The current study is a within x between subjects design. Participants are randomly assigned to the vicarious non-vicarious safety learning condition. We will compare the effects of vicarious versus non-vicarious safety learning, as measured physically (by means of skin conductance response) and subjectively (self-reported level of distress and US expectancy ratings). We will compare two groups: clinical anxiety and typically developing adolescents. Lastly, in the clinical anxiety group, the relation between safety learning (physical and subjective) and treatment effectiveness of CBT treatment as usual (by means of reduction in anxiety symptoms), is investigated on within subject level.

Study burden and risks

The burden to participants is considered to be minimal, as the study consists only of questionnaires and one behavioural task. For the typically developing adolescents, the study consists of one session, which includes the safety learning task and questionnaires. For the clinically anxiety group, the study consists of six sessions. The first session is equal to the typically developing group, consisting of the safety learning task and questionnaires. The other five session consists of questionnaires that are conducted during and after treatment as usual. All session will take between 20-60 minutes. Risk of participation is also considered to be minimal, because the behavioural task is based on validated safety learning paradigms used with children and adolescents (Britton et al., 2013; Lau et al., 2011;), and in clinically anxious adolescents (Lau et al., 2008; Waters, Henry & Neumann, 2009), which were shown to be safe to use.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Typically developing adolescents
- Sufficiency in the Dutch language
- In between age 12 to 18 years old

For the clinical anxiety group, the following additional inclusion criteria are in place:
- Diagnosed with a clinical anxiety disorder
- Awaiting the start of CBT treatment for their anxiety disorder, or recently started CBT treatment but not yet received exposure therapy.
- Not currently receiving other forms of treatment for anxiety

Exclusion criteria

For the clinical anxiety group, the following additional exclusion criteria are in place:
- Current PTSD diagnosis
- Current autism spectrum disorder diagnosis
- Current use of psychotropic medications (unless they quit 24 hours before participation). For this criterium, a consult with the general practitioner or

the psychiatrist is needed before participants can enroll.

For the typically developing group, the following additional exclusion criterium is in place:
- Any current or past diagnosed psychiatric disorders

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	08-11-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87055.058.24