

Online medical hypnosis exercises to improve mental health in primary school children and prevent future mental health issues.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON57387

Source

ToetsingOnline

Brief title

Hypnosis to improve mental health in primary school children

Condition

- Anxiety disorders and symptoms

Synonym

improvement of self-esteem and resilience

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: een deel wordt gefinancierd door de ontwikkelaar van de online hypnose oefeningen (=de Breinbaas academy BV). Een kleiner deel wordt gefinancierd door de Stichting Hypnose voor Kinderen

Intervention

Keyword: hypnosis, primary school children, resilience, self-esteem

Outcome measures

Primary outcome

The primary outcome measure is the difference in self-esteem at week six compared to the baseline. This is measured using the "Rosenberg Self-Esteem Scale for Children." As one of the secondary outcome measures, it will also be measured at 6 months.

Secondary outcome

Secondary outcome measures include the difference between baseline and 6 weeks or 6 months in terms of resilience, measured using the "Connor-Davidson Resilience Scale for Children". Additionally, improvements in psychosocial functioning ("Strength and Difficulties Questionnaire"), stress ("Chronic Stress Questionnaire for Children and Adolescents"), and sleep will be assessed at these time points.

There is also a short, self-designed questionnaire for parents regarding short-term effects on mood, sleep, behavior, and social interactions at 6 weeks. .

Study description

Background summary

Early adolescence marks a crucial period for the development and onset of mental health problems, which often manifest as disorders in the course of adulthood if they are not dealt with early on. Moreover, there is an increased prevalence of disorders like anxiety and depression in adolescence.ue to long waiting lists, teenagers have to wait long for adequate treatment. Prevention of these mental health problems is therefore of great importance.

Study objective

The primary objective is to study the effect of daily listening for 6 weeks to the Breinbaas hypnosis recordings on self esteem compared to controls. Secondary objective(s) are studying the effect of daily listening to the Breinbaas hypnosis recordings for 6 weeks on change in resilience, psychosocial functioning, overall stress level, and other effects like sleep compared to controls.

Study design

Study design: This is a randomized, controlled, open-label study with a duration of six months. All children from the same school will be randomized to start immediately with the online program (Group A) or after six months (Group B). Group B will, therefore, be the control group of A.

Intervention

The online Breinbaas academy program consists of hypnosis audio recordings that children will listen to on every schoolday for six weeks. The hypnosis audio recordings aim to improve children*s mental health. During the listening stories children will receive suggestions for improvement of self-esteem, self-love, relaxation etc.

Study burden and risks

Hypnosis is a very safe intervention; it is being used in the Netherlands by hundreds of children with irritable bowel syndrome and functional abdominal pain. Side effects are rare. Some children may mention some dizziness during the first time they listen to the exercises, and we then advocate them to listen while lying in bed. Rarely, children may feel some emotions coming up, like sadness. This can occur during the relaxation, which is a part of the trance induction. Explanaton on this phenomen will be given before start of the exercises including advice on how to deal with it.The possible benefits are that hypnosis can improve self-esteem and resilience and hopefully decrease feelings of anxiety and depression, and improve quality of life at adolescence.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Children visiting group 6 or 7 of the participating primary schools will be invited to participate. Schools will be recruited in 3 areas in the Netherlands: in and around the cities of Eindhoven, Leiden, and Utrecht. In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- a. Fluent in Dutch
- b. Permission of the parents to participate in this study and to listen daily to one of the Breinbaas hypnosis exercises (maximum 20 minutes per day)
- c. Access to an electronic device to listen to the Breinbaas exercises (phone, tablet, computer)

Exclusion criteria

- a. Children treated with hypnotherapy in the three years preceding potential inclusion
- b. Children currently receiving psychological treatment

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	340
Type:	Anticipated

Medical products/devices used

Registration:	No
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Ethics review

Approved WMO	
Date:	08-04-2025
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL87558.100.24