

Effect study of school-based sleep intervention for autistic adolescents

No registrations found.

| | |
|------------------------------|----------------|
| Ethical review | Not applicable |
| Status | Pending |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON20865

Source

NTR

Brief title

TBA

Health condition

Autism Spectrum Disorder (ASD)

Sponsors and support

Primary sponsor: N/A

Source(s) of monetary or material Support: The Taskforce for Applied Research SIA [RAAK.PRO 02.150]

Intervention

Outcome measures

Primary outcome

This study has two primary outcome variables: sleep quality (mean of questions about how well they slept, their feeling of being rested when waking up and difficulties with waking up) and daytime functioning as reported by adolescents (sum of scores on mood, concentration, daytime sleepiness). These variables are measured by self-reports and rated from 1 to 10

(see also https://aspredicted.org/XFK_HHG).

Secondary outcome

Besides primary outcome measures, we also have 14 secondary outcome measures:

- Insomnia severity total score (ISI; Bastien, Vallières, & Morin, 2001) completed by adolescents
- Sleep onset latency
 - objectively measured by adolescents
 - subjectively measured by adolescents
- Total sleep time
 - objectively measured by adolescents
 - subjectively measured by adolescents
- Wake time after sleep onset
 - objectively measured by adolescents
 - subjectively measured by adolescents
- Behavioral problems total score (SDQ; Goodman, 2001):
 - completed by adolescents
 - completed by parents
 - completed by teachers
- Sleep disturbances total score (CSHQ; Owens et al., 2000) completed by parents
- Daytime functioning: average of the scores on mood, concentration, sleepiness:
 - completed by parents
 - completed by teachers
- Grades in school: average of the subjects Dutch, English and Math

Study description

Background summary

In this study the effectiveness of the, previously developed, school-based sleep intervention is investigated by means of a multiple baseline design. The sleep intervention consists of three parts: 1) monitoring the adolescents' sleep and daytime functioning, 2) holding a sleep consultation with a teacher based on the monitoring, and 3) executing the sleep recommendations.

Study objective

The school-based sleep intervention is effective in improving self-reported sleep quality.

Study design

1. Baseline (2 to 3 weeks)

2. During intervention (every 3 weeks for 1 week)
3. Follow-up (8 weeks after the intervention for 1 week)

Intervention

The school-based personalized sleep intervention is provided by teachers and consists of three parts: 1) monitoring the adolescents' sleep and daytime functioning, 2) holding a sleep consultation with a teacher based on the monitoring, and 3) executing the sleep recommendations. The intervention follows a modular approach to allow teachers to focus on the specific sleep problem of each adolescent.

Contacts

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Eligibility criteria

Inclusion criteria

(a) follow education at one of the participating schools, (b) diagnosed with an autism spectrum disorder by a psychiatrist or psychologist, based on DSM-IV or DSM-5 criteria, (c) presence of sleep problems, reported by the pupil based on the total score (> 7 ; which means sub-threshold insomnia) on the Insomnia Severity Index, (d) medication free or at a stable dose during participation in the study, (e) have access to a smartphone, pc, or tablet, and (f) have an own e-mail address.

Exclusion criteria

(a) intellectual disability, (b) indications of or diagnosed depression, anxiety disorder, substance dependence or game addiction, (c) disturbed parent-child relationship that can hinder the intervention, and (d) indications that pupil (and parent) will have difficulties to

perform the requested activities.

Study design

Design

| | |
|---------------------|-------------------------|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Pending |
| Start date (anticipated): | 13-09-2021 |
| Enrollment: | 20 |
| Type: | Anticipated |

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

| | |
|-------------------|----------------|
| Not applicable | |
| Application type: | Not applicable |

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

NTR-new NL9685

Other Ethics Review Board of the Faculty of Social and Behavioral Sciences of the University of Amsterdam : 2021-EXT-13604

Study results