Effectiveness of a guided e-health CBT-I based intervention for insomnia in autistic adults (i-Sleep Autism)

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Objective: To test if participants with autism engaging in a CBT-I based online guided intervention (i-Sleep Autism) will experience a significant reduction in insomnia symptoms and improved mental health outcomes compared to the control group (…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56692

Source
ToetsingOnline

Brief title
i-Sleep Autism

Condition

- Other condition

Synonym
Insomnia, sleeplessness

Health condition

insomnia, slaapstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw;grant number: 60-63600-98-834

Intervention

Keyword: autistic adults, cbt-i, e-health, insomnia

Outcome measures

Primary outcome

Main study parameters/endpoints: The primary outcome will be insomnia severity.

Secondary outcome

Secondary outcomes will be mental health, quality of life, depression, anxiety,

and daily functioning. Outcomes will be measured at baseline, mid-intervention

(3 weeks), at post-intervention (6 weeks after baseline), and at 6 months

follow up. We will also explore moderators (expectations, preference,

motivation, baseline symptom severity, insomnia duration) of the intervention

effect.

Study description

Background summary

Rationale: Sleeping problems, particularly insomnia, are among the most common problems that autistic adults face, and these problems have an enormous impact on the quality of life of this population. CBT-I is the first treatment choice for insomnia, but autistic individuals might require an adjusted approach, considering for example differences in sensory- and information processing, social interactions, and (un)employment rates when compared to neurotypical individuals. Internet-based CBT-I might be a promising venue to target insomnia in this population, but to our knowledge, no guided internet-based CBTi interventions have previously been developed and tested in adults with autism, despite the pressing need.

Study objective

Objective: To test if participants with autism engaging in a CBT-I based online guided intervention (i-Sleep Autism) will experience a significant reduction in insomnia symptoms and improved mental health outcomes compared to the control group (online psychoeducation and sleep hygiene).

Study design

Study design: We will employ a pragmatic, parallel, superiority randomized controlled trial design comparing a guided e-health intervention to a minimally active waitlist control condition with psychoeducation and sleep hygiene.

Intervention

Intervention: i-Sleep Autism is an adapted version of i-Sleep, a guided e-health intervention based on CBTi principles, aimed at improving sleep problems (insomnia) in autistic adults. It consists of 5 modules, which are to be completed in about 5 weeks, and a sleep diary. The intervention will be entirely held online, and participants will receive weekly feedback from a coach.

Study burden and risks

The provision of a free, low-intensity CBTi self-help intervention poses minimal risks. During sleep restriction, participants may experience increased fatigue, and we provide adequate warnings for this. Thus far, no adverse events have been reported in previous trials similar to CBTi. Adverse events are regularly assessed at each follow-up, with coaches monitoring progress. In the event of any (serious) adverse events, the researcher, under the supervision of a licensed psychologist, will promptly reach out to the participant. The burden for participants is limited, as participation in the research requires no travel time, and interventions can be accessed at their convenience. The completion of questionnaires takes approximately 15 minutes per assessment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, the following inclusion criteria apply:
(1) A participant must have a formal clinical diagnosis of Autism Spectrum Disorder (ASD) as established by an authorized professional (e.g., psychiatrist/psychologist). This information is provided by the participant.
(2) A participant must be at least 18 years of age.
(3) A participant must have self-reported insomnia, with a cut-off score of 10 or higher on the Insomnia Severity Index.
(4) A participant must possess a desktop, laptop, tablet or mobile phone with internet connectivity. The Minddistrict platform (on which the intervention will be provided) does not have minimal hardware specifications. Minddistrict and the Minddistrict app work best on modern devices that are not older than 5 years, with a preference for devices that are not older than 3 years.
(5) A participant must be able to read and write in the Dutch language.

Exclusion criteria

The following exclusion criteria apply to potential participants:
(1) Not being able to comply to the intervention due to night shifts, meaning work between 2AM and 6AM at least once a week.
(2) Current or planned pregnancy or breast feeding, since sleep problems often

occur in pregnancy and parents of a newborn.

Other comorbid psychological disorders and somatic diseases are allowed, since rates of psychiatric comorbidity are very high (81%) in this population (Vohra et al., 2018). The use of (sleep) medication is also allowed and tracked by asking: *Have you used sleep medication in the past 4 weeks?* (Yes/no). If yes, we will ask which medications and how frequently these medications were taken. Cannabis will also be included in the list of medications.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-04-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL86228.018.24