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RESEARCH ARTICLE

The effects of a sleep robot intervention on sleep, depression and anxiety in adults with insomnia—A randomized waitlist-controlled trial

Siri Jakobsson Støre[1] | Maria Tillfors[1] | Erik Wästlund[1] | Charlotte Angelhoff[2] | Gerhard Andersson[3,4] | Annika Norell-Clarke[1,5]

[1]Department of Social and Psychological Studies, Karlstad University, Karlstad, Sweden

[2]Crown Princess Victoria's Child and Youth Hospital and Department of Biomedical and Clinical Sciences (BKV), Linköping University, Linköping, Sweden

[3]Department of Behavioural Sciences and Learning, Department of Biomedical and Clinical Sciences, Linköping University, Linköping, Sweden

[4]Department of Clinical Neuroscience, Karolinska Institute, Stockholm, Sweden

[5]Faculty of Health Sciences, Kristianstad University, Kristianstad, Sweden

Correspondence
Siri Jakobsson Støre, Department of Social and Psychological Studies, Karlstad University, SE-651 88 Karlstad, Sweden.
Email: siri.store@kau.se

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Summary

The study objective was to assess if a 3-week intervention with the *Somnox* sleep robot had effects on symptoms of insomnia, somatic arousal, and/or concurrent symptoms of depression and anxiety in adults with insomnia, compared with a waitlist-control group. The participants ($n = 44$) were randomized to a 3-week intervention with the sleep robot ($n = 22$), or to a waitlist-control group ($n = 22$). The primary outcome measure was the Insomnia Severity Index administered at baseline, mid-intervention, post-intervention and at 1-month follow-up. Secondary outcome measures were the Pre-Sleep Arousal Scale, and the Hospital Anxiety and Depression Scale. Additionally, sleep-onset latency, wake time after sleep onset, total sleep time and sleep efficiency were measured the week prior to and the last week of the intervention, both subjectively with the Consensus Sleep Diary and objectively with wrist actigraphy. Mixed-effects models were used to analyse data. The effect of the sleep robot on the participants' insomnia severity was not statistically significant. The differences between the intervention group and the control group on the measures of arousal, anxiety and depression were also not statistically significant, and neither were the sleep diary and actigraphy variables. In conclusion, a 3-week intervention with daily at-home use of the robot was not found to be an effective method to relieve the symptom burden in adults with insomnia.

KEYWORDS
arousal, hyperarousal, robot, sleep

1 | INTRODUCTION

One of the most common sleep disorders in adults is insomnia (Riemann et al., 2017). The Diagnostic and Statistical Manual of the American Psychiatric Association's (DSM-5) criteria of insomnia lists prolonged sleep latency, unwanted wake time after sleep onset (WASO), and unwanted early awakenings (one or more of the three symptoms), combined with daytime symptoms such as tiredness, and significant impairment or distress (APA, 2013). About 10% of the population in Europe, North America and Australia suffer from chronic insomnia (> 3 months; Mellon et al., 2014). Insomnia often occurs alongside other psychiatric disorders such as anxiety and depression (Wilson et al., 2010). The aetiology of insomnia is not fully known. Chronic insomnia may be caused by factors such as a genetic

FIGURE 1 The Somnox sleep robot. Copyright 2021 by Somnox; used with permission

predisposition and/or a stressful life event, but the diagnosis does not require knowledge about what causes the sleep problem (Wilson et al., 2010). The same goes for maintaining factors, including but not limited to poor sleep habits, and negative thoughts and feelings about sleep (Wilson et al., 2010).

Models of insomnia can be grouped into physiological/neurobiological and cognitive/psychological models. Elevated arousal is included in most insomnia models (Buysse et al., 2011; Espie et al., 2006; Harvey, 2002; Lundh & Broman, 2000; Morin, 1993; Ong et al., 2012; Perlis et al., 1997), but the hyperarousal model recognizes arousal as a possible causal factor in insomnia, without necessarily involving negative thoughts (Kay & Buysse, 2017; Morin, 1993; Riemann et al., 2010). Hyperarousal is an ill-defined construct, but is often understood as the opposite to a relaxed state (Spiegelhalder & Baglioni, 2019). Hyperarousal has been operationalized in many different ways, such as increased cortisol levels (Roth et al., 2007), increased heart rate (Stein & Pu, 2012) and increased body temperature (Lack et al., 2008). Different relaxation techniques have been found to reduce arousal and improve sleep (i.e. sleep-onset latency [SOL] and sleep quality). For instance, muscle relaxation (Manzoni et al., 2008), cognitive techniques (Stetter & Kupper, 2002), mindfulness (Gong et al., 2016), and slow deep-breathing techniques (Jerath et al., 2019) are associated with sleep enhancement.

The gold-standard treatments of insomnia are Cognitive Behavioural Therapy (CBT-I) and pharmaceuticals (Riemann et al., 2017). Sleep medication use is common among adults with insomnia, which is unfortunate considering the risk of adverse effects and addiction with certain medicines (Albrecht et al., 2019; Riemann et al., 2017). Regarding CBT-I, the treatment does not suit everyone and is not effective for all (Fernandez-Mendoza, 2019). Considering the high prevalence of insomnia, not everyone who meets the diagnostic criteria can be offered CBT-I, let alone those with subclinical symptoms, hence the need for additional treatment options. Many people with insomnia are willing to test complementary and alternative medicine (CAM), but CAM methods often lack the empirical support needed to enable for healthcare professionals to recommend them (Ng & Parakh, 2021; Riemann et al., 2017). People with insomnia are often left without trustworthy information about the efficacy and safety of alternative methods and products—hence the need for independent research studies on products that are marketed as sleep-enhancing.

The *Somnox* sleep robot (Figure 1) is promoted as sleep-enhancing (Somnox, 2021). The robot's auditive and physical "breathing" is meant to guide humans into deep breathing and relaxation, and ultimately sleep. Considering what we know about the positive effects on arousal of relaxation in general, and breathing techniques in particular, the sleep robot might help people with insomnia to sleep better. The current study is a pre-registered randomized waitlist-controlled trial of the effects of the sleep robot on insomnia, arousal, depression and anxiety in adults with insomnia. We hypothesized that the intervention would have positive effects on the participants' symptoms of insomnia and somatic arousal, compared with the waitlist-control group. The research questions were as follows. (1) Does the sleep robot have positive effects on the participants' concurrent symptoms of insomnia (main outcome measure), somatic arousal, anxiety and depression? (2) Does the sleep robot have positive effects on the participants' SOL, WASO, total sleep time (TST) and sleep efficiency (SE), as measured both subjectively and objectively?

2 | METHODS

2.1 | Study design

The study was a randomized waitlist-controlled trial evaluating the effect of a 3-week at-home intervention with the *Somnox* sleep robot

versus no intervention. The methodology has previously been described in a published study protocol (Støre et al., 2020). The study was conducted at Karlstad University in Värmland County, Sweden, between July 2021 and December 2021. The study was approved by the Swedish Ethical Review Authority (DNR 2020–06975), and registered with ISRCTN (ISCRTN35134834). No incentives, financial or otherwise, were given for their time.

2.2 | Participants and procedures

Participants were recruited through the university website, the website of the study, social media (several different groups on Facebook and Instagram), and as a result of the research project receiving attention from a local newspaper. Those who showed interest in the study were screened for eligibility in a two-staged process by a clinical psychologist (first author SJS). The first stage consisted of two questionnaires, the Insomnia Severity Index (ISI; Bastien et al., 2001) and the Pre-Sleep Arousal Scale (PSAS; Nicassio et al., 1985). Persons who had a total score of 11 or more on the ISI (conforming to Bastien et al., 2001), and 10 or more on the somatic scale of the PSAS (in line with Jansson-Fröjmark et al., 2012) were considered eligible. Those who met the criteria went ahead to the second stage of the screening, consisting of two structured clinical interviews. The first clinical interview, the Duke Structured Interview for Sleeping Disorders (DSISD; Carney et al., 2009), was conducted to ensure that the participants would meet the DSM-5 diagnostic criteria for insomnia as suggested by the ISI results, and that they did not meet the criteria of any other sleep disorder, or, if they did, that they were under adequate treatment for the other sleep disorder(s). As the interview was developed for the former version of the DSM, certain questions were omitted or adjusted to fit the current criteria. The second clinical interview, the Mini International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al., 1998) was conducted to ensure that the participants did not meet the DSM-5 diagnostic criteria of any current psychiatric diagnosis that offered a better explanation of the insomnia symptoms (e.g. PTSD). Participants were eligible for the study if they: (1) were fluent in Swedish; (2) were adults (18+ years); (3) met the criteria for insomnia according to DSM-5; (4) did not meet the criteria of any other untreated sleep disorder; and (5) did not meet the criteria of any current psychiatric diagnosis that could explain the symptoms of insomnia.

Of the 54 people who showed an interest in the study and were screened for eligibility, 10 people did not meet the eligibility criteria, either because they scored below the cut-off score of 11 on the ISI or below 10 on the somatic scale of the PSAS ($n = 3$), or because they met the DSM-5 criteria of/were diagnosed with other current psychiatric disorders: panic disorder with agoraphobia ($n = 1$), depression and generalized anxiety disorder ($n = 1$), depression and PTSD ($n = 1$), and attention-deficit/hyperactivity disorder ($n = 3$). One person did not answer by phone or e-mail post-screening, and was therefore also excluded from the study. The 44 eligible participants were randomized to the robot intervention or to the waitlist-control group (see Figure 2 for the participant flow in the study).

2.3 | Randomization and masking

The participants were sequentially randomized to either the intervention group or the parallel waitlist-control group (1:1 allocation ratio), with a block size of 12 (one group of 8). Potential participants were successively screened and randomized once we had 12 eligible participants. Block randomization was chosen to ensure equally large treatment arms. The randomization was prepared and recorded in Excel by a statistician outside the research group to prevent the risk of allocation bias. The allocation was, however, not concealed to the participants or to the study coordinator.

2.4 | Intervention and control conditions

After 10–15 min of training in how to use the Somnox sleep robot, participants in the intervention group retrieved the robot for at-home use for 21 days. The manufacturer has stated that one can expect an effect after a week of familiarization with the sleep robot (Somnox, 2021), which is why 3 weeks was deemed sufficient to detect an effect, if there is one. The participants were instructed to use the robot actively in bed until sleep onset, and after nightly awakenings. They were coached to hold the robot against their abdomen. The sleep robot is 355 × 203 × 127 mm (14 × 8 × 5 in) large, and weighs 1.9 kg (4 lb). Its estimated battery life is 10 hr. Its fabric is made of "recycled fabrics and foams", and its main features have been described as breathing simulation and relaxation audio (Mann, 2022). The sleep robot was set on the "sleeping" programme, which focuses on deep breathing (1:2 ratio of inhalation and exhalation), as opposed to "napping" (1:15) and "relaxing" (1:25). The default programmes last for 30 min. The participants were encouraged to use the robot actively in bed until sleep onset, and in case of unwanted WASO. Via a control panel, the breathing settings could be changed manually. The waitlist-control group retrieved no intervention during the randomized phase of the study, but received an equivalent 3-week intervention with the sleep robot immediately after the post-intervention measure had been conducted.

3 | MEASURES

3.1 | Demographic variables

The following demographic information about the participants was collected: gender, marital status, number of children in the household, highest level of education, employment, and whether they were born in Sweden or not.

3.2 | Primary outcome

Insomnia severity was assessed with the ISI, which is the first-line measurement of insomnia symptoms and treatment effects on

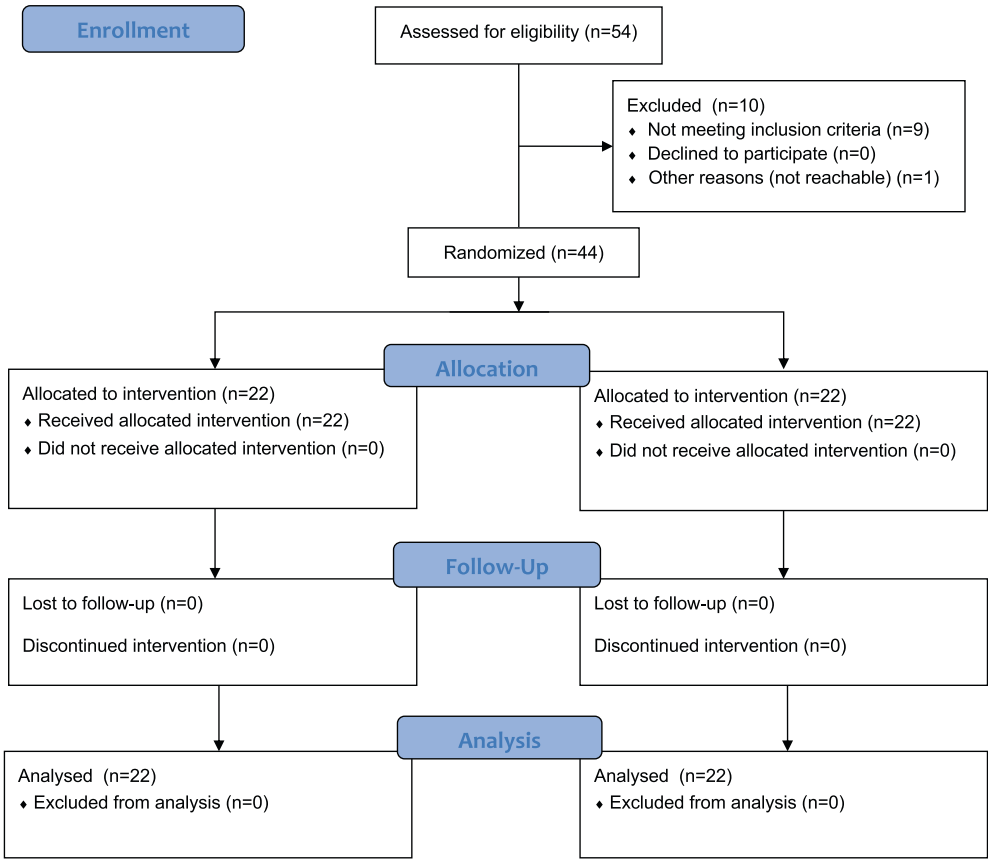

FIGURE 2 Study flow chart

insomnia. The scale consists of seven items (total score range 0–28). Higher values stand for more severe insomnia (Bastien et al., 2001). A score of 11–14 is considered to be mild insomnia, thus 11 was used as the cut-off in the current study. A change of −4.7 on the ISI is considered to be a slight improvement, a change of −8.4 a moderate improvement, and a change of −9.9 a marked improvement (Morin et al., 2011). The participants completed the ISI 4 days before the start of the intervention, 10 days into the intervention, 3 days after the end of the intervention, and 1 month after the end of the intervention. To determine whether a change has occurred from baseline to post-intervention, additional time points of measurement in between can potentially increase the power of the statistical test (Hox, 2010), which is why our main outcome measure was administered at an additional time point mid-treatment. All the self-assessments were completed on the online platform Iterapi, which has been used in a plethora of treatment studies (Vlaescu et al., 2016).

3.3 | Secondary outcomes

3.3.1 | Sleep

The following sleep variables were measured both subjectively with the Consensus Sleep Diary (Carney et al., 2012), and objectively with wrist actigraphy (Actigraph Link GT9X, 2022), the week immediately before the start of the intervention, and the last week of the intervention: SOL, WASO, TST and SE. Single summary scores (means) were computed for each of the variables at both measurement time points. Group allocation and measurement time points were concealed to the assessor of the actigraph data, to avoid the risk of detection bias. The sleep diary included questions about prescribed sleep medication use (yes/no and a comment field).

3.3.2 | Somatic arousal

The Pre-Sleep Arousal Scale measures symptoms of sleep-related arousal. The questionnaire consists of two scales that measure cognitive and somatic arousal, respectively, but the current study only used the somatic scale as this was the focus in our study, and because the cognitive scale has been found to have weaker psychometric properties than the somatic scale (Jansson-Fröjmark & Norell-Clarke, 2012). The somatic scale consists of eight items (total score range 8–40). Higher scores indicate hyperarousal and a cut-off of 10 was used in the current study, in line with Jansson-Fröjmark et al. (2012). The PSAS was administered pre- and post-intervention, and at 1-month follow-up.

3.3.3 | Emotional distress

The Hospital Anxiety and Depression Scale (HADS) measures symptoms of anxiety and depression, which are common in adults with insomnia. The scale has 14 items: seven anxiety items and seven

depression items (total score range 0–21). Higher values mean more anxiety and depression (Zigmond & Snaith, 1983). The cut-off of 8 indicates a clinical level of anxiety or depression symptoms, respectively. A change of 1.3 for the anxiety scale and a change of 1.4 for the depression scale are considered slight improvements (Puhan et al., 2008). The HADS was administered pre- and post-intervention, and at 1-month follow-up.

3.3.4 | Adherence

The following questions were included in the sleep diary during the intervention. (1) Did you use the sleep robot? (yes/no); (2) number of minutes in use; and (3) position (sitting up/lying down/other).

3.4 | Sample size

The selected sample size of 44 participants was based on a power analysis of the pilot data, which is described in the study protocol (Støre et al., 2020), and on previous studies (Garland et al., 2021). The power analysis only regards the main outcome measure, the ISI. There were two groups in the current study and three repeated measurements on the ISI. The established cut-off limit for a slight clinical improvement on the ISI is −4.7, that is, smaller changes were deemed clinically irrelevant. As stated in the study protocol (Støre et al., 2020, p. 4): "The control group was assumed to have the same standard deviation as the active treatment group. In order to detect an effect of −5 on the ISI in the active treatment group, while also assuming a slight improvement of −1 in the control group (with a significance level of 0.05, a power of 0.8, and a moderate correlation among repeated measures of 0.3, based on other studies), a sample of 30 participants is needed." Several outcomes based on varying power and correlation among repeated measures (e.g. 0.7 instead of 0.3) were provided in the study protocol, all in line with 44 participants being sufficient to detect a −5 change on the ISI. The recruitment was stopped once we reached our target of 44 participants.

3.5 | Statistical analyses

The data were analysed using the intention to treat principle (Hollis & Campbell, 1999), in line with the CONSORT guidelines on reporting of randomized-controlled trials (Moher et al., 2001). The analyses were conducted in SPSS.27 (IBM). The outcome measures were analysed with linear mixed-effects regression models (Heck et al., 2014), with group and time point as fixed effects, and participants as random effects. The covariance structure for random effects (participant) was set to variance components, which is the default in SPSS, and which is also in line with the *Guidelines for selecting the covariance structure in mixed model analysis* (Kincaid, 2005). The mixed-effects model was chosen prospectively as a safeguard to attrition and missing data, as the model enables inclusion of missing data (Heck et al., 2014). This was not relevant for our main outcome measure, as there were no missing data. Another benefit with the mixed-effects model is that it takes into account that the data are not independent with repeated measurements. The prospectively published study protocol was followed (Støre et al., 2020). Additional explorative analyses of WASO and SE were conducted with mixed-effects models.

4 | RESULTS

4.1 | Participant characteristics

Table 1 provides information on the baseline demographic characteristics, the self-reported duration of insomnia symptoms, and the sleep medication use of the participants in total, and for each of the two groups. The participants were predominantly females with a mean age of 48.91 years. More than half of the participants had graduated from university/college, and about two-thirds had permanent employment. Most were born in Sweden. More than 60% of the participants were married or living with their partner, and about half had children in the household. The participants reported that their sleep problems had been present for an average of 14.05 years. A little less than a third of the participants were taking prescribed sleep medications.

4.2 | Outcome measures

Table 2 presents the results of the mixed-effects analyses comparing the change in outcomes for the intervention group between pre- and post-intervention (the ISI, the PSAS, the HADS anxiety subscale, the HADS depression subscale) minus the change in the control group between pre- and post-intervention. Also presented in the table are the self-reported differences between the baseline week and the last week of the intervention (diary-defined SOL, WASO, TST and SE) for the intervention group minus the control group.

4.3 | Primary outcome

4.3.1 | Insomnia severity

Regarding insomnia severity, the difference between the groups was not statistically significant: ISI (95% confidence interval [CI]), 0.14 (−2.06 to 2.33); $p = 0.90$. The result is also shown in Figure 3 (and Table 2).

4.4 | Secondary outcomes

4.4.1 | Subjective sleep

The effect of the robot on diary-defined SOL was not statistically significant: SOL-diary (95% CI), −10.11 (−47.42 to 27.21); $p = 0.59$. Nor was the difference between the groups regarding WASO as measured with the diary statistically significant: WASO-diary (95% CI), 3.46

TABLE 1 Demographic characteristics of the participants

Variable	Overall $N = 44$ Mean (SD) or % (*n*)	Intervention group $N = 22$ Mean (SD) or % (*n*)	Waitlist-control group $N = 22$ Mean (SD) or % (*n*)
Age, in years	48.91 (13.21)	50.05 (13.23)	47.77 (12.60)
Gender			
Female	79.55% (35)	86.36% (19)	72.73% (16)
Male	20.45% (9)	13.64% (3)	27.27% (6)
Marital status			
Single	25.00% (11)	31.82% (7)	18.18% (4)
Partner	2.27% (1)	0.00% (0)	4.55% (1)
Married/cohabiting	61.36% (27)	54.55% (12)	68.18% (15)
Divorced/separated	11.36% (5)	13.64% (3)	9.09% (2)
Children in household			
% Yes	52.27% (23)	54.55% (12)	50.00% (11)
% No	47.73% (21)	45.45% (10)	50.00% (11)
Born in Sweden			
% Yes	93.18% (41)	86.36% (19)	100% (22)
% No	6.82% (3)	13.64% (3)	0.00% (0)
Level of education			
Middle school	4.55% (2)	4.55% (1)	4.55% (1)
High school	29.55% (13)	36.36% (8)	22.73% (5)
Vocational	6.82% (3)	0.00% (0)	13.64% (3)
University/college	59.09% (26)	59.09% (13)	59.09% (13)
Employment			
Permanent	65.91% (29)	63.64% (14)	68.18% (15)
Temporary	9.09% (4)	9.09% (2)	9.09% (2)
Self-employed	2.27% (1)	0.00% (0)	4.55% (1)
Student	6.82% (3)	9.09% (2)	4.55% (1)
Retired	13.64% (6)	18.18% (4)	9.09% (2)
Sickness			
Compensation	2.27% (1)	0.00% (0)	4.55% (1)
Insomnia symptoms, in years	14.05 (11.94)	14.38 (12.17)	13.68 (12.00)
Sleep medications			
% Yes	27.27% (12)	22.72% (5)	31.82% (7)
% No	72.73% (32)	77.27% (17)	68.18% (15)

(−17.98 to 24.91); $p = 0.75$. Regarding diary-defined TST, the difference between the groups was not statistically significant: TST-diary (95% CI), −27.69 (−67.89 to 12.52); $p = 0.17$. Nor was the effect on subjectively measured SE statistically significant: SE-diary (95% CI), −3.76 (−9.79 to 2.27); $p = 0.21$ (see Table 2 for the subjective sleep outcome measures).

4.4.2 | Objective sleep

The difference between the groups regarding SOL as measured with wrist-actigraphy was not statistically significant: SOL-actigraphy (95% CI), −0.12 (−0.65 to 0.41); $p = 0.65$. Nor was actigraphy-defined WASO statistically significant: WASO-actigraphy (95% CI), −5.94 (−15.95 to 4.08); $p = 0.24$. The effect of the robot on objectively measured TST was not statistically significant: TST-actigraphy (95% CI), −33.40 (−66.92 to .12); $p = 0.051$. Nor was actigraphy-defined SE statistically significant: SE-actigraphy (95% CI), 0.16 (−1.61 to 1.92); $p = 0.86$ (see Table 3 for the objective secondary sleep outcome measures).

4.4.3 | Somatic arousal

The difference between the groups on the PSAS was not statistically significant: PSAS (95% CI), −0.23 (−2.41 to 1.96); $p = 0.84$.

TABLE 2 Main and secondary outcome measures at each time point by intervention group ($N = 44$, 22 intervention, 22 control)

		Pre-intervention			Mid-intervention			Post-/last week of intervention			Difference between groups in change from 1		*p*-Value	Effect size (*d*)
Outcome	Group	M	SD	95% CI	M	SD	95% CI	M	SD	95% CI	Estimate	95% CI	*p*	*d*
ISI	Intervention	17.73	3.57	15.79–19.6	15.50	4.55	13.56–17.4	16.09	5.14	14.15–18.0	0.14	−2.06–2.33	0.90	0.03
	Control	17.05	4.95	715.11–18.98	15.50	5.09	413.56–17.44	15.27	3.73	313.34–17.21				
PSAS	Intervention	17.64	6.06	15.17–20.11	N/A	N/A	N/A	16.86	6.36	14.40–19.33	−0.23	−2.41–1.96	0.84	0.06
	Control	15.00	5.69	12.53–17.47				14.46	4.84	11.99–16.92				
HADS-A	Intervention	7.41	4.64	5.63–9.19	N/A	N/A	N/A	6.50	4.43	4.72–8.28	−0.09	−1.11–0.93	0.85	−0.05
	Control	8.09	3.66	6.31–9.88				7.27	3.82	5.49–9.06				
HADS-D	Intervention	4.73	2.98	3.42–6.04	N/A	N/A	N/A	5.05	2.85	3.73–6.36	−0.05	−1.06–0.97	0.93	−0.03
	Control	4.36	2.90	3.05–5.68				4.73	3.47	3.42–6.04				
SOL-d, min	Intervention	60.05	62.42	39.86–80.24	N/A	N/A	N/A	39.85	24.79	18.54–61.16	−10.11	−47.42–27.21	0.59	−0.18
	Control	49.57	45.43	29.91–69.24				39.48	32.50	20.27–58.68				
WASO-d, min	Intervention	48.16	29.35	32.92–63.39	N/A	N/A	N/A	38.09	21.38	21.92–54.26	3.46	−17.98–24.91	0.75	0.11
	Control	60.78	42.70	45.67–75.89				47.25	33.12	32.40–62.10				
TST-d, min	Intervention	370.68	56.87	341.87–399.50	N/A	N/A	N/A	382.20	68.75	352.24–412.16	−27.69	−67.89–12.52	0.17	−0.56
	Control	341.28	59.28	313.40–369.15				380.48	66.31	353.07–407.88				
SE-d, %	Intervention	71.52	10.08	66.81–76.24	N/A	N/A	N/A	72.66	12.22	67.78–77.54	−3.76	−9.79–2.27	0.21	−0.46
	Control	66.83	8.80	62.28–71.38				71.72	9.35	67.24–76.21				

Note: The ISI was measured pre- (1), mid- (2) and post-intervention (3). The PSAS and the HADS were measured pre- (1) and post-intervention (3). Diary-defined SOL, WASO, TST and SE were measured, and the average scores computed for the week before (1) and the last week of the intervention (3). Effect size (*d*) was estimated using Cohen's *d*.

Abbreviations: CI, confidence interval; HADS-A/D, Hospital Anxiety and Depression Scale – Anxiety/Depression Scale; ISI, Insomnia Severity Index; N/A, not applicable; PSAS, Pre-Sleep Arousal Scale; SE-d, sleep efficiency-diary; SOL-d, sleep-onset latency-diary; TST-d, total sleep time-diary; WASO-d, wake time after sleep onset-diary.

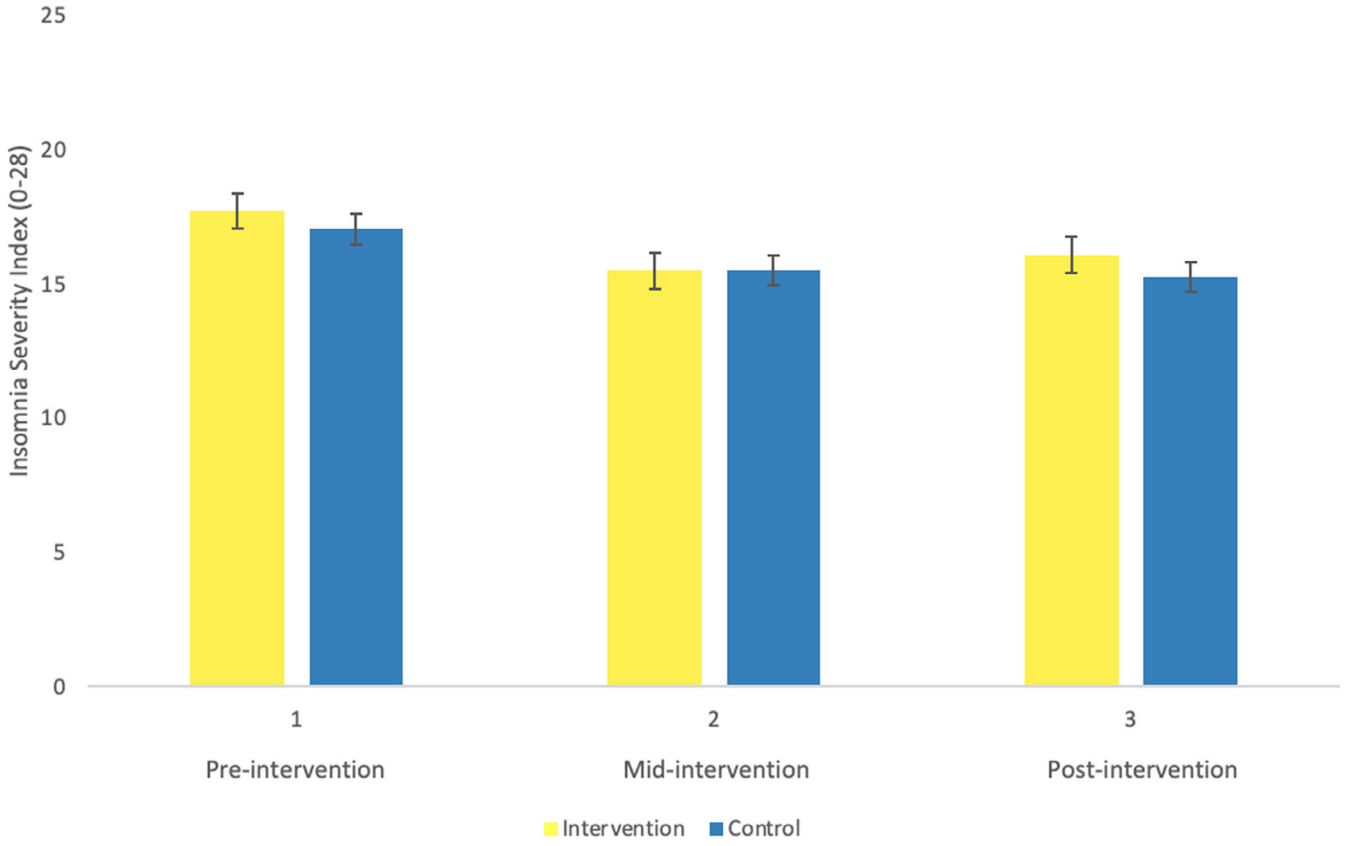

FIGURE 3 Changes in insomnia severity (primary outcome measure) across groups and time points. Raw means (± 1 SE) are presented for both the intervention and the control groups at pre- (1), mid- (2) and post-intervention (3)

TABLE 3 Objective secondary sleep outcome measures at each time point by intervention group ($N = 44$, 22 intervention, 22 control)

		Pre-intervention			Post-/last week of intervention			Diff. between groups in change from 1		*p*-Value	Effect size (*d*)
Outcome	Group	M	SD	95% CI	M	SD	95% CI	Estimate	95% CI	*p*	*d*
SOL-a, min	Intervention	0.42	0.81	0.17–0.68	0.50	0.66	0.22–0.77	−0.12	−0.65–0.41	0.65	0.31
	Control	0.11	2.97	−0.15–0.36	0.30	0.56	0.04–0.56				
WASO-a, min	Intervention	45.75	17.61	39.04–52.47	37.66	11.00	30.58–44.76	−5.94	−15.95–4.08	0.24	−0.34
	Control	40.55	14.21	33.83–47.26	38.34	14.63	31.57–45.22				
TST-a, min	Intervention	326.65	79.96	297.02–356.28	293.94	54.29	263.23–324.64	−33.40	−66.92–0.12	0.051	−0.75
	Control	312.05	66.60	282.42–341.68	312.74	60.89	282.78–342.69				
SE-a, %	Intervention	87.98	3.65	86.35–89.61	88.56	3.00	86.87–90.24	0.16	−1.61–1.92		
	Control	88.40	3.99	86.77–90.03	88.82	3.86	87.17–90.47			0.86	0.22

Abbreviations: SOL, WASO, TST and SE were measured, and the average scores computed, the week before (1) and the last week of the intervention (2). CI, confidence interval; Effect size (*d*) was estimated using Cohen's *d*; SE-a, sleep efficiency-actigraphy; SOL-a, sleep-onset latency-actigraphy; TST-a, total sleep time-actigraphy; WASO-a, wake time after sleep onset-actigraphy.

4.4.4 | Emotional distress

The effects of the robot on symptoms of anxiety and depression as measured with the HADS were not statistically significant: HADS-anxiety (95% CI), −0.09 (−1.11 to 0.93); $p = 0.85$; HADS-depression (95% CI), −0.05 (−1.06 to.97); $p = 0.93$.

4.4.5 | Adherence

The participants in the intervention group used the robot 15.60 (SD 5.38) days out of 21 on average. Five participants (22.73%) used the robot less than 50% of the days of the intervention, three participants (13.63%) used the robot between 50% and 75% of the days,

three participants (13.63%) used the robot between 75% and 90% of the days, and nine participants (40.91%) used the robot for more than 90% of the days. The robot was used an average of 65.50 (SD 83.13) min each day it was actively used. All participants in the intervention group used the robot while lying down in bed, except for two participants (9.09%), who alternated between sitting upright and lying down. For another two participants (9.09%), adherence data were missing.

5 | DISCUSSION

The current study is the first to evaluate the efficacy of the *Somnox* sleep robot in a rigorous randomized waitlist-controlled trial. The study found that a 3-week intervention with at-home use of the *Somnox* sleep robot did not have an effect on the level of insomnia symptoms (main outcome measure), nor did it impact any of the secondary outcome measures of pre-sleep arousal, anxiety, depression, SOL, WASO, TST and SE. Some possible reasons for the results will be discussed.

Firstly, for five participants in the intervention group the treatment adherence was low (< 50% of the nights), for another three participants it was moderate (50%–75%), and for two participants adherence data were missing. It is possible that a higher level of adherence could have led to greater effects on the outcome measures. However, it is hard to think of a population where the adherence level would be higher, considering this being a population of relatively healthy adults besides suffering from insomnia symptoms on a clinical level (main target group according to the robot's webpage), who actively sought out and completed the study. The participants in both the intervention and the control groups had, in addition to chronic insomnia, objective short sleep (< 6 hr) at baseline, as measured with actigraphy: an average of 5.44 hr (4.95–5.94 hr) for the intervention group and 5.20 hr (4.71–5.69 hr) for the control group. They also had short sleep or close to short sleep as subjectively reported in the sleep diary: 6.18 hr (5.69–6.65 hr) for the intervention group, and 5.69 hr (5.22–6.15 hr) for the control group. Objective short sleep constitutes a more severe phenotype of insomnia compared with adequate sleep hours (Vgontzas et al., 2013), all reasons for why we did expect greater effects of the robot.

Secondly, in view of the hyperarousal model of insomnia (Kay & Buysse, 2017; Morin, 1993; Riemann et al., 2010), it makes sense that the robot did not affect the level of insomnia symptoms, given that it did not affect the potential mechanism of pre-sleep arousal. It was surprising that the robot, which has been produced to assist people into deep breathing, did not have a greater effect on arousal, especially as all participants had a relatively high level of somatic arousal at baseline (i.e. there was room for improvement). Arousal was perhaps not the most important maintaining factor for the participants' insomnia. Furthermore, close to one-third of the participants were taking prescribed sleep medications during the intervention (a higher proportion in the control group compared with the intervention group), which may have constituted ceiling effects of possible improvements.

Last but not least, the robot might simply not work as intended. Most robots are in fact limited by the current available technology (Broadbent, 2017). Relatedly, peoples' ideas about robots are very much based on how robots are portrayed in films, that is, much more advanced (and human-like) than what is currently possible (Broadbent, 2017). Discrepancies between what people expect a robot to look like or how they expect it to behave, and what the robot actually looks like and how it behaves, have been found to affect peoples' feelings towards robots in negative ways (Broadbent, 2017). The participants' prior assumptions may have affected their experience of the sleep robot in some ways. For illustration, two participants spontaneously commented that they had experienced the robot as infantilizing. How the robot was experienced may have affected the results, for instance through a lower level of treatment adherence than some of the participants would have had, had the robot lived up to their expectations. Hudson et al. (2020) conclude in their study of robotic use among older adults that active and social people were less than ideal participants, and that these participants expressed a preference for robots with more interactive features. Specific subgroups may therefore respond to the *Somnox* sleep robot in different ways.

One limitation with the current study is the waitlist-control group, as research has found the use of waitlist-controls to overestimate treatment effects (Furukawa et al., 2014). This is, however, not relevant for our null effects. About a third of all participants used prescribed sleep medications during the trial and, even though the treatments were stabilized, these medicines did perhaps hamper a more positive effect of the robot in the current study. A final limitation is the fact that we only calculated a power analysis for the main outcome measure. A larger sample size could perhaps detect statistically significant differences between the groups regarding the other outcomes.

A first strength with the current study is the rigorous research design used, and the blinding of the researchers responsible for the randomization of participants and the analysis of actigraphy data. A second strength is the prospectively published study protocol (Støre et al., 2020), including a statistical analysis plan, which was followed, to reduce the risk of bias even further. Thirdly, the use of standardized assessment is a strength, as this is a common limitation in other robot studies (Mizuno et al., 2021; Støre et al., 2022). A fourth strength is the fact that we studied a robot that has been created to target sleep, as opposed to previous studies conducted on the effects of robots on sleep, where the companion robot Paro has been used (Mizuno et al., 2021; Støre et al., 2022). The relatively long intervention phase is yet another strength, although it is possible that a 3-week intervention was too brief to induce an effect. Previous studies on the effects of robots on sleep have been conducted in care facilities or in lab settings (Mizuno et al., 2021), which is why a major strength of our study is that it is conducted in real-life settings, that is, it has high ecological validity. Another important strength is the low level of attrition and missing data in our study and main outcome measure, respectively (none).

One idea for the future is to compare the effects of CBT-I-relaxation techniques alone versus a combination with the *Somnox* sleep robot. Another is to combine the sleep robot with a complete course of CBT-I versus CBT-I only. A third is to include advice on

sleep hygiene in the robot intervention. There were no attempts to affect the participants' sleep habits in the current intervention, which may have led to greater effects of the robot if such advice had been included. The DSISD clinical interview did, however, include questions about sleep hygiene, and participants whose insomnia symptoms were mainly due to poor sleep hygiene were potentially excluded (not relevant in the current study). It is a strength that we demarcate the effect of the sleep robot in the current study, but healthcare practitioners would likely contribute with a broader intervention. Other ideas for future studies are to include participants with other or concurrent conditions also characterized by atypical levels of arousal, such as anxiety disorders or attention-deficit/hyperactivity disorder. Studies conducted in a sleep laboratory would yield knowledge with more internal validity, albeit at the expense of the external validity.

6 | CONCLUSIONS

A 3-week at-home intervention with the *Somnox* sleep robot was not found to be an effective method to relieve the symptom burden in adults with insomnia. Insomnia is a heterogenous condition symptom-wise, and it has been suggested to have a multifaceted pathophysiology (Kay & Buysse, 2017). For more tailored insomnia treatments in the future, research on alternative treatment methods should be encouraged.

AUTHOR CONTRIBUTIONS

Annika Norell-Clarke was the principal investigator. Annika Norell-Clarke, Maria Tillfors and Siri Jakobsson Støre designed the study, in collaboration with Erik Wästlund, who bought the sleep robots. Siri Jakobsson Støre was the study coordinator, responsible for the data collection and statistical analyses. Charlotte Angelhoff was responsible for analysing the actigraph data. Gerhard Andersson provided access to the Iterapi platform, where the self-assessments were conducted. Siri Jakobsson Støre drafted the manuscript. All authors have read and approved the final manuscript.

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CONFLICT OF INTEREST

Siri Jakobsson Støre has nothing to declare. Maria Tillfors has nothing to declare. Erik Wästlund has nothing to declare. Charlotte Angelhoff has nothing to declare. Gerhard Andersson has nothing to declare. Annika Norell-Clarke has nothing to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Siri Jakobsson Støre https://orcid.org/0000-0001-5749-0774
Maria Tillfors https://orcid.org/0000-0002-9688-5805
Erik Wästlund https://orcid.org/0000-0001-8102-8168
Charlotte Angelhoff https://orcid.org/0000-0002-0174-8630
Gerhard Andersson https://orcid.org/0000-0003-4753-6745
Annika Norell-Clarke https://orcid.org/0000-0003-2008-0784

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