Research Article

BASELINE DEPRESSION LEVELS DO NOT AFFECT EFFICACY OF COGNITIVE-BEHAVIORAL SELF-HELP TREATMENT FOR INSOMNIA

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Background: *Cognitive-behavioral therapy can effectively treat insomnia (CBT-I). Randomized controlled trials have shown efficacy of self-help CBT-I, but unclear is whether excluding depressive patients boosted treatment effects.* **Method:** *We administered unsupported self-help CBT-I to insomnia patients with low and high depression levels. Based on the validated Centre of Epidemiological Studies-Depression (CES-D) scale, the internet-recruited sample (N = 479) was divided into three groups: low depression scores (n = 198), mild depression scores (n = 182), and high depression scores (n = 99). Follow-ups were 4 and 18 weeks after completion of the treatment.* **Results:** *At 4-week follow-up, all groups had a similar amelioration on the primary sleep measures (d = 0.1–0.7; P < 0.05) and the secondary insomnia ratings (d = 1.2; P < 0.001). The only difference was that the high/mild depression groups had a steeper reduction in depression (d = 1.0–1.1; P < 0.001) and anxiety scores (d = 0.7–0.8; P < 0.001) than the low depression group (depression and anxiety: d = 0.3; P < 0.01), possibly due to floor effects in the latter group. The observed effects were sustained at the 18-week follow-up.* **Conclusions:** *This study showed that CBT-I is effective regardless of baseline depression levels. Treating the combination of insomnia and depression is an extra challenge since it is associated with increased sleep problems. These data may help us understand the relationship between insomnia and depression and indicate that self-help CBT-I may be a promising addition to regular depression treatment. Depression and Anxiety 30:149–156, 2013.* ©

Key words: *CBT; Depression; Insomnia; Internet; self-help*

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INTRODUCTION

Insomnia is a common disorder that is characterized by having trouble falling asleep, maintaining sleep, and feeling tired during the day. For chronic insomnia, complaints have to persist for at least a month.[1] Impaired sleep causes fatigue and distress.[2–4] Insomnia is associated with psychological problems such as anxiety and depression.[5,6]

Cognitive-behavioral therapy can effectively treat insomnia (CBT-I),[7–11] but current waiting lists may only be shortened by less intensive approaches such as self-help therapy.[12] A meta-analysis found small-to-moderate effects of self-help CBT-I on subjective insomnia complaints.[13] More recently, several studies[14–17] observed larger effects on subjective sleep measures and insomnia complaints. One study[15] also found that therapist support boosted these effects.

In our previous study,[16] we compared unsupported self-help CBT-I delivered through the internet with unsupported self-help delivered through written materials. We found that both self-help treatments generated large effects compared to a waiting list on global insomnia measures and moderate effect on subjective sleep measures. However, in our study[16] and in many other self-help treatment studies (e.g. [14,18]) insomnia patients with high depression or major psychiatric disorders were excluded.

Our reason for this exclusion was that depression may interact with treatment motivation, adherence, and efficacy. This opened the possibility that the large effects may partly be attributed to the exclusion of subjects with high depression scores. This would suggest that CBT-I is more effective, or more appropriate, for insomnia patients without co-morbid depression. That would be unfortunate since several studies found a strong relationship between insomnia and depression.[5,6,19–21] Insomnia can be a predictor of developing depression; a recent meta-analysis reported that nondepressed people with insomnia had a twofold risk of developing depression.[22] Moreover, insomnia is a frequent residual symptom of depression treatment.[23–25] This indicates that insomnia is not just a frequent symptom in depression but potentially a separate sleep disorder that exacerbates major depressive disorder. Specific treatment of insomnia during CBT for depression (that typically does not focus on sleep) may therefore be beneficial to depression as well—if CBT-I is equally effective for insomnia patients with high depression levels.

There is evidence that face-to-face CBT-I is equally effective for insomnia patients with low and high depression levels.[26,27] Studies employing face-to-face therapy demonstrated that CBT-I for depressed patients can have an additional effect to medication[28] and that it can help in residual depression.[29] Moreover, one pilot study found promising effects of self-help CBT-I for depressed patients with insomnia.[30] Another study[15] observed positive effects of self-help CBT-I in a group with heterogeneous co-morbid disorders and concluded that depression at baseline was not significantly related to level of improvement. The authors argued that studies addressing the effect of CBT-I on specific co-morbid disorders are much needed.[15] If self-help CBT-I is indeed beneficial for insomnia patients with high depression scores, this may help improve treatment for depression as self-help CBT-I can easily be added to standard therapy.

The current study investigated the efficacy of unsupported self-help CBT-I in a sample that was stratified by baseline Centre of Epidemiological Studies-Depression scale (CES-D) depression scores following guidelines of Zich et al.[23] We expected that insomnia patients benefit equally from self-help CBT-I regardless of their depression score.

MATERIALS AND METHODS

PARTICIPANTS

Inclusion criteria were lying awake at least 30 min a night at least three nights a week, having insomnia disorder according the SLEEP-50 (cut off ≥ 19[31]) and the Insomnia Severity Index (ISI; which was filled out after the SLEEP-50; cutoff > 7[32]), being 18 years or older, and having a valid e-mail address. Exclusion criteria were sleep apnea (cut off ≥ 15[31]); more than three glasses of alcohol a day for at least 21 days a month, marihuana use more than once a week, schizophrenia/psychosis, and current suicidal plans (thus, people with suicidal ideation were not excluded; see Table S1 for the specific questions). We did not exclude on bipolar disorder specifically.

Seven hundred and ninety persons started the online questionnaire, 181 did not complete the baseline assessment, 55 did not meet inclusion criteria, four were considered outliers (see statistical analysis), and 127 were excluded from the study due to reasons mentioned above (see Fig. 1 for a flow chart). The final sample ($N = 479$) had a mean age of 47.0 ($SD = 13.6$; range = 18–84 years) and included 316 (66.0%) women (Table 1).

PROCEDURE

The study was in line with the Declaration of Helsinki, approved by the Medical Ethical Committee of the University Medical Center Utrecht, and registered at clinicaltrials.gov (ID: NCT01224912). Participants were recruited via a popular scientific Dutch insomnia website (www.insomnie.nl). Visitors of this website could fill out the insomnia scale of the SLEEP-50[31] online. If this test screened positive, people interested in research participation could leave their e-mail address. All persons that left their email address in the period from December 2009 to May 2011 were e-mailed by the first author with study information. After completing the online baseline questionnaire, eligible participants filled out an online seven-day diary. After written informed consent was obtained and the online diary was filled out, participants could start their internet-delivered self-help treatment directly.

Four weeks (4-week follow-up) and 18 weeks (18-week follow-up) after completion of the 6-week intervention, participants filled out online questionnaires and an online 7-day sleep diary. Participants were considered dropouts after three unanswered reminders (two e-mails and one postal). The total sample was stratified into three groups based on the baseline CES-D scores, following the guidelines by Zich et al.[23]: low depression scores (score lower than 16; $n = 198$); mild depression scores (score between 16 and 27; $n = 182$); high depression scores (score of 27 or higher; $n = 99$; see "Results" for post hoc power analyses). The mean CES-D score in the current sample was 18.8 ($SD = 9.5$). In comparison, a trial on internet-delivered treatment for individuals with symptoms of depression had a mean score of 21.5 ($SD \approx 10.7$).[33]

INTERVENTION

The intervention consisted of a 6-week treatment program of approximately 9,000 words. The intervention comprised a multicomponent approach with the following elements: diary; psycho-education; relaxation exercises; stimulus control/sleep hygiene; sleep restriction; challenging misconceptions about sleep; paradoxical exercise. The self-help program was also used in our previous study where it is described more elaborately.[16] No module for sleep medication was included; participants were advised to contact their general practitioner if they wanted to quit sleep medication. In addition, no CBT interventions for depression were used.

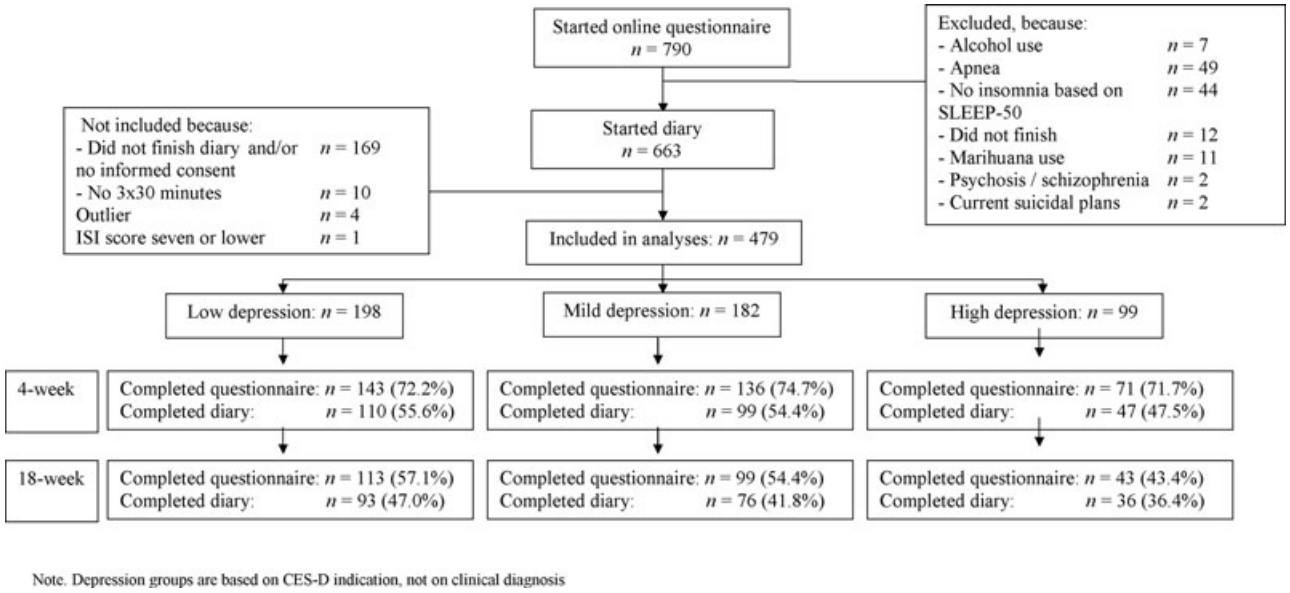

Figure 1. Flowchart.

The intervention consisted of a simple website that was essentially digitalized and fitted to a website format. It did not offer interaction or individual tailoring that is often employed in internet interventions. E-mail support by a therapist was not offered, but participants had the opportunity to e-mail the first author. In the low depression group, 11 participants asked content-related questions, in the mild depression group nine, and in the high depression group four (*e.g. "Does the website calculate the sleep restriction window?"; "My bedroom is the only place where I can study quietly, how can I use this place for sleeping only?"*).

MEASUREMENTS

Primary measures—Diary. Participants filled out a 7-day online diary at baseline and the two follow-up measurements. They recorded bed time, final arising time, sleep onset latency (SOL), number of nocturnal awakenings (NWAK), and wake after sleep onset (WASO). From these variables, the time in bed (TIB = final arising time − bed time), total sleep time (TST = TIB − SOL − WASO), and sleep efficiency (SE = (TST/TIB) × 100) were calculated.

Secondary measure—Questionnaire. The following descriptive variables were addressed in the baseline questionnaire: gender, age, whether one received psychological treatment, took sleep medication, or medication other than for sleeping, and if they perceived their insomnia to be due to a physical condition.

Insomnia complaints were measured by the Insomnia Severity Index (ISI). The questionnaire uses a 5-point Likert scale (e.g. 0 = no problem to 4 = very severe problem; total score range = 0–28) and is a valid and reliable measure to detect changes in insomnia severity (internal consistency = 0.78).[32,34] A change of eight points or greater is suggested as a clinical meaningful change.[35] A cut-off of seven is used to determine insomnia.

Depression was measured by a Dutch translation of the 20-item CES-D.[36,37] This scale has good internal consistency (α = 0.79–0.92; test–retest correlation is 0.90). Zich et al.[23] suggested 16 as the

TABLE 1. Demographic characteristics of participants per group

		Low depression (n = 198)		Mild depression (n = 182)		High depression (n = 99)			
Mean age (*SD*)		50.8 (13.9)		44.87 (12.5)		43.1 (12.9)		F (2, 478) = 15.0	$P < 0.001$
		n	%	n	%	n	%		
Gender	Male	81	40.9	63	34.6	19	19.2	χ^2 (2) = 13.9	$P = 0.001$
	Female	117	59.1	119	65.4	80	80.8		
Prescribed sleep medication*	No	134	67.7	124	68.1	61	61.6	χ^2 (2) = 1.40	$P = 0.50$
	Yes	64	32.3	58	31.9	38	38.4		
Medication other than for sleeping**	No	189	95.5	165	90.7	80	80.8	χ^2 (2) = 16.6	$P < 0.001$
	Yes	9	4.5	17	9.3	19	19.2		
In psychological treatment	No	181	91.4	158	86.8	34	34.3	χ^2 (2) = 34.5	$P < 0.001$
	Yes	17	8.6	24	13.2	65	65.7		
Insomnia due to a physical condition	No	173	87.4	157	86.3	87	87.9	χ^2 (2) = 0.18	$P = 0.92$
	Yes	25	12.6	25	13.7	12	12.1		

* = Weekly usage as measured by sleep diary; ** = Psychopharmacological medication other than for sleeping
Depression groups are based on CES-D indication not on clinical diagnosis.

standard cutoff and 27 as the stringent cutoff. In the current study, this resulted in the following groups: low depression scores (score lower than 16); mild depression scores (score between 16 and 27); high depression scores (score of 27 or higher). In the current sample, the CES-D had an internal consistency of $\alpha = 0.90$, a correlation of $r = 0.43$ ($P < 0.001$) with the Insomnia Severity Index, and $r = 0.01$ ($P = 0.92$) with sleep efficiency in the diary.

Anxiety was measured by the Dutch version of the seven anxiety items of the Hospital Anxiety and Depression Scale (HADS).[38] The reliability of the HADS is good ($\alpha = 0.80$–0.84), and so is the test–retest correlation (0.89; $P < 0.001$).

At 4-week follow-up, participants rated the seven modules of the self-help intervention on a Likert scale on whether they completed the exercises (1 = not completed to 5 = fully completed). Modules were considered completed if they were rated a four or above. Participants adhered to the intervention if they completed at least half of the modules (four or more).

STATISTICAL ANALYSIS

To test for time and interaction effects (time × group), a multilevel regression analysis was conducted. Multilevel regression is an intention-to-treat procedure that allows participants with only one measurement in the analyses.[39] A logistic regression analysis was performed for each group to evaluate variables that were associated with both questionnaire and diary nonresponse. If these variables correlated with the dependent variables, they were taken into account by adding them as covariates in the multilevel analysis. For the dependent variables, depression and anxiety no time × group interaction analyses were conducted because of the large baseline differences (Table 2). Four participants were excluded from the analysis because they were considered outliers (z-score > |3.29| on baseline sleep efficiency; one in the "low," two in the "mild," and one in the "high" depression group). Cohen's *d*s were calculated on the observed data with $(M_{pre1} - M_{post1})/\sigma_{pooled}$. A significance level of $P < 0.05$ (two sided) was used throughout the study.

We also imputed the missing post-test values with multiple imputation to test whether attrition influenced the follow-up scores.[40] However, multiple imputation is based on the "missing at random" assumption and this might be too liberal since attrition might be correlated to cases of failed or less effective treatment. Therefore, we included these files as a comparison in Supporting Information (Table S2).

TABLE 2. Observed pre- and posttreatment means and standard deviations with corresponding Cohen's *d* for high, mild, and low depression groups

		Pretreatment		4-week follow-up			18-week follow-up		
		M	(*SD*)	*M*	(*SD*)	*d*	*M*	(*SD*)	*d*
Primary measures Diary									
SE (%)	Low depression	72.95	(10.90)	80.60	(10.10)	0.73***	80.81	(11.77)	0.69***
	Mild depression	72.12	(12.98)	78.43	(15.40)	0.44***	78.78	(13.99)	0.49***
	High depression	72.82	(12.37)	80.21	(10.72)	0.64***	82.29	(8.16)	0.90***
TST (minutes)	Low depression	360.7	(62.17)	388.9	(61.00)	0.46***	387.9	(65.25)	0.43***
	Mild depression	365.7	(72.77)	394.2	(90.18)	0.35***	392.2	(81.08)	0.34***
	High depression	380.6	(80.18)	406.5	(78.20)	0.33***	418.9	(67.05)	0.52***
SOL (minutes)	Low depression	53.13	(35.38)	36.42	(28.12)	0.52***	35.46	(28.69)	0.55***
	Mild depression	58.50	(44.02)	47.37	(46.46)	0.25***	46.36	(54.11)	0.25***
	High depression	65.11	(42.93)	42.03	(26.91)	0.64***	39.52	(31.26)	0.68***
WASO (minutes)	Low depression	80.87	(49.99)	56.81	(35.52)	0.55***	57.37	(42.41)	0.51***
	Mild depression	83.78	(55.78)	60.94	(52.93)	0.42***	60.91	(48.12)	0.44***
	High depression	77.64	(55.09)	56.39	(44.71)	0.42***	57.30	(43.13)	0.41***
NWAK	Low depression	2.68	(2.11)	2.20	(1.37)	0.27***	2.21	(1.60)	0.25***
	Mild depression	2.80	(3.08)	2.39	(3.38)	0.13***	2.07	(1.30)	0.31***
	High depression	2.67	(1.54)	2.36	(1.58)	0.20*	2.19	(1.47)	0.32*
Secondary measures Questionnaire									
Insomnia (ISI)	Low depression	16.73	(3.52)	11.63	(5.13)	1.16***	11.01	(5.14)	1.30***
	Mild depression	18.63	(3.56)	12.72	(5.65)	1.25***	12.44	(5.45)	1.34***
	High depression	20.69	(3.60)	14.23	(6.65)	1.21***	12.67	(7.18)	1.41***
Depression (CES-D)	Low depression	10.09	(3.76)	8.45	(6.06)	0.33**	8.28	(5.63)	0.38**
	Mild depression	20.55	(2.97)	15.15	(8.13)	0.88***	13.64	(6.55)	1.36***
	High depression	33.17	(5.49)	23.83	(11.55)	1.03***	22.16	(11.28)	1.24***
Anxiety (HADS)	Low depression	4.91	(2.74)	4.12	(3.08)	0.27**	3.86	(2.62)	0.39***
	Mild depression	8.26	(3.39)	5.94	(3.31)	0.69***	5.97	(3.17)	0.70***
	High depression	11.67	(3.31)	8.77	(4.37)	0.75***	7.84	(4.10)	1.03***

Significance levels were calculated using multilevel regression; $^{*}P < 0.05$; $^{**}P < 0.01$; $^{***}P < 0.001$ (two sided). See Table S2 and S3 for the multilevel regression analyses and the imputed follow-up means and Cohen's *d* effect sizes. Depression groups are based on CES-D indication not on clinical diagnosis. SE, sleep efficiency; TST, total sleep time; SOL, sleep onset latency; WASO, wake after sleep onset; NWAK, number of nocturnal awakenings.

RESULTS

BASELINE DIFFERENCES AMONG GROUPS

At baseline, we observed significant differences among groups for ISI insomnia rating (F (2, 478) = 42.4, $P <$ 0.001), anxiety (F (2, 478) = 161.8, $P < 0.001$), and depression (F (2, 478) = 1168, $P < 0.001$; Table 2). There were also baseline differences for gender, age, medication, and being in treatment (Table 1).

NONRESPONSE

Response rates to the questionnaire and the diary are depicted in the flow chart (Fig. 1). At 4-week follow-up, there was no significant difference in nonresponse on the diary and questionnaire among the low, mild, and high depression groups ($P > 0.05$). Furthermore, in the mild ($P = 0.03$) and high ($P = 0.01$) depression group, completing the questionnaire was associated with high age. In addition, in the mild depression group, high NWAK was associated with increased completion of the pretreatment diary ($P = 0.01$).

At 18-week follow-up, there was a marginally significant difference in nonresponse on the questionnaire among the groups ($P = 0.08$). In the low depression group, gender ($P = 0.03$) was associated with completing the questionnaire and low SOL ($P = 0.045$) with completing the diary. In the mild depression group, high WASO was associated with completing the diary ($P =$ 0.02).

COMPLETION OF THE MODULES

No statistical differences were found among the three groups in completion rates ($P > 0.05$). In the low depression group, participants that filled out the 4-week follow-up questionnaire, completed on average 3.83 ($SD = 2.43$) out of seven modules and 89 (62.2%) adhered to the intervention. In the mild depression group, participants completed on average 3.78 ($SD = 2.32$) modules and 78 (57.4%) adhered to the intervention. In the high depression group, participants completed on average 3.79 ($SD = 2.15$) modules and 39 (54.9%) adhered to the intervention (two scores were missing).

POWER

Post hoc, a power calculation was performed using G*power 3.1. In G*power 3.1., the effect size "f" is used for a repeated measurements design.[41] For the power calculation, we assumed all groups had as much 4-week follow-up diary responders as the high depression group ($n = 47$). This is a conservative estimate since more participants completed the questionnaire, the other groups had also more responders on the diary, and the multilevel regression analyses takes all baseline measurements into account; the actual power is thus likely higher. Based on three groups with a 4-week follow-up, sample size of $n =$ 47, an α level of 0.5 (two sided), and a repeated measure time × group interaction, we achieved a power of 1.00 to detect a medium effect size ($f = 0.25$) and a power 0.55 to detect a small effect size ($f = 0.10$).

EFFECTIVENESS OF THE SELF-HELP TREATMENT

At 4-week follow-up, all groups showed within group effects on all primary (diary) and secondary (questionnaire) measures ($P < 0.05$; Table 2). Multilevel regression analyses showed no significant time × group interaction effect among groups on ISI insomnia rating, SE, TST, SOL, WASO, and NWAK ($P > 0.05$; Fig. 2).

At 18-week follow-up, the effects were sustained. In addition, on SOL ($P < 0.05$) and the ISI ($P < 0.01$) we observed a significant interaction effect for the high depression group compared to the mild (SOL: $b = -12.74$; $SE = 5.04$; ISI: $b = -1.83$; $SE = 0.79$) and low group (SOL: $b = 10.21$; $SE = 4.91$; ISI: $b = -2.14$; $SE = 0.78$). See Table S2 and S3 for all multilevel regression coefficients and imputed datasets (which rendered roughly the same results).

There was no significant correlation between baseline depression score and the change score for ISI, SE, TST, SOL, WASO, and NWAK at 4- and 18-week follow-up (all $r < 0.08$; all $P > 0.25$). For anxiety and depression, we performed only within-group analyses and no between group analyses because of the large baseline differences (see statistical analysis).

CLINICAL CHANGES

Of the participants that completed the 4-week follow-up, the following percentages achieved a clinical meaningful change on the Insomnia Severity Index (change ≥ 8): low depression: $n = 46$ (32.2%); mild depression: $n = 47$ (34.6%); high depression: $n = 25$ (36.23%). In the mild and high depression group, about 60% of the participants improved to a more favorable CES-D cutoff score. In the low/mild depression groups, 10% deteriorated. At 18-week follow-up, we found similar percentages among the groups. See Table 3 for changes stratified by group.

ADVERSE EVENTS

Three participants stopped with the treatment because their sleep problems got worse (one in the mild and two in the high depression group) and five stopped because of a lack of efficacy (two in the low and three in the mild depression group). A considerable larger portion of the sample did not respond to the follow-ups; however, only a few provided us with reasons for their drop out.

DISCUSSION

In this study, participants with high depression scores at baseline did not react differently to self-help treatment for insomnia than participants with low depression scores. At 4-week follow-up, we found no differences in effect among the three groups on the variables of SE, SOL, WASO, TST, and insomnia rating (ISI). There

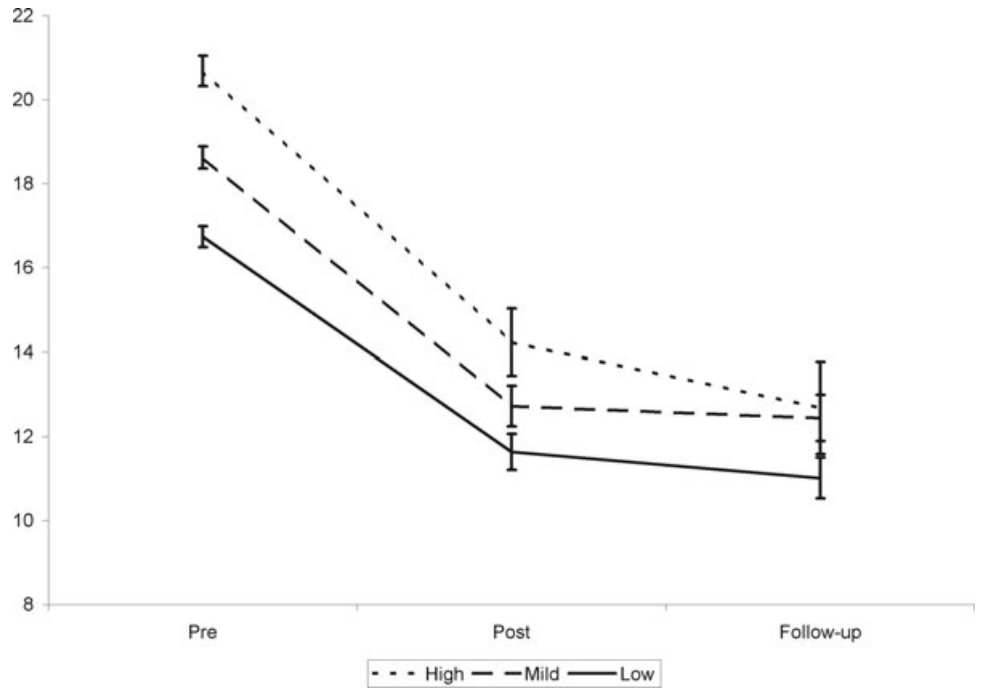

Figure 2. Baseline, 4-week and 18-week follow-up Insomnia Severity Index scores among high, mild, and low depression groups.

TABLE 3. CES-D cutoff score distribution at 4- and 18-week follow-up based on the baseline depression groups

		4-week follow-up		
Pretreatment		Low	Mild	High
Low depression	*n* (%)	126 (88.1%)	14 (9.8%)	3 (2.1%)
Mild depression	*n* (%)	79 (58.1%)	44 (32.4%)	13 (9.6%)
High depression	*n* (%)	18 (26.1%)	25 (36.2%)	26 (37.7%)
		18-week follow-up		
		Low	Mild	High
Low depression	*n* (%)	102 (91.1%)	9 (8.0%)	1 (0.9%)
Mild depression	*n* (%)	66 (67.3%)	28 (28.6%)	4 (4.1%)
High depression	*n* (%)	16 (37.2%)	11 (25.6%)	16 (37.2%)

were baseline differences on ISI insomnia rating, but in all groups insomnia was ameliorated to the same degree (with clinical meaningful changes in 32–34% of the cases). At 18-week follow-up, the effects were sustained and we observed a significant time × group interaction effect on SOL and the ISI: the high depression group improved more than the two other groups. However, only the SOL difference was observable in Cohen's *d* effect sizes. In general based on these data, depressed patients with high depression scores seem to benefit equally from unsupported self-help CBT-I compared to nondepressed patients.

Another finding was that in both the mild and high depression group, the depression scores dropped considerably. About 60% of the participants in the mild/high depression groups improved to a more favorable cutoff score (against around 10% that deteriorated in the low/mild depression groups). The only difference among the three groups was that in the current study, participants in the mild/high depression group improved more on CES-D/anxiety scores compared to the low depression group; most likely due to a floor effect of the latter.

Because of the uncontrolled nature of the study, it is unsure whether the large improvement on depression ratings in the mild/high groups can be attributed to the insomnia self-help treatment. However, previous research has shown a causal effect of CBT-I on insomnia and sleep measures[7–11,14,16] and it is known that insomnia and depression complaints are strongly correlated,[5,6,19–21] so a causal effect of CBT-I on depression scores is expected. This study demonstrates that depression levels do not affect efficacy of CBT-I and shows a correlation between CBT-I and reductions in depression scores. This is relevant for the observation that insomnia is a risk factor for depression[22] and it supports the notion that insomnia exacerbates depression.[5,6,19–21] Furthermore, it suggests that insomnia treatment is beneficial for high depression. At this point, randomized controlled studies that compare insomnia self-help treatments to valid control groups or depression-directed treatment would constitute a valuable next step.

In general, the effects of this self-help study were similar to the treatment without support in Jernelöv et al.[15] and to our previous study that delivered unsupported self-help treatment.[16] The effects were smaller than insomnia self-help treatment with support[15] and

the trials where sophisticated websites with computerized feedback were used.[14,17] This gives support to the notion that feedback either computerized or provided by humans enhances the effectiveness of self-help treatment.[42]

In addition to the equal effects on outcome measures, we did not observe any differences regarding nonresponse among the three groups. The generally high nonresponse rates are a limitation of this study and studies evaluating comparable internet-delivered treatment methodologies. The primary measures had the highest attrition: at the 4-week follow-up, 53% completed the diary and 73% completed the questionnaire; even less completed the 18-week follow-up. To control for this influence, we used multilevel regression modeling and multiple imputation; but even with these state-of-the-art techniques,[43] the missing values are estimated and may even lead to inaccurate estimations. Therefore, limiting attrition in future studies is essential.

Furthermore, we divided the groups based on baseline CES-D scores. This type of depression questionnaire may have lower validity in an insomnia group because of the relationship between depression and daytime insomnia symptoms (there was a substantial correlation of $r = 0.43$ between the CES-D and the ISI on baseline; however, we observed that the correlation between CES-D and SE was not significant—$r \approx 0$). We did not use a clinical interview because face-to-face contact might have contaminated the design. However, by doing so, we cannot rule out the possibility that the groups should have been stratified differently. It would be very helpful to investigate the cutoffs for the CES-D in an insomnia population (as was done for the Beck Depression Inventory[44]).

Of note is that we decided to exclude patients with current suicidal plans. Our reason was that an online design without any face-to-face interaction could not ensure their safety. By excluding only patients with suicidal plans (and not on suicidal ideation), we think we were able to include the vast majority of the group (only 2 of 790 were excluded). Another issue is the exclusion of apnea. We used a cutoff score on a questionnaire (sensitivity: 0.85; specificity 0.88) and this might have led to false positives.

In short in accordance with previous studies,[26,27,29,30] this study supports the hypothesis that patients with insomnia and co-morbid depression can benefit considerably from CBT-I. This is important because treating the combination of insomnia and depression constitutes an extra challenge since it may exacerbate the sleep problems. Of note, is that the participants in the mild/high depression groups were not without depressive complaints after the current treatment and therefore CBT-I should not be regarded as a replacement of depression-directed treatment. Therapists might want to consider including more insomnia directed treatment in their depression programs. For example, in this study about 30% of the participants in the high depression group also received psychological treatment and apparently this treatment did not adequately target insomnia complaints. A promising option may be to employ a combined depression–insomnia protocol or an (unsupported) self-help format for insomnia in an early phase of (face to face) depression treatment.

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