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SHORT REPORT

The clinical effect of digital cognitive behavioural therapy for insomnia in subgroups with depressive and anxiety symptoms: A secondary analysis of a randomized–controlled trial

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Summary

Insomnia is a highly prevalent mental disorder, and is often co-occurring with depression and anxiety disorders. Cognitive behavioural therapy for insomnia as treatment of choice for insomnia can also be applied digitally (digital cognitive behavioural therapy for insomnia), making it more accessible. This is a secondary data analysis of a two-armed parallel randomized–controlled trial. In the primary publication, $N = 238$ participants meeting criteria for the 5th edition of Diagnostic and Statistical Manual of Mental Disorders chronic insomnia disorder were randomly assigned to either 8 weeks of digital cognitive behavioural therapy for insomnia + treatment-as-usual, or waitlist + treatment-as-usual. To determine the clinical effects of digital cognitive behavioural therapy for insomnia in populations with comorbid anxiety and depression symptoms, this secondary analysis focused on two subgroups: (1) participants with high initial depressive symptoms; and (2) participants with high initial anxiety symptoms. Symptoms of insomnia, depression and anxiety as primary outcome measures were obtained at baseline, 8 weeks post-randomization and, in the intervention group only, at 6- and 12-months follow-up. At 8 weeks post-randomization, the use of digital cognitive behavioural therapy for insomnia in both subgroups was associated with large reductions in insomnia severity in comparison to control (depression subgroup: $d = 2.37$; anxiety subgroup: $d = 2.13$). Between-group treatment effects were also observed for symptoms of depression in the depression subgroup ($d = 1.59$), and for symptoms of anxiety in the anxiety subgroup ($d = 1.28$). Within-group effects were stable over time ($d = 0.64$–1.63). This secondary analysis shows that digital cognitive behavioural therapy for insomnia reduces insomnia and comorbid symptoms in participants with high initial symptoms of either depression or anxiety with sustained long-term effects.

KEYWORDS

anxiety, cognitive behavioural therapy for insomnia, comorbid insomnia, depression, digital cognitive behavioural therapy for insomnia, digital health, digital therapy, secondary analysis

1 | INTRODUCTION

One-quarter to one-third of patients with insomnia have a comorbid mental disorder, mostly depression or anxiety (Taylor et al., 2005). At the same time, 5th edition of Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for depression as well as anxiety disorder include sleep disturbance as a relevant symptom. The risk of developing an anxiety disorder or depression is increased in insomnia populations with, odds ratio (OR) 3.23 for anxiety disorders and OR 2.83 for depression (Hertenstein et al., 2019). Explanations for this bi-directional relationship are provided by neurobiological processes: neurotransmitters such as serotonin and dopamine (Adrien, 2002) as well as changes in the activity of the hypothalamic–pituitary–adrenal axis (Balbo et al., 2010) represent common neurobiological mechanisms underlying impaired regulation of both mood and sleep–wake rhythm. It is suspected that a disturbed sleep–wake rhythm can increase symptoms of a comorbid depression or anxiety disorder through these mechanisms (Harvey et al., 2011). As a result, addressing sleep disturbances may be a critical aspect of treating depression and anxiety, and there is evidence that sleep improvement through cognitive behavioural therapy for insomnia (CBT-I) mediates the reducing effect on depressive symptoms (Henry et al., 2021) and anxiety (Hagatun et al., 2018).

In October 2020, the Digital Health Application ("DiGA") *somnio* was introduced in Germany, enabling prescription-based treatment of insomnia via evidence-based digital CBT-I (dCBT-I) and thereby offering a new scalable treatment solution within regular care. Although the effects of dCBT-I on insomnia have been tested in multiple randomized–controlled trials (RCTs) and meta-analyses (Soh et al., 2020), its use in regular care demands for more evidence in comparable populations, such as those with the most common mental health comorbidities. Therefore, the aim of this secondary analysis is to investigate the effects of the dCBT-I intervention "somnio" (mentor DE GmbH, DiGA in Germany) in participants with high initial symptoms of anxiety and depression, recruited as part of a larger RCT (ONSET study; Schuffelen et al., 2023).

The following hypotheses were tested.

1. In those with high initial symptoms of depression ("depression subgroup"), dCBT-I decreases insomnia symptoms compared with a waitlist + treatment-as-usual (TAU) control group at 8 weeks post-randomization, and compared with baseline at 6- and 12-months follow-up assessments.
2. In the depression subgroup, dCBT-I decreases depressive symptoms compared with control at 8 weeks post-randomization, and compared with baseline at 6- and 12-months follow-up assessments.
3. In those with high initial symptoms of anxiety ("anxiety subgroup"), dCBT-I decreases insomnia symptoms compared with control at 8 weeks post-randomization, and compared with baseline at 6- and 12-month follow-up assessment.
4. In the anxiety subgroup, dCBT-I decreases anxiety symptoms compared with control group at 8 weeks post-randomization, and compared with baseline at 6- and 12-months follow-up assessments.

2 | METHODS

2.1 | Study design and participants

This secondary data analysis of the ONSET study (Schuffelen et al., 2023) aimed to determine clinical effects of dCBT-I in populations with comorbid anxiety and depression symptoms. The ONSET study was a large-scale RCT. In total, 238 participants (161 female, mean age = 43.73 ± 13.90 years) were randomized to 8 weeks dCBT-I (somnio, mementor DE GmbH) and TAU (dCBT-I + TAU), or to the control group (waitlist + TAU) using a 1:1 randomization sequence with no stratification factors. The intervention group was followed up at 6 and 12 months. Participants were recruited from the community via mail outs by a German health insurance company and social media. Those who were interested in participating underwent a two-step screening process (online screening and telephone screening). Inclusion criteria were the diagnosis of chronic insomnia according to DSM-5; exceeding a cut-off of ≥ 10 in the Insomnia Severity Index (ISI); and aged 18 years and older. Exclusion criteria were acute suicidality; diagnosis for epilepsy or schizophrenia; frequent use of alcohol and drugs. Participants were not blinded to the intervention. The recruitment period was between February and May 2021. There was no financial incentive to participate in the study. More details on the methods can be found in the previous publication of this trial (Schuffelen et al., 2023). The ONSET study was conducted in Duesseldorf, Germany, and approved by the Ethics Committee of Heinrich Heine University Duesseldorf (file number: GI01-2020-01). It was registered at the German Clinical Trials Register (Deutsches Register Klinischer Studien; DRKS) under DRKS00024477.

To determine the clinical effects of dCBT-I in populations with comorbid anxiety and depression, we defined two subgroups: participants with high initial depressive symptoms with a baseline General Depression Scale (German: Allgemeine Depressions-Skala, Kurzversion; ADS-K) score ≥ 18 were defined as "depression subgroup". Participants with high initial anxiety symptoms with a baseline State–Trait Anxiety Inventory (STAI-T) score ≥ 46 were defined as "anxiety subgroup". The objectives for the present report were registered with the Open Science Framework (10.17605/OSF.IO/EYX8F) prior to data analysis.

2.2 | Measures

2.2.1 | Insomnia

The ISI (German version; Dieck et al., 2018) measures complaints about sleep in the past 2 weeks using 7 items that are rated on a five-point Likert scale. A total score between 0 and 28 is calculated, with

higher scores indicating greater insomnia severity. Cut-off for remission is a total ISI score < 8 (Bastien et al., 2001).

2.2.2 | Depression

The ADS-K is a self-report instrument consisting of 15 items that can be used to assess the impairment caused by depressive symptoms within the last week. Participants are asked to rate emotional, motivational, cognitive, somatic and motor/interactional complaints on a 0–3 scale. The total score range of the ADS-K is between 0 and 45 points. The cut-off value for evidence of depressive disorder is ≥ 18, with a sensitivity of 89.7% and a specificity of 86.9% (Lehr et al., 2008).

2.2.3 | Anxiety

To assess anxiety symptomatology, the trait anxiety questions from the STAI-T were applied, consisting of 20 items, which ask the participant to rate one's general feelings on a four-point Likert scale from 1 to 4. This version was found to be less affected by day-by-day changes than the state version, which asks the participants to rate one's feelings right now. Total score range is between 20 and 80 points. There is no firmly established cut-off value for evidence of anxiety disorder. For the definition of the anxiety subgroup, we used the cut-off value of ≥ 46 proposed by Fisher and Durham (1999).

2.3 | Intervention

The dCBT-I-program (somnio, *mementor DE GmbH*) is a CE-certified application for the treatment of insomnia, approved by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) as a DiGA. The program uses evidence-based and guideline-compliant CBT-I content to improve participants' sleep, including psychoeducation, sleep hygiene, sleep restriction therapy, relaxation, cognitive techniques, and stimulus control. A digital sleep diary is used to record and analyse sleep data, such as information on sleep times and general well-being. Participants are guided through the program by a 3D animated digital coach. A detailed description of the dCBT-I program *somnio* can be found in Schuffelen et al. (2023), Maurer et al. (2023) and Lorenz et al. (2019). The control group (waitlist + TAU) was not given access to the dCBT-I program until 8 weeks after randomization. Otherwise, the control group was not restricted compared with the dCBT-I group.

2.4 | Statistical analyses

SPSS.29 (IBM) was used for the data analyses. Data were analysed for each subgroup and according to the intention-to-treat-approach (Moher et al., 2001). Missing values were analysed for systematic patterns. If the missing at random (MAR) condition was confirmed, missing values were replaced by multiple imputation using the linear regression model with data from five imputed datasets. For continuous outcomes, unadjusted means (*M*) and standard deviations (*SD*) are used to present descriptive statistics, binary outcomes are described by frequencies. We conducted ANCOVAs to assess outcome variables at 8 weeks post-randomization with baseline-data entered as covariate. Between-group effect sizes of continuous outcomes were calculated by dividing the adjusted mean difference by the pooled standard deviation of both groups at baseline (Cohen, 1988). Remission rates for insomnia (ISI < 8), depression symptoms (ADS-K < 18) and anxiety symptoms (STAI-T < 46) were calculated to determine clinical significance. Pearson chi-squared tests were used to analyse between-group differences of dichotomous outcomes, and effect sizes were quantified using phi. For the analysis of follow-up assessments, we fitted linear mixed models (LMMs) with fixed effects for time point (baseline, 8 weeks, 6 months, 12 months). Within-group effect sizes were calculated by dividing the mean difference by the standard deviation of the change (Cohen, 1988).

3 | RESULTS

3.1 | Participants and clinical characteristics

From overall $n = 238$ participants, $n = 88$ scored ≥ 18 in the ADS-K (dCBT-I = 40; waitlist-control [WLC] = 48) and $n = 120$ scored ≥ 46 in the STAI-T (dCBT-I = 53, WLC = 67) at baseline, and were consequently assigned to the depression and anxiety subgroups, respectively. In the depression subgroup, 10% ($n = 9$) did not complete outcomes at 8 weeks post-treatment (dCBT-I: 18% [$n = 7$]; WLC: 4% [$n = 2$]) and were defined as drop-outs (lost-to-follow-up). At 6 months follow-up (dCBT-I group only), the drop-out rate was 28% ($n = 11$) and 40% ($n = 16$) at 12 months follow-up. In the anxiety subgroup, 10% ($n = 12$) did not complete outcomes at 8 weeks post-treatment (dCBT-I: 15% [$n = 8$]; WLC: 3% [$n = 2$]), while the drop-out rate at 6 months follow-up (dCBT-I group only) was 26% ($n = 14$) and 38% ($n = 20$) at 12 months follow-up. There was an overlap between the two subgroups: in the depression subgroup, 84% fulfilled the criteria for the anxiety subgroup (dCBT-I group: 80%; WLC: 88%); and in the anxiety subgroup, 61% fulfilled the criteria for the depression subgroup (dCBT-I group: 60%; and WLC: 62%). Baseline characteristics of both subgroups are presented in Table 1. For further details on the participants, the participant flow chart and clinical characteristics of all participants, see Schuffelen et al. (2023).

3.2 | Effects on symptoms of insomnia, depression and anxiety

3.2.1 | Depression subgroup

In the depression subgroup, large between-group effect sizes were found at 8 weeks post-randomization in favour of the dCBT-I

group on the ISI ($F_{1,179.43} = 83.18$, $p < 0.001$, $d = 2.37$) and on the ADS-K ($F_{1,3090.42} = 19.44$, $p < 0.001$, $d = 1.59$; Table 2). Remission rate from insomnia was 28% ($n = 11$) in the dCBT-I group, and 0% ($n = 0$) in the control group ($\chi^2(1, n = 79) = 17.81$, $p < 0.001$, $\varphi = -0.48$). Remission rate from depressive symptoms was 53% ($n = 21$) in the dCBT-I group, and 38% ($n = 18$) in the control group ($\chi^2(1, n = 79) = 4.62$, $p < 0.032$, $\varphi = -0.24$). Symptoms of insomnia and depression were also reduced at 6- and 12-months follow-up as indicated by large within-group effect sizes (Table 3).

TABLE 1 Participants and clinical characteristics.

	Depression subgroup		Anxiety subgroup	
	dCBT-I + TAU	WLC + TAU	dCBT-I + TAU	WLC + TAU
	n = 40	*n* = 48	*n* = 53	*n* = 67
Baseline characteristics				
Age, M (SD)	42.98 (14.67)	41.63 (14.08)	42.02 (14.30)	40.93 (12.48)
Female, *n* (%)	31 (77.5)	34 (70.8)	40 (75.5)	49 (73.1)
Psychotherapy				
Current, *n* (%)	11 (27.5)	11 (22.9)	15 (28.3)	13 (19.4)
Former, *n* (%)	13 (32.5)	26 (54.2)	18 (34.0)	35 (52.2)
CNS med., *n* (%)	1 (2.5)	0 (0)	2 (3.8)	3 (4.5)
Sleep med., *n* (%)	15 (37.5)	25 (52.1)	26 (49.1)	30 (44.8)
Other med., *n* (%)	8 (20)	17 (35.4)	7 (13.2)	8 (11.9)
Psy. diagnoses				
Current, *n* (%)	6 (15)	9 (18.8)	10 (18.9)	11 (16.4)
In the past, *n* (%)	12 (30)	15 (31.3)	16 (30.2)	24 (35.8)
Outcomes at baseline				
ISI, M (SD)	18.95 (4.00)	18.42 (3.04)	18.68 (3.76)	17.76 (3.31)
ADS-K, M (SD)	23.28 (4.12)	22.27 (4.44)	20.32 (5.66)	18.99 (6.24)
STAI-T, M (SD)	52.95 (8.39)	53.75 (7.80)	54.74 (5.42)	53.81 (6.24)

Abbreviations: Anxiety subgroup, anxiety symptoms subgroup scoring STAI-T ≥ 46 at baseline; ADS-K, General Depression Scale; CNS med., central nervous system medication; dCBT-I, digital cognitive behavioural therapy for insomnia; depression subgroup, depressive symptoms subgroup scoring ADS-K ≥ 18 at baseline; ISI, Insomnia Severity Index; STAI-T, State–Trait Anxiety Inventory (trait anxiety questions); TAU, treatment-as-usual; WLC, waitlist-control.

TABLE 2 Unadjusted means and ANCOVA results for post-effects 8 weeks after randomization on depression and anxiety between intervention- and control-groups in both subgroups.

		dCBT-I + TAU			WLC + TAU							
		n	M	SD	*n*	M	SD	$Diff_{adj}$	95% CI		*p*	ES
	Depression subgroup											
ISI	BL	40	18.95	4.00	48	18.42	3.04					
	PT	33	9.39	5.06	46	17.76	3.61	−8.33	−10.05	−6.64	< 0.001	2.37
ADS-K	BL	40	23.28	4.12	48	22.27	4.44					
	PT	33	14.64	8.30	46	20.61	6.96	−6.69	−9.69	−3.69	< 0.001	1.59
	Anxiety subgroup											
ISI	BL	53	18.68	3.76	67	17.76	3.31					
	PT	45	9.49	5.02	63	16.71	4.11	−7.54	−9.11	−5.98	< 0.001	2.13
STAI-T	BL	53	54.74	5.42	67	53.81	6.20					
	PT	45	46.33	10.12	63	53.46	7.01	−7.41	−10.09	−4.92	< 0.001	1.28

Abbreviations: ADS-K, General Depression Scale; anxiety subgroup, subgroup scoring STAI-T ≥ 46 at baseline; BL, baseline; CI, confidence interval; dCBT-I, digital cognitive behavioural therapy for insomnia; depression subgroup, subgroup scoring ADS-K ≥ 18 at baseline; ES, effect size; ISI, Insomnia Severity Index; PT, post-treatment; STAI-T, State–Trait Anxiety Inventory (trait anxiety questions); TAU, treatment-as-usual; WLC, waitlist-control.

TABLE 3 Unadjusted means and results of the LMMs in ADS-K and STAI-T at post-treatment, and 6 and 12 months follow-up in the CBT-I + TAU group.

	Time	*n*	M (SD)	$Diff_{adj}$	*p*	95% CI		ES
	Depression subgroup							
ISI	BL	40	18.95 (4.00)					
	PT	33	9.39 (5.06)	−9.44	< 0.001	−11.31	−7.58	1.63
	6 M-FU	29	10.72 (6.04)	−7.78	< 0.001	−9.65	−5.90	1.34
	12 M-FU	24	10.17 (6.10)	−8.50	< 0.001	−10.97	−6.02	1.11
ADS-K	BL	40	23.28 (4.12)					
	PT	33	14.64 (8.30)	−8.62	< 0.001	−11.58	−5.67	0.94
	6 M-FU	29	15.79 (8.74)	−7.51	< 0.001	−10.27	−4.75	0.87
	12 M-FU	24	15.46 (7.96)	−7.90	< 0.001	−10.78	−5.03	0.89
	Anxiety subgroup							
ISI	BL	53	18.68 (3.76)					
	PT	45	9.49 (5.02)	−9.13	< 0.001	−10.76	−7.49	1.54
	6 M-FU	39	9.97 (5.54)	−8.35	< 0.001	−9.96	−6.74	1.44
	12 M-FU	33	10.27 (6.11)	−7.99	< 0.001	−10.05	−5.92	1.08
STAI-T	BL	53	54.74 (5.42)					
	PT	45	46.33 (10.12)	−8.42	< 0.001	−11.03	−5.82	0.90
	6 M-FU	39	47.33 (8.49)	−7.91	< 0.001	−10.30	−5.51	0.91
	12 M-FU	33	48.00 (10.56)	−6.93	< 0.001	−9.94	−3.91	0.64

Abbreviations: 6 M-FU, 6 months follow-up; 12 M-FU, 12 months follow-up; ADS-K, General Depression Scale; anxiety subgroup, scoring STAI-T ≥ 46 at baseline; BL, baseline; CI, confidence interval; depression subgroup, scoring ADS-K ≥ 18 at baseline; ES, effect size; ISI, Insomnia Severity Index; PT, post-treatment at 8 weeks post-randomization.

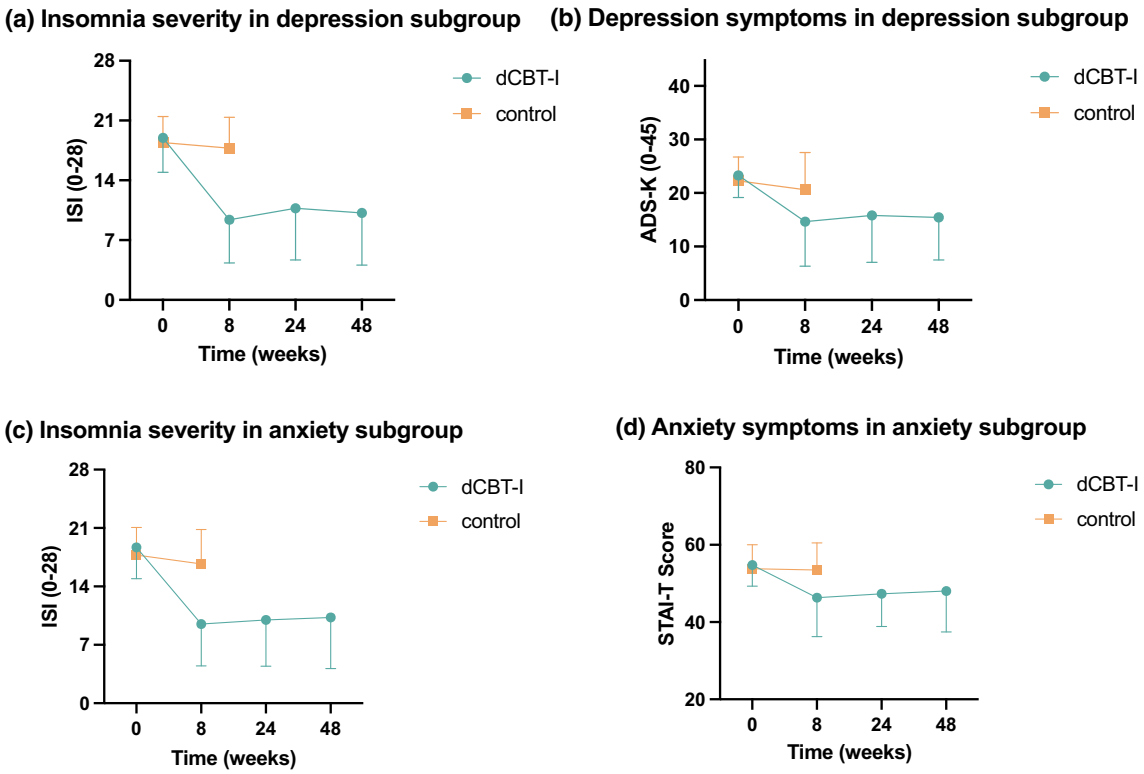

FIGURE 1 Unadjusted means and standard deviation (displayed one-sided for better visualization) on outcomes in the depression subgroup (a: insomnia severity; b: depression symptoms) and in the anxiety subgroup (c: insomnia severity; d: anxiety symptoms) in all measured time points.

3.2.2 | Anxiety subgroup

In the anxiety subgroup, large between-group effect sizes were found at 8 weeks post-randomization in favour of the dCBT-I group on the ISI ($F_{1,388.47} = 84.41$, $p < 0.001$, $d = 2.13$) and on the STAI-T ($F_{1,160,004} = 32.50$, $p < 0.001$, $d = 1.28$; Table 2). Remission rate from insomnia was 34% ($n = 18$) in the dCBT-I group and 2% ($n = 1$) in the control group ($\chi^2(1, n = 108) = 26.71$, $p < 0.001$, $\varphi = -0.50$). Remission from anxiety symptoms was 42% ($n = 22$) in the dCBT-I group and 15% ($n = 10$) in the control group ($\chi^2(1, n = 108) = 13.72$, $p < 0.001$, $\varphi = -0.36$). Insomnia and anxiety symptoms were also reduced at 6- and 12-months follow-up assessment, when compared with baseline ($d = 0.64$–1.54; Figure 1; Table 3).

4 | DISCUSSION

The focus of the study was to investigate the effects of dCBT-I in subgroups of patients with: (1) high initial depressive symptoms; and (2) high initial anxiety symptoms on the outcomes of insomnia, depression and anxiety. Results show that dCBT-I treatment reduces insomnia symptoms in both subgroups, and also reduces comorbid symptoms of depression and anxiety in the corresponding group.

With regard to the symptoms of insomnia, large post-treatment effect sizes ($d = 2.13$–2.37) were shown in both subgroups. These effects are comparable to the effects on insomnia symptoms ($d = 2.08$) in the primary study by Schuffelen et al. (2023), and support evidence that CBT-I is an effective treatment for insomnia independent of the presence of comorbid conditions (Hertenstein et al., 2022). The results at 6 and 12 months follow-up indicated a stability of the effects on insomnia symptoms for both subgroups.

In both subgroups, insomnia remission rates were higher in the dCBT-I group. Compared with the remission rate of the intervention group in the primary study (64%), the number of remitted participants was lower in the depressive subgroup (27%) and in the anxiety subgroup (34%), although the mean reduction in insomnia symptoms at post-treatment was comparable between intervention groups (depression subgroup: $\text{Diff}_{\text{adj}} = -9.44$; anxiety subgroup: $\text{Diff}_{\text{adj}} = -9.13$; original study population: $\text{Diff}_{\text{adj}} = -9.05$). Remission rates for comorbid outcomes indicate that after treatment 1 in 2 patients still reported clinically relevant depression, and 3 in 5 still reported clinically relevant anxiety. Although these rates might be comparable to remission rates of depression- and anxiety-specific CBT treatment programs (Cuijpers et al., 2020; Springer et al., 2018), it clearly highlights the need for better treatment solutions. Potentially, more complex, transdiagnostic treatment options are needed for patients with comorbid disorders (Harvey & Buysse, 2017).

Large post-treatment effect sizes were also shown for the respective comorbid outcomes ($d = 1.59$ for ADS-K; $d = 1.28$ on the STAI-T) in both subgroups. Again, results at 6 and 12 months follow-up indicated a stability of the effects in the long term. Overall, the presented results support: (1) evidence on the intertwined relationship between insomnia and depression, and insomnia and anxiety; and (2) the beneficial effects of CBT-I on depression (Cunningham & Shapiro, 2018; Lee et al., 2023) and anxiety (Lee et al., 2023). Observed effects for both outcomes were comparatively larger compared with the total study population of this trial (Schuffelen et al., 2023), but also in comparison to effects reported in previous meta-analyses on dCBT-I reporting small to moderate effects (Lee et al., 2023; Ye et al., 2016), potentially because a high initial score in the comorbid symptomatology is associated with a higher potential for more pronounced symptom improvement.

It should be noted that there was a strong overlap of participants between the two subgroups. In the depression subgroup, many patients also met the definition criteria of the anxiety subgroup; and in the anxiety group, many patients also met the cut-off of the depression subgroup. This overlap reflects the frequent co-occurrence of anxiety and depression in the reality of care (Lamers et al., 2011), and explains why there were similar baseline characteristics and similar effects on insomnia in both subgroups.

The study has several limitations. All analyses were exploratory, and the power of the primary study was not calculated for the analyses conducted in this secondary analysis, resulting in higher risk for type 1 and 2 errors. Moreover, due to the nature of the study, participants were not blinded to the intervention and their group allocation, which may have resulted in an expectation and reporting bias. Similarly, researchers were not blinded to group allocation; however, data collection was standardized and completely online. Additionally, data were blinded before analysis to mask group allocation. Compared with the overall population, the numbers of participants analysed in the subgroups ($n = 88$ for the depression subgroup; $n = 120$ for the anxiety subgroup) are small, and distribution within the groups was not equal (about 20% more participants in the control group). Effect sizes therefore should be interpreted with caution. Nevertheless, this secondary analysis was registered before the statistical analyses were conducted, and the effect sizes indicate that the study was sufficiently powered. The interpretation of the results should also take into account that there was no clinical diagnosis for the comorbid diseases. Although the ADS-K is a good approximation with high accuracy in detecting depression (Lehr et al., 2008), further studies should include participants with a diagnosis of a clinical expert. Moreover, while drop-out rates at 8 weeks post-randomization were acceptable, we observed higher drop-outs in the dCBT-I groups compared with WLC groups (depression subgroup: dCBT-I: 18%, WLC: 4%; anxiety subgroup: dCBT-I: 15%, WLC: 6%). While this is a common observation in WLC trials and may be due to the missing incentive in the dCBT-I group for completing the assessment (the WLC group received access to the intervention after completing the assessments, the intervention group received no incentive), it may have biased our analyses. Additionally, we cannot rule out that missing data in the intervention group was due to the participants' dissatisfaction with the program, therefore potentially violating the MAR condition for data imputation. We further noticed that drop-out rates at 6 and 12 months follow-up (28%–40% in the depression subgroup, and 26%–38% in the anxiety subgroup) were comparatively high (Table 3), and it can be discussed whether the imputed data correctly represent the missing data. Internal sensitivity analysis of original data only revealed comparable mean differences for all comparisons (e.g. ANCOVA: ISI mean diff. for dCBT-I group at post-treatment

= −8.43; LMMs: ISI mean diff. for dCBT-I group at post-treatment = −9.29, 6 months follow-up = −7.71, 12 months follow-up = −8.25). Still, this is a significant problem in the study design, and future studies should aim to minimize drop-outs by implementing higher incentives or more personal contact.

More often than isolated, insomnia occurs in the presence of comorbid conditions (Taylor et al., 2005), and dCBT-I is an easy to access option to provide early and evidence-based care for those being affected (Hertenstein et al., 2022). It is therefore important to translate findings from controlled studies to regular care, and to investigate whether dCBT-I can improve the care situation in patients with comorbid conditions. There is first evidence that CBT-I may overall be more effective than CBT for depression for patients with both diagnoses (Blom et al., 2013), and equally that CBT-I might be as effective as CBT for the reduction of anxiety in those with anxiety and insomnia (Mason et al., 2022). It is therefore of great interest to further examine whether dCBT-I may be a suitable low-threshold, transdiagnostic intervention for other disorders in regular care.

AUTHOR CONTRIBUTIONS

Alexander Rötger: Conceptualization; methodology; visualization; writing – review and editing; software; investigation; writing – original draft; validation; formal analysis; project administration. **Jennifer Schuffelen:** Conceptualization; project administration; methodology; formal analysis. **Leonie Maurer:** Conceptualization; methodology; validation; writing – review and editing; formal analysis. **Noah Lorenz:** Software; conceptualization. **Bettina Pollok:** Conceptualization; writing – review and editing; supervision. **Annika Gieselmann:** Conceptualization; methodology; supervision.

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CONFLICT OF INTEREST STATEMENT

AR and NL are founders of and salaried employees of mementor DE GmbH, a company that developed somnio, a digital health application to treat insomnia. JS is a part-time salaried employee of mementor DE GmbH. LFM is a salaried employee of mementor DE GmbH. BP and AG do not have any financial interests. AG declares non-financial support in the form of no cost access to somnio for use in clinical research.

DATA AVAILABILITY STATEMENT

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

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