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Review Article

Effectiveness of Digital Cognitive Behavioral Therapy for Insomnia: A Meta-Analysis of Randomized Controlled Trials

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Abstract

Objective: This study aimed to evaluate the effectiveness of fully automated Digital Cognitive Behavioral Therapy for Insomnia (dCBT-I) interventions in reducing insomnia severity through a systematic review and meta-analysis of randomized controlled trials (RCTs).
Method: A systematic search was conducted across multiple databases, including PubMed, PsycINFO, Web of Science, Scopus, and Google Scholar, to identify RCTs evaluating fully automated dCBT-I. Eligible studies were included those assessing adults diagnosed with insomnia using validated criteria or scales, utilizing digital delivery platforms, and reporting quantitative insomnia severity outcomes. A meta-analysis was performed using a random-effects model, with standardized mean differences (SMDs) and 95% confidence intervals (CIs) as the primary effect measures. Subgroup and sensitivity analyses were conducted to explore sources of heterogeneity.
Results: A total of 49 RCTs involving 20,118 participants were included. Fully automated dCBT-I significantly reduced insomnia severity compared to control conditions (WMD: -3.42; 95% CI: -4.35 to -2.48; $P < 0.001$). Subgroup analyses revealed greater effectiveness in studies using rigorous diagnostic criteria, as well as among U.S.-based populations. Despite substantial heterogeneity ($I^2 > 98\%$), sensitivity analyses confirmed the robustness of findings. Funnel plot asymmetry suggested minor potential publication bias, though Egger's test did not confirm significant bias ($P = 0.494$).
Conclusion: Fully automated dCBT-I programs effectively reduce insomnia severity, offering a scalable, accessible solution to overcome barriers in traditional CBT-I delivery. However, variability in study methodologies and the predominance of studies from high-income countries highlight the need for further research. Future directions include incorporating objective sleep measures, assessing long-term outcomes, and adapting interventions to diverse cultural and economic contexts. Fully automated dCBT-I holds transformative potential for addressing insomnia on a global scale.

Key words: *Cognitive Behavioral Therapy; Digital Health; Insomnia; Meta-Analysis; Randomized Controlled Trials*

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Insomnia is a widespread sleep disorder that impacts a substantial segment of the global population. It is defined by persistent problems with initiating or maintaining sleep, or experiencing non-restorative sleep, despite having sufficient opportunity to sleep. This condition can severely affect individuals' physical health, psychological state, and social life (1, 2). Additionally, insomnia has been associated with various negative health outcomes, such as an elevated risk of cardiovascular diseases, mood disorders including depression and anxiety, and diminished cognitive abilities (3). The economic repercussions are also significant, encompassing increased medical expenditures, reduced efficiency at work, and a decline in overall quality of life (4).

The prevalence of insomnia has grown in part due to modern lifestyle factors, such as excessive use of digital technologies, irregular sleep-wake patterns, and heightened stress levels. Work-related pressures, shift-based jobs, prolonged screen time, and poor sleep practices are frequent contributors to sleep disturbances (5). With these lifestyle patterns becoming more common worldwide, the need for effective and widely accessible treatment options has become increasingly urgent.

Cognitive Behavioral Therapy for Insomnia (CBT-I) is widely acknowledged as a highly effective approach for treating insomnia. This therapy targets the behavioral and cognitive elements that lead to sleep issues (6, 7). It includes a range of strategies such as sleep restriction, stimulus control, cognitive restructuring, and relaxation techniques to help individuals adopt healthier sleep-related habits and beliefs (8). Numerous clinical studies have validated the effectiveness of CBT-I in alleviating insomnia symptoms and enhancing sleep quality (9).

Despite its effectiveness, the traditional delivery of CBT-I—typically through face-to-face sessions with trained clinicians—presents notable accessibility challenges. These include a lack of available therapists, high session costs, and logistical barriers, especially for individuals in rural or underserved regions. Consequently, many people with insomnia are unable to access this form of care (10).

In recent years, digital health innovations have significantly transformed healthcare delivery. Internet-based and mobile app interventions have gained widespread adoption due to their scalability, ease of access, and affordability (11). These technologies present an opportunity to extend evidence-based treatments to broader populations, overcoming many of the logistical and financial barriers linked with conventional therapy formats.

Fully automated dCBT-I (dCBT-I) programs have emerged as a compelling alternative to therapist-led interventions. Delivered entirely through web platforms or mobile applications, these tools do not require direct human support and are designed to be both cost-effective and accessible to a wide audience (12). Over the past decade, these digital therapies have continued to evolve, with increasing research demonstrating their capacity to reduce insomnia symptoms and improve sleep-related outcomes (13).

Several systematic reviews and meta-analyses have explored the effectiveness of internet-delivered or digital CBT for treating insomnia. Zachariae (14) and Seyffer (15) found notable improvements in sleep outcomes from digital CBT programs, though many studies they reviewed included therapist-supported elements or did not exclusively examine fully automated versions. More recently, Hwang (16) conducted a focused review of fully automated dCBT-I and confirmed its effectiveness, although their meta-analysis included a relatively limited number of RCTs (35), lacked detailed subgroup analyses, and did not explore differences in diagnostic criteria or geographical regions.

In comparison, the current meta-analysis includes a more extensive dataset of 49 randomized controlled trials involving more than 20,000 participants. It incorporates the latest available evidence up to January 2025 and features comprehensive subgroup and sensitivity analyses. These analyses assess variations in results based on diagnostic criteria (e.g., ISI cut-offs), country of study, sample sizes, and risk-of-bias evaluations—factors that were not systematically addressed in prior research. As such, this study offers a more thorough and methodologically rigorous assessment of the effectiveness of fully automated dCBT-I interventions, with important implications for their scalability and global applicability.

The principal aim of this meta-analysis is to assess how effective fully automated dCBT-I interventions are in reducing insomnia severity, using validated instruments such as the Insomnia Severity Index (ISI) (17). By synthesizing results from numerous studies, this review provides a broad evaluation of the clinical effectiveness, feasibility, and user acceptability of these interventions. The key research question addressed is: How effective are fully automated dCBT-I programs in enhancing sleep outcomes among individuals diagnosed with insomnia?

Materials and Methods

Search Strategy and Data Sources

This review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (18). A comprehensive systematic search was performed across multiple databases, including PubMed,

PsycINFO, Web of Science, and Scopus, to identify randomized controlled trials (RCTs) evaluating the efficacy of fully automated digital cognitive behavioral therapy for insomnia (dCBT-I). The search strategy incorporated terms related to digital delivery (e.g., "Internet-based," "web-based," "mobile app"), cognitive-behavioral therapy (e.g., "CBT-I," "cognitive therapy"), and insomnia (e.g., "sleep disorders," "insomnia"). Articles published from inception up to January 2025 were included in the review.

All identified articles were screened to assess their relevance to the study aims. Additionally, Google Scholar and references from included articles were also screened for further studies of interest. Only English-language articles were considered in this review. This systematic review and meta-analysis was registered in PROSPERO (ID: CRD42023455678).

Inclusion and Exclusion Criteria

Studies were included if they met the following criteria:

1. ***Population***: Adults aged 18 years diagnosed with insomnia using validated criteria (e.g., DSM, ICD) or validated scales (e.g., ISI, ISI).
2. ***Intervention***: Fully automated dCBT-I programs delivered via digital platforms (e.g., web, mobile app).
3. ***Comparator***: Control conditions, including waitlists, treatment as usual, or placebo.
4. ***Study Design***: RCTs.
5. ***Outcomes***: ISI.

Studies involving therapist-guided CBT-I, interventions primarily targeting comorbidities (e.g., depression), or non-RCT designs were excluded.

Selection of Studies

Three authors (A.N., M.A., and A.M.) independently screened the titles and relevant abstracts. They retrieved and reviewed the full text of the selected studies. They resolved any disagreements by discussion or referral to the third author (GH.G.). Some studies were excluded as irrelevant after full text review.

Data Extraction

The extracted data encompassed several key elements, including the name of the first author, year of publication, country of study, target population, definition of insomnia used, study design, components of the dCBT-I intervention, level of therapist involvement, type of control condition, and the number of sessions. Additionally, mean and standard deviation (SD) values for the ISI before and after the intervention were recorded for each group. When studies reported data as standard errors (SEs) or interquartile ranges, these were converted to SDs using appropriate statistical formulas.

Risk of Bias Assessment

To evaluate the methodological quality of the included RCTs, the Cochrane Risk of Bias Tool (RoB) was utilized (19). This tool is widely recommended for assessing bias in RCTs and is generally regarded as more robust than alternatives like the Jadad Scale or the Delphi List (20). The RoB framework assesses potential bias across five key areas: the randomization procedure, deviations from intended interventions, incomplete outcome data, outcome measurement, and selective reporting of results. Each study was then assigned an overall judgment of risk—categorized as "Good," "Fair," or "High." The bias assessments were independently conducted by A.N. and A.M., with oversight from GH.G. Any discrepancies were resolved through discussion and consensus among the authors.

Statistical Analysis

The mean change (SD) was used to estimate the overall effect size of the intervention. If the standard deviation (SD) was not reported in individual studies, it was calculated using the formula: SD_change = √((SD_baseline^2 + SD_final^2) - (2 × R × SD_baseline × SD_final)) where R = 0.8, the assumed correlation coefficient between baseline and final measurements (21). When only the standard error of the mean (SEM) was reported, the SD was calculated as: SD = SEM × √n, where n is the number of participants in each group. For studies reporting outcome measures graphically, data extraction was performed using GetData Graph Digitizer 2.24(22). Estimates of effect sizes were expressed as standardized mean differences (SMDs) with 95% confidence intervals (CIs) using a random-effects model. Heterogeneity was assessed using the Q test and I^2 statistic, with $I^2 > 75\%$ indicating substantial heterogeneity (23). Subgroup and sensitivity analyses were performed to explore heterogeneity sources and assess robustness. Publication bias was evaluated with funnel plots and Egger's regression tests.

Additionally, meta-regression analyses were performed to investigate whether continuous study-level covariates, such as mean age of participants and follow-up duration, moderated the effect size. These analyses were conducted using the restricted maximum likelihood (REML) estimation method, and the Knapp-Hartung adjustment was applied to standard errors to improve inference accuracy. Meta-regression results were reported with regression coefficients, 95% CIs, and corresponding p-values. All analyses were conducted using Stata software version 17 (Stata Corp, USA), with a P-value < 0.05 considered significant.

Results

Study Characteristics

We removed the duplicates and got 1569 records from 3210. The screening and selection process is illustrated in more detail in Figure 1. A total of 49 studies involving 20,118 participants from various countries, including Australia, South Korea, Austria, Germany, the UK, Hong Kong, China, the USA, Switzerland, Norway, Japan, Iran, Canada, the Netherlands, and Denmark, were encompassed in the meta-analysis. These studies assessed the effectiveness of fully automated dCBT-I interventions against control conditions such as waitlist, treatment as usual, and placebo. Intervention components varied, including sleep restriction, stimulus control, cognitive restructuring, relaxation training, and sleep hygiene education (Table 1).

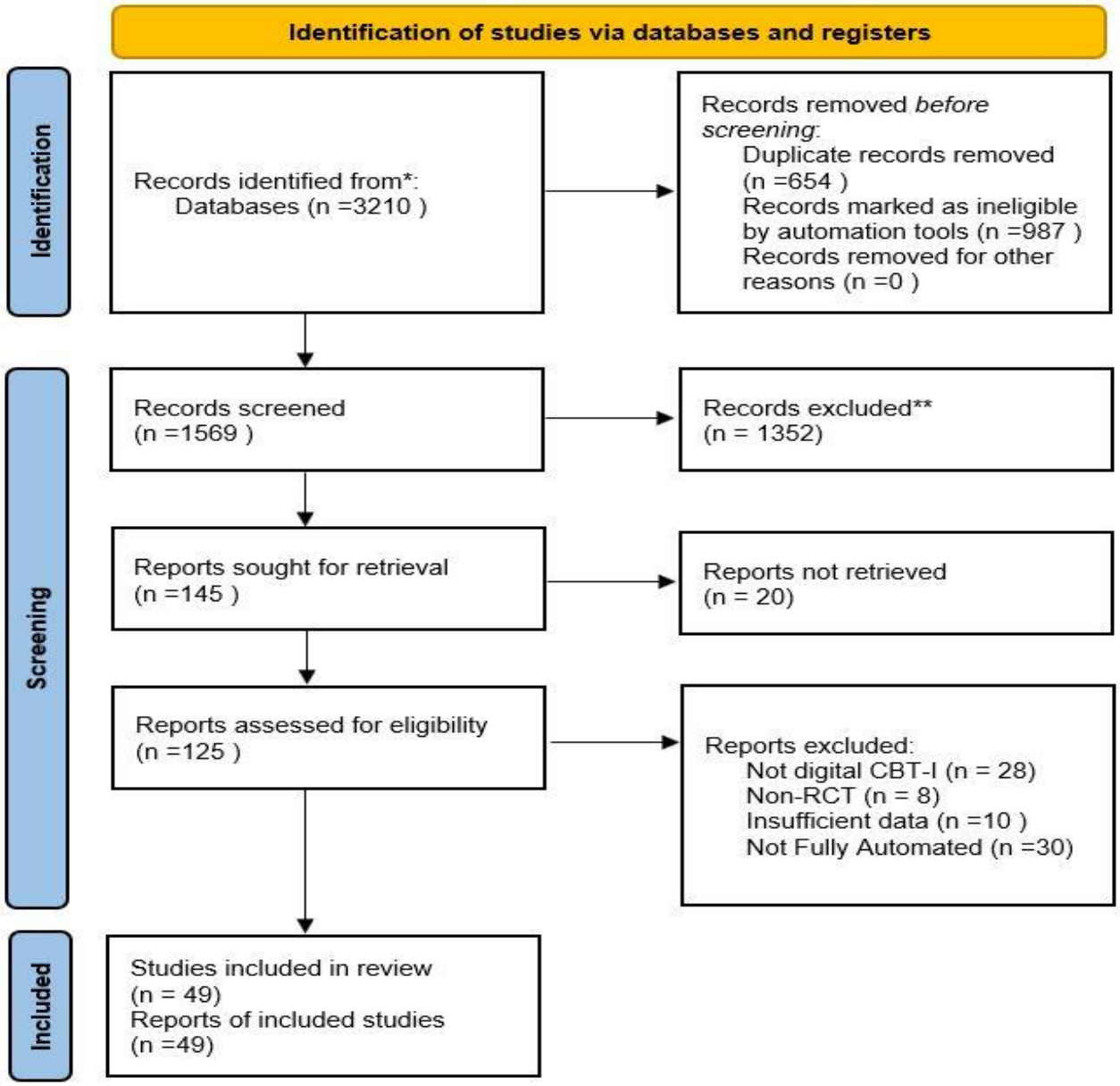

Figure 1. PRISMA 2020 Flow Diagram of Papers Included in the Review The Effectiveness of Fully Automated Digital Cognitive Behavioral Therapy for Insomnia

Table 1. Characteristics of the Included Trials on The Effectiveness of Fully Automated Digital Cognitive Behavioral Therapy for Insomnia

Author, Year (Country)	Gender (% Of Female)	Mean Age	Insomnia Definition	dCBT-I Components	Follow-Up Duration (Months)	Control Intervention	Degree of Therapist Support	Number of Sessions
Sweetman, 2024 (Australia) (24)	82	52.5	ISI 15	SR, SC, CR, PE, RP	6	Digital sleep education (five weekly sessions)	Fully automated (self-guided digital platform)	5
Shin, 2024 (South Korea) (25)	61	42.3	ISI 8	SR, SC, SHE, RT, CT	4	Sleep hygiene education (SHE) app	Fully automated (Somzz app with real-time feedback)	6
Hinterberger, 2024 (Austria) (26)	68	45.7	ISI 8, PSQI 6	SHE, CR, RE, SD, FB	1	Waitlist control	Fully automated (app with sleep feedback)	6
Maurer, 2024 (Germany) (27)	85.8	45.5	ISI 10	SR, SC, CT, RE, SDI, FB	4	Digital sleep monitoring app (Malio)	Fully automated (Somnio app for CBT-I)	8
Rötger, 2024 (Germany) (28)	74.2	41.8	ISI 10	SR, SC, CR, SHE, RE, PE	12	Waitlist control	Fully automated (somnio platform with minimal guidance)	8
Fleming, 2024 (UK) (29)	48.2	58.6	SCI-8 16	SHE, SR, SC, CR, RE	2	Sleep hygiene education (brochure)	Fully automated (Sleepio platform)	6
Chan, 2024 (Hong Kong) (30)	76	34	ISI 10	DCBT (chatbot, assistant, therapist)	1	Digital sleep hygiene and self-monitoring (dSH)	Various (None, Chatbot, Assistant, Therapist)	6
Wu, 2024 (China) (31)	81.3	21	PSQI 7	SR, SC, CR (WeChat applet)	1	Conventional sleep education with articles and diaries	self-administered via applet	5

Author, Year (Country)	Gender (% Of Female)	Mean Age	Insomnia Definition	dCBT-I Components	Follow-Up Duration (Months)	Control Intervention	Degree of Therapist Support	Number of Sessions
Batterham, 2024 (Australia) (32)	76	43	BIS, MMDII	SHUTi: six CBT-I cores	18	Health Watch - an attention-matched internet placebo program	None (fully automated digital CBT)	6
Starling, 2024 (USA) (33)	100	60.2	ISI > 7	Voice-CBT	3	Static educational website about CBT-I and sleep	fully automated	6
Hürlimann, 2023 (Switzerland) (34)	78	47.8	ISI 8	SHE, SC, CR, PE, SRE	3	Waitlist control	Fully automated (online course with self-analysis exercises)	6
Ramfjord, 2023 (Norway) (35)	71.5	44.5	ISI 12	SR, SC, CT, SHE, FB	2	Patient education (written text)	Fully automated (SHUTi platform)	9
Nazem, 2023 (USA) (36)	26	39.3	DSM-5	SHUTi: interactive program	12	Insomnia Education Website (IEW) - static information	self-administered	6
Zhang, 2023 (China) (37)	72.8	49.67	ISI > 14	SHE, CT, RE, SC (tailored app)	6	Sleep education using the same app interface	fully automated via smartphone app	6
Watanabe, 2023 (Japan) (38)	58	44.1	ICSD-3 criteria	SR, SC, CS, SHE (smartphone app)	2	Sham app missing CBT-I components	fully automated app	8
Ho, 2022 (Australia) (39)	67	52.7	ISI 13	SR, SC, CR, RE	3	General sleep education via weekly emails	Fully automated (Sleepio platform)	6
Li, 2022 (China) (40)	73.1	20.96	PSQI 5	SHE, SR, SC, RE, CR, GJ	1	Conventional education (sleep hygiene)	Fully automated (via WeChat app)	21

Author, Year (Country)	Gender (% Of Female)	Mean Age	Insomnia Definition	dCBT-I Components	Follow-Up Duration (Months)	Control Intervention	Degree of Therapist Support	Number of Sessions
Zhou, 2022 (USA) (41)	100	59.5	ISI 15	SR, SC, CT, RE, SHE (cultural)	6	Patient education (PE) about sleep	Fully automated (SHUTi platform with cultural tailoring)	6
Shimamoto, 2022 (Japan) (42)	32.7	40.6	ISI 8	SD, SHE, SC, SR, PPM	1	Waitlist control	Fully automated (SPA via smartphone app)	4
Spanhel, 2022 (Germany) (43)	50.3	26.3	ISI 8	SHE, CR (reduce rumination), PE	3	Waitlist control	Fully automated (unguided internet-based intervention)	3
Felder, 2022 (USA) (44)	100	33.6	ISI 11 or DSM-5 criteria	Sleepio: SHE, RE, SC, CT	4.5	Waitlist control	None (fully automated digital program)	6
Godzik, 2021 (USA) (45)	76.6	65.3	ISI > 10	SR, SC, CR, PE, RP	2	Psychoeducational modules on healthy living	Fully automated (SHUTi platform)	6
Cheng, 2021 (USA) (46)	84%	44.7	DSM-5 criteria	Virtual-CBT	12	Sleep education delivered via email	None (fully automated)	6
Kallestad, 2021 (Norway) (47)	75	41.3	DSM-5 criteria	SHUTi: SHE, BC, CS	8.2	Face-to-face (FtF) CBT-I provided by experienced therapists	None (fully automated)	6
Luik, 2020 (UK) (48)	77.6	48	SCI 16	SR, SC, CR, RE	12	Sleep Hygiene Education (SHE)	Fully automated (no direct therapist support)	6
Felder, 2020 (USA) (49)	100	33.5	ISI 11 or DSM-5 criteria	SR, SC, CT, RE, PE	4.5	Standard care with no study intervention restrictions	Fully automated (Sleepio platform)	6

Author, Year (Country)	Gender (% Of Female)	Mean Age	Insomnia Definition	dCBT-I Components	Follow-Up Duration (Months)	Control Intervention	Degree of Therapist Support	Number of Sessions
Behrendt, 2020 (Germany) (50)	65.5	46.5	ISI 10	SR, SC, CR, SHE, RE, WCA	6	Waitlist control	Fully automated (self-help web-based platform)	6
Rajabi Majd, 2020 (Iran)(51)	55.8	35.7	ISI 10	CBT-I, TPB, HAPA, CT, SM	6	Patient Education (PE) through app	Fully automated (App-based interventio n)	6
Kalmbach, 2020 (USA) (52)	100	29	ISI 10	SR, SC, CR, SHE (Sleepio)	2-3	Digital sleep education based on NIH guide to healthy sleep	fully automated digital CBT	6
Vedaa, 2020 (Norway) (53)	68	44.5	ISI 12	SHUTi: behavioral, cognitive, educational	2	Online patient education program about sleep	fully automated digital CBT	6
Shaffer, 2020 (USA) (54)	72	43.2	ISI 8	SHUTi: dCBT-I	6	Internet-based patient education (PE) program	fully automated	6
Kyle, 2020 (UK) (55)	86.6	52.5	DSM-5 criteria, ISI 15	Sleepio: SR, SC, CR, RE, PE	6	Waitlist control	fully automated	6
Denis, 2019 (UK) (56)	100	20	SCI 16	SR, SC, CR, MF	6	Puzzles control group (6 weeks, time-matched)	Fully automated (no direct therapist support)	6
Espie, 2019 (UK) (57)	77.7	48	Sleep Condition Indicator (SCI) 16	SR, SC, CT, SHE, RP	3	Sleep hygiene education (SHE)	Fully automated (Sleepio platform)	6

Author, Year (Country)	Gender (% Of Female)	Mean Age	Insomnia Definition	dCBT-I Components	Follow-Up Duration (Months)	Control Intervention	Degree of Therapist Support	Number of Sessions
Short, 2019 (USA) (58)	84	19.4	ISI 8	FAST (anxiety, insomnia aids)	1	Physical Health Education Treatment (PHET) - active control	self-guided computerized intervention	1
Cheng, 2018 (USA) (59)	79	45.1	DSM-5 criteria and ISI 8	Behavioral-CBT (Sleepio)	3	Online sleep education	fully automated	6
Glozier, 2018 (Australia) (60)	0	58.4	DSM-IV criteria and ISI 8	Behavioral-CBT (SHUTi)	3	Online psychoeducation program for insomnia	fully automated	6
Lorenz, 2018 (Switzerland) (61)	68.5	42.8	DSM-5 criteria and ISI 8	SR, SC, CR, RE, PE (mementor)	12	Waitlist control	fully automated	6
Zachariae, 2018 (Denmark) (62)	100	53.1	PSQI > 5 and DSM-5 criteria	SHUTi: SR, SC, CR, RP	3.7	Waitlist control	fully automated	6
Hagatun, 2017 (Norway) (63)	67	44.9	ISI 10, DSM-IV	SR, SC, CR, SHE, RP	6	Online patient education	Fully automated (self-guided SHUTi platform)	6
Ritterband, 2017 (USA) (64)	71.9	43.2	Chronic insomnia lasting > 6 months; ISI assessed	SHUTi: tailored program	12	Online patient education (PE) program	fully automated	6
Freeman, 2017 (UK) (65)	71.5	24.7	SCI 16 and DSM-5 criteria	Sleepio: tailored sessions	5.5	Waitlist control	fully automated	6
Bernstein, 2017 (USA) (66)	88.2	55.4	DSM-IV criteria	SR, SC, SM (Go! To Sleep)	4.2	Waitlist control	fully automated web-based program	6

Author, Year (Country)	Gender (% Of Female)	Mean Age	Insomnia Definition	dCBT-I Components	Follow-Up Duration (Months)	Control Intervention	Degree of Therapist Support	Number of Sessions
Taylor, 2017 (USA) (67)	17	32.7	DSM-IV criteria	SR, SC, RE, CR, SHE (internet)	1	Minimal contact control group (brief biweekly phone check-ins)	unguided	6
Batterham, 2017 (Australia) (68)	74	43	DSM-5 criteria, ISI 15, PHQ-9 > 4 and	SHUTi: SR, SC, RE, CT, RP	6	HealthWatch - an interactive online health education program (placebo control)	fully automated	6
Ebert, 2015 (Germany) (69)	74.2	48.5	ISI 15	GET.ON: SHE, SC, MT, RA	6	Waitlist control	fully automated	6
Holmqvist, 2014 (Canada) (70)	80.6	Not reported	Self-reported chronic insomnia	Manual CBT-I (telehealth/web)	1.5	Comparison between two active interventions (web-based vs telehealth-based)	Telehealth: group-based with direct therapist interaction; Web-based: none (self-guided)	6
Lancee, 2012 (Netherlands) (71)	65	50.6	DSM-IV criteria	Self-help CBT: internet or mail	6.5	Waitlist control	unsupported self-help	6
Ritterband, 2009 (USA) (72)	77	44.8	DSM-IV criteria	SHUTi: SR, SC, CR, SHE, RP	3	Waitlist control	fully automated	6

SR: Sleep Restriction, SC: Stimulus Control, CR: Cognitive Restructuring, PE: Psychoeducation, RP: Relapse Prevention, SHE: Sleep Hygiene Education, RT: Relaxation Therapy, CT: Cognitive Therapy, RE: Relaxation Exercises, SD: Sleep Diaries, FB: Feedback, SDI: Sleep Diary Integration, GJ: Gratitude Journal, BC: Behavioral Changes, CS: Cognitive Strategies, WCA: Work-related Cognitive Activity Reduction, TPB: Theory of Planned Behavior, HAPA: Health Action Process Approach, SM: Self-monitoring, MT: Metacognitive Techniques, RA: Recovery Activities, BIS: Bergen Insomnia Scale, and MMDII: Morina's modified diagnostic insomnia interview.

Table 2 shows the risk-of-bias assessment for randomized trials using the RoB 2. Studies were evaluated across five domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result. The color-coded ranking system highlights green for low risk of bias, yellow for some concerns, and red for high risk of bias. Most studies demonstrated a low risk of bias across all domains, particularly in randomization, measurement, and selection processes. However, several studies presented "some concerns" in the domain of missing outcome data, as indicated in yellow. Overall, the majority of studies were rated as having a "Good" risk-of-bias profile, while a smaller proportion were classified as "Fair." No studies were found to have a "High" overall risk of bias, reinforcing the methodological rigor of the included trials.

Table 2. Cochrane Risk-of-Bias Tool for Randomized Trials Version 2 (RoB 2)

Author	Bias Arising from the Randomization Process	Bias Due to Deviations from Intended Interventions	Bias Due to Missing Outcome Data	Bias in Measurement of the Outcome	Bias in Selection of the Reported Result	Overall Risk Of Bias
Sweetman, 2024 (Australia) (24)	Low	Low	Some Concerns	Low	Low	Fair
Shin, 2024 (South Korea) (25)	Low	Low	Some Concerns	Low	Low	Fair
Hinterberger, 2024 (Austria) (26)	Low	Low	Some Concerns	Low	Low	Fair
Maurer, 2024 (Germany) (27)	Low	Low	Some Concerns	Low	Low	Fair
Rötger, 2024 (Germany) (28)	Low	Low	Some Concerns	Low	Low	Fair
Fleming, 2024 (UK) (29)	Low	Low	Some Concerns	Low	Low	Fair
Chan, 2024 (Hong Kong) (30)	Low	Low	Low	Low	Low	Good
Wu, 2024 (China) (31)	Low	Low	Low	Low	Low	Good
Batterham, 2024 (Australia) (32)	Low	Low	Low	Low	Low	Good
Starling, 2024 (USA) (33)	Low	Low	Low	Low	Low	Good
Hürlimann, 2023 (Switzerland) (34)	Low	Low	Some Concerns	Low	Low	Fair
Ramfjord, 2023 (Norway) (35)	Low	Low	Some Concerns	Low	Low	Fair
Nazem, 2023 (USA) (36)	Low	Low	Low	Low	Low	Good
Zhang, 2023 (China) (37)	Low	Low	Low	Low	Low	Good
Watanabe, 2023 (Japan) (38)	Low	Low	Low	Low	Low	Good
Ho, 2022 (Australia) (39)	Low	Low	Some Concerns	Low	Low	Fair
Li, 2022 (China) (40)	Low	Low	Some Concerns	Low	Low	Fair
Zhou, 2022 (USA) (41)	Low	Low	Some Concerns	Low	Low	Fair
Shimamoto, 2022 (Japan) (42)	Low	Low	Some Concerns	Low	Low	Fair
Spanhel, 2022 (Germany) (43)	Low	Low	Some Concerns	Low	Low	Fair

Author	Bias Arising from the Randomization Process	Bias Due to Deviations from Intended Interventions	Bias Due to Missing Outcome Data	Bias in Measurement of the Outcome	Bias in Selection of the Reported Result	Overall Risk Of Bias
Felder, 2022 (USA) (44)	Low	Low	Low	Low	Low	Good
Godzik, 2021(USA) (45)	Low	Low	Some Concerns	Low	Low	Fair
Cheng, 2021 (USA) (46)	Low	Low	Low	Low	Low	Good
Kallestad, 2021 (Norway) (47)	Low	Low	Low	Low	Low	Good
Luik, 2020 (UK) (48)	Low	Low	Some Concerns	Low	Low	Fair
Felder, 2020 (USA) (49)	Low	Low	Some Concerns	Low	Low	Fair
Behrendt, 2020 (Germany) (50)	Low	Low	Some Concerns	Low	Low	Fair
Rajabi Majd, 2020 (Iran) (51)	Low	Low	Some Concerns	Low	Low	Fair
Kalmbach, 2020 (USA) (52)	Low	Low	Low	Low	Low	Good
Vedaa, 2020 (Norway) (53)	Low	Low	Low	Low	Low	Good
Shaffer, 2020 (USA) (54)	Low	Low	Low	Low	Low	Good
Kyle, 2020 (UK) (55)	Low	Low	Low	Low	Low	Good
Denis, 2019 (UK) (56)	Low	Low	Some Concerns	Low	Low	Fair
Espie, 2019 (UK) (57)	Low	Low	Some Concerns	Low	Low	Fair
Short, 2019 (USA) (58)	Low	Low	Low	Low	Low	Good
Cheng, 2018 (USA) (59)	Low	Low	Low	Low	Low	Good
Glozier, 2018 (Australia) (60)	Low	Low	Low	Low	Low	Good
Lorenz, 2018 (Switzerland) (61)	Low	Low	Low	Low	Low	Good
Zachariae, 2018 (Denmark) (62)	Low	Low	Low	Low	Low	Good
Hagatun, 2017 (Norway) (63)	Low	Low	Some Concerns	Low	Low	Fair

Author	Bias Arising from the Randomization Process	Bias Due to Deviations from Intended Interventions	Bias Due to Missing Outcome Data	Bias in Measurement of the Outcome	Bias in Selection of the Reported Result	Overall Risk Of Bias
Ritterband, 2017 (USA) (64)	Low	Low	Low	Low	Low	Good
Freeman, 2017 (UK) (65)	Low	Low	Low	Low	Low	Good
Bernstein, 2017 (USA) (66)	Low	Low	Low	Low	Low	Good
Taylor, 2017 (USA) (67)	Low	Low	Low	Low	Low	Good
Batterham, 2017 (Australia) (68)	Low	Low	Low	Low	Low	Good
Ebert, 2015 (Germany) (69)	Low	Low	Low	Low	Low	Good
Holmqvist, 2014 (Canada) (70)	Low	Low	Low	Low	Low	Good
Lancee, 2012 (Netherlands) (71)	Low	Low	Low	Low	Low	Good
Ritterband, 2009 (USA) (72)	Low	Low	Low	Low	Low	Good

In This Color-Coded Ranking, Green Color Represents Low Risk of Bias, Yellow Some Concerns, and Red High Risk of Bias

Overall Meta-Analysis Findings

The random-effects model analysis revealed a significant reduction in insomnia severity with dCBT-I interventions. The weighted mean difference (WMD) in insomnia severity was -3.42 (95% CI: -4.35 to -2.48; $P < 0.001$). Despite significant heterogeneity ($I^2 = 98.1\%$), results consistently favored dCBT-I (Figure 2).

Subgroup Analysis Findings

Subgroup analyses identified variability in the effectiveness of fully automated dCBT-I across different study characteristics (Table 3). The studies exhibited significant heterogeneity ($I^2 = 98.1\%$, $P < 0.001$). To explore the sources of this heterogeneity, we conducted a subgroup analysis, which found no significant differences between the subgroups. Studies published in or after 2020 (32 trials) demonstrated a WMD of -3.23 (95% CI: -4.31 to -2.14; $P < 0.001$; $I^2 = 97.7\%$), while those published before 2020 (19 trials) reported a slightly larger effect with a WMD of -3.97 (95% CI: -5.84 to -2.09; $P < 0.001$; $I^2 = 98.5\%$). USA-based studies (16 trials) indicated a more pronounced effect (WMD = -4.02; 95% CI: -5.15 to -2.89; $P < 0.001$; $I^2 = 88.4\%$) compared to studies conducted in other countries (35 trials, WMD = -3.28; 95% CI: -4.43 to -2.13; $P < 0.001$; $I^2 = 98.6\%$). Studies using an ISI threshold of ≤ 10 (19 trials) reported a greater reduction in insomnia severity (WMD = -4.25; 95% CI: -5.01 to -3.48; $P < 0.001$; $I^2 = 77.0\%$) compared to those using ISI > 10 or other indices (32 trials, WMD = -3.11; 95% CI: -4.42 to -1.80; $P < 0.001$; $I^2 = 98.5\%$). Studies with a good overall risk of bias rating (30 trials) demonstrated a larger effect (WMD = -3.79; 95% CI: -4.81 to -2.77; $P < 0.001$; $I^2 = 96.0\%$) compared to those with a fair or high risk of bias (21 trials, WMD = -3.07; 95% CI: -4.73 to -1.41; $P < 0.001$; $I^2 = 98.8\%$).

Follow-up duration and participant age were additional factors considered. Trials with follow-up periods of six months or less (28 trials) showed a smaller effect size (WMD = –0.40; 95% CI: –0.64 to –0.15; $P = 0.001$; $I^2 = 97.1\%$) compared to those with longer follow-up periods (> 6 months; 20 trials), which reported a WMD of –1.00 (95% CI: –1.31 to –0.69; $P < 0.001$; $I^2 = 97.4\%$). Finally, studies with a mean participant age of 40 years or younger (13 trials) demonstrated a WMD of –0.47 (95% CI: –0.63 to –0.30; $P < 0.001$; $I^2 = 77.7\%$), whereas those with older participants (34 trials) reported a stronger effect

(WMD = –0.77; 95% CI: –1.03 to –0.52; P < 0.001; I^2 = 97.9%).

Overall, while significant improvements were consistently observed across all subgroups, high levels of heterogeneity remained, and no clear moderators of treatment effect were identified.

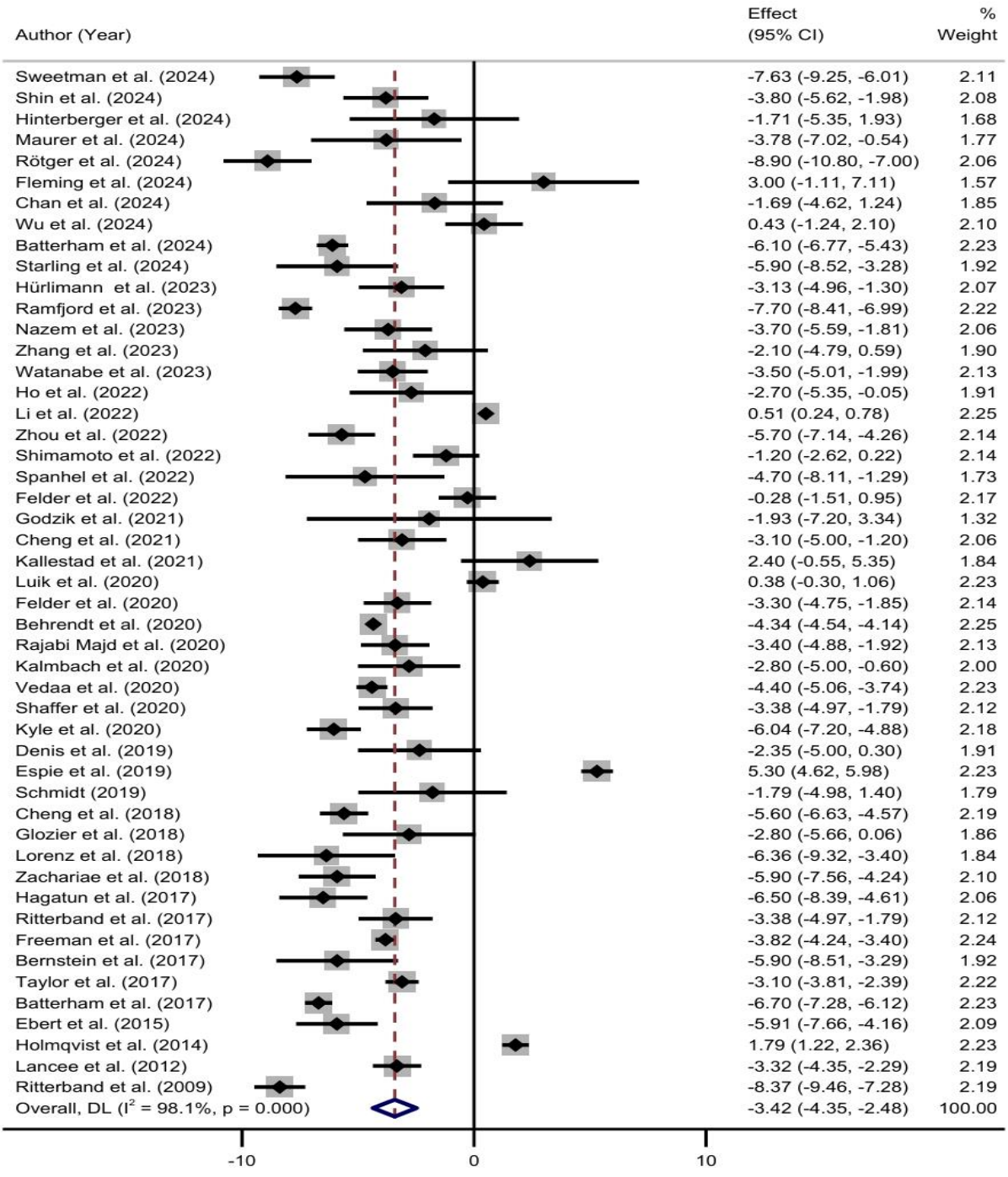

Figure 2. Forest Plot The Effectiveness of Fully Automated Digital Cognitive Behavioral Therapy for Insomnia, Expressed as the Mean Differences between the Intervention and the Control Groups.

The area of each square is proportional to the inverse of the variance of the SMD. Horizontal lines represent 95% CIs. Diamonds represent pooled estimates from random-effects analysis

Table 3. Subgroup Analysis of Included Randomized Controlled Trials in Meta-Analysis of the Effectiveness of Fully Automated Digital Cognitive Behavioral Therapy for Insomnia

Group	No. of Trials	WMD (95% CI)	P-Value	I^2 (%)	P-Heterogeneity
Year					
Year ≥ 2020	32	-3.23(-4.31, -2.14)	< 0.001	97.7	< 0.001
Year < 2020	17	-3.78(-5.80, -1.77)	< 0.001	98.5	< 0.001
Country					
USA	15	-3.97(-5.18, -2.77)	< 0.001	89.1	< 0.001
Other	34	-3.18(-4.35, -2.02)	< 0.001	98.6	< 0.001
Insomnia Definition					
ISI ≤ 10	18	-4.09(-4.88, -3.31)	< 0.001	75.9	< 0.001
ISI ≥ 10 or other index	31	-3.06(-4.40, -1.73)	< 0.001	95.6	< 0.001
Intervention Group Number					
≤ 100	29	-3.23(-4.47, -1.98)	< 0.001	97.9	< 0.001
> 100	20	-3.66(-5.24, -2.07)	< 0.001	98.4	< 0.001
Risk of Bias Overall					
Fair/High	21	-3.07(-4.73, -1.41)	< 0.001	98.8	< 0.001
Good	28	-3.66(-4.74, -2.59)	< 0.001	96.2	< 0.001
Control Intervention					
Waitlist Control	15	-4.63(-5.51, -3.75)	< 0.001	91.6	< 0.001
Other	34	-2.84(-4.17, -1.52)	< 0.001	98.2	< 0.001
Follow-Up Duration					
≤ 6 months	28	-0.40(-0.64, -0.15)	0.001	97.1	< 0.001
> 6 months	20	-1.00(-1.31, -0.69)	< 0.001	97.4	< 0.001
Mean Age					
≤ 40	13	-0.47(-0.63, -0.30)	< 0.001	77.7	< 0.001
> 40	34	-0.77(-1.03, -0.52)	< 0.001	97.9	< 0.001

Sensitivity Analysis

Sensitivity analysis, excluding individual studies, confirmed the robustness of the findings. The pooled WMD ranged from -3.394 to -3.707, consistently excluding null effects, demonstrated that no single study disproportionately influenced the results.

Publication Bias

A funnel plot assessing publication bias showed slight asymmetry, indicating potential small-study effects. However, consistent findings across sensitivity analyses suggest minimal impact on overall conclusions (Figure 3). Egger's test was also performed, which yielded a bias coefficient of -0.856 (P = 0.569), indicating that there was no systematic tendency for studies with positive or negative results to be more or less likely to be published.

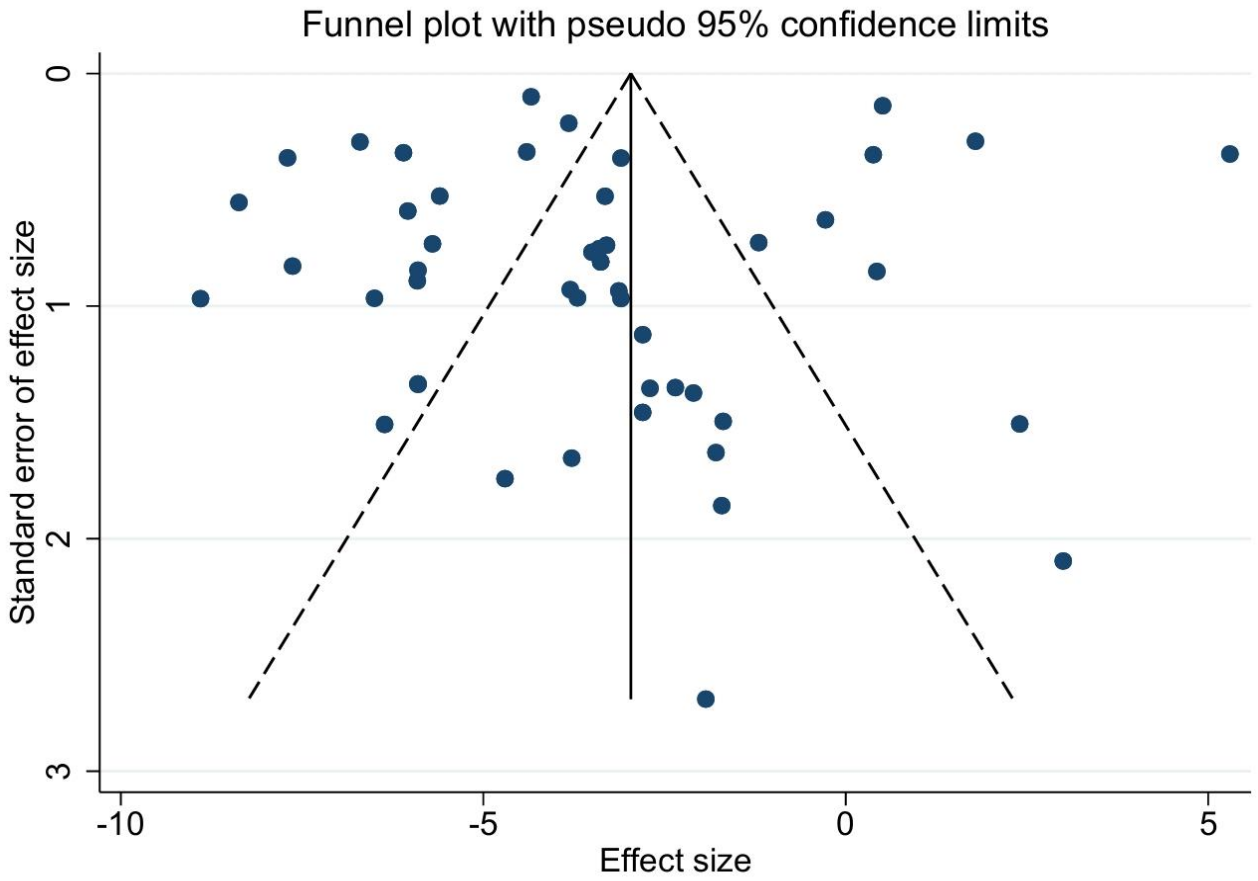

Figure 3. Funnel Plot for Assessing Publication Bias in Meta-Analysis of Fully Automated Digital Cognitive Behavioral Therapy for Insomnia

Meta-Regression Analysis

To investigate potential sources of heterogeneity across studies, two separate meta-regression analyses were conducted using the REML estimation method with the Knapp-Hartung adjustment for standard errors (Figure 4). In the first model, we examined whether the mean age of participants (Mean Age) moderated the effect size. The analysis revealed a negative association, indicating that the effect size tended to decrease as participant age increased (coefficient = –0.015, 95% CI: –0.043 to 0.012). However, this relationship was not statistically significant (P = 0.267). The model explained 81% of the between-study variance (Adjusted R^2 = 0.81), though substantial residual heterogeneity remained (τ^2 = 0.91; $I^2_{(residual)}$ = 97.28%).

In the second model, we assessed the influence of Follow-Up Duration on the effect size. Similarly, a negative but non-significant association was observed, with longer follow-up periods associated with slightly lower effect sizes (coefficient = –0.047, 95% CI: –0.127 to 0.032; P = 0.239). Notably, this model accounted for nearly all between-study variance (Adjusted R^2 = 1.00), although residual heterogeneity persisted (τ^2 = 0.99; $I^2_{(residual)}$ = 97.30%).

In summary, while both mean age and follow-up duration showed a trend toward decreasing effect sizes, neither variable significantly moderated the observed effects across studies.

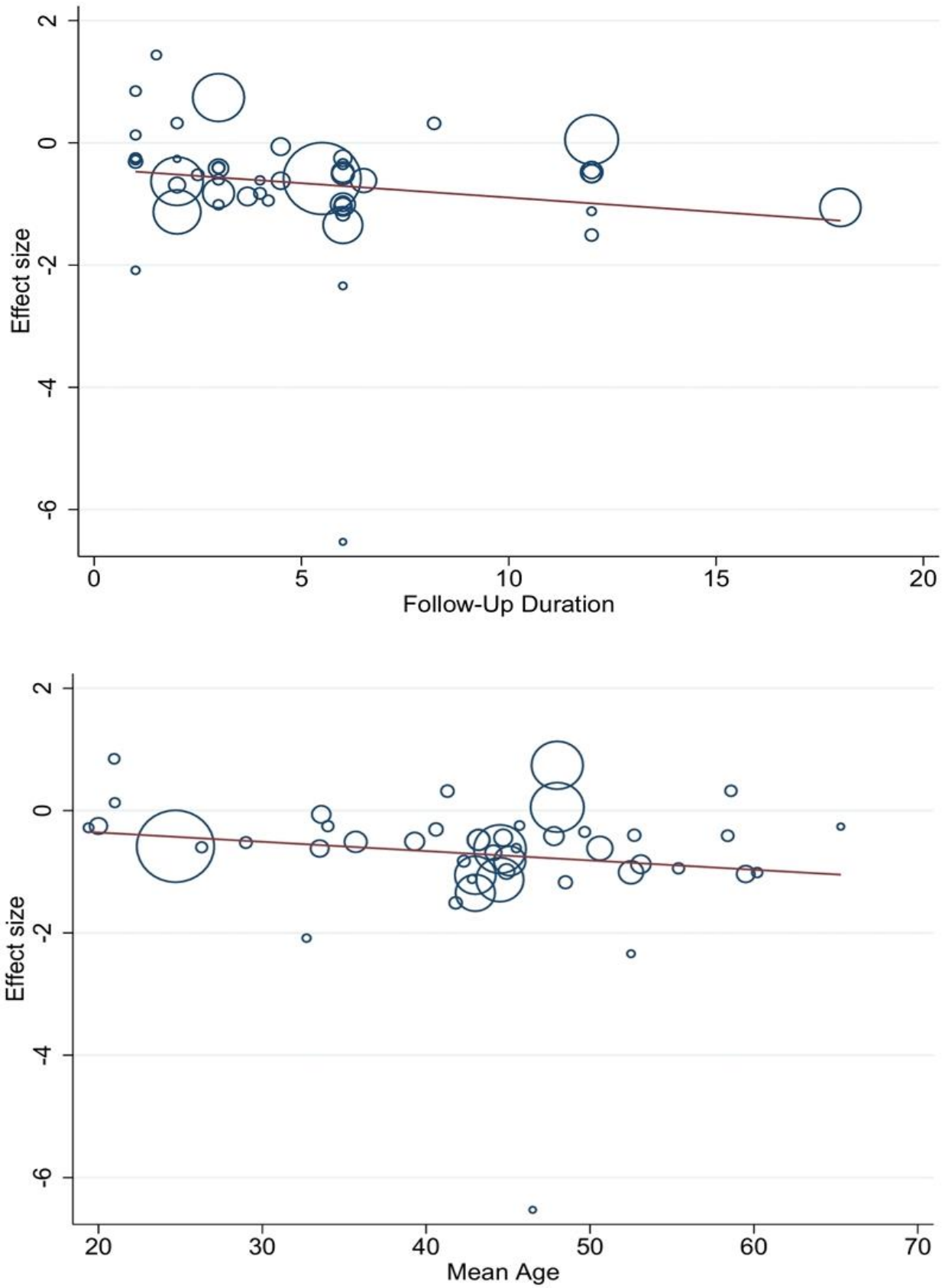

Figure 4. Meta-Regression Plots Showing the Relationship between Effect Size, Mean Age, and Follow-up Duration

Discussion

The results of this meta-analysis suggest that fully automated dCBT-I is an effective clinical method for reducing insomnia symptoms. The overall WMD of –3.42 on the ISI indicates a notable and significant improvement in sleep quality.

These results are in agreement with earlier research that has shown the effectiveness of digital-based interventions for treating insomnia. For instance, several past meta-analyses and clinical trials have identified notable improvements in sleep outcomes following the use of dCBT-I approaches, particularly when structured formats were applied (73-75). The present findings contribute further to this evidence by concentrating specifically on entirely automated dCBT-I programs, which are delivered without the involvement of a human therapist, and nonetheless achieve significant therapeutic outcomes.

Comparison with Previous Studies

Although earlier research has explored different types of digital interventions, a large number of those studies included formats that were blended or involved therapist assistance. Our review underscores that fully automated dCBT-I is capable of producing effective results on its own, which is especially important for improving access to care in populations with limited resources. Importantly, research conducted in the United States and using more rigorous inclusion standards (such as ISI ≥ 10) demonstrated more pronounced outcomes, supporting previous evidence that stresses the importance of precise diagnostic criteria for accurate results (15, 73, 76).

Subgroup analyses further suggest that newer studies (post-2020) showed slightly smaller effect sizes than earlier ones. This may reflect increased methodological rigor or changes in participant characteristics over time (14, 71, 77). In alignment with former meta-analyses, our results also revealed that trials using waitlist controls showed larger effect sizes than those employing active comparators, which may be due to the therapeutic influence present in active control conditions (78).

Clinical Implications

The results of our study indicate that fully automated dCBT-I represents a practical and scalable approach to addressing the increasing worldwide challenge of insomnia. In contrast to conventional CBT-I, which depends on the availability of trained professionals, digital programs can lower expenses, extend accessibility, and support implementation in geographically isolated or low-resource environments (12). This becomes particularly significant considering the rise in sleep-related problems observed during and following the COVID-19 pandemic.

Notably, interventions that applied validated tools for insomnia assessment, such as the ISI, and followed standardized diagnostic guidelines were associated with stronger treatment effects, highlighting the importance of uniform evaluation methods in clinical research (1).

Heterogeneity and Variability

Although the overall outcomes were favorable, we detected considerable heterogeneity ($I^2 > 98\%$), which could be attributed to differences in the specifics of the interventions, their length, the demographics of participants, and the measurement tools used for outcomes (79, 80). As an illustration, some programs incorporated additional elements like relaxation exercises or education on sleep hygiene, which may have had an effect on the results (76).

Variations in initial insomnia severity, participant age, co-occurring psychological disorders, and levels of comfort with digital technology among study groups likely played a role in this observed inconsistency as well (81, 82). These results emphasize the importance of future research adopting standardized intervention structures and analyzing outcomes based on participant subgroups.

Limitation

There are several limitations to keep in mind when interpreting these findings. First, although self-reported measures are practical, they may introduce subjective bias (83). Although validated tools such as the ISI were widely used, objective measures like actigraphy or polysomnography were less frequently reported, limiting the ability to comprehensively assess sleep architecture. Second, the potential for publication bias, as suggested by slight asymmetry in the funnel plot, may have led to an overestimation of intervention effects, despite sensitivity analyses confirming robustness (15).

Third, most studies were conducted in high-income countries, which raises concerns about the applicability of these results to low- and middle-income regions where differences in culture, language, and technology might affect how interventions work (71). Finally, excluding studies not published in English might have unintentionally left out important data from other areas, further limiting the generalizability (84).

Future Directions

This meta-analysis identifies key priorities for future investigations. Firstly, research should examine the long-term maintenance of reductions in insomnia severity, since most of the analyzed trials had relatively brief follow-up periods (18). Secondly, assessing the cost-effectiveness of fully automated dCBT-I is essential to guide its incorporation into healthcare frameworks (77). Thirdly, studies need to focus on tailoring these interventions to different cultural and language settings to enhance their wider applicability (85).

Moreover, new technologies like artificial intelligence and machine learning hold promise for further personalizing dCBT-I, potentially improving both its effectiveness and user engagement. Lastly, upcoming trials should incorporate objective measures of sleep and explore how these interventions may impact related conditions such as anxiety and depression, which frequently accompany insomnia (76).

Conclusion

In summary, this meta-analysis offers strong evidence supporting the effectiveness of fully automated dCBT-I in reducing insomnia severity. These interventions demonstrate clinically significant improvements consistent with prior studies, emphasizing the promise of digital approaches to effectively manage insomnia, particularly in settings with limited resources. By overcoming traditional challenges such as scarce therapist availability, high costs, and geographic barriers, fully automated dCBT-I provides a scalable and accessible treatment option. This expands access to evidence-based insomnia care for underserved populations and diverse communities, enabling more people to benefit from these therapies. However, it is important to address the noted limitations. The heavy reliance on self-reported data, potential publication bias, and the predominance of research from high-income countries highlight areas that require careful attention. Future studies should include objective sleep assessments, investigate the durability of treatment effects over time, and assess the cost-effectiveness of dCBT-I. Moreover, tailoring interventions to various cultural and linguistic contexts will be vital to enhance their acceptance and applicability. The adoption of emerging technologies such as artificial intelligence and machine learning offers further opportunities to personalize dCBT-I, improving both effectiveness and user engagement. Overall, this meta-analysis highlights the transformative potential of fully automated dCBT-I to advance global insomnia management and promote equitable access to quality sleep treatments.

Conflict of Interest

None.

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