Sleep Medicine 132 (2025) 106551

Contents lists available at ScienceDirect

Sleep Medicine

journal homepage: www.elsevier.com/locate/sleep

Stepped care for insomnia in primary care using digital and face-to-face cognitive behavioral therapies: A pragmatic nonrandomized clinical trial

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ARTICLE INFO

Keywords:
Cognitive behavioral therapy for insomnia
Digital
In-person
Stepped-care model
Insomnia
Primary care

ABSTRACT

Objective: To evaluate the effectiveness of a stepped-care intervention for insomnia in primary care.
Methods: In this non-randomized pragmatic clinical trial, patients from primary care clinics and with chronic insomnia disorder were allowed to choose between continuing their usual treatment (prescribed sleep medication) or receiving digital CBT-I (dCBT-I), either alone or in combination with medication. After the first treatment step, non-remitters were provided with the choice of receiving face-to-face CBT-I (FtFCBT-I), medication, or no additional treatment. The primary outcome was insomnia symptoms as measured by the Insomnia Severity Index.
Results: Among 154 adults with insomnia, 73 were allocated to dCBT-I, 66 to combined treatment and 15 to medication alone based on their preference. When compared to medication alone, first-step treatment with dCBT-I or combined treatment both produced significantly larger effects on reducing insomnia severity (dCBT-I vs Med, difference in the mean changes = −3.3; Comb vs Med, −3.7), and led to higher percentages of responders (dCBT-I vs Med, 54.8 % vs 16.0 %, OR = 6.38; Comb vs Med, 53.6 % vs 16.0 %, OR = 6.07) and remitters (dCBT-I vs Med, 65.8 % vs 9.4 %, OR = 18.61; Comb vs Med, 67.5 % vs 9.4 %, OR = 20.13). Adding FtFCBT-I as second-step treatment offered an added value for non-remitters after the first-step treatment. Improvements achieved at post-treatment were sustained through the 6-month follow-up for most of the treatment sequences.
Conclusions: These findings demonstrated the feasibility and efficiency of implementing digital and in-person CBT-I within a stepped-care model in primary care practice.
Trial registration: ClinicalTrials.gov Identifier: NCT03633305.

1. Introduction

Insomnia is a major public health problem affecting broad segments of the general population [1]. Approximately 10 %–20 % of patients attending primary care report insomnia symptoms with functional impairments, reduced quality of life and productivity, leading to increased healthcare utilization and costs [2,3]. Despite the high prevalence, adverse impact, and economic burden of insomnia [4], it remains an undertreated and sub-optimally managed condition [5]. Although cognitive behavioral therapy for insomnia (CBT-I) is recognized as the first-line treatment for chronic insomnia [6–8], current treatments offered in primary care are often not aligned with guideline recommendations, with pharmacotherapy and general sleep hygiene education recommendations remaining the primary therapeutic modalities [9]. The underutilization of CBT-I can be attributed to the shortage of therapists with CBT-I expertise, as well as limited time and lack of

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https://doi.org/10.1016/j.sleep.2025.106551
Received 7 February 2025; Received in revised form 8 April 2025; Accepted 1 May 2025
Available online 3 May 2025
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awareness of this treatment option among primary care clinicians [10], which underlines the need to promote broader use of CBT-I in clinical practice.

Digital therapeutics may be a promising alternative to face-to-face CBT-I (FtFCBT-I) which could increase access to treatment. Previous studies have documented the efficacy of digital CBT-I (dCBT-I) for improving sleep symptoms [11,12]. However, a recent real-world study revealed that while most insomnia patients experience a meaningful response to dCBT-I intervention, 60 % do not achieve full remission [13]. For patients who fail to achieve remission after digital CBT-I, stepping them up to in-person treatment could enhance outcome [14]. Therefore, it is important to evaluate the feasibility of offering dCBT-I and FtFCBT-I within a stepped-care approach in primary care settings.

In stepped care, the entry-level generally involves a low-intensity intervention (e.g., dCBT-I), followed by a more intensive and specialized treatment (e.g., FtFCBT-I) for non-remitters [15]. Although a stepped-care model of insomnia was proposed more than a decade ago [16], very few studies have been conducted to test its feasibility and efficacy. One previous study conducted in cancer patients with insomnia found that stepped-care CBT-I produced sleep improvements that were not inferior to a standard in-person intervention [17], highlighting the potential value of this approach.

The present study evaluated the effectiveness of a stepped-care intervention for insomnia in primary care. Research questions were (1) whether dCBT-I is an effective treatment delivery modality for patients with chronic insomnia in primary care, and (2) whether there is an added value for stepping-up non-remitters to FtFCBT-I.

2. Methods

2.1. Study design

This was a pragmatic nonrandomized clinical trial with two treatment steps and two delivery modalities of CBT-I for insomnia (i.e., digital and face-to-face) for each step (Fig. 1). Participants were enrolled from three primary care clinics in the Quebec City metropolitan area between March 2018 and March 2023.

By using a shared decision-making tool [18], eligible participants were allowed to choose between continuing their treatment as usual (prescribed sleep medication) without additional intervention or receiving digital CBT-I (Sleep Healthy Using the Internet, SHUTi), either alone or in combination with their usual treatment, as the first treatment step. Thus, there were three treatment arms at the first treatment step: 1) dCBT-I alone, 2) combined treatment of digital CBT-I plus medication (Comb), and 3) medication alone (Med).

After the first-stage therapy, patients who achieved remission (ISI score <8) were followed up for the next 6 months. Non-remitters after the first treatment step were provided with the choice of receiving an additional 6-week course of FtFCBT-I, medication, or no additional treatment, leading to six potential treatment sequences (Fig. 1). For participants who chose not to receive additional treatment following first-stage therapy, no treatment visits were scheduled during the six weeks of second treatment step, while they were asked to complete all the scheduled assessments. Measurements were conducted at baseline, end of first treatment step (post1), end of second treatment step (post2), and at 6-month follow-up. Ethical approval for the study was granted by the local ethics committees and all participants provided written informed consent.

2.2. Participants

Adult patients (18 years or older) registered at the three participating primary care clinics were recruited through the referral of their physicians. A total of 154 participants who met DSM-5 criteria for chronic insomnia disorder were enrolled in the study. Exclusion criteria were (1) an unstable or untreated psychiatric or medical disorder (e.g., major depression), (2) a lifetime diagnosis of any psychotic or bipolar disorder, (3) an imminent risk for suicide, (4) Mini-Mental State Examination (MMSE) score <24 [19], (5) an untreated sleep disorder other than insomnia, (6) current use of medications known to cause insomnia (e.g., corticosteroids), (7) shift work or habitual bedtime later than 2:00 a.m. or rising time later than 10:00 a.m., and (8) women being pregnant or expecting to become pregnant during treatment (see Fig. 1 for number of patients assessed for eligibility and reasons for exclusion).

2.3. Outcome measures

The primary outcome was insomnia symptoms severity as measured by the *Insomnia Severity Index* (ISI) [20]. Treatment response was defined at each assessment as a reduction of 8 points or more on the ISI

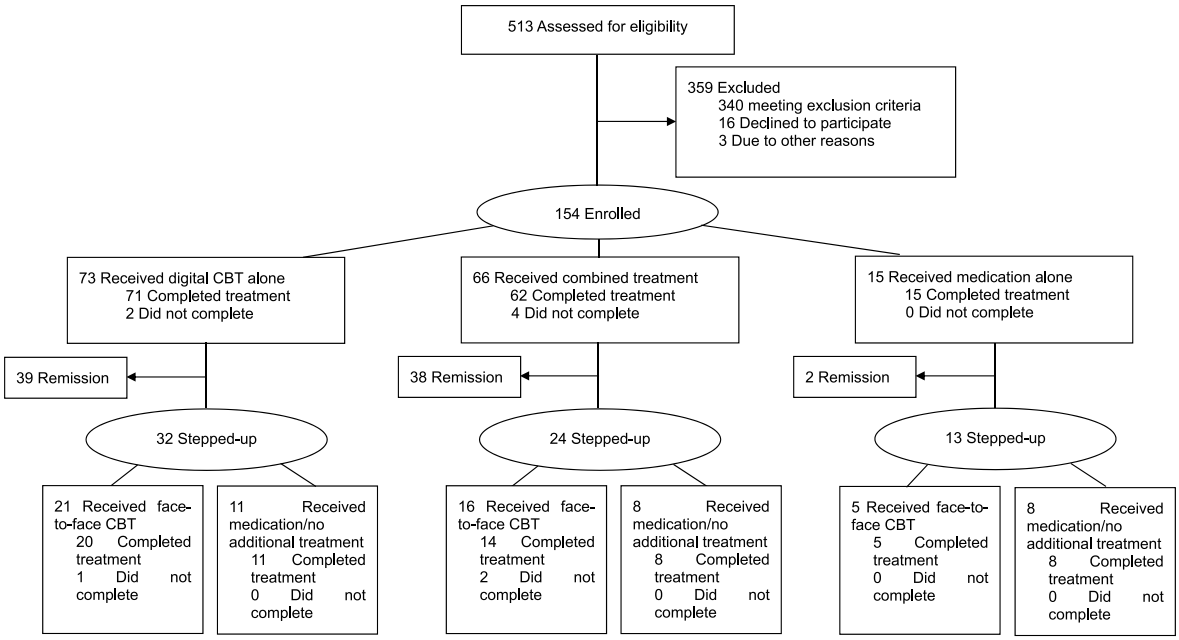

Fig. 1. Participant flow diagram.

compared with the baseline score. Remission was defined as a total ISI score <8.

The secondary outcomes were fatigue, functional impairments of insomnia, mood symptoms and sleep-wake parameters derived from sleep diaries. Daytime fatigue was measured by the *Flinders Fatigue Scale* (FFS) [21]. The *Work and Social Adjustment Scale* (WSAS) was used to assess the functional impact of insomnia on five domains: ability to work, home management, social leisure activities, private leisure activities, and relationships [22]. Changes in mood status were assessed with the *Patient Health Questionnaire-9* (PHQ-9) [23] and the *Generalized Anxiety Disorder 7-item* (GAD-7) [24].

2.4. Treatments

2.4.1. Digital cognitive behavioral therapy (SHUTi)

SHUTi is a fully automated and interactive dCBT-I intervention delivered through an internet-connected browser on mobile devices and computers. The program is based on key elements of CBT-I and consists of six, 45–60-min sequential cores, including an overview of insomnia, sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention [25]. Additional information about SHUTi can be found in previous publications [26,27].

2.4.2. Face-to-face cognitive behavioral therapy

Patients who chose to receive additional FtFCBT-I as the second-step treatment attended four individually tailored CBT-I sessions over the six weeks of treatment. The therapy was delivered by master's level clinical psychologists. The therapeutic components used were the same as in dCBT-I, but the psychologist had flexibility in administering the treatment based on a case-by-case functional analysis.

2.4.3. Medication

Participants who chose to continue using prescribed medications (either in the combined treatment or medication alone condition) were instructed to take sleep-promoting medications as prescribed by their physicians during the initial 6-week therapy. The same medication regimen (molecule, dosage, frequency) patients had been using prior to the study was prescribed to them in the first treatment step. Those medications and dosages included benzodiazepine receptor agonists (i.e., alprazolam [1 mg]; bromazepam [1.5 mg]; clonazepam [dose range, 0.25–1 mg]; flurazepam [15 mg]; lorazepam [0.5–1.5 mg]; oxazepam [15 mg] and temazepam [15 mg]; n = 24), non-benzodiazepine receptor agonists (i.e., zolpidem [2.5–10 mg] and zopiclone [1.25–7.5 mg]; n = 46), lemborexant (15 mg; n = 1), antidepressants (i.e., doxepin [6 mg]; trazodone [25–100 mg] and amitriptyline [10–20 mg]; n = 11) and quetiapine (50–100 mg; n = 2). After the first treatment step, if patients selected medication as the second-step treatment, they would receive medication therapy for an additional six weeks under the guidance of the study physicians. For individuals who were not using medication at step 1, a new prescription was written, while for those who were already taking medication at step 1, a new medication was prescribed, or the dosage or frequency of medication use was changed.

2.5. Statistical analyses

Analyses were conducted using SAS 9.4 based on the Intent-to-Treat principle. To evaluate each treatment sequence while considering the nature of the stepped care design (i.e., two steps, where the second is conditional on the response to the first) and the inclusion of remitted patients after 1st step, the analytic strategy was based on the recommendations of Nahum-Shani [28]. Study outcomes were analyzed using weighted linear (continuous outcomes) and logistic (binary outcomes) generalized estimating equations (WGEE) models [29]. Since the treatment allocation at each step was based on the participants' preference instead of randomization, the propensity scores were included in the analyses to control for pre-existing differences. The propensity weights were computed using baseline variables showing the largest contributions to reduction of baseline differences: age, biological sex, education level, sleep diary data, benzodiazepines and non-benzodiazepines usage, presence of anxiety disorder, and motivation to change. A priori contrasts within the WGEE models were used to test significance for comparisons between and within conditions.

3. Results

3.1. Participants

A total of 154 adults (113 women; mean [SD] age, 51.8 [14.2] years) with chronic insomnia disorder (mean duration, 13.9 years) were included in the study and allocated to dCBT-I (n = 73), combined treatment (n = 66) or medication condition (n = 15) based on their preference. Forty-eight participants (31 %) had a psychiatric comorbidity, the most common ones being generalized anxiety disorder (n = 29), panic disorder (n = 12), and major depression (n = 12). Use of prescribed sleep medications in the previous month was reported by 102 participants (66 %) at baseline (Table 1). At baseline, participants in the medication alone and combined treatment conditions reported using prescribed sleep medications for an average of 5.3 (SE = 0.5) and 5.9 (SE = 0.3) nights/week in the previous month, respectively.

Six participants (4 %) did not complete the first-step treatment (Fig. 1), including two in dCBT-I (3 %) and four (6 %) in the combined treatment condition. Of the unremitted and available participants after first-step treatment, 69 participants, including 32 in dCBT-I, 24 in combined treatment and 13 in the medication condition, accepted stepping-up to the second treatment stage. Of those, 3 participants (4 %) did not complete the second-step treatment.

Table 1
Sociodemographic and clinical characteristics of participants (unweighted).

	dCBT-I (n = 73)	Comb (n = 66)	Med (n = 15)	Total (n = 154)
Age, mean (SD), years	51.6 (13.4)	50.7 (13.9)	57.7 (18.3)	51.8 (14.2)
Biological sex, n (%)				
Female	60 (82 %)	45 (68 %)	8 (53 %)	113 (73 %)
Male	13 (18 %)	21 (32 %)	7 (47 %)	41 (27 %)
Race/Ethnicity n (%)				
White	71 (100 %)	63 (95 %)	15 (100 %)	149 (98 %)
Visible Minority	0 (0 %)	3 (5 %)	0 (0 %)	3 (2 %)
Education, mean (SD), years	14.9 (2.8)	14.6 (3.6)	12.8 (1.6)	14.6 (3.1)
Occupation, n (%)				
Employed, full/part time	48 (66 %)	42 (66 %)	8 (53 %)	98 (64 %)
Student	1 (1 %)	2 (3 %)	0	3 (2 %)
Unemployed	4 (6 %)	3 (5 %)	0	7 (5 %)
Retired	20 (27 %)	17(26 %)	7 (47 %)	44 (29 %)
Duration of insomnia, mean (SD), years	13.0 (14.4)	15.0 (14.2)	14.0 (15.5)	13.9 (14.4)
Psychiatric comorbidity, n (%)	23 (32 %)	21 (32 %)	4 (27 %)	48 (31 %)
Medical comorbidity, n (%)	26 (36 %)	15 (23 %)	8 (53 %)	49 (32 %)
Use of sleep-promoting prescribed medication in the last month, n (%)	22 (30 %)	66 (100 %)	14 (93 %)	102 (66 %)
Use of psychotropic medication at baseline, n (%)				
BzRAs	7 (10 %)	16 (24 %)	6 (40 %)	29 (19 %)
Non-BzRAs	8 (11 %)	40 (61 %)	6 (40 %)	54 (35 %)
Antidepressants	4 (6 %)	10 (15 %)	2 (13 %)	16 (10 %)

Abbreviations: BzRAs, benzodiazepine-receptor agonists.

3.2. Insomnia symptoms

3.2.1. Insomnia symptoms severity

Changes in insomnia severity based on conditions and assessments are shown in Table 2. Significant reduction in insomnia severity was observed in all three conditions at post1 (dCBT-I, mean changes = −8.7, 95 % CI = −9.8, −7.7; $p < 0.001$; Comb, −9.1, 95 % CI = −10.5, −7.6; $p < 0.001$; Med, −5.4, 95 % CI = −7.5, −3.3; $p < 0.001$), with significantly larger effects for dCBT-I (−3.3, 95 % CI = −5.7, −1.0; $p = 0.005$) and combined treatment (−3.7, 95 % CI = −6.2, −1.1; $p = 0.005$) than the medication condition. At post2, further reductions in insomnia severity were observed in all sequences that included FtFCBT-I as second-step treatment (dCBT-I + FtFCBT-I, −2.1, 95 % CI = −3.2, −1.0; $p < 0.001$; Comb + FtFCBT-I, −2.6, 95 % CI = −4.6, −0.5; $p = 0.01$; Med + FtFCBT-I, −7.1, 95 % CI = −8.5, −5.7; $p < 0.001$), but not in sequences followed by medication or no additional treatment. In addition, comparisons of the three sequences followed by FtFCBT-I with those followed by medication or no additional treatment all yielded significant group differences.

3.2.2. Response and remission rates

At post1, both dCBT-I and combined treatment produced higher percentages of responders (dCBT-I vs Med, 54.8 % vs 16.0 %; OR = 6.38, 95 % CI = 1.61, 25.31; Comb vs Med, 53.6 % vs 16.0 %; OR = 6.07, 95 % CI = 1.51, 24.33) than medication treatment. Similar results were noticed for the percentages of remitters (dCBT-I vs Med, 65.8 % vs 9.4 %; OR = 18.61, 95 % CI = 3.55, 97.60; Comb vs Med, 67.5 % vs 9.4 %; OR = 20.13, 95 % CI = 3.74, 108.32). There were no significant differences in response (OR = 1.05, 95 % CI = 0.49, 2.25) and remission rates (OR = 0.92, 95 % CI = 0.41, 2.11) between dCBT-I and combined treatment. For patients whose insomnia did not remit with first-step treatment, significant increases in responders were only observed in Comb + FtFCBT-I sequence (from 46.1 % to 68.2 %; OR = 2.52, 95 % CI = 1.15, 5.53), though a nonsignificant increase was observed in other sequences. Despite the increases in responders noticed in Comb + FtFCBT-I sequence, its comparison with Comb + Med/no additional treatment failed to yield significant group differences (OR = 1.73, 95 % CI = 0.86, 3.49). For remission rates, the addition of FtFCBT-I as second-step treatment produced significant increases of remitters in sequence starting with medication (from 23.4 % to 88.9 %; OR = 26.32, 95 % CI = 1.59, 435.16), and a nonsignificant increase in sequences starting with dCBT-I (44.5 %–58.4 %; $p = 0.06$) and combined treatment (55.7 %–69.4 %; $p = 0.18$) at post2. Group comparisons of the three sequences involved FtFCBT-I with those followed by medication/no additional

Table 2
Temporal changes of primary outcome.

Step 1	Pre (a) M (SE)[a]	Post1 (b) M (SE)	Change (b-a) [95 % CI][b]	Step 2	Post2 (c), M (SE)	Change (c-b) [95 % CI]	FU-6mo (d), M (SE)	Change (d-c) [95 % CI]
Insomnia Symptom Severity (Total ISI score)								
dCBT-I	16.2 (0.7)	7.5 (0.8)	−8.7 (0.5)[e] [-9.8, −7.7][d]	FtFCBT-I	6.7 (0.8)	−2.1 (0.6)[f] [-3.2, −1.0][d]	9.1 (1.3)	2.4 (0.8)[f] [0.8, 4.0][d]
				Med/no add.[c]	5.7 (0.8)	−0.3 (0.5) [-1.3, 0.6]	5.7 (0.8)	−0.0 (0.6) [-1.1, 1.1]
Comb	15.8 (0.8)	6.7 (0.8)	−9.1 (0.8)[e] [-10.5, −7.6][d]	FtFCBT-I	5.8 (0.8)	−2.6 (1.0)[f] [-4.6, −0.5][d]	6.5 (0.8)	0.7 (0.6) [-0.4, 1.9]
				Med/no add.	5.6 (0.8)	−0.4 (0.4) [-0.3, 1.2]	6.9 (0.9)	1.4 (0.5) [0.4, 2.3][d]
Med	17.5 (0.8)	12.2 (1.3)	−5.4 (1.1) [-7.5, −3.3][d]	FtFCBT-I	3.7 (1.9)	−7.1 (0.7)[f] [-8.5, −5.7][d]	8.2 (2.1)	4.5 (1.9) [0.7, 8.2][d]
				Med/no add.	12.5 (2.3)	−1.0 (1.3) [-3.5, 1.5]	12.0 (1.7)	−0.5 (1.9) [-4.1, 3.2]
Response rates (changes in ISI ≥8), %								
dCBT-I	.	54.8 (7.4)[e]	.	FtFCBT-I	63.4 (9.2)	1.67 [0.99, 2.84]	45.1 (9.5)	0.47 [0.23, 0.97][d]
				Med/no add.	67.4 (8.3)	1.45 [0.71, 2.97]	59.9 (9.0)	0.72 [0.36, 1.43]
Comb	.	53.6 (7.7)[e]	.	FtFCBT-I	68.2 (9.5)	2.52 [1.15, 5.53][d]	51.4 (10.7)	0.49 [0.26, 0.92][d]
				Med/no add.	69.5 (7.6)	1.46 [0.82, 2.58]	59.2 (9.7)	0.64 [0.28, 1.47]
Med	.	16.0 (9.0)	.	FtFCBT-I	88.5 (11.5)	13.41 [0.90, 199.87]	45.6 (23.6)	0.11 [0.01, 1.02]
				Med/no add.	31.9 (17.4)	7.38 [0.94, 58.15]	54.4 (21.4)	2.55 [0.26, 24.81]
Remission rates (ISI <8), %								
dCBT-I	.	65.8 (7.6)[e]	.	FtFCBT-I	58.4 (9.5)	1.75[f] [0.98, 3.13]	49.7 (9.9]	0.71 [0.35, 1.41]
				Med/no add.	73.3 (8.2)	0.59 [0.28, 1.28]	69.7 (8.6)	0.84 [0.38, 1.84]
Comb	.	67.5 (7.5)[e]	.	FtFCBT-I	69.4 (8.0)	1.81 [0.76, 4.29]	68.7 (8.7)	0.97 [0.48, 1.96]
				Med/no add.	71.6 (8.6)	0.73 [0.40, 1.34]	61.3 (10.3)	0.63 [0.34, 1.17]
Med	.	9.4 (7.0)	.	FtFCBT-I	88.9 (11.9)	26.32 [1.59, 435.16][d]	56.0 (22.8)	0.16 [0.02, 1.29]
				Med/no add.	27.6 (18.6)	10.88 [0.81, 145.60]	24.7 (15.4)	0.86 [0.11, 6.81]

Abbreviations: add., additional treatment; Comb, combination treatment; dCBT-I, digital cognitive behavioral therapy for insomnia; FtF, face-to-face; ISI, Insomnia Severity Index; Med, medication; pre, before first treatment step; post1, after first treatment step; post2, after second treatment step.

[a] All values are adjusted for missing data and propensity scores. Data are adjusted mean (SE) for continuous variables or adjusted percentage (SE) for categorical variables.

[b] For continuous variable, intervention effect is presented as the mean change from baseline to each time points; for categorical variable, intervention effect is presented as odds ratio.

[c] In step 2, participants receiving medication and those who declined any additional treatment were combined into a single group, due to the small number of patients who chose to receive medication in step 2.

[d] Significant within group differences compared to previous time point.

[e] Significant between-group differences compared to medication condition.

[f] Significant between-group differences compared to medication/no additional treatment condition.

treatment were nonsignificant.

3.2.3. Follow-up assessments

Improvements achieved at the end of first-step and second-step treatment were well sustained over time, with the exception that insomnia severity was slightly increased in the dCBT-I + FtFCBT-I sequence from post2 to 6-month follow-up (2.4, 95 % CI = 0.8, 4.0; $p = 0.004$). The percentages of responders and remitters remained stable throughout follow-ups for most of the sequences. A reduction of response rates from post2 to 6-month follow-up was noticed for two sequences, dCBT-I + FtFCBT-I (from 63.4 % to 45.1 %; $p = 0.04$) and Comb + FtFCBT-I (68.2 %–51.4 %; $p = 0.03$). Group comparisons of response and remission rates between FtFCBT-I and medication/no additional treatment as second-step treatment were nonsignificant at 6-month follow-up.

3.2.4. Medication use

Significant decreases in the frequency of medication use were observed in the combined treatment condition at post1 (pre vs post1, 5.9 vs 4.4 nights/week; $p < 0.001$), whereas a non-significant increase was observed in the medication alone condition (5.3 vs 5.8 nights/week; $p = 0.19$); there was a significantly lower frequency of medication use for combined treatment relative to the medication alone condition at post 1 ($p < 0.001$).

3.3. Daytime functional and psychological outcomes

Psychological and daytime functional outcomes are presented in Table 3. Significant reductions in fatigue (FFS) and functional impairments (WSAS) were observed in both dCBT-I and combined treatment at post1. The effects were significantly larger for the dCBT-I and combined treatment conditions in terms of functional impairments when comparing to the medication alone condition (mean change in WSAS score: dCBT-I vs Med, −6.3, 95 % CI = −12.2, −0.4; $p = 0.04$; Comb vs Med, −7.9, 95 % CI = −14.2, −1.7; $p = 0.01$). At post2, the addition of FtFCBT-I as a second-step treatment produced significant reductions of fatigue in sequences starting with combined treatment and medication, with lager effects for these two sequences compared to sequences followed by medication/no additional treatment (Comb + FtFCBT-I vs Comb + Med/no add., −2.7, 95 % CI = −5.2, −0.1; $p = 0.04$; Med + FtFCBT-I vs Med + Med/no add., −3.7, 95 % CI = −6.0, −1.4; $p = 0.002$). For functional impairments, significant improvements from post1 to post2 were obtained in all sequences that included FtFCBT-I. Comparisons of the sequences involving FtFCBT-I with those followed by medication/no additional treatment yielded significant group differences for sequences starting with combined treatment (mean change in WSAS score = −2.5, 95 % CI = −4.2, −0.8; $p = 0.004$).

All first-step treatments produced significant improvements for depressive symptoms, with significantly larger effects for combined treatment relative to the medication alone condition (mean changes in PHQ-9 score = −1.7, 95 % CI = −3.3, −0.0; $P = 0.05$). While significant improvements of anxiety symptoms were only made with dCBT-I and

Table 3
Temporal changes for daytime functional and psychological outcomes.

Step 1	Pre (a) M (SE)[a]	Post1 (b) M (SE)	Change (b-a) [95 % CI]	Step 2	Post2 (c), M (SE)	Change (c-b) [95 % CI]	FU-6mo (d), M (SE)	Change (d-c) [95 % CI]
PHQ-9								
dCBT-I	7.2 (0.8)	4.1 (0.7)	−3.1 (0.5) [-4.0, −2.2][c]	FtFCBT-I	3.6 (0.7)	−0.9 (0.4) [-1.6, −0.2][c]	5.4 (1.1)	1.8 (0.7)[e] [0.4, 3.1][c]
				Med/no add.[b]	3.4 (0.8)	−0.3 (0.4) [-1.1, 0.5]	3.1 (0.7)	−0.3 (0.5) [-1.3, 0.8]
Comb	6.5 (0.7)	3.1 (0.6)	−3.4 (0.4)[d] [-4.2, −2.5][c]	FtFCBT-I	2.4 (0.6)	−1.7 (0.6)[e] [-2.9, −0.6][c]	3.4 (0.6)	1.0 (0.4) [0.3, 1.7][c]
				Med/no add.	2.2 (0.6)	0.1 (0.2) [-0.3, 0.5]	3.1 (0.7)	0.9 (0.4) [0.2, 1.7][c]
Med	7.5 (1.4)	5.8 (1.2)	−1.7 (0.7) [-3.1, −0.3][c]	FtFCBT-I	3.1 (2.1)	−2.3 (0.9)[e] [-4.0, −0.6]	3.0 (1.8)	−0.2 (0.5) [-1.2, 0.9]
				Med/no add.	6.4 (1.8)	0.2 (0.6) [-0.9, 1.3]	6.4 (2.1)	0.0 (1.2) [-2.4, 2.4]
GAD-7								
dCBT-I	6.1 (0.8)	3.5 (0.8)	−2.6 (0.5)[d] [-3.6, −1.7][c]	FtFCBT-I	2.2 (0.7)	−1.7 (0.4)[e] [-2.5, −0.8][c]	4.0 (0.8)	1.8 (0.5)[e] [0.8, 2.8][c]
				Med/no add.	2.4 (0.8)	−0.7 (0.4) [-1.5, 0.2]	3.0 (0.8)	0.5 (0.3) [-0.0, 1.1]
Comb	6.2 (0.9)	2.7 (0.6)	−3.5 (0.7)[d] [−4.9, −2.2][c]	FtFCBT-I	2.2 (0.6)	−0.7 (0.4) [-1.4, −0.0][c]	2.7 (0.7)	0.4 (0.4) [-0.4, 1.2]
				Med/no add.	2.1 (0.6)	−0.3 (0.3) [-0.8, 0.2]	2.2 (0.8)	0.1 (0.4) [-0.7, 0.9]
Med	5.1 (1.4)	4.1 (1.4)	−1.0 (0.6) [-2.1, 0.2]	FtFCBT-I	2.8 (2.3)	−1.3 (0.7) [-2.6, 0.0]	3.2 (2.4)	0.4 (0.5)[e] [-0.4, 1.3]
				Med/no add.	4.9 (1.8)	0.8 (1.3) [-1.8, 3.4]	2.6 (1.1)	−2.3 (1.1) [-4.5, −0.1][c]
WSAS								
dCBT-I	13.6 (1.4)	6.9 (1.1)	−6.7 (1.0)[d] [-8.7, −4.8][c]	FtFCBT-I	5.6 (1.5)	−2.9 (1.1) [-5.0, −0.7][c]	7.4 (1.6)	1.8 (1.1) [-0.4, 4.0]
				Med/no add.	4.1 (1.3)	−1.1 (0.6) [-2.3, 0.1]	4.0 (1.2)	−0.1 (0.9) [-1.8, 1.6]
Comb	13.5 (1.6)	5.2 (1.1)	−8.4 (1.5)[d] [-11.2, −5.5][c]	FtFCBT-I	4.5 (1.2)	−2.1 (0.9)[e] [-3.9, −0.3][c]	5.0 (1.4)	0.5 (0.9) [-1.3, 2.2]
				Med/no add.	4.0 (1.3)	0.4 (0.5) [-0.6, 1.4]	4.8 (1.2)	0.8 (0.9) [-0.9, 2.6]
Med	14.7 (3.0)	14.3 (2.3)	−0.4 (2.8) [-6.0, 5.1]	FtFCBT-I	4.2 (3.5)	−6.6 (1.3) [-9.2, −4.1][c]	6.3 (3.7)	2.1 (2.0) [-1.9, 6.1]
				Med/no add.	14.0 (4.3)	−3.7 (2.2) [-8.0, 0.6]	14.0 (4.2)	−0.0 (3.3) [-6.6, 6.5]
FFS								
dCBT-I	13.9 (0.9)	10.1 (0.9)	−3.8 (0.7) [-5.2, −2.4][c]	FtFCBT-I	9.6 (1.1)	−1.7 (0.9) [-3.4, 0.0]	10.9 (1.2)	1.3 (1.1) [-1.0, 3.5]
				Med/no add.	7.5 (1.0)	−1.3 (0.7) [-2.6, −0.0][c]	7.7 (1.0)	0.2 (0.6) [-1.0, 1.3]
Comb	13.8 (1.0)	9.2 (1.0)	−4.6 (0.9)[d] [-6.3, −2.9][c]	FtFCBT-I	7.7 (0.9)	−2.9 (1.3)[e] [-5.5, −0.4][c]	9.3 (1.1)	1.5 (0.7) [0.3, 2.8][c]
				Med/no add.	7.4 (0.8)	−0.3 (0.8) [1.8, 1.2]	7.9 (0.9)	0.5 (0.7) [-1.0, 1.9]
Med	13.7 (1.6)	12.2 (1.2)	−1.5 (1.1) [-3.6, 0.5]	FtFCBT-I	6.0 (1.8)	−5.1 (1.1)[e] [-7.2, −2.9][c]	8.6 (3.0)	2.6 (2.3) [-1.9, 7.0]
				Med/no add.	11.9 (1.5)	−1.4 (0.8) [-2.9, 0.2]	11.6 (1.7)	−0.3 (1.8) [-3.9, 3.3]

Abbreviations: add., additional treatment; Comb, combination treatment; dCBT-I, digital cognitive behavioral therapy for insomnia; FFS, Flinders Fatigue Scale; FtF, face-to-face; Med, medication; GAD-7, Generalized Anxiety Disorder 7-item; pre, before first treatment step; PHQ-9, Patient Health Questionnaire-9; post1, after first treatment step; post2, after second treatment step; WSAS, Work and Social Adjustment Scale.

[a] All values are adjusted for missing data and propensity scores.

[b] In step 2, participants receiving medication and those who declined any additional treatment were combined into a single group, due to the small number of patients who chose to receive medication in step 2.

[c] Significant within group differences compared to previous time point.

[d] Significant between-group differences compared to medication condition.

[e] Significant between-group differences compared to medication/no additional treatment condition.

combined treatment, both treatments showed significantly greater changes compared to medication alone (mean change in GAD-7 score: dCBT-I vs Med, −1.6, 95 % CI = −3.1, −0.1; $p = 0.03$; Comb vs Med, −2.6, 95 % CI = −4.3, −0.8; $p = 0.004$). At post2, further reductions in depressive symptoms severity were observed in all sequences that included FtFCBT-I as a second-step treatment. In addition, comparisons of the sequences that involved FtFCBT-I with those followed by medication/no additional treatment yielded significant group differences in favor of sequences starting with combined treatment (−1.8, 95 % CI = −3.0, −0.6; $p = 0.003$) and medication (−2.5, 95 % CI = −4.5, −0.4; $p = 0.02$). For anxiety symptoms, the addition of FtFCBT-I produced further reductions of anxiety symptoms in sequences starting with dCBT-I and combined treatment, with significant group differences favoring the dCBT-I + FtFCBT-I sequence (mean change in GAD-7 score = −1.0, 95 % CI = −1.8, −0.2; $p = 0.01$).

At 6-month follow-up, improvements in fatigue and functional impairments achieved with treatments were maintained over time for most of the sequences, except for slight increases of fatigue observed in the Comb + FtFCBT-I sequence (mean changes in FFS score = 1.5, 95 % CI = 0.3, 2.8; $p = 0.02$). For psychological outcomes, slight increases in depressive symptoms severity were observed in the dCBT-I + FtFCBT-I sequence (mean changes in PHQ-9 score = 1.8, 95 % CI = 0.4, 3.1; $p = 0.01$) and two sequences starting with Comb treatment (Comb + FtFCBT-I, 1.0, 95 % CI = 0.3, 1.7; $p = 0.005$; Comb + Med/no additional treatment, 0.9, 95 % CI = 0.2, 1.7; $p = 0.02$), though depressive symptoms remained in the normal to mild range for these sequences. Increases in anxiety severity were also noticed in dCBT-I + FtFCBT-I sequence at follow-up (mean changes in GAD-7 score, 1.8, 95 % CI = 0.8, 2.8; $p < 0.001$), but the anxiety levels remained within the minimal range. Improvements in depressive and anxiety symptoms achieved with treatment were well sustained throughout the 6-month follow-up for other sequences.

3.4. Sleep diary data

Both dCBT-I and combined treatment produced significant improvements in sleep onset latency, time awake after sleep onset (WASO), and sleep efficiency at post1 (Table S1). At post2, the addition of FtFCBT-I as second-step treatment produced further gains in WASO and total sleep time. Improvements achieved with treatments were well sustained throughout the 6-month follow-up for most of the treatment sequences.

4. Discussion

The current study showed that dCBT-I is an effective treatment delivery modality for patients with chronic insomnia in primary care, and the addition of FtFCBT-I as a second-step treatment produced an added value for those who do not remit with dCBT-I. In addition, stepped-care intervention for insomnia also produced significant benefits on secondary outcomes, including sleep parameters derived from sleep diaries, mood symptoms, fatigue, and functional impairments of insomnia. This pragmatic clinical trial demonstrated the feasibility and efficiency of implementing digital and in-person CBT-I within a stepped-care model in primary care practice.

Consistent with previous studies comparing in-person CBT-I to various insomnia medications [30–32], our study demonstrated that fully automated dCBT-I, either applied alone or in combination with medication, is superior to treating insomnia with medication alone. In addition, dCBT-I was more beneficial than medication alone for improving psychological and functional outcomes, probably due to its broader spectrum of action in targeting some perpetuating mechanisms (e.g., ruminations and worries) that are implicated in the association between insomnia and psychological symptoms [33]. Despite its potential to capitalize on the immediate benefits of medication and the long-lasting benefits of CBT-I, combined treatment was not more effective than dCBT-I alone, a finding similar to previous studies [30,31,34]. Nonetheless, additional randomized controlled trials are warranted to examine the speed and sustainability of insomnia treatment response produced with digital therapeutics in primary care settings [35,36].

The addition of in-person CBT-I for non-remitters produced a significant added value in alleviating sleep and daytime functional symptoms relative to the addition of medication or no additional treatment, which reflects the potential of sequential, stepped-care intervention to optimize insomnia care. However, the finding that some clinical benefits were not fully sustained at 6-month follow-up suggests that extended therapy may be needed for patients with treatment-resistant insomnia [37]. Furthermore, although the current study explored several strategies to optimize the sequence of different CBT formats, with or without medication therapy based on patient preference, additional studies are required to further refine insomnia stepped care algorithms.

The present findings have significant implications for clinical practice. First, they showed that dCBT-I is a feasible alternative to in-person CBT-I for increasing its accessibility. The added value provided by second-step treatment using in-person CBT-I also support the adoption of a stepped-care intervention for insomnia to facilitate the provision of guideline care. In addition, the allocation of patients based on treatment preference revealed that most patients selected CBT-I over medication for treating their insomnia, highlighting the critical importance of involving patients in the decision-making process of selecting among different treatment options.

Limitations to the current study include the lack of a control condition and the small sample size for the medication only condition, as well as for the treatment sequences in step 2, which may have reduced the statistical power for some comparisons. In addition, treatment allocation was based on patient preference rather than randomization, which led to unequal sample sizes and precluded a direct comparison of FtFCBT and medication in the second treatment step. Finally, although the current study showed that adapting digital therapeutics for insomnia by using a stepped-care approach resulted in higher remission rates compared to previous findings (60 %–70 % vs 40 %) [13], the generalizability of the findings was limited by the inclusion of participants who represented a relatively uncomplicated insomnia disorder group. Therefore, there remains room for further tailoring of insomnia care in clinical practice based on insomnia severity, prior treatment exposure, comorbid conditions and clinical status, in order to achieve the best possible outcome for patients.

5. Conclusion

In summary, the current study demonstrated that dCBT-I is an effective treatment delivery modality for patients with chronic insomnia in primary care and there is added value for stepping-up non-remitters to FtFCBT-I. These findings support the integration of CBT-I in a stepped-care intervention for insomnia into clinical practice to promote the provision of guideline-based care for insomnia.

CRediT authorship contribution statement

Charles M. Morin: Writing – review & editing, Writing – original draft, Supervision, Methodology, Funding acquisition, Conceptualization. **Si-Jing Chen:** Writing – review & editing, Writing – original draft. **Kathleen Lemieux:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Hans Ivers:** Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. **Janet M. Y. Cheung:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Manon Lamy:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Lee Ritterband:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Funding

This study was funded by the Canadian Institutes of Health Research (no. 148410).

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Charles M. Morin reports a relationship with Canadian Institutes of Health Research that includes: funding grants. Charles M. Morin reports a relationship with National Institutes of Health that includes: funding grants. Charles M. Morin reports a relationship with Eisai Inc that includes: consulting or advisory, and funding grants. Charles M. Morin reports a relationship with Idorsia Pharmaceuticals Ltd that includes: consulting or advisory, and funding grants. Charles M. Morin reports a relationship with Lallemand Health Solution that includes: funding grants. Charles M. Morin reports a relationship with Haleon that includes: consulting or advisory. Charles M. Morin has patent with royalties paid to Mapi Research Trust. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sleep.2025.106551.

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