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Digital cognitive behavioural therapy (D.CBT) for pregnancy-related depression and sleep disturbances: a systematic review and meta-analysis

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ABSTRACT

Objective. Between 5% and 30% of women during the pregnancy and postpartum periods may suffer from depression. The management modalities are ranging from coping and support to medications and electroconvulsive therapy. Our study aimed to assess whether digital cognitive behavioural therapy (D.CBT) can improve pregnancy-related mood and sleep disorders.
Materials and Methods. We combed four databases, Web of Science, PubMed, Scopus, and Cochrane Library. Randomized control trials comparing D.CBT with any control group for pregnancy-related depression and sleep disorders were selected for this study.
Results. We included 14 studies based on the original data of 12 trials. D.CBT significantly decreased the Patient Health Questionnaire-9 (PHQ-9) after eight weeks compared to the control (MD = -2.77; 95%CI -4.01 to -1.53; $p < 0.0001$); however, no significant difference after four weeks of intervention or after six weeks of delivery. After eight weeks, D.CBT significantly decreased Inventory of Depression and Anxiety Symptoms (IDAS) (SMD = -0.48; 95%CI -0.78 to -0.18; $p = 0.002$), while after only four weeks, D.CBT was associated with higher IDAS than the control (SMD = 0.56; 95%CI 0.26 to 0.86; $p = 0.0002$). Also, D.CBT significantly decreased Generalized Anxiety Disorder Scale (GAD-7) (MD = -1.73; 95%CI -2.63 to -0.83; $p = 0.0002$), and Insomnia Severity Index (ISI) (MD = -3.45; 95%CI -5.66 to -1.24; $p = 0.002$) when compared to the control.
Conclusions. D.CBT shows some promising outcomes in treating pregnant women's depression and sleep difficulties as decreasing Patient Health Questionnaire-9 (PHQ-9), Depression and Anxiety Symptoms (IDAS), Generalized Anxiety Disorder Scale (GAD-7), and Insomnia Severity Index (ISI), especially after eight weeks of the intervention.

INTRODUCTION

The pregnancy and postpartum phases are critical periods for mental health problems because of the different ways in which a woman's life is impacted socially, emotionally, physically, and hormonally [1]. Around 5-30% of women have depressive symptoms due to prenatal psychosocial trauma [1]. Perinatal depression is a common kind of nonpsychotic depression that affects women from conception until after birth and may have devastating implications [2, 3]. Prenatal depression seems to be more prevalent in nations with lower incomes (7%-15%) than in countries with higher incomes (19%-25% *vs* 7%-15%) [4, 5]. Anxiety and mood swings are also prevalent during pregnancy because of the hormonal changes and other physical shifts that occur during the pregnancy [6]. Additionally, sleep quality decreases for over half of pregnant women, which is linked to the frequency of mood disorders, anxiety, and stress. There are negative effects on the pregnant woman's and her child's psychosocial functioning as a result of these challenges [7-9]. Moreover, women's risk for postpartum depression is greatly raised due to the heightened stress response and psychosocial symptoms they experience throughout pregnancy. Also, women who gave birth to a stillborn baby were more likely to experience depression than mothers of healthy newborns. In the subset of women studied who had a previous diagnosis of depression, no link was found between stillbirth and increased risk for depression [10].

These considerations imply that psychosocial adjustment therapies for pregnant women may reduce clinically significant psychiatric symptoms and improve quality of life and happiness. Digital solutions may be suitable for cognitive-behavioural therapies (CBTs), especially third-generation CBTs that use exact protocols and practical exercises. Sleep hygiene instructions, stimulation control, relaxation training, sleep restriction, and cognitive therapy are all parts of digital CBT's multi-faceted strategy [11, 12]. Traditional CBTs, in contrast to third-generation CBTs, depend on classical and operant conditioning concepts to alter dysfunctional cognitive processes that underpin maladaptive situational evaluation. Third-generation CBTs, on the other hand, prioritize experiential and contextual awareness enhancement by selecting more adaptable coping techniques [13, 14]. CBT apps help with journaling, exercise, cognitive restructuring, behavioural activation, and problem-solving. Mobile health apps may enhance adherence, user engagement, retention, and learning [15].

Patients are instructed about proper sleeping practices in the Sleep Hygiene Education component. This education includes guidance on creating a conducive bedroom environment, as well as instruction on daily habits and dietary guidance [16]. Patients are taught in the Stimulus-Control phase the value of forming positive associations between their sleeping space and their sleep routines. If a patient can't go sleep in the bedroom after 15 minutes, for instance, they should go do something relaxing and come back when they're tired. When it comes to the Relaxation component, patients are taught and encouraged to consistently employ several relaxation techniques that might help them overwhelm cognitive and physical arousal. Deep breathing, progressive muscle relaxation, and visual training are the gold-standard relaxation techniques [16, 17].

Regarding Sleep Restrictions, patients are urged to limit their sleep period based on their previous week's average sleep length(s). The quality of prescriptions is based on frequent and precise diary reporting. When recommending a restricted-sleep schedule, the schedule's viability is considered. The period will be prolonged in the future weeks based on the patients' development and sleep efficiency [1]. The ultimate objective is to enhance sleep pressure while decreasing arousal [16, 17]. Moreover, cognitive therapy focuses on identifying and changing problematic ideas and negative sleep-thinking patterns, such as worrying. Then, different techniques are used to overcome unwanted sleep-related thoughts and false anxieties. Cognitive retraining, paradoxical intention, and thought blocking are the top three methods [16, 17].

The previous meta-analysis showed the usefulness of D.CBT in emphasizing the need to build evidence-based digital preventive programs for pregnant women with sub-clinical symptoms, but no strong conclusions can be formed about the effectiveness of the studied intervention [18]. In that meta-analysis, the effects of D.CBT on the treatment of depression and sleeplessness in pregnant women ranged from significant to non-significant results regarding different outcomes. Also, some studies observed no difference between D.CBT and control whereas others indicated a good function for DCBT in lowering depression and anxiety symptoms [19-21].

Therefore, we aim in this systematic review and meta-analysis to compare the efficacy of digital cognitive behavioural therapy with that of traditional treatment for reducing symptoms of depression, anxiety, and sleep disturbances in pregnant women.

MATERIALS AND METHODS

The Cochrane Handbook of systematic reviews and meta-analyses of interventions served as our guide while carrying out our study then we presented it following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [22, 23].

Search strategy

A systematic literature search approach was applied to four databases: PubMed, Cochrane Library, Web of Science, and Scopus. The search was conducted from scratch to September 2022. The following search phrases were used in the above databases: digital, cognitive-behavioural intervention, pregnancy, and depression. The search terms have been modified for each database according to its recommendations. We used EndNote, an electronic reference management program, to import all entries (version X8) and remove the duplicates. We only listed citations found in English. Double-blind screening of titles and abstracts was conducted independently by two authors. The eligibility of the studies was then evaluated using full-text screening. Additionally, we used the snowballing methodology to review the reference lists of chosen publications for any overlooked research as an alternative way of identification.

Eligibility criteria

The following components were our PICOS criteria: "Population" women above the age of 18 who are pregnant physiologically, "Intervention" digital CBTs, "Comparator" inactive control conditions such as no intervention group, usual care, waiting list, or active control, "Outcomes" depression, anxiety, and sleep problems, and "Study designs" randomized controlled trials.

Women with high-risk pregnancies, medical issues unrelated to pregnancy, or those who had a pregnancy that was artificially induced were not included in our analysis. Research conducted in languages other than English, conference abstracts, and works for which the full text was unavailable were also left out.

Quality assessment

Using version 2 of the Cochrane Risk of Bias assessment, two authors independently rated the reliability of the included studies (RoB 2.0). Any differences between the assessors were resolved by contacting a third author. Each included research took into account the randomization procedure, and deviations from the intended interventions. Each domain was assessed as "low", "moderate concern", or "high" in terms of bias risk. Each domain's evaluation was combined into one overall domain, known as the overall assessment, which is included in the RoB 2.0 to provide a summary of each research's quality assessment. synthesize each research's overall quality assessment [24]. We did not conduct publication bias since the number of included studies was more than 10, but most studies included in any analysis were less than 10.

Data extraction

Two authors performed the data extraction separately, and any conflicts were settled by a third. The extracted data included the following:

1. Baseline characteristics of included studies (which include sample size, age, gestational age, marital status, and first pregnancy percentage).
2. Summary of included studies (which include country, trial registration number, gestational age at entry, intervention and control details, length of intervention, primary outcomes, and the result of study).
3. Risk of bias domains.
4. Studies outcomes (which include Patient Health Questionnaire-9 (PHQ-9), 2-Inventory of Depression and Anxiety Symptoms (IDAS), Edinburg Postnatal Depression Scale (EPDS), Generalized Anxiety Disorder Scale (GAD-7), Change after intervention in Pregnancy Distress Questionnaire (PDQ), Pittsburgh Sleep Quality Index (PSQI), and Change in insomnia severity index (ISI).

Data analysis

For the statistical analysis, we utilized Review Manager software V5.4 (Cochrane, Alberta, Canada) in the inverse variance method. When outcomes were measured using the same scale, the mean difference was used; otherwise, the standardized mean difference (SMD) was applied to determine statistical significance (CI). Our analyses were based on the pre-treatment and post treatment changes, not only the post-treatment values. When the P-value of heterogeneity was more than 0.1, we used a fixed-effect model, and when $p < 0.1$, we switched to the random-effect model. The

extent of heterogeneity among the pooled studies was measured by the I^2 index, which indicated the level of variation in intervention effects that may be attributed to "real" heterogeneity among trials. We conducted subgroup analyses according to post-treatment even before or after labour.

RESULTS

Search results

Our literature search approach yielded 3,195 results. After reviewing titles and abstracts, we identified 44 papers eligible for full-text screening. Finally, our systematic review included 14 RCTs, of them, ten RCTs were incorporated in the meta-analysis [19-21, 25-35] (**Figure 1**).

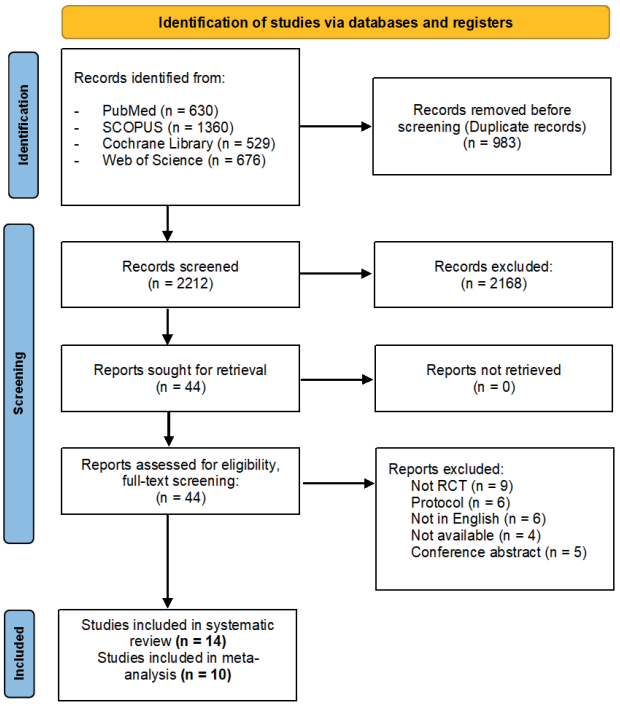

Figure 1. *PRISMA flow diagram.*
PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only. From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/.

Characteristics of the included studies

We included 14 studies; however, they were based on the original data of 12 trials. Felder *et al*. [33], Felder *et al*. [34], Larsson *et al*. [25] and Rondung *et al*. [30] included the same patients' data. The average age in the trials ranged between 29 and 35 years. The gestational age upon admission was between 15 and 26 weeks. Except for Loughnan *et al*., the proportion of married or cohabiting women was high, topping 90% in all studies. Regarding the intervention, all the included studies applied digital-based intervention, while the control varied between standard care, treatment as usual, or active control. The length of the intervention was varying between 3 and 16 weeks. **Tables 1** and **2** provide an in-depth review of the included studies and the baseline characteristics of their patients, respectively.

Quality assessment

The overall risk of bias was high in three studies [21, 28, 31], and low in two studies [18, 29], and there were moderate concerns in the other nine studies [19, 20, 25-27, 30, 32-34]. In terms of the randomization process, six studies reported an appropriate randomization approach with allocation concealment, therefore we classified them as low risk [26, 27, 29, 32-34], while it was determined that the other studies had some concerns. Seven studies were found to have a high bias because of inadequate blinding of patients and examiners, while the other seven were found to have moderate problems. Four studies were flagged as having some concerns when it came to missing outcome data [25, 26, 28, 30], and the risk of bias in the other studies was also deemed to be low. Furthermore, regarding outcomes assessment, just one study was deemed to have a significant risk of bias [21], a low risk of bias was found in three studies [20, 29, 35], and the remaining studies were deemed to have methodological or other flaws. Regarding the selection of the reported results, six studies were judged as having a low risk of bias [19, 20, 25, 30, 34, 35], and the other studies were considered to have some concerns. **Figure 2** summarizes the included studies' risk of bias evaluation.

Outcomes (quantitative evidence)

Change in Patient Health Questionnaire-9 (PHQ-9)

The pooled results showed no significant difference between the D.CBT group and the control group in reducing PHQ-9 after four weeks of intervention and after six weeks of delivery as follows: MD = -0.46; 95%CI -2.09 to 1.16; p = 0.58, and MD = 0.81; 95%CI -1.07 to 2.7; p = 0.40, respectively). The data were pooled from three [19, 21, 27] and two studies [21, 27],

Table 1. *Baseline characteristics of the enrolled patients in the included studies.*

Study ID	Study arms	Sample	Age, years, Mean (SD)	Gestational age, weeks, Mean (SD)	Married or cohabitating (%)	First pregnancy, (%)
Duffecy *et al.* 2019	D.CBT	18	30.5 (4.05)	NR	20 (83%)	NR
	Control	7		NR		NR
Duffecy *et al.* 2022	D.CBT	152	29.11 (4.8)	NR	138 (90.8%)	95 (62.5%)
	Control	56	29.00 (4.8)	NR	53 (94.6%)	40 (71.4%)
Felder *et al.* 2020	D.CBT	103	33.90 (3.38)	17.1 (6.4)	100 (95.2)	46 (43.8)
	Control	105	33.2 (4.0)	18.07 (6.27)	96 (93.2)	66 (64.1)
Felder *et al.* 2021	D.CBT	103	33.90 (3.38)	17.1 (6.4)	100 (95.2)	46 (43.8)
	Control	105	33.2 (4.0)	18.07 (6.27)	96 (93.2)	66 (64.1)
Forsell *et al.* 2017	D.CBT	22	31.2 (3.7)	15.9 (6.5)	21 (96)	10 (22)
	Control	20	30.8 (5.3)	18.6 (6.5)	20 (100)	5 (20)
Haga *et al.* 2018	D.CBT	678	31.0 (4.6)	NR	NR	393 (58.0)
	Control	664	31.1 (4.5)	NR	NR	382 (57.5)
Kalmbach *et al.* 2020	D.CBT	46	28.9 (4.91)	NR	NR	29 (63)
	Control	45	29.16 (4.11)	NR	NR	30 (66.7)
Larsson *et al.* 2017	D.CBT	127	Reported as age groups	NR	NR	77 (60.6)
	Control	131		NR	NR	77 (58.8)
Loughnan *et al.* 2019	D.CBT	36	31.69 (4.44)	20.54 (6.01)	10 (28)	10 (28)
	Control	41	31.54 (3.63)	22.63 (5.76)	4 (10)	15 (41)
Puertas-Gonzalez *et al.* 2022	D.CBT	70	35.11(3.60)	19.04 (7.40)	69(98.6%)	30(42.9%)
	Control	68	34.31(4.85)	21.28 (7.19)	62(91.2%)	29(42.6%)
Rondung *et al.* 2019	D.CBT	127	Reported as age groups	NR	NR	77 (60.6)
	Control	131		NR	NR	77 (58.8)
Sikar *et al.* 2016	D.CBT	32	33.81(2.53)	16.15 (2.88)	32 (88.9)	NR
	Control	14				NR
Sun *et al.* 2021	D.CBT	84	30.27 (3.80)	13.8 (2)	NR	56 (67)
	Control	84	29.55 (4.21)	14.4 (2.6)	NR	28 (33)
Yang *et al.* 2019	D.CBT	62	31.31 (4.97)	25.52 (1.84)	NR	39 (62.9)
	Control	61	30.38 (3.91)	26.33 (3.45)	NR	38 (62.3)

D.CBT: digital cognitive behavioral therapy; NR: not reported.

with a total sample of 245 patients and 179 patients respectively. The pooled data were homogenous as follows: p= 0.44, I^2=0, and p= 0.29, I^2=9%. On the other hand, pooled data from four studies [19, 21, 26, 27] with a total sample of 381 showed that D.CBT significantly decreased the PHQ-9 compared to the control after eight weeks of intervention as follows: MD = -2.77; 95%CI -4.01 to -1.53; p < 0.0001, and the data was homogenous (p= 0.97, I^2=0) (**Figure 3**).

Change in Inventory of Depression and Anxiety Symptoms (IDAS)

The pooled data from two studies [21, 35] with a total sample of 222 showed that after four weeks of intervention D.CBT have less change effect when compared to the control (SMD = 0.56; 95%CI 0.26 to 0.86; p =0.0002), and the data was homogenous (p= 0.60, I^2=0). On the contrary, after eight weeks of the intervention, D.CBT significantly decreased IDAS compared to the control (SMD = -0.48; 95%CI -0.78 to -0.18; p =0.002), and the data was homogenous (p= 0.52, I^2=0) (**Figure 4**).

Change in Edinburg Postnatal Depression Scale (EPDS)

The pooled MD showed no significant difference between the D.CBT group and control group after intervention (first reported endpoint before labour) and after 6 weeks of delivery as following: MD = -0.54; 95%CI -0.1.16 to 0.08; p = 0.09, and MD = -0.7; 95%CI -1.52 to 0.12; p = 0.14, respectively; and the data were pooled from six studies [19, 20, 27, 28, 31, 32] and three studies [20, 31, 32] respec-

Table 2. *Summary of the key features of the included studies.*

Study ID	Country	Trial registration	Gestational age at entry	Intervention	Control	length of intervention	Intervention details	Primary outcomes	Conclusion
Duffecy *et al.* 2019	USA	NCT02121015	Between 20- and 28-weeks	Share Web-based	Active; same as Share without the group activities	8 weeks	16 unguided didactic group activities. Provided Pregnancy and postpartum information. Also, 3-postpartum bust sessions (not considered in the current study). CBT Thought restructuring, mood monitoring, scheduling; monitoring; relaxing; goal-setting were used.	Symptoms of depression	Both social support and individual online therapies were effective in preventing postpartum depression, and peer support may help keep participants engaged.
Duffecy *et al.* 2022	USA	NCT02121015	Between 20- and 28-weeks	Share Web-based	Active; same as Share without the group activities	8 weeks	16 unguided didactic group activities. Provided Pregnancy and postpartum information. Also, 3-postpartum bust sessions (not considered in the current study). CBT Thought restructuring, mood monitoring, scheduling; monitoring; relaxing; goal-setting were used.	Depression and anxiety Symptoms	Group intervention wasn't better than individual. Many measurements improved with time, disregarding groupings. This research showed that mood improved with online postpartum depression prevention.
Felder *et al.* 2020	USA	NCT02805998	Self-reported pregnancy up to 28 weeks' gestation	Digital cognitive behavioral therapy	Standard care	6 weeks	6-week digital CBT-I sessions were offered through the website or iOS app. Sleep restriction, stimulation management, cognitive therapy, relaxation approaches, and sleep hygiene and education were used. Interactive program conducted by the digital therapist. Participants received automatic reminders to complete each session, a daily sleep log, and automated help. The online sleep community and library were available to participants.	Sleep diaries	When compared to traditional therapy, digital CBT had the following advantages: appropriate intervention for alleviating pregnancy-related insomnia.
Felder *et al.* 2021	USA	NCT02805998	Self-reported pregnancy up to 28 weeks' gestation	Digital cognitive behavioral therapy	Standard care	6 weeks	6-week digital CBT-I sessions were offered through the website or iOS app. Sleep restriction, stimulation management, cognitive therapy, relaxation approaches, and sleep hygiene and education were used. Interactive program conducted by the digital therapist. Participants received automatic reminders to complete each session, a daily sleep log and an automated. The online sleep community and library were available to participants.	Sleep diaries	Using digital-CBT while pregnant has been shown to have long-lasting effects in terms of alleviating insomnia after giving birth. Results give an early indication that digital-CBT.

Study ID	Country	Trial registration	Gestational age at entry	Intervention	Control	length of intervention	Intervention details	Primary outcomes	Conclusion
Forsell *et al.* 2017	Sweden	NCT02366429	Internet-delivered	Internet-delivered cognitive behavior therapy	TAU	10 weeks	Not reported clearly.	Depression symptoms	It was possible, appropriate, and effective to use ICBT with pregnant women who are experiencing prenatal depression.
Haga *et al.* 2018	Norway	ISRCTN91808706	Self-reported pregnancy up to 20 weeks gestation	Mamma Mia Web-based	TAU	16 weeks	Unguided program with 11 sessions that must be completed to go on. Step-by-step psychoeducational and cognitive/behavioral assignments on pregnancy. The intervention focused on: (1) prenatal knowledge; (2) expectations and attitudes; (3) attachment, emotion management, and help-seeking; and (4) relationship satisfaction and communication skills.	Depression symptoms	The results of the research showed that the global automated web-based intervention Mamma Mia was effective in reducing perineal depressive symptoms.
Kalmbach *et al.* 2020	USA	NCT03596879	Between 25 and 30 weeks	Sleepio Web-based CBTI program	Active; sleep education	6 weeks	6-session digital CBT for insomnia included. New sessions could only be started after completing the previous one. Interventions included sleep restriction, stimuli management, cognitive restructuring, progressive muscle relaxation, and sleep hygiene.	Depression symptoms and sleep quality	The use of digital CBTI throughout pregnancy and after delivery has been shown to increase both the quality and length of sleep. CBTI should be adapted as women go through pregnancy and the early years of parenthood to suit their changing needs and improve results.
Larsson *et al.* 2017	Sweden	NCT02306434	Between 17 and 20 weeks	Internet-based Cognitive Behavior Therapy	Standard care	NR	The program was based on Barlow et al three components theory of emotions, prior ICBT manuals for anxiety, and sections of the third wave of CBT treatment. The curriculum presents fear as a cognitive, behavioral, and bodily experience. Participants are taught to understand their emotional experience (fear), how to prevent unpleasant feelings, and how to employ acceptance, awareness, and exposure.	Women's birth preferences	Pregnancy and the postpartum period saw changes in women's birth choices independent of intervention. When compared to ICBT, women reported greater fear reduction and satisfaction with face-to-face therapy.
Loughnan *et al.* 2019	Australia	ACTRN12616000560493	Between 13 and 30 weeks	MUMmentum Web-based	TAU	4 weeks	Unguided CBT for anxious or depressed pregnant women. It included three slide-illustrated lessons on self-managing anxiety and depression. The intervention comprised psychoeducation, relaxation methods, thought challenging, organized issue solving, active planning and monitoring, grade exposure, assertive communication, relapse prevention, sleep hygiene, enjoyable activities, and self-care plans.	Depression symptoms	This was the first research to examine short unguided prenatal iCBT. Additional RCTs were needed to confirm therapy effectiveness, especially for anxiety reduction.

Study ID	Country	Trial registration	Gestational age at entry	Intervention	Control	length of intervention	Intervention details	Primary outcomes	Conclusion
Puertas-Gonzalez *et al.* 2022	Spain	NCT03404141	Between 12 and 28 weeks	online cognitive behavioral therapy group	TAU	8 weeks	Two specialists with considerable training and expertise in psychological treatment led 8 weekly online cognitive behavioral therapy sessions lasting 1.5–2 hours each. Before the epidemic, these psychologists ran the program face-to-face. After a welcome, participants recounted how their week had gone and was given feedback on their behavioral self-records; they were then taught a new skill and performed it via role-play; questions were addressed, and they were assigned homework.	Stress, resilience, and psychopathology	The online CBT group had reduced rates of pregnancy-specific stress and perceived stress, as well as improved resilience and decreased anxiety, sadness, and OCD symptoms.
Rondung *et al.* 2019	Sweden	NCT02306434	Between 17 and 20 weeks	Internet-Based Cognitive Behavioral Therapy	Standard care	NR	The intervention was inspired by UP, a face-to-face CBT for anxiety and mood disorders. 7 UP courses were utilized to make study aids (eg, about the content and order of psych educative elements and using FOB-specific examples). UP Module 6 is about symptom exposure. Missing from the pregnant sample. We avoided cognitive reappraisal to avoid perceived hazards, particularly online (as presented in Module 4 in the UP). We focused on cognitive defusion, automatic thinking, and reappraisal.	Fear of Birth	In both intervention groups, fear of delivery reduced with time; although the drop was bigger in the guided ICBT group, time alone was the most obvious. Poor ICBT adherence indicated poor feasibility and acceptability.
Sikar *et al.* 2016	Ireland	NR	Between 10 and 22 weeks	Gratitude and Mindfulness Web-based	TAU	3 weeks	The unguided intervention focused on two primary components: (1) a gratitude notebook to encourage pregnancy reflection; (2) mindfulness audio tracks, especially the body scan exercise, which focused on breathing and body awareness.	Prenatal stress	Pregnancy stress may be mitigated with the use of short mindfulness and gratitude-oriented intervention.
Sun *et al.* 2021	China	ChiCTR1900028521	Between 12 and 20 weeks	Spirits Healing Smartphone-based	Active; attention control group	8 weeks	Unguided CBT targets prenatal depression, negative emotions, and physical changes. Mindfulness practices included videos, books, and audio. It includes 8 sessions on mindfulness, increasing concentration on the present, encouraging awareness of unpleasant emotions, accepting problems, realizing that ideas are merely thoughts, supporting everyday happiness, and maintaining mindfulness practice.	Depression symptoms	Those mothers who were at risk for developing perinatal depression during pregnancy might benefit from mindfulness training delivered by smartphone. Women who had not yet given birth are an encouraging demographic who may get more from mindfulness training.

Study ID	Country	Trial registration	Gestational age at entry	Intervention	Control	length of intervention	Intervention details	Primary outcomes	Conclusion
Yang *et al.* 2019	China	NR	Between 24 and 30 weeks	Mindfulness intervention Smartphone-based	TAU	8 weeks	Unguided mindfulness was developed by a multidisciplinary team and overseen by mindfulness-trained nurses. Four mindfulness sessions were videotaped and shared on Wechat with text, photographs, and audio. Body scanning, meditation, and relaxation were incorporated. In each session, participants reviewed and taught mindfulness topics. Intervention includes homework.	Depression and anxiety Symptoms	According to the findings, an online mindfulness intervention might be an effective method for teaching women to practice mindfulness.

NR: not reported; TAU: treatment as usual; CBT: cognitive behavior therapy..

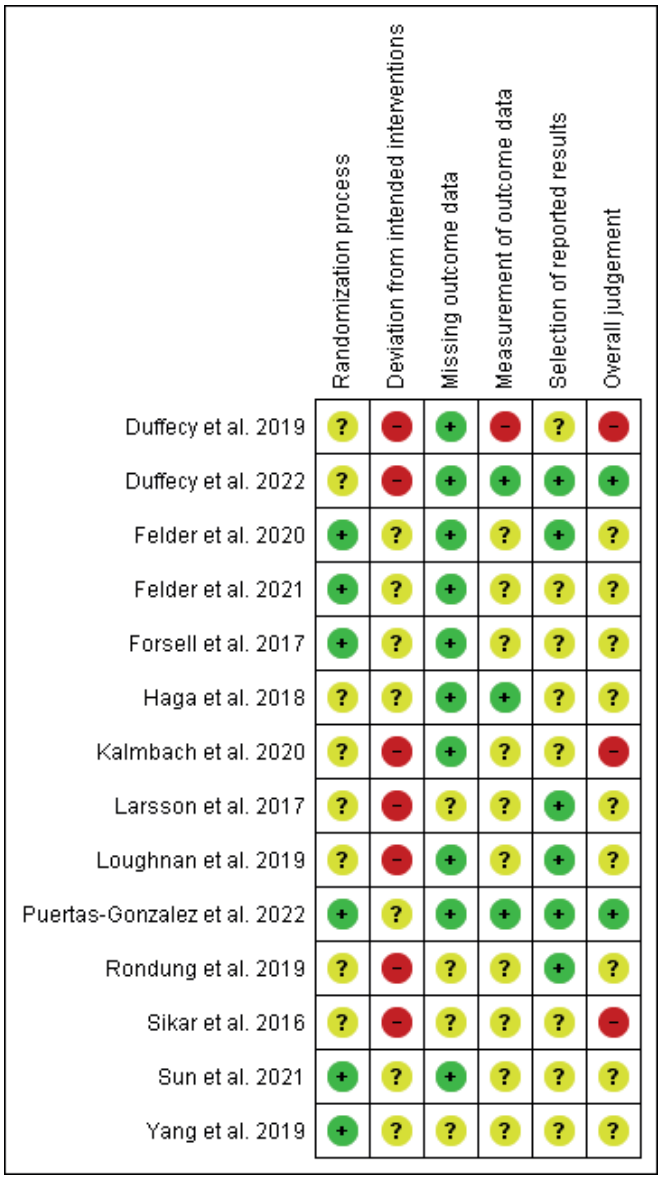

Figure 2. *Summary of the risk of bias.*

tively. The data was homogenous as follows: p = 0.19, I^2 = 32%, and p = 0.10, I^2 = 57% (**Figure 5**).

Generalized Anxiety Disorder Scale (GAD-7)

Data from four studies [19, 26, 27, 32] with a total sample of 392 showed that after intervention (first reported endpoint before labour), D.CBT significantly decreased GAD-7 when compared to control (MD = -1.73; 95%CI -2.63 to -0.83; p = 0.0002), and the data was homogenous (p = 0.18, I^2 = 38%) (**Figure 6**).

Change after intervention in Pregnancy Distress Questionnaire (PDQ)

The pooled data from two studies [28, 29] with a total sample of 181, showed no significant effect for

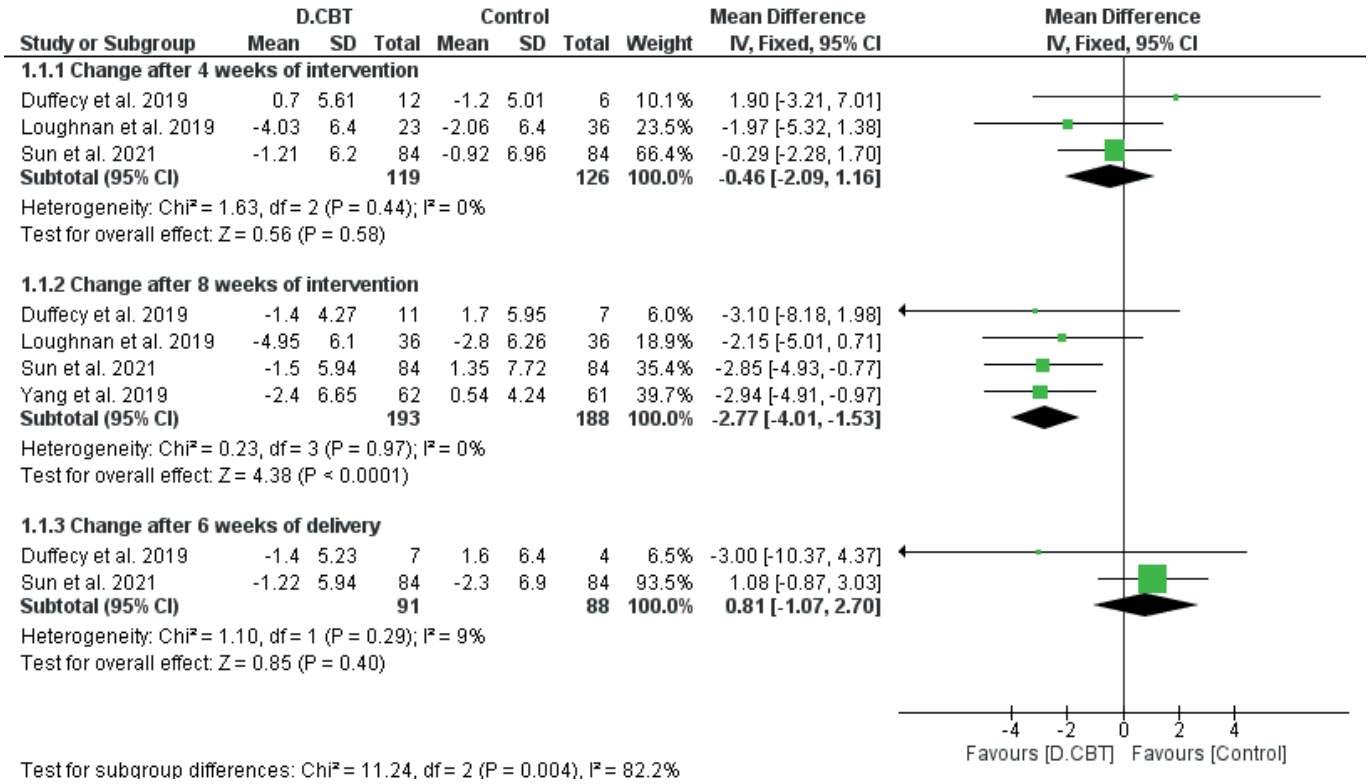

Figure 3. *Change in Patient Health Questionnaire-9 (PHQ-9).*

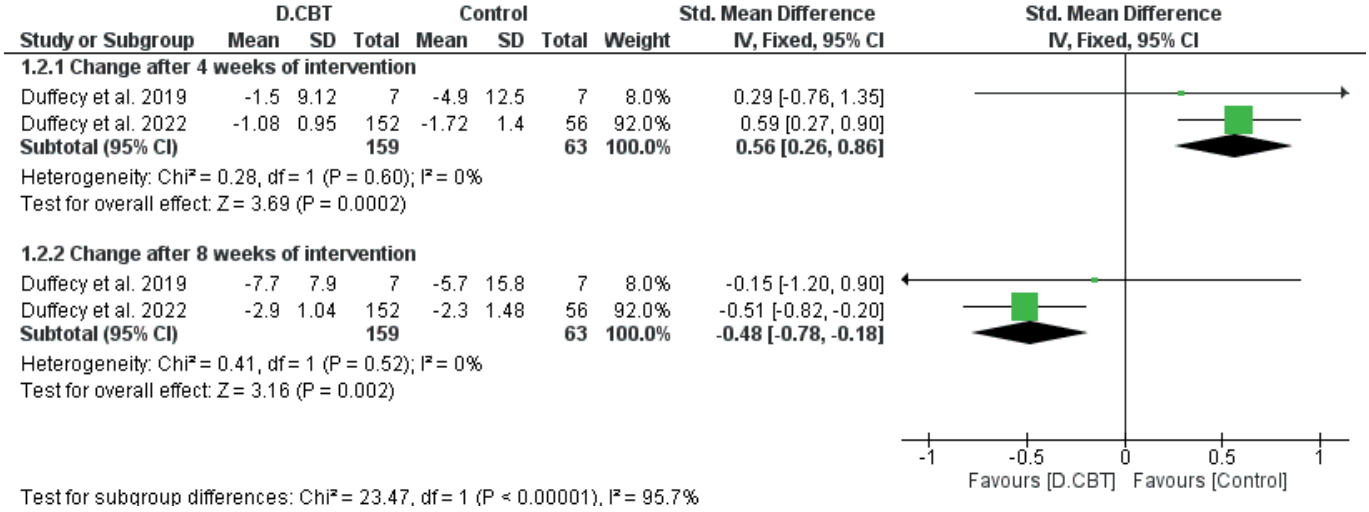

Figure 4. *Change in Inventory of Depression and Anxiety Symptoms (IDAS).*

D.CBT compared to the control (MD =-2.4; 95%CI -5.17 to 0.38; p =0.09), and the data was homogenous (p= 0.56, I^2=0) (**Figure S1**).

Pittsburgh Sleep Quality Index (PSQI)

There was no meaningful difference between the D.CBT group and control group after intervention (first reported endpoint before labour) and postpartum following: MD = -0.39; 95%CI -1.42 to 0.64; p = 0.46, and MD = -0.4; 95%CI -1.52 to 0.73; p = 0.49, respectively; and the data were pooled from two studies [27, 31]. The data was homogenous as follows: p= 1, I^2=0, and p= 0.4, I^2=0, respectively (**Figure S2**).

Change in Insomnia Severity Index (ISI)

Pooled data from two studies [31, 32] with a total sample of 133 showed that D.CBT significantly decreased ISI when compared to the control (MD =

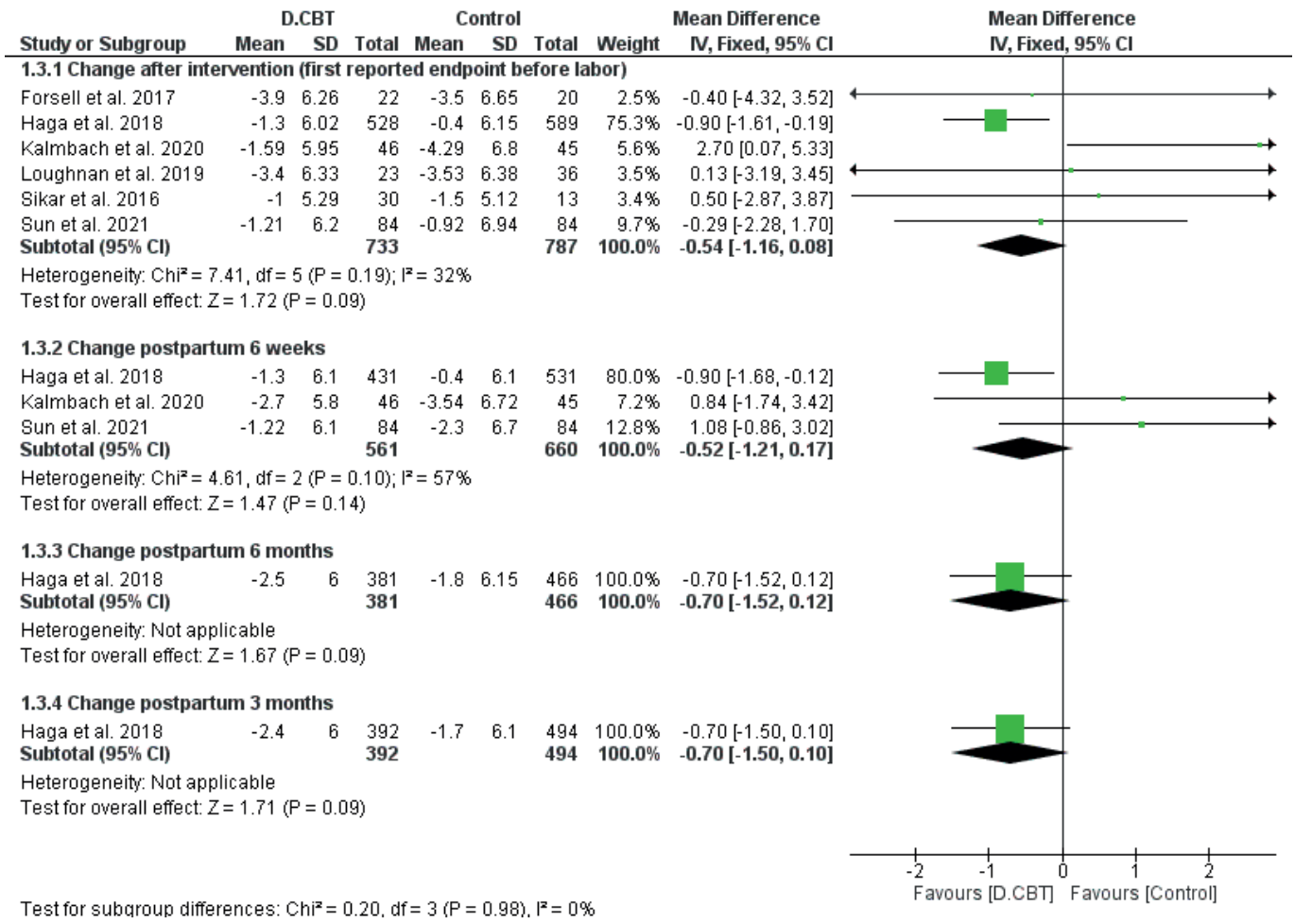

Figure 5. *Change in Edinburg Postnatal Depression Scale (EPDS).*

-3.45; 95%CI -5.66 to -1.24; p = 0.002), and the pooled results were homogenous (p = 0.68, I^2 = 0) (**Figure S3**). The summary of our outcomes is in **Table 3**.

Narrative evidence

Four studies have not been included in our meta-analysis [19, 25, 33, 34]. According to Felder *et al.* [33] and Felder *et al*. [34], CBT-I treatments were effective in reducing sleeplessness, as well as mild to moderate levels of anxiety and depression. Digital CBT-I has great promise as a treatment for insomnia in pregnant women due to the intervention's scalability, its low-risk profile, and its proven efficacy. Both single and multiparous women were included in the study by Rondung *et al*. [25] regarding the Fear of Birth scale (FOB), both CBT and the control group showed significant reduction but with no significant differences between them. One year after delivery, the CBT group showed a larger decrease in FOB, but due to the limited adherence to the CBT over time, it was difficult to interpret this finding. Larsson *et al*. [30] reported that no statistically significant improvement was detected between CBT and the standard care group in the preference for caesarean section or birth experience. However, less treatment satisfaction among the female in the CBT group was found.

DISCUSSION

The current meta-analysis set out to evaluate the efficacy of digital CBTs in alleviating preclinical symptoms of depression, anxiety, and stress and improving sleep quality for pregnant women.

Change in Patient Health Questionnaire-9 was the primary endpoint, and the findings showed that, after four weeks of intervention or six weeks of delivery, there were no significant differences between the D.CBT and control groups. However, after eight weeks of treatment, the D.CBT significantly decrease in PHQ-9 compared to the control group. Another finding was the effect of treatment on EPDS. After intervention (first reported endpoint before labour) and

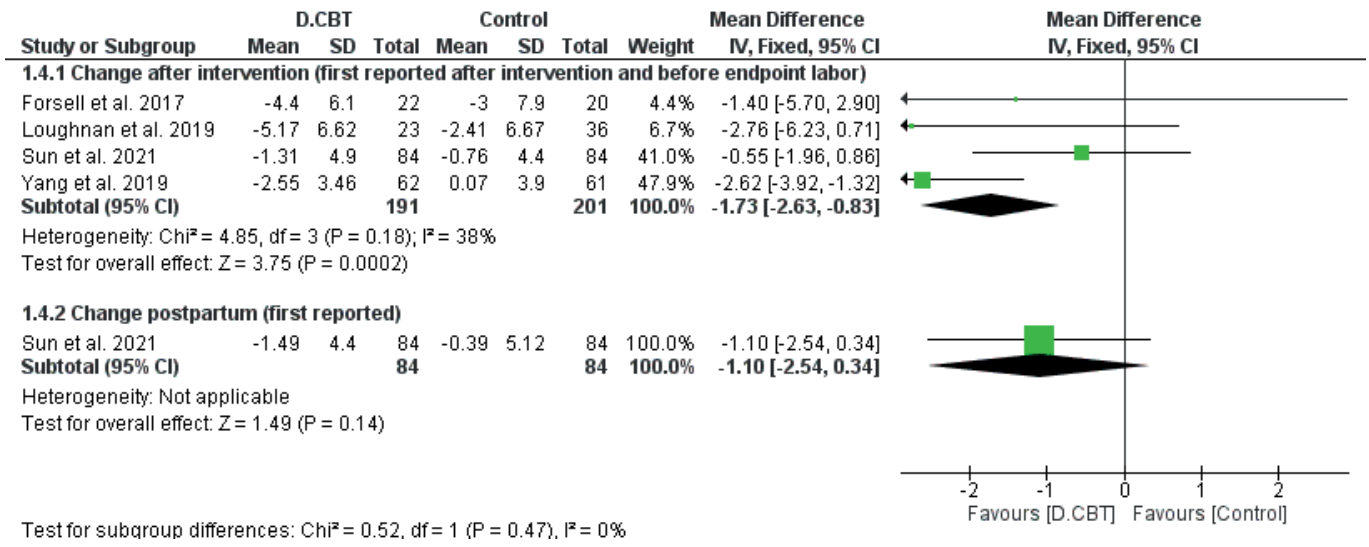

Figure 6. *Change in Generalized Anxiety Disorder Scale (GAD-7).*

Table 3. *Summary of the outcomes.*

Outcome	Time point	Effect estimate	Significance
Change in Patient Health Questionnaire-9 (PHQ-9)	After four weeks	MD = -0.46; 95%CI -2.09 to 1.16; p = 0.58	Non-Significant
	After six weeks	MD = 0.81; 95%CI -1.07 to 2.7; p = 0.40	Non-Significant
	After eight weeks	MD = -2.77; 95%CI -4.01 to -1.53; p < 0.0001	Significant
Change in Inventory of Depression and Anxiety Symptoms (IDAS)	At four weeks	SMD = 0.56; 95%CI 0.26 to 0.86; p = 0.0002	Significant
	At eight weeks	SMD = -0.48; 95%CI -0.78 to -0.18; p = 0.002	Significant
Change in Edinburg Postnatal Depression Scale (EPDS)	The first reported endpoint before labor	MD = -0.54; 95%CI -0.1.16 to 0.08; p = 0.09	Non-Significant
	After 6 weeks of delivery	MD = -0.7; 95%CI -1.52 to 0.12; p = 0.14	Non-Significant
Generalized Anxiety Disorder Scale (GAD-7)	At last follow-up	MD = -1.73; 95%CI -2.63 to -0.83; p = 0.0002	Significant
Change after intervention in Pregnancy Distress Questionnaire (PDQ)	At last follow-up	MD = -2.4; 95%CI: -5.17 to 0.38; p = 0.09	Non-Significant
Pittsburgh Sleep Quality Index (PSQI)	The first reported endpoint before labor	MD = -0.39; 95%CI: -1.42 to 0.64; p = 0.46	Non-Significant
	Postpartum	MD = -0.4; 95%CI: -1.52 to 0.73; p = 0.49	Non-Significant
Change in Insomnia Severity Index (ISI)	At last follow-up	MD = -3.45; 95%CI: -5.66 to -1.24; p = 0.002	Significant

six weeks postpartum, there was no significant difference between the D.CBT group and the control group. The analysis of change in the PSQI PDQ showed no significant difference between D.CBT and control. On the other hand, D.CBT significantly decreased ISI and GAD-7. Lastly, the D.CBT was better than the control in reducing IDAS after 4 weeks of treatment, as opposed to after eight weeks of treatment.

Regarding potential predictors of postpartum depression, one of the risk factors for postpartum mood disorders is a history of, or a tendency toward, expressing anger. In particular, releasing anger at other people or things in the environment (anger expression out) is a reliable indicator of future occurrences of postpartum depression (PPD), while the opposite behaviour – repressing or stuffing anger inside (anger expression-in) – may increase the likelihood of developing PPD [36]. Moreover, preventative measures in maternal mental health greatly benefit from the early detection of signs that may suggest the onset of depression and other mood disorders [37, 38]. We were unable to make solid conclusions about the usefulness of digitalized CBT for depression during pregnancy due to a lack of data and a high risk of bias in several of the included trials. Also, it should be highlighted that the included trials employed conventional care, active control, or another intervention as control groups, which may clar-

ify why the majority of the studies had different impact sizes. However, our findings provide some positive evidence for the efficacy and benefits of digitalized CBT for expectant mothers.

A previous study has shown that depression symptoms during pregnancy may predict the occurrence of postnatal depression symptoms [39]. Prenatal interventions provide a window of opportunity for women to acquire and improve coping skills before the onset of depressive symptoms. Due to the short duration of pregnancy, interventions that can be completed in less time may be more desirable to the pregnant. CBT is well-suited for technological improvements that may streamline its delivery and reduce its already low overhead costs because of its problem-oriented orientation and its foundation in patients' cognition and behaviour patterns.

National Institute for Health and Care Excellence (NICE) [40] reported that CBT may be used for depression, generalized anxiety disorder, panic disorder, obsessive-compulsive disorder, and post-traumatic stress disorder [40]. Doctors and nurses should be aware that CBT is often used in conjunction with medication treatment. Compared to just using the medication, CBT has been demonstrated to be more beneficial, or at least as effective. A mental health nurse can also educate patients about their treatment choices and is a good resource for those who suspect they may be suffering from a mental health condition. Moreover, a primary care physician is in a prime position to introduce and track the efficacy of cognitive-behavioural treatment.

Cognitive behavioural therapy (CBT) has evolved through three waves; the first, the first generation, is grounded in operant and classical conditioning, while the second, the second generation, emphasizes information processing. The emergence of third-wave CBT was a response to the success of the first two waves, with an emphasis on contextual and experiential change strategies [41, 42].

The MUMentum Pregnancy Program from Australia showed similar findings [19]. According to their results, compared to traditional treatment, CBT was more effective in alleviating feelings of distress and anxiety while negatively affecting depression. Their results imply that rapid, unsupervised CBT may be widely provided, especially among women in rural and regional Australia. To supplement more intensive CBT courses and in-person treatment, MUMentum Pregnancy may be utilized as a first-line intervention for pregnant women who test positive for depression, distress, or anxiety.

Regarding the available pharmacological clinical practice guidelines (CPGs) for depression in pregnancy, Molenaar *et al*. showed that, despite the lack of evidence, some recommendations were advocated for maintaining antidepressant treatment during pregnancy. Psychotherapy (especially CBT) is recommended for mild to moderate depression, whereas sertraline is recommended for severe depression. Women using antidepressants should breastfeed and keep a close eye on their infants [43]. Nonpharmacological therapies such as CBT and interpersonal therapy are advised as first-line treatment for women with moderate to severe perinatal depression symptoms because of the absence of CPGs for the pharmaceutical treatment of peripartum depression [44-46]. Because the postpartum period is so crucial to a woman's health, it is important to set aside dedicated time to counsel women on how to manage and the check to do during this time when their attention is naturally focused solely on the well-being of their newborn. Quaresima *et al*. [47] found that recent Gestational diabetes mellitus was not diagnosed in the majority of women because they did not undergo the postpartum screening for glucose intolerance test. Their lack of motivation for self-care, and their primary care physicians' inability to adequately counsel them. Based on these results, they have spread information about the benefits of a patient-centered educational consultation during the last few weeks of pregnancy.

Our results were somewhat similar to the results of the previous meta-analysis conducted by Mancinelli *et al*. specifically in depression-related outcomes [18]. Regarding depression, by pooling PHQ-9 and EPDS together, they reported a significant effect for D.CBT in decreasing depressive symptoms after treatment, but there was no significant difference after six months of labour. We reported the results of each of the two depression-related scales alone: PHQ-9 and EPDS. Also, PHQ-9 data were analysed after four weeks and eight weeks of treatment, and after six weeks of delivery. There was no significant difference after four weeks of treatment and after six weeks of delivery, but after eight weeks of treatment, D.CBT significantly decreased the PHQ-9 scale. Regarding EPDS results, there was no significant difference after treatment or six weeks postpartum. Regarding sleep quality results, they reported the results after treatment or after six weeks of labour by pooling two studies with different scales: PSQI, and ISI. They found no significant difference between D.CBT and control after treatment and postpartum. However, we analysed the data for PSQI and ISI, each alone.

Our results were similar to the last meta-analysis in PSQI; however, D.CBT significantly decreased insomnia measured by the ISI scale. Additionally, we investigated the data for three other important scales not reported in the previous meta-analysis: GAD-7, IDAS, and PDQ, and their results reported before. They analysed the data collected after the intervention, ignoring pre-treatment values which may misrepresent the therapy's true impact. While our results are likely to be more confident, as we calculated and then pooled the changes between post-treatment and pre-treatment values. Also, in the previous meta-analysis, when an outcome was measured using different scales in the same study, they extracted the data for each scale and pooled them in the same analysis, that may affect the true effect size as the same number of patients pooled twice affecting the total sample size of the outcome. On the other hand, we extracted and analysed the data regarding each scale alone, thus we did not duplicate the sample, which also is much easier to interpret the results and facilitate its application in clinical practice.

Our study has some strengths points as the following: the PRISMA checklist and the Cochrane Handbook for systematic reviews were used to guide our work. Only RCTs were included insuring a high class of evidence. Moreover, rigorous inclusion and exclusion criteria were enforced to reduce heterogeneity as possible. Most of the detected heterogeneity could be resolved. Also, we performed a subgroup analysis to investigate the efficacy at different time points. Additionally, unlike the previous meta-analysis, in which only the post-treatment data were retrieved and analysed, which may affect the results due to the difference between the groups in their baseline values, we calculated the difference between post- and pre-treatment to capture the actual change and impact of the intervention. The main limitation of our study was that we could not do a more thorough analysis due to the restricted outcomes examined in each study. Also, the poor quality of some included studies may affect their results. Additionally, there are some differences in the control group among studies; however, there was no heterogeneity in our analysis. Our meta-analysis was also helpful in highlighting the limitations of the literature that are crucial to future research, emphasizing the necessity and significance of developing D.CBT programs to support pregnant women with sub-clinical psychological symptoms, especially given that the latter frequently go unappreciated. Additionally, by carefully concentrating on the user experience quality during the creation of these digital solutions, adherence to the treatments should be maintained. Greater investment in preventative programs should be made by the integrated care approach, promoting the coordination of primary and secondary mental health services and lowering health care system costs.

CONCLUSIONS

Digital cognitive behavioural therapy (D.CBT) shows some promising outcomes in treating pregnant women's depression and sleep difficulties as decreasing patient health questionnaire-9 (PHQ-9), depression and anxiety symptoms (IDAS), generalized anxiety disorder scale (GAD-7), and insomnia severity index (ISI), especially after eight weeks of the intervention. However, these results should be used under caution because of the large variabilities between the included clinical trials. Also, future RCTs are highly recommended for further assessment of the efficacy of D.CBT.

COMPLIANCE WITH ETHICAL STANDARDS

Author contributions

All the authors: Conceptualization, design, writing – review & editing. H.A.F., A.M.O., R.A.E.: Data acquisition. A.A.M., W.A.B., G.S.E., M.A.A., N.S.E.: Data analysis and interpretation. H.I.H., S.T.A., H.S.M., W.H.T., O.A.H., H.A.F.: Writing - original draft.

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Study registration

N/A.

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

N/A.

Informed consent

N/A.

Data sharing

Because no datasets were created or examined during this study, data sharing is irrelevant to this article. We don't have any saved data since this is a systematic review and meta-analysis of previously published research.

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SUPPLEMENTS

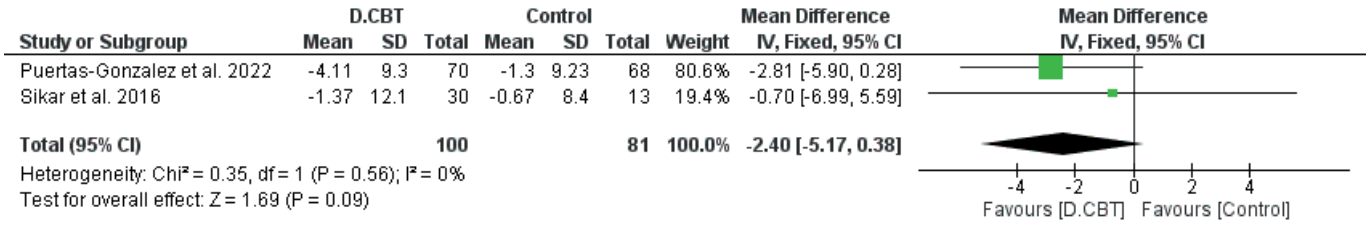

Figure S1. *Change after intervention in Pregnancy Distress Questionnaire (PDQ).*

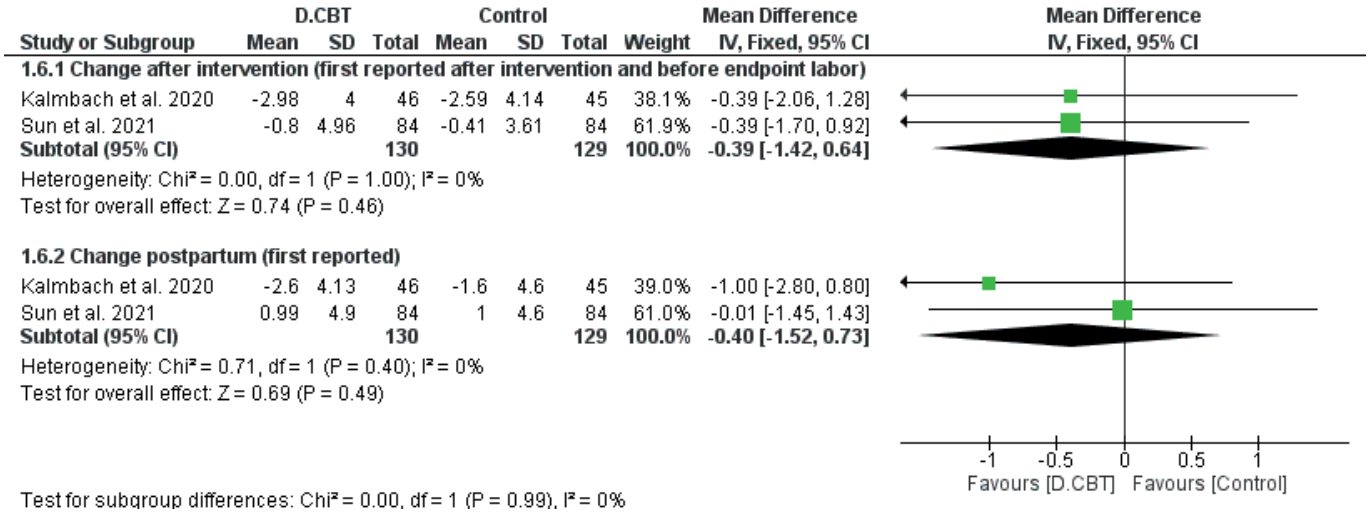

Figure S2. *Randomized control trial (PSQI).*

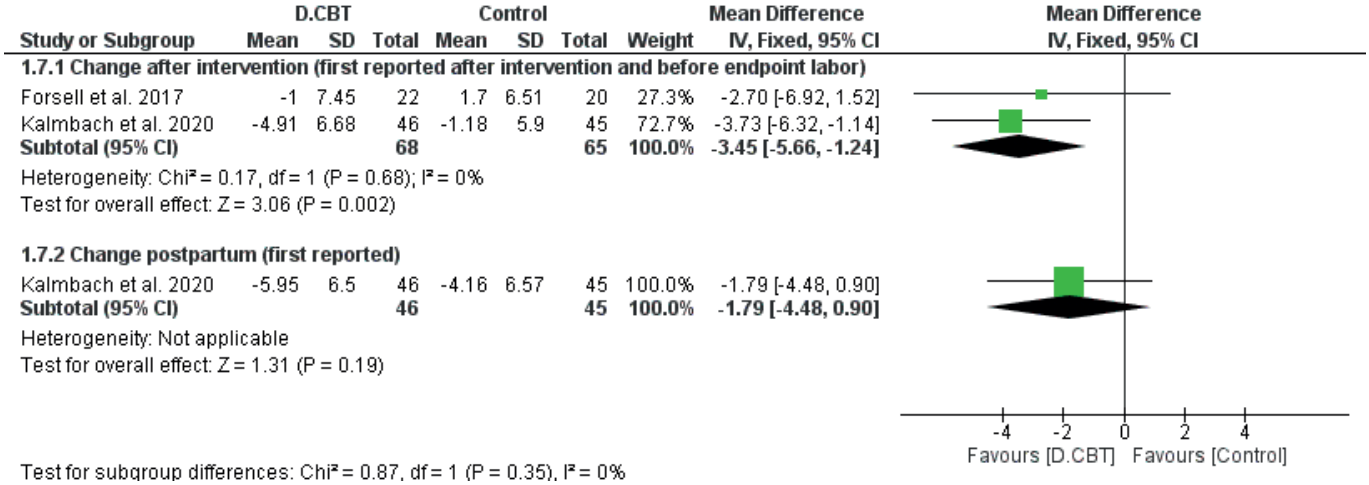

Figure S3. *Change in insomnia severity index (ISI).*