

Supplementary Online Content

Felder JN, Epel ES, Neuhaus J, Krystal AD, Prather AA. Efficacy of digital cognitive behavioral therapy for the treatment of insomnia symptoms among pregnant women: a randomized clinical trial. *JAMA Psychiatry*. Published January 22, 2020.
doi:10.1001/jamapsychiatry.2019.4491

eMethods. Changes to Eligibility Criteria, Sample Size Considerations, and Statistical Analysis

eResults. Analysis Adjusting for Primiparity and Sensitivity Analysis

eTable. Sensitivity Analysis Results of Linear Mixed-Effects Analysis to Assess Categorical Time (Baseline to Postintervention) by Group (Digital CBT-I vs Standard Treatment) Interaction

This supplementary material has been provided by the authors to give readers additional information about their work.

eMethods. Changes to Eligibility Criteria, Use of Nonstudy Treatments, Sample Size Considerations, and Statistical Analysis

Changes to Eligibility Criteria

After trial commencement, three changes were made to the eligibility criteria. First, in order to enroll women whose insomnia symptoms onset during pregnancy, we changed the eligibility criteria to include women who reported on the Sleep Condition Indicator that they experienced insomnia symptoms ≥ 1 month, in contrast to the DSM5 criterion that requires symptoms ≥ 3 months. Second, we modified our criteria to include women with Insomnia Severity Index scores ≥ 11 . Finally, as we neared our enrollment target, we modified our eligibility criteria to focus our remaining enrollment on Black women, who were under-enrolled.

Sample Size Considerations

Existing literature comparing CBT-I to TAU for the treatment of insomnia disorder suggests a large effect size (Cohen's $d=0.95$) for baseline to post-intervention differences and a medium effect size (Cohen's $d=0.69$) for baseline to 8-week follow-up on sleep efficiency.⁸ As for depression symptom severity, existing literature comparing CBT-I to TAU suggests a small to medium effect size (Cohen's $d=0.20-0.69$) for baseline to post-intervention differences and a medium effect size (Cohen's $d=0.48-0.78$) for baseline to 8-week follow-up.^{14,31}

Statistical Analysis

For a sensitivity analysis, we fit mixed models that used a categorical indicator of timepoint, as opposed to a continuous measure of time. Models included the sleep (i.e., ISI, diary-defined sleep efficiency, diary-defined sleep duration, PSQI, SCI) and mental health outcomes (EPDS, GAD-7) as the dependent variables, along with time, intervention group, and time by group interactions as the predictors. The models also included random intercepts to accommodate the correlation among the repeated responses within women.

eResults. Analysis Adjusting for Primiparity, Sensitivity Analysis, and Use of Nonstudy Treatments

Analyses Adjusting for Primiparity

Participants randomized to TAU were more likely to be primiparous compared to women randomized to digital CBT-I (n=66, 64.1% vs n=46, 43.8%; $\chi^2(1) = 8.60, p=.003$). Although rates of primiparity were statistically different between the two treatment groups, subsequent analyses showed that results of mixed effects analyses that adjusted for primiparity were virtually identical to those from the previously specified models that did not adjust for this variable. Thus, we present results from models without adjustment for primiparity. There were no other statistically significant differences in participant baseline characteristics.

Sensitivity Analysis

Sensitivity analyses that utilized a categorical indicator of timepoint were consistent with the primary analyses. Results are available in eTable 1.

eTable. Sensitivity Analysis Results of Linear Mixed-Effects Analysis to Assess Categorical Time (Baseline to Postintervention) by Group (Digital CBT-I vs Standard Treatment) Interaction

Outcome	Weekly Change for Digital CBT-I	Weekly Change for Standard Treatment	95% CI for Time-by-Group Interaction	Interaction χ^2	P value
Insomnia symptom severity	-6.21	-2.31	-5.17, -2.62	33.04	<0.0001
Sleep efficiency	8.88	0.78	4.28, 11.94	16.47	0.0001
Sleep duration	0.38	0.02	0.002, 0.71	3.85	0.05
Global sleep quality	-3.25	-0.21	-3.86, -2.21	46.16	<0.0001
Insomnia caseness	-2.78	-0.18	-3.79, -1.40	22.55	<0.0001
Depressive symptom severity	-2.25	-0.11	-3.15, -1.13	16.52	<0.0001
Anxiety symptom severity	-1.97	0.04	-2.83, -1.17	21.08	<0.0001

Note. Chi-square is from a likelihood ratio test.