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BRIEF COMMUNICATION

Smartphone-assisted online brief cognitive behavioral therapy to treat maternal depression: findings of a randomized controlled trial

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Objective: To test the efficacy of smartphone-assisted online brief cognitive behavioral therapy (b-CBT) to treat maternal depression compared to online brief CBT plus an active control app.
Methods: A randomized controlled trial was conducted. Assessments were performed at baseline (T0), midpoint (T1, week 4-5), post-treatment (T2, week 8), and follow-up (T3, 2-month postnatal follow-up) by blinded interviewers. The primary outcome was depression measured by the Edinburgh Postnatal Depression Scale (EPDS) at T2. We also assessed anxiety, stress, sleep quality, well-being, physical activity, treatment response, and offspring child behavior problems.
Results: Eighty-one participants were randomized to the intervention (n=37) or active control (n=44) groups. Seventy-one participants completed the post-treatment assessment or reported primary outcome data. No differences were found between the intervention and active control groups regarding maternal depression or other mental health outcomes. Overall, we found large within-group effect sizes, with 80% of the total sample responding to treatment.
Conclusions: Our data showed no difference between the groups, suggesting that adding apps to psychotherapy treatment may not enhance treatment effects on prenatal depression. A within-groups analysis showed that most participants with depression responded to treatment; however, future studies are needed to confirm whether this effect is related to factors other than the intervention.

Keywords: Maternal depression; clinical trial; cognitive-behavior therapy; digital intervention; smartphone app

Introduction

Prenatal depression is a global health challenge with high prevalence estimates, disproportionately affecting people in low-and middle-income countries (LMICs).[1] Current estimates suggest that 51% of patients with depression do not receive treatment during pregnancy.[2] To circumvent this problem, interventions delivered through digital technology may be an important avenue to ensure scalability, since smartphones and computers have become ubiquitous. More specifically, smartphone apps developed to deliver self-guided cognitive behavioral therapy (CBT) may work in synergy with CBT delivered online by a therapist.[3] However, the potential of such strategies to treat maternal depression remains untapped.[4] More importantly, to the best of our knowledge, no study so far has tested the use of digital technology to deliver an intervention to treat maternal depression in LMICs, where most mothers with depression live. Therefore, we developed Motherly, an app designed to treat maternal depression using behavioral activation (BA) and psychoeducation. This app was used alongside online brief CBT (b-CBT) consisting primarily of BA adapted for delivery in four sessions throughout an 8-week period. We sought to test the efficacy of this treatment program to reduce depression symptoms during pregnancy.

Methods

Design, participants, and setting

We conducted a randomized controlled trial (RCT) to test the efficacy of a smartphone-assisted online b-CBT intervention to treat maternal depression. Participants with the following characteristics were included in the study: a) age 16-40 years; b) Edinburgh Postnatal Depression Scale (EPDS) score > 7[5]; c) 17-26 weeks of

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gestational age; d) literate; e) ownership of a personal smartphone. Exclusion criteria were: a) pregnancies classified as high-risk; b) visual, auditory, or intellectual disabilities, or chronic diseases affecting fetal development; or c) other severe/chronic mental disorders.

Sample size (n=71) was calculated based on a standardized effect size (ES) of 0.65 on depression (type I error probability = 5%, statistical power = 80%, two-tailed test, with a dropout rate = 15%). Our study was approved by the ethics committee at Faculdade de Medicina da Universidade de São Paulo.

Procedures

Potential participants recruited via social media responded to an online survey containing questions on the eligibility criteria. If the criteria were met, the respondent was invited to a baseline online assessment in which instructions were provided for app installation and registration to obtain login information. Randomization and allocation occurred automatically in real time using PHP 7. Due to the real-time nature of the randomization procedure, the minimal number of participants needed in each group (n=35) was not met when the total sample size was 71. Therefore, we proceeded until the minimal number needed in each group was reached (n=81, allocation ratio = 1:1.2).

Participants were randomly assigned to receive 1) intervention: Motherly app + online b-CBT or 2) active control: educational app + online b-CBT. Treatment duration was eight weeks for both groups. Participants were assessed by blinded trained psychologists at baseline (T0), weeks 3-4 (mid-treatment; T1), week 8 (post-treatment; T2), and 2-month postnatal follow-up (T3). Data were stored in Research Electronic Data Capture (REDCap).

Intervention and active control

The intervention group received the Motherly 1.0 app and online b-CBT. Motherly is a smartphone app developed by the authors and designed to promote positive life habits known to improve mental health. The app is based on three main concepts – psychoeducation, behavior monitoring, and gamification – and encompasses a package of interventions divided into eight modules: mental health, sleep, nutrition, physical activity, social support, prenatal support, postnatal support, and library of health-related content. The main driver of change is BA delivered via the mental health module, which was designed to assist users in scheduling, engaging in, and monitoring activities according to a plan, to avoid acting exclusively according to their mood. Further details of the app can be found elsewhere.[6]

An online b-CBT protocol for depression was delivered to participants by CBT psychotherapists. b-CBT consisted primarily of BA adapted to be delivered in four sessions throughout an 8-week period. The structure of the sessions was based on a manual specifically developed for this study by the authors. Details of the CBT intervention can be found in the Supplementary Methods (available online only) and elsewhere.[6]

The active control group received a modified version of the Motherly app consisting of articles covering aspects of pregnancy, maternal physical/mental health, and child development. All other functionalities, such as BA and activity scheduling, were not present in this version. In addition, participants also received the same brief online CBT protocol as the intervention group. Psychotherapists were aware of randomization statuses so that they could guide participants on how to best use both versions.

Assessment

Sociodemographic and clinical information was collected at baseline. The primary outcome was depression at T2 measured by the EPDS.[5] We also assessed the following secondary outcomes: anxiety (Generalized Anxiety Disorder Scale),[7] stress (Perceived Stress Scale),[8] sleep quality (Single-item Sleep Quality Scale),[9] physical activity (International Physical Activity Questionnaire-Short Form),[10] psychological well-being (Ryff's Psychological Well-being Scale),[11] treatment response (Clinical Global Impression-Improvement [CGI-I]),[12] child development (Survey of Well-being of Young Children),[13] and child behavior problems (Baby Pediatric Symptom Checklist).[13]

Statistical analysis

We used Welch's and Fisher's exact tests to investigate differences between groups at baseline. To analyze the impact of the intervention, we used linear regressions with each outcome as dependent variable and randomization status as an independent variable. In order to include participants with missing data, we used multiple imputation by chained equations (100 imputations). Pooled estimates of means were extracted, and ES were calculated. Tests were 2-sided, and p-values < 0.05 were considered statistically significant. Analyses were conducted using Stata 17.

Ethics statement

All participants were required to provide informed consent. Participants with suicidal ideation and/or severe functional impairment were referred to specialized care. The study was registered at clinicaltrials.gov (NCT04495166).

Results

Recruitment and retention

From August to September 2020, 320 people registered to be part of our study. After ascertainment of eligibility criteria, 81 participants were randomized to intervention (n=37) or active control (n=44). Figure S1, available as online-only supplementary material, presents the study flowchart. Seventy-six participants (93.8%) received at least one psychotherapy session. The mean number of

psychotherapy sessions delivered was 3.3 (SD = 1.2). Seven participants discontinued online b-CBT during the study and only one participant opted to uninstall the app. Seventy-one participants completed the post-treatment component or reported at least primary outcome data. Not completing assessments was not associated with randomization status.

Sample characteristics

The mean age of participants was 32.5 (SD = 4.7) years, while the mean gestational age in weeks was 19.4 (SD = 3.1). Most participants were married or in a stable relationship (87.6%). The number of prenatal visits was associated with randomization status (p = 0.038) (Table 1).

Intervention effects

No differences in depression scores were found between the groups at post-treatment (p = 0.688) and follow-up (p = 0.338). Within-group ES showed improvements in depression and mental health. Secondary outcomes were also not associated with the intervention (Table 2). According to the CGI-I, 80% of the sample responded to treatment at T2. Table S1 shows missing data patterns by outcome. Child outcomes were analyzed (Table S2), but given that no impact was detected on maternal outcomes, these data were not interpreted. Table S3 reports the ES of treatments at different time points. Tables S1, S2, and S3 are available as online-only supplementary.

Discussion

We tested a smartphone-assisted online b-CBT program for maternal depression. To the best of our knowledge, this was the first study to test such a program using an RCT design in a LMIC.

We did not find significant differences between the groups in any of the outcomes. These results could be potentially explained by the fact that CBT is an intervention with a large effect, and therefore it may be difficult to increase this effect by adding other components. Also, participants may have had difficulties using the app and/or sufficiently engaging with it. We suggest clinicians should be cautious when adding apps to psychotherapy treatment for prenatal depression, since our findings did not show an added benefit. Future research may be able to shed light on how apps can work in tandem with psychotherapy to enhance therapeutic effects. For instance, clinicians could benefit from having direct access to user data, such as BA activities and mental symptoms. Lastly, we observed a large ES in the within-groups analysis, and a high treatment response rate. Moreover, we recorded a low dropout rate, showing adequate adherence.

However, important limitations must be acknowledged. First, the number of prenatal visits was associated with randomization status. More prenatal care visits can positively impact our outcomes. Second, a substantially larger sample size would be needed to show superiority of the intervention. Third, we did not have a comparison group without CBT, and thus it is difficult to understand if other factors could have contributed to the large within-group ES. Fourth, our sample primarily comprised highly educated participants, limiting generalizability. Fifth, psychotherapists were aware of the randomization status, which may have influenced the active control group. Sixth, the mean depression scores at post-treatment and follow-up indicated that participants did not achieve full remission.

We developed a smartphone app and an online b-CBT program to work in tandem for reducing depression symptoms during pregnancy. Our data showed no difference between the groups on outcomes, suggesting that adding apps to psychotherapy may not enhance treatment effects in prenatal depression. Furthermore, within-group analysis showed that most participants with depression responded to treatment. Future studies will be needed to confirm whether this effect is due to other factors not related to the intervention. If confirmed, our online b-CBT program with or without smartphone assistance could be a promising intervention in maternal depression in LMICs.

Table 1 Sample characteristics at baseline

	Intervention (n=37)	Control (n=44)	Total sample (n=81)	p-value
Age (years)	32.8 (4.6)	32.3 (4.9)	32.5 (4.7)	0.631
Number of people in the household	3.0 (1.2)	2.8 (1.2)	2.9 (1.2)	0.634
Participant is white	25 (67.6%)	26 (59.1%)	51 (63.0%)	0.493
Participant has a college degree or higher	22 (59.5%)	30 (68.2%)	52 (64.2%)	0.488
Participant is working for pay	23 (62.2%)	30 (68.2%)	53 (65.4%)	0.642
Family income (Brazilian reais)	5,108.8 (4,434.7)	4,214.8 (3,179.3)	4,623.1 (3,805.8)	0.309
Participant is studying	12 (32.4%)	16 (36.4%)	28 (34.6%)	0.816
Participant is married or in a stable relationship	33 (89.2%)	38 (86.4%)	71 (87.6%)	0.748
Number of prenatal visits	3.8 (1.6)	4.6 (1.8)	4.3 (1.7)	0.038
Gestational age (weeks)	18.7 (2.8)	19.9 (3.3)	19.4 (3.1)	0.074
Participant diagnosed with high-risk pregnancy	13 (35.1%)	7 (15.9%)	20 (24.7%)	0.069
Participant is receiving mental health treatment	10 (27.0%)	8 (18.2%)	18 (22.2%)	0.340
Participant used alcohol during pregnancy	7 (18.9%)	3 (6.8%)	10 (12.3%)	0.173
Participant used tobacco during pregnancy	3 (8.1%)	3 (6.8%)	6 (7.4%)	1.000
Participant used other substances during pregnancy	1 (2.7%)	3 (6.8%)	4 (4.9%)	0.621
Depression score	17.3 (4.5)	16.8 (4.3)	17.0 (4.3)	0.626

Data presented as n (%) or mean (SD).

Table 2 Primary and secondary outcomes

	Post-treatment (T2)			2-month postnatal follow-up (T3)		
Outcomes	Mean	95%CI	p-value	Mean	95%CI	p-value
Depression						
Active control	10.7	9.1-12.3		10.5	8.9-12.0	
Intervention	11.2	9.4-13.0	0.688	9.4	7.6-11.1	0.338
Anxiety						
Active control	9.6	7.8-11.4		10.4	8.7-12.2	
Intervention	9.9	7.9-11.9	0.823	10.0	8.0-12.0	0.749
Stress						
Active control	22.7	20.4-24.9		23.5	21.3-25.8	
Intervention	24.0	21.4-26.5	0.452	23.7	21.2-26.3	0.915
Sleep						
Active control	5.4	4.6-6.1		4.3	3.5-5.0	
Intervention	5.6	4.7-6.4	0.731	4.8	4.0-5.7	0.342
Well-being						
Active control	153.2	145.5-160.9		154.6	146.4-162.7	
Intervention	157.0	148.5-165.6	0.511	163.3	154.4-172.1	0.153
Physical activity						
Active control	1560.4	219.1-2901.7		-	-	
Intervention	2740.8	1247.3-4234.2	0.245	-	-	-

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Disclosure

GVP has been a member of the advisory board of Shire/Takeda and Medice; has been a speaker for Shire/Takeda, Novo Nordisk, and Aché; has received travel expenses for continuing education support from Shire/Takeda and royalties from Editora Manole. The other authors report no conflicts of interest.

References

1 Gelaye B, Rondon MB, Araya R, Williams MA. Epidemiology of maternal depression, risk factors, and child outcomes in low-income and middle-income countries. Lancet Psychiatry. 2016;3:973-82.
2 Sanmartin MX, Ali MM, Chen J, Dwyer DS. Mental health treatment and unmet mental health care need among pregnant women with major depressive episode in the United States. Psychiatr Serv. 2019;70:503-6.
3 Ly KH, Topooco N, Cederlund H, Wallin A, Bergström J, Molander O, et al. Smartphone-supported versus full behavioural activation for depression: a randomised controlled trial. PLoS One. 2015;10:e0126559.
4 Lau Y, Htun TP, Wong SN, Tam WSW, Klainin-Yobas P. Therapist-supported internet-based cognitive behavior therapy for stress, anxiety, and depressive symptoms among postpartum women: a systematic review and meta-analysis. J Med Internet Res. 2017;19:e138.
5 Matijasevich A, Munhoz TN, Tavares BF, Barbosa APPN, Silva DM, Abitante MS, et al. Validation of the Edinburgh Postnatal Depression Scale (EPDS) for screening of major depressive episode among adults from the general population. BMC Psychiatry. 2014;14:284.
6 Zuccolo PF, Xavier MO, Matijasevich A, Polanczyk G, Fatori D. A smartphone-assisted brief online cognitive-behavioral intervention for pregnant women with depression: a study protocol of a randomized controlled trial. Trials. 2021;22:227.
7 Moreno AL, DeSousa DA, Souza AMFLP, Manfro GG, Salum GA, Koller SH, et al. Factor structure, reliability, and item parameters of the Brazilian-Portuguese version of the GAD-7 questionnaire. Temas Psicol. 2016;24:367-76.
8 Reis RS, Hino AAF, Añez CRR. Perceived stress scale: reliability and validity study in Brazil. J Health Psychol. 2010;15:107-14.
9 Snyder E, Cai B, DeMuro C, Morrison MF, Ball W. A new single-item sleep quality scale: results of psychometric evaluation in patients with chronic primary insomnia and depression. J Clin Sleep Med. 2018;14:1849-57.
10 Lear SA, Hu W, Rangarajan S, Gasevic D, Leong D, Iqbal R, et al. The effect of physical activity on mortality and cardiovascular disease in 130 000 people from 17 high-income, middle-income, and low-income countries: the PURE study. Lancet. 2017;390:2643-54.
11 Machado WL, Bandeira DR, Pawlowski J. Validação da Psychological Well-being Scale em uma amostra de estudantes universitários. Aval Psicol. 2013;12:263-72.
12 Guy W. ECDEU assessment manual for psychopharmacology. Maryland: National Institute of Mental Health. 1976.
13 Moreira RS, Magalhães LDC, Siqueira CM, Alves CRL. Adaptação transcultural do instrumento de vigilância do desenvolvimento infantil "Survey of Wellbeing of Young Children (SWYC)" no contexto brasileiro. J Hum Growth Dev. 2019;29:28-38.