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ScienceDirect

Behavior Therapy 51 (2020) 616–633

Behavior Therapy

www.elsevier.com/locate/bt

Be a Mom, a Web-Based Intervention to Prevent Postpartum Depression: Results From a Pilot Randomized Controlled Trial

Ana Fonseca*
Stephanie Alves
Fabiana Monteiro
CINEICC – Center for Research in Neuropsychology and Cognitive-Behavioral Intervention, University of Coimbra

Ricardo Gorayeb
University of São Paulo

Maria Cristina Canavarro
CINEICC – Center for Research in Neuropsychology and Cognitive-Behavioral Intervention, University of Coimbra

Be a Mom is a self-guided web-based intervention, grounded in cognitive behavioral therapy, delivered to postpartum women to prevent persistent postpartum depression [PPD] symptoms. We aimed to evaluate Be a Mom in terms of its preliminary efficacy, feasibility, and acceptability. A pilot randomized, two-arm controlled trial was conducted. Eligible women (presenting PPD risk-factors and/or early-onset PPD symptoms) were enrolled in the study and were randomly assigned to the intervention (Be a Mom) or to the waiting-list control group. Participants in both groups completed baseline (T1) and postintervention (T2) assessments. The 194 women presenting risk factors/early-onset PPD symptoms were allocated to the intervention (n=98) or to the control (n=96) group. A significant Time×Group interaction effect was found for both depressive and anxiety symptoms, with women in the intervention group presenting a larger decrease in symptoms from T1 to T2 ($p<.05$). Less than half of the women (41.8%) completed Be a Mom. Most women (71.4%) would use Be a Mom again if needed. Results provide preliminary evidence of the Be a Mom's efficacy, acceptability and feasibility, although further research is needed to establish Be a Mom as a selective/indicative preventive intervention for persistent PPD.

Keywords: Be a Mom; pilot randomized trial; postpartum depression; selective/indicative prevention; web-based interventions

This project was co-funded by the European Regional Development Fund (FEDER), through the Portugal-2020 program (PT2020), under the Centre's Regional Operational Program (CENTRO-01-0145-FEDER-028699), and by the Portuguese Foundation for Science and Technology/MCTES through national funds (PIDDAC). Stephanie Alves and Fabiana Monteiro were supported by a doctoral grant from the Portuguese Foundation for Science and Technology (SFRH/BD/102717/2014 and SFRH/BD/115585/2016, respectively).

This study is part of the Relationships, Development & Health Research Group of the R&D Unit Center for Research in Neuropsychology and Cognitive-Behavioral Intervention (CINEICC) of the Faculty of Psychology and Educational Sciences, University of Coimbra (PEst-OE/PSI/UI0730/2014).

* Address correspondence to Ana Fonseca, Ph.D., CINEICC – Center for Research in Neuropsychology and Cognitive-Behavioral Intervention, Faculty of Psychology and Educational Sciences, University of Coimbra, Rua do Colégio Novo, 3001-802 Coimbra, Portugal; e-mail: anadfonseca@fpce.uc.pt..

POSTPARTUM DEPRESSION (PPD) affects 13%–20% of new mothers (Gelaye, Rondon, Araya, & Williams, 2016). When untreated, PPD has detrimental effects on the mother's health (Woolhouse, Gartland, Perlen, Donath, & Brown, 2014), the mother-child interaction (Tronick & Reck, 2009), the child's development (Stein et al., 2014), and the

couple's dyadic satisfaction (Barnes, 2006), resulting in significant health care and productivity costs to the community (Petrou, Cooper, Murray, & Davidson, 2002).

PPD is a clinical condition amenable to preventive efforts (Werner, Miller, Osborne, Kuzava, & Monk, 2015), in particular to selective/indicated interventions (targeting subgroups of women that are at increased risk for PPD or that present early signs of the clinical condition; Clatworthy, 2012; Werner et al., 2015). Preventive interventions for PPD have been found to be effective (Sockol, Epperson, & Barber, 2013), although these effects are modest when compared to PPD treatments. The modest nature of the intervention effects seems to be related not only with the high variability of the intervention characteristics (e.g., target population, modality of delivery; Werner et al., 2015), but with the fact that most interventions focus on minimizing PPD risks factors (e.g., lack of social support) without grounding in psychological therapy models (e.g., cognitive-behavioral therapy [CBT]; Clatworthy, 2012; Werner et al., 2015), or are based in a therapeutic model but neglect perinatal-specific concerns (O'Mahen et al., 2012). Moreover, research has shown that few women proactively seek professional assistance concerning their perinatal depression symptoms (Fonseca, Gorayeb, & Canavarro, 2015; McGarry, Kim, Sheng, Egger, & Baksh, 2009). Despite the lack of specific studies, it is possible to hypothesize that women who present high-risk for the development of PPD may show a similar pattern of low help-seeking, which translates into reduced access to preventive interventions. Due to its characteristics (e.g., patients are allowed to self-refer, private and flexible use, at any time and from any location; Anderson & Titov, 2014), web-based interventions may reduce treatment uptake barriers among at-risk women (e.g., stigma, access constraints to health care services, childcare constraints; Bina, 2019) and increase their access to interventions to prevent PPD.

Despite preliminary evidence of the efficacy of web-based interventions for PPD (Lee, Denison, Hor, & Reynolds, 2016), particularly for treatment purposes (e.g., Milgrom et al., 2016), the results concerning web-based preventive interventions for PPD showed inconsistent findings (e.g., Barrera, Wickhman, & Munoz, 2015; Haga, Drozd, Brendryen, & Slinning, 2013). Specifically, the web-based Mothers and Babies program failed to demonstrate effectiveness in preventing PPD (Barrera et al., 2015), while the results of the Mamma Mia trial showed evidence of its feasibility (Haga et al., 2013) and follow-up effectiveness in reducing depressive symptoms (Haga, Drozd, Lisoy, Wentzel-Larsen, & Slinning, 2018). However the Mamma Mia program is a universal program delivered during pregnancy, with a long duration (44 sessions during a 11.5-month period), and grounded in Positive Psychology models; these program features were not in line with prior research supporting the greater effectiveness of selective/indicated, short-term postnatal preventive interventions for PPD, that were grounded in CBT or Interpersonal Therapy (Claridge, 2014; Sockol, 2015). Moreover, the Mamma Mia program was developed within the context of a specific cultural background and may not be suitable to other contexts. Therefore, further research is needed to develop effective web-based preventive interventions for PPD adapted to the Portuguese context and other similar contexts.

Be a Mom: a Web-Based Psychological Intervention to Prevent the Development of Pervasive PPD Symptoms

Considering the limitations identified in the existing preventive interventions, a formative evaluation process was conducted (Fonseca et al., 2018), which informed the design and content of a new intervention: Be a Mom. Be a Mom has the characteristics of the most effective face-to-face preventive interventions (short-term, targeted to at-risk women in the early postpartum period). Be a Mom is a web-based, self-guided selective/indicated preventive intervention grounded in CBT principles, a solid therapeutic approach that has been found to be effective in preventing PPD (Sockol, 2015). Moreover, it is innovative in incorporating the recent contributions of third-wave CBT approaches (e.g., self-compassion and acceptance and commitment therapy) applied to the perinatal context (Cree, 2015; Klausen, 2005), as third-wave CBT approaches have been found effective as selective/indicated preventive interventions for depression (e.g., Bohlmeijer, Fledderus, Rokx, & Pieterse, 2011).

BeaMomcombinesCBT strategies for depression prevention (e.g., psychoeducation about the cognitive-emotional-behavioral link, changing the relationship with private negative experiences) with strategies that address specific concerns of the perinatal period (e.g., promotion of interpersonal functioning—relationship with the partner, with others). Within this combination of strategies, Be a Mom simultaneously addresses the minimization of risk factors for PPD (e.g., lack of social support, poor marital relationship) and the promotion of CBT-based psychological processes/skills that may help to prevent the establishment of a diagnosis of depression. Specifically, Be a Mom has a modular

setup, with each of the 5 modules addressing one or two specific thematic contents (see Appendix A, supplemental material). In each module, after the presentation of the session goals, the session's thematic contents are presented using psychoeducational tools (text format, audio, video and animations) and interactive exercises with personalized feedback tools (as a function of the user's responses) to support learning. The content of the modules is customized to the user's needs (e.g., content related to the promotion of the couple's satisfaction and intimacy is not displayed in the case of single mothers). At the end of each module, a 2–3 minutes video is presented in which a mental health professional synthesizes the main content of the module, and users are assigned a homework activity to guarantee therapeutic practice (Fonseca et al., 2018).

THE PRESENT STUDY

The present study describes the results of a pilot randomized indicated prevention trial of the Be a Mom program. Indicated prevention trials include participants who show signs of the condition of interest (e.g., participants can be included if they present risk factors or early-onset symptoms) but not a clinical diagnosis of the disorder (Bunwasser & Garber, 2017). Given the pilot nature of this study, we aim to assess the program's acceptability and feasibility, and to gather preliminary evidence of its efficacy. Therefore, we aimed to evaluate Be a Mom by considering several indicators: (a) preliminary evidence of Be a Mom's efficacy in terms of primary (depressive symptoms) and secondary outcomes (anxiety symptoms, maternal confidence, negative thoughts, dyadic satisfaction); (b) Be a Mom's feasibility in terms of adherence and the pattern of program usage; and (c) Be a Mom's acceptability in terms of users' global perceptions of the program.

To gather preliminary evidence of Be a Mom's efficacy, we consider depressive symptoms as the primary outcome. There is evidence that the presence of clinically relevant depressive symptoms is an important risk indicator for major depressive disorder (Cuijpers & Smit, 2004), and that selective/indicated interventions targeting individuals who suffer from clinically relevant risk factors or symptoms but who do not meet the criteria of a clinical disorder were found to be the most effective in preventing the onset of depression (Cuijpers, van Straten, Smit, Mihalopoulos, Beekman, 2008). Therefore, preliminary evidence of Be a Mom's efficacy was defined as the program's ability to significantly reduce early-onset depressive symptoms, and thus, prevent the establishment of a clinical diagnosis of PPD. Moreover, we consider the Be a Mom's efficacy in terms of other secondary outcomes that were found to be related with PPD. On the one hand, we considered individual outcomes, such as anxiety symptoms which occur often comorbid with PPD (Falah-Hassani, Shiri, & Dennis, 2016), and postpartum negative thoughts, which were found to be associated with the maintenance of depressive sympotms (Fonseca & Canavarro, 2018). On the other hand, we considered variables that are associated with the mothers' interpersonal domain, such as maternal confidence (Reck, Noe, Gerstenlauer, & Stehle, 2012) and dyadic satisfaction (Barnes, 2006).

Methods

The trial is registered at clinicaltrials.gov (NCT03024645) and was approved by the Ethics Committees of Faculty of Psychology and Educational Sciences, University of Coimbra, and Centro Hospitalar e Universitário de Coimbra, EPE. The extensions of the CONSORT 2010 checklist for pilot (Eldridge et al., 2016) and ehealth (Eysenbach & CONSORT-EHEALTH Group, 2011) trials were used for study reporting.

Study participants and recruitment settings

Eligibility criteria to participate in the study were (a) having given birth to a child and being in the early postpartum period (up to 3 months postpartum); (b) being 18 years old or older; (c) being at risk for PPD (assessed by scores above the cutoff score (5.5) on the Postpartum Depression Predictors Inventory-Revised [PDPI-R]; Alves, Fonseca, Canavarro, & Pereira, 2018) and/or presenting early-onset PPD symptoms (assessed by scores above the cutoff score (10) on the Edinburgh Postpartum Depression Scale [EPDS]; Areias, Kumar, Barros, & Figueiredo, 1996); (d) having access to a computer/tablet/smartphone and internet access at home; (e) being able to read and speak Portuguese; and (f) being a resident of Portugal. Exclusion criterion was the presence of a serious medical condition (physical or psychiatric) in the mother or in the infant (self-reported).

Participants in the early postpartum period (up to 3 months postpartum) were recruited both in-person and online. Recruitment commenced in June 2017 and continued until October 2017. Although only in-person recruitment was initially planned, the slow flow of participants who met all the inclusion criteria instigated a change in the original recruitment design after September 2017. The option to include online recruitment produced a rapid increase in the number of enrolled

participants. In-person recruitment occurred at the Maternity Daniel de Matos (Centro Hospitalar e Universitário de Coimbra, EPE). During their postpartum hospitalization, participants were invited to participate in the study by one of the two researchers responsible for participant recruitment. The researchers approached all participants that had given birth to a healthy child and were hospitalized at the maternity and presented them with the study goals. Participants who gave consent to participate in the study were asked some questions to assess eligibility criteria (except criterion c) and provided their contact information (email, telephone number) to be contacted by the researchers 4–6 weeks postpartum. Online recruitment occurred on social media websites (Facebook), both through unpaid cross-posting and through paid boosting campaigns (two campaigns for 7 days each, targeting women 20–40 years old with interests in maternity topics). Participants who filled out the online form provided their contact information (email, telephone number) and answered some questions to assess eligibility criteria (all except criterion c). In both cases, the study goals and procedures were described, and the participants' (e.g., voluntary participation) and researchers' (e.g., guarantee of confidentiality) roles were clarified. Participants gave their informed consent to participate in the study. Participants who gave their consent to participate in the study and met the remaining eligibility criteria were assessed (by telephone in the case of in-person recruitment or online in the case of online recruitment) regarding the presence of risk factors for PPD and early-onset PPD symptoms (Time 0 – T0).

A sample size of at least 50 participants per condition in both assessments was needed to assess preliminary evidence of efficacy for the primary outcome (detecting a medium effect size [$d = .50$] with a statistical power of .80 in a two-tailed test, $p < .05$). Considering the expected dropout rate for self-guided interventions (>50%), at least 200 participants were needed for randomization.

Study design

This was a two-arm, open-label, pilot randomized indicated prevention trial. Participants who met the eligibility criteria were randomly assigned (simple randomization procedure; allocation rate 1:1) to either the intervention group with access to the Be a Mom program, or the wait-list control group. Randomization was assured by a third researcher (different from the two responsible for enrollment and assignment of the participants to the study groups) who had no information about the participants (except from their code). The randomization sequence was concealed from the two researchers responsible for participants' enrollment and assignment to groups.

The intervention arm consisted of the Be a Mom program, a self-guided web-based intervention grounded in CBT principles, as described above (see Appendix A, supplementary material). Participants assigned to Be a Mom received an invitation by email to register in the intervention platform (beamom.pt; access to the program is restricted to invitation). After receiving the invitation email, they completed the registration form, and only then could they access Be a Mom's content. Participants are instructed that they should complete one module per week, although they are allowed to complete the program at a slower or faster pace. One automatic reminder was sent to the users if they went 7 days without accessing Be a Mom. Be a Mom is completely self-guided, so no human support is given. An email contact was provided for technical support. Access to the program is free of cost. Participants in the waiting-list control arm were offered no intervention but were free to access other forms of care (as were all participants). At the end of the pilot trial, participants in the control group were offered the opportunity to access Be a Mom.

Outcome variables were assessed at baseline (Time 1 – T1) and 8 weeks later (posttreatment, Time 2–T2). At T2, participants in the intervention group filled out a questionnaire to assess the program's feasibility and acceptability. In the intervention group, participants who completed Be a Mom received an automatic email inviting them to complete the assessment protocol 2–3 days later. If women dropped out of the program, an automatic email was sent 8 weeks after registration asking them to complete the postintervention assessments. In the control group, an email inviting participants to complete the assessment protocol was sent 8 weeks after T1. T1 and T2 assessments were self-assessed through online questionnaires (hosted on Limesurvey®). Website system data concerning Be a Mom's usage were also gathered at T2.

Measures

Sociodemographic and Clinical Form

The participants' sociodemographic (e.g., age, marital status, number of children, educational level, professional status, average monthly income, socioeconomic status, and residence) and clinical (pregnancy complications, type of labor, psychopathology history, psychological/psychiatric treatment history) data and the infants' data (infant's

age, infant's sex and infant's gestational weeks at birth) were collected through a self-report form.

Risk for PPD

The postnatal version of the Postpartum Depression Predictors Inventory-Revised (PDPI-R; Alves et al., 2018) was used at T0 to assess PPD risk factors (e.g., low socioeconomic status, prenatal depression/anxiety, lack of support, child care stress). The questionnaire is composed of 39 items answered on a dichotomous scale (yes *vs.* no, except for the first two items in which participants report their marital status and socioeconomic status). The PDPI-R total score ranges from 0–39. The Portuguese postnatal version of the PDPI-R was found to accurately predict 82% of cases with probable depression, suggesting moderate diagnostic accuracy. In Portuguese validation studies, a score of 5.5 or higher is indicative of higher PPD risk (Alves et al., 2018).

Depressive Symptoms

The Portuguese version of the Edinburgh Postpartum Depression Scale (EPDS; Areias et al., 1996) was used at T0 to identify participants with early-onset PPD symptoms and as the primary outcome of the efficacy evaluation. EPDS is the most widely used self-report questionnaire to assess the presence and severity of clinically relevant depressive symptoms. Participants were asked to rate how frequently they felt several symptoms in the prior week (e.g., sadness, tearfulness) using a 4-point scale. Higher scores indicate higher depressive symptoms. In the Portuguese population, scores of 10 or higher are indicative of clinically relevant depressive symptoms. In this study the Cronbach's alpha values ranged from .74 (intervention group – T2) to .90 (control group – T1).

Anxiety Symptoms

The Anxiety subscale of the Portuguese version of the Hospital Anxiety and Depression Scale (HADS) was used to assess anxiety symptoms (Pais-Ribeiro et al., 2007). The HADS scale is a 14-item scale developed to assess the presence of anxiety (7 items) and depressive (7 items) symptoms in the week prior to the completion of the scale. Items were answered on a 4-point scale (0–3). Higher scores were indicative of higher anxiety symptoms. A score of 11 points or higher is indicative of the presence of clinically relevant anxiety symptoms. In our sample, the Cronbach's alpha values ranged from .75 (intervention group – T1) to .87 (control group – T1 and T2).

Maternal Confidence

The Portuguese version of the Maternal Confidence Questionnaire (MCQ; Nazaré, Fonseca, & Canavarro, 2013) was used to assess maternal confidence. The MCQ is composed of 13 items (e.g., "I am able to feed my baby properly") that can be averaged for a total score of maternal confidence. Items were answered on a 5-point Likert scale ranging from 1 (*Never*) to 5 (*Always*). Higher scores indicate higher perceptions of maternal confidence. In our sample, the Cronbach's alpha values ranged from .75 (intervention group – T2) to .83 (control group – T2).

Postpartum Negative Thoughts

The Portuguese version of the Postnatal Negative Thoughts Questionnaire (PNTQ; Rodrigues, Costa, Canavarro, & Fonseca, 2017) was used to assess negative thoughts. The PNTQ is composed of 17 items, assessing the frequency of specific postnatal thoughts on a 4-point frequency scale (from 0 = *Never* to 3 = *Almost Always*), and is organized into two dimensions: Baby-Related and Motherhood Negative Thoughts (BRMNT, the content of negative thoughts; 8 items, e.g., "I do not want to be alone with my baby") and Appraisals of Cognition, Emotion, and Situation (ACES, metacognitive appraisal of thoughts' content; 9 items, e.g., "There must be something wrong with me"). Higher scores are indicative of a higher frequency of postpartum negative thoughts. In the present study, the Cronbach's alpha values ranged from .67 (intervention group – T1) to .85 (control group – T2).

Dyadic Satisfaction

The Portuguese version of the Revised Dyadic Adjustment Scale (RDAS; Pereira, Moura-Ramos, Narciso, & Canavarro, 2017, July) was used to assess the couple's relationship satisfaction, only for participants who were in a couple relationship. The RDAS is composed of 14 items organized into three dimensions (relationship satisfaction, relationship cohesion, and relationship consensus), although only the relationship satisfaction dimension (4 items, e.g., "How often do you usually argue with your partner?") was used in this study. Items are rated on a 6-point Likert scale (from 0 = *Never* to 5 = *Always*). Higher scores indicate higher relationship satisfaction. In our sample, the Cronbach's alpha values were .86 for both the intervention and control groups at T1 and T2.

Be a Mom: Acceptability

Participants were asked questions regarding their intention to use the program (2 items; e.g., "I would use Be a Mom again, if I were to be in a similar situation"), satisfaction with the program (3 items; e.g., "I am satisfied with the help I received at Be a Mom"), usefulness/relevance (5 items; e.g., "Be a Mom has helped me deal with my everyday

situations more effectively"), credibility (1 item; "I consider Be a Mom to be a credible program"), and demandingness (1 item; "I feel that participation in Be a Mom was very demanding for me"). Participants answered each question with a Likert-type response scale (from 0 = *Not at all applicable to me* to 3 = *Totally applicable to me*). The items of the dimensions comprising more than one item were averaged to compute a dimension score.

Be a Mom: Access

Participants were asked about the presence of others when accessing the program ("*Has anyone accessed the Be a Mom modules with you?*", and "*If yes, who?*").

Be a Mom: Web System Data

Data were gathered concerning the number of completed modules, number of pages accessed in each module, number of logins, average time between logins (in days), average time spent on Be a Mom at each login (minutes), number of interactive exercises completed in each module and the number of times each audio exercise was played.

DATA ANALYSES

Analyses were conducted using the Statistical Package for the Social Sciences (IBM SPSS, version 22.0; IBM SPSS, Chicago, IL). Descriptive statistics were used to describe recruitment and retention data and the sociodemographic and clinical characteristics of the sample, and comparison tests (Student's *t-tests* or chi-square tests) were used to compare the intervention and the control group in terms of sociodemographic characteristics. Missing endpoints at posttest ranged from 48/194 (24.7%) on EPDS to 61/194 (31.4%) on dyadic satisfaction (Little's MCAR test $X^2 = 36.27$, $p > .05$). Comparison analyses (Student's *t-tests* or chi-square tests) of the baseline characteristics between women who completed both assessments and those who dropped out of the study were also conducted.

To examine the preliminary evidence of efficacy of the program, statistical analyses were performed in accordance with the intention-to-treat (ITT) principles following the CONSORT recommendations (Eldridge et al., 2016; Eysenbach & Group, 2011). Linear Mixed Models (LMMs) (Heck, Thomas, & Tabata, 2014) were used to determine the effects of the intervention over time on primary and secondary outcomes. LMMs is a statistical model particularly used for repeated, longitudinal measures and is a reliable procedure to handle missing data because this approach allows incomplete cases to be included in the analysis, and all available data are used to obtain parameter estimates (Mallinckrodt, Clark, & David, 2001). Data were hierarchically arranged in two levels, with Time (level 1) nested within individuals (level 2). Group (Intervention × Control), Time, and Group × Time interaction were entered as fixed effects. Covariates (sociodemographic variables that differ between the intervention and the control group and between study completers and dropouts) were included as predictor variables in the linear mixed model. This allowed to examine the effect of each of the covariates in the outcome measure, and to control the effects of the covariates when estimating the Time, Group, and Group × Time interaction effects. The effects of the covariates were only reported if significant. Models including two different covariance matrixes (*unstructured covariance matrix* – variances and covariances are allowed to be different in each pair and have no relation to the others; *autoregressive* – homogeneous variances and covariances that decline exponentially with distance) were tested as well as a model including fixed effects only and a model including a random intercept. The final model presented the best fit to the data, as evaluated by Akaike Information Criterion (AIC) comparison. Independent and paired sample *t*-tests were also computed considering only the participants who completed both assessment times.

For depressive and anxiety symptoms, further analyses were conducted considering the presence of clinically relevant symptoms. First, women's scores on EPDS and HADS were classified at each assessment time (T1 and T2) as a function of the cutoff scores indicating clinically relevant symptoms: women presenting clinical levels of depressive (if EPDS > 9) or anxiety (if HADS-A ≥ 11) symptoms, and women not presenting clinical levels of depressive/anxiety symptoms. Second, women were classified in accordance with their pattern of change from T1 to T2: (a) maintenance – clinical levels (if they presented clinical levels of EPDS/HADS at both T1 and T2); (b) maintenance – nonclinical levels (if they presented nonclinical levels of EPDS/HADS at both T1 and T2); (c) improvement (if they presented clinical levels of EPDS/HADS at T1 and nonclinical levels of EPDS/HADS at T2); (d) deterioration (if they presented nonclinical levels of EPDS/HADS at T1 and clinical levels of EPDS/HADS at T2). Chi-square tests were used to examine differences in the proportion of patterns of change, as a function of group (intervention vs. control group).

To examine the program's feasibility and acceptability, descriptive statistics were computed. Comparison tests were conducted to compare women who completed the program (completers) with

women who did not complete the program (non-completers).

Results

Participants

Figure 1 shows the flow of participants through the study. Participants were enrolled in the study both in person (n = 377) and through online recruitment (n = 266). Of the total of enrolled participants, 142 were excluded for several reasons (see Figure 1). A total of 501 participants agreed to be assessed concerning the presence of risk factors for PPD or early-onset PPD symptoms, although 7.98% (n = 40) did not complete the assessment. Concerning the participants assessed, 47.7% (n = 220) did not score above the cut-off scores concerning risk factors for PPD or early-onset PPD symptoms. Of the participants who were at-risk for PPD (n = 241), 47 did not start the baseline assessment and were excluded from the randomization. Therefore, 194 at-risk participants were randomized and allocated to the intervention group (n = 98) or to the control group (n = 96). Most of the participants in both groups were enrolled because they presented risk factors for PPD (intervention group: n = 93, 94.9% *vs.* control group: n = 92, 95.8%), and only a minor proportion because they presented early-onset symptoms, despite not presenting high-risk (intervention group: n = 5, 5.1% *vs.* control group: n = 4, 4.2%; X^2 = 0.10, p = .757). No significant

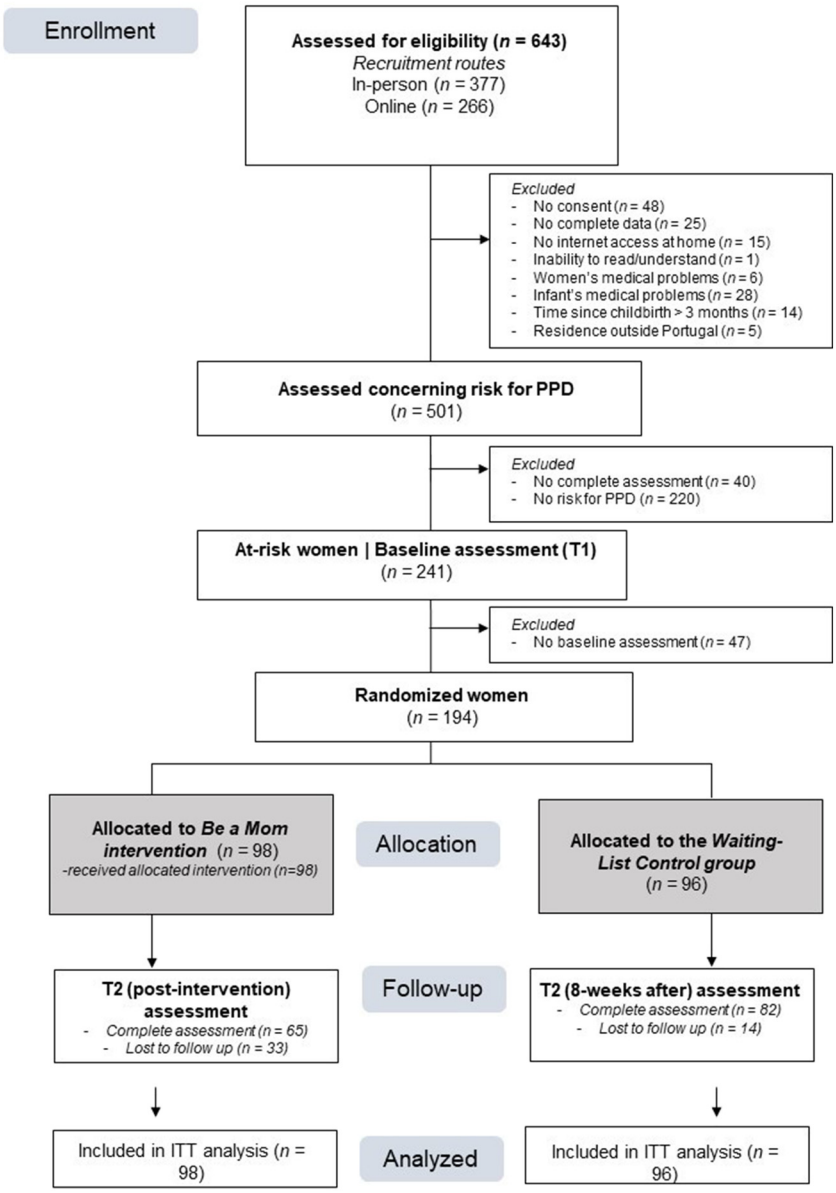

FIGURE 1 CONSORT flow chart.

differences were found as a function of enrollment reason (high-risk for PPD *vs.* early-onset PPD symptoms; data not shown). Moreover, the proportion of participants enrolled in person (intervention group: $n = 30$, 30.6% *vs.* control group: $n = 32$, 33.3%) and enrolled online (intervention group: $n = 68$, 69.4% *vs.* control group: $n = 64$, 66.7%) was similar in both groups ($X^2 = 0.17$, $p = .684$).

Of the 194 participants, 147 completed the postintervention assessment (global retention rate: 75.77%). The retention rate in the control group (85.4%) was higher than the retention rate in the intervention group (66.3%). 93.9% ($n = 31$) of the dropouts in the intervention group discontinued the intervention and did not complete the questionnaires, and 6.1% ($n = 2$) completed the intervention but did not complete the postintervention assessment. Finally, the proportion of women seeking psychological/psychiatric treatment after childbirth was similar in both groups (intervention group: $n = 10$, 15.2% *vs.* control group: $n = 7$, 8.5%, $X^2 = 1.57$, $p = .210$).

Table 1 shows the participants' sociodemographic and clinical characteristics at baseline. A significantly higher proportion of participants in the control group was single (16.7% vs. 4.1%) and had an average income lower than 1000€ (57.3% vs. 19.4%). Baseline sociodemographic characteristics between participants who completed the T2 assessments ($n = 147$) and those who dropped out of the study ($n = 47$) were tested for differences. When compared with participants who completed both assessment times, participants who dropped out from the study had, with a higher frequency, basic or secondary education (48.9% vs. 23.8%, $X^2 = 11.49$, $p = .009$), a low socioeconomic status (25.5% vs. 10.2%, $X^2 = 7.91$, $p = .019$) and lived with more frequency in a rural area (40.4% vs. 21.1%, $X^2 = 6.96$, $p = .008$). Moreover, the infants of the participants who dropped out from the study were older ($M = 2.22$ months, $SD = 0.91$) than the infants of the participants who completed both assessment moments ($M = 1.92$, $SD = 0.87$, $t = 2.04$, $p = .043$). The dropouts of the intervention and of the control group had similar sociodemographic characteristics (data not shown).

Preliminary evidence of efficacy: comparison with the control group

Table 2 shows the estimated marginal means of the primary (depressive symptoms) and secondary outcomes as a function of Time and Group.

Concerning depressive symptoms, the model presenting the best fit included only the fixed effects with an unstructured covariance matrix (AIC = 1885.427; fixed effects only with auto-regressive covariance matrix: AIC = 1888.998; fixed effects and random intercept: AIC = 1890.998, with the random intercept variance being nonsignificant, $p = .995$). As shown in Table 2, a significant Time × Group interaction effect was found, suggesting that the decrease in depressive symptoms from Time 1 to Time 2 was larger in the intervention group. No significant effects of covariates were found. Comparison analyses performed with the participants who completed both assessment times showed that, although no significant differences between groups were found at T2 ($t = -0.53$, $p = .610$, d = 0.01), the changes between EPDS scores from T1 to T2 were significantly higher in the intervention group ($t = 4.95$, $p < .001$, $d = 0.623$) than in the control group ($t = 3.162$, $p = .002$, $d = 0.275$).

Moreover, a significantly higher number of participants in the intervention group ($n = 27$, 42.2% *vs.* control group: $n = 15$, 18.3%) showed an improvement trajectory (i.e., clinical levels of symptoms at T1 and absence of clinical symptoms at T2) from Time 1 to Time 2 ($X^2 = 10.69$, $p = .013$; see Figure 2).

For anxiety symptoms, the model presenting the best fit included only the fixed effects with an autoregressive covariance matrix (AIC = 1779.703; fixed effects only with unstructured covariance matrix: AIC = 1781.445; model including the fixed effects and random intercept: AIC = 1781.703, with the random intercept variance being nonsignificant, $p = .997$). As seen in Table 2, a significant Time × Group interaction effect was found, with the clinical group showing a pattern of a larger decrease in anxiety symptoms from Time 1 to Time 2. No significant effects of covariates were found. Comparison analyses performed with the participants who completed both assessment times showed that, although no significant differences between groups were found at T2 ($t = -0.12$, $p = .903$, $d = 0.002$), changes in anxiety scores from T1 to T2 were significant in the intervention group ($t = 3.02$, $p = .004$, $d = 0.377$) while nonsignificant in the control group ($t = 0.494$, $p = .622$, $d = 0.055$). Moreover, a higher proportion of participants in the intervention group (15.6% vs. 6.1% in the control group) showed a trajectory of improvement of symptoms over time, although the differences were not statistically significant ($X^2 = 5.23$, $p = .156$; see Figure 2). Significant and large associations between anxiety and depression symptoms were found at T1 ($r = .781$, $p < .001$) and at T2 ($r = .704$, $p < .001$).

Concerning maternal confidence levels, the model presenting the best fit included only the

Table 1
Participants' Sociodemographic and Clinical Characteristics at Baseline

	Intervention group (n = 98)	Control group (n = 96)	t/X^2
Participants' sociodemographic characteristics			
Age (in years), M (SD)	32.22 (4.36)	32.94 (5.24)	1.03
Relationship, n (%)			
Married/living together	88 (89.8)	75 (78.1)	**9.08***
Single	4 (4.1)	16 (16.7)	
Divorced	2 (2.0)	3 (3.1)	
In a relationship (not living together)	4 (4.1)	2 (2.1)	
Number of children, n (%)			
Primiparous	62 (63.3)	71 (74.0)	4.07
Educational level, n (%)			
Basic or secondary education	28 (28.5)	30 (31.2)	0.76
Higher education	42 (42.9)	43 (44.8)	
Postgraduate education (M.Sc; PhD)	28 (28.6)	23 (24.0)	
Professional status, n (%)			
Employed	82 (83.7)	76 (79.2)	0.81
Unemployed	16 (16.3)	20 (20.8)	
Income, n (%)			
Less than 500€	3 (3.1)	5 (5.2)	**57.78****
500€-1,000€	16 (16.3)	50 (52.1)	
1,000€-2,000€	51 (52.0)	17 (17.1)	
2,000€-3,500€	22 (22.4)	3 (3.1)	
More than 3,500€	6 (6.1)	21 (21.9)	
Socioeconomic status, n (%)			
Low	13 (13.3)	14 (14.6)	2.17
Medium/High	85 (86.7)	82 (85.4)	
Residence, n (%)			
Urban	74 (75.5)	70 (72.9)	0.17
Women's clinical characteristics			
Pregnancy complications, n (%)			
Yes	32 (32.7)	30 (31.2)	0.04
PPD Risk			
Proportion at risk, *n* (%)	93 (94.9)	92 (95.8)	0.10
PDPI-R scores, *M (SD)*	9.82 (4.00)	9.90 (4.20)	0.14
Psychopathology history, n (%)	53 (54.1)	44 (45.8)	1.32
Psychiatric/Psychological treatment history, n (%)	44 (44.9)	30 (31.2)	3.83
Clinical levels of depressive symptoms, n (%)	48 (49.0)	37 (38.5)	2.15
Clinical levels of anxiety symptoms, n (%)	14 (14.3)	14 (14.6)	0.003
Infant's characteristics			
Infant's Sex, n (%)			
Male	58 (59.2)	54 (56.2)	1.14
Infant's age (in months), M (SD)	2.00 (0.83)	1.99 (0.95)	–0.08
Infant's gestational weeks at birth, M (SD)	39.10 (1.32)	38.99 (1.48)	–0.55

*$p < .05$; **$p < .01$; ***$p < .001$.

fixed effects with an unstructured covariance matrix (AIC = 215.427; fixed effects only with auto-regressive covariance matrix: AIC = 220.943; model including the fixed effects and random intercept: AIC = 222.943, with the random intercept variance being nonsignificant, p = .989). As shown in Table 2, no significant Time × Group interaction was found. However, a significant effect of Group was found, with women in the control group presenting higher global levels of maternal confidence, and a significant Time effect was found, with women showing higher levels of maternal confidence at T2 (see Table 2). Moreover, significant covariate effects of income (B = –0.07, SE = 0.02, t = –2.78, p = .006) and of infant's age (B = 0.09, SE = 0.03, t = 3.22, p = .002) were found.

Concerning postnatal negative automatic thoughts, separate models were examined for each

Table 2
Primary and Secondary Outcome Measures: Estimated Marginal Means for Time and Group and Time, Group and Interaction Effects

Outcome variable		Estimated Marginal Means		Linear Mixed Model Effects Estimates			
	Group	Time 1 *M (SE)*	Time 2 *M (SE)*	Effect	*B (SE)*	95% CI	*P*
Depressive symptoms (EPDS)	Intervention	9.32 (0.51)	6.91 (0.45)	Time	2.41 (0.43)	[1.57, 3.26]	<.001
	Control	8.10 (0.46)	6.87 (0.41)	Group	−0.03 (0.62)	[−1.25, 1.19]	.958
				Time × Group	−1.18 (0.58)	[−2.32, −0.04]	.043
Anxiety symptoms (HADS)	Intervention	6.91 (0.36)	5.50 (0.42)	Time	1.41 (0.39)	[0.65, 2.17]	<.001
	Control	5.94 (0.36)	5.76 (0.38)	Group	0.26 (0.57)	[−0.87, 1.38]	.653
				Time × Group	−1.23 (0.52)	[−2.25, −0.21]	.019
Maternal confidence (QCP)	Intervention	4.24 (0.04)	4.31 (0.04)	Time	−0.13 (0.04)	[−0.21, −0.06]	.001
	Control	4.38 (0.04)	4.51 (0.04)	Group	0.14 (0.05)	[0.03, 0.24]	.010
				Time × Group	−0.07 (0.05)	[−0.017, 0.03]	.176
Baby-Motherhood Thoughts (BRMNT)	Intervention	2.74 (0.23)	2.39 (0.27)	Time	0.35 (0.25)	[−0.14, 0.85]	.161
	Control	2.19 (0.23)	1.46 (0.25)	Group	−0.93 (0.37)	[−1.66, −0.20]	.013
				Time × Group	0.37 (0.34)	[−0.29, 1.03]	.270
Metacognitive appraisal (ACES)	Intervention	3.71 (0.38)	3.30 (0.37)	Time	0.41 (0.38)	[−0.33, 1.16]	.273
	Control	3.35 (0.39)	2.74 (0.33)	Group	−0.56 (0.50)	[−1.56, 0.43]	.265
				Time × Group	0.20 (0.51)	[−0.81, 1.20]	.701
Dyadic Satisfaction (DAS-R)	Intervention	3.91 (0.08)	3.80 (0.08)	Time	0.12 (0.06)	[−0.00, 0.24]	.057
	Control	3.95 (0.08)	3.90 (0.09)	Group	0.10 (0.12)	[−0.13, 0.33]	.406
				Time × Group	−0.06 (0.09)	[−0.23, 0.11]	.509

Note: Estimated means adjusted for the covariates (marital status, educational level, income, socioeconomic status, and infant's age).

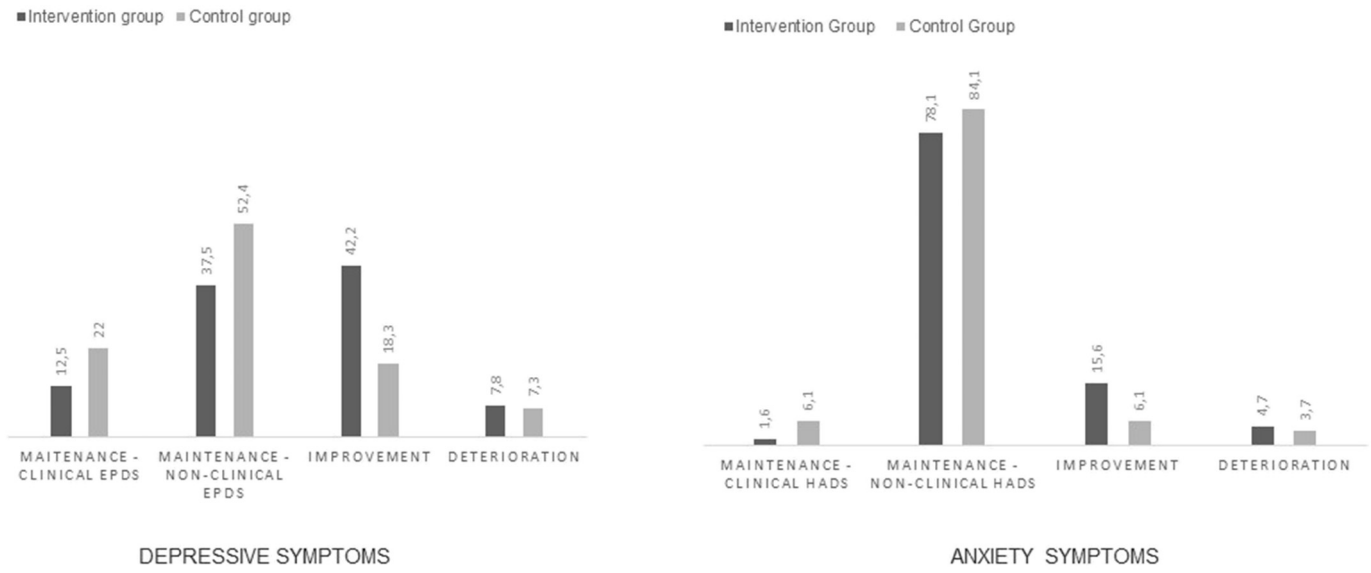

FIGURE 2 Patterns of change from Time 1 to Time 2 in clinically relevant depressive (EPDS) and anxiety (HADS) symptoms: Intervention and Control Groups.

dimension: BRMNT and ACES. For the BRMNT dimension, the model that presented the best fit to the data was the model including fixed effects only with an autoregressive covariance matrix (AIC = 1470.102; fixed effects only with unstructured covariance matrix: AIC = 1471.946; fixed effects and random intercept model: AIC = 1472.102, with the random intercept variance being non-significant, $p = .999$). As seen in Table 2, no significant Time × Group interaction or Time effects were found, but a significant Group effect was found, with women in the intervention group presenting more frequent negative thoughts. Moreover, a significant covariate effect of educational level was found ($B = 0.43$, $SE = 0.19$, $t = 2.24$, $p = .026$). For the ACES dimension, the model that fit best the data was the model including fixed effects only with an unstructured covariance matrix (AIC = 1753.763; fixed effects only with auto-regressive covariance matrix: AIC = 1760.324; fixed effects and random intercept model: AIC = 1762.324, with the random intercept variance being nonsignificant, $p = .995$). No significant effects of Time, Group or Time × Group interaction were found (see Table 2). No significant effects of covariates were found.

Finally, concerning dyadic satisfaction, the model presenting the best fit included only the fixed effects with an unstructured covariance matrix (AIC = 579.609; fixed effects only with auto-regressive covariance matrix: AIC = 579.668; model including the fixed effects and random intercept: AIC = 581.609, with the random intercept variance being non-significant, $p = .987$). No significant effects of Time, Group or Time × Group interaction were found. No significant effects of covariates were found.

Be a Mom Feasibility: Compliance with Intervention

Of the 98 participants who registered for Be a Mom, 41.8% ($n = 41$) completed the program (completers), while 58.2% ($n = 57$) dropped out without completing (noncompleters). The recruitment route (in person *vs.* online) was not significantly associated with the proportion of completers ($X^2 = 1.29$, $p = .257$). No significant sociodemographic differences or in PPD risk were found between completers and noncompleters (data not shown).

Among noncompleters, more than half (50.9%, $n = 29$) did not complete any module, and 20 (68.9%) of these participants accessed 18 pages or less of the first module (total number of pages of module 1: 36). In fact, 7 participants did not access any page of the module. Moreover, 28.1% of the noncompleters ($n = 16$) completed only the first module, 15.8% ($n = 9$) completed the first two modules, and only 5.3% ($n = 3$) completed the three first modules. The average number of logins was 6.51 ($SD = 5.60$, *Range* = 1–25). Women who completed Be a Mom had a higher average number of logins ($M = 10.68$, $SD = 5.92$) than women who did not complete the program ($M = 3.51$, $SD = 2.71$; $t_{96} = -7.23$, $p < .001$). The average time that women spent on Be a Mom in each login was 15.88 minutes ($SD = 22.37$), with no significant differences between completers and noncompleters ($t_{96} = -0.71$, $p = .481$). Most participants accessed to the modules of Be a Mom alone ($n = 53$, 86.9%).

When considering both completers and non-completers, the majority of participants finished at least one interactive exercise within module 1 ($n = 86$, 87.8%; 60.2% of participants finished the range of proposed exercises), within module 2 ($n = 59$, 85.5%; 69.6% finished the range of exercises), within module 3 ($n = 50$, 95.1%; 83.1% completed all the exercises), and within modules 4 and 5 ($n = 40$, 90.9%; 88.6% and 59.1%, respectively, finished the range of proposed exercises in module 4 and module 5). When compared with noncompleters, the participants who completed Be a Mom completed a higher number of interactive exercises in all modules (Module 1: $X^2 = 24.08$, $p < .001$; Module 2: $X^2 = 52.69$, $p < .001$; Module 3: $X^2 = 84.48$, $p < .001$; Module 4: $X^2 = 93.96$, $p < .001$; Module 5: $X^2 = 93.96$, $p < .001$). Concerning the audio exercises (modules 1 and 2), most participants who completed the first module did not listen the audio exercise "*observing thoughts*" while accessing the module ($n = 48$, 69.6%). Moreover, the majority of participants who completed the second module listened to the audio exercise "*thoughts suppression*" while accessing the module ($n = 30$. 56.7%), although only 43.4% ($n = 23$) listened to the "*distancing of thoughts*" audio exercise. Only 4 participants have listened the audio exercises more than once. Concerning homework activities, 76.5% ($n = 75$) performed the homework activities of the first module at least once, but this percentage drops significantly in the remaining modules (module 2: 43.5%, $n = 30$; module 3: 43.3%, $n = 23$; module 4 = 54.6%, $n = 24$; and module 5: 43.9%, $n = 18$).

Be a Mom: Users' Acceptability

Figure 3 presents the results concerning the users' acceptability of Be a Mom. Overall, most women had positive perceptions about the program.

When compared with noncompleters, women who completed Be a Mom perceived significantly higher levels of satisfaction with the program

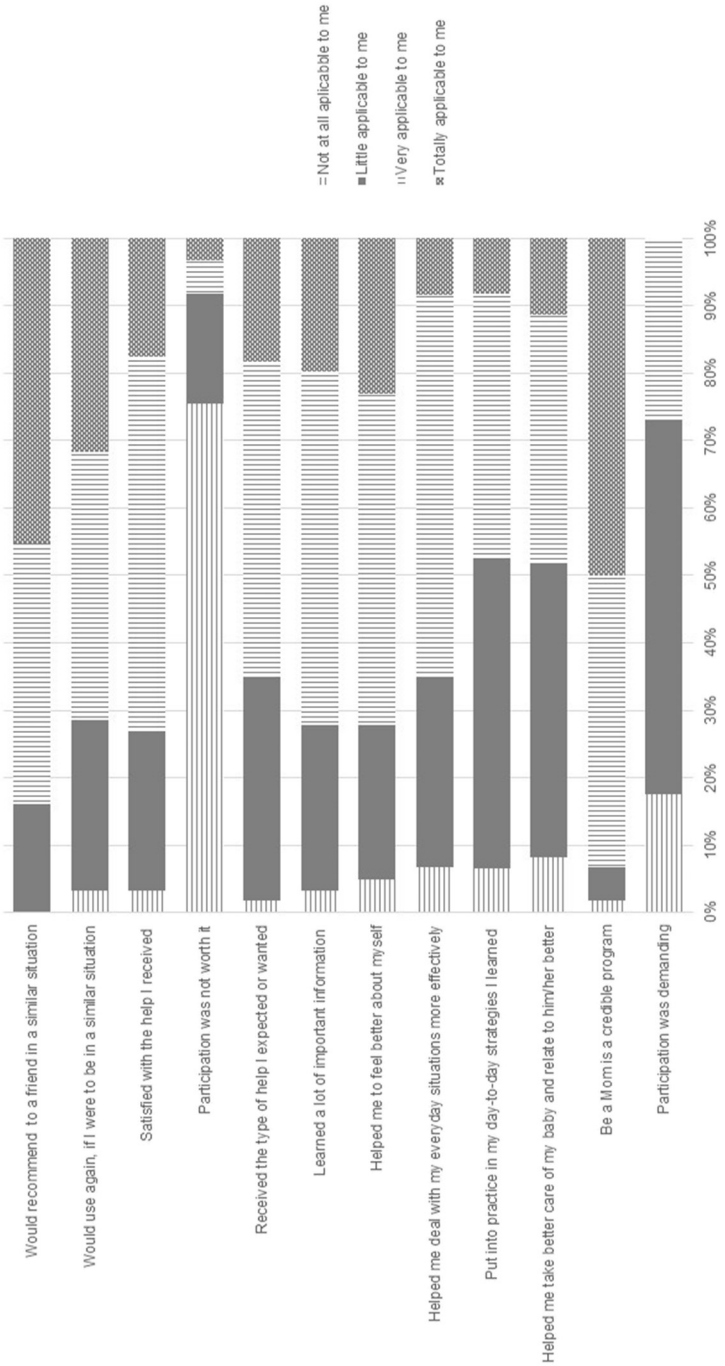

FIGURE 3 Participant's acceptability of Be a Mom.

(Completers: $M = 2.30$, $SD = 0.53$ *vs.* Noncompleters: $M = 1.76$, $SD = 0.51$, $t_{60} = -3.97$, $p < .001$), reported a significantly higher intention to use it if needed (Completers: $M = 2.36$, $SD = 0.72$ *vs.* Noncompleters: $M = 1.77$, $SD = 0.61$, $t_{60} = -3.35$, $p < .001$), and perceived the program as more useful (Completers: $M = 1.86$, $SD = 0.60$ *vs.* Noncompleters: $M = 1.40$, $SD = 0.65$, $t_{60} = -2.85$, $p = .006$) and credible (Completers: $M = 2.63$, $SD = 0.49$ *vs.* Noncompleters: $M = 2.05$, $SD = 0.79$, $t_{60} = -3.57$, $p = .001$). No significant differences were found in the perceived demandingness of using the program (Completers: $M = 1.13$, $SD = 0.66$ *vs.* Noncompleters: $M = 1.04$, $SD = 0.69$, $t_{60} = -0.50$, $p = .620$).

Discussion

The present study aimed to evaluate Be a Mom, a selective/indicated preventive intervention for PPD. The relevance of selective/indicated preventive interventions for PPD is supported by the fact that although most women (>90%) were enrolled in the study because they presented risk factors for PPD, a significant proportion of women already presented clinical levels of depression and anxiety symptoms in the early postpartum period (baseline assessment) both in the intervention and control groups. The results of this pilot trial are generally promising and provide preliminary evidence of the efficacy of the Be a Mom program in reducing early-onset PPD symptoms, and thus in preventing the establishment of a clinical diagnosis of PPD, as well as its feasibility and acceptability.

Preliminary Evidence of Efficacy, Acceptability and Feasibility

Women in the intervention group experienced a significantly larger decrease in depressive (primary outcome) and anxiety symptoms from baseline to postintervention compared to the control group. Specifically, the average reduction of depressive scores from baseline to postintervention was almost double in the intervention group compared to the control group (1.96), and the average levels of depressive symptoms in the intervention group dropped to values that are well bellow the cutoff scores for clinical symptoms, which suggests the effectiveness of Be a Mom in targeting and reducing early-onset depressive symptoms. The reduction of subthreshold depressive symptoms was found to be of utmost importance for preventing the establishment of a clinical diagnosis of major depression (Cuijpers, van Straten, Smit, Mihalopoulos, & Beekman, 2008). Moreover, taking into account the considerable empirical evidence suggesting that depression may be conceptualized as a continuum (Solomon, Haaga, & Arnow, 2001), the reduction of levels of depressive symptoms even in women who score below the cut-off score (i.e., who do not present early-onset symptoms) may exert a protective effect for the development of a clinical diagnosis of PPD.

Furthermore, the average reduction of anxiety scores from baseline to postintervention assessment is almost eight times higher (7.8) in the intervention group than in the control group, suggesting that although Be a Mom was designed to address depressive symptoms, the strategies included in the program seem to have also a clinical effect in the reduction of anxiety symptoms, which are often comorbid with PPD (Falah-Hassani et al., 2016). Taken together, and although this should be further explored in other studies, the high associations found between anxiety and depression symptoms in both assessment times and the significant effect of the Be a Mom intervention in reducing both depression and anxiety symptoms may be suggestive of the importance of targeting both anxiety and depressive symptoms when designing interventions to prevent PPD. Congruently, the results also showed that compared to the control group, a higher proportion of women in the intervention group presented an improvement trajectory over time with regard to depressive symptoms, and a similar trend was found for anxiety symptoms. Although we cannot exclude that these results may be partially due to the fact that women are allocated to an active (intervention) arm rather than a waiting-list arm (e.g., feeling compelled to show an improvement in postintervention assessments), these results suggest that Be a Mom is effective in reducing early postpartum depressive and anxiety symptoms and consequently in preventing the establishment of a clinical diagnosis of PPD. Interestingly, these results also point to the need to further examine if Be a Mom can be used not only as an indicative preventive intervention (i.e., targeting women with early-onset PPD symptoms) but also as an early-intervention tool, targeting women with a diagnosis of mild to moderate depression, as assessed by a clinical interview.

Moreover, no significant interaction effects of time and group were found for the remaining secondary outcomes (maternal confidence, postnatal negative thoughts and dyadic satisfaction), suggesting that the Be a Mom intervention did not significantly impact these outcomes. On the one hand, as the program's content did not directly target caregiving behaviors, the benefits for maternal confidence were only expected to be indirect through the improvement of women's mental health and may not be immediately observed. On

the other hand, benefits were expected for both the frequency of postnatal negative thoughts and dyadic satisfaction. Concerning postnatal negative thoughts, the intervention group presented more frequent baby-related and motherhood thoughts than the control group, but no differences were found in the metacognitive appraisal of the thoughts' content. It is possible that this may result from a greater tendency to stop avoiding negative thoughts by the intervention group, which may be a consequence of the content and skills learned in the second module of the intervention. However, changes in the cognitive pattern of functioning may occur at a slower pace than changes in symptoms and require practice for these skills, so these effects may not be substantially observed at postintervention. This pattern of results should be further explored in trials with follow-up evaluations. Moreover, the absence of effects on dyadic satisfaction despite the existence of a module specifically addressing the couple's relationship may be justified by the fact that most women accessed the program alone. Changes in the couple's functioning may be more likely if both members of the couple are involved in the process (Halford, Petch, & Creedy, 2010), and this should be encouraged in the final version of Be a Mom. Taken together, these results suggest that the change that occurred in depressive and anxiety symptoms was not associated with these theorized mechanisms (e.g., porstpartum thoughts and dyadic satisfaction), suggesting the need to better explore in further studies other mechanisms (e.g., psychological competences or resources) that may be involved in explaining the treatment response.

The results for Be a Mom's acceptability were also globally encouraging, as most women reported a higher intention to use the program and found it relevant, useful and credible, although a third of women considered their participation in the program demanding. Interestingly, women's perceptions of the program's usefulness were congruent with preliminary efficacy findings. A higher proportion of women reported that Be a Mom helped them to learn important information that allowed them to feel better about themselves and to deal effectively with everyday situations, which may translate into a reduction of anxiety and depression symptoms. However, fewer women reported that Be a Mom helped them to put into practice the strategies learned (e.g., to improve cognitive functioning or the couple's relationship) and to improve the mother-child relationship, which is congruent with the absence of differences in these secondary outcomes. Finally, Be a Mom's feasibility results showed a dropout rate of approximately 60%, a proportion similar to the dropout rates of other self-guided interventions for PPD (Lee et al., 2016) and for depression (Karyotaki et al., 2015). This is an important challenge in self-guided interventions because there is evidence that treatment adherence is significantly related to treatment outcomes (Karyotaki et al., 2017). However, the fact that about 40% of the women presenting risk factors for PPD have completed the intervention may represent a significant contribution in terms of improving women's access to interventions aiming to prevent PPD.

When simultaneously considering acceptability and feasibility results, it seems that Be a Mom intervention is seen as acceptable and relevant for the ones who use it, but there is still a significant proportion of women that drop out from the intervention—and only half of noncompleters provide acceptability data—and for whom the intervention might be seen as less useful and, consequently, less helpful and effective. Moreover, it is important to note that most of the women dropped out of the intervention before completing the first module, suggesting that they were not sufficiently attracted to Be a Mom from the beginning and felt diminished motivation to complete it. In addition to the lack of time due to caregiving demands that may have prevented some women to participate in the program, it is possible that women who dropped out early from the intervention may have disliked some of the intervention features (e.g., content, design, characters). On the other hand, it is possible that the women who completed the program were the ones who perceived that they were more in need of it, finding it more relevant and useful. Further studies should explore these hypotheses.

FEASIBILITY OF THE RESEARCH PROTOCOL

While the study is promising, there are several limitations of the current study that need to be addressed in future research to fully evaluate the effectiveness of Be a Mom in preventing persistent PPD. A larger randomized controlled trial (RCT), which is the gold-standard for evaluating the efficacy of health care interventions, will be an important next step, considering the following issues. First, although we initially planned to recruit participants in person at a health care unit, the slow flow of participants instigated a change to include online recruitment, which was found to be an effective way of enrolling participants. In fact, Be a Mom is a self-guided selective/indicated preventive intervention that may be considered a self-care intervention within a stepped care approach

(Perkins, 2016) for PPD. Therefore, there is no need for it to be articulated with a health care institution. Additionally, one of the advantages of unguided interventions, despite their lower completion rates and effects, is their scalable nature and potential to reach a higher number of participants (Donker & Kleiboer, 2018). Therefore, we will opt for online recruitment in the RCT.

Second, randomization was not completely successful because the two groups differed with regard to some sociodemographic characteristics (marital status and income) despite presenting similar levels of PPD risk and symptoms. To improve the success of randomization in the RCT, a stratified randomization method will be used to control and balance the influence of participants' baseline characteristics (covariates). Third, a high number of dropouts occurred in the study, both between eligibility assessment and baseline assessment and between baseline and postintervention assessments. Although the proportion of dropouts was similar to other studies in the field, measures to minimize dropouts will be carefully considered (e.g., introduction of a telephone contact with the researchers between eligibility and baseline assessments to remind participants of the study design and assessment times; preference for short versions of the assessment instruments; measures to improve adherence to the Be a Mom program). In the pilot trial, and following intention-to-treat principles, a statistical approach that handles missing data was used. Additionally, to minimize the effects of sociodemographic characteristics that were found to differentiate women who dropped out of the study from those who completed both assessments, the influence of such variables was controlled for in the statistical analyses, and the same procedures will be considered when defining the RCT's analytic plan. Finally, particularly with regard to the intervention group, it would have been useful to assess the reasons for dropout. The inclusion of such questions, preferably in the format of open-ended questions, will be considered in the RCT.

Furthermore, in the present study the mechanisms that explain the participants' response to treatment were not directly explored, although its exploration will allow the refinement of existing treatment procedures by providing a better comprehension about the treatment components that are responsible for change (Kazdin, 2007). The results showed that the Be a Mom program had no significant impact in the levels of postnatal negative thoughts or dyadic satisfaction, suggesting the need to explore other possible mechanisms responsible for the participant's treatment response. There is preliminary evidence that changes in core psychological processes (e.g., emotion regulation abilities, self-compassion and psychological flexibility) may be associated with changes in depressive symptoms (Fonseca, Monteiro, Alves, Gorayeb, & Canavarro, 2019), although this should be further explored in a full-powered RCT.

Finally, given the specific goals, the pilot trial only comprised a postintervention assessment, and the exact time between assessments was not controlled for in the analyses. However, to provide further evidence of the efficacy of Be a Mom in preventing persistent PPD, additional follow-up assessments are needed (up to 12 months postpartum) and the time between assessments should be considered. Moreover, the use of a clinical interview by an independent rater to complement data from screening tools (risk and symptoms assessment) will provide additional and valuable information. In addition, future studies with greater sample sizes should try to examine if participants' treatment responses are dependent on their pattern of participation in the Be a Mom program (e.g., completion of the modules, completion of interactive exercises or of the homework activities). This will be considered when planning the RCT design. As mentioned, an RCT that can integrate these modifications, and that can include the cost-effectiveness evaluation of Be a Mom, will provide valuable evidence concerning the effectiveness of Be a Mom and of web-based interventions to prevent PPD, in general. Despite these limitations, the present study constitutes an important contribution to the further development of the Be a Mom program and more broadly to the acceptability and efficacy of web-based interventions to prevent PPD.

Conflict of Interest Statement

The authors have no conflict of interest to disclose.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.beth.2019.09.007.

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Received: December 27, 2018
Accepted: September 24, 2019
Available online: 20 November 2019