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Effectiveness of Smart Mama application on postpartum depression, anxiety, and maternal-infant bonding among women during the postnatal period: a randomized controlled trial

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Abstract

Background Postpartum depression and anxiety are significant public health concerns that have serious well documented negative effects on mothers and their families. However, they often remain under-recognized because of limited in-person interactions, time restrictions, lack of adequate support, and pervasive stigmatization. This study investigated the effectiveness of the Smart Mama application on postpartum depression, anxiety levels, and maternal-infant bonding at 12 weeks postpartum.

Materials and methods This prospective parallel-group randomized controlled trial included 148 participants from March 1, 2023, to March 31, 2024. Those who agreed to participate were randomly assigned to receive the Smart Mama intervention ($n=74$) or routine care ($n=74$), using permuted stratified block randomization. The primary outcome was assessed using the Edinburgh Postnatal Depression Scale (EPDS). The secondary outcomes were evaluated using the State-Trait Anxiety Inventory (STAI) and Maternal-Infant Bonding Scale (MIBS) at baseline and the 12-week follow-up using validated standardized tools.

Results Compared with the control group, the Smart Mama intervention group showed a significant reduction in postpartum depressive symptoms (P for time × group interaction = 0.04), with a reduction in the EPDS mean score from 9.03 (standard deviation, 2.47) to 5.61 (3.3), whereas the control group showed a change from 9.01 (2.75) to 7.16 (3.1) at 12 weeks post-intervention. Similarly, the Smart Mama intervention led to a significantly greater decrease in both state and trait anxiety levels (both P for time × group interaction < 0.05) compared to the control group. No statistically significant effect on maternal-infant bonding was observed between the intervention and control group (P for time × group interaction = 0.25).

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Conclusion and implications The Smart Mama intervention significantly reduced postpartum depressive symptoms and anxiety. This study provides empirical evidence and novel insights into the effectiveness of mobile device applications. By integrating a holistic approach, Smart Mama represents a promising and innovative solution for enhancing maternal health outcomes, empowering self-care activities, and overcoming barriers to accessibility.

Trial registration The study was registered in the University Hospital Medical Information Network (UMIN) Clinical Trial Registry (ID: (UMIN000050065) on January 19, 2023 (https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000056562).

Keywords Postpartum depression, Anxiety, Mother-infant bonding, Telenursing, Smart Mama app, Mobile health, Randomized controlled trial

Introduction

The postpartum period is a critical transitional phase in parenthood requiring adjustment [1]. Despite being perceived as a positive experience, the postpartum period poses numerous challenges for women that can affect their health and well-being and increase their risk of mental health issues [2]. Postpartum depression (PPD) and anxiety are the leading causes of maternal morbidity and mortality [3]. According to the largest meta-analysis to date, PPD has a global prevalence of approximately 17.22%, with less than 1% of women diagnosed with postpartum psychosis and 15.0% experiencing postnatal anxiety [4, 5].

According to Japanese birth cohort studies [6], Japanese women often experience anxiety and depression after childbirth. The Japan Environment and Children's Study (JECS) reported a prevalence of PPD of 13.7% among women at 1 month after childbirth [7]. Another Japanese study found a cumulative prevalence of 15.2% among women at a high risk of developing PPD within 12 weeks of giving birth. One of the most serious adverse outcomes of PPD is suicide; in one study in Japan, 8.7/100,000 births resulted in maternal and late-maternal suicides [8]. PPD is commonly characterized by diminished interest; feelings of inadequacy; loneliness; guilty conscience; insomnia; sense of helplessness; suicidal ideation; diminished maternal-infant attachment and bonding; and impairment of the emotional, mental, and social development of children [9].

As part of its Sustainable Development Goals, the World Health Organization (WHO) has launched crucial recommendations for decreasing maternal and child morbidity and mortality. In response, various interventions have been designed for women experiencing PPD, including supportive nursing interventions, psychotherapy, cognitive behavioral therapy, and pharmacotherapy; nevertheless, concerns regarding the side effects of certain medications such as antidepressants in lactating mothers have been raised [10]. According to the American College of Obstetricians and Gynecologists (ACOG), achieving optimal postpartum care requires restructuring of current care services by leveraging telenursing services [11]. Telenursing enables nurses to provide patient care remotely via various telecommunication channels and platforms, such as mobile health applications (apps) [12].

Owing to the scarcity of resources and technological advancements, telehealth interventions for PPD have emerged as a promising option in healthcare delivery services for improving maternal outcomes [13]. One of the key advantages of mobile app-based telenursing is its ability to deliver customized features and holistic support to women during the postnatal period [14]. Additionally, many women have limited access to these interventions because of financial constraints, time restrictions, concerns about medication side effects, privacy concerns, and social stigmatization [15].

Mobile health interventions are increasingly being considered promising solutions for preventing postpartum depression (PPD) and anxiety. Telenursing using the Smart Mama application provides a holistic approach that integrates physical, psychological, and informational support for mothers experiencing PPD. However, rigorous evaluations through well-designed randomized controlled trials (RCTs) are limited. Despite the extensive literature on PPD, the urgent need for innovative, holistic, and tailored interventions to alleviate PPD and anxiety remains. However, telenursing via mobile apps for PPD is still in its infancy, and few RCTs have evaluated its effectiveness. Therefore, to address this research gap, we conducted an open-label randomized controlled trial to evaluate the effectiveness of telenursing using a smartphone app (Smart Mama) in addressing PPD, anxiety levels, and maternal-infant bonding among Japanese women.

Objectives of the study

The primary aim of this study was to evaluate the effectiveness of telenursing using a smartphone application (Smart Mama) in improving postpartum depressive symptoms among women at 12 weeks postpartum.

The secondary aim of this study was to determine whether the Smart Mama intervention was effective in reducing postnatal anxiety levels and enhancing maternal-infant bonding at 12 weeks postpartum.

Research hypothesis

Compared to women who received standard or routine postpartum care (control group), postpartum women who received telenursing through a smartphone app (Smart Mama) were likely to perceive reduced postpartum depressive symptoms, decreased postnatal anxiety levels, and enhanced maternal-infant bonding.

Theoretical framework

Our study is grounded in the Roy Adaptation Model (RAM) developed by Callista Roy in the 1960s [16]. Roy's model emphasizes the concept of adaptation, which includes the interactions of a person with health, the environment, and nursing care. In our research study, postnatal women who experienced depressive symptoms and anxiety were viewed as "persons" who were influenced by various focal stimuli that affected their adjustment to the environment. Contextual stimuli such as demographic variables of age, educational status, income, and parity affect coping mechanisms. Women's adaptation levels can be determined by how positively they respond to environmental changes.

The intervention group received the Smart Mama intervention, whereas the control group received routine care. The adaptive responses among mothers in the intervention group were expected to promote their well-being, leading to decreased depressive symptoms and anxiety, and improved maternal-infant bonding. In contrast, maladaptive responses were expected in the control group, resulting in either no changes or negative outcomes Figure 1.

Methods

Study design

This was an open-label, parallel-group, randomized controlled trial (RCT) that aimed to evaluate the effectiveness of telenursing using a smartphone app (Smart Mama) in improving postpartum depressive symptoms in women 12 weeks postpartum. The primary outcome was the postpartum depressive symptoms and the secondary outcomes were postnatal anxiety and maternal-infant bonding, all stages of RCT were selected according to the Consolidated Standards of Reporting Trials (CONSORT) [17] Fig. 2. The RCT study was registered with the University Hospital Medical Information Network (UMIN) Clinical Trial Registry (UMIN000050065) on January 19, 2023.

Participant recruitment and study setting

Study participants were recruited from Kanagawa, Japan's second-most populous prefecture, after Tokyo, with a population of approximately 9.2 million. This prefecture provides healthcare services and facilities for low-risk mothers to meet their perinatal and postnatal needs, well-established maternity services, and resources for postpartum women. In addition, healthcare facilities provide high-quality healthcare services, comprehensive postpartum support, and well-structured care systems.

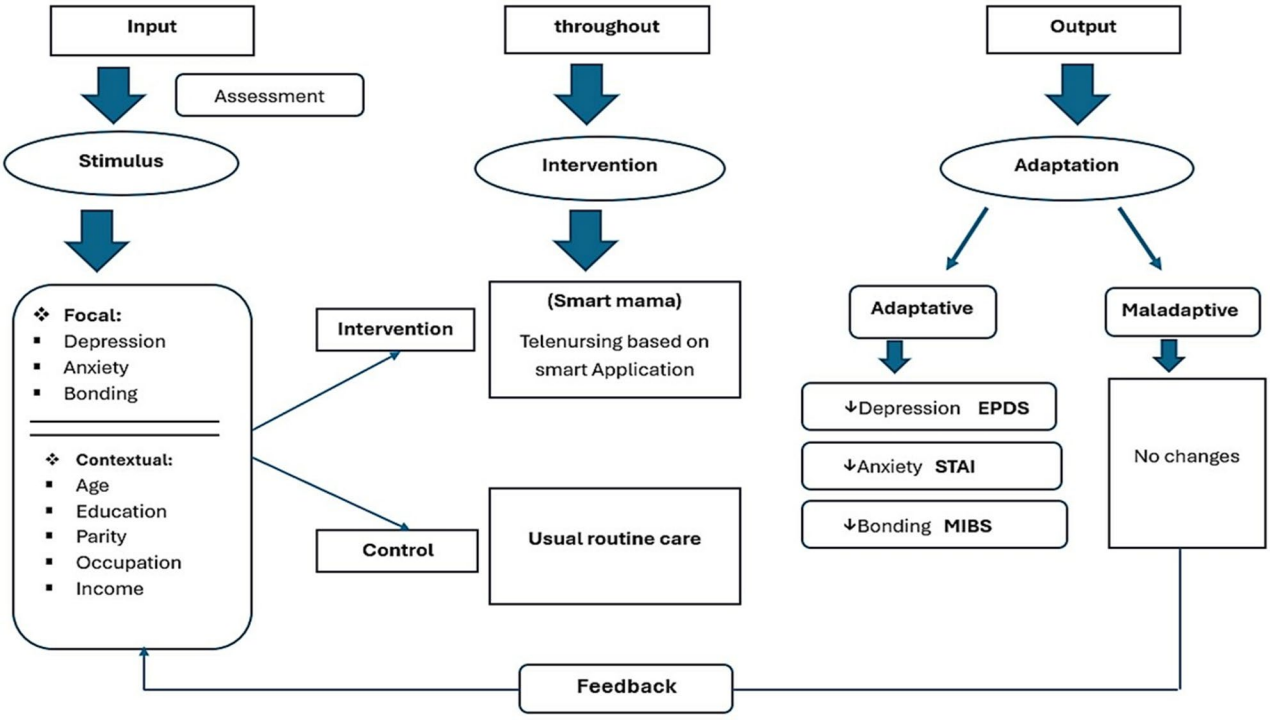

Fig. 1 Theoretical framework (Roy adaptation model)

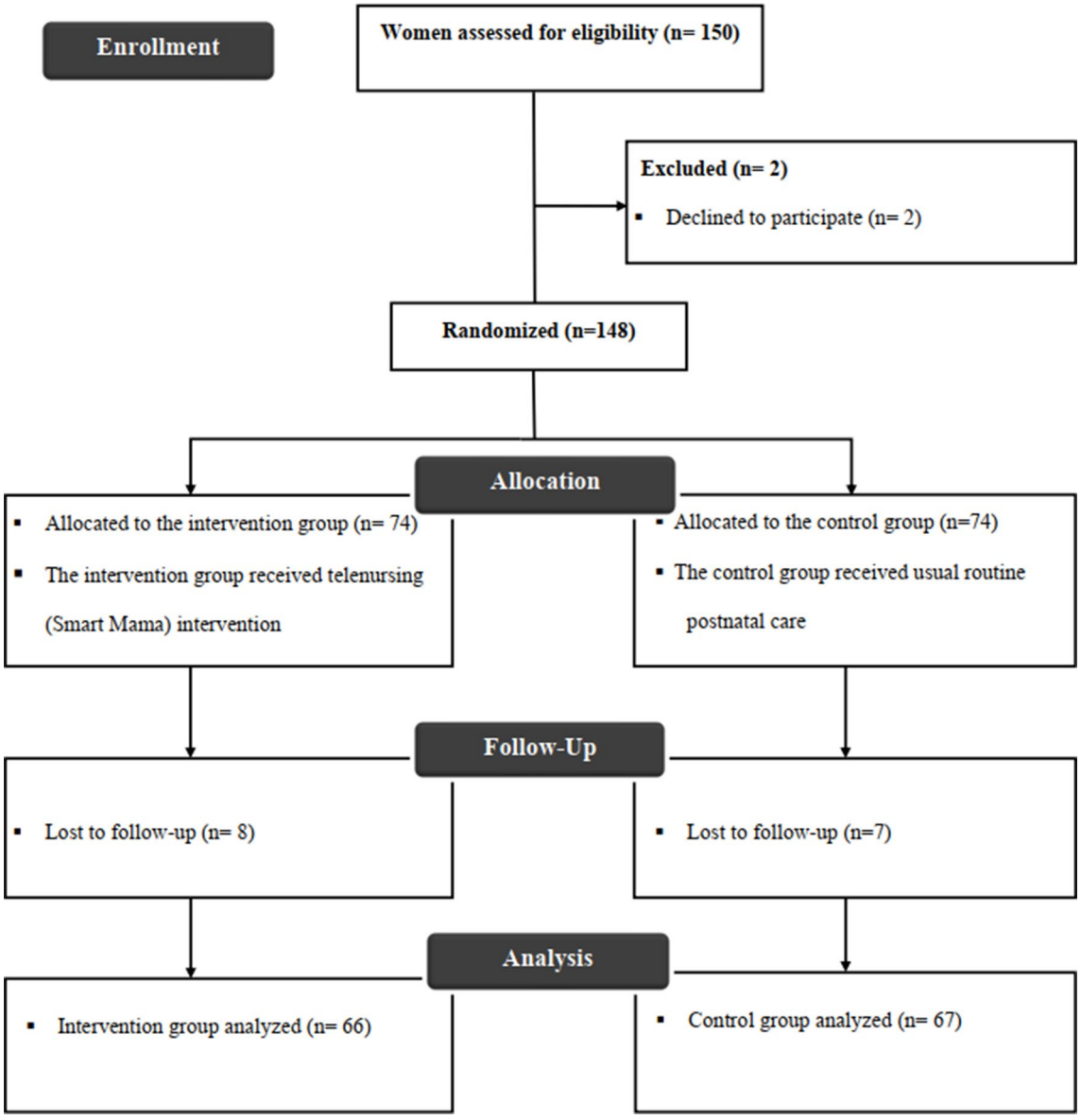

Fig. 2 Consolidated standards of reporting trials flow diagram. Legend: Participant recruitment and steps of the randomized controlled trial are depicted in this flow diagram

Participant recruitment occurred from March 1, 2023, to March 31, 2024. As part of the recruitment strategy, a poster was displayed to inform potential participants about the purpose and content of the study. The poster included information on the study objectives, eligibility criteria, research period, incentives for participation, and how to complete the initial survey and access the Smart Mama application.

Sample size and sampling method

The sample size was calculated using the G*power program, version 3.1.9.7, (analysis of variance [ANOVA] with repeated measures [for within- and between-group interactions]) to account for repeated observations over time and ensure both within-group and between-group effects are captured, assuming a medium effect size of 0.5 with 80% power and significance level of 0.05. These parameters were based on the findings of prior similar studies that assessed the effect of mobile apps on anxiety and depression levels, which reported similar effect sizes [18, 19]. The sample size was initially calculated to be 130 mothers: 65 in the intervention group and 65 in the control group. Based on these recommendations and anticipating potential attrition, the sample size was increased by approximately 15%, resulting in 150 participants (75 per group) at the beginning of the study. During the intervention period, 15 participants (8 in the intervention group and 7 in the control group) dropped out or were

lost to follow-up. To maintain the validity and internal consistency of the study, we adopted a per-protocol analysis that included only 133 participants (66 interventions) and (67 control) who completed the baseline and follow-up assessments. This approach helped preserve the statistical power and group balance for outcome evaluation.

Eligibility criteria

The participants were postpartum women aged ≥ 18 years (primiparous and multiparous) who delivered at full-term. The eligibility criteria were postnatal status without a history of mental disorders, obstetric diseases (such as eclampsia or placenta previa), or alcohol or substance abuse; ability to use the app with internet access and communicate in Japanese; and willingness to participate in the study. Additionally, for postnatal women with an Edinburgh Postnatal Depression Scale (EPDS) score ≥ 8, we used a validated cutoff score of 8/9 according to previously validated studies conducted in Japan; a validated Japanese version of the EPDS translated by Okano et al., [20] was used to define elevated postpartum depressive symptoms [21]. The exclusion criteria included women with serious underlying diseases (including autoimmune diseases), those who had given birth to a newborn with an apparent congenital anomaly, women with infants hospitalized in the neonatal intensive care unit, and those who had a complicated fourth-degree perineal tear. Women were excluded if they exhibited any risk of suicide or self-harm (suicidal intent).

According to the established inclusion and exclusion criteria, 150 eligible participants were recruited; two opted not to participate. Of the remaining 148 participants, 74 were randomly allocated to the intervention ($n = 74$) or control ($n = 74$) group. The intervention group received Smart Mama intervention, whereas the control group received routine postnatal care. During the follow-up period, eight and seven participants were lost to follow-up in the intervention and control group. Consequently, 66 participants in the intervention group and 67 in the control group completed both baseline and follow-up assessments. Therefore, we ultimately chose to perform a per-protocol analysis of the data of 133 participants who completed both baseline and follow-up assessments (66 in the intervention group and 67 in the control group) (see Fig. 2). This approach was adopted to preserve statistical power, ensure data integrity, and maintain balance between groups, despite attrition, for valid comparisons of outcomes.

Allocation, randomization, and blinding

Eligible women who agreed to participate were randomly assigned to the intervention or control groups to ensure that they had an equal chance of being included in this study. We used randomly permuted stratified block randomization of different sizes to achieve a balance between the study arms and reduce the opportunity for bias and confounding using an online randomization tool (www.sealedenvelope.com).

First, we divided the participants into intervention and control groups. We then stratified them by parity (primiparous or multiparous) in each stratum, such that both groups had a similar distribution of first-time mothers and those who had delivered before. We then utilized random permutated blocks of size 4 to maintain balance and prevent predictability between the groups. As the participants in each stratum had similar characteristics, grouping them under strata enhanced the reliability of the experiment. Once the list was generated, it was categorized as intervention primi, intervention multi, control primi, or control multi. The entire randomization sequence process was independently generated by another researcher who was not involved in participant recruitment, intervention provision, outcome assessment, or data analysis.

Owing to the nature of our intervention, blinding was difficult because the researchers had to assess, implement, and evaluate the intervention's effectiveness, whereas the mothers in the intervention group had to install the app on their phones. The participants were blinded to the outcome analysis. We assigned codes (A) and (B) to the intervention and control groups and concealed them in the statistical analysis phase.

Study procedure

Data were collected after obtaining ethical approval, and written consent was obtained from all individuals who agreed to participate. Eligible participants in both groups were approached on the day of discharge. They received information on the study's purpose, participant rights, and how to complete the questions on the baseline demographic characteristics, EPDS, State-Trait Anxiety Inventory (STAI), and Mother-to-Infant Bonding Scale (MIBS). The questionnaires were administered on the day of discharge and took approximately 20–30 min to complete. At 12 weeks postpartum, the research team emailed the intervention and control groups and asked them to answer an online questionnaire using Google Forms. After the participants completed the follow-up questionnaire, we sent them gifts and letters of appreciation. The participants were encouraged to respond via email reminders.

Intervention

The women in the intervention group received the Smart Mama intervention, a smartphone app-based intervention developed to reduce PPD and anxiety, alongside their regular postnatal care. Before discharge from the hospital, each woman received a comprehensive

explanation of registration and logging into the Smart Mama app. In addition, the printed pamphlet provided clear step-by-step instructions as a supplementary guide. To address the challenges associated with accessing particular modules, managing notifications, and tracking progress within the app, the app included a help section and technical support section that enabled users to obtain assistance when necessary. Furthermore, a system for progress tracking and badges was designed to enhance user motivation and encourage continued engagement. The app download link (https://play.google.com/store/apps/details?id=com.castalia.goocus3) was sent to the women via email and to the relevant mobile app store. The mothers accessed the app on their mobile devices (Android or iPhone) by signing in with their registered emails and passwords Fig. 3.

The intervention comprised a comprehensive package of modules including physical, psychological, and informational support (Supplementary file 1). The physical support intervention included teaching women how to perform light-to-moderate stretching exercises. We provided more than seven types of stretching exercises, including chest stretch, cross-body stretch, standing quadriceps stretch, lower lung stretches, standing hip flexor stretch, and lying whole-body stretch. The frequency and duration of the exercises were based on their capabilities. To maximize efficacy and prevent strain, each exercise was performed in a structured manner with an emphasis on posture, controlled breathing, and gradual movements. Stretching exercises were performed for 10–60 s, with repetitions as tolerated, to enhance flexibility and muscle strength, while also promoting mental well-being after birth. The intervention also included pelvic floor muscle exercises such as Kegel exercises.

Psychological support consisted of muscle relaxation techniques through different phases of muscle relaxation, beginning with the "tense-relax" technique, where they intentionally tensed a muscle group and then released the tension to experience relaxation. This method was followed by a "contrast method" that combined controlled breathing muscle contractions and relaxation. In the final phase, the women were encouraged to concentrate on muscle awareness without movement, allowing them to recognize and release mental tension without bending or

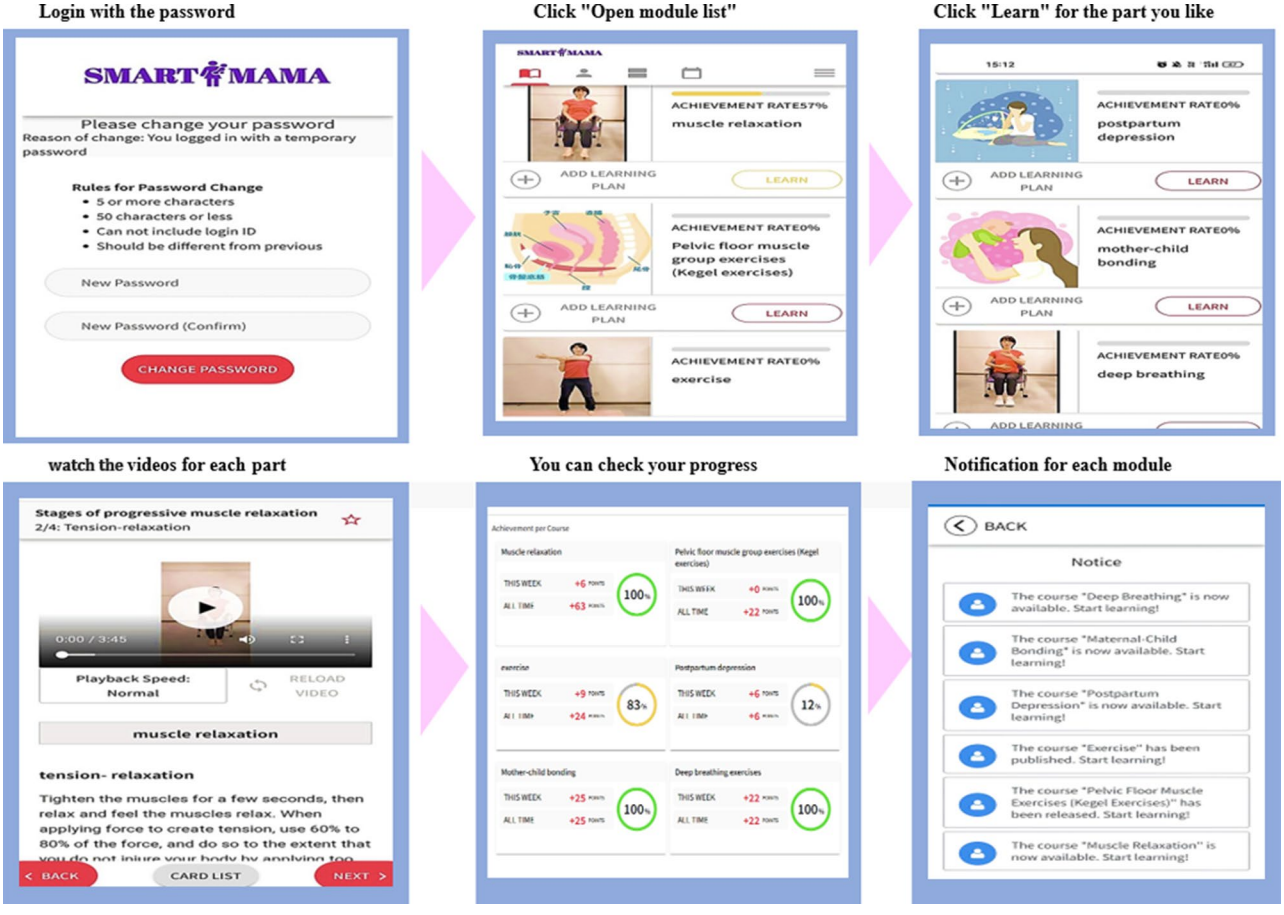

Fig. 3 Screenshot of smart Mama application: registration instructions, homepage, and sessions. Legend: Key features of the Smart Mama app and learning modules. During the first login to the site, a secure password is requested to ensure user privacy and security. The application includes text-based information, videos, illustration tutorials, and notifications to keep users informed when new modules become available

stretching. Breathing exercises that promoted relaxation through controlled breathing were also provided.

Informational support was provided by giving the women information about PPD signs and symptoms, preventing and managing depressive symptoms, and the potential consequences of untreated PPD for mothers and infants. Additionally, the mothers were instructed about self-care activities, including seeking physical, psychological, and social support, and ways to enhance infant-maternal bonding for 12 weeks in the form of text-based information, videos, and illustrated photos.

The smart Mama is self-guided and was developed to provide a holistic approach to self-care activities. However, the app also includes interactive components, such as a support platform where participants can receive reminders. The most motivational aspect of the Smart Mama instructional videos was that a trained midwife, who was a member of our research team, demonstrated stretching exercises to ensure that the women could perform them independently. Throughout the intervention, the participants received personalized notifications encouraging and motivating them to regularly utilize the app while tracking their progress in real-time and cumulative learning time once they completed each module.

Adherence to the Smart Mama app

To enhance the mothers' adherence to the Smart Mama app, a push notification reminder was sent from the app to inform them that a new module was available, e.g., "Pelvic Floor Muscle Group Exercises was released. Let's start." Activities and progress could also be tracked on a dashboard where the achievement rate was recorded. In this study, user engagement with and adherence to the Smart Mama application were objectively assessed using system-generated data. Through the backend tracking system of the Smart Mama app, user interaction metrics, such as time spent in the app, progress in modules, and completion of learning cards, were tracked. In addition, the app records user interactions over time, including how many learning modules are completed and how long users engage with the app. Consequently, it was possible to directly compare the actual engagement levels with projected engagement levels.

A progress indicator in the application allowed users to monitor their progress over time. The completion metrics for each learning module were maintained automatically, providing users with a clear picture of their progress over time. Although these data were not statistically analyzed in the current study, the dashboard summaries generated by the system indicated that the participants engaged regularly with the app. The indicators of visual progress indicated that most users had completed all the educational modules and interactive learning cards. Throughout the 12-week program, users were sent daily push notifications prompting them to log in and complete their assigned content. These features enabled high exposure to the intervention and helped sustain participant engagement.

Control group (routine care)

The mothers in the control group received standard or routine care. In Japan, mothers who gave birth vaginally stay in the hospital for 5 days, while mothers who deliver by cesarean section stay for 7 days. Women in the control group received the recommended standard of routine postnatal care outlined in the Maternal and Child Health Handbook, according to the standards set by the Ministry of Health, Labor, and Welfare of Japan. Standard care consisted of 2-week and 1-month health checkups for the mother and baby. This care typically involves a comprehensive postnatal assessment (history-taking, general advice about infant care examinations, and health education). Additionally, the mental status of the mothers was examined along with their physical recovery and lactation status at 2 weeks and/or 1 month after delivery at obstetric institutes (Postpartum Maternity Checkup Programs) [22].

Development of the app

Description and aim We selected Smart Mama because it provides holistic postpartum supportive interventions (physical, psychological, and informational) using smartphones for 12 weeks. The application was designed by an experienced team of information technology specialists, under the supervision of the research team. A software developer applied the implementation conditions, and all the content was transformed into a computational Japanese language for smartphone use. The app was arranged into indices, scripts, access structures, images, and videos to facilitate participants' use.

Components of the app

Management system interface Using the interface, a new user can register and sign into the application using an email address and create a protected password. A unique login ID is assigned to each user to personalize their experience. After logging in, users can access their learning histories and progress on their personalized dashboards.

Timeline interface This interface displays a structured list of educational modules that users can access at any time. It comprises videos, pictures, and text-based materials. Each module is displayed as an interactive card accompanied by progress bars and achievement rates, allowing users to monitor their progress. Users can also access (add learning plans) personalized study schedules.

Notification The app sends push notifications to users as reminders of daily learning and courses, e.g., "Today's learning time." These reminder notifications encourage and motivate the mothers to regularly engage with the app and complete the learning modules.

Progress tracking The progress tracking system monitors the real-time user activity and total study time spent on the app. The cumulative learning time represents the total learning time of all users during the selected period. The achievement rate was also estimated for each module (e.g., 100% for breathing techniques). Badges made the learning interactive and engaging.

Data collection and outcome measures

After a comprehensive literature review, a sociodemographic and clinical assessment questionnaire was developed. Demographic data included age, educational level, parity, residence, marital status, employment status, and monthly income. The clinical health assessment form included data related to pregnancy, labor, and the postpartum period.

Edinburgh Postnatal Depression Scale (EPDS)

One of the most common self-report questionnaires used to measure PPD is the EPDS, developed by Cox [23]. It comprises 10 questions scored on a four-point Likert scale of one to four, with a total score ranging from 0 to 30, and a higher score indicating worse depressive symptoms. We used the Japanese version of the EPDS; its internal consistency was excellent (Cronbach's alpha = 0.75), and the test-retest reliability was excellent, with a sensitivity of 75% and 82% and specificity of 92% and 95%. We used a validated cutoff score of > 8 /9 to define the presence of elevated postpartum depressive symptoms [20].

State-Trait Anxiety Inventory Scale (STAI)

The State-Trait Anxiety Inventory Scale (STAI) was originally developed by Spielberger [24] to measure the anxiety levels. We used the validated Japanese version of the scale (STAI-JY) [25, 26], which had reliability coefficients ranging from 0.76 to 0.71 and internal consistency coefficients (Cronbach's alpha) ranging from 86 to 95. This test is administered using two forms: State-Trait Anxiety Inventory Form Y (STAI-Y), the most popular and psychometrically robust version, consisting of two subscales: State Anxiety (STAI-S) and Trait Anxiety (STAI-T), each consisting of 20 items. State anxiety (STAI-S) items include "I am tense; I am worried" and "I feel calm; I am secure." Trait anxiety items include "I worry too much over something that really doesn't matter" and "I am content, and I am stable." Trait anxiety (STAI-T) items include: "I worry too much over something that really doesn't matter" and "I am content; I am a steady person." Each item is rated on a four-point Likert scale, typically ranging from "Almost Never" to "Almost Always," with higher scores indicating greater levels of anxiety.

Mother-to-Infant Bonding Scale (MIBS)

The MIBS is a self-rated scale developed by Taylor [27] to assess the level of bonding between the mother and infant postpartum. The MIBS consists of 10 feeling descriptors (loving, resentful, neutral/feeling nothing, joyful, disliked, protective, disappointed, and aggressive). The MIBS is rated on a 4-point Likert scale (from 0, "very much," to 3, "not at all"), with the scale of some items reversed. A high score indicates poor mother-to-infant bonding. The validity and reliability of the Japanese version of the MIBS have been reported previously [28].

Content validity

The content used in the intervention was prepared and validated by three experts in obstetrics and gynaecology, nursing and midwifery, and psychiatry to test its clarity, comprehensiveness, appropriateness, and content validity before using the tool. Modifications were made according to the recommendations of the experts.

Data analysis

Data were collected and analyzed using IBM SPSS Statistics for Windows version 26 (IBM Co., Armonk, NY, USA). Numerical data are presented as the mean and standard deviation (SD) and categorical data are presented as frequency and percentage. Data were analyzed using the chi-square test to compare the intervention and control groups at baseline. Two-way ANOVA with repeated measures was conducted, with the group (intervention and control) as a between-subject factor and time (pre- and post-intervention), and the group × time interaction to test whether the effect of time differed by group. Statistical significance was set at $p < 0.05$.

Results

A total of 150 women were assessed for eligibility, and 148 were recruited and randomly assigned to the intervention ($n = 74$) or control ($n = 74$) group from March 1, 2023, to March 31, 2024. Table 1 shows the baseline sociodemographic characteristics of the participants. The mean (SD) age was 32.59 ± 4.271 years in the intervention group and 33.20 ± 3.90 in the control group. Most participants in both groups were university graduates ($n = 93$, 62.8%) or employed ($n = 107$, 72.3%). Regarding parity, 37 (50%) women were multiparous, and 37 (50%) were primiparous in the intervention group. In contrast, 36 (48.6%) women were multiparous and 38 (51.4%) were primiparous in the control group. No statistically significant differences were observed in these variables, except

Table 1 Baseline sociodemographic characteristics of the study participants

Sociodemographic Characteristics	Study group (n = 74)	Control group (n = 74)	*P*-value
Age (years), n (%)			
20–29	20 (27.0)	16 (21.6)	0.71
30–39	49 (66.2)	54 (73.0)	
40–45	5 (6.8)	4 (5.4)	
Age, mean (SD)	32.6 (4.3)	33.2 (3.9)	0.36
Educational level, n (%)			
Junior high school	1(1.4)	0 (0.0)	
High school	4 (5.4)	9 (12.2)	
Vocational school	16 (21.6)	14 (18.9)	
Junior college	2 (2.7)	5 (6.8)	0.46
University graduate	49 (66.2)	44 (59.5)	
	2 (2.7)	2 (2.7)	
Graduate school			
Occupation, n (%)			
Housewife	22 (29.7)	19 (25.7)	
Working	52 (70.3)	55 (74.3)	0.58
Marital status, n (%)			
Married	74 (100.0)	73 (98.6)	0.31
Not married	0 (0.0)	1 (1.4)	
Parity, n (%)			
Primipara	37 (50.0)	36 (48.6)	0.86
Multipara	37 (50.0)	38 (51.4)	
Household's monthly income, n (%)			
Sufficient	19 (25.7)	18 (25.0)	
Just meet life expenses	43 (58.1)	30 (49.3)	0.02*
Insufficient	12 (16.2)	26 (25.7)	
Maternity leave (for those who are working), n (%)			
Taking maternity leave	49 (94.2)	53 (96.4)	0.67
Plan to return to work	3 (5.8)	2 (3.6)	
Family members living with you after giving birth, n (%)			
Husband	72 (97.3)	68 (91.9)	0.14
Older child	37 (50)	37 (50)	0.99
Parents	7 (9.5)	8 (10.8)	0.78
Parents-in-law	1 (1.4)	2 (2.7)	0.99
Others	1 (1.4)	2 (2.7)	0.99

Categorical variables are presented as frequency (n) and percentage (%), and continuous variables are presented as mean and standard deviation (SD)

* Statistical significance at P value < 0.05

SD: Standard Deviation

for monthly income, supporting comparability between the groups.

Most women did not attend parent-taught classes: 51 (68%) in the intervention group and 53 (71%) in the control group. Regarding the mode of delivery, 87.8% and 83.8% of the women in the intervention and control groups, respectively, underwent vaginal delivery. Furthermore, most participants in both groups reported combined or mixed feeding patterns ($n = 103$; 69.6%). The

Table 2 Comparison of the clinical obstetric characteristics between intervention and control group

Variables	Study group (*n* = 74)	Control group (*n* = 74)	*P*-value
Parent-teaching classes, n (%)			
Attend	23 (31.1)	21(28.4)	
Did not attend	51 (68.9)	53 (71.6)	0.71
Feeling when you got pregnant, n (%)			
Overjoyed	23 (31.1)	23 (31.1)	
Happy	38 (51.4)	37 (50)	0.98
Mixed feeling	13 (17.6)	13 (17.6)	
Mode of delivery, n (%)			
Vaginal birth	65 (87.8)	62 (83.8)	0.48
Cesarean section	9 (12.2)	12 (16.2)	
Placental delivery, n (%)			
Spontaneous	32 (43.2)	39 (52.7)	0.51
Manually removed	28 (37.8)	23 (31.1)	
I don't know	14 (18.9)	12 (16.2)	
Episiotomy, n (%)			
Yes	30 (40.5)	38 (51.4)	0.18
No	44 (59.5)	36 (48.6)	
Feeding pattern, n (%)			
Breastfeeding	9 (12.2)	9 (12.2)	
Combined	50 (67.6)	53 (71.6)	
Formula or milk only	15 (20.3)	12 (16.2)	0.81

Obstetric outcomes between groups regarding parent class attendance during pregnancy, mode of delivery, and feeding patterns. Data are presented as frequencies (*n*) and percentages (%) for categorical variables and were analyzed using the chi-square test. * Statistical significance at *P* value < 0.05

SD: standard deviation

two groups were matched across various clinical obstetric outcomes, and the data were homogeneous with no significant differences Table 2.

Table 3 presents the estimated marginal means of the primary (depressive symptoms) and secondary outcomes (postnatal anxiety and maternal-infant bonding) based on time, group, and time × group interaction. The mean EPDS scores in the Smart Mama group decreased from 9.03 (SD = 2.47) at the baseline to 5.61 (SD = 3.30) postintervention, while in the control group, the scores decreased from 9.01 (SD = 2.75) to 7.16 (SD = 3.1), showing a significantly greater reduction in postpartum depressive symptoms (P for time × group interaction = 0.04) in the intervention group compared to in the control group.

Concerning postnatal anxiety, a significant time × group interaction effect was observed for both state and trait anxiety scores. State anxiety scores decreased from 47.41 (SD = 4.65) to 34.80 (SD = 5.03) in the intervention group and from 45.66 (SD = 5.39) to 35.82 (SD = 4.09) in the control group ($P = 0.023$). Trait anxiety scores declined from 47.70 (SD = 4.31) to 33.65 (SD = 5.41) in the intervention group and from 46.84 (SD = 8.14) to 37.16

Table 3 Comparison of the primary and secondary outcomes within (over time) and between-group interactions effects

Variables	Intervention (N = 66)		Controls (N = 67)		Time main effect *P*	Group main effect *P*	Group x Time effect *P*
	Before mean (SD)	After mean (SD)	Before mean (SD)	After mean (SD)			
EPDS score	9.03 (2.47)	5.61 (3.3)	9.1 (2.75)	7.16 (3.1)	0.001	0.023	0.043
STAI-S score	47.41 (4.65)	34.80 (5.03)	45.66 (5.39)	35.82 (4.09)	0.001	0.526	0.023
STAI-T score	47.70 (4.31)	33.65 (5.41)	46.84 (8.14)	37.16 (6.23)	0.001	0.077	0.005
MIBS score	5.06 (1.86)	2.82 (2.53)	5.79 (2.75)	4.24 (3.04)	0.001	0.002	0.249

The outcome measures changed within and between the intervention and control groups using two-way ANOVA

With repeated-measures tests at baseline and after the intervention, the main effect of time, and (group × time) effect

SD: standard deviation; EPDS, Edinburgh postnatal depression scale; N: number of participants; STAI-S, State-Trait Anxiety Inventory; STAI-T: Trait Anxiety Inventory Scale; MIBS: Mother-to-Infant Bonding Scale

(SD = 6.23) in the control group. Time was found to have a significant effect. Although no overall significant group effect was observed, the time × group interaction led to a significantly greater decrease in trait anxiety scores in the intervention group than in the control group (P for time × group interaction = 0.005).

Regarding maternal-infant bonding, the MIBS scores in the intervention group decreased from 5.06 (SD = 1.86) to 2.82 (SD = 2.53) and from 5.79 (SD = 2.75) to 4.24 (SD = 3.04) in the control group. The decrease in maternal-infant bonding did not statistically differ by group (P for time × group interaction = 0.25), despite the significant main effects of both time and group.

Figure 4 illustrates the comparisons of the mean score changes over time for all maternal outcomes, including the EPDS, STAI, and MIBS scores, from baseline to 12 weeks postpartum. Based on the figure, mothers who received the Smart Mama intervention had better maternal outcome scores than those in the control group at three months postpartum.

Discussion

To the best of our knowledge, this is the first RCT to focus strongly on a holistic approach that combines physical, emotional, and informational support for postpartum women. This study aimed to evaluate the effectiveness of telenursing using a smartphone app to alleviate maternal PPD and anxiety and enhance the relationship between mothers and infants. If effective, Smart Mama could be an alternative to in-person services that are not always available during the postnatal period. This intervention could also reduce mothers' fear of stigma against PPD and transportation costs.

Smart Mama's effect on maternal postpartum depressive symptoms

Our results indicate that postnatal women who received the Smart Mama intervention displayed a significant reduction in depressive symptoms compared to the control group at 3 months postpartum. Based on the estimated marginal mean, we found that the women who received the Smart Mama intervention group had lower EPDS scores than the women in the control group, in light of the time, group, and time × group interaction effects. Regarding PPD prevention, the findings of previous studies have been inconsistent. The significant reduction in the EPDS scores in this study may be related to the timing, content of the app, and means of communication used in the intervention.

Timing of the intervention

The findings of our study are comparable with the results of Yeon [19] and Liu et al. [29], who found that their postpartum care mobile app was effective in reducing depressive symptoms at 6 weeks postpartum. Similarly, Fonseca et al. [18] "Be a Mom," a large-scale web-based intervention, found that the intervention group experienced a significantly greater decrease in depressive symptoms than the control group at 3 months postpartum. Moreover, the average reduction in EPDS scores from baseline to post-intervention was almost double that in the intervention group (1.2 and 1.96, respectively). Additionally, our results correspond with those of Shorey et al. [30], whose study lasted from 2017 to 2018; they found that the technology-based app effectively reduced the risk of depression and loneliness during the early postpartum period (3 months postpartum).

Most women in our study lived alone with their husbands after delivery and needed instructions on caring for their infants. Because postpartum mothers need to rest and undergo examinations during hospitalization, have busy schedules, and care for their infants, Smart Mama can provide timely informational support. Although it cannot completely replace in-person social support, it can be a vital adjuvant if used as intended [31]. The use of mobile health apps has grown rapidly because they can be used without time or space limitations [32].

In contrast to this study, Shorey et al. [33] investigated the effectiveness of the supportive parenting app which introduced their intervention at an earlier phase than

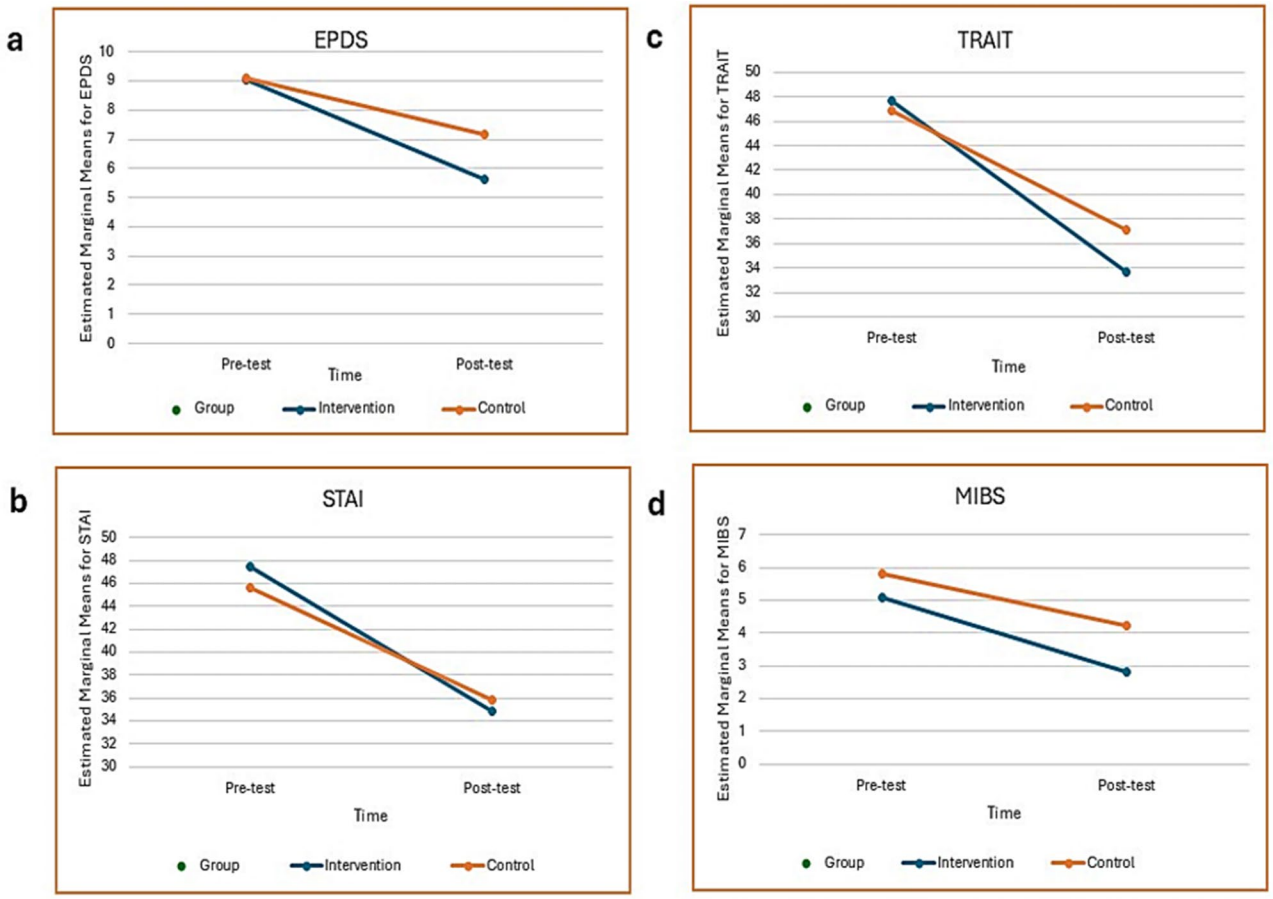

Fig. 4 Comparison of mean outcome scores changes between intervention and control groups pre- and post-intervention (overtime). Legend: Changes in mean outcome scores over time for the intervention and control groups are shown as (**a, b, c, d**). Edinburgh Postnatal Depression Scale (EPDS) (**a**), State Anxiety Inventory Scale (STAI-S) (**b**), Trait Anxiety Inventory Scale (STAI-T) (**c**) and Mother-to-Infant Bonding Scale (MIBS) (**d**) from the baseline to post-intervention

the above-mentioned study, and found that their app did not significantly reduce postnatal depressive symptoms. In this study, conducted from February 2020 to February 2022, both parents in the intervention group received emotional and informational support through a parenting app (SPA) from 24 weeks of gestation to 12 months postpartum. In contrast, the control group received standard perinatal care, including antenatal checkups, optional prenatal classes, and a 6-week postnatal follow-up. The authors indicated that the COVID-19 pandemic resulted in increased psychological stress among new parents. Therefore, the content should be carefully adjusted according to increased social needs.

Contents of the app

Regarding content, we considered a holistic approach to be essential for providing a positive impact. Two studies showed that combining physical exercise, information, and psychological support interventions during the postnatal period positively affected maternal well-being and reduced PPD [34–36]. One of these studies included specialized exercise combined with parenting education at 8 weeks postpartum, which reduced the risk of PPD. Another study employed online relaxation exercises, training, and counselling, demonstrating a positive impact on PPD and maternal attachment at 6 weeks postpartum. Considering the results of studies that showed non-significant outcomes [37, 38], combining different support dimensions can have a stronger impact on postpartum maternal well-being.

Smart Mama provides holistic support for early postpartum needs, such as physical recovery and adjustment to motherhood. Smart Mama offers an approach that combines physical support (stretching and pelvic floor muscle exercises), psychological support promoting relaxation and breathing, and informational support explaining depressive symptoms and coping strategies. This approach not only addresses the different aspects of support but also encourages self-care practices that target depression and enhance bonding between mothers and their infants. It is likely that Smart Mama's integration of physical, psychological, and informational support

and the early initiation of the intervention in the postpartum period contributed to the observed differences.

Means of communication

McCarter et al. [39] found no significant changes in the EPDS scores between the intervention and control groups despite higher satisfaction scores with the technology-assisted intervention. In their study, the intervention group received 4-weekly electronic messages over 26 weeks, followed by nurse-initiated phone calls. The content included educational messages on infant care, maternal self-care, and inspirational messages for mothers. Their tool used the Televox technology, originally designed for appointment reminders. Smart Mama offers messages and a support platform that mothers can access easily. This feature could have fostered connections between the women and the intervention, resulting in a greater sense of social support than in one-way communication via electronic messages.

Smart Mama's effect on postpartum anxiety

Based on the estimated marginal mean, we found that the state-trait anxiety scores of the intervention group decreased over time, and the interaction between group and time showed statistically significant differences at 12 weeks postintervention in the intervention group compared to the control group. Postpartum anxiety is more prevalent than PPD but is often misdiagnosed by clinicians and patients because it is difficult to distinguish between mild postpartum symptoms and those leading to considerable impairment [40]. Depression is receiving more attention in the literature on interventions during the postnatal period. However, information on the effects of interventions on subjective anxiety after childbirth is lacking [41].

Our study results are consistent with the findings of Lawrence et al. [42] who demonstrated that web-enabled psychoeducational interventions consisting of information on the causes and protective factors of postnatal depression and anxiety, self-care practices, building social networks and community groups, and resources for general postnatal mental health significantly reduced postnatal anxiety and depression among women in British Colombia [42]. One possible explanation is that the content delivered by these interventions was psychoinformational, which may have played a critical role in the effectiveness of the intervention.

Another study conducted by Fonseca et al. [18] reported that the use of Be MOM, a self-guided web-based intervention, resulted in a significant decrease in anxiety symptoms 3 months postintervention in the intervention group compared to in the control group. Furthermore, Bozkurt and Büşra's [43] Ebe Evimde app provided three online home visits by a midwife and offered support about breastfeeding, danger signs, and general infant care. They reported significantly reduced postpartum-specific anxiety levels and increased self-efficacy among mothers.

Throughout Smart Mama's content, we incorporated deep breathing and relaxation techniques, which are well-established methods for relieving anxiety, boosting a sense of calm, promoting wellness, and effectively reducing PPD. Consequently, the strategies incorporated into Smart Mama appear to have a clinical effect on reducing anxiety symptoms, which are often present in conjunction with PPD. Therefore, interventions that target both anxiety and depressive symptoms are needed to prevent PPD [44].

Conversely, Koçak et al. [45] demonstrated that although the post-test state and trait anxiety scores were lower than the pre-test scores in the experimental group, no significant difference was observed between the intervention and control groups, indicating that the mobile support app alone was not adequate for decreasing anxiety levels owing to insufficient information. Their mobile app provided information about the postpartum period (infant care, maternal care, and breastfeeding); however, information about the signs and symptoms of depression and anxiety was limited. Similarly, Ashford et al. [46], in their iWaWa web-based study, found no significant difference in the postnatal anxiety between the experimental and control groups from the early postpartum period to the 8-week postpartum period. They concluded that the mobile app did not lead to the desired outcome probably because of the burden of the program, inadequate support, technical access issues, and lack of women's motivation.

Smart Mama's effect on maternal-infant bonding

As part of her adaptation to motherhood, a woman needs support to establish a strong attachment to her baby in a normal and healthy way. Disruptions in this bond can have long-term negative consequences [47]. Previous studies have shown that maternal anxiety and depression can affect maternal-infant bonding [48]. Therefore, paying attention to maternal-infant bonding during the early postnatal period is imperative.

Our study found a slight decrease in maternal-infant bonding over time and between groups. However, the interaction effect between time and group was not statistically significant, suggesting that our intervention had no significant effect on maternal-infant bonding. These findings were somewhat unexpected, as they contradict previous literature suggesting that mobile health interventions have a significant impact on maternal-infant bonding. Our findings are comparable to those of Ahn et al. [49] who demonstrated no significant difference in maternal-infant bonding after the participants had used a

mobile app-based parenting support program. One possible explanation for this finding is the study duration. In their study, the intervention duration was 2 weeks, which might be short and inadequate to capture the full effects of postpartum bonding. This limited timeframe may not accurately reflect the evolution of the outcomes, underscoring the point that long-term educational support programs are more effective than short-term interventions such as ours.

Our findings align closely with the results of Ayse et al. [50], who found that the intervention group who received online parenting-based education consisting of six online educational sessions (on postpartum changes, emotional bonding, maternal and infant care, and information about early attachment roles) for 3 weeks showed significant improvements in time and group main effect in maternal bonding scores but had no significant time × group interaction effect between the intervention and the control group. Although the Smart Mama intervention provided comprehensive information on breastfeeding, maternal care, and bonding practices, such as skin-to-skin contact, the improvement in bonding observed across both groups was not statistically attributable to the intervention itself. Mother-infant bonding may develop naturally over time as part of normal postpartum adaptation [51], regardless of the use of interventions.

In contrast to our results, Sawyer et al. [52] demonstrated that mothers who received a nurse-moderated app-based intervention (e-Mum Plus) for 4 months showed significant improvements in maternal bonding levels. Their program provided information on parenting and how to solve problems, including feeding, sleeping, and improving parent-infant bonding, and modulated group treatment programs for postnatal depression. Similarly, Fernandes et al. [53] found that web-based parenting training significantly improved mother-infant bonding in the intervention group compared to in the control group.

Accordingly, the difference between the abovementioned studies and our results may be attributed to the Smart Mama intervention, which mainly offered informational support and did not confer an additional advantage over and above this expected progression without interactive components and social peer support. Furthermore, the duration of our intervention was 12 weeks, unlike the abovementioned studies that extended this period, allowing time for enhancing maternal-infant bonding. Therefore, long-term or personalized interventions beyond informational support may be necessary to ensure a substantial impact on maternal-infant bonding. Furthermore, many Japanese mothers today live in nuclear families in urban areas rather than traditional extended-family households and balance work responsibilities, and this aspect may interfere with the development of secure maternal-infant bonding [54].

Strengths and limitations of the study

Our study had several strengths. First, our study adopted an RCT design despite the fact that conducting RCTs in clinical settings is often difficult. The strength of the app is that it provides accessible, cost-effective, and convenient postpartum support through digital platforms, benefitting mothers who are unable to attend face-to-face intervention sessions for reasons such as limited time during weekdays because of work or pandemic situations where gathering people is a concern. Moreover, the Smart Mama intervention included physical, psychological, and informational support, indicating a holistic supportive approach to address and prevent PPD. Self-care activities are also encouraged to increase mothers' autonomy in engaging in activities that resonate with their needs. Additionally, this study is among the few conducted in Japan to evaluate the effects of smartphone applications on postpartum depression, anxiety, and maternal-infant bonding.

This study has several limitations that should be addressed. First, this was an open-label RCT, making it challenging for blind participants and researchers because of the required use of the application and its corresponding explanations. Furthermore, a potential bias existed in estimating the effects of the intervention. Nevertheless, the allocation was concealed and performed by another researcher to minimize bias. Second, the mothers were not interviewed during the intervention; their feedback could provide insights into app usage experiences and opportunities for future improvements. Third, we did not consider app usage frequency, adherence, or engagement levels to be correlated with the outcomes when analyzing the results. Therefore, this point must be considered when interpreting our results. Fourth, the participants were exclusively recruited from one center in one city, which could have reduced the bias of institutional differences. However, the generalizability of these results to the broader population of the country is limited. Future studies are needed to evaluate the effectiveness of smart mamas in multiple centers and across different geographic regions. Moreover, the inclusion criteria for this study required internet access, which might have contributed to selection bias by excluding women who did not have such access, possibly limiting the diversity of the participants. Additionally, limited personalized healthcare guidance is a disadvantage of digital interventions; therefore, future digital interventions could benefit from hybrid models that integrate telehealth consultations. Finally, the self-reported scale measures may have been subject to recall bias, affecting the validity of the results.

Conclusion and recommendations

The findings of our study underscore the fact that the Smart Mama app was effective in reducing postpartum depressive symptoms and postnatal anxiety levels and enhancing bonding between mothers and infants. Smart Mama can complement traditional healthcare strategies and reshape the management of postnatal depression. We employed a novel technology that was convenient, accessible, cost-effective, and holistic that participants could access using their smartphones. RCTs with larger sample sizes and qualitative studies should evaluate the application's use, barriers to use, and positive and negative aspects of the application. Additionally, long-term follow-up assessments are needed to determine the benefits beyond 12 weeks and explore the potential reasons behind them.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12912-025-03072-2.

Supplementary Material 1

Supplementary Material 2

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Author contributions

YMO: Conceptualization of the study design, data curation, formulation of intervention content, formal statistical analysis, Funding acquisition, Writing an original draft, Writing– review & editing. YS: Conceptualization, Visualization, Methodology, Validation, Supervision, App content translation, Writing - review & editing. MT: App content translation, Methodology, data curation, re-¬view & editing. AO: Investigation, Methodology, Data curation. NH: Software, review & editing. SC: Investigation, Software, statistical analysis review & editing. HK: Visualization, Supervision, Validation, re¬view & editing. All authors have read, critically revised, and approved the final manuscript for publication.

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Data availability

The complete data sets are not publicly available to protect participants' privacy but can be available upon reasonable request from the corresponding author.

Declarations

Ethical approval and consent to participate

All procedures in this study adhered to the ethical standards of the Helsinki Declaration of 1975. This study was approved by the Research Ethics Committee for Clinical Research (Life Science and Medical Research for Humans) of the Graduate School of Biomedical and Health Sciences, Hiroshima University, Japan (C2022-0012) on December 21, 2022. This study was registered with the University Hospital Medical Information Network (UMIN) Clinical Trial Registry (UMIN-CTR ID: (UMIN000050065) on January 19, 2023 (https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000056562). Written informed consent was obtained from all participants, and the data were stored in a location that was locked using a key. Participants were informed that all the data collected would be used exclusively for research purposes only and that the women were free to withdraw from the study at any time.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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