Testing the Birth APP: a Randomized Controlled Trial

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Abstract

Background: Early labor is often managed at home without professional support. The Birth APP is a mHealth application designed to support women during early labor. A pilot-study revealed that women found the app's exercises simple, understandable, and useful. The app was perceived as useful and appreciated by women, although areas for improvement were identified, primarily related to technical issues. During the development and test period the updated app was tested in a randomized controlled trial (RCT).

Objective: To investigate whether women using the Birth APP during pregnancy and childbirth experience less distress during early labor compared to those receiving standard antenatal care.

Methods: This RCT used online recruiting in a non-blinded three-part blended care model with 1:1:1 randomization. Group 1: Birth APP intervention. Group 2: Birth APP Plus, combining the app with in-person additional midwifery contacts. Group 3: Control group receiving standard antenatal care.

Pregnant nulliparous women were invited via social media. Eligibility criteria were: nulliparity, planning a vaginal birth, from gestational week 25+0 to 35+6 weeks, proficiency to understand Swedish, and having access to a smartphone or tablet.

Results: A total of 391 women completed the baseline questionnaire, and 334 women responded to the questionnaire 1 month postpartum, yielding a response rate of 85.4%. Most participants experienced a spontaneous onset of labor across all groups, with no significant statistical differences. Women in the intervention groups remained at home longer during early labor, with a mean of 16.76 hours (SD 20.45) for group 1, and 14.47 hours (SD 16.82) for group 2 compared to 12.90 hours (SD 15.99) for group 3 (control), although this difference was not statistically significant. For the primary outcome, emotional distress in early labor, only women with spontaneous onset of labor were included in the analysis. The primary outcome showed similar mean values across groups. No statistically significant differences were identified for any of the secondary outcomes (childbirth experience, pain-relief and support from partner). However, when assessing fear of future birth, the intervention groups had lower mean values than the control group and pairwise testing revealed a statistically significant difference for both intervention groups (p-value .002 and < .001) with a medium effect size from baseline to follow-up.

Conclusions: Our results indicate that the Birth APP, in conjunction with additional midwifery support, can serve as a valuable tool for pregnant women and their partners, during pregnancy and childbirth. The observed reduction in fear of forthcoming childbirth associated with the Birth APP warrants further investigation. Clinical Trial: ClinicalTrials.gov (ref. no. NCT05122390).

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Introduction

The first part of childbirth, called early labor, is often handled at home by the women and their partners themselves, without support from professionals [1]. However, it could be difficult for first-time mothers to know what to expect at labor onset, and their experiences in early labor may differ from their expectations [2]. A newly published scoping review showed that positive and negative emotions were perceived during early labor [2]. The Early Labor Experience Questionnaire (ELEQ) was developed to assess women's affective experiences [3] showing primiparous women experiencing higher emotional distress during early labor compared to multiparous women [4]. Emotional distress during childbirth, perceived lower quality of care and a negative childbirth experience in general are associated with a longer latent phase of labor in first-time mothers [5], however women are encouraged by professionals not to be in the labor ward during early labor, to reduce the risk of the use of unnecessary medical interventions [6].

Structured antenatal education programs to prepare for childbirth are offered to women and their partners, and they address both physiological, emotional, and social aspects during pregnancy, childbirth, and early parenthood. However, these programs vary across countries and contexts, and the benefits of these programs remain unclear [7]. Several studies have shown that special targeted antenatal education enabling the women and her partner to feel more confident, is beneficial for the outcome of labor, both in terms of arriving at the hospital in more advanced labor, less use of epidural anesthesia, a better childbirth experience, and fewer acute caesarean sections [8-10].

To enhance women's confidence to remain at home during early labor adequate preparation for managing pain in early labor is important [1], as feeling anxious increases the perception of pain [2]. Birth preparation training for women, with mindfulness has been tested in a few small, randomized controlled trials (RCTs), demonstrating a higher ability to manage pain, increased psychological well-being, a trend towards lower use of opioids during labor, increased self-efficacy and decreased fear of childbirth among women [11, 12].

Since 2009, pregnant women and their partners have had the option to enroll in

antenatal training classes, for a fee, utilizing the Birth Without Fear© method [13]. This method aims to equip women and their partners with the knowledge and skills to better manage pain and experiences during childbirth through active measures, including support and stress-relief techniques. The method uses four different tools to enhance relaxation: soft and silent breathing through contractions, relaxed muscles, a deep pitch of the voice and positive expectation of the mind [13]. The Birth Without Fear© method was later conceptualized in a digital application (app), and a first version was tested in a feasibility pilot study. The result showed that the app was perceived as useful and appreciated by women and suitable for efficacy testing in an RCT [14]. The company Birth by Heart led the app development, involving senior software developers with expertise in health and fitness apps, and an expert group to define the requirements. Regular stakeholder meetings ensured alignment, reviewed app versions, and incorporated feedback throughout the process. The app development process is more thoroughly described in another publication [15]. In June 2023, the enhanced and tested Birth APP was launched and made available for download at no additional cost on Google Play and the App Store.

Previous studies have reported that mobile health (mHealth) apps designed to prepare women for the forthcoming labor and birth can be beneficial in terms of a better experience and labor outcome [16-18]. Fleming and colleagues demonstrated the importance of ensuring credible electronic links, cell phone technology, videos, and access to hospital websites, which are created by the healthcare provider to educate expectant parents [19]. However, only a few evidence-based apps are developed and available on the market [20]. The advent of digital health technologies offering unprecedented opportunities for patient engagement and monitoring is rising, and mHealth apps have gained attention in various fields to improve women’s health [21]. However, the proliferation of such apps has not always been accompanied by rigorous scientific validation, raising concerns regarding their efficacy and safety [22]. Apps can offer access to online education and training programs, enabling women and their partners, to gain new skills regardless of their geographical location, which can be particularly beneficial for women living in rural or remote areas, and more knowledge is needed about how evidence-informed apps can

be a complement to usual customary antenatal education[20].

The aim of the project was to investigate whether women using the Birth APP during pregnancy and childbirth experienced less distress during early labor, compared to women who received standard antenatal care. We hypothesized that women assigned to the Birth APP groups would experience lower emotional stress during early labor compared to a control group that did not have access to the app. Additionally, we hypothesized that women assigned to the Birth APP Plus group would have additional benefits from using the app.

Methods

Ethical considerations

This study was approved by the Swedish Ethical Board (ref.no **2021-03028)** and registered in ClinicalTrials.gov (ref. no NCT05122390), and the first version of the protocol was uploaded on November 16, 2021.

Swedish study setting

Midwives in Sweden have an autonomous role as primary care providers for women with uncomplicated pregnancies, labor, and birth, while obstetricians are consulted and responsible if complications arise. The antenatal care operates through community-based public health clinics, with midwives serving as the primary caregivers. Health education is a crucial aspect of prenatal care, focusing on lifestyle changes during pregnancy and parental education are offered mainly to first-time parents. Almost all Swedish women give birth in hospitals, and maternity care is publicly funded [23].

Trial design

This RCT applied online recruiting in a non-blinded 3-part blended care model with a 1:1:1 randomization design. Group 1: Women assigned to the Birth APP intervention. Group 2: Women assigned to Birth APP Plus, combining the app with in-person additional midwifery contacts. Group 3: The control group receiving standard antenatal care, based on the preparations available at the antenatal care clinic in which the woman was enrolled for pregnancy checkups.

Recruitment

Pregnant nulliparous women were informed and invited to participate in the research study through a national invitation on the social media platforms Facebook and Instagram via paid advertising. Eligibility criteria included: *nulliparous women planning to undergo a vaginal birth, pregnancy between 25+0 and 35+6 weeks at the time of registration, ability to speak, read, and understand Swedish, and access to a smartphone or tablet.* Women interested in participation reported their interest on the research website. After receiving information about regulations according to the General Data Protection Regulation (GDPR) and signing digital informed consent, they were automatically linked to the baseline digital questionnaire in the Research Electronic, Data Capture system (RedCap) [24]. Thereafter, women were randomized by one of the research midwives using a block randomization of 6 with a computer-generated allocation list in Excel. Next, participating women were informed about their allocated group by e-mail and short message service (SMS) from the research midwives.

Calculation of sample size

The Emotional Distress domain in the Swedish Early Labor Experience (SWE-ELEQ-PP) questionnaire was used as the primary outcome measure. Ängeby et al. (2018) demonstrated significant differences in emotional distress among first-time mothers who were dissatisfied with leaving the delivery ward during early labor. The sample size was calculated using IBM SPSS version 28. The hypothesis was that the Birth APP could enhance women's sense of security, thereby reducing stress and anxiety during early labor. With a power level of 80% and a significance level of *P*<.05, the required sample size was calculated to be 82 participants in each group to detect a significant difference in the primary outcome between one of the intervention groups and the control group. The significant difference is calculated between the control group and the 2 experimental groups. Previous research with the targeted group of pregnant women has shown a 50% dropout rate, necessitating the inclusion of 160 participants in each group for sufficient statistical analysis. Therefore, the total number of participants needed for the study was 480 women. Additionally, participants who underwent induction of labor and did not spend time at home during early labor, were thus unable to contribute to the primary analysis. In Sweden, approximately 25% of nulliparous women undergo induction, which needed to be considered as well for power estimation [25].

Interventions

Intervention group Birth APP

Participants randomized to the Birth APP group received an email with personalized instructions for downloading the app via TestFlight for iPhone users and Google Play for Android users. Each participant was provided with a unique personal code from a pre-generated list, consisting of 4 capital letters and 4 numbers. No additional follow-up was provided thereafter. The app has 2 parts: one for education and practical exercises, and 1 for use during actual labor. It aims to boost women's self-efficacy and sense of security. The partner's involvement is emphasized, with a dedicated section for non-pharmacological pain relief methods. The app provides information on the partner's supportive

role and includes exercises on contraction signs, closeness, and various pressure techniques to help the laboring women during childbirth [14].

Intervention group Birth APP Plus

Participants randomized to the Birth APP Plus group received personalized instructions identical to those given to the Birth APP group. Additionally, they were contacted by a research midwife via SMS, email, or phone conversations 2 weeks after enrolment, based on their preferred method of contact. During the initial contact, questions regarding the app's use and usability were addressed. The midwife was also available to answer other questions related to the method or the use of it during pregnancy. Topics such as feelings toward the forthcoming birth, coping ability, and partner support were discussed. This conversation aimed to strengthen the effectiveness of app usage and thereby enhance the outcomes. A second follow-up contact was conducted 2–6 weeks after the first contact, serving as a follow-up to the previous conversation.

Control group

Participants in the control group received usual antenatal care where antenatal education is integrated in the care and provided free of charge by midwives and offered to all primiparous women and their partners.

Questionnaire at baseline

Participants completed a web-based questionnaire in RedCap prior to randomization with baseline data accordingly.

Demographic Characteristics

Participating women provided information about age, marital status, level of education, profession, country of birth, as well as information concerning their physical and mental health.

Psychological traits measures

Using various psychological assessment tools at enrolment allows us to control for personality traits, ensuring these traits do not confound the study results. This approach enhances the validity and reliability of the study findings by accounting for individual differences that might influence responses to the intervention.

Sense of Coherence-13 (SOC) [26], was used to examine the resource of

promoting individual health, composing (a) comprehensibility, (b) manageability, and (c) meaningfulness dimensions [27]. The scale can be used as a continuous variable from 13-91, or categorized into low (≤60), moderate (61-75) or high (≥76) SOC [28]. A strong sense of coherence helps individuals mobilize resources to cope with stressors effectively, contributing to better health outcomes and a higher quality of life.

The Swedish Childbirth Self-Efficacy Inventory (Swe-CBSEI) [29], is a pre-validated, self-report instrument that measures an individual's expectancies of coping with childbirth and describes an individual's belief in their own ability to behave in a particular way in a specific situation [30]. The scale measures 2 different subscales during active labor: Outcome expectancy (O-AL) and Self-Efficacy expectancy (E-AL), and a higher value represents a higher degree of self-efficacy expectancy, ranging from 15-150. It measures a person's belief in their capacity to act effectively in specific childbirth-related situations.

The Fear of Birth-scale (FOBS) [31] was used to measure fear of birth. The FOBS scale is based on 2 visual analogue scales from 1-100 for identifying fear of birth during pregnancy, and a cut-off value of ≥60 is normally used for identifying women with fear of birth [31]. High scores on FOBS indicate significant fear of childbirth, which can lead to increased anxiety, stress, and potential negative birth experiences. We used FOBS to measure fear of childbirth at baseline and follow-up, with questions adapted to assess fear retrospectively and for future births. This approach allowed us to track changes in fear over time and create a composite variable to categorize fear levels across different time points.

Questionnaire at follow-up with outcome measures

One month postpartum, participants received a link to a follow-up questionnaire in RedCap. Upon completing the questionnaire, all participating women received a gift card valued at SEK 200 for use in a supermarket.

The **primary outcome** was emotional distress in early labor. To address the primary outcome, SWE-ELEQ-PP [4] was used. The questionnaire was designed to measure women's experience during early labor. The questionnaire covers 3 subscales: emotional distress (6 items), emotional well-being (7 items) and experiences of midwifery care (10 items). Emotional well-being and experiences

of midwifery care are ranked from 1-5, meaning a higher value represents a more positive value. The subscale Emotional distress, ranked from 1-5, meaning a higher value represents a higher distress were used as the primary outcome.

The questionnaire included study-specific questions about childbirth events such as labor onset, hours in labor before hospital admission, pain relief methods used during labor, and birthing mode. Additionally, questions about the gestational week at birth, the baby's care in the Neonatal Intensive Care Unit, and which maternity clinic the birth took place.

The **secondary outcomes** were mode of birth, emotional well-being in early labor, and midwifery support during early labor (SWE-ELEQ-PP), childbirth experience, support from partner, pain relief methods and fear of birth in a potential future birth.

The Childbirth Experience Questionnaire (CEQ) [32] were used to measure the total multidimensional childbirth experience. CEQ is developed and validated in Sweden and represents 4 domains or subscales of childbirth experience. Own capacity (8 items), perceived safety (6 items), professional support (5 items) and participation (3 items). Higher values represent a more positive experience in all subscales.

The Birth Companion Support Questionnaire (BCSQ) was used to measure women's perceptions of companion support during childbirth with 2 subscales: emotional support (8 items) and tangible support (6 items). Ranging from 1-4, with a higher value representing a higher perceived support from partner [33].

The FOBS scale, rephrased as “when thinking about potential future birth,” was used to measure fear in forthcoming births. The scale ranges from 1-100, and a higher value represents a higher degree of fear in forthcoming births [34].

Statistical Methods

Descriptive statistics for each group, such as mean, standard deviation, median, and frequencies for categorical variables, were initially compiled. The Chi-square test was used to examine differences between groups for categorical variables by comparing observed frequencies with expected frequencies to determine if there was a statistically significant difference. Analysis of Variance (ANOVA) was used to compare means between the 3 groups for continuous variables. If

ANOVA showed a significant difference, Tukey's post hoc test was used to identify group differences. Sensitivity testing was conducted by analyzing subgroups or using alternative statistical methods to explore differences between the intervention groups and the control group.

Pairwise testing was employed to explore differences in the FOBS scores before and after childbirth. This statistical method allows for the comparison of each participant's scores at 2 different time points, thereby accounting for individual variability and providing a more accurate assessment of changes over time. All outcomes were analyzed according to the intention-to-treat principle. Since the primary outcome was emotional distress during early labor, only women with spontaneous labor onset were included in the analysis of primary and secondary outcomes. Women with induced labor were excluded, since they are hospitalized before labor onset. The data were analyzed using IBM SPSS Statistics version 28, with a $P< .05$ considered statistically significant [35].

Results

Digital advertisements via social media were conducted from October 15, 2022, to March 15, 2023. A total of 539 women registered for participation on the study website. Following redirection to RedCap, 461 women were assessed for eligibility and 391 women being allocated to the study (Flowchart, Figure 1).

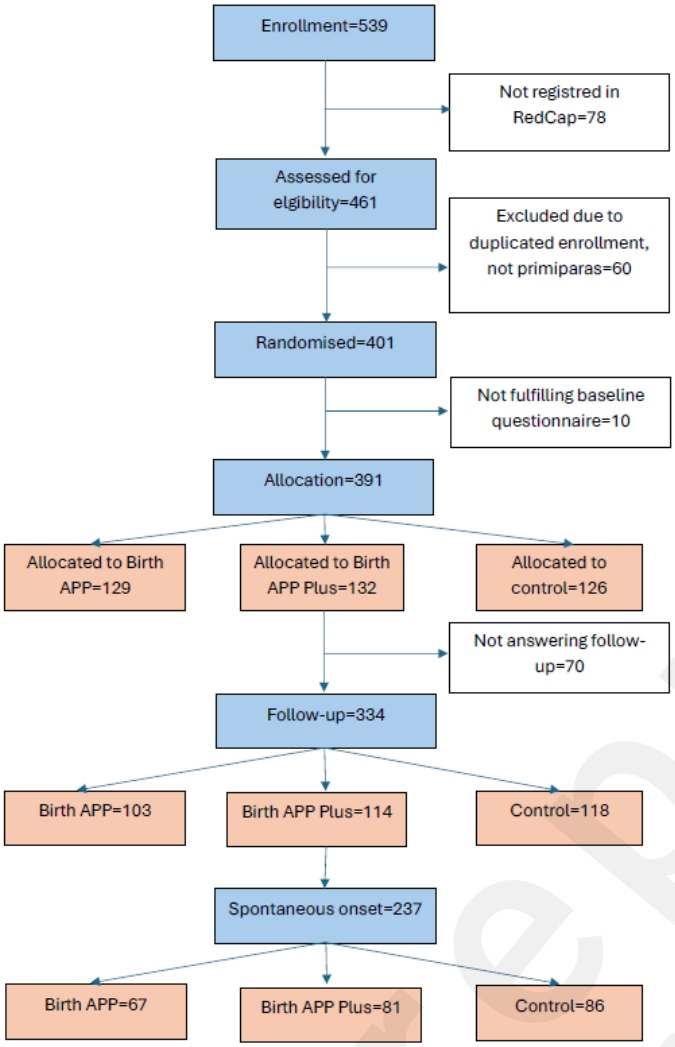

Figure 1. Flowchart

A total of 391 women completed the baseline questionnaire, and 334 women responded to the questionnaire 1 month postpartum, yielding a response rate of 85.4%. At follow-up, 103 women in the Birth APP group, 114 women in the Birth APP Plus group, and 118 women in the control group completed the questionnaire. Mean age of the respondents were 31.30, 30.89, and 30.89 years, respectively. Most participants were living with a partner, had a university education, and were born in Sweden. Participants in all 3 groups reported similar values for the SOC, the CBSEI, and the FOBS at baseline. More than half of the participants attended antenatal birth classes during pregnancy. No statistically significant differences were observed between the intervention

and control groups at baseline (Table 1).

Insert table 1 here

Participating women gave birth in all regions of Sweden. Most women gave birth in the Stockholm-Gotland region (100/330, 30.3%), followed by the Mid-Sweden region (86/330, 26.1%), south-east region (55/330, 16.7%), western region (34/330, 10.3%) and least in northern region (28/330, 8.5%) and southern region (27/330, 8.2%).

Most participants experienced a spontaneous onset of labor across all groups, with no significant statistical differences. A small number of women (n=8) had an elective caesarean section and were therefore removed from the analysis. Approximately 25% of participants had induced labor, with no significant differences between groups. (Table 2)

Insert table 2

Table 2 shows that women in the intervention groups remained at home longer during early labor, with a mean of 16.8 hours (SD 20.45) for group 1 and 14.5 hours (SD 16.82) for group 2 compared to 12.9 hours (SD 15.99) in the control group, although this difference was not statistically significant (*P*=.316). To assess the robustness, we conducted a sensitivity analysis by combining the 2 intervention groups. The result showed a mean difference of 2.71, CI -1.51 to 6.93, *P*=.201. The mode of birth showed no significant differences between the groups. Most women used pharmacological pain relief during labor (Entonox, Epidurals) with no significant differences between groups.

Insert table 3 here

Table 3 shows the primary and secondary outcome for women with spontaneous onset of labor (n=234). For the **primary outcome**, emotional distress in early labor showed similar mean values across groups (Birth APP, M=2.42 [SD 0.78]; Birth APP Plus, M=2.29 [SD 0.84]; and control group, M=2.45 [SD 0.83]), indicating that women in the Birth APP Plus group experienced slightly less

emotional distress, though not statistically significant, with a *P*-value of .435. The sensitivity analysis, with interventions grouped together, showed mean difference -.085, CI -.276 to .106, *P*=.384. For **secondary outcomes**, women in all groups reported nearly identical values for emotional well-being and midwifery support, as measured by the two subscales in the SWE-ELEQ-PP. Regarding the dimensions in the CEQ, including own capacity, professional support, and participation, similar mean values were reported across the groups. However, for the subscale perceived safety, women in the APP Plus group scored higher (M=3.28 [SD 0.62]), compared to Birth APP (M=3.14 [SD 0.62]) and control group (M=3.14 [SD 0.71]), though these differences were not statistically significant. When measuring partner support, no statistical differences were found between groups. All women rated their emotional support statistical significantly higher than tangible support, (M=3.76 [SD 0.39]) vs. (M=3.49 [SD 0.65], *P*<.001) with similar mean values across all groups, Birth APP (M=3.81 [SD .27]), Birth APP Plus (M=3.80 [SD .33]) and control group (M=3.74 [SD .45]).

Insert table 4 here

Table 4 presents how women rated their fear of childbirth with FOBS comparing the mean value from baseline and follow-up. When assessing fear at baseline, women in all groups scored similar mean values, Birth APP (M=45.7 [SD 24.6]) Birth APP Plus (M=44.9 [SD 25.3]) and control group (M=47.0 [SD 22.6]) *P*=.862. When assessing their fear of childbirth in forthcoming births, the intervention groups indicated lower mean values than the control group (M=32.78/M=31.17 vs. M=38.47, *P*=.067). In a sensitivity test, using pairwise testing, we were able to control for individual differences and obtain a clearer understanding of the impact of the intervention on participants' fear of childbirth. It revealed a statistically significant difference for both intervention groups (*P*=.002 and *P*<.001) with a medium effect size according to Cohen *d* (0.40 and 0.47), while the control group showed a non-significant value (*P* .085).

Discussion

The aim of this study was to investigate whether women using the Birth APP during pregnancy and childbirth experienced less distress during early labor compared to women who received customary antenatal care. However, women in the Birth APP Plus group, which included additional midwifery support, reported less emotional distress, but not at a statistically significant level.

A similar pattern was observed for the subscale of perceived safety during labor, where women in the Birth APP Plus group reported higher scores compared to the control group although not statistically significant. However, when assessing fear of forthcoming birth with the pairwise test, results showed a statistically significant reduction in FOBS in both intervention groups, indicating that the Birth APP can be an effective tool for reducing fear of future births.

The hypothesis that women in the intervention groups experienced less distress in early labor could not be established, which is consistent with findings from other studies testing different interventions aiming at reducing early labor distress without showing statistically significant differences [30, 36, 37]. The results in our study however showed that women in the intervention groups stayed at home longer during early labor compared to women in the control group, although with considerable variation. This suggests that the app functions can be a useful tool for pregnant women and increased coping and management ability during early labor. Similar results were also identified in our previous pilot study [14].

For secondary outcomes, the four different dimensions of childbirth was similar in all groups. However, for the subscale perceived safety, women in the APP Plus group scored higher, compared to the other groups, although not reaching statistically significant difference. Dencker and colleagues [32] demonstrated that non-vaginal births, oxytocin augmentation, and longer labors negatively affected all subscales. For the subscale perceived safety an intercorrelation between fear, sense of security and negative memories from the childbirth were established [32]. A systematic review indicated that mindfulness-based

interventions could reduce fear of childbirth and promote self-efficacy [38]. Another study by Carlsson et al. [39] found that self-efficacy correlated with reduced use of epidural analgesia among primiparous women, which may reflect their ability to exert control, and experience safety as observed in the present study.

In this study, fear of forthcoming births was significantly lower in both intervention groups compared to the control group. By using pairwise testing, we were able to control for individual differences and obtain a clearer understanding of the impact of the intervention on participants' fear of childbirth. Klabbers et al. [40] showed in an RCT that haptotherapy could significantly reduce fear of birth compared to psycho-education via the internet and usual care. Haptotherapy is designed to promote a more positive attitude in pregnant women and change cognitive appraisal to improve readiness for childbirth [41]. The Birth APP, tested in this study is based on the Birth Without Fear© method, which also focuses on cognitive aspects, aiming to strengthen both physical and emotional capacity [15]. Other studies have shown that mHealth apps align with pregnant women's preferences for a mHealth app during pregnancy [42, 43].

A strength of this study is that the 3 groups were equal in background characteristics. The similarity in educational level across all groups increases the trustworthiness of our results. Another strength is the high response rate, with 85% of participating women completing the postpartum questionnaire, consistent across all groups. The majority had a spontaneous onset of labor, and the group with induced labor (25%) was identical to a national sample [25]. Additionally, online recruitment allowed women from all parts of Sweden to participate, providing a broad sample of primiparous women. Participating women gave birth in almost all maternity clinics in Sweden, which is a strength regarding generalization. The rate of acute caesarean section was similar in all groups, and a percent of 16.2% of caesarean sections are lower than the average in Sweden [45] and the reason for this can only be speculated about. The participating women were higher educated, slightly older and interested in

using different antenatal preparation methods which possibly can explain the result.

This study also has some limitations. The participating women had a higher level of education compared to the Swedish female population of the same age. Previous research has shown that women with lower education levels are less likely to use information from the Internet [46]. Another limitation is that most women in all groups participated in various antenatal classes, which may have provided additional education that we could not control for, potentially affecting the results. It is possible that women randomized to the control group were dissatisfied with their enrolment and, therefore, used another app or attended private antenatal classes instead. Another aspect is the number of women completing the research: Birth APP group, n=103; Birth APP Plus group, n=114; and control group, n=118. In the power calculation, we accounted for 160 participants in each group. However, the attrition rate was lower than expected, and the induction rate was accounted for and therefore, the expected power in all groups was achieved.

Conclusions

The trial evaluating the Birth APP yielded several important findings. Although the hypothesis that the Birth APP would reduce emotional distress in early labor was not confirmed in this study, our results indicate that the app, in conjunction with additional midwifery support, can serve as a valuable tool for pregnant women and their partners, enhancing their confidence during early labor. The observed reduction in fear of forthcoming childbirth associated with the Birth APP warrants further investigation.

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Conflicts of Interest

The authors declare no conflicts of interest. None of the researchers involved have any financial interest in the Birth APP.

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Supplementary Files