

Early Labour App: Developing a practice-based mobile health application for digital early labour support

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ABSTRACT

Background: Pregnant women in early labour have felt excluded from professional care, and their partners have been restricted from being involved in the birthing process. Expectant parents must be better prepared to deal with fear and stress during early labour. There is a need for evidence-based information and digital applications that can empower couples during childbirth.

Objective: To develop and identify requirements for a practice-based mobile health (mHealth) application for Digital Early Labour Support.

Methods: This research started with creating an expert group composed of a multidisciplinary team capable of informing the app development process on evidence-based practices. In consultation with the expert group, the app was built using an agile development approach (i.e., Scrum) within a continuous software engineering setting (i.e., CI/CD, DevOps), also including user and security tests.

Results: During the development of the Early Labour App, two main types of challenges emerged: (1) user challenges, related to understanding the users' needs and experience with the app, and (2) team challenges, related to the software development team in particular, and the necessary skills for translating an early labour intervention into a digital solution. This study reaffirms the importance of midwife support via blended care and the opportunity of complementing it with an app. The Early Labour App was easy to use, the women needed little to no help, and the partner's preparation was facilitated. The combination of the app together with blended care opens up awareness, thoughts and feelings about the method and provides good preparation for the birth.

Conclusion: We propose the creation of the Early Labour App, a mHealth app for early labour support. The preliminary tests conducted for the Early Labour App show that the app is mature, allowing it to be used in the project's Randomised Control Trial, which is already ongoing.

1. Introduction

Early labour, or latent phase of labour, is the onset of labour that can be rapid or last for an extended period, characterised by short and irregular contractions and, for some women, painful. This stage of

labour can significantly heighten the levels of fear and stress for the women [1,2,3], especially for first-time mothers with longer early labour [3]. Furthermore, since early labour most often happens at home, women and their partners also reported feeling excluded from care by professionals [1] and feeling left out on their own about decisions of

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when seeking care and coping strategies in early labour [4].

The feeling of abandonment is also linked to a gap in the maternity care system in Sweden. Antenatal care operates primarily through community-based midwives' public health clinics. During labour and birth, each woman is attended by hospital midwives previously unknown to the woman [5]. During early labour, it is also crucial to attend to the importance of the partners who want to be involved yet also need to be better prepared, as discussed in various studies [6,7,8]. Therefore, raising awareness and better educating the pregnant woman and her partner would be beneficial in dealing with the fear and stress during early labour [4]. However, for first-time parents, it is hard to navigate the vast amount of information found on the Internet. Research also shows that the existing materials tend to over-focus on pharmacological pain relief methods and parenthood issues. Altogether, this need for web-based information sources and digital medias that can empower couples during pregnancy is becoming increasingly evident [9], especially in early labour [4].

With that in mind, mobile health (mHealth) applications (apps) could be leveraged to support women and their partners in early labour in a scalable and cost-effective manner. Digital health technologies, such as mHealth apps, can be used in blended care strategies that combine online and in-person treatment [10], extending care provision. Scientifically underpinned mobile apps could also reduce the burden on midwives since apps provide alternative digital channels to disseminate health information and raise awareness. In addition, the apps' content can be quickly reviewed and updated whenever necessary. Furthermore, mHealth solutions can also be leveraged to empower couples [11], potentially improving self-efficacy and helping them take more control of their *journey* during pregnancy [12]. Overall, mHealth apps have also enhanced equity in healthcare access, enabling better support to underserved communities (e.g., remote and rural areas) [13].

Today, the most common features in pregnancy-related apps are contraction timers, journaling/photo uploads, appointment trackers, checklists, and calendars. The least common features are tools for obtaining safety and health/fitness information [14]. Some apps are designed to have ample content on prenatal care, such as the mHealth apps developed by Souza *et al.* [15] with 111 screens of material. However, there is still a lack of apps specifically designed for early labour support, with focused and easily digestible content, that can breach the above mentioned healthcare gap between antenatal care and hospitalisation for active labour.

This paper aims to describe the creation of the Early Labour App, a mHealth app for early labour support. Our app is based on the *Birth Without Fear* method (also known as the *Confident Birth* method) developed to strengthen the mother's inherent physical, emotional, and self-efficacy capabilities and, together with their support partner, to achieve a confident birth [16,17]. The entire app development process is presented, describing the app's conceptualisation, requirement analysis, design, development, and user and security testing. In addition, we also share experiences and lessons learnt, such as the creation of the project's expert group, the importance of involving multidisciplinary stakeholders, and the importance of evidence-based research for generating digital health technologies.

The preliminary tests conducted for the Early Labour App show that the app is at a mature stage, allowing it to be used in the project's Randomised Control Trial (RCT), which is already ongoing [18]. Overall, this paper contributes to a diverse group of researchers, software developers, health professionals, and public and private sectors involved in implementing new mHealth initiatives.

In what follows, the study's methodology is detailed in Section 2, explaining the formation of an expert group, the application scenario, and software development and testing approaches. The results and key findings are described in Section 3. A discussion is provided in Section 4, covering the main challenges in the project, implications to health and software practitioners involved in developing digital health solutions, and future research areas. Lastly, Section 5 concludes the paper.

2. Methodology

2.1. Expert group and key stakeholders

In 2018, the project started by creating an expert group led by health professionals and researchers at Region Värmland, Dalarna University, Karlstad University and Luleå University Technology. Over the years, this group evolved, including more experts from different universities in Sweden and Norway, i.e., Oslo University Hospital, Uppsala University Hospital, University of South-Eastern Norway, and Oslo Metropolitan University. Currently, a diverse and multidisciplinary group of experts in midwifery, nursing, digital health technologies, and information security and privacy compose the expert group in the project, supporting and advising the research and app development processes.

Another key stakeholder is the organisation Birth by Heart,¹ of which the founder is also behind the Birth Without Fear method. This organisation comprises today a network of about 400 + certified instructors and several certified maternity and delivery wards. Birth by Heart led the design of the Early Labour App with a team of software developers and closely cooperating with the project's expert group.

2.2. Scenario description

The Early Labour App was primarily designed to be used by pregnant women and their support partners. However, it is worth stressing that the app was not meant to be used in isolation but as a part of a service ecosystem with multiple stakeholders (see Fig. 1). In this project, a blended care strategy is considered, combining the use of mHealth solutions that support online therapy ("anywhere and anytime") and traditional in-person treatment [10]. Such approaches that leverage integrated services, combining appointments, self-monitoring activities, and mHealth solutions, are reported to establish a strong trust between the midwife and a pregnant woman [19]. Furthermore, the app is also an extension of the Birth Without Fear method, which was already disseminated in various forms, e.g., childbirth classes, books, video lessons, and presentational workshops. The method consists of four main tools used during the contractions: (1) Breathing, emphasising the technique of silent and calm breathing; (2) Relaxation, letting the body relax and become heavy; (3) Vocalising, using a deep-pitched voice as a soothing tool; and, (4) the mind, practising positive thoughts and words. The birth support partner also plays a crucial role in preventing worry and fear during birth. The Birth Without Fear method is based on comprehensive physiological knowledge and expertise, and its tools and techniques were developed around scientifically proven outcomes [16,17].

As a result, this blended care approach can be adopted as a package of services designed to enhance the antenatal midwives' support to expectant couples. For midwives, the Early Labour App also helps to scale the provision of curated health information, educating and raising awareness among couples. Likewise, the couples benefit from using the app and learning together, empowering and preparing them for the early labour stage during pregnancy. Based on such improved understanding, couples are better equipped to communicate with healthcare professionals, enabling professionals to tailor treatment to personal demands [20,21].

It is worth noting that, apart from the app, smart wristbands were also considered as an added mHealth component of the study's blended care strategy. For example, pregnant women can use wristbands to enable the collection of three key indicators during early labour: sleep quality, heart rate, and the daily number of steps. This data can help the researchers cross-examine these health indicators and the app usage, helping to analyse other correlations within the data linked to the

¹ Birth by Heart is the organisation behind the Birth Without Fear method (<https://birthbyheart.com/>).

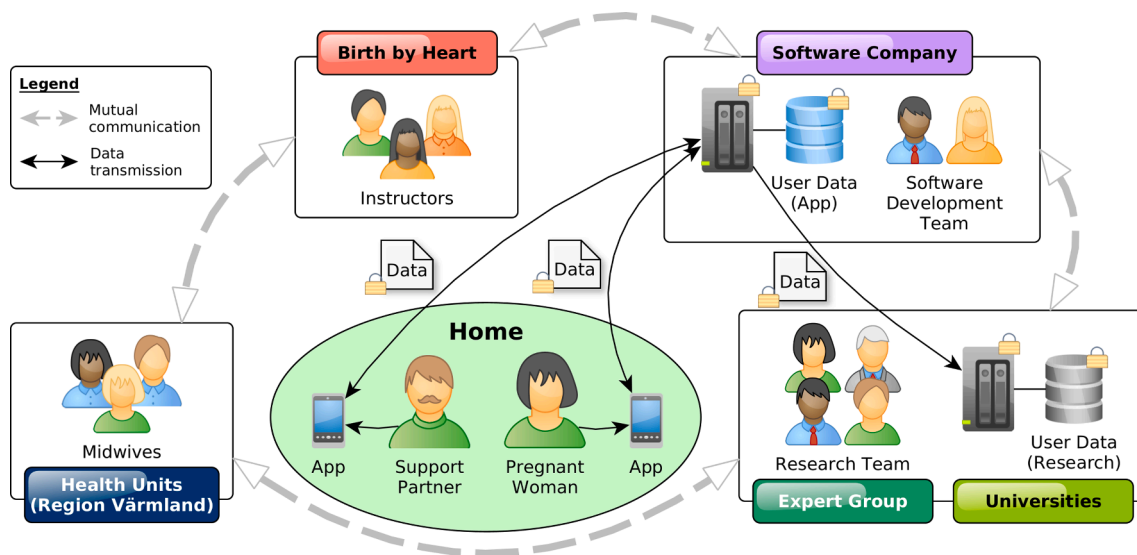


Fig. 1. The Early Labour App ecosystem and stakeholders.

study's primary health outcomes. An exploratory evaluation of commercially available wristbands has already been done in 2021 [22] and 2022 [23] to support the requirements engineering and technology selection process for app development. An overall summary of the investigations is described in [24], benchmarking the wristbands' core functionalities (e.g., battery lifetime, reliability and precision of measurements), accessibility, data export mechanisms and available APIs, and compliance with privacy regulations, e.g., EU GDPR.

2.3. App development process

The development of the app was led by the *Birth by Heart* organisation, with the creator of the Birth Without Fear method working closely with the software development team and the expert group to determine the app's requirements. Notably, the software development team included many senior developers with experience in developing apps for the medical, health, and fitness sectors. Throughout the development process, regular communication was maintained between all stakeholders, with multiple meetings taking place to discuss requirements, review versions of the app, and gather feedback.

The idea for an early labour app was first conceived in 2018, but the development of the first prototypes did not begin until 2020. Unfortunately, the first two prototypes were unsuccessful and were discontinued as they did not meet stakeholders' expectations. The main reason for these failures was that the initial prototypes were built as flat summaries of the book, making the app dull, text-heavy and with little to no interactive features. In retrospect, these early failures helped the product owners (i.e., Birth by Heart) better understand the app development process and address communication barriers with software development teams. However, on the third attempt, a viable prototype evolved into the latest version of the Early Labour App, released in November 2022. The development process of this app is described in this section.

2.3.1. Main methodologies

The software development team is composed of ten professionals with different specialisations. It primarily follows agile practices [25], using Scrum as the central project management methodology and adopting continuous software engineering routines (i.e., Continuous Integration/Continuous Delivery (CI/CD), Development and Operations (DevOps)). The team worked with two-week sprint cycles, allowing the project stakeholders to have frequent updates on the app development. The short sprint cycles help the development team to prioritise the development of features, identify issues within the group, and manage

changes. Aligned with the agile practices, the team also adopted a feature-driven development approach for building the app, emphasising the user- and client-valued functionality perspectives.

The software company has also developed its approach for user-centred design, consisting of three phases: discover, define, and prototype. The "discover" phase involves benchmarking other similar apps and conducting focus groups and interviews. The "define" phase comprises the creation of personas and flow charts of the system. The "prototype" phase is characterised by the design of UI elements, mock-ups and high-fidelity prototypes. Designed prototypes are then tested with representative users, which included first-time pregnant couples (i.e., the main target group), couples with children, and prospective parents (all 18 years and older). Following the feature-driven development, the user-centred design process also evolved on a feature-by-feature basis, with an ongoing collaboration of representative users throughout the app development process.

It is also important to stress that all software developers received in-depth guidance on the Birth Without Fear method, consisting of two workshops (90 min each) organised to teach them the method's principles and foundations. Full access to all the material was also provided, besides the ongoing contact with the Birth by Heart team of instructors and the project's expert group for discussions and consultation.

2.3.2. Main requirements

The software development team gathered the main requirements for building the Early Labour App through stakeholder interviews and iterative design. Initial prototypes were built and tested, refining the design and requirements based on feedback. For instance, stakeholder input led to the adoption of a blended care strategy, and iterative design gave rise to features such as the "Contraction Coach". Data security and privacy requirements were set based on industry standards and regulations.

The app's requirements also overlap with the project's primary research outcomes, i.e., reducing emotional distress and fear of birth during pregnancy. Software developers boarded this project with this clear goal in mind but were also posed with the challenge of translating the Birth Without Fear method from a book to a mobile app. Besides, previous experience from the Birth by Heart organisation also pointed out that the readers of Birth Without Fear would often refer to the book as a "friend" helping them through their pregnancy journey. Similar to the book, the app would assume a friendly guiding role, helping to not only transmit knowledge and raise awareness but, at the same time, acting as a digital midwife that helps to create emotional support, build

confidence, and support the couple in working together as a team.

The combination of inputs and processes helped us establish the app's requirements. Table 1 summarises the overarching requirements for building the Early Labour App.

2.4. App testing

Throughout the project, the team adopted a user-centred design process characterised by ongoing consultation with representative users and several short testing sessions carried out periodically as new features were developed. When the mockups and high-fidelity prototypes were ready, potential users were consulted again to identify whether their needs were fulfilled or the design needed improvement. The software team had access to many representative test users over time, with 7 to 12 participants as part of an internal testing team and 6 to 10 external participants, allowing them to pull participants from the internal and external pools as needed. To test mockups and high-fidelity prototypes, the team customarily set the users in a scenario (i.e., present the prototype and features to be tested) using a think-aloud protocol that encouraged them to narrate their experience while interacting with the prototype. Common questions at this stage were: "What are the most important things here?" and "How should the courses/exercises be displayed?". The team also uses follow-up questions for more general insight, e.g., "What do you think of feature X?", or "Why would feature X be useful to you?". If the users find it difficult to answer such general questions, the team can also ask more personal questions, such as "Would you use the app?", "What is your overall impression?" or "Is there anything you miss?". Users were also encouraged to share thoughts freely at the end of testing sessions. Nonetheless, even though the high-fidelity design can be quite near to the end result, the whole user experience cannot be tested entirely without them using the actual app; therefore, when possible, potential users were also invited to try the app on their devices.

The app's first version was concluded in June 2022, enabling us to test it more thoroughly and identify the main issues that were later addressed in the second version. This manuscript focuses on this battery of tests, detailing them further since they constitute the most critical testing milestones in the project, highlighting the transition from the first to the second version of the app.

Table 1

Main requirements identified for building the Early Labour App.

#	Requirement description
1	The app should be part of a package and not designed to be used in isolation, thus supporting a blended care strategy and encouraging users to seek additional materials (i.e., book, and video lessons).
2	The app's content should be a <i>condensed</i> and <i>simplified</i> version of the book, synthesising all the main principles and exercises.
3	The app's content should be provided in <i>text</i> and <i>audio</i> , allowing users to read and listen to the material as they prefer.
4	The app's content should provide a series of audio tracks for <i>guidance</i> during the exercises and when timing the contractions in the app.
5	Particular focus should be given to the User Interface and User Experience (UI/UX) components to create a <i>calming</i> and <i>soothing</i> app, aiming for friendly emotional support, a feeling of safety, and nudging users towards reading and completing exercises in the app.
6	The app should be designed to be used by both the pregnant woman and her support partner, <i>building a team</i> and preparing them during the pregnancy.
7	The app should provide a separate component known as the " <i>Contraction Coach</i> " that enables timing the contractions, tracking and keeping a history of all contractions, and an audio player that can play in the background any of the guiding audios provided in the app (e.g., guided breathing, relaxation, voice).
8	The app's content should contain a section with the most <i>frequently asked questions</i> (FAQs) based on midwives' reported experiences.
9	The app should ensure the <i>security and privacy</i> of the users' data, including functionalities such as user authentication, encrypted communication, secure storage, and informed consent.

- **Internal user test** – The organisation Birth by Heart and the software development team conducted a preliminary user test of the app, gathering early feedback during June and October 2022. Participants were recruited from the organisation's contact network (e.g., couples already participating in courses and other activities). A convenience sample of ten first-time pregnant couples was selected and asked to install and use the Early Labour App on their phones for a week. After that, the couples were asked to respond to a short questionnaire on their impressions of the app in terms of satisfaction, user-friendliness, the relevance of content and exercises, and add or remove features (all questions in Appendix A). The Birth by Heart team collected and analysed these answers, and seven couples were invited for a follow-up face-to-face conversation to discuss their answers to the questionnaire and overall experience with the app. Notes were taken during the interviews. This process allowed the company to gather preliminary positive and negative feedback on the app's features, interface, and content coherence. The main results from this internal user test were then shared with the expert group researchers.

- **Security test** – Various security tests were performed by researchers from the expert group using the Mobile Security Framework (MobSF²) for automated static and dynamic analysis of the app. MobSF can reverse engineer the app's code and run a series of checks, e.g., used permissions, pen-testing with attack scripts, an inspection of network traffic, insecure coding, logging or data storage.

- **Pilot study** – It is also worth mentioning that the app was tested as part of a pilot study from June to August 2022 before conducting the RCT (described in [18]). Forty-eight women in their first pregnancy planning to undergo a vaginal birth, pregnancy week 25–36 at the time of registration, participated in this study. The validation study used log entries, i.e., app activity measured as many actions made by the user and a survey focusing on app feasibility, perceived usefulness and usability as well as Sense of Coherence, Self-Efficacy and Fear of Birth. However, this pilot study has a broader scope, testing the entire blended care intervention rather than testing the app *per se*. Thus, the pilot study is presented in a separate publication [26].

This series of tests allowed us to identify many issues with the app's first version, as discussed in the remainder of this paper.

2.5. Ethical considerations

This study was approved by the Ethical Research Committee of Sweden (Dnr. 2021–03028). The participants were informed about the General Data Protection Regulation (GDPR) and provided informed consent to participate in the study. It is also worth stressing that only authorised developers in the collaborating company have access to the app's usage statistics (e.g., modules completed, time spent in the app, use of various functions). The app also only collects the users' email addresses used for authentication, extensively minimising the collection of personal information. Any identifiable user data is hashed using SHA-256, a secure hash algorithm. This process transforms the identifiable information into a unique string of characters, which does not allow the original information to be retrieved or reconstructed. The company uses a different development environment with dedicated servers and databases, isolating the app currently being tested. Only authorised personnel in the company has access to the development environments. The servers hosted on the Google Cloud Platform benefit from Google's high-standard security model, which includes built-in firewalls. All the

² Mobile Security Framework (MobSF) is an automated, all-in-one mobile application (Android/iOS/Windows) pen-testing, malware analysis and security assessment framework capable of performing static and dynamic analysis. (<https://mobsf.github.io/Mobile-Security-Framework-MobSF/>).

communication traffic between the app and servers is done using HTTPS implemented over a secure protocol (i.e., Transport Layer Security). This ensures that all data transmitted is safe from potential eavesdropping or interception. No third-party service providers can access any personal data, whether grouped or anonymised. Other data collected by the researchers, such as surveys used in the study, are securely stored through the universities' systems and databases. Such data is never shared with the company, not even in anonymised form.

3. Results

This section describes the second version of the Early Labour App that will be used as part of the RCT. Besides providing a detailed description of the app, the main issues identified in the first version, respective improvements, and most liked features are also discussed in section "3.2 Preliminary User Test". A few comments on future work on the app are later mentioned in section "4. Discussion".

The Early Labour App was built using the React Native³ framework with TypeScript, for a high-performance, cross-platform app with improved scalability and maintainability. This framework allows us to write a single JavaScript codebase that can be used to natively render mobile apps for iOS and Android, i.e., creating truly native apps without compromising the users' experiences. Apart from such advantages, the React Native framework is also maintained by one of the largest communities of open-source software, enabling us to not only leverage high-performance and up-to-date releases of the framework but also have access to extensive documentation and support channels. We complemented this with a backend server built on Strapi, also leveraging TypeScript, for easy content management and distribution. Our chosen database system is PostgreSQL, known for its advanced features and reliability, creating a robust mix of modern tools for our application development. Figma⁴ was an important design tool used by the team, enabling quick prototyping and user tests.

3.1. Early Labour App: main content and features

The app's user interface was designed to be concise and with simple navigation, as presented in Fig. 2. The vast majority of the content and information provided in the app is based on the Birth Without Fear method. Users can easily start from the Home screen that provides an overview of all structured material about: (1) the Birth Without Fear method, covering its foundational principles; (2) practice, with expanded information, audio and exercises on the principles of Support, Breathing, Relaxation, The Voice, and The Mind; and, (3) the Contraction Coach, on how to time the contractions and use audios for guiding an emotionally safe birth. A family of soft pastel colours was used in the various components of the apps since these shades are often described as "calming" and "soothing".

The app's content was carefully written in Swedish and English by the author of Birth Without Fear [16,17]. This material was crafted to synthesise all the main concepts and principles described in the book and provide an overview and "mini course" for the users. The most important texts are also provided with an audio version, enabling the users to read or listen to the material (see Fig. 3). However, we were also mindful of not providing texts and audio that are too long since, in the context of a mobile device, short pieces of content are more easily and efficiently learned by the users, and they can go through all the material at their own pace.

As shown in Table 2, the whole app's content contains 172 short texts, 32 audio, and 150 small optional exercises. In addition, the users

can also track their progress in the app since an associated percentage is recorded and shown on the Home screen for every part of the app's content that they finish reading or listening to.

The Contraction Coach module also provides an enhanced timer that can be used during the early labour stage. As shown in Fig. 3, this timer can be used to track the start and stop of the contractions. In addition, a history of all the contractions is kept for future reference of the users and other supporting caretakers, e.g., midwives and doulas. An important feature introduced to the timer is the guided audios that can be played in the background, "coaching" the users during the contractions on several principles of the Birth Without Fear method, such as breathing, self-soothing, relaxation, partner contact, and voice and mind. These audios can be played on repeat, running in the background of the contraction timer.

3.2. Preliminary user tests

As mentioned, after developing the first versions of the Early Labour App (built for iOS only), two separate tests were conducted as part of our preliminary evaluation: internal user testing and security testing.

The issues raised by the users were mainly related to a lack of coherence in the content. Users felt that the navigation through the materials could have been more intuitive and that some of the concepts needed to be clearly defined, which could be confusing. They also found that the app had too much text, making parts of the content redundant. Besides, users also wanted to be able to read the content at their own pace and be able to pause and resume activities at any time. Such feedback caused the software development team and the author of the Birth Without Fear method to restructure the app's information hierarchy completely, simplifying the text, removing technical terminology, and improving all the materials' overall consistency and readability.

Users also considered the app's first version "unappealing" and "unpolished". Results for the items on "overall satisfaction" and "user friendliness" of the app (i.e., questions 2 and 3 in Appendix A) averaged respectively 3.3/5 and 3.1/5, indicating that couples were feeling neutral about the app. This also led the development team to completely re-design the user interfaces, adopting the React Native framework to build the apps for both Android and iOS. Therefore, the user interface was more heavily changed to make the app easier to use, appealing, soothing, calming, and with intuitive navigation through all the content.

Nonetheless, participants of the internal user test expressed that the app is simple and easy to use, i.e., it does not require assistance, and it is self-explanatory. Even if the app's content could have been improved in terms of coherence, the couples found that the descriptions provided in the modules and exercise sections were good educational summaries that helped to complement the book and courses. Furthermore, in both user tests, participants expressed positive feedback regarding their trust in the Birth Without Fear method, enjoying the assisted exercises, taking the opportunity to learn together with their support partner, and feeling guided on what to do and when.

Finally, regarding the security tests, the app was classified as "low risk" since very few vulnerabilities were found – none severe/critical. The main issues were related to using dangerous permissions in the app, such as access to the microphone and location information. These permissions were removed since they were unnecessary. These positive results were partly possible because the software development team was already employing good data minimisation strategies, collecting only the user data needed (e.g., only the email address for authentication) and avoiding third-party libraries.

Based on the app's first version, these tests significantly helped address usability issues, such as lack of coherence of the content, non-intuitive navigation, and removal of unnecessary features. All the feedback was considered by the software development team and expert group, resulting in the second version of the Early Labour App for iOS and Android that will be used in the RCT.

³ React Native is a modern JavaScript framework developed by Meta Platforms, Inc (<https://reactnative.dev/>).

⁴ Figma is a collaborative web application for interface design. (<https://www.figma.com/>).

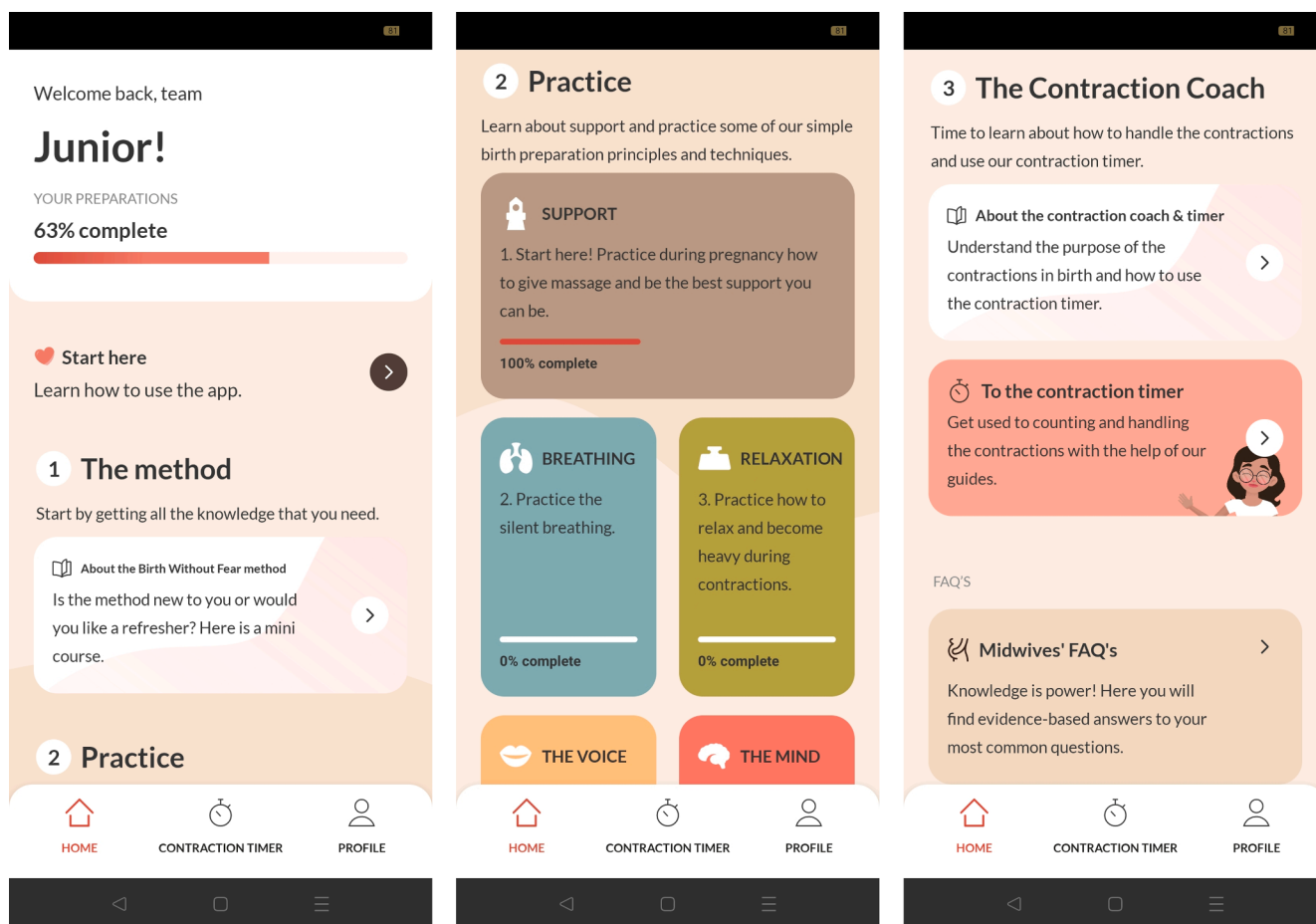


Fig. 2. The “Home” page of the Early Labour App is the application’s main screen.

4. Discussion

This research project started with recognising a healthcare gap in practice in which pregnant women in early labour reported feelings of exclusion from care by professionals [2,3]. Aiming to breach this gap, this study contributes with the detailed proposal of a mHealth app for digital early labour support, the Early Labour App. Furthermore, necessary practical experience and lessons learnt are shared, benefiting other stakeholders in creating new digital health solutions and conducting mHealth interventions. In this section, the main challenges faced by our team are summarised, and future work is discussed.

During the development of the Early Labour App, two main types of challenges emerged: (1) user challenges, related to understanding the users’ needs and experience with the app, and (2) team challenges, related to the software development team in particular, and the necessary skills for translating an early labour intervention into a digital solution.

From the users’ perspective, essential feedback concerned synthesising and simplifying – without distorting – an extensive amount of information on the Birth Without Fear method. The users’ preferences for easily digestible information, summarised content, multimedia content, and activities that the couples can do together were challenging for the development team. One of the strategies to tackle such issues was to identify the other types of apps used by our target population so that similar features that the users already know how to use (e.g., YouTube media player, Instagram “stories”) could be included in the Early Labour App. It was also helpful to design the Early Labour App bearing in mind that this app is just one of the moving pieces in a broader blended care strategy. The app is vital to extend the support provided by midwives

and doulas through a cost-effective way to scale the dissemination of health information and raise awareness during pregnancy. However, we believe that it would not be as valuable if used in isolation.

Even more challenging was putting together the right software development team to build the Early Labour App. Translating the Birth Without Fear method into a digital solution was a non-trivial task that requires extensive engagement from health professionals, researchers and software developers. Our agile teams have a “product owner” as part of the software team, acting as the primary point of contact on behalf of the customer to identify the app requirements for the development team. In our experience, the product owner must delve deep and study and learn extensive materials. This time invested in studying pays off in the future and helps to prevent problems. Even then, the continued engagement of a domain expert (i.e., the healthcare intervention specialist) was found to be irreplaceable given the complexity of the content, tools and exercises that should be translated into the app.

Building a digital community, such as the expert group in this project, was also crucial for bringing the expertise of a multidisciplinary research team into the app development process. For the app development, having academics from computer science, particularly with a mHealth systems background, helped consult and translate needs from health professionals to the software teams, as well as having experts to assist in the app’s security and privacy testing.

On the other hand, the “inventors” of a new digital health solution can also benefit from a better understanding of the personal and technical limitations faced by the software teams (e.g., lack of clinical knowledge, communication challenges, lack of resources). Especially when adopting agile software development processes, it is essential to acknowledge that the teams will start by building rough and incomplete

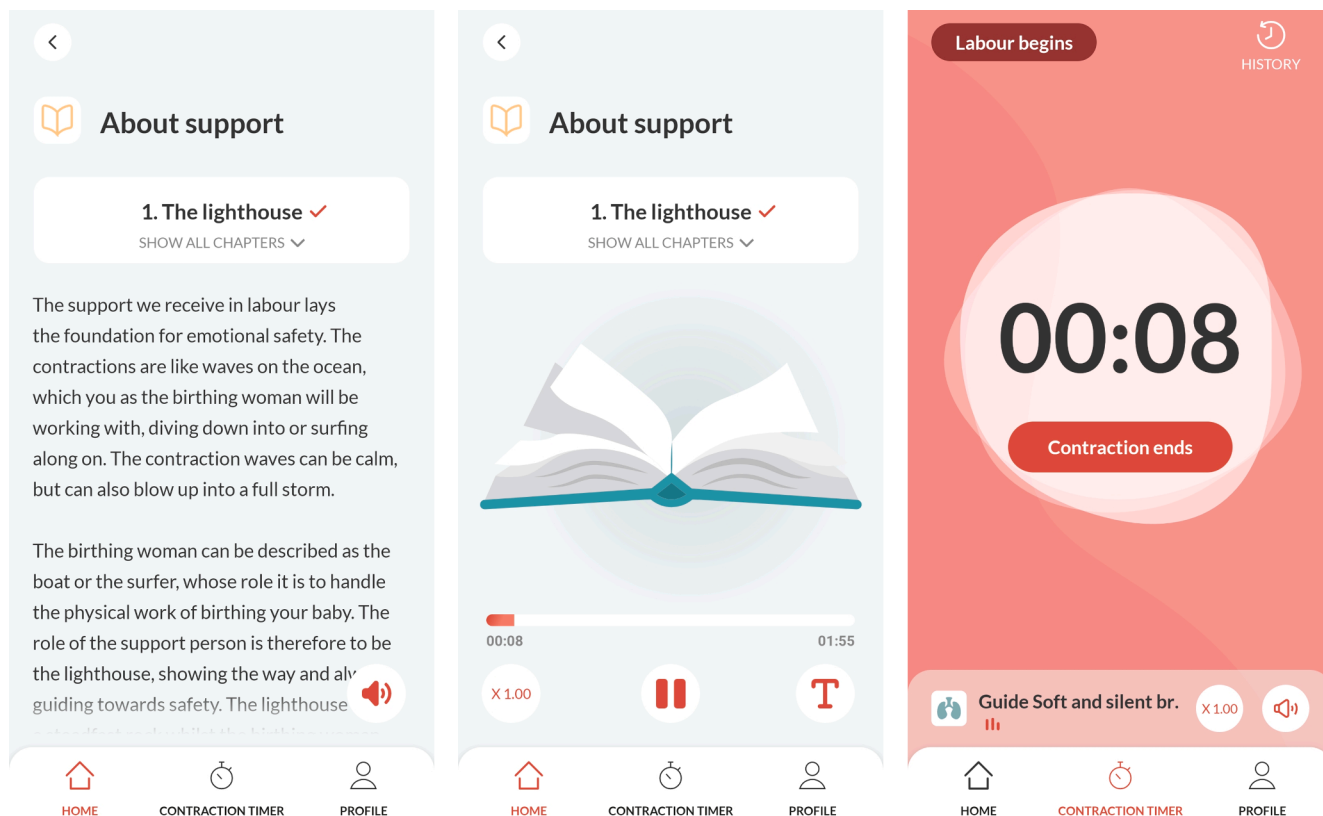


Fig. 3. Most of the application’s content is also provided in audio format, enabling users to listen and read the condensed material to improve learning. The Contraction Timer (right) allows the timing of contractions and enables users to play different audios in the background (e.g., breathing or relaxation guides).

Table 2
Summary of the content and features provided in the Early Labour App. **Acronyms:** Text (T), Audio (A), Exercises (Exr), Proportion (Pro).

Pages	Module	Sub-module	Description	T/A	Exr	Pro (%)
Welcome message	–	–	Description of the Birth Without Fear method and Early Labour App.	1/0	–	–
Home	Start	–	Introduction on how to use the app: 1. The app’s three sections; 2. Coping and handling; 3. Your support during early labour.	1/0	–	7
	1. The method	–	Overview about the Birth Without Fear method, explained in sections: Intro; 1. The body knows; 2. Fear is the break; 3. Feeling safe is the accelerator; 4. Four tools to minimise fear; 5. Breathing; 6. Relaxation; 7. The Voice; and, 8. The Mind.	9/8	–	19
	2. Practice	Support	Information for birth partners to give support during labour, structured in sections: 1. Summary sheet; 2. Become a team; 3. Contraction signs; 4. Closeness; 5. Firm hand with pressure; 6. Stroking; 7. Pressure and strokes; 8. Tickle the belly; 9. Sacrum press; 10. Pelvic squeeze; and, 11. A stronger team.	72/12	66	11
		Breathing	About the silent breathing and linked techniques, covering: 1. Forced vs. calm breathing; 2. Affirmation; and, 3. Example during contractions.	18/2	18	26
		Relaxation	About how to let the body relax and become heavy during contractions, covering: 1. Tense and relaxed; 2. Affirmation; and, 3. Example during contractions.	24/2	24	7
		The voice	About the use of deep-pitched voice as a tool, including: 1. Deep vs. high-pitched sound; 2. Affirmation; and, 3. Example during contractions.	19/2	19	7
		The mind	About the practice of positive thoughts and words, including: 1. Yes and no; 2. Affirmation; 3. Example during contractions.	23/2	23	7
	3. The Contraction Coach	–	About using the Contraction Coach for emotional safety in labour and birth.	4/3	–	16
Midwives’ FAQs	–	–	List of answers to the most frequently asked questions.			
Contraction Coach and Timer	–	–	Main page for keeping track of contractions, with features such as: Labour begins; History; Contraction starts – timer; and, Select guidance – listen to audios.	1/1		
				172/32	150	100

solutions that need to be continuously refined as the project matures within the team. Given that, identifying the core features, usually the 20% of features that users will use about 80% of the time (i.e., following the Pareto principle) [27,28,29], is also relevant for prioritising work and quickly achieving a minimum viable product [30,31]. In our project,

it was also important to make the health professionals responsible for writing and reviewing the app’s content, which would be highly challenging if left to the software team.

Security and privacy played a role in the app development process throughout this project. From the beginning, concerns about collecting

personal data from couples were discussed among the expert group and development team, which helped us minimise the data collection. Such considerations were also discussed for the commercial wristbands used in the broader blended care strategy. For instance, key criteria, such as features for data access, facilitated software integration, and privacy-respecting data flows of personal data to cloud services, were decisive factors. As a result, only one vendor of commercial wristbands was found to match the requirements of this project [24].

As future work, an RCT is ongoing to evaluate the whole blended care intervention using the Early Labour App. This study will also help us to identify further feedback from the participants about the app. Nonetheless, we are already planning new features for the next release, including linkage of the couples' apps and joint learning and exercises; setting reminders for support partners; the creation of support groups within the app ecosystem, e.g., allowing other mothers to know when someone is giving birth; improving nudges in the app to guide users to a calm and relaxed state while learning; and, adding "gamification" strategies that increase engagement and reward positive behaviour of the users in the app. Nonetheless, we also consider that using a mobile app is only one of the potential digital alternatives for breaching the information gap in healthcare for women and their partners in early labour. Other digital technologies such as web-based patient portals, sensors and wearables, and Internet of Things (IoT) devices may also be part of other potential solutions. As the proposed app, more research is needed to understand users' needs, rigorously designing and evaluating digital health technologies to determine the best alternatives for improved healthcare outcomes.

5. Conclusion

This study described the development process of the Early Labour App, introducing preliminary test results and the necessary re-designs required before deploying the app in a more extensive RCT study. In brief, the Early Labour App was easy to use, the couples needed little to no help using it, and the partner's preparation was also facilitated. Furthermore, including the app as part of blended care raises awareness, allows couples to share thoughts and feelings about the method, and provides good preparation for the birth. The end vision for the Early Labour App is to create an emotionally supporting digital tool that could extend the work performed by midwives for pregnant women and their partners. In this project, we found that innovation drivers in digital health technologies can significantly benefit from an expert group, joining multidisciplinary research teams and health professionals, and assisting in designing relevant solutions. Moreover, digital health solutions for mHealth interventions must be rigorously evaluated before full-scale deployment, ensuring evidence-based blended care practices. Such steps are being taken by the research team so that the Early Labour App can be released to the market as a solidly built solution.

Summary table:

What was already known on the topic:

- First-time parents deal with higher levels of fear and stress during pregnancy, particularly in the early labour phase, where there is a gap in healthcare provision (i.e. the transition to a hospital only in active labour).
- mHealth apps can be used in blended care strategies for enhanced support of pregnant women and their partners in different stages of pregnancy.
- mHealth apps have the potential to empower patients, enabling them to take better care of their health.

What this study added to our knowledge:

- Describes the development process of the Early Labour App, designed to instruct and guide first-time parents during the early labour phase.
 - The software development team should work in consultation with an interdisciplinary expert group, helping to identify evidence-based midwifery practices and avoid security and privacy pitfalls.
 - mHealth apps, such as the Early Labour App, are promising digital technologies for achieving better health outcomes, i.e., reduced fear and stress levels during early labour.
-

CRedit authorship contribution statement

Leonardo Horn Iwaya: Methodology, Formal analysis, Writing – original draft, Validation, Investigation, Visualization. **Anna Nordin:** Conceptualization, Methodology, Writing – review & editing. **Lothar Fritsch:** Methodology, Software, Investigation, Writing – review & editing. **Elin Børøsdund:** Conceptualization, Methodology, Writing – review & editing. **Margareta Johansson:** Conceptualization, Validation, Investigation, Resources, Data curation, Writing – review & editing. **Cecilie Varsi:** Conceptualization, Methodology, Writing – review & editing. **Karin Ångeby:** Conceptualization, Validation, Investigation, Resources, Data curation, Writing – review & editing, Project administration, Funding acquisition.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A

Questionnaire used for the Internal User Test.

1. Have you attended our prophylaxis course online or physically? [Answer: Yes or No.]
2. In general: How satisfied were you with the pregnancy part of the app overall? [Answer: 5-point Likert scale: 1. Very unsatisfied, 2. Unsatisfied, 3. Neutral, 4. Satisfied, 5. Very Satisfied. Answer: free input field for participants to write.]
3. In general: How did you experience the user-friendliness of the app? Please describe below. [Answer: 5-point Likert scale: 1. Very unsatisfied, 2. Unsatisfied, 3. Neutral, 4. Satisfied, 5. Very Satisfied. Answer: free input field for participants to write.]
4. In general: What would you like more of? What could you have removed that felt unnecessary or did you have the energy to do? [Answer: free input field for participants to write.]
5. The introductory courses: Was there too much, too little or just enough information in the introductory courses? Please describe. [Answer: free input field for participants to write.]
6. The intro courses: Was there any function that you would have liked in the intro courses that was not there? Make suggestions for improvement or change. [Answer: free input field for participants to write.]
7. The introductory courses. Applicable pedagogy, animations or other. Was there something you thought was good or wished for or was missing in the introductory courses? [Answer: free input field for participants to write.]
8. The support part. Was there too much, too little or just enough information in the support section? Please describe? [Answer: free input field for participants to write.]
9. Support section: Was it easy to understand the content of the support section? Please describe. [Answer: free input field for participants to write.]

10. The support part: Was the content interesting or rewarding for you as a team in the support part? For example, the feeling of understanding your different roles and feeling like a team? Please describe. [Answer: free input field for participants to write.]
11. The support part. Applicable pedagogy, animations or other. Was there something you wanted or missed in the support section? [Answer: free input field for participants to write.]
12. The exercise part. How was it for you to perform the exercises under the tools and support? For example regarding pedagogy, user-friendliness or other. Please describe. [Answer: free input field for participants to write.]
13. The exercise part: Which exercises did you appreciate the most? Least? Please describe. [Answer: free input field for participants to write.]
14. The exercise part: Were there too many or too few exercises? [Answer: free input field for participants to write.]
15. The Exercises: Was there a feature you wanted in these exercises that wasn't there? Make suggestions for improvement or change. [Answer: free input field for participants to write.]
16. Other feedback. [Answer: free input field for participants to write.]

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