

The iCARE project: Formative research to develop a self-guided digital intervention for postpartum depression for integration into the Danish home visiting program

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Abstract

Background: Postpartum depression (PPD) is a major public health concern. Despite advancements in treatment, many barriers to accessing care remain. There has been growing interest in digital interventions to prevent and treat PPD. However, for mothers with mild and moderate symptoms of depression, there is a lack of self-guided internet-based interventions developed with user input and with considerations on how to integrate the intervention into stepped care models for postpartum depression.

Objective: The aim of this study was (I) to describe the process of the design and development of iCARE: A self-guided digital psychological intervention for mothers with mild and moderate symptoms of PPD, (II) present the program's theory illustrated by a Logic Model, and (III) explore its initial usability and prospective acceptability.

Methods: Applying user-centered design methods, the intervention development was informed by five supplementary strategies: (1) a systematic review of minimally guided, internet-based interventions for postpartum depression; (2) an existing internet-based cognitive behavioral therapy intervention for depression; (3) findings from two cycles of interviews with 9 mothers with lived experience of PPD, (4) twenty focus group interviews with maternal health care providers (MHCP) who screen mothers for PPD, and (5) discussions with a group of experts in mental health, PPD, and public health interventions.

Results: Initial interviews with mothers and MHCP emphasized the importance of a digital intervention offering timely psychoeducation, coping strategies, and pathways to in-person care, while addressing the diversity of expressions of PPD symptoms. Stakeholders recommended a flexible program, multimodal content, and integration into maternal care systems with community health nurses supporting engagement and participation. The prototype was designed to be user-centered, engaging and with multiple interactive features. It included components on psychoeducation, cognitive exercises grounded in cognitive behavioral, acceptance, and commitment principles, and mood-monitoring. Prototype testing resulted in five themes that lead to a refinement of content: motivation and engagement, de-stigmatization and diversity of symptoms, gender and family representation, understanding of therapeutic model, and clarity of instructions.

Conclusions: iCARE is a self-guided internet-based psychological intervention for mothers with mild and moderate symptoms of PPD. It was developed with user input using qualitative methods, user-centered design, and psychological theory. Further research is needed to evaluate the feasibility and effectiveness of the program in a randomized controlled trial and its integration into maternal healthcare models such as universal PPD screening and home visiting.

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Original Manuscript

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Conclusions:

iCARE is a self-guided internet-based psychological intervention for mothers with mild and moderate symptoms of PPD. It was developed with user input using qualitative methods, user-centered design, and psychological theory. Further research is needed to evaluate the feasibility and effectiveness of the program in a randomized controlled trial and its integration into maternal healthcare models such as universal PPD screening and home visiting.

Keywords: postpartum depression, mother, digital intervention, cognitive therapy,

Introduction

Postpartum depression (PPD) affects between 10% and 15% of mothers globally [1]. Universal PPD screening is increasingly common in healthcare, but its effectiveness depends on systems that ensure timely interventions for those who screen positive [2, 3]. Stepped care models address this gap by pairing systematic screening with risk assessment and tailored interventions. [4]. Despite treatment advancements, access to care remains limited due to stigma, service fragmentation, resource shortages, high costs, and logistical challenges [2, 3]. Persistent barriers highlight the need for

accessible, innovative approaches integrated into existing stepped care models. To enhance the stepped care model for PPD in Denmark, this study explored how formative research can facilitate the development of a self-guided digital mental health intervention (iCARE) for mothers with mild to moderate symptoms of PPD.

Digital mental health interventions (DMHIs) offer a promising alternative to traditional face-to-face care [5]. Over the past decade, DMHIs for PPD prevention and treatment have shown modest effects in reducing short-term depressive and anxiety symptoms [6]. These typically include cognitive-behavioral therapy (CBT), psychoeducation, mindfulness, or combinations thereof, with psychotherapeutic components proving more effective than psychoeducation alone. DMHIs vary in delivery, from self-guided to blended models (combining digital tools with in-person or telehealth support), and technology (app- or web-based) [7]. While self-guided interventions can broaden access, challenges with engagement and retention often limit their implementation, effectiveness and scalability[8]. Addressing these issues through improved design, content, and delivery is crucial for enhancing their use and impact.

To inform the development of iCARE, we first conducted a systematic review of self-guided DMHIs targeting women with elevated PPD symptoms. Seven studies involving 648 participants (identified through EPDS, BDI-II, or PHQ-9 screenings) were reviewed. These interventions showed a significant reduction in depressive symptoms, but considerable heterogeneity among the studies limits their generalizability (protocol registration, PROSPERO [CRD42023482966](https://doi.org/10.1186/1745-6215-13-2966)). Notably, few studies incorporated formative research including women with lived experience, even though co-development approaches can help tailor interventions to users' needs, potentially resulting in more effective outcomes [9]. In addition, none were integrated into routine maternal care, leaving gaps in implementation knowledge. Hence, little is known about *how* self-guided DMHIs can be integrated into existing maternal healthcare systems.

Denmark provides a compelling context for exploring the integration of self-guided DMHIs into maternal care. The country's highly digitalized healthcare system and established internet-based therapies for general depression form a strong foundation for integration. Additionally, Denmark features key elements of a stepped care model, including a universal nurse home-visiting program for all families with newborns.

Maternal health care providers (MHCPs) conduct five visits during the first year postpartum, including visits approximately 8 weeks after delivery where PPD screening is offered using the Edinburgh Postnatal Depression Scale (EPDS). Based on screening results, MHCPs may provide additional support, such as extra visits, group sessions (available in some municipalities), or recommendations to contact general practitioners for access to specialized care. Despite this infrastructure, access to mental healthcare for mothers with PPD varies widely across municipalities, with two-thirds of mothers who screen positive not receiving appropriate care [10]. Integrating a self-guided DMHI into Denmark's framework could offer insights into addressing care gaps and the potential of digital tools to enhance stepped care models for PPD, informing practices in countries with similar care models.

This study

This study aimed to conduct formative research to develop iCARE, a self-guided digital psychological intervention for mothers in Denmark with mild to moderate PPD. The intervention was designed for integration into postnatal maternal care. Using an iterative, user-centered design approach, this study also evaluated the initial usability and prospective acceptability of the prototype intervention. Two key questions guided this research: (1) What are the preferences and recommendations of mothers, MHCPs, and experts for a self-guided digital intervention for PPD integrated into Denmark's maternal care system? (2) What is the initial usability and prospective acceptability of the iCARE prototype? These questions shaped the iterative development and refinement of iCARE.

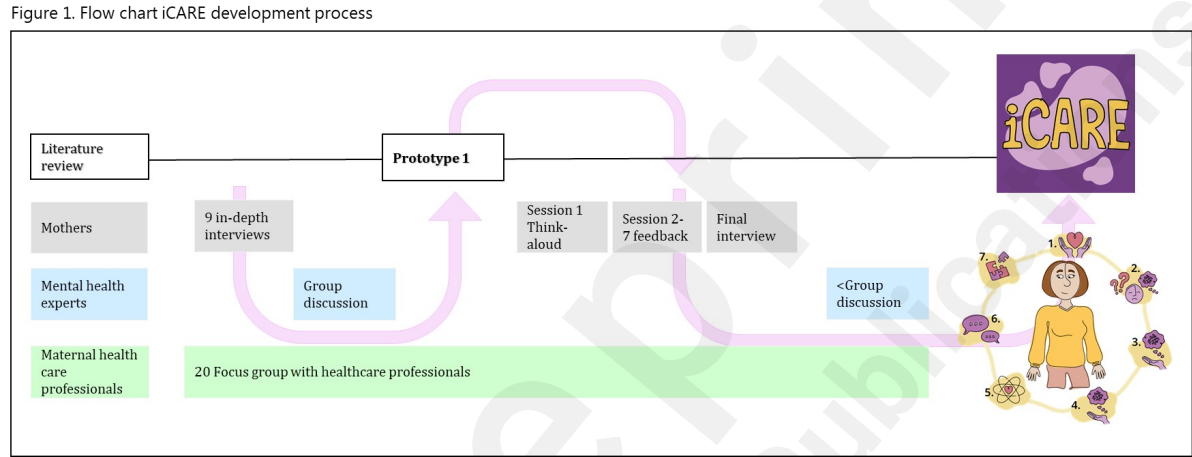
Methods

Study Design

We used an iterative intervention development process guided by the Medical Research Council (MRC) framework for the development of complex interventions [11]. This framework was useful given that the aim of the digital intervention is to be integrated into a complex system, the home visiting program. The MRC framework consists of several key phases—development, feasibility, evaluation, and implementation—which guide the design and testing of interventions. In the

development phase, the MRC framework focuses on understanding the problem and establishing the theoretical basis for the digital intervention under development. Formative research is used to gather needs and preferences from the target group that inform the development of the intervention. Before feasibility testing the intervention, prototypes of the digital intervention are developed, incorporating user feedback to ensure the intervention is appropriate and acceptable.

Following the MRC approach and user- centered design methods [12] we used an iterative design (Figure 1) to develop iCARE that comprised the following steps: (1) a systematic literature review, including prior systematic reviews, to identify evidence for self-guided interventions for women with PPD and interventions' therapeutic components; (2) interviews with women with lived experience of PPD, and group discussions with mental health experts and MHCPs from the home visiting program to identify needs and preferences for a self-guided digital intervention for PPD and its integration into maternal care; (3) design and content development incorporating feedback from stakeholders in collaboration with developers at the Department of Digital Psychiatry; (4) prototype testing including think-aloud usability testing and interviews with five mothers previously interviewed to evaluate the program's usability and prospective acceptability; (5) group cognitive walkthrough with mental health experts; (6) final refinement of iCARE content and implementation in collaboration with developers and designers.



A self-guided intervention for depression (not specific to PPD) based on cognitive behavioral therapy (CBT) developed by the Center of Digital Psychiatry first inspired the development of our PPD intervention. This intervention consisted of nine consecutive modules in which the end user learned about depression (psychoeducation), set their own treatment goals based on behavioral activation, learned and practiced cognitive restructuring skills, and focused on relapse prevention. The intervention included text and videos, in-site exercises, and digital diaries. In step 3, this intervention initially inspired iCARE's digital format (use of graphics, videos, exercises, diaries), structure (progressive modules), and some content (e.g., psychoeducation about the cognitive behavioral diamond) based on CBT principles.

Participants, Recruitment and Procedures

The study took place from June 2023 to October 2024. We recruited mothers with lived experience of PPD through social media accounts. Despite we aimed for diversity, all mothers had at least high school education and Danish background. Additionally, we recruited 20 municipal maternal health care provider teams (out of 98 municipalities) for the study and iCARE implementation and formed an expert advisory board. Table 1. describes the different participants, modes of recruitment, inclusion criteria, and methods used.

Table 1. Summary of participants, modes of recruitment, inclusion criteria, and methods used.

Participants	Recruitment	Inclusion criteria and characteristics	Methods
Mothers with lived experience N=9	Advertisement on the social media account of	- >18 years - Experience of PPD	Round #1: In depth interview (online or in

	<i>Sind og Fødsel</i> (Mind and Birth), a non-profit patient organization and Facebook groups for mothers	within the last 2 years - Danish-speaking - self-report not having active depressive symptoms	person based on mothers' preference) to assess their needs, values, and preferences and translate them into intervention requirements for content and format.
			<u>Round #2:</u> Prototype testing - Individual think aloud exercise - Short post session survey - Final semi-structured interview
MHCH in municipalities. N=20 focus groups (2-6 MHCH in each)	LinkedIn and direct reach out to head nurses via convenience sampling and purposive sampling (targeting municipalities without offers for mothers with PPD)	All municipalities were eligible.	In person and online focus groups to examine MHCP needs and suggestions to integrate iCARE in their stepped care model for PPD.
Mental health experts N=7	Identified based on their expertise through professional networks	2 directors of the patient organization 'Sind og Fødsel', 1 psychiatrist, 1 psychologist and global mental health researcher, 1 clinical psychologist expert in maternal mental health and e-health interventions, 1 clinical psychologist expert in digital interventions 1 researcher expert in complex interventions, 1 psychologist expert in PPD and attachment-based interventions	<u>Round #1:</u> Group discussion about initial Logic Model and intervention therapeutic components <u>Round #2:</u> Presentation of snippets of the prototype and group cognitive walkthrough to provide feedback about design, content, and format. Additional individual interview with 1 expert

Data collection

Interviews with mothers

Round 1: Interviews were conducted by five different researchers with health backgrounds and supervised by the first author (a clinical psychologist). All lasted between 45 minutes and 1 hour and 30 minutes. We used a topic guide (Appendix 1) developed by the whole research team that was pilot tested. The topic guide was structured into two sections. Participants first discussed experiences with PPD, support preferences, and technology use, then shared feedback on digital interventions, including content, design, and usability. All interviews were audio-recorded and transcribed.

Round II: After finalizing the first prototype of iCARE, we invited the same participants to test the prototype and perform a think-aloud exercise [13]. Five of the nine women accepted the invitation, four declined due to time constraints. In an online interview, participants were shown the first session of iCARE. The second author guided them through the session and instructed them to react and respond aloud to various parts of the intervention using guiding questions (Appendix 2). Participants were then given three weeks to review all sessions and complete a short survey after each session (Appendix 2). Four brief questions asked the participants to describe their reactions to each module and to the exercises in terms of resonance, understandability and navigation. After three weeks, we conducted semi-structured interviews with the five participants to gather overall feedback about the usability and prospective acceptability of the iCARE prototype.

Focus groups with MHCPs

Focus groups consisted of two to six participants, mostly child health nurses, and in some cases, psychologists or family counsellors who worked within the home visiting program. The goals of these focus groups were to understand and document the PPD screening practices in each municipality, how MHCPs provided support to women experiencing PPD, and what limitations and possibilities they foresaw in implementing iCARE in their existing practices. The interview guide was inspired by the Normalization Process theory [14] (see interview guide in Appendix 3).

Discussions with mental health experts

During the development of iCARE, we consulted with all experts twice. In the first meeting, we discussed the initial logic model based on findings from the literature review and first interviews with mothers, and the potential intervention structure and general content. Before the second meeting, experts were given access to the prototype to explore the different sessions. In the second online meeting, we presented the iCARE prototype and showcased specific components of the intervention asking specific questions guided by cognitive walkthrough methodologies to obtain feedback about functionality and content of the intervention. Additionally, we had further discussions with one expert who provided several rounds of feedback to improve one of the sessions based on her expertise.

Data analysis

We used a combination of traditional thematic analysis with rapid qualitative analysis to respond to the project's needs and the multiple data sources. This approach has been deemed efficient and appropriate for studies applying a user-centered design approach to intervention development [15]. Below, we detail the processes used to develop the intervention combining and integrating different sources of data.

Initial interviews with mothers

In the first phase, we analyzed the transcripts from interviews with nine mothers using thematic analysis [16]. This method entails coding data and iteratively developing a set of themes through several stages of data review and comparison. First, two research assistants worked together using thematic network analysis [17] to code the first five interviews and clustered codes into themes through interpretation of how they related and were linked to each other. This initial coding was first done inductively and then using Borghouts's framework concerning barriers and facilitators for engagement in digital interventions [5]. In a second stage, the first author analyzed all interviews using the thematic analysis and in discussions with the research team synthesized and reorganized the basic themes into four main themes and 32 basic themes to guide the development of the intervention. For each basic theme, the first author identified actions to be taken in the intervention. This step was discussed with the research team and directly informed the development of the intervention (see Table S1, Appendix 4). This step specifically informed the content of each module (including examples and exercises), format and learning modalities, and integration into maternal care.

Prototype testing with mothers

The second author took notes of the interviews concurrently, identified themes for improvement recommended by the mothers and subsequently discussed specific suggestions with the research group. All interviews were recorded. Some surface changes were made immediately (i.e. deleting a graph of a pacifier that was used to divide sections). Then, using rapid qualitative analysis the first author read the transcripts and noted suggested changes regarding format (videos, audios, graphs, text), structure (number of modules, progression, time to complete them), and content (clarity and acceptability of therapeutic components, exercises, language) based on participants' feedback. The two researchers discussed their independent analysis and arrived at five themes for improvement that were linked to the prospective acceptability of iCARE. The intervention was revised guided by these themes. The research group made collective decisions on which elements of the feedback would instead be tested and revised in the feasibility study given time constraints.

Data from MHCPs and mental health experts

During the discussions with mental health experts, detailed notes were taken. After each meeting, notes were discussed in the research team and rapid qualitative analysis was used to identify any feedback related to the format, structure, content, and implementation of the intervention.

Focus groups with the MHCP informed the intervention's tailoring and integration on a running basis as the focus groups took place over the entire development phase. Salient themes were identified along the way using rapid qualitative analysis and choices were made to respond to feedback on the intervention and its implementation. However, an independent analysis of the focus groups will be reported separately.

Feedback from mental health experts and MHCP was integrated with the analysis of mothers' responses to the prototype, which we describe in the results section, and informed the refinement of iCARE.

Ethical Approval

This research project was approved by the Regional Data Protection Centre in Psychiatry in Region of Southern Denmark (23/15327), University of Copenhagen (514-1114-25-3000) Aarhus University (2022-0367531) and University of Southern Denmark (12.250)

Results

Development of logic model and first prototype

Below, we described the themes from interviews and discussions with stakeholders that served as the foundation for the logic model. In accordance with the MRC framework, Logic Models illustrate the program theory and how intervention activities can lead to the desired outcomes. This model served as a guide during the program's development, influencing both its content (psychoeducation, exercises, examples), its design, and implementation based on contextual factors that could affect how users respond to the intervention. Finally, we describe how the first prototype was developed.

Themes from interviews, group discussions, and focus groups

Four themes were identified and organized in four main categories: 1) need for a digital intervention based on experiences with current offers, 2) experiences of PPD, 3) preferences for program content and approach, 4) design, technology and implementation focused on engagement. Based on each theme, we made a recommendation for the program development that led to choices made in the development of iCARE (see. Table S, Appendix 4).

Theme #1: Need for a digital intervention based on experiences with current offers

All mothers, MHCPs, and mental health experts found the innovation of an internet-based intervention highly relevant and useful for women with symptoms of PPD in the Danish context. All noted its potential to provide support immediately after screening or when the first symptoms appear. MHCPs in municipalities that did not have resources to offer support groups found the innovation particularly relevant. Additionally, mothers mentioned that an internet-based intervention would benefit those who did not wish to participate in group-based interventions. These sentiments aligned with MHCP's observations that existing group programs might not suit all women, highlighting the gap digital alternatives could help fill. Generally, MHCPs expressed enthusiasm about such interventions, acknowledging that while in person support might be ideal, it is not always feasible. They noted that mothers were already seeking advice and information online.

Nonetheless, mothers emphasized the importance of also having access to in-person support, especially for severe symptoms. By offering psychoeducation and strategies to manage symptoms, users may be more inclined to seek further treatment. Therefore, the intervention should provide information on how to access in-person support.

Theme #2: Experiences of PPD

Interviews with mothers and mental health experts also revealed the variety of emotional responses (sadness, anger, anxiety) and thus the intervention should address diverse symptoms and experiences. Mothers also identified various triggers for their prolonged distress, such as difficult fertility treatments and pregnancies, traumatic birth, having COVID-19 during pregnancy, difficulty breastfeeding, lack of sleep, the upheaval of becoming a mother and the baby's temperament and health.

However, a common experience among all mothers was the disparity between their expectations of pregnancy and motherhood and their actual experiences, exacerbating feelings of guilt, hopelessness, and shame.

"I had this bad conscience towards not being able to be there and my expectation about being a mother... I had this guilty conscience about not doing enough for my child" (W1)

The postpartum period was experienced as a "period of pure survival," contrasting sharply with the "baby bubble of pure happiness and joy" they had imagined. MHCPs and mental health experts also noted that social pressures about being a "good mother" led to increased anxiety and guilt among mothers whose experience did not fit into idealized models of motherhood.

Relationships with families, partners, friends, and healthcare providers were crucial, providing either support or compounding feelings of guilt and shame. Particularly, some mothers describe how feeling and being alone in caring for their babies contributed to feelings of isolation, sadness, and unfairness. In contrast, mothers who were met with understanding and support in their inner circle felt more empowered to deal with symptoms of PPD.

All agreed on persistent significant stigma around PPD, even though it is more openly discussed now.

"I felt that I met a huge taboo, so I felt that the first thing people thought when I told them how bad I felt was whether I could look after my child. And that made me not want to talk to a lot of people about it" (W2)

This taboo and the judgment mothers felt about their caregiving abilities led to further isolation and suffering. It was crucial that the intervention did not intensify the pressure on what is considered the 'good' way of mothering or contribute to stigmatizing mothers' emotional experiences.

Theme #3: Preferences for program content and approach

Mothers expressed a need for information about PPD, its prevalence, and its causes based on scientific evidence. They found it challenging to locate reliable information online. Psychoeducation about PPD was deemed crucial for both mothers and their partners and help partners provide better support.

Mothers also wanted information presented in a way that reduces self-blame and taboos, normalizing their experiences and making them feel less alone. *"We need information that will help kill it (the taboo)."* They suggested that hearing other mothers' stories could help reduce stigma.

They emphasized the importance of including diverse stories that focus on different stressors and symptoms of PPD. There was a clear preference for audio over written stories, as mothers found it challenging to concentrate on reading longer texts. These stories could also demonstrate how therapeutic skills can be used in practice.

"I definitely think it would be really great to have some stories and to have some women who have been in the same situation and as such can put into words what they thought was difficult...I think that maybe there are some universal topics, and get some tools to navigate the loss of control or the feeling of inadequacy or the longing for one's old life, which at least was also a theme for me." (W1)

Besides psychoeducation, mothers and mental health experts discussed the importance of providing therapeutic tools to cope with self-blame, unrealistic expectations, and anxiety. Mothers also stressed that the program should provide self-care tools and strategies for maintaining one's well-being, both during and after the program.

"And the same with the ending... And what should you do going forward to take care of yourself. Because you are not healthy just because you have gone through such a 6-8-week program" (W8)

Theme #4: Design, Technology and implementation for increasing engagement

Mothers, MHCPs, and experts emphasized that the intervention's content should be presented clearly and be easy to navigate in. An initial framing was seen as essential.

"...it's one of the first things you have to meet in it besides some info about postpartum depression, it has to be "How to get something out of this app", it has to be one of the first things you encounter because time is a

really scarce resource when you are a new parent." (W2)

Mothers noted that if they cannot quickly figure out how to navigate the intervention and its benefits, they would not prioritize it. Flexibility to complete the intervention at their own pace and the ability to start and pause as needed were identified as crucial for continued engagement.

All participants also suggested that the intervention should be available beyond the planned two-month access period, as PPD symptoms can recur. Mothers appreciated that an online intervention could be revisited, unlike the in-person group therapy offered in some municipalities.

At the same time, experiences of in-person therapy highlighted the need for the digital intervention to address how to maintain structured engagement, allow time between sessions, and encourage users to set time aside for the intervention and follow-up exercises.

All participants agreed that the intervention should combine text with other learning modalities, including videos, audios, images, and interactive exercises where mothers actively engage, such as ticking boxes. The combination was seen to make the intervention different to existing online content.

"(...) you can go in and read so much on the internet, so I definitely want, if it will be possible, some audio files or some video." (W9)

The graphics and images were deemed appropriate, engaging, and diverse. Mothers emphasized that the facial expressions of the characters should capture a variety of feelings and emotions.

They also emphasized the importance of easy-to-understand exercises offered in different modalities that do not require much time. They noted that presenting exercises that can be done "on the move," such as while walking, could benefit some.

"Audio files where the exercise comes in while you go for a walk and listen. But it shouldn't be just reading something and then doing an exercise; it should be guided by a voice saying: 'Now try to do this.'" (W9)

Some participants and experts also pointed to the potential for personalized treatment within the software, allowing users to choose parts of the intervention based on their needs, instead of following the modules in order.

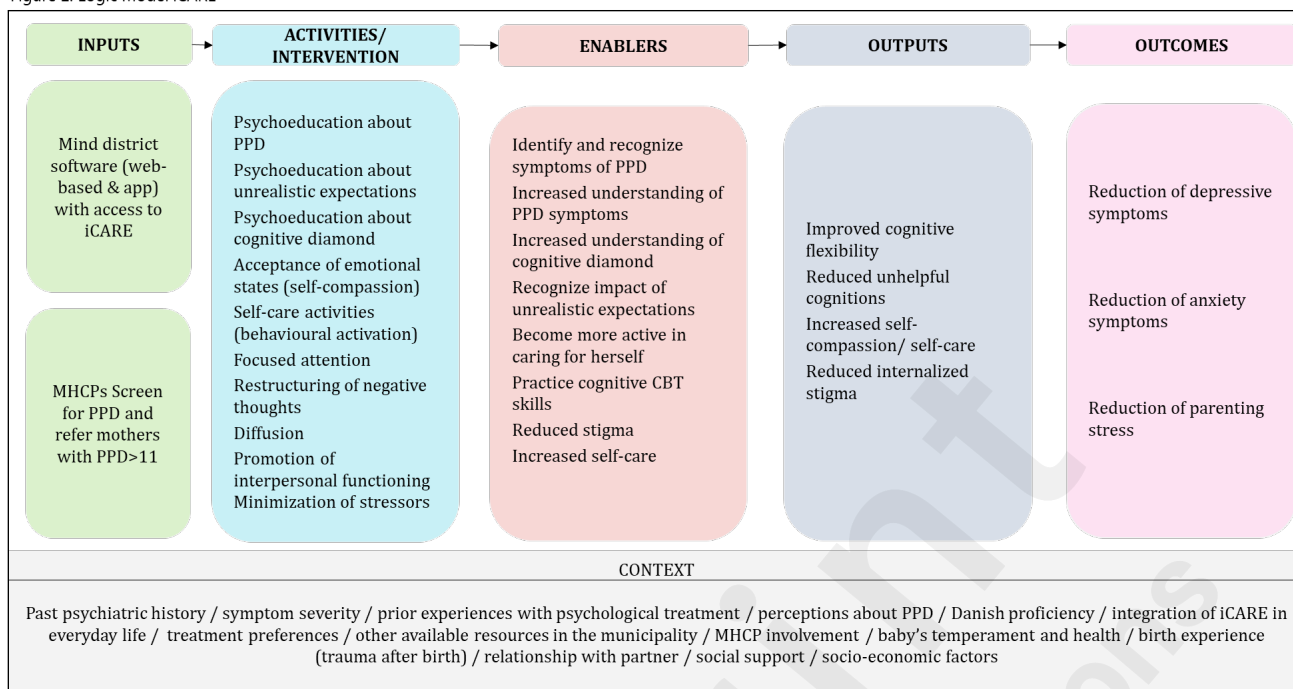
Participants also discussed integrating the intervention into the existing maternal care model, which includes PPD screening. Mothers and MHCP highlighted the central role of MHCP in the care of women with PPD. While they cannot offer treatment, they listen, help mothers recognize their distress, and guide them to further support. However, not all mothers experienced the same level of support. Some felt that the MHCP role was more about caring for the baby than for them. Therefore, if MHCP refer women to iCARE after screening for PPD, it is crucial that they have a common understanding of PPD and the intervention, and that they encourage mothers to participate.

"(...) but if it's something that the health visitor presents, so it could be the one who says "hey this one exists" or "this one exists" or "maybe it could be something for you", then you don't have to dig it up yourself. That could be an advantage. And she can come back and say "have you looked at it?"" (W10)

Logic Model of iCARE

We developed a logic model (Figure 2) based on the literature review (PROSPERO [CRD42023482966](https://doi.org/10.1111/CRD4.2023.482966)) and results from the first round of interviews with stakeholders. Our logic model outlined the inputs and intervention components (activities), mechanisms of change (enablers), and both short-term and long-term outcomes, along with contextual factors that might impact the intervention's effectiveness. The logic model was an essential result for the development of the iCARE program prototype, as it outlined the expected mechanisms of the intervention to support mothers with symptoms of PPD and provided a framework that we further evaluated in the feasibility study and randomized control trial.

Figure 2. Logic Model iCARE



Theoretically, the program draws from CBT approaches to PPD, as they have been shown to be effective in digital interventions [18]. Accordingly, the intervention includes psychoeducation on postpartum depressive and anxiety symptoms, emphasizes behavioral activation through self-care activities, and helps participants identify the links between thoughts, feelings, bodily sensations, and actions. It also focuses on recognizing self-critical and negative thoughts, offering cognitive restructuring techniques to find alternative explanations and interpretations.

However, iCARE also incorporates Acceptance and Commitment Therapy (ACT) principles and therapeutic tools into the program content. Interviews with mothers revealed that women have different preferences regarding psychological approaches, and these preferences can influence their engagement with interventions. Additionally, guilt and self-criticism were found to be very common, a pattern observed in other studies [19]. One way to reduce self-criticism is to promote self-compassion, which ACT supports by encouraging acceptance of one's feelings. In addition, recent evidence indicates that ACT is effective in preventing PPD and reducing anxiety symptoms[20]. While combining CBT and ACT might seem counterintuitive; CBT focuses on restructuring thoughts that lead to emotional distress, while ACT promotes accepting difficult thoughts and emotions using for example mindfulness techniques—this integration can be beneficial, as it offers more flexibility and a broader range of strategies [21]. Digital interventions, such as *Be a Mom*[22], which was developed to prevent PPD, already combine CBT and ACT approaches, showing both effectiveness and high retention rates. This suggests the potential value of integrating CBT and ACT principles and strategies in interventions for postpartum depression[23].

Design and Content of first Prototype

In Table S1 (Appendix 4), we describe how the results of stakeholder interviews informed the decisions made both in terms of content, design, functionality, and implementation. Based on the results from the first round of data collection and the logic model, we developed the first prototype which we describe below.

Structure, content, and functionality of the ICARE program.

The intervention consists of seven modules covering different topics. Interviews with mothers and mental health experts revealed experiences that are unique to the postnatal period, which guided the tailoring of CBT and ACT components to mothers with PPD. Module 1 focuses on reflecting on normal changes associated with motherhood and psychoeducation about PPD, introduces self-care activities and finding focus. Module 2 introduces CBT principles and supports women in identifying how thoughts, feelings, actions, and bodily sensations are connected. Before introducing cognitive restructuring techniques, this module introduces simple diffusion techniques in the context of self-care activities. Module 3 introduces the role of positive emotions and how to refocus attention on them. It discusses how

social pressures and unrealistic expectations about motherhood can affect thoughts about oneself. Then it introduces cognitive restructuring by focusing on how to find alternative responses to unrealistic expectations and self-criticism. Module 4 delves into additional examples of common difficult thoughts or interpretations and introduces cognitive restructuring techniques. Module 5 focuses on changes in relationships after giving birth, activating social networks, and promoting interpersonal functioning using assertive communication. Module 6 fosters connection between mother and baby while coping with symptoms of PPD. Module 7 summarizes the skills learned and acknowledges future stressors and how to handle them. In addition, the intervention contains psychoeducation for partners and other family members and friends about PPD, which mothers can choose to share through a PDF. Table 2 describes in detail the components of each module/session.

Across all modules, the intervention encourages acceptance of emotional states/self-compassion. The language used is de-stigmatizing, de-pathologizing and non-judgmental. Rather, the intervention addresses the user in an encouraging and inclusive manner normalizing the variety of experiences mothers may have. CBT techniques are also incorporated in Modules 6 and 7. For example, in module 6 one example focuses on how self-criticism can prevent mothers from asking for support, and how to use some of the CBT techniques in response. In module 7, one example focuses on how to use CBT techniques if the mother is having difficult thoughts when being with the baby.

Each module takes approximately 45 minutes to complete and must be followed in sequence. It is recommend going through one module per week to leave time to reflect on the content and practice exercises. Pausing is possible at any point. The program integrates different learning modalities and seeks to be as interactive through various functionalities including videos, text, exercises and activities, feedback loops, diaries, symptom checks and audio files following the stories of two mothers who have experienced PPD. Mothers are accompanied by instructions, examples and encouragement throughout the progression of the program [24].

Table 2. Summary of iCARE sessions, content, features, and activities

Module	Content	In-site exercises	Diary/weekly activity	Audio clips with mothers' stories	Videos	Symptom check
1: Understanding postpartum depression	-Introduction to the program -Recognizing changes in motherhood -Understanding postpartum depression -Self-compassion, acceptance of difficult feelings -Importance of self-care Normalizing of ups and downs	-Write about changes during and after birth -Write about how you are currently feeling -Check symptoms you are experiencing -Write about a chosen self-care activity -Audio grounding exercise	-Daily self-care activity using grounding technique	-	5	no
2: Understanding the interaction between your thoughts, emotions and actions	-Introduction to cognitive diamond and the negative circle -Postpartum depression and the negative circle -Differentiating between feelings and thoughts	-Check options evaluating an example of the negative circle -Write an example about a negative thought about yourself -Identify a negative circle (situation, feelings, thoughts, actions)	-Identify a negative circle unhooking	a 1	2	yes

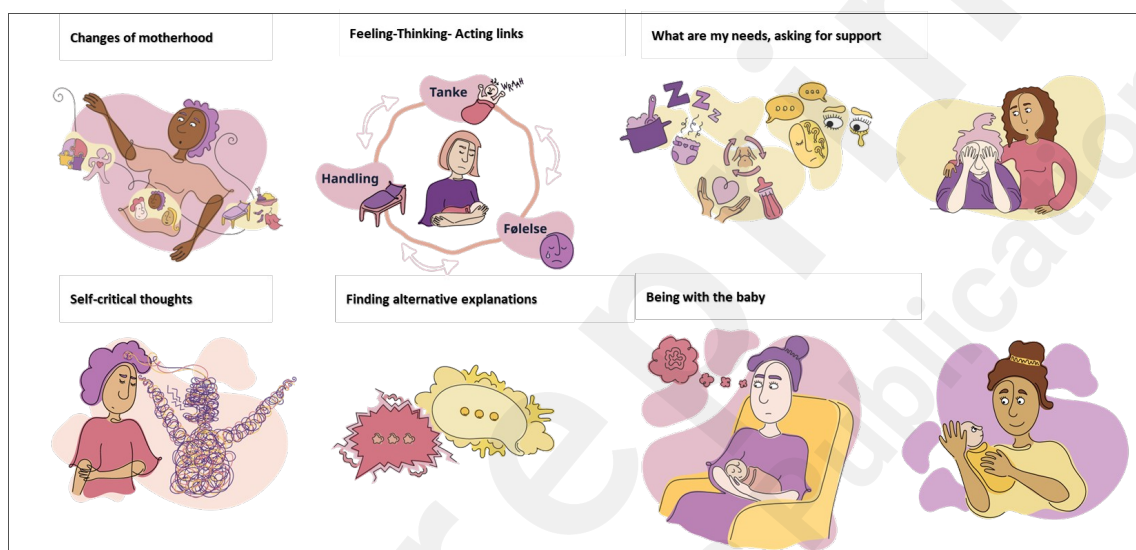
	-Unhooking from difficult thoughts	-Unhooking (audio clip)	exercise					
3: Developing skills to manage your negative thoughts	-Automatic thoughts and thoughts -Finding positive experiences in everyday life -Motherhood, unrealistic expectations, and self-critical thoughts -Alternative responses to self-critical thoughts	negative -Write about a positive experience of the day -Check the unrealistic expectations that you can recognize -Write about unrealistic self-expectations -Map negative and self-critical thoughts with alternative responses	-The daily positive experience	1	3	yes		
4: Developing skills to manage your negative thoughts	-Identifying interpretations -Cognitive restructuring -Breaking the negative circle	unhelpful -Reflection about modules 1-3 -Write about an unhelpful interpretation Practice cognitive restructuring	-Challenging negative thoughts	2	2	yes		
5: Communicating your needs and asking for help	-Normalizing transformation and change in relationships -Relationships, social support, and mental wellbeing -Identifying own needs -Using assertive communication to express emotional and practical needs -Using restructuring and diffusion when negative thoughts affect relationships	-Identify what I need from others -Imagine how you would respond to a friend in a similar situation -Using cognitive restructuring in relationships	-My network: Identify needs, communicate needs	2	1	yes		
6: Being with your baby	-How babies communicate -Developing a relationship with your baby -Understanding your baby's signals -Managing negative thoughts and feelings while being with your baby	-Check experience of negative circles interacting with the baby -Write an example using the cognitive diamond	Activities with	2	4	yes		
7: Putting all your skills together and	-How symptoms can come and go	-Check what tools have helped you from each module		2	1	yes		

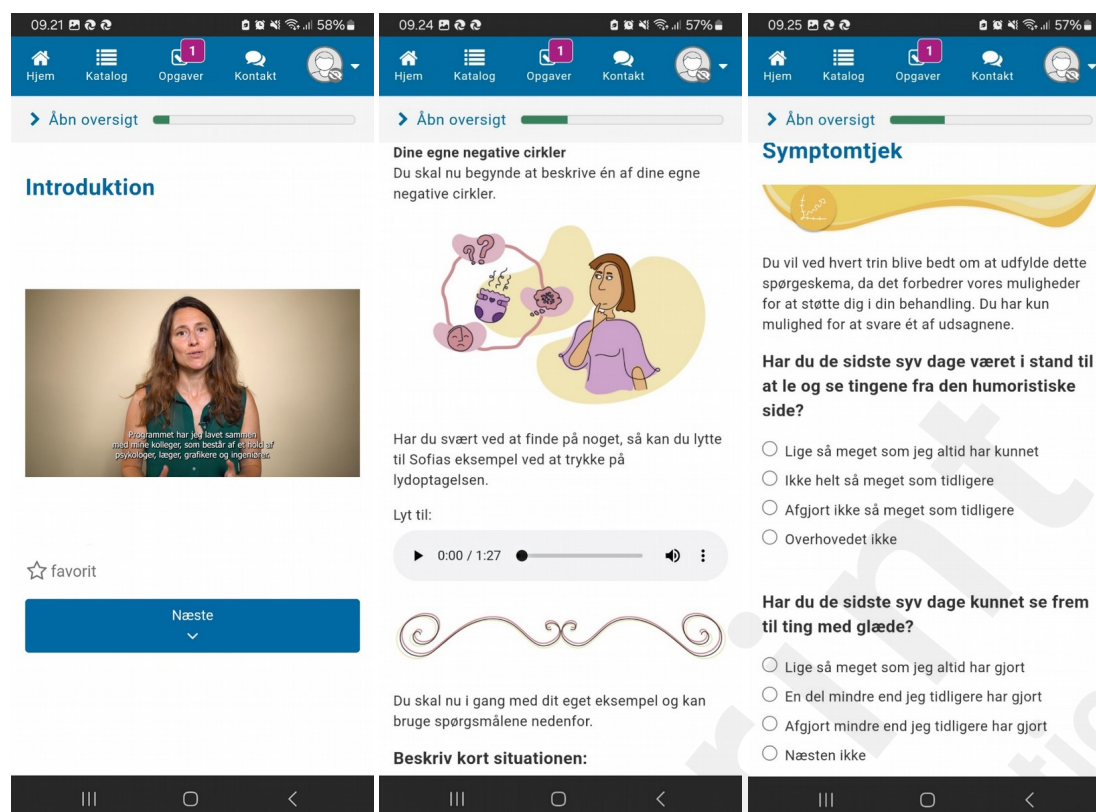
reducing stressors	-Maintaining what you have learned		-Write your stressors
	-Identifying stressors		-Write your early signs
	Mapping early signs		-Write an action plan

Graphics and Representation

Illustrations include mothers, partners and babies with the intention of representing diverse experiences and setting the right mood for the intervention (Figure 3). Some illustrations move (GIF) and thereby engage the user in a different way. Each page is composed of illustrations and text in an appropriate ratio. In the videos, two of the research team's psychologists present content with a focus on psychoeducation and teaching psychotherapeutic skills.

Figure 3. Examples of iCARE interface, graphics, and diverse representation





Integration into maternal care

The intervention was designed to complement existing offers and could therefore be viewed as an offer without waiting time. We emphasize compatibility with current offers in the municipalities as MHCPs should not change existing practices and mothers can continue participating in e.g. group offers concurrently. iCARE seeks a clear referral pathway from screening. Based on feedback from MHCPs, training is provided for all MHCPs on referring mothers to the intervention and on using the EPDS. Even though some municipalities offer additional visits for mothers with EPDS scores above 7, we have chosen the cut off score of 11 as the intervention was developed not as selective/targeted prevention, as other former interventions (see for example Be a Mom[22]) but indicated prevention for mothers that have elevated symptoms of depression and anxiety indicating a potential need for care. However, during the pilot study we will explore whether this cut off as inclusion criteria is meaningful.

Usability Test and Refinement of Prototype: iCARE

The usability test with the five mothers and the mental health experts rendered positive feedback. Mothers expressed appreciation for the approachable and compassionate use of language, in which they “felt seen”, “not alone”, “mirrored” and “hopeful”.

“I actually think it feels accommodating, concrete and... Well, I don't know what to say. For me, it's just important not to be talked down to, I think, and I don't think you do that at all.” (W4)

They emphasized an appropriate tone, which in their opinions was not “pathologizing”, “patronizing” nor “too emotional”.

“There is language that is very different, and very different from symptom-focused, and visibilizing. It's a completely different language. I think it is one of the strengths of this, I think it's been put together in a way that normalize. We all do a lot of what the individual sits with, like this is hugely destigmatising in relation to guilt and shame” (W1)

There was also agreement on the relevancy of the content, some of the accentuated components included self-care activities, positive experiences, challenging negative thoughts, being with your baby, support from network and the

audios files. Lastly, the design, illustrations, functionality, navigation and clarity of instructions were evaluated very positively.

We clustered the feedback in five main themes representing areas for improvement: 1) encourage motivation and engagement, 2) increase focus on destigmatization and diversity of symptoms, 3) more gender and family representation, 4) promote understanding of therapeutic method and 5) improve clarity of instructions. Below we present examples of feedback, and which refinements were made. Table 3 summarized all the feedback and changes made and table S2 (Appendix 5) gives examples of the changes made to the content of the intervention in detail.

Encourage Motivation and Engagement

Mothers and mental health experts' immediate reactions to iCARE revolved around the effort it takes to go through it with PPD symptoms, which could include lack of energy and motivation, and concerns around continued engagement and retention.

"(...) the first session needs to be very appealing from the beginning to capture women. (...) I also think that maybe (...) some more interactivity within the program would be helpful." (Clinical Psychologist and expert in maternal mental health and e-health interventions)

To meet this feedback, we made several changes to the content (see Table s2, Appendix 5). We added more encouraging language equivalent to in person therapy. As such, we sought to prepare mothers for the challenges they could encounter during the program, giving them options and flexibility, and adding more ways of interacting with the material e.g. by ticking boxes to prompt reflections.

"Then I thought, oh no, then you have to sit in front of a computer or something and there will definitely not be time for that. But if it is audio clips, then you can just listen on your phone, right? (...) and then just (...) make a bottle or breastfeed the baby at the same time, right?" (W4)

Another salient point concerned how mothers could make time to sit down in front of the computer or app to concentrate on the content, especially because of the perceived text-heaviness of the program. Due to the appreciation for audio content, we made changes to functionality, adding more audio files and instructions on how to have the content read aloud from one's browser as an immediate compromise. Future adaptation could include recordings of all text.

De-stigmatization and diverse symptoms

Despite including a wide range of symptoms, two mothers felt that there was a lot of focus on sadness and self-criticism, and that other symptoms such as (e.g. irritability, anger, and aggressiveness) were not mentioned enough.

"I also had the more masculine symptoms, that is symptoms of running away and extreme aggression actually (...) which might be more rare among women, but also exists (...) so you don't just get a mother who sits there and cries." (W1)

In response, we introduced more diverse symptoms in the content to offer a broader spectrum of potential symptoms mothers could mirror themselves in. In addition, we developed more illustrations that mirror such feelings. Mental health experts also suggested to tone down language of symptoms and depression and focus more on distress and emotions in order to reduce stigma.

Gender and Family Representation

Mothers pointed to differences in family constellations and the gendered assumption that the baby is largely considered the mother's responsibility rather than being shared between parents.

"I mean, one's partner doesn't look after the baby, right? (...) they are just the other parent, but okay..." (W4)

Based on this feedback, discussions transpired on how to strike the right balance between mothers' real experiences and representations of gender and family, which could relieve some of the pressure on mothers. We made changes to the language while not moving too far away from how the interviewed mothers identified with their parenting role.

Understanding of Therapeutic Method

A final theme that emerged mainly from the feedback from the mental health expert group, was communicating the therapeutic methods behind iCARE clearly as well as considering transdiagnostic approaches and a structure with core and optional components.

"I think that's a good option to explain it in the beginning and to say why people need to go through the whole program step by step, but I think you could also play with the idea of having some core content and then some content that you can skip through with your own." (Global Health Expert)

We made changes to ensure a better understanding of the applied therapeutic methods but introducing transdiagnostic approaches. Designing additional optional modules was considered too extensive. However, the need for additional modules will be explored during the feasibility trial.

Clarity of Instructions

In general, mothers and experts found the instructions on how to navigate in and follow the intervention modules clear. Only a few suggestions were made to improve the clarity of instructions. For example, participants suggested clearer information on how long mothers would have access to the iCARE, whether they could be in contact with the research teams, and who could see their written answers. This information was made more explicit and clear.

Table 3. Feedback from usability test and changes made to iCARE prototype

Theme/End-user and expert feedback on intervention components	Changes made
Encourage Motivation and engagement	
Include more options and optionality	Present iCARE as a toolbox in introduction module Option to opt-out in in-site exercises Give mothers examples in addition to asking them to provide their own in a box.
Mothers should know that it takes effort to go through iCARE (as therapy does) and should not be discouraged despite experiencing difficulties	Add text to note that effort is needed just as in other therapies and to be understanding of oneself when encountering difficulties in introduction module Remind importance of practice
Offer flexibility and advice on how find time to go through the intervention	Additional advice on how to make time for iCARE and ask for support
Retention is important as early as possible	Encouragement added to prevent early drop-out
Text-heavy content can be a burden	Minimal deletions or reduction of text but included more interaction and audios
Avoid implying that negative circles are easy to identify or can be eliminated	Text taken out
More interaction and repetition with the acquired knowledge	More multiple choice options added
More encouragement for trying exercises	Encouraging sentences added throughout iCARE
Replicate micro feedback from talk therapies	Added to accompany mothers through iCARE
Acknowledge how difficult it can be to confront one's symptoms and expectations about motherhood	Encouraging working through the difficult parts
Normalize feeling worse before feeling better	Emphasis on fluctuations rather than relapse

Encourage symptom check as a self-assessment tool	Added that symptom check can be an indication, but only an indication
Voice-over of all text	Option to have text read aloud with Microsoft Edge added (introduction step)
Learning for visual materials needs repetition (videos with mom and baby)	Add each video two times and signal what we want mothers to pay attention to
Audio files appreciated, more audio files to help understanding of exercises and	Audio clips added in modules 1, 2 and 4. Reminder to use audio exercises
Answers to exercises not only in writing	Text changed to encourage doing the exercises in different ways (introduction step)
Increase focus on destigmatization and diversity of symptoms	
More diverse symptoms should be represented	Changed to reflecting which symptoms depression may entail Check list of symptoms expanded to include more symptoms Including range of symptoms
Less focus on thoughts being negative	Using difficult/self-critical thoughts over negative thoughts
Tone down language of symptoms and depression and focus more on distress and emotions (treatment vs. prevention)	Language minimally revised. Assess whether use of the term postpartum depression is well received by mothers, or it is felt as pathologizing
Recognize the reality of feeling guilt	Changed to acknowledge the existence of guilt instead of prescribing 'do not feel guilty'
Recognize that mothers may not at first like the way their babies look	Adjectives deleted in exercise to connect with the baby and talk to the baby
Recognize difficulty in assessing the baby's needs	Added that it is not always possible to ascertain the baby's needs
Introduce more diversity in the audio examples of the two mothers	No audios changed due to time constraints. Revise audios to make them more diverse (for example, one mothers could be single or have a partner of the same gender)
Promote understanding of therapeutic method	
Cognitive therapy as the basis of iCARE should be conveyed clearer	Added that intervention uses cognitive therapy
More gender and family representation	
Emphasize shared responsibility between mother and partner	Language revised
Use parents instead of mothers and fathers	
The colors in the beginning are gender stereotypical (referring to the pink and purple first shot of the videos)	No change because this comment came from only one participant

Illustrations should include more family constellations	Comment came from one participant. Will be reviewed in the pilot
Improve clarity of instructions	
It should be clear that the research group contacts a mother if symptoms worsen	Text added
Clearer who can see the written answers and what they are used for	Text added
It should be clear that mothers can do the exercises when they are ready.	Encouraging sentences added to make clear that users can stop and return to exercises when they feel ready.
Mothers should know until when they have access to iCARE	Added until when access ceases
Illustration of modules and overview of modules cannot be seen at the same time	Illustration changed to include the titles of the modules (introduction module)
"PDF" (for partners) is not a descriptive name and is hard to find	Changed to "Information for partner and relatives"
	Placed in catalog
Subtitles should be slower in the first video	Changed to more subtitles at a time so they appear for longer

Discussion

Principal Results

This study describes the formative process of developing iCARE, a digital intervention tailored to bridge the maternal care gap within Denmark's universal healthcare system, considering the lived experiences of women with symptoms of PPD as well as the existing challenges that other digital intervention for PPD have reported. Our formative research underscored the critical need for accessible interventions for PPD. The formative phase also confirmed an interest in a digital intervention, particularly in municipalities in Denmark lacking resources for group support or for women who prefer alternatives to in-person programs. Participants highlighted the potential of such an intervention to provide timely, accessible psychoeducation and coping strategies, while also ensuring pathways to in-person care. It was agreed that the program should address diverse emotional responses and triggers of PPD, normalize diverse experiences of the changes associated with motherhood, and reduce stigma by incorporating relatable stories and practical tools. Clear, flexible, and multimodal content (e.g., audio, video, interactive exercises) was emphasized as crucial for engagement, alongside ease of navigation and options for personalizing engagement. Integrating the intervention into existing maternal care models was also recommended, with MHCPs playing a key role in offering/presenting mothers with the intervention alongside other offers. Overall, the intervention should balance digital accessibility with sensitivity to individual needs, promoting empowerment and destigmatization.

Initial usability testing showed that iCARE was well-accepted by both mothers and mental healthcare experts. Participants appreciated its practical content, relatable narratives, and multimodal delivery. These features could enhance the intervention's usability and acceptability. Improvements, such as additional audio content and interactive elements to better support participants, were made in response to concerns about the program's heavy text content and the effort required to engage. A significant strength of iCARE was its compassionate tone and stigma-reducing approach. Participants emphasized the importance of normalizing experiences of motherhood to counter guilt and shame. The intervention employed language that validates emotions, encourages self-compassion, and avoids pathologizing mothers' experiences. For example, framing PPD symptoms as reactions rather than just clinical labels could help reduce stigma and facilitate acceptance of the intervention. In addition, iCARE effectiveness will hinge on overcoming common challenges in digital mental health interventions, such as low engagement and retention,

particularly in the self-guided. These issues will be further explored during the feasibility study.

Including MHCP in the process of developing iCARE allowed the design of the intervention to be integrated into Denmark's stepped care model. MHCPs, who conduct PPD screenings, could play a central role in introducing and endorsing the program. Preliminary results suggest the need to train and support MHCPs in order to invite women to iCARE after the EPDS screening. Leveraging existing healthcare infrastructure to provide timely digital interventions could help address gaps in traditional maternal care pathways. Further, exploration of MHCPs' perspectives will be essential to ensure successful implementation and alignment with current practices.

Limitations and next steps

While the study makes a strong case for iCARE's potential, it acknowledges limitations in participant diversity. The sample largely comprised of well-educated women with Danish background who previously experienced severe PPD symptoms and received in person therapy, which could affect the generalizability of findings. In our further iterative process of the program, we will make additional efforts to engage with more diverse socio-cultural backgrounds to review the content of iCARE. Together with findings from the pilot study, this will inform further refinement and adaptation. The next steps involve evaluating iCARE's feasibility, effectiveness, and retention rates in a randomized controlled trial. Given concerns about dropout rates in digital mental health interventions, strategies to sustain user engagement will be crucial. Furthermore, the integration of iCARE into Denmark's stepped care model will offer an opportunity to test its scalability and alignment with existing maternal healthcare practices.

Comparison with Prior Work

A recent bottom-up review of the lived experiences of PPD among women, co-designed and co-conducted by both experts by experience and academics [19]. It is highlighted the pervasive guilt that many women with PPD experience, which is further compounded by societal norms around motherhood. In addition, prior qualitative studies have highlighted how the differences and complexities women face during the perinatal period merit modifications to existing treatments such as CBT [25]. As we have also observed in our formative research, the findings emphasize the importance of incorporating the varied and nuanced experiences of mothers with PPD into practice and research. In this context, our findings advocate for advancing the debate on how digital interventions can better reflect and address the diverse realities of mothers experiencing PPD symptoms and help reduce guilt and stigma. One way to achieve this is by actively engaging women with different lived experience throughout the development and evaluation of digital interventions. However, our literature review revealed a noticeable gap: only three out of seven studies on self-guided interventions for PPD published formative research before launching clinical trials, ensuring that the interventions were shaped by real user experiences rather than only theoretical assumptions.

Two of these trials focused on the same intervention—*MomMoodBooster*, which evolved from an existing group-based CBT treatment for PPD [26]. This intervention engaged mothers in focus groups to refine content, structure, and design. It also used usability testing with the think-aloud method to gather insights into user experience and functionality, leading to iterative adjustments to enhance engagement and effectiveness. The resulting program incorporated essential components like psychoeducation, mood monitoring, cognitive restructuring, communication skills, stress management, and baby-care strategies.

Similarly, the development of *Happy Mother* followed a multi-stage process but with a stronger emphasis on mobile app development principles [27]. The content, rooted in CBT, was crafted based on literature reviews and maternal needs assessments before undergoing expert validation. The design phase focused on app functionalities, interface usability, and storyboard creation, leading to a prototype that was tested in real-world mobile environments and subjected to usability assessments by both health experts and mothers postpartum. The final product offered tools for psychoeducation, mood tracking, cognitive restructuring, engagement in positive activities, and seeking professional help.

Our own development approach aligns with these studies in several ways. Like them, we prioritized user-centered design, beginning with interviews and usability testing and incorporating CBT-based exercises such as psychoeducation, mood monitoring, and self-care based on the literature review. However, our approach also diverges in important areas. Unlike *MomMoodBooster* and *Happy Mother*, we focused on integrating our self-guided digital intervention into existing

maternal healthcare services. This distinction led us to engage maternal health care providers (MHCPs) early on, exploring practical pathways for implementation. Additionally, while both prior interventions were grounded in CBT, our study expanded the therapeutic framework by incorporating Acceptance and Commitment Therapy (ACT), providing mothers with a more versatile "toolbox" of skills to manage symptoms of postpartum depression. This approach has been proposed by other preventive interventions such as *Be a Mom* [28, 29] and warrants further exploration. By comparing these development pathways, we highlight the evolving landscape of digital interventions for maternal mental health. While previous research underscores the value of formative work, our study aims to further explore how system integration and a blended therapeutic approach could enhance engagement.

Conclusions

Engaging with relevant stakeholders is essential for the development of an intervention that can meet the needs of the target population. In our study, mothers, MHCPs, and mental health experts allowed us to identify a range of pertinent aspects to consider in the development of iCARE and its refinement. The initial usability test suggests that the content of iCARE is acceptable and appropriate for mothers with mild and moderate symptoms of PPD.

Retention remains a critical challenge for digital mental health interventions. The study's iterative development process directly addressed this issue by involving end users in the design and refinement of iCARE. Features like flexible pacing, relatable content, and multimodal delivery were tailored to sustain engagement. Following the MRC framework, we will continue tailoring the program further to accommodate diverse needs and explore its scalability within Denmark's healthcare system during the pilot phase.

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Conflicts of Interest

None declared

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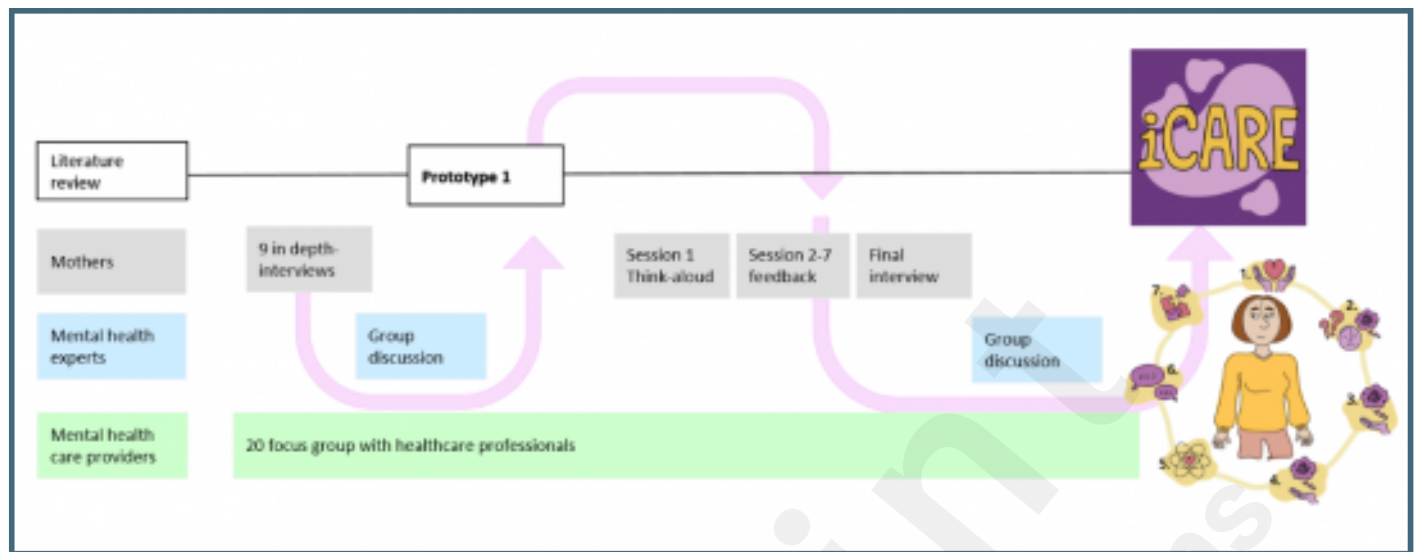
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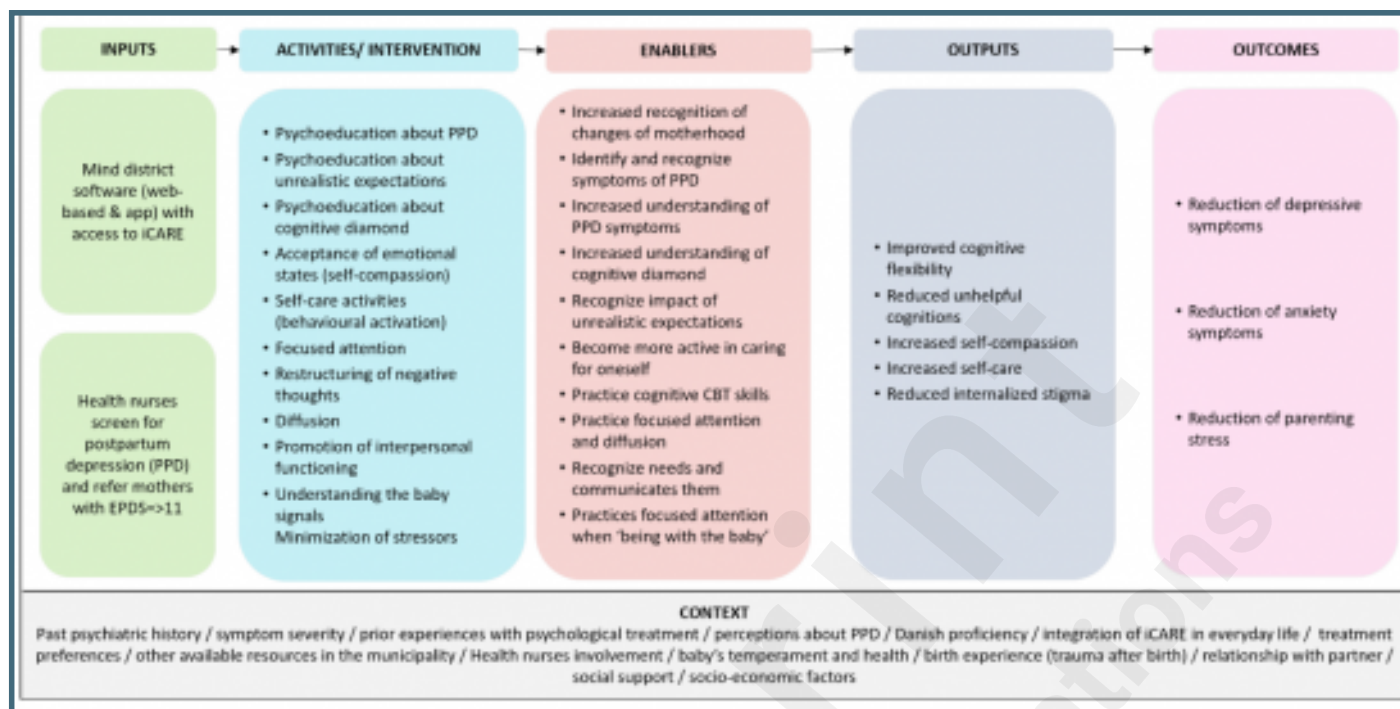
Supplementary Files

Figures

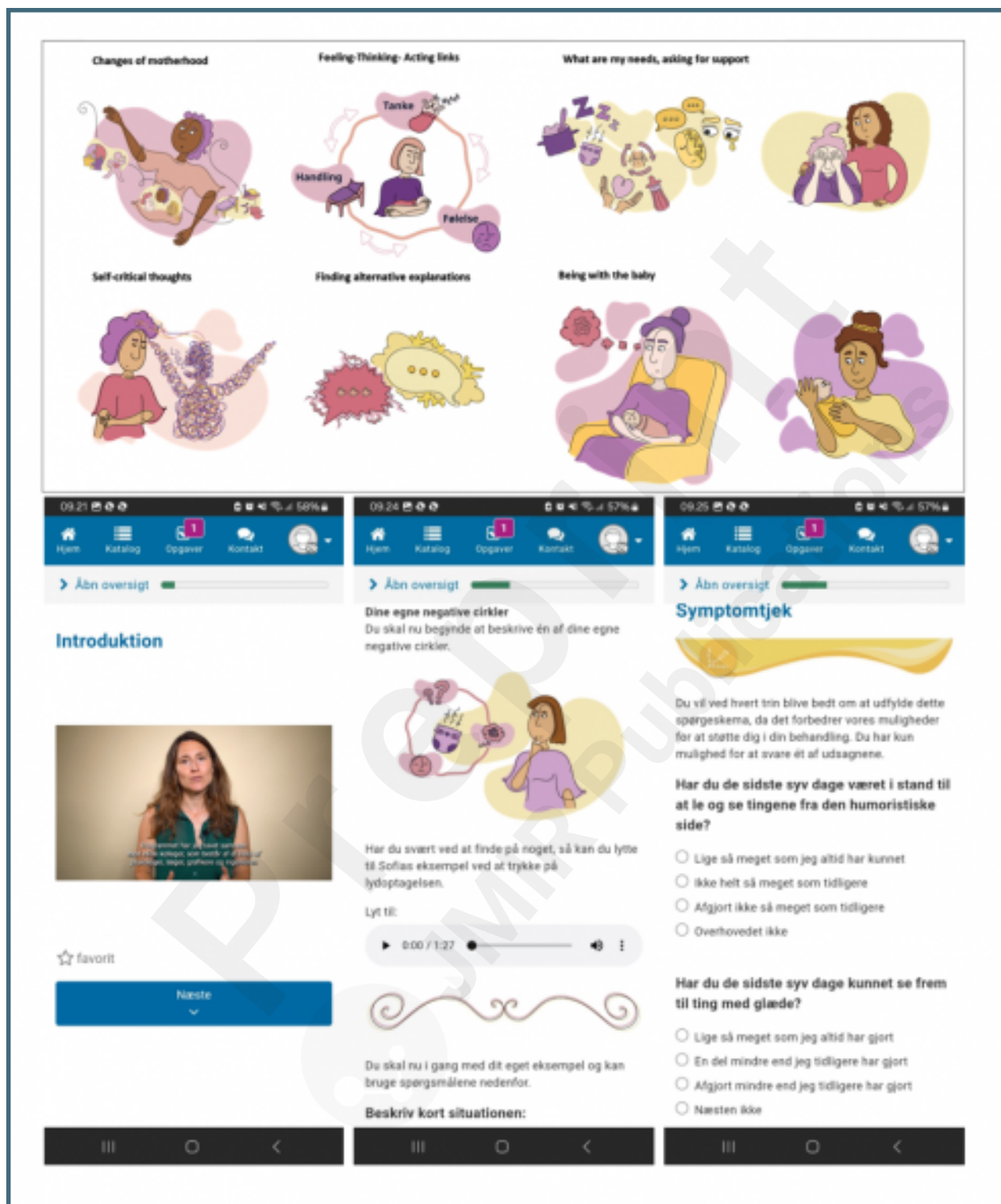
Flow chart iCARE development process.



Logic Model iCARE.



Examples of iCARE interface, graphics, and diverse representation.



Multimedia Appendixes

Interview guide with mothers.

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Prototype testing interviews.

URL: <http://asset.jmir.pub/assets/a5135137a4859668591921d2c6f976ec.docx>

Interview guide with maternal healthcare professionals.

URL: <http://asset.jmir.pub/assets/3bedae1846c81185a9ab7b92869ec51c.docx>

Table S1 From themes to action in the development of iCARE.

URL: <http://asset.jmir.pub/assets/0c23ca3af9cf940aec06b7be655428c8.docx>

Table S2 Feedback from end-users and mental health experts through the development process and changes made to iCARE.

URL: <http://asset.jmir.pub/assets/82fbc14b7c2e4f6291243a67cf1f4f6.docx>