


User-centered development process of an evidence-based mHealth intervention for psychosocially burdened families during the transition to parenthood

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Abstract

Mobile health (mHealth) interventions are a promising approach to promote mothers' and fathers' health in the perinatal period. This may be particularly true for psychosocially burdened families who are poorly reached by current preventive services. Studies are needed that examine how user-centered and evidence-based mHealth interventions look like for this target group. The objective of this paper is to describe the iterative development process of the I-PREGNO app intervention that aims to prevent unhealthy weight gain and to promote mental health in psychosocially burdened families during the perinatal period. The systematic content development process was divided into four stages. User needs were assessed through focus group discussions with psychosocially burdened mothers and healthcare professionals (HPs; stage I). In stage II, a prototype of the app was developed and evaluated through usability tests and a walkthrough with the target group and HPs (stage III). Finally, the behavior change techniques implemented in the app were assessed using an existing taxonomy (stage IV). The focus group discussions revealed that HPs as well as end-users would benefit from an intervention that addresses psychosocial aspects (i.e., emotion regulation, coping) and links these to health behaviors. The identified needs of the target group during the perinatal period were combined with existing evidence-based content and translated into 12 app modules. Most of the behavior change techniques used in these thematic modules were assigned to the clusters self-monitoring, knowledge building, and goal planning. The I-PREGNO app development process was guided by an iterative and user-centered approach involving the target audience and a multi-disciplinary team of experts. The findings provide valuable implications for the design and development of evidence-based self-guided mHealth for hard-to-reach groups

Lea Vogel and Carmen Henning share joint first-authorship for this study.

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during the transition to parenthood. The efficacy of the I-PREGNO intervention will be evaluated in randomized controlled trials in routine care.

KEYWORDS

behavior change techniques, digital health, mHealth, perinatal period, prevention, psychosocial burden, user-centered design

1 | INTRODUCTION

The transition to parenthood represents a critical period of time with physical, behavioral, psychological, and social changes (Saxbe et al., 2018; Versele et al., 2021; Versele, Stok, et al., 2022). These changes influence each other reciprocally and may lead to adverse health outcomes, such as unhealthy weight gain (Ferraro et al., 2015; Mannan et al., 2013; Versele et al., 2023) or perinatal psychopathology (e.g., depression, anxiety) (Leach et al., 2017; Smythe et al., 2022; Vesga-López et al., 2008). Furthermore, fathers' and mothers' health behavior as well as their mental health status can negatively affect child development, especially during the perinatal period (Catalano et al., 2009; Coneus & Spiess, 2012). A large body of literature has shown that psychosocially burdened individuals (e.g., individuals with low socioeconomic status [SES] and high levels of psychosocial stress) are at higher risk to develop negative health outcomes and have fewer buffering mechanisms such as social support or stress management during the transition to parenthood (Bazzazian et al., 2021; Cena et al., 2021; Coneus & Spiess, 2012; O'Brien et al., 2018).

Preventive interventions that address behavior modification with regard to physical activity, nutrition, or psychological coping represent a promising approach to promote health behavior and mental health in the transition to mother- and fatherhood (Christiansen et al., 2019; Refaeli et al., 2024). However, families with psychosocial burden (i.e., low levels of educational and social support, welfare dependency, migrant background) represent a target group which is often difficult to reach through existing prevention services (Ulrich et al., 2022). This corresponds to the so-called prevention dilemma, which indicates that individuals with higher burden, and thus higher needs, are often less reached by prevention services than individuals with lower burden and higher (socio-economic) resources (Bauer, 2005).

In recent years, the implementation of mobile health (mHealth) interventions has shown promising potential to promote well-being and health behavior in different stages of life and to offer a way to overcome the prevention dilemma (Baumann et al., 2022; Chan & Chen, 2019). Digital approaches combine valuable features, such as all-time availability, low-threshold access as individuals can access information without a third party, and geographical independence (Mendes-Santos et al., 2022). Additionally, anonymity in mHealth interventions potentially avoids the likelihood of experiencing mental health stigma and therefore encourages help-seeking behavior (Mendes-Santos et al., 2022; Naslund & Deng, 2021). However, research has shown that the engagement with self-guided digital

interventions varies according to indicators of inequality, such that (pregnant) individuals from low SES or ethnic minority backgrounds are less likely to use and benefit from such interventions than their higher SES counterparts (Brusniak et al., 2020; Szinay et al., 2023; Western et al., 2021). According to Western and colleagues (2021), this is because lower SES is associated with generally less frequent use of the internet to access health information, lower eHealth literacy (i.e., the ability to appraise and apply health information from a digital intervention to improve health), and increased social and environmental barriers to behavior change. In addition, digital interventions are often developed by people with high levels of education and higher SES, affecting the fit between content and target group (Western et al., 2021).

The use of participatory approaches and a user-centered design (UCD) have emerged as a solution to address issues such as low uptake rates and low fit to the user's needs (McCurdie et al., 2012; Seiferth, Vogel, et al., 2023). Those approaches follow the assumption that interventions may be more effective when they are developed to fit the needs and life realities of the target group, which have to be identified at the beginning of the development process (Stowell et al., 2018). Next to participative input, mHealth interventions should include evidence-based and theoretically underpinned strategies that are relevant for health behavior change, such as cognitive behavioral therapy (CBT) strategies (i.e., emotion regulation strategies, cognitive restructuring, relaxation techniques; Haga et al., 2019; Jannati et al., 2020; Rhodes et al., 2020) or behavior change techniques (BCTs; e.g., Michie et al., 2013). BCTs target fundamental mechanisms with the aim to change behavior and are incorporated in health interventions to promote engagement and effectiveness (Michie et al., 2013). Several BCTs have been shown to be effective in promoting behavior change during pregnancy and postpartum period (e.g., intention formation, problem solving, goal setting, reviewing goals, feedback, self-monitoring) (Lim et al., 2020). A meta-analysis has shown promising short- as well as long-term effects of BCTs on physical activity and nutrition (Samdal et al., 2017).

In sum, there are promising advantages for digital preventive interventions during the perinatal period. Moreover, digital interventions might represent a way to overcome the prevention dilemma by reaching psychosocially burdened families who are at increased risk to develop negative health outcomes during the transition to parenthood. However, existing mHealth interventions during the perinatal period are not specifically tailored to the needs of psychosocially burdened families, have been evaluated in samples with high SES, and neglect the family system by addressing only

maternal health (Chan & Chen, 2019; Daly et al., 2018; Gilmore et al., 2017; Guerra-Reyes et al., 2016; Sherifali et al., 2017).

To address these gaps, we developed a multicomponent intervention named I-PREGNO, which consists of a self-guided mHealth application (I-PREGNO app) and face-to-face counseling sessions. This blended counseling approach should help to mitigate the deficits in eHealth literacy and environmental support identified as barriers for participants from low SES backgrounds (Western et al., 2021). The I-PREGNO app addresses the prevention of unhealthy weight gain and stress in psychosocially burdened fathers and mothers (i.e., parents with low SES, single parenthood, mental illness of one parent, underaged mother at time of birth, insecure living situation, experiences of traumatic events, premature birth) during the transition to parenthood (Vogel, Färber, et al., 2023). For the app development, we followed a user-centered and participative development process that was based on UCD (McCurdie et al., 2012; Seiferth, Vogel, et al., 2023). Further, we selected evidence-based BCTs and CBT-based strategies for psychosocially burdened families.

The objective of the present paper is to systematically describe the iterative development process of the I-PREGNO app. Within the developmental phase, we focused on identifying the needs of psychosocially burdened families during the transition to parenthood, modifying evidence-based content that would enhance the app's usability, the app's ease of use, and user engagement. With this paper, we aim to increase the transparency of content creation and development processes of mHealth interventions and to derive implications for research and practice for the app development especially with regard to interventions addressing psychosocially burdened individuals.

2 | METHODS

This paper was preregistered at the OSF platform (<https://osf.io/p4et8>) (Vogel, Henning, et al., 2023, March 22). The development of the I-PREGNO app was divided into four stages (I–IV) with different aims, methods and research questions (see Figure 1). The latest version of the app is now being evaluated (stage V) in three (cluster-) randomized controlled trials (RCT) in Austria and Germany (Vogel, Färber, et al., 2023).

2.1 | Stage I: User needs assessments

For the user needs assessments, we conducted focus group discussions in November and December 2021 with family nurses, family midwives and social workers (=healthcare professionals [HPs]) working within a national early childhood intervention program in Germany ("Frühe Hilfen") which aims to support psychosocially burdened families with children aged 0–3 years. The eligibility criteria for HPs were sufficient knowledge of German and at least 1 year of professional experience in the early childhood intervention program. To motivate HPs to participate in our focus group discussion, we

worked closely with the program's coordinating units in Germany. To recruit mothers with psychosocial burden, we again contacted the HPs of the national early childhood intervention program and a mother–child facility in Germany that supports psychosocially burdened mothers with young children. We asked them to contact suitable mothers to take part in our focus group discussions. To participate in the study, mothers had to have sufficient knowledge of German. As we were only recruiting mothers from health services specifically offered to families with psychosocial burden, we did not define any further inclusion criteria. Information on psychosocial distress was assessed by the HPs and a short questionnaire at the beginning of the focus group discussions. In sum, we conducted one focus group discussion with HPs ($n = 6$, duration = 180 min) and two focus group discussions ($n = 3$; $n = 4$, duration = 120 min) with psychosocially burdened mothers (Table 1). All focus group discussions were conducted by a psychologist and psychotherapist in training, ensuring that the participants received support when dealing with sensitive and stressful issues. In addition, it was also emphasized that the mothers could speak to their HPs if they felt emotionally affected by the focus groups at any time. Each participant received €50.

The focus group discussions consisted of an explanation of the purpose, the discussion itself, and the completion of a short questionnaire including sociodemographics. All focus group discussions were moderated by the same moderator and assisted by an observer, who took notes during the discussion. All discussions were conducted in German following a semistructured interview guide, which is attached in the Supporting Information (Table S3). The focus group discussions were audiotaped and transcribed into minutes afterward. The data analysis was based on techniques to identify central statements as proposed by Ruddat (2012). Data analysis was conducted by two researchers independently and conflicts of analyses were discussed afterward within the research team. Results were then formulated in guidelines for the app development (stage II).

2.2 | Stage II: Development of an I-PREGNO app prototype

The aim of stage II was to create a prototype of the smartphone app and to develop intervention content that fits the needs of the target group. The multidisciplinary research team (i.e., clinically trained psychologists, psychiatrist, nutritionists, sport scientists) worked closely together with an external software development company (groupXS Solutions GmbH). Weekly virtual meetings took place between the authors and the IT specialists over a 12-month period where mock ups and visualizations were shown and progress was discussed. The underlying technical and modular structure of the I-PREGNO app was derived from the former mHealth intervention I-GENDO which was developed and evaluated by the research group at the University of Bamberg (Pape et al., 2022; Seiferth, Färber, et al., 2023).

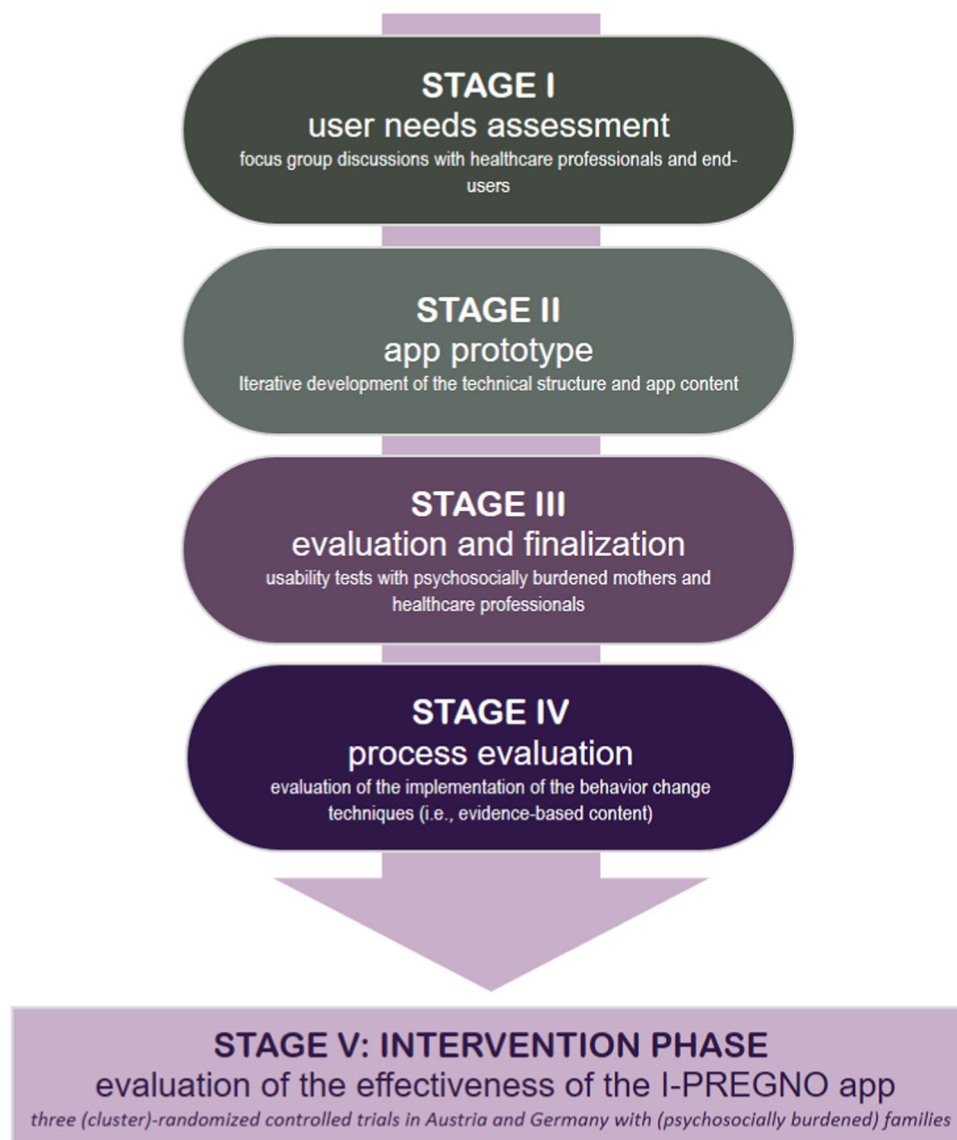


FIGURE 1 Overview of the intervention development process.

TABLE 1 Description of the focus group's participants.

Participating healthcare professionals				Participating mothers (end users)			
P	Gender	Degree	Professional experience (years)	P	Gender	Age (years)	Psychosocial burden
1	Female	Family nurse	2	1	Female	36–40	Low socioeconomic status
2	Female	(Family) midwife, social worker	5	2	Female	25–30	Low socioeconomic status, single parent
3	Female	Family nurse	1	3	Female	16–24	Single parent, young age, low socioeconomic status
4	Female	(Family) midwife	5	4	Female	31–35	Low socioeconomic status
5	Female	Family nurse	4	5	Female	36–40	Low socioeconomic status
6	Female	Social worker	5	6	Female	25–30	Single parent, low socioeconomic status
				7	Female	25–30	Single parent

The content of the app was adapted to the target group based on

- (a) an extensive literature research on behavioral and mental health variables within the perinatal period and within the target group;
- (b) the results of a focus group study conducted by the research group before the start of the I-PREGNO project (Versele et al., 2021; Versele, Deforche, et al., 2022; Versele, Stok, et al., 2022);
- (c) the results of the user need's assessments of stage I;
- (d) the counseling of an external advisory board consisting of experts in the field of (digital) prevention, clinicians and practitioners who support psychosocially burdened families;
- (e) existing content of the DALI intervention (Diabetes and Pregnancy Vitamin D and Lifestyle Intervention for Gestational Diabetes Mellitus Prevention) (Jelsma et al., 2013; Simmons et al., 2016) for the modules targeting nutrition and physical activity.

Following an evidence-based approach, the app features were based on the BCTs (Michie et al., 2013) and CBT-based strategies (i.e., emotion regulation skills, cognitive restructuring).

2.3 | Stage III: Evaluation and finalization of the I-PREGNO app

In stage III, the prototype of the app was evaluated and refined with end-users and HPs. To recruit possible end-users, we contacted the mother-child facility again (see stage I) and asked them to recruit psychosocially burdened mothers to test the app, who did not participate in stage I. In total, four psychosocially burdened mothers (age range: 16–35; three with low SES, and one single parent with young age) carried out the usability tests. To test the comprehensibility of the German language, two of the four mothers were nonnative speakers of the German language. During the usability tests, mothers were instructed to perform particular tasks (e.g., navigating through the emotion regulation module, using the self-monitoring function, selecting a virtual coach) with the prototype app which was installed on their own smartphone for 60 min to explore technical functionality and user experience (McCurdie et al., 2012). Mothers were asked to think aloud so that the observers could learn what the person was currently looking for and what they were thinking during the use of the app. Two observers made notes about important thoughts and difficulties within the usability process. After the usability test, additional feedback was gathered via a focus group discussion with the same mothers (open discussion without an interview guide). The usability tests and focus group discussion were conducted by a psychologist and psychotherapist in training, ensuring that the participants received support when dealing with sensitive and stressful issues. In a second step, the app was presented to six HPs in a walkthrough, where app features were presented (e.g., navigating through the emotion regulation module, presentation of the home screen). The aim was to identify shortcomings of the app

that could affect the adherence, efficacy of the app, and user-app interaction. Four of the six HPs were the same as in stage I. As the remaining two were unable to attend the walkthrough's appointment, two professionals with the same professional background and experience were recruited. The usability tests/focus groups were conducted in March 2022 and took 120 min in total. Participation was incentivized with 50€. Both were audiotaped and observers took notes during the discussions. The audiotapes were transcribed and data was analyzed consistent with the procedure in stage I. Afterward, the authors and groupXS adapted the content, features of the app according to the results of the evaluation tests from stage III, and finalized the app development.

2.4 | Stage IV: Process evaluation of the implementation of the BCTs

For stage IV, two reviewers coded the presence of BCTs within the final app version to evaluate if the implementation of evidence-based strategies has been successfully realized. The BCT v1 taxonomy (Michie et al., 2013; see Supporting Information) comprises 93 different BCTs (e.g., information about antecedents), which are summarized in 16 clusters (e.g., shaping knowledge). In preparation for the coding, both reviewers completed existing online training materials (<https://www.bct-taxonomy.com/>). First, both reviewers coded BCTs within the first module ("introduction") and discussed potential deviations or discrepancies afterward. Next, each reviewer independently coded the remaining modules of the I-PREGNO app. For the coding process, reviewers worked through the modules page by page while simultaneously inspecting if the app-presented material matched any of the BCT-definitions. Generally, if a BCT was presented over the course of multiple pages within a session it was combined and coded as one technique. An example of the coding process is presented in the Supporting Information (Supporting Information: Figure S1). Intercoder reliability Cohen's κ was in total 0.93, which can be interpreted as nearly perfect agreement (range: 0.67–1). Discrepancies were resolved via consensus discussion between the reviewers.

3 | RESULTS

3.1 | Stage I

3.1.1 | Perspective of HPs

According to the participating HPs, the app should complement their psychosocial support of the families and draw attention to the relationship between parents' mental and physical well-being and their child's development. The analysis of the focus group followed a bottom-up approach and revealed categories with respective suggestions for features and strategies that were taken into account in the implementation of the I-PREGNO app (Table 2).

TABLE 2 Results of the analysis of the healthcare professionals' focus group.

Categories	Subcategories	Description	Strategies implemented in the I-PREGNO app
Aim of the app	Awareness of associations between different factors	Build awareness of associations between different factors including health and health behavior like parental eating behavior and child's eating behavior.	Psychoeducation about the associations between different health behaviors of parents and children in various modules. Implementation of a self-monitoring module.
	Benefit for HPs	The app should complement the HPs' everyday work with the families. This means that HPs could refer to content in the app, outsource topics and give homework.	This aspect was taken into account by selecting specific thematic modules.
Content of the app	Target groups	Different target groups with different burdens and social backgrounds.	Targeted content to the needs of the families and adapted language and content to various burdens and backgrounds.
	Information about the care/upbringing of the child	Offer information about the developmental status of children, breastfeeding and dealing with regulation problems.	Module "nutrition" offers information about breastfeeding, further online sources for childcare are linked within the app.
	Provide tools	Include exercises and tips.	The app offers a variety of BCTs and CBT-based strategies, that is, breathing exercises, meditation, cognitive restructuring, goal setting.
	Fathers	Provide motivational content and practical advices for fathers. Answer the question, how to support mothers.	Two versions of the app exist (one for mothers, one for partners), which are adapted to the respective role (i.e., the partner version of the module social competences includes tips and information about offering help and ways to support the mother, whereas the mother version includes tips about how to request and accept help).
	Well-being	Improve well-being of mothers by working on issues such as body-self-awareness and stress reduction.	Implementation of modules such as self-esteem, emotion regulation, stress management, body image which contain CBT-based strategies.
	Feedback	Positive or neutral feedback should be given on the content that families enter. Negative feedback or criticism should be avoided.	Gamification elements are not linked to direct feedback (i.e., this is good or bad behavior). Users are encouraged to reflect on and classify their answers themselves (i.e., you answered this, what does that mean for you?), use of benevolent wording.
Design	Presentation of the content	Presented briefly and concisely; different applications like short videos, web links or cartoons. The app should be adapted to the language skills of the target group; only positive and nonstigmatizing terms should be included.	Use of various multimedia elements (i.e., images, podcasts, mini games, input fields, links). The images used in the app are neutral icons.
	Appealing to the target group	Individuality of families and children must be taken into account; general advices or recommendations about children and their developmental stage should be avoided.	The app focuses on the mental health and health behavior of the parents, therefore general information about children/child development is not given. A benevolent language is used and generalizations are avoided.
Other app relevant information	Sensitive topics	Maternal mental health and body weight is perceived as a sensitive topic.	The app offers a vehicle to get in touch with these sensitive topics. The introduction modules offer psychoeducation (why is it important to take care of myself and my mental health?). Tools like self-monitoring can represent a touch point with this topic.

TABLE 2 (Continued)

Categories	Subcategories	Description	Strategies implemented in the I-PREGNO app
	Fit between app and HPs	HPs would like to be informed about the app. They need concrete instructions on when, by whom and how the app can be used.	HPs receive information about the app and receive a training before the family receives access to the app.
	Media consumption	Concerns about whether the app will lead to even more media consumption.	Many exercises and information within the app is offered as a podcast. Users are encouraged to listen to the audio without looking at the phone (i.e., mediation practices). User receive tips and suggestions for rewarding and self-care activities that do not require phone usage.

Abbreviations: BCT, behavior change technique; CBT, cognitive behavioral therapy; HP, healthcare professional.

3.1.2 | End users' needs

The participants of the focus group discussions reported that they often experience negative thoughts, self-doubts, anxiety, guilt, and increased stress leading to a lack of confidence in their new role as a parent. They expressed a desire for evidence-based information, strategies, and features that support their daily routines and help them establish new, healthy habits, especially after giving birth. They also emphasized that the app should be accessible to families in different situations. A list of the detailed results is presented in Table 3.

3.2 | Stage II

3.2.1 | Development of the app

App content

Figure 2 provides an overview of the I-PREGNO app interface. The final intervention contained the following elements: (a) module-based interventions; (b) self-monitoring of health behavior; (c) toolbox to store favorite content; (d) information about the trial; (e) crisis support; (f) selection of an accompanying virtual coach, and (g) selection of the pregnancy or postpartum version.

The module-based intervention section represents the core of the app and comprises 12 modules: (1) tutorial of the app, (2) introduction (i.e., what is self-care, goal setting), (3) self-esteem, (4) stress management, (5) emotion regulation, (6) self-efficacy, (7) social competences, (8) mindfulness, (9) nutrition, (10) physical activity, (11) self-monitoring, and (12) conclusion (i.e., reflection of goals, relapse prevention strategies). Each module consists of a variable number of sessions (range: 2–19). An overview of the content and aims of each module, and the respective sessions is available in the Supporting Information (Table S2).

Presentation of the app content

Each module, respective each session, includes a variety of text-based and audiovisual psycho-educational material (i.e., podcasts), but also interactive multimedia content (i.e., mini-games) that

require users' interaction (i.e., filling out text, answering quizzes or self-report questions) and aim to enhance app engagement (Figure 3). Overall, special attention was devoted to the aspect that the content is understandable and appropriate for the target group, which was tested and re-evaluated in the usability tests (stage III) subsequently.

Individualization of the app content

To address the perinatal lifespan two versions of the app content were developed (pregnancy period, postpartum period). The users are able to activate the postpartum content by clicking on the respective button on the home screen. When this happens, the pregnancy content is still available and previously entered content is still there, but the focus is on the postpartum period. Next to this time-sensitive content, each module of the app exists in two versions, one for mothers and one for their partner. For example, in the “stress management” module, the content is adapted to provide coping strategies for the mother to ask for support and to hand over responsibility and for the partner to offer support. The content in the partner version focuses on strengthening the partner's self-efficacy. In addition to these content-related approaches, the main differences between the module versions are in the way they are addressed and the examples given.

To enhance personal relevance of the content, the app followed an “always available” delivery logic, meaning that all content was available to the users at all times after completing the first two mandatory modules (tutorial and introduction). Users could skip sessions or modules and were instructed to engage with the content that appealed to them personally. Sessions within the modules could be repeated as many times as desired and users could set individualized short links to their favorite exercises via the toolbox. Furthermore, as suggested in the focus group discussions, the content of specific modules (i.e., stress management, emotion regulation, and nutrition) could be customized to the user's preferences by modifiers which displayed or enabled specific sessions. To accommodate the reality of the users' lives and to avoid the app being another stressor, a notification to use the app was sent only if the app was not opened for more than

TABLE 3 Results of the analyses of the focus groups with psychosocially burdened mothers.

Categories	Subcategories	Description	Strategies implemented in the I-PREGNO app
Aim of the app	Self-esteem	Increase the user's self-esteem and self-care. This includes that the app promotes a positive attitude and convey positive feelings.	Development of specific content, that is, self-efficacy, emotion regulation, introduction and self-esteem modules that focus on these topics and offer psychoeducation as well as exercises. Self-guided approaches offers users the possibility to work with the content that appeals to them.
	Support	Support of mothers during and beyond pregnancy, by providing reliable, helpful and high-quality information.	The provided content is highly reliable, helpful and high-quality with a focus on psychosocial wellbeing, physical activity and nutrition.
	Healthy child development	Serve as a practical guide to parents by providing information about important developmental spurts of the child.	The app does not provide concrete information, but encourages the users to ask for support and offers support hotlines and links. Furthermore, the app validates the users feelings and thoughts and enhances the understanding and function of these.
	Co-parenting	Education and training of the fathers in their parenting skills, which can increase their self-confidence.	The version for the partners includes information about the "role as a father" and which tasks the partner can take over.
	Motivation	Increase the motivation of families to improve their health behavior through positive content and appreciation.	Users are repeatedly encouraged to reflect their goals and to identify barriers that hinder successful goal achievement or implement reward strategies for goal achievement.
	Health behavior	Establish healthier behaviors (e.g., eating behavior) in the long term.	General tips and health messages in the modules "nutrition" and "physical activity" which can be applied to different recipes and habits (i.e., Make water YOUR drink of choice, Colorful and healthy: plant-based foods, Finding joy in movement and sitting less).
	Reality	Mind the reality of psychosocially stressed families.	Self-guided approach, users can choose the modules and topics that are most relevant to them. Examples used in the app are diverse and include various life realities.
Content of the app	Special content for fathers	Provide information and practical advices for fathers on raising and caring for young children. It is important to create positive and motivating content for fathers.	The version for the partners includes information about the "role as a father" and which tasks and functions the partner can take over.
	Nutrition	Include practical tips on healthy eating habits for adults as well as for infants (e.g., recipe ideas for parents and infants); Education about breastfeeding and its social pressure for mothers.	General tips and health messages in the modules "nutrition" and "physical activity" which can be applied to different recipes and habits (i.e., Make water YOUR drink of choice, Colorful and healthy: plant-based foods, Finding joy in movement and sitting less).
	Self-monitoring	Through a self-monitoring function, users should be able to track their weight and physical activity.	Implementation of a self-monitoring function (i.e., diary) where users can track their mood and quality of sleep, eating behavior and physical activity.
	Calendar feature	A calendar function should be set, where mothers can include the female cycle and reminders for doctor appointments.	<i>This function was not implemented in the app due to limited technical and financial resources.</i>
	Exchange	Promote exchange, by providing a forum with experts and a chat function for mothers and professionals.	<i>This function was not implemented in the app due to limited technical and financial resources.</i> Users were encouraged to get in touch with other individuals in similar situations (i.e., module social competences).

TABLE 3 (Continued)

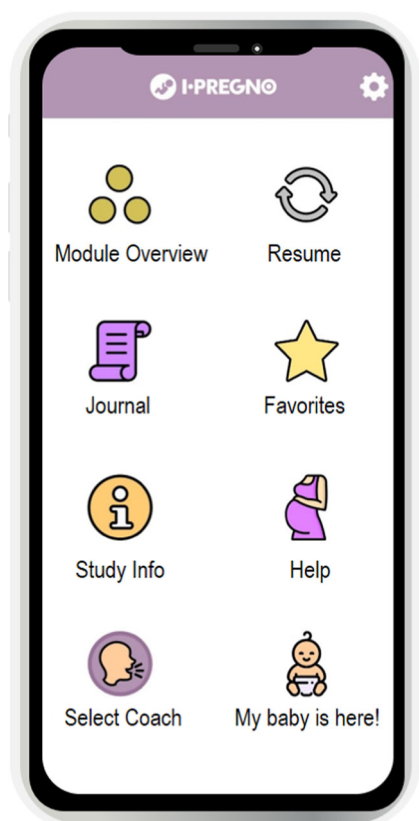
Categories	Subcategories	Description	Strategies implemented in the I-PREGNO app
	Healthcare services	Provide contact details of several healthcare services, like counseling service and emergency centers.	Implementation of the “Quick Help” button, where various contact details of support centers are listed.
	Social interaction	How to deal with partnership and family members; improving social competences and encouraging to seek external support.	Exercises included in the module “social competences” which aim to increase social skills and improve relations (i.e., “recognizing and communicating personal needs,” “asking other people for something”).
	Physical activity	Provide a sample of exercises that are easy to incorporate into everyday life. Moreover, other apps or courses for physical activity could be recommended.	Module “physical activity” offers a range of exercises for the perinatal period, psychoeducation about being physically active after the birth.
	Stress regulation	Cover topics such as dealing with difficult situations and societal pressure and normalize feelings of helplessness and self-doubts in this period of life.	Implementation of a module about stress-regulation. The module “self-esteem” focuses on identifying difficult situations and building up coping strategies (i.e., “dealing with difficult situations in a self-assured manner”), validation of negative feelings and thoughts within this period that require self-care.
	Education	Information about care and upbringing of toddlers.	This information was not implemented in the app, because the focus of the app was to enhance psychological well-being and health behavior.
	Negative thoughts	Offer strategies and information about how to deal with negative thoughts, self-doubts and feelings of a guilt as a mother.	Module “emotion regulation” offers various strategies to identify negative cognitions and to enhance emotion regulation deal with them (i.e., cognitive restructuring, self-compassion, behavioral tasks).
	Self-care	Improve self-care (of mothers), for example, “learn integrating, timeouts” in everyday life.	Modules “self-care” and “self-esteem” stress the importance of self-care for parents and offer exercises in which one deals with the experienced changes and the meaning for one's own identity.
	Content quality	To achieve high-quality content, the information offered should be validate, current, easy to understand and from professional experts.	Information within the app is evidence-based; a multidisciplinary team of researchers and practitioners of different areas (i.e., psychology, nutrition, physical activity) was involved in developing the app.
Design of the app	Diversity	Appeal to families in different life situations and with different family backgrounds.	An effort was made to use inclusive language and examples which represent different life realities. The coaches who guide through the app represent different cultures.
	Reminder and notifications	Possibility to activate and deactivate reminders and notifications. Sometimes notifications can build pressure for mothers but in other cases, they are considered as helpful.	A notification was implemented which was only activated if the user was not active for more than 72 h. Users are able to deactivate this function.
	Personalization	Personalized content should be included so that user's own personal information and goals can be entered.	An effort was made to include personalization features (i.e., selection of the coach). Some modules included “module modifier” that could be activated depending on the personal needs (i.e., exercises focusing on behavioral aspects versus cognitive aspects; breastfeeding yes/no).
	Seen critically	Families did not like gaming features and short videos (10–30 s). They explained that these	Content was presented as podcast or text or mini game without an evaluation of the entered content, image. No videos were included.

(Continues)

TABLE 3 (Continued)

Categories	Subcategories	Description	Strategies implemented in the I-PREGNO app
	Anonymity	features lead them to feel not being taken seriously. By ensuring anonymity, trust can be strengthened and low uptake rates can be reduced.	For study purposes, the user data will be saved to a protected server with a pseudonymized code. Users have to agree to the data protection agreement before signing in to the app.
Other app relevant information	Life situation	The life situation of mothers with infants is marked by missing autonomy and motivation, no time for oneself, pressure from outside, frequent self-doubt and wrong conclusions. This leads to the fact that oneself becomes a lower priority.	Information was implemented in various modules (i.e., introduction, self-esteem, emotion regulation, self-efficacy). Content was developed in such a way as to highlight and repeatedly emphasize the changes that can occur (validation).
	Time for app usage	Mothers could use the app during pregnancy and in the evening during the postpartum period.	App usage is self-guided and did not follow a predefined structure or scheduled times.
	Development of the app	For the app development process, midwives and other professionals of early intervention programs should be involved.	HPs were included in the app development process.

Abbreviation: HP, healthcare professional.

**FIGURE 2** The I-PREGNO app interface.

72 h. An additional individualization feature was the selection of an accompanying virtual coach. Users could choose from eight different virtual coaches, varying in sex, profession, ethnicity and manner, to guide them through the app (i.e., presentation of tips, detailed explanation during sessions).

3.3 | Stage III

3.3.1 | Evaluation of the prototype

Feedback from psychosocially burdened mothers (stage III) who tested the I-PREGNO prototype suggested that the content of the app may increase awareness of mental and physical health, as well as generate interest in promoting one's own well-being. Images and visualization in general play an important role in simplifying the text. Positive content (e.g., encouragement) was also appreciated by both mothers and HPs. To enhance comprehensibility, they recommended the use of more images and emoji's. The app's esthetics and graphics were rated as very appealing. The virtual coaches, who serve as guides, were perceived as helpful and motivating.

Furthermore, HPs and mothers reported missing certain features that may increase app use: a calendar function, which includes reminders for important appointments; exercises and strategies to improve physical activity in the postpartum period; the option of sleep tracking; content and additional virtual coach for mothers who feel insecure and anxious, would be useful. To improve the app, participants suggested to increase personalized content by including automated birthday wishes, regional services, and more personalized strategies and recommendations.

3.4 | Stage IV

3.4.1 | Implementation of BCTs

A summary of the 15 identified BCT clusters in the I-PREGNO app is provided in Table 4 for each module. The three most-represented clusters were *feedback and monitoring* (12 modules), *shaping*

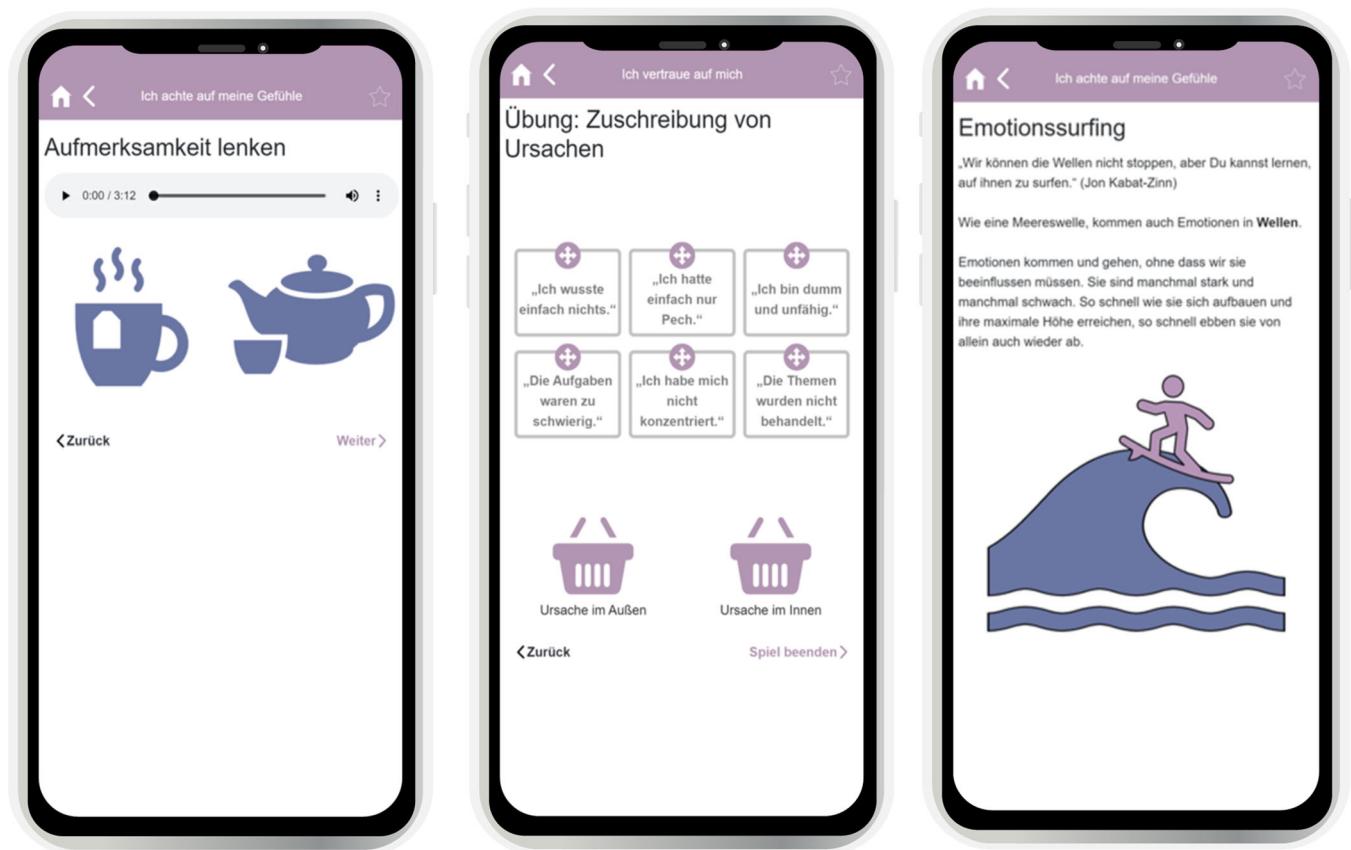


FIGURE 3 Exemplary screenshots of the module “emotion regulation” illustrating the multimedia content implemented in the I-PREGNO app.

knowledge (11 modules), and goals and planning (10 modules). The least-represented cluster was *covert learning* (1 module). No content was coded from the cluster *scheduled consequences*. At the level of single BCTs, 53 of the available 93 techniques have been coded at least once (Supporting Information: Table S1). In total, 1037 techniques were coded across all modules ($M = 86.42$ BCTs/module, range: 2–225; Supporting Information: Table S2).

4 | DISCUSSION

The objective of the paper was to describe and evaluate the development process of the multicomponent I-PREGNO app. I-PREGNO is a self-guided mHealth intervention that aims to support psychosocially burdened (expectant) fathers and mothers in enhancing their mental health and improving or establishing health behavior with the overall target to prevent unhealthy weight gain of all family members. To ensure that the app content is specifically tailored to the needs of the target group, individuals with psychosocial burden were integrated in the UCD process. Further, we implemented evidence-based BCTs and CBT-based strategies. With this paper, we aimed to promote transparency in the development of evidence-based mHealth solutions, increase methodological quality, and make our findings from the four development stages available to

researchers and practitioners. This may increase the quality of digital interventions for psychosocially burdened individuals.

4.1 | Stages I–III: Development of the I-PREGNO app based on an UCD process

In sum, results of the focus group discussions, walkthrough with HPs, and usability tests show that the transition to parenthood represents a time in which parents experience considerable high psychological pressure, a loss of self-efficacy, and are confronted with many self-doubts. While mothers with psychosocial burden described that they often feel overwhelmed in everyday life and role conflicts, HPs and mothers described that fathers experience uncertainty about their role and how to support their partner and newborn. Due to negative thoughts and self-doubts, mothers favor an app that allows them to look at the positive side of being a mother and normalize negative feelings of anxiety or stress. All these identified topics were taken into account in the development of the I-PREGNO app content and thematic modules. Developers of interventions for individuals with lower SES should have in mind that users may take instructive or corrective statements as criticism, which may lead them to cancel the interventions. Therefore, we ensured that the content does not sound instructive or judgmental, and that parental attitudes, thoughts

TABLE 4 Overview of the modules and identified BCT clusters within each module.

Module	Module content	BCT cluster (technique)
Tutorial	When first opening the I-PREGNO app, the user is asked to complete a tutorial where an audio clip welcomes the user. A module-overview and the features are presented. The connection between the modules, the possibilities, restrictions, functions and handling of the app is explained.	Feedback and monitoring (2.3) Shaping knowledge (4.2) Comparison of outcomes (9.1)
Introduction	Self-care, its benefits and importance during the transition to parenthood are presented. The changes in the new role as a parent are emphasized before individual goals are defined using a goal-setting framework.	Goals and planning (1.1–1.4, 1.6, 1.9) Feedback and monitoring (2.3) Social support (3.1, 3.2) Shaping knowledge (4.1, 4.2) Natural consequences (5.1, 5.3, 5.6) Comparison of behavior (6.1) Repetition and substitution (8.1) Comparison of outcomes (9.1) Reward and threat (10.2–10.4, 10.9, 10.10) Regulation (11.2) Identity (13.1, 13.2) Self-belief (15.4)
Self-esteem	The users are given an understanding upon the pillars of self-esteem. Positive self-reflection is provoked. Self-assured manner and a positive body image are strengthened through various cognitive-behavioral strategies.	Goals and planning (1.1–1.7) Feedback and monitoring (2.3, 2.4) Social support (3.1, 3.2) Shaping knowledge (4.1, 4.2, 4.4) Natural consequences (5.1–5.3, 5.6) Comparison of behavior (6.1) Repetition and substitution (8.1, 8.2) Comparison of outcomes (9.1, 9.2) Reward and threat (10.7, 10.9) Antecedents (12.3, 12.4) Identity (13.1–13.4) Self-belief (15.1, 15.3, 15.4)
Stress management	Multimodal (e.g., mental, regenerative) strategies to reduce stress are implemented. Problem solving, time management, meditation and enjoyment practices are trained. The significance of sleeping difficulties as a stressor is mentioned and ways on how to delegate responsibilities to reduce stressful events are being discussed.	Goals and planning (1.1, 1.2, 1.4–1.7) Feedback and monitoring (2.3, 2.4) Social support (3.1, 3.2) Shaping knowledge (4.1, 4.2) Natural consequences (5.1–5.3, 5.6) Comparison of behavior (6.1) Associations (7.1) Repetition and substitution (8.1–8.3) Comparison of outcomes (9.1–9.3) Reward and threat (10.4) Regulation (11.2, 11.3) Antecedents (12.1, 12.3, 12.5, 12.6) Identity (13.1, 13.2) Self-belief (15.2–15.4)
Emotion regulation	Cognitive distortions are identified and strategies to change them are being presented. The connection between emotions and hormones, physical activity, mindfulness, conscious behaviors, and styles of thinking are stressed.	Goals and planning (1.2, 1.4, 1.5, 1.7) Feedback and monitoring (2.3, 2.4) Social support (3.1) Shaping knowledge (4.1, 4.2) Natural consequences (5.1–5.4, 5.6)

TABLE 4 (Continued)

Module	Module content	BCT cluster (technique)
		Comparison of behavior (6.1) Repetition and substitution (8.1, 8.3) Comparison of outcomes (9.1) Reward and threat (10.4) Regulation (11.2) Antecedents (12.4, 12.6) Identity (13.1–13.3) Self-belief (15.1, 15.2, 15.4)
Self-efficacy	Sources of self-efficacy, attribution styles, dealing with success and failure as well as the relevance of role models are discussed. Personal resources are encouraged and examples are given through mini-games.	Goals and planning (1.1, 1.2, 1.4–1.7) Feedback and monitoring (2.3, 2.4) Shaping knowledge (4.1–4.3) Natural consequences (5.1–5.3, 5.6) Comparison of behavior (6.1, 6.2) Associations (7.1) Repetition and substitution (8.1) Comparison of outcomes (9.2) Reward and threat (10.4) Regulation (11.2) Antecedents (12.5, 12.6) Identity (13.1, 13.2) Self-belief (15.1–15.4) Covert Learning (16.3)
Social competences	The importance of social relationships, communication and the benefits when asking for or accepting help from others are being emphasized. The recognition of individual needs and emotions as well as asking for help is being trained.	Goals and planning (1.2, 1.4, 1.5, 1.7) Feedback and monitoring (2.3, 2.4) Social support (3.1–3.3) Shaping knowledge (4.1, 4.2) Natural consequences (5.1, 5.3, 5.6) Comparison of behavior (6.1) Repetition and substitution (8.1) Comparison of outcomes (9.1) Regulation (11.2) Antecedents (12.6)
Mindfulness	The concept of mindfulness, its uses and application examples get explained. Different audio guides help practicing mindfulness, meditation, self-reflection, yoga, and gratitude.	Goals and planning (1.2, 1.4, 1.5, 1.7) Feedback and monitoring (2.3, 2.4) Shaping knowledge (4.1, 4.2) Natural consequences (5.1, 5.3, 5.6) Repetition and substitution (8.1) Regulation (11.2, 11.3) Antecedents (12.6) Self-belief (15.1, 15.4)
Nutrition	Information about healthy lifestyle-choices, for example, water as the main beverage, the right amount of meat, sweets, and other fast foods, as well as the link between nutrition and weight are being presented using mini-games, audio clips and info pages. Optional information about nursing is available upon request.	Goals and planning (1.2) Feedback and monitoring (2.3) Shaping knowledge (4.1, 4.2) Natural consequences (5.1) Associations (7.1) Repetition and substitution (8.1) Comparison of outcomes (9.1) Identity (13.2)

(Continues)

TABLE 4 (Continued)

Module	Module content	BCT cluster (technique)
Physical activity	Advantages of increased physical activity and decreased sedentary behavior are shown. Furthermore, various strength exercises are being demonstrated using pictures of role models.	Goals and planning (1.2, 1.4) Feedback and monitoring (2.3) Social support (3.1) Shaping knowledge (4.1, 4.2) Natural consequences (5.1) Comparison of behavior (6.1, 6.2) Repetition and substitution (8.1) Comparison of outcomes (9.1) Antecedents (12.6) Identity (13.1) Self-belief (15.3)
Self-monitoring	This module provides the opportunity to track ones' personal mood, physical activity, nutrition behavior, and sleeping quality on a daily basis using emojis. Additional comments regarding the present day as well as the future can be made. All the information tracked in the diary can be accessed further on and may help in the self-reflection process.	Feedback and monitoring (2.3, 2.4)
Conclusion	The focus is on relapse prevention. This intend is divided by first looking into the past and re-emphasizing the advantages gained by working through all the modules as well as an evaluation of the personal objectives. Subsequently the module assists on how these goals can stay within reach and how to handle setbacks.	Goals and planning (1.2, 1.4–1.7) Feedback and monitoring (2.3) Social support (3.1–3.3) Shaping knowledge (4.1, 4.2) Natural consequences (5.1, 5.3, 5.6) Reward and threat (10.2–10.4, 10.9, 10.10) Regulation (11.2) Antecedents (12.6) Identity (13.2) Self-belief (15.2–15.4)

Note: Number in brackets indicate the presented BCTs of this respective cluster denoted according to the taxonomy of Michie et al. (2013). Clusters in bold indicate the three most-highly represented clusters within the respective module. The cluster "Natural consequences" includes information about health, social, emotional or environmental consequences as well as salience of consequences.

Abbreviation: BCT, behavior change technique.

and feelings are not judged as right or wrong. Personalized, individualized and interactive content holds promise for digital interventions in this target population. We attempted to implement a level of personalization in the app by engaging users to enter their own content (e.g., goal setting, cognitive restructuring) and choosing a suitable virtual coach. However, the approach of personalization could be much deeper and more complex (e.g., by giving personalized feedback or suggesting suitable modules). Moreover, the mHealth content is presented in an easy language, many images are used which lead to an easier understanding.

4.2 | Stage IV: Implementation of BCTs

Next to participative input, the content development of the app was guided by the integration of evidence-based strategies to promote sustainable behavior change. The classification of the content along the BCT taxonomy (Michie et al., 2013) indicated that except one, each BCT cluster was present in the final I-PREGNO app version, with *goals and planning*, *shaping knowledge*, and *natural consequences* being the clusters most frequently used.

Previous research identified that the BCTs from the clusters *goals and planning*, *shaping knowledge*, *social support*, and *comparison of outcome* are linked to decreased physical inactivity and a favorable eating behavior during the perinatal period (Hayman et al., 2021; Smith et al., 2016). More specifically, the following BCTs were marked as particularly effective for behavior change in this critical period: *problem solving*, *goal setting of outcome*, *goal setting of behavior*, *review outcome goal*, *behavior substitution*, *self-monitoring of behavior*, *credible source*, *feedback on outcome of behavior*, *implemented graded tasks*, and *adding objects to the environment* (Currie et al., 2013; Lim et al., 2019; Samdal et al., 2017).

In the I-PREGNO app, the vast majority of this effective clusters and techniques are presented repeatedly. Due to the self-guided mHealth approach, certain techniques (i.e., "feedback on outcome of behavior," "implementing graded tasks," "adding objects to the environment") and BCT cluster (i.e., "comparison of outcome") were not implemented. Users receive global feedback for reported behavior within the app, however, there is no direct feedback on the actual behavior. This aspect is included in the accompanied face-to-face counseling sessions with the HPs in routine care. Furthermore, the possibility of direct comparison is very limited. Even though

the partners' version of the app allows for a manual comparison of behavior, the possibility of social comparison or joint performance of exercise units using artificial intelligence could be considered in further developments of the app.

Dusseldorp et al. (2014) suggest that the combination of follow-up prompts with information about health behavior and health consequences is an effective combination to facilitate behavior change. We combined information about health behaviors with information about consequences and barriers within the app. However, following the results of the UCD, we decided against repeated follow-up prompts to avoid pressure. The evaluation of the RCTs will show whether more follow-up prompts are needed in a further development of the app to increase adherence in this specific target group or whether users should decide how often to be reminded.

4.3 | Strengths and limitations

To our knowledge, I-PREGNO is the first app that provides a smartphone-based intervention for the prevention of unhealthy weight gain and parenting stress in psychosocially burdened families during the perinatal period. The different modules focus on transdiagnostic factors that influence both, perinatal psychological and physical changes that can lead to perinatal diseases in (expectant) parents. I-PREGNO represents a holistic approach that supports a particularly burdened population in a particularly vulnerable period. A strength of the explorative, systematic, and iterative development process is that we included hard-to-reach (expectant) mothers between gestation and 24 months postpartum in different stages during our development process. This participative approach provided valuable insights in the life realities of families with psychosocial burden. Second, we also involved HPs in different stages of the development process who have extensive expertise in working with psychosocially burdened families during the perinatal period. Third, the UCD and content development was carried out by two independent sites to minimize the bias of the qualitative researchers conducting and evaluating the focus groups and usability tests. Finally, the identification of a comparatively high number of BCTs reinforces the evidence- and theory-based content development process, which increases the likelihood of sustainable behavior change.

However, certain limitations need to be considered when evaluating the development process of the I-PREGNO app. Although the purpose of this study was explorative in nature, generalizability may be limited due to the small sample size. Second, we analyzed the qualitative data based on a technique that identifies central statements of focus group discussion as suggested by Ruddat (2012). Although this method represents an economic approach to identify key topics, it limits the generalizability of the results (e.g., no possibility to count the frequency of responses). Third, it was not possible to involve fathers within the UCD process even though we were able to gather indications of what professionals and mothers

felt could be important topics for fathers in the group discussions. The development process of I-PREGNO has shown that it is very difficult to reach and motivate fathers of psychosocially burdened families to participate. HPs who recruited mothers for our study reported that they usually had no contact with fathers as they were usually absent from counseling appointments. In future projects, it will be crucial to involve fathers personally to tailor interventions specifically to their needs. For this, it is necessary to find out how to access fathers and motivate them to participate in studies during the transition to parenthood. Fourth, several effective BCTs as well as identified needs of the target group (e.g., networking among users, a more complex calendar function, and detailed information about the child's development) were not implemented in the final app version due to limited resources, data protection and technical reasons. Furthermore, we developed two versions of the I-PREGNO app to address the divergent needs of fathers and mothers during the perinatal period. It would be desirable to adapt the content of the app to the needs of other family constellations (e.g., same-sex parents, adoptive families) to include more diverse representations.

5 | CONCLUSION

This study is a first step toward developing frameworks that provide suggestions for the development of digital interventions that are tailored to the needs and life realities of hard-to-reach target groups. To address this, we followed a user-centered, theory driven approach that included an extensive literature review for effective evidence-based strategies as well as the involvement of the target group through usability testing and focus group discussions. In addition, this paper provides an overview of what the development of an mHealth intervention might look like and highlights the complexity of this time-consuming process. With this paper, we aim to share our findings with other research groups on mHealth interventions and increase the transparency of the I-PREGNO app to give practitioners insight into the quality and content of the app. Results of the RCTs will provide important guidance on which BCTs are most beneficial for families with high psychosocial burden.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data sets and codes used or analyzed during the current study are available from the corresponding author on request.

ETHICS STATEMENT

The study has received ethical approval from the ethical committee of the University in Bamberg (nr. 2022-02/09) and of the Medical University in Graz (nr. 34-249 ex21/22).

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