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STUDY PROTOCOL

A cognitive behavioural mHealth intervention for families in the postpartum period to enhance weight management, mental well-being and resilience – a study protocol for a randomised controlled trial (I-PREGNO)

[version 1; peer review: 1 approved with reservations, 1 not approved]

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Abstract

Introduction: The postpartum period goes along with an increased risk of unhealthy weight gain and numerous physical and psychological challenges, which are associated with mental well-being and resilience. Given the individual circumstances and the accompanying time constraints, evidence-based mHealth interventions may be useful for flexible, spot-on complementary care. Thus, the mHealth app I-PREGNO aims to enhance mental well-being and resilience by offering cognitive-behavioural and behaviour change skills training to prevent unhealthy weight development in this vulnerable life episode. In a randomised controlled trial, we will examine its effectiveness and acceptance.

Protocol: Parents of infants between 0 and 12 months will be randomised to the intervention or control group. Both groups will take part in a baseline survey (t0) and further assessments after 12 weeks (intervention duration, t1), and 6 months (t2). The intervention group will use the self-guided mHealth app after t0 and both groups will get unlimited access after t2. The primary outcomes will be i) *weight* (difference of weight in kg after the intervention and pre-

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pregnancy); ii) *mental well-being* assessed through the Edinburgh-Postnatal-Depression-Scale and Parenting Stress Index; iii) *resilience* assessed through the General Self-Efficacy Scale and Difficulties in Emotion Regulation Scale. Secondary outcomes will be sociodemographic variables, eating behaviour, physical activity, relationship experiences, childhood trauma, postpartum bonding, regulatory disorders, and app usability. Gender differences between mothers and fathers will be considered.
Conclusion: Positive effects on weight development in the postpartum period, mental well-being, and resilience due to the I-PREGNO intervention will support parental health in the critical postpartum phase. The study results will contribute to the growing field of evidence-based, highly scalable, low-cost, geographically independent, just-in-time mobile support for a target group that is restricted in time and resources.
Trial registration: The trial has been registered at the German Clinical Trials Register (DRKS00031067) in January 2023 prospectively.

Keywords
mHealth, postpartum, parenthood, weight, health, family health, randomised controlled trial, prevention

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Introduction

The first year after the birth of a child represents a challenging phase of life for families, especially in terms of establishing and maintaining mental well being and resilience, which are associated with health behaviour and thus weight management. Psychosocial (e.g. role conflicts), behavioural (e.g. sleep behaviour), and physical (e.g. previous pregnancy) changes can have an unfavourable effect on health related behaviour (Saxbe *et al.*, 2018b). Hence, the postpartum period represents a critical time for the development of long-term weight gain, and thus a risk for (long-term) overweight and obesity as mothers have a 17% greater absolute body mass index (BMI) gain between 15 and 35 years than non-mothers (Corder *et al.*, 2020; Saxbe *et al.*, 2018a). While many women tend to lose the extra weight after giving birth, about 20% of them remain more than 5 kg heavier than their pre-pregnancy weight (Calfas & Marcus, 2007). A gestational weight gain higher than recommended resulted in an increased risk of postpartum weight retention (> 2 kg after 18 months), especially for nulliparous women with overweight/obesity (Haugen *et al.*, 2014). Increasing physical activity (PA) and healthy eating by improving coping strategies was shown to be an effective component of postpartum weight management interventions (Østbye *et al.*, 2012). Treatment guidelines for preventive interventions of overweight and obesity also suggest the integration of dietary behaviour, PA, and (cognitive) behavioural strategies (Deutsche Adipositas Gesellschaft e.V., German Association for the Study of Obesity [DAG], 2014; National Institute for Health and Care Excellence [NICE], 2014). Fathers also have an increased risk for unhealthy weight gain in the pre- and postpartum period with a mean increase of 5 kg (Haugen *et al.*, 2014; Versele *et al.*, 2023a; Versele *et al.*, 2023b). Hormonal (e.g. testosterone, cortisol), behavioural (e.g. diet), and psychological (e.g. parental stress) processes are considered to be underlying mechanism for father's weight gain in this time period (Saxbe *et al.*, 2018a). On the other hand, social support, e.g. by the father, is associated with favourable health behaviour and less depressive symptoms in postpartum women (Faleschini *et al.*, 2019; Zhao & Zhang, 2020). Hence, the involvement of fathers himself for strengthening his resilience and mental well-being as a source of social support for the mother could be an effectiveness booster in postpartum interventions.

Several meta-analyses showed that not only poor health of the fathers, but also partnership dissatisfaction, perceived stress, and low socio economic status (SES) are associated with postpartum depression of both parents and thus, the mental well-being of the whole family (Ansari *et al.*, 2021; Vehmeijer *et al.*, 2020; Wang *et al.*, 2021). Factors such as a history of depression, anxiety, single parenthood, unplanned pregnancy, stressful life events, and poor social support contribute to this heightened risk (Cena *et al.*, 2021; Silverman *et al.*, 2017). Above that, the first year of a child and its socialisation within the family is substantial for the offspring's risk of developing physical and mental diseases, which is associated with their parent's care, quality of interaction with their child and the parents´ mental health (Goodman & Gotlib, 1999; Hosman *et al.*, 2009; Lampert, 2010; Pinquart & Silbereisen, 2002).

In a comprehensive study involving 8,063 parents with varying SES and risk factors, Lorenz and colleagues (2020) identified that parents with low SES (18.8%), high parental stress (17.3%), and multiple risk for child neglect and abuse (5.2%) displayed elevated scores of depression, anxiety, and experienced increased family conflicts. A meta-analysis observed a prevalence of 10.4% paternal depression (28,004 participants), with a higher rate during the 3- to 6 months postpartum period (25.6%), and a positive moderate correlation between paternal and maternal depression (Paulson & Bazemore, 2010). Hence, supporting parents to adapt strategies that promote parental mental well-being by reducing parental stress and postpartum depressive symptoms, e.g. by optimising PA and healthy eating, are important for family health (Kołomańska-Bogucka & Mazur-Bialy, 2019).

For enhancing the weight management in the postpartum period, not only the prevention of postpartum depression or parental stress is beneficial, but also strengthening resilience factors like self-efficacy and emotion regulation (Hinton & Olson, 2001; Versele *et al.*, 2021; Versele *et al.*, 2022). Emotion regulation is the ability to influence the intensity, the duration, the time, and the expression of emotions, which can strengthen, weaken or maintain positive and negative emotions (Gross, 1998). Functional emotion regulation promotes the interaction of mother and child, and enables the mother to respond sensitively to babies' crying and needs (Rutherford *et al.*, 2015; Schultheis *et al.*, 2019; Shaffer & Obradović, 2017). Above that, sleep quality such as sleep interruptions, which are common in the postpartum phase, are associated with maladaptive changes in the regulation (process) of emotions (Palmer & Alfano, 2017). Difficulties in emotion regulation are associated with reduced cortisol reactivity and may increase the risk for severe difficulties in the long term (England-Mason *et al.*, 2017). Furthermore, cognitive emotion regulation strategies and perceived social support six weeks after the birth were able to predict depressive symptoms six months postpartum (Haga *et al.*, 2012).

Another resilience factor, that is associated with family health, social support, and depressive symptoms in the postpartum phase, is self-efficacy, reflecting an optimistic self-belief (Leahy-Warren *et al.*, 2012; Schwarzer & Jerusalem, 1995). An increase in self-efficacy can not just reduce postpartum depression, but also improve maternal role competencies (Dlamini *et al.*, 2023). Above that, studies have shown, that self-efficacy should be targeted in interventions for women in the postpartum phase to increase PA, which is associated with weight retention (Hinton & Olson, 2001).

Due to the multifactorial aetiology of overweight and obesity and the individual circumstances in the postpartum period, the individualisation of interventions targeting weight management, mental well being, and resilience factors is essential. To address the numerous personal challenges of internal and external conditions due to parenthood, customisable, highly flexible self guided mobile health (mHealth) interventions are particularly promising for postpartum women (Sherifali *et al.*, 2017; Teufel, 2015). Furthermore, smartphone applications

offer a convenient, cost-effective, and particularly useful approach during time constrained periods such as the postpartum phase (Ebert *et al.*, 2018; Feierabend *et al.*, 2021). Mhealth interventions reach parents, who are well versed in digital tools, and thus a high acceptance rate for such interventions can be shown (Ebert *et al.*, 2018; Feierabend *et al.*, 2021). Many mHealth interventions for expectant parents primarily focus on maternal needs and lack the integration of fathers. However, paternal involvement can significantly increase the effectiveness of digital interventions by providing additional social and practical support for mothers (Pebryatie *et al.*, 2022; Versele *et al.*, 2022). Also, parents within the postpartum period experience individual barriers to enhance a healthy lifestyle, which is why a gender sensitive, self guided app could be favourable (Carter-Edwards *et al.*, 2009). Although a plethora of free-market health apps is available, the empirical evidence for their effectiveness is scarce. Further, limitations of current apps include unclear long-term effects on mental well-being, methodological and data security issues, and shortcomings in transparency for the user (Larsen *et al.*, 2019).

In summary, personalised mHealth interventions have a great potential for the prevention of weight problems, the enhancement of mental well being and resilience by addressing the needs of parents in the postpartum period. However, to unfold this potential of scalable and low-threshold mHealth interventions, evidence on its efficacy and acceptance by the target group is still needed.

Therefore, the aim of the proposed project is the development and evaluation of a mHealth intervention, the self-guided I-PREGNO app, which was developed from June 2021 to July 2022. The app consists of 12 modules, which besides PA and nutrition focus on cognitive-behavioural modules: emotion regulation, self-efficacy, stress management, self-esteem, social competences, self-monitoring, and mindfulness. All modules take into consideration behaviour change techniques (BCTs) based on the taxonomy of Michie and colleagues (2013), which are associated with intervention effectiveness in regard to parents' involvement in weight related nutrition of their children, changes of weight, and PA in postpartum women (Golley *et al.*, 2011; Lim *et al.*, 2020). The focus of the app development was on individualising the user's options in order to reflect individual needs and lifestyles (user centred approach).

In the randomised controlled trial (RCT) described here, we examine the effects of the I-PREGNO app intervention in a field study in mothers and fathers with children aged 0 to 12 months. Another trial will examine the app in a blended counselling condition (Vogel *et al.*, 2023). We expect a positive intervention effect on i) the prevention of unhealthy weight management (indicated by the weight difference after the intervention (follow-up) and pre pregnancy), ii) promoting mental well-being by reducing depressive symptoms and parental stress, iii) enhancing resilience by strengthening self efficacy and emotion regulation. Additionally, psychological constructs and variables that are associated with the three main outcomes, such as dietary behaviour, PA, psychosocial burdens, or bonding, as well as app usability will be assessed.

Protocol

Sample

The sample of this field study will consist of mothers and fathers, whereby a registration of the father will require a prior registration of the mother. Parents are eligible if they a) have a child aged 0 12 months, b) possess a smartphone (android or iOS), c) are at least 16 years old, and d) speak German. The online registration form will be available online from February 2023 until July 2023 and participants will be excluded from the trial, when a) they do not fulfil the inclusion criteria, b) have severe mental health problems that hamper the ability to participate, or c) have a chronic disease that can influence behaviour related to energy balance (e.g. diabetes). The app is available in Austria and Germany.

The target group will be recruited by press releases, social media adverts, and the distributions of leaflets and posters at paediatricians, kindergartens, and child guidance counselling. All promoting material consists of a short description of the project and a link to the study-website, where the online registration form is available. After the registration, the mother will be randomised to one of the two study conditions (IG = intervention group; CG = control group). See Figure 1 for an overview of the study process. The randomisation will be performed using a computerised random number generator, which is provided by an external, independent expert from the Department of Computing in the Cultural Sciences at the University of Bamberg. Subsequently, the mothers will be contacted by the study coordination team of the University of Bamberg (see Figure 1). In a 15 20 minutes phone call, the mothers will be informed about the study condition and procedure. In case the father is interested in participating, the mother will receive an email with his invitation to t0, which can be linked to the corresponding mother's assessment. The completion of the t0 questionnaire is the precondition for receiving the individual access code and password for the I-PREGNO mHealth app (IG only). After 12 weeks, all participants will be asked to fill out the post assessment (t1) and the study coordination center will deactivate the app for the IG. The follow up online questionnaire (t2) will be sent out via email six months after the baseline assessment. The completion of the t2 questionnaire will be the requirement for reactivation of the app for the IG (all content from the intervention phase will be available again) and initial access to the app for the CG. Each family will be incentivised after t1 (€20) and after t2 (€30). To avoid dropouts, the participants will be reminded via email and telephone to fill out the questionnaires.

Intervention

The interactive self-guided 12-week modular I-PREGNO app integrates basic principles of evidence-based cognitive-behavioural therapy and BCTs (Michie *et al.*, 2013). The modular structure of I-PREGNO was based on the technical and content-related knowledge and experiences gained from the gender-sensitive mHealth weight loss intervention I-GENDO

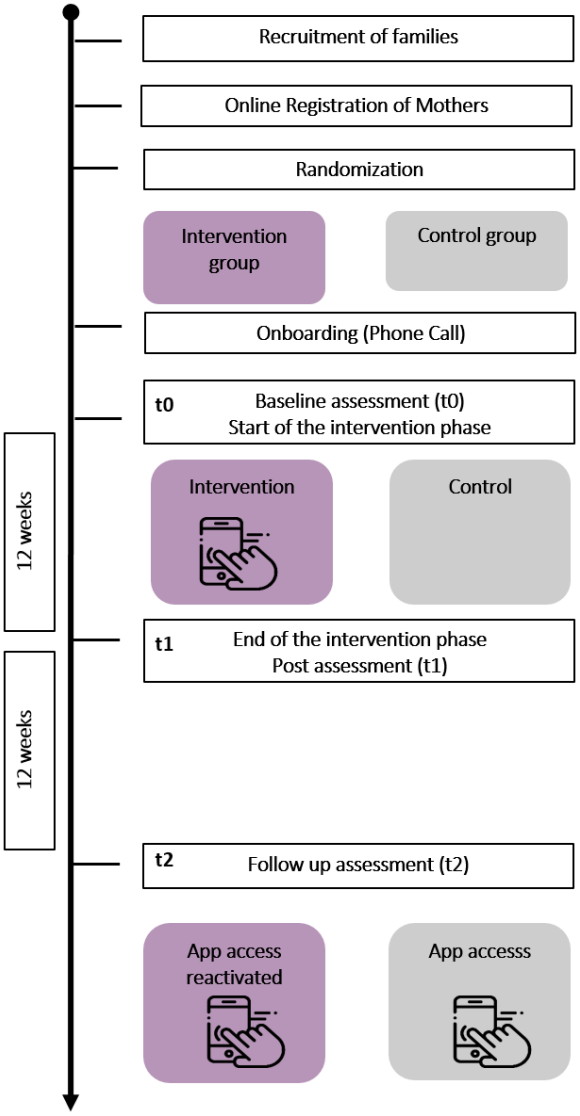


Figure 1. Study process for mothers.

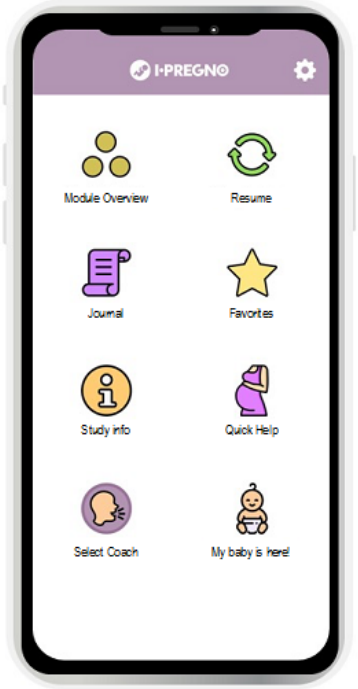


Figure 2. App interface.

(Pape *et al.*, 2022), further extended and developed within an iterative process by the authors working closely with the target group, health professionals, and an external software provider (groupXS Solutions GmbH). The developmental process was further in accordance to methodological standards seeking high transparency for the users and data protection (Seiferth *et al.*, 2023).

Figure 2 provides an overview of the I-PREGNO home screen. The app consists of a modular psychological intervention, self-monitoring of mood, PA, eating behaviour, and sleep quality through a personalised diary; a folder to save favourite exercises and strategies; information about the study itself and emergency contacts, and a selection of accompanying coaches. In addition to the individual customisation (e.g. coach) within the app, we provided two app releases with slightly adapted content, one for the mothers and one for the fathers to ensure that the app content fits to the different needs and perspectives. The core of the app, the psychological intervention, includes 12 modules that focus on improving specific psychosocial or behavioural aspects associated with weight management in the postpartum phase. Three modules address the introduction to (getting to know the app, goal setting) and conclusion (review and relapse prevention) of the intervention program. Eight more modules focus on improving core behaviour change skills for parents: self-care, stress management skills, emotion regulation skills, self-efficacy, self-esteem, mindfulness, social competences, and self monitoring of health behaviour. The remaining two modules address nutrition and PA.

To ensure an independent exploration of content of individual interest, users are able to work through the modules and sessions as desired. According to the existing literature and to prevent parents to spend too much time with digital devices, we recommend that participants interact with the app three times a week for a duration of approximately 15 minutes (Saur *et al.*, 2022). Each module consists of various sessions (n = 2 18). The app contains a progress bar, which tracks the finished sessions. The sessions include psychoeducational information, several cognitive behavioural therapy-based self-help techniques, skills (i.e., cognitive restructuring) and, a range of BCTs (i.e., goal setting, self-monitoring) delivered through text, audio, images, and interactive elements that require participants' input (i.e., swiping boxes down the screen into baskets, filling out gap texts or questionnaires). The content was developed and pre-tested with psychosocially burdened parents as well

as health care professionals to enhance usability and facilitate the user experience.

Sample size calculation

An a priori power analysis for ANOVA, repeated measures and within-between interaction, was conducted with G*Power (version 3.1.9.7). A difference of 1 kg weight change between intervention and control group after the intervention will be considered as clinically significant (f = .1), which is based on studies investigating weight development pre pregnancy vs. postpartum (Haugen *et al.*, 2014; Nehring *et al.*, 2011). This small effect size, according to Cohen, can be expected also for the other outcome variables (Cohen, 1977).

The sample size resulted in 125 participants for each group, assuming 20 % drop out and aiming for at least 80 % power (α = .05 and retest r = .5).

Primary and secondary outcomes

Our primary outcomes will be *weight management*, *mental well-being*, and *resilience*.

Weight management will be operationalised by the difference of the self reported weight (kg) at t1, respectively at t2 for the long-term effect, and pre-pregnancy weight. The pre-pregnancy weight will be assessed retrospectively at the baseline assessment (t0).

Mental well-being will be conceptualised by postpartum depressive symptoms and parental stress using the German versions of the Edinburgh-Postnatal-Depression-Scale (EPDS; Bergant *et al.*, 1998; Cox *et al.*, 1987) and the Parenting Stress Index – Short Form (PSI-SF; Abidin *et al.*, 2006; Tröster, 2011). The EPDS consists of ten items (e.g. 'I have been anxious or worried for no good reason'), which are rated on a 4-point-Likert scale ranging from 0 (e.g. 'No, not at all') to 3 (e.g. 'Yes, quite a lot.'). A sum score is conducted to screen for parental postpartum depression (0 = 'no postpartum depression'; 30 = 'severe postpartum depression'). Parental stress will be assessed by the 28 items of the parent's section of the PSI-SF, whereby four items will be only asked, when a partnership exists. The seven subscales ('depression', 'competence', 'parental attachment', 'isolation', 'spouse', 'health', 'role restriction'), include four items each, which will be rated on a 5 point Likert-scale ranging from 1 ('strongly disagree') to 5 ('strongly agree') with higher scores indicating higher levels of parental stress.

Resilience will be assessed through emotion regulation and self-efficacy. Emotion regulation will be measured by the short form of the Difficulties in Emotion Regulation Scale (Ehring *et al.*, 2013; Gratz & Roemer, 2004), which consists of six subscales: non-acceptance of emotional responses, difficulty engaging in goal-directed behaviour, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity. *General self-efficacy*, general optimistic self-beliefs to cope with difficult situations, will be assessed by the ten items of the German version of the General Self-Efficacy Scale (Schwarzer & Jerusalem, 1995; Schwarzer & Jerusalem, 2010). The 4 point Likert scale ranges from 1 ('not at all true') to 4 ('exactly true') and a total sum score will be calculated.

All questionnaires for well being and resilience show acceptable psychometric properties (Abidin *et al.*, 2006; Cox *et al.*, 1987; Damásio *et al.*, 2016; Hutcheson & Black, 1996; Reitman *et al.*, 2002; Victor & Klonsky, 2016).

Aspects, which are associated with these three main outcomes such as dietary behaviour, PA, psychosocial burdens, sociodemographics or bonding as well as app usability will be assessed:

The *socio-demographic characteristics* and socio-economic stressors (e.g. lack of social support, migrant status of the parents, difficult living conditions, e.g. single parent) will be assessed to measure psychosocial burdens of families. A detailed description of the instruments and subscales can be found in the study protocol of the I PREGNO blended counselling study (Vogel *et al.*, 2023)

To assess *eating styles*, total scores of the German version of the Dutch Eating Behaviour Questionnaire (Nagl *et al.*, 2016; van Strien *et al.*, 1986) will be used, which consists of 30 items with three subscales: emotional eating, restrained eating, and external eating. For eating behaviour, two additional questions will be asked that measure diagnostic criteria of an undereating disorder based on the Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood (Frankel *et al.*, 2018). Additionally, participants will be asked to indicate the average *food intake frequency* for following food groups: a) vegetables, b) fish, c) meat, d) meat replacement products/eggs, e) fruit, f) processed pasta/rice, g) potatoes/whole grain pasta/whole grain rice, h) sweet and savory snacks, i) seeds and nuts, j) whole grain bread, k) white bread, l) sugary drinks.

PA (vigorous, moderate or walking activities) will be assessed using the German short version of the International Physical Activity Questionnaire (Lee *et al.*, 2011).

To assess *attachment anxiety and avoidance in adult partnerships*, the German version of the Experiences in Close Relationships-Revised questionnaire will be used (Brennan *et al.*, 1998; Ehrenthal *et al.*, 2009).

The Childhood Trauma Screener (CTS) is the short form of the Childhood Trauma Questionnaire with five items (Bernstein *et al.*, 2003; Grabe *et al.*, 2012). The CTS will be used to assess *parental childhood maltreatment experiences*.

Parent-child interaction (bonding) will be assessed by the German version of the Postpartum Bonding Questionnaire (Brockington *et al.*, 2006; Reck *et al.*, 2006).

To assess the *parental perception of the child's emotions*, the Infant Facial Expressions of Emotion from Looking at Pictures (IFEEL) approach was conducted, by using 16 infant pictures with adapted answering format (Emde *et al.*, 1993).

To gauge the potential stress by a *present regulatory disorder*, families will be asked to rate how burdened they are by the crying, sleeping, and eating behaviour of their child. For each of these three areas, families will answer one question, each on a 4-point Likert scale and ranging from 0 ('not at all') to 4 ('very').

In order to assess *app usability* the German version of the mHealth app usability questionnaire (MAUQ) for standalone mHealth apps (patient version) will be used (Pape *et al.*, 2022; Zhou *et al.*, 2019), which contains the subscales 'ease of use', 'interface and satisfaction', and 'usefulness' (six items).

The quantitative (i.e., login, logout times, modules completed, time spent in the app) and qualitative (i.e., participants input, used features, content utilised) app usage and engagement will be assessed by the apps' meta-data log files. The fundamental data are internally tracked within the app and downloaded to secure servers. Treatment adherence will be operationalised as time spent using the app, numbers of days using the app, and percentage of worked-through modules.

Data analysis and statistical plan

The impact of the intervention on the primary outcomes (weight, mental well being, resilience) will be analysed using multilevel analysis. Analyses of intervention effects will be based on the intention-to-treat principle. Given the randomised design of the study, analyses on intervention effects will be adjusted for baseline values of the outcomes. If suitable, missing data will be checked for randomness. Potentially confounding variables will be assessed and their impact explored (e.g see Table 1 *). Additionally, we will check for differences between conditions and mothers and fathers. Table 1 provides an overview of data collection and time points.

Table 1. Data collection and time points.

Questionnaire	t_0	t_1	t_2
Postnatal Depression (EPDS)	x	x	x
Parenting stress (PSI-SF)	x	x	x
Emotion Regulation (DERS-SF)	x	x	x
Self-efficacy (GSE)	x	x	x
Sociodemographics *	x		
Eating behaviour (DEBQ) *	x	x	x
Frequency of food intake (FFQ) *	x	x	x
Physical Activity (IPAQ) *	x	x	x
Relationship experience (ECR-RD) *		x	
Childhood trauma (CTS) *	x		
Postpartum bonding (PBQ) *	x	x	x
Emotion recognition, parent (I-FEEL) *			X
Regulatory Disorders *			X
mHealth app usability (MAUQ) *		X	

Notes. * = secondary outcomes, associated variables; EPDS = Edinburgh-Postnatal-Depression-Scale; PSI-SF = Parenting Stress Index; DERS-SF = Difficulties in Emotion Regulation Scale; GSE = General Self-Efficacy Scale; DEBQ = Dutch Eating Behaviour Questionnaire; FFQ = Food Frequency Questionnaire; IPAQ = International Physical Activity Questionnaire; ECR-RD = Experiences in Close Relationships; CTS = Childhood Trauma Screener; PBQ = Postpartum Bonding Questionnaire; I-FEEL = Infant Facial Emotion Expressions from Looking at Pictures; MAUQ = mHealth app usability questionnaire.

Ethical approval and consent

The study is in line with the declaration of Helsinki and has received ethical approval from the ethical committee of the University of Bamberg (nr. 2022-02/09) and the trial was registered in the German register for clinical trials (DRKS00031067). No harms of side effects for the participating families are expected. However, since we aim to include participants in a potential stressful time, we will put great emphasis on the personal support on families and their well-being by providing initial personal contact via phone. Informed consent will be obtained from all participating families at the beginning of the study by phone and via online questionnaire.

Dissemination

Dissemination activities include the identification of relevant groups, i.e., pediatrics, psychologists, and gynecologists, for dissemination and subsequent identification of appropriate communication channels per target group (e.g. newsletters, Twitter, Instagram, Facebook, local press). This ensures that the delivered content is suitable to the target population and media outlets. Dissemination partners will be involved during different stages of the project. The process of the app development as well as the results of the RCT will be disseminated by articles for scientific journals as well as press releases and journalistic reportage. In addition, project members will hold presentations at conferences and organise symposia and events. A closing event for professionals and scientists as well as families will be conducted.

Study status

Enrolment of the participants was going on while first submission of this manuscript and ended at the end of July 2023. Most of the participants of the intervention group are now using the app, some of the participants already filled out the questionary for t1.

Conclusion

In this longitudinal, randomised controlled and prospective study, we aim to evaluate a self-guided mHealth intervention (I PREGNO) addressing mothers and fathers in the postpartum phase to establish and maintain resilience and mental well-being for the prevention of unhealthy weight development. In case of success and positive intervention effects, this mHealth intervention can provide a low-threshold, scalable, flexible, and low-cost access to primary preventive support. Following a holistic approach, the I-PREGNO app enhances health behaviour by offering a variety of evidence-based strategies to improve sustainable weight management and mental well-being.

In the long-term, the results will help to support evidence-based mHealth interventions that can be applied in a flexible and individualised manner and thus promote comprehensive health care in this vulnerable phase of life. Furthermore, this study will contribute to the lack of high-standard, evidence-based and transparent mHealth solutions.

The strength of this study is the focus on individualisation (e.g. self-guided) within the intervention, inclusion of fathers, and a holistic approach. In addition, the self-help intervention goes along with potential cost effectiveness. Furthermore, the intervention may be available especially when health care infrastructure is scarce.

However, self-help interventions were shown to be associated with high drop-out rates and lower compliance than guided interventions, e.g. supported by a coach, therapist (Carlbring *et al.*, 2018). To encounter this limitation, we will establish personal contact via telephone early on and support families throughout the whole process.

This study investigates the effects of a mHealth intervention for preventing unhealthy weight gain and increase mental well being and resilience in parents in the postpartum period. Results may contribute substantially to provide early on health support for the whole family and improve evidence on mHealth interventions as potential additional health services.

Data availability

Underlying data

No data are associated with this article.

Reporting guidelines

Open Science Framework: SPIRIT checklist for 'A cognitive behavioural mHealth intervention for families in the postpartum period to enhance weight management, mental well-being and resilience – a study protocol for a randomised controlled trial (I PREGNO)'

This project contains the following data:

- Study Protocol mHealth_Appendix_A_Spirit Checklist (https://osf.io/vtkbx)

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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Open Peer Review

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✗ **Kasia Kostyrka-Allchorne**
Department of Psychology, Queen Mary University of London, London, England, UK

This protocol refers to the randomised controlled trial of a mHealth application, I-PREGNO, designed to reduce the risk of excessive weight gain in the postpartum period by improving parents' mental wellbeing and resilience and promoting nutritious diet and physical activity. This is a very interesting and important project and supporting both parents during this challenging period is crucial. However, the protocol would benefit from some revision to include more details and clarify some aspects of the study. Please see below.

One, the role of fathers as participants is not clear. It appears that both mothers and fathers are included as participants, but only mothers are randomised? Also, some cited evidence refers to the research showing that paternal involvement increases the effectiveness of digital interventions – so, is the fathers' role in this study to support mothers?

Relatedly, it is not clear which measures are completed by mothers and which by fathers/both parents.

The introduction should be clearer in terms of specifying the research questions and clearly distinguishing which are the primary and which are the secondary outcomes.

Methods

- Screening: Please provide information about the screening procedure. How did the study team ensure that participants met all the eligibility criteria?
- Randomisation: it appears that randomisation was performed before baseline data collection. This is quite unusual approach, as randomisation typically takes place as late as possible before the intervention starts. The choice of randomisation timing should be explained.
- Consent: Please provide information about consent procedure. It appears that information about the study is given to participants after randomisation has been performed. Please clarify at what point consent is take and how it is recorded.
- Sample size: this appears relatively small, given that there are three primary outcomes – as

having more than one primary outcome will affect the sample size calculation. Based on the current reading of the article, it seems like the study was powered on one outcome only (i.e., weight management, expected a difference of 1kg). Please clarify whether the number of outcomes was considered in power calculations.

- Outcomes and their measures: Please clarify whether primary outcomes will be based on the information provided by mothers or by fathers, or both.Please clarify how parental stress and symptoms of postnatal depression will be combined into one primary outcome of 'mental wellbeing'. The same applies to emotion regulation and self-efficacy that constitute the 'resilience' outcome.
- More clarify is needed about the other outcomes measured in the study: "Aspects, which are associated with these three main outcomes" – please explain what is meant by 'aspects'. Are these secondary outcomes? Moderators? Other. Also, please describe the measures used to assess these in more details and their scoring. For example, how information derived from the food frequency measure will be scored and used in the study?
- Relatedly, the protocol describes childhood adverse experiences as one of the secondary outcomes. Please could you clarify this, as this information will be collected retrospectively and only at baseline.
- The app: Please provide more information about the app. For example, does the content for mothers and father is different? What is the role of coaches? Is the use of the app going to be encouraged? Are there any reminders sent to participants to remind them to use the app?

Data collection: please provide more information about data collection procedures.

Adverse events monitoring. While the risk of participant experiencing adverse events during the trial is low, it still should be monitored. Please explain what steps have been taken to monitor this during the trial and to ensure the safety of participants.

Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
No

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Digital parenting interventions, developmental psychology, mental health, trials.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for

reasons outlined above.

Reviewer Report 12 April 2024

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Iman Azimi
Department of Computer Science, University of California Irvine, Irvine, California, USA

In this paper, the authors present a study protocol including mHealth interventions enabled by the I-PREGNO app. The study consists of intervention and control groups including parents of infants aged 0 to 12 months. The primary outcomes are weight, mental well-being, and resilience, and the secondary outcomes include sociodemographic variables, dietary behavior, physical activity, psychosocial burdens, and app usability. Due to advancements in ICT technology, smart devices are increasingly accessible and viable for use in mHealth applications. The authors address an important topic by exploring the potential use of a smartphone application for postpartum intervention. Below are my comments and suggestions.

The first page of the Introduction describes the challenges during postpartum and the significance of utilizing intervention tools, which is good. However, I suggest reducing this part to allocate more space to discussing state-of-the-art methods. What are the existing methods used for postpartum intervention? Which other applications have been utilized in similar studies? Please highlight the benefits of using the I-PREGNO app for these interventions in comparison to existing applications.

“Further, limitations of current apps include unclear long-term effects on mental well-being, methodological and data security issues, and shortcomings in transparency for the user (Larsen et al., 2019).” How does this study / app address these limitations related to long-term effects?

Please provide more details regarding the interventions and data collection of the app. Does the app only provide questionnaires, or are there other features for data collection? Do user’s inputs influence the intervention methods? What are the limitations or challenges of using the app for both data collection and intervention?

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Digital Health and AI

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.