Understanding and Preventing Postpartum Depression -

Investigating Risk Factors, Consequences, and Digital Prevention Strategies

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General Abstract

With a global prevalence of 17 % (Wang et al., 2021), Postpartum Depression represents one of the most common psychological complications for women after childbirth. Postpartum Depression is associated with far-reaching consequences for mothers, their families and the society (O'Hara & McCabe, 2013). Women facing high levels of psychosocial stress are at particularly high risk of developing symptoms of Postpartum Depression (Hutchens & Kearney, 2020). However, this vulnerable group was often neglected in previous research and is considered as hard-to-reach using preventive measures (Ulrich et al., 2022).

The objective of the current dissertation was to enhance the understanding of Postpartum Depression by expanding research on its risk factors, consequences and prevention, particularly in psycho-socially burdened families. The body of this dissertation consists of five publications, each of which contributes to these aims. The current thesis investigated the association between maternal and paternal experiences of childhood maltreatment and symptoms of Postpartum Depression (*Publication I*), and examined Postpartum Depression as a mediator for the relationship between maternal experiences of childhood maltreatment and impairments in mother-infant bonding (*Publication II*). Furthermore, the current thesis includes three publications (*Publication III - V*) about the development and evaluation of a mobile health (mHealth)-based preventive intervention (*I-PREGNO*) specifically tailored to the needs of psycho-socially burdened families.

In *Publication I,* pooled data from two German studies (n = 349 mothers and n = 46 fathers) were analyzed. Hierarchical regression models examined experiences of childhood maltreatment, educational background, single parenthood, emotion regulation, and attachment style as predictors of Postpartum Depression. Along with low levels of education, difficulties in emotion regulation and attachment anxiety, maternal experiences of childhood maltreatment were identified as a predictor of Postpartum Depression. Additionally, the article highlights

difficulties in emotion regulation as a promising target for psychological preventive measures focusing mothers and fathers during the transition to parenthood.

The aim of *Publication II* was to disentangle the link between maternal experiences of childhood maltreatment and impairments in mother-infant bonding during the postpartum period. To achieve this objective, a path model which included longitudinal data from $N = 128$ mothers was performed. Symptoms of Postpartum Depression were identified as a mediator for the link between maternal experiences of childhood maltreatment and impairments in mother-infant bonding, highlighting the pivotal role of Postpartum Depression during the postpartum period.

Publication III and *Publication IV* target the development and evaluation of an mHealth-based intervention (*I-PREGNO*) specifically tailored to the needs of psycho-socially burdened families. While preregistered analyses of a two-arm parallel cluster randomized controlled trial (cRCT, N=108) did not find a significant effect of *I-PREGNO* on maternal postpartum mental well-being (postpartum depressive symptoms and parenting stress), exploratory analyses revealed reduced scores in parenting stress among mothers in the intervention group who started the intervention within the first four months postpartum.

Finally, *Publication V* presents a consensus statement providing guidelines for scientists and practitioners in the field of digital health. It was written by one think tank and 25 international experts in this domain using a Delphi-adapted process. Overall, the consensus statement addresses 11 topics covering the development, evaluation and implementation of digital assessments and interventions (Where to start, Content Development, Participatory Research, Suicidality, Data Protection and Data Security, Artificial Intelligence, Sensing and Wearables, Efficacy evaluation, Ecological Momentary Assessment, Transfer into (clinical) practice, App evaluation frameworks).

In conclusion, this thesis addressed research gaps in the field of preventing Postpartum Depression. The findings of this thesis emphasize the need for preventive interventions

targeting mothers during the transition to parenthood who have survived maltreatment in their own childhood and highlights emotion regulation as a promising target for the prevention of Postpartum Depression. Furthermore, the thesis provides first findings about the development and evaluation of an mHealth-based intervention specifically tailored to the needs of psycho-socially burdened families. Future studies should explore ways to enhance the efficacy of interventions like *I-PREGNO* in preventing Postpartum Depression in psycho-socially burdened families.

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Abbreviations

ACE	Adverse Childhood Experiences
AI	Artificial Intelligence
APA	American Psychiatric Association
App	Application
BÄK	Bundesärztekammer
BBC	British Broadcasting Corporation
CBT	Cognitive Behavioral Therapy
CM	Childhood Maltreatment
cRCT	Cluster Randomized Controlled Trial
DSM-5	Diagnostic and Statistical Manual of Mental Disorders
EMA	Ecological Momentary Assessment
EPDS	Edinburgh Postnatal Depression Scale
JPI HDHL	European Joint Programming Initiative: A Healthy Diet for a Health Life
MDD	Major Depressive Disorder
mHealth	Mobile Health
NZFH	National Center for Early Prevention / Nationales Zentrum Frühe Hilfen
OCD	Obsessive Compulsive Disorder
PACT	Postpartum Depression: Action Towards Causes and Treatment
PHQ-9	Patient Health Questionnaire - 9
PPD	Postpartum Depression
PMS	Premenstrual Syndrome
PTSD	Posttraumatic Stress Disorder
RCT	Randomized Cotrolled Trial

SCID-CV	Structured Clinical Interview for DSM-5
SES	Socioeconomic Status
SMD	Standardized Mean Difference
WHO	World Health Organization

1 General Introduction

> "*Well, everybody was thrilled to bits. It had been quite a difficult pregnancy - I hadn't been very well throughout it - so by the time William arrived it was a great relief because it was all peaceful again, and I was well for a time. Then I was unwell with postnatal depression, which no one ever discusses, postnatal depression, you have to read about it afterwards, and that in itself was a bit of a difficult time. You'd wake up in the morning feeling you didn't want to get out of bed, you felt misunderstood, and just very, very low in yourself […] I never had had a depression in my life. But then when I analyzed it I could see that the changes I'd made in the last year had all caught up with me, and my body had said: 'We want a rest.' […] I received a great deal of treatment, but I knew in myself that actually what I needed was space and time to adapt to all the different roles that had come my way. I knew I could do it, but I needed people to be patient and give me the space to do it.*"
>
> Diana, Princess of Wales (BBC, November 20, 1995)

In November 1995 Princess Diana gave an interview to the British Broadcasting Corporation (BBC). In this interview, Princess Diana talked openly about her experiences of becoming a mother. She admitted experiencing symptoms of postpartum depression (PPD) after Prince William's delivery, a mental illness with far-reaching consequences for mothers and their families. When reading her statement, one can sense the suffering and loss of control she experienced due to PPD, especially at a time when the world outside focuses on the joy about the new-born child. Princess Diana's experience was not unique. With a prevalence of 17% worldwide, research highlights PPD as one of the leading complications after childbirth (Wang et al., 2021; Zauderer, 2009). Moreover, PPD represents one of the most prevalent mental disorders during the transition to parenthood (Wang et al., 2021). PPD does not only

affect mothers but also fathers, and in some cases both parents simultaneously (Rao et al., 2020; Smythe et al., 2022).

The birth of a child represents one of the most significant, life-changing events in the life of parents. Parents are confronted with a plethora of psychological, social and physical changes, have to adapt to new circumstances and have to learn to bear the responsibility for a new-born child (Saxbe et al., 2018). From psychological research, we know that periods of transition are vulnerable phases associated with an increased risk of developing symptoms of psychopathology. Hence, the transition to parenthood represents a critical window for the mother's and father's mental health (Saxbe et al., 2018).

In addition to the changes and challenges emerging during the transition to parenthood, many women experience a lot of pressure from the world outside. The society expects mothers to be the happiest in the world because they have been blessed with a child. However, the negative sides of a childbirth, such as pain, birth injuries, childbirth related trauma or postpartum mental illness, are topics people rarely talk about. Women with such experiences often feel misunderstood or that their suffering is not fully acknowledged (Zauderer, 2009). Princess Diana told in the aforementioned interview (BBC, 1995) that people who were close to her at this time, did not understand the seriousness of their condition and described her as "unstable" and "mentally unbalanced". For this reason, it is not surprising that women experiencing symptoms of PPD tend to suffer with their symptoms on their own and do not admit or seek help for quite a long time (Zauderer, 2009).

Although PPD has received increased attention from the public in recent years, PPD remains underdiagnosed and undertreated leading to far-reaching consequences for the new-born children (e.g., impaired mother-infant bonding, problems in social and emotional development; Pawils et al., 2022). Moreover, PPD has a strong influence on a societal level

(A. Bauer et al., 2016). Due to the direct and potentially long-lasting effects on the well-being of mothers and their children, the World Health Organization (WHO, 2015) emphasizes the fundamental importance of maternal mental health for the achievement of global health goals. Although the BBC's interview shows, PPD can affect anyone during the transition to parenthood, even the most privileged individuals in the world, a large body of literature identifies psycho-socially burdened mothers (e.g., mothers with low levels of education, low socioeconomic status [SES]) as a vulnerable group for developing symptoms of PPD (Hutchens & Kearney, 2020; Wang et al., 2021). This vulnerable group is not only at higher risk of developing symptoms of PPD but is also more likely to remain untreated, reflecting existing inequalities within the healthcare system (Dickman et al., 2017).

However, the perinatal period, that is from beginning of pregnancy until the end of the first year postpartum, provides numerous opportunities to identify maternal depression at an early stage (O'Hara & McCabe, 2013). Rarely are women as closely integrated into the healthcare system as during this period. In Germany, women are accompanied by their gynecologist during pregnancy and the postpartum period, usually receive home-visits from their midwives, attend birth educational classes and maternity clinics during their childbirth, and visit pediatricians after the birth of the child for regularly check-ups, the so called "U-Untersuchungen" (Pawils et al., 2022; Stentzel et al., 2024). Hence, there are multiple opportunities to identify women at-risk and refer them to preventive measures or treatment. However, this potential has not been fully utilized, yet. Many experts share the opinion that early identification and treatment of PPD is often not guaranteed, making it a serious public health problem and highlighting the need for research in the field of preventing and treating PPD (Goldin Evans et al., 2015; Pawils et al., 2022; Stewart & Vigod, 2019).

With this thesis, I aim to deepen our understanding of PPD by addressing unresolved questions regarding its etiology, consequences and prevention. My motivation was to enhance

the development of effective prevention strategies for mothers and fathers during the postpartum period. Furthermore, a central focus of my work lies in addressing the needs of mothers facing psychosocial burdens, particularly those most vulnerable during this period of life, with the aim of ensuring their voices are heard and their challenges are addressed within the scientific and clinical field.

1.1 The Clinical Picture of Postpartum Depression

The American Psychiatric Association (APA, 2013) defines PPD as a Major Depressive Disorder (MDD) 'with peripartum onset'. Hence, according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; APA, 2013) PPD shares the same diagnostic criteria as MDD: depressed mood most of the day and/or markedly diminished interest/pleasure in all or almost all activities most of the time; alterations in appetite up to significant weight loss or weight gain; sleep disturbances; impaired concentration; fatigue or loss of energy; psychomotor agitation or retardation; feelings of worthlessness and inappropriate guilt; and suicidality. The symptoms cause clinically significant distress and lead to functional impairment in the individual's daily life (APA, 2013, p.160).

Although PPD is not regarded as an independent diagnosis or disease, a growing body of literature challenges this assumption (Radoš et al., 2024). Besides the symptoms mentioned in the DSM-5, postpartum depressive symptoms also include feelings of anxiety and irritability (Jolley & Betrus, 2007), feeling overwhelmed (Stewart & Vigod, 2019), excessive worry and rumination about the baby's health and safety (DeJong et al., 2016; Fox et al., 2018). Studies comparing women with PPD to those with MDD indicate that anxiety, psychomotor symptoms and impaired concentration are more prevalent and pronounced in women with PPD (I. H. Bernstein et al., 2008; Hendrick et al., 2000; Radoš et al., 2024). Additionally, research indicates that differences and subtypes exist within individuals with PPD, varying in severity of symptoms, timing of onset, comorbid anxiety, and suicidal ideation (Postpartum Depression: Action Towards Causes and Treatment (PACT), 2015).

The specifier 'with peripartum onset' can be applied to all MDD-diagnoses occurring during pregnancy and in the four weeks following delivery. However, studies investigating the course and onset of PPD suggest that PPD can also occur later during the first year after birth

(Bai et al., 2023). Therefore, researchers and clinicians often adopt a broader definition of PPD, describing PPD as a depressive episode emerging within the first year postpartum (O'Hara & McCabe, 2013).

For the detection of PPD, questionnaires like the Edinburgh Postnatal Depression Scale (EPDS; Bai et al., 2023; Cox et al., 1987) or Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) are widely used and recommended for the screening of PPD symptoms (Siu et al., 2016; Stewart & Vigod, 2019). The usage of standardized clinical interviews represents the gold standard in clinical practice as well as in research (Stewart & Vigod, 2019). From a differential diagnostic viewpoint, diagnoses like a birth related Post-traumatic Stress Disorder (PTSD), Anxiety Disorders, Obsessive Compulsive Disorder (OCD), Bipolar Disorder, postpartum Psychosis, and untreated medical conditions (e.g., thyroid dysfunction and anemia) should be considered (Stewart & Vigod, 2019). Moreover, a diagnosis of PPD must be distinguished from the so called 'postpartum blues' or 'maternity blues'(Stewart & Vigod, 2019). 'Postpartum blues' comprises symptoms similar to PPD, but tend to last less than two weeks during the first weeks after birth (O'Hara & Wisner, 2014).

1.1.1 Postpartum Depression as a Global Health Challenge

Studies investigating prevalence rates of PPD show a wide range. In a meta-analysis with a total of 565 studies from 80 different countries, Wang et al. (2021) report a pooled prevalence from 17% for the world's female population. Differences in prevalence rates exist depending on geographic regions, with high-income countries showing the lowest and low to middle-income countries showing higher prevalence rates (Mitchell et al., 2023).

Moreover, prevalence of PPD varies substantially between different systematic reviews and meta-analyses depending on the definition of PPD, countries involved, diagnostic tools, threshold of discrimination chosen for the screening measure, and period over which the

prevalence is determined (Bai et al., 2023; Slomian et al., 2019). For instance, another meta-analysis including only studies assessing PPD based on clinical interviews, found a prevalence of 7% (Bai et al., 2023). Importantly, beyond methodological differences, research also suggests that external factors, such as the COVID-19 pandemic, have contributed to an increase in the occurrence of PPD (Chen et al., 2022). Although PPD represents a disorder typically associated with women and has predominantly been studied in mothers, fathers can also experience symptoms of PPD. Studies show prevalence rates for peripartum depression ranging from 7 to 14% in fathers (Rao et al., 2020). The prevalence rate for the occurrence of PPD in both parents at the same time is about 3% (Smythe et al., 2022). In such cases, the combined impact on the family system is likely to be profound, potentially leading to far-reaching effects on both parental well-being and child development.

1.1.2 Postpartum Depression and Its Wide-Ranging Consequences

PPD is associated with far-reaching consequences for mothers, their families and in particular their children, and society as a whole (Coretti et al., 2019; Slomian et al., 2019). On societal level, the economic burden of perinatal mental health issues, particularly perinatal psychosis, anxiety and depression, are substantial (A. Bauer et al., 2016). For instance, in United Kingdom, a single case of perinatal depression is estimated to cost society approximately £74,000 (A. Bauer et al., 2014). The costs are related to the long-term consequences for mothers (e.g. productivity losses, losses of quality of life) and for their children (e.g., mental health issues, infant death; A. Bauer et al., 2014).

Women experiencing severe forms of PPD are more likely to experience a socioeconomic decline (Slomian et al., 2019) and are more likely to end up in homelessness (Curtis et al., 2014). Furthermore, PPD does not only impact the mental health of mothers in the long run (Da Costa et al., 2006); it also affects the maternal physical health. Women with

symptoms of PPD tend to neglect their health behaviors after birth leading to poor physical health conditions, such as obesity due to weight retention and cardio-vascular diseases (Lu et al., 2024; Papadopoulou et al., 2023; Van Uytsel et al., 2022; Versele et al., 2021). In addition to a decline in quality of life (Li et al., 2022), maternal suicidality is probably the most severe consequence of PPD and represents a leading cause of maternal mortality during the postpartum period (Lindahl et al., 2005; PACT, 2015).

On family level, mothers suffering from PPD experience more financial problems, illness among relatives, lower quality in romantic relationships, and worse household functioning (Slomian et al., 2019). One of the most relevant consequences of PPD is the adverse impact on mother's caregiving behavior, including breastfeeding practices (Papadopoulou et al., 2023; Slomian et al., 2019). Moreover, maternal PPD has a negative impact on mother-child bonding and mother-child interaction. Mothers managing symptoms of PPD report reduced feelings of closeness, warmth, maternal sensitivity, and emotional involvement (Lanzi et al., 2009; Lilja et al., 2012; Mielke et al., 2020; Slomian et al., 2019) and a heightened risk of maladaptive parenting (Subbiah et al., 2024), hindering the development of a strong bond between a mother and her child and causing problems in the mother-child interaction. Disturbances in mother-child interaction, in turn, are seen as risk factors for child abuse and neglect (Mielke et al., 2020). These findings underscore the pivotal role of postpartum depressive symptoms in mothers, as disruptions in the mother-infant relationship can have profound and long-lasting effects on a child's emotional, cognitive, and social development. Therefore, disruptions in mother-infant relationship play a key role in the intergenerational transmission of depression (Felitti et al., 1998; Hosman et al., 2009; Löchner, Ulrich, et al., 2024).

Given the serious and far-reaching consequences of PPD on mothers, children, families, and even society as a whole, it is crucial to identify vulnerable families as early as possible.

Understanding the risk factors associated with PPD plays an important role in this process, enabling targeted prevention and intervention efforts to support families at high risk.

1.1.3 The Roots of Postpartum Depression: Exploring Its Risk Factors

Over 50 years ago, Rosenthal (1963) emphasized the interaction of genetic or psychological vulnerability with stressful life-events leading to the development of psychopathology, also known as the diathesis-stress model. According to the diathesis-stress model, women enter pregnancy and the postpartum period with pre-existing physiological and psychological vulnerabilities. These vulnerabilities, combined with stressors related to childbirth and the postpartum period, can increase the likelihood of developing depressive symptoms (Wolkenstein, 2023). Hence, a range of social, psychological and biological risk factors exist heightening the risk of PPD. Figure 1 provides an overview of vulnerability factors and stressors for the development of PPD during the transition to parenthood.

Hormonal changes, particularly fluctuations in reproductive hormones (i.e., estrogen and progesterone), as well as alterations in immune function have been implicated to play a role in developing symptoms of PPD (Stewart & Vigod, 2019). Hence, physical diseases affecting endocrine systems as well as genetic influences represent biological risk factors for the development of PPD. For instance, suffering from pre-pregnancy diseases like gestational diabetes mellitus (Liu et al., 2022) and premenstrual syndrome (PMS; Cao et al., 2020) might increase the risk of developing postpartum depressive symptoms. Furthermore, a family history of mental illness elevates the risk, underscoring the importance of genetic and familial predispositions (Zacher Kjeldsen et al., 2022).

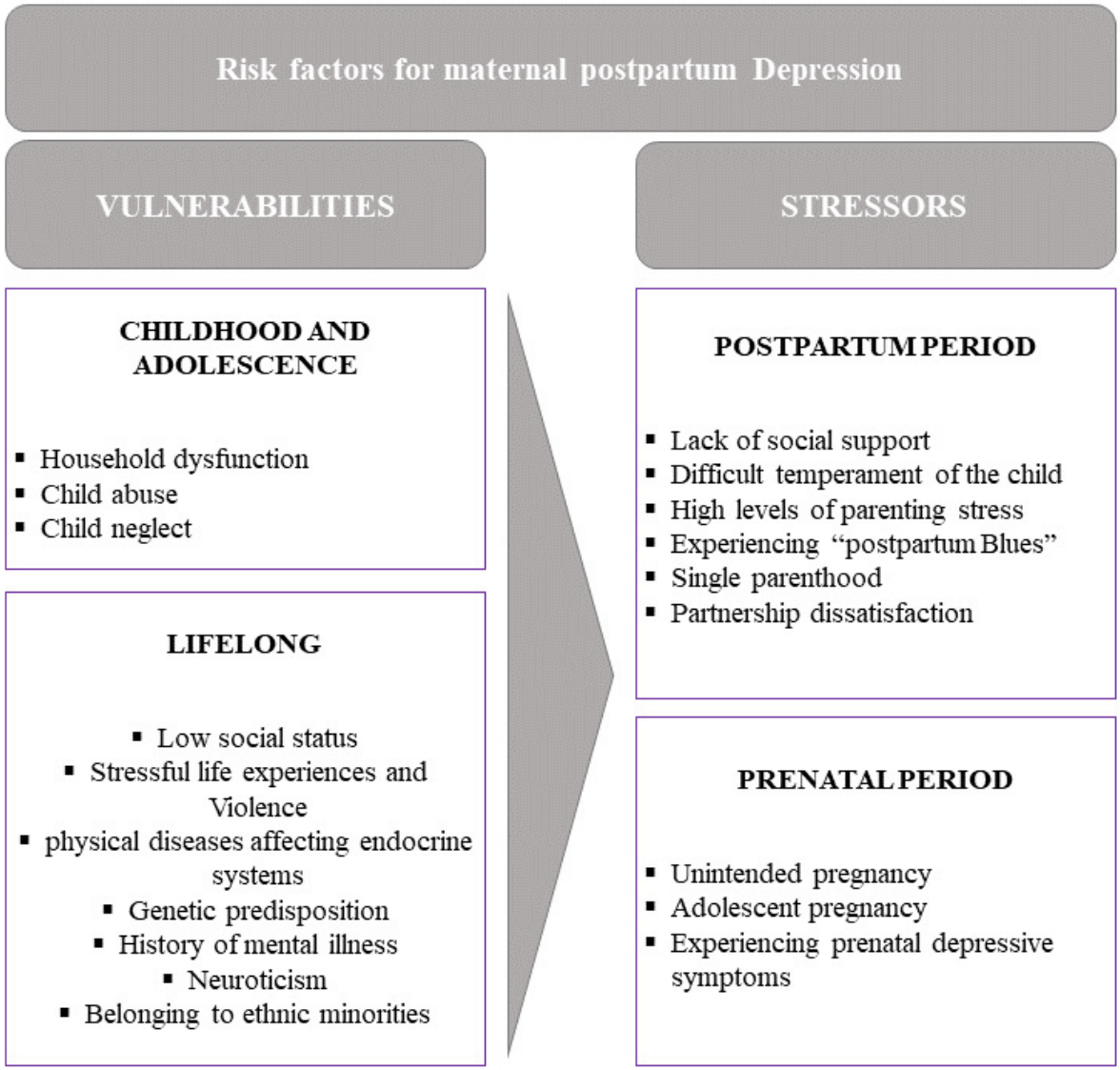
Besides biological factors, several psychological factors increase the risk of PPD. A history of one or more depressive episodes (Beck, 2001; Gopalan et al., 2022), experiencing prenatal depressive symptoms or ‘postpartum blues’ after delivery (Beck, 2001; Hutchens &

Kearney, 2020) increase the risk of PPD after birth. Additionally, high levels of distress during pregnancy and neuroticism are also associated with PPD (Hutchens & Kearney, 2020; Puyané et al., 2022). Furthermore, a large body of literature indicates a link between maternal adverse childhood experiences (ACE) and the development of PPD (Hutchens & Kearney, 2020; Racine et al., 2021), including experiences of loss, criminality, abuse and neglect as well as growing up with a mentally ill parent (Felitti et al., 1998).

Lastly, various social and environmental factors contribute to the risk of PPD. Lack of social support represents a well-studied and significant risk factor (Cho et al., 2022; Hutchens & Kearney, 2020; Racine et al., 2020). Support by the partner appears to play a particularly important role (Hitzler et al., 2022) while marital or partnership dissatisfaction, intimate partner violence and single parenthood are associated with PPD (Beck, 2001; Hutchens & Kearney, 2020; Wang et al., 2021). Moreover, parents with socioeconomic disadvantages (e.g., low income, low educational level, financial problems) have a greater risk of developing symptoms of PPD (Beck, 2001; Gopalan et al., 2022; Wang et al., 2021). Additionally, women from racial or ethnic minority groups are at an increased risk (Gopalan et al., 2022). Furthermore, experiencing parenting stress, being an adolescent mother, having an unintended pregnancy as well as certain child characteristics, such as a difficult temperament and, in some cultures, gender, have been identified as potential risk factors (Liu et al., 2022; Nelson et al., 2022; Venkatesh et al., 2014).

Figure 1

Risk Factors for Maternal Postpartum Depression According to the Diathesis-Stress Model (Rosenthal, 1963)



Note. The model presents risk factors, divided into vulnerabilities and stressors, heightening the risk of developing symptoms of Postpartum Depression (based on Rosenthal, 1963 and Wolkenstein, 2023).

1.1.4 Summary

In sum, PPD represents a widespread mental illness affecting men and women during the postpartum period with far-reaching consequences. A large body of literature investigated risk factors for PPD and identified several biological, psychological, and social risk factors that heighten the risk of developing symptoms of PPD. With respect to these findings, more research is needed on investigating the link between risk factors and PPD to better understand the development of PPD. Moreover, mechanisms mediating the link between risk factors and PPD should be investigated to identify personalized targets for preventive measures and the treatment of mothers and fathers with PPD. Aiming to advance research in this field, the next chapter will focus on traumatic childhood experiences of parents as one potential psychological risk factor for the development of PPD.

1.2 Shadows of the Past: The Impact of Maternal Experiences of Childhood Maltreatment During the Postpartum Period

The WHO (2024) defines childhood maltreatment (CM) as abuse and neglect that occurs to children under the age of 18 which results in "actual or potential harm to the child's health, survival, development or dignity in the context of a relationship of responsibility, trust or power". According to D. P. Bernstein et al. (2003), CM comprises five forms of abuse and neglect: *emotional abuse*, *physical abuse*, *sexual abuse*, *emotional neglect*, and *physical neglect*. These five subtypes of CM are defined by D. P. Bernstein et al. (2003, p. 175):

Sexual abuse is defined as "sexual contact or conduct between a child younger than 18 years of age and an adult or older person". *Physical abuse* is defined as "bodily assaults on a child by an adult or older person that posed a risk of or resulted in injury". *Emotional abuse* is defined as "verbal assaults on a child's sense of worth or well-being or any humiliating or demeaning behavior directed toward a child by an adult or older person". *Physical neglect* is defined as "the failure of caretakers to provide for a child's basic physical needs, including food, shelter, clothing, safety, and health care". The definition of physical neglect also includes poor parental supervision if it places children's safety in jeopardy. *Emotional neglect* is defined as, "the failure of caretakers to meet children's basic emotional and psychological needs, including love, belonging, nurturance, and support" (D. P. Bernstein et al., 2003, p. 175).

CM represents a common and widespread issue worldwide (Hillis et al., 2016). In Germany, the prevalence rates for experiencing at least one subtype of CM range from 28% to 35% in the general population (Klinger-König et al., 2023; Witt et al., 2018). Although many CM survivors have experienced a single subtype of CM, meta-analyses reveal moderate to strong positive associations between the five subtypes of CM indicating a frequent co-occurrence of the different subtypes (Matsumoto et al., 2023).

CM imposes significant societal costs due to its far-reaching consequences (Ferrara et al., 2015; Peterson et al., 2018). For instance, a study conducted by Habetha et al. (2012) estimated costs associated with the long-term consequences of CM in individuals aged 15 to 64 in Germany: The annual costs of trauma follow-up related to CM range from EUR 11.1 billion and EUR 29.8 billion. On an individual level, survivors of CM show an increased risk of developing negative physical health outcomes like obesity (Danese & Tan, 2014) or cardiovascular diseases (Basu et al., 2017), and psychopathology (Walsh et al., 2017). Moreover, CM is associated with less socioeconomic well-being (e.g., more unemployment, poverty; Herbert et al., 2023; Zielinski, 2009) over the whole life-span.

1.2.1 Childhood Maltreatment Increasing the Risk of Postpartum Depression

According to the in *chapter 1.1* presented diathesis-stress model (Rosenthal, 1963; Wolkenstein, 2023; see Figure 1), experiences of CM represent a risk factor heightening the vulnerability for psychopathology by weakening the stress response system and altering psychological processes (Heim et al., 2008; McLaughlin et al., 2020). The transition to parenthood can be particularly challenging for CM survivors, as the experience of bearing the responsibility for one's own new-born child might evoke memories or feelings related to negative experiences during their own childhood, including neglect, threat, or abandonment (Christie et al., 2017). Moreover, survivors of CM may fear that they will repeat the patterns of maltreatment they experienced as children (Madden et al., 2015; Roberts, 2014).

Over the past decades, research on the prevalence and consequences of traumatic childhood experiences on adult mental health has increased exponentially. Recent research has highlighted maternal ACEs, such as abuse, neglect, and household dysfunction before the age of 18, as factors contributing to anxiety and depression during the perinatal period (see meta-analysis from Racine et al., 2021). The relationship between ACEs and depressive symptoms

were even stronger during the postpartum period compared to the prenatal period, indicating that ACEs represent a powerful risk factor for PPD (Racine et al., 2021). However, the meta-analysis leaves open to which extend different types of ACEs are associated with PPD. While most of the studies examined the influence of a variety of ACEs on postpartum depressive symptoms (e.g., household dysfunction, abuse, neglect), nine studies investigated the association between (subtypes of) CM and postpartum depressive symptoms (Abboud et al., 2024; Cárdenas et al., 2022; De Venter et al., 2016; Epstein et al., 2024; Gartland et al., 2016; Letourneau et al., 2019; Nagl et al., 2017; Nidey et al., 2020; Seng et al., 2013). Seven studies found an association between CM and PPD (Abboud et al., 2024; Cárdenas et al., 2022; Epstein et al., 2024; Gartland et al., 2016; Letourneau et al., 2019; Nagl et al., 2017; Nidey et al., 2020). For instance, Nidey et al. (2020) report a 2.7-fold increased risk of developing symptoms of PPD for mothers with experiences of emotional and physical abuse compared to mothers without or with low exposure to CM. Furthermore, Letourneau et al. (2019) report small to moderate correlations between subtypes of CM and postpartum depressive symptoms. However, the remaining two studies could not find a significant association between CM and PPD (De Venter et al., 2016; Seng et al., 2013).

As a result of this body of research, there has been a growing call to implement trauma-informed approaches to perinatal care (Racine et al., 2021). However, research gaps remain and several questions regarding this field are still unanswered. Most studies investigated the relationship without controlling for the interaction of other risk factors potentially influencing the relationship between experiences of CM and PPD (e.g., level of SES, education). Regarding the association between subtypes of CM and postpartum depressive symptoms, studies showed inconclusive findings. Hence, further research is needed to explore the relationship between CM and PPD, particularly in understudied populations (e.g., psycho-socially burdened mothers, fathers), and to consider additional variables that may influence this association (e.g.,

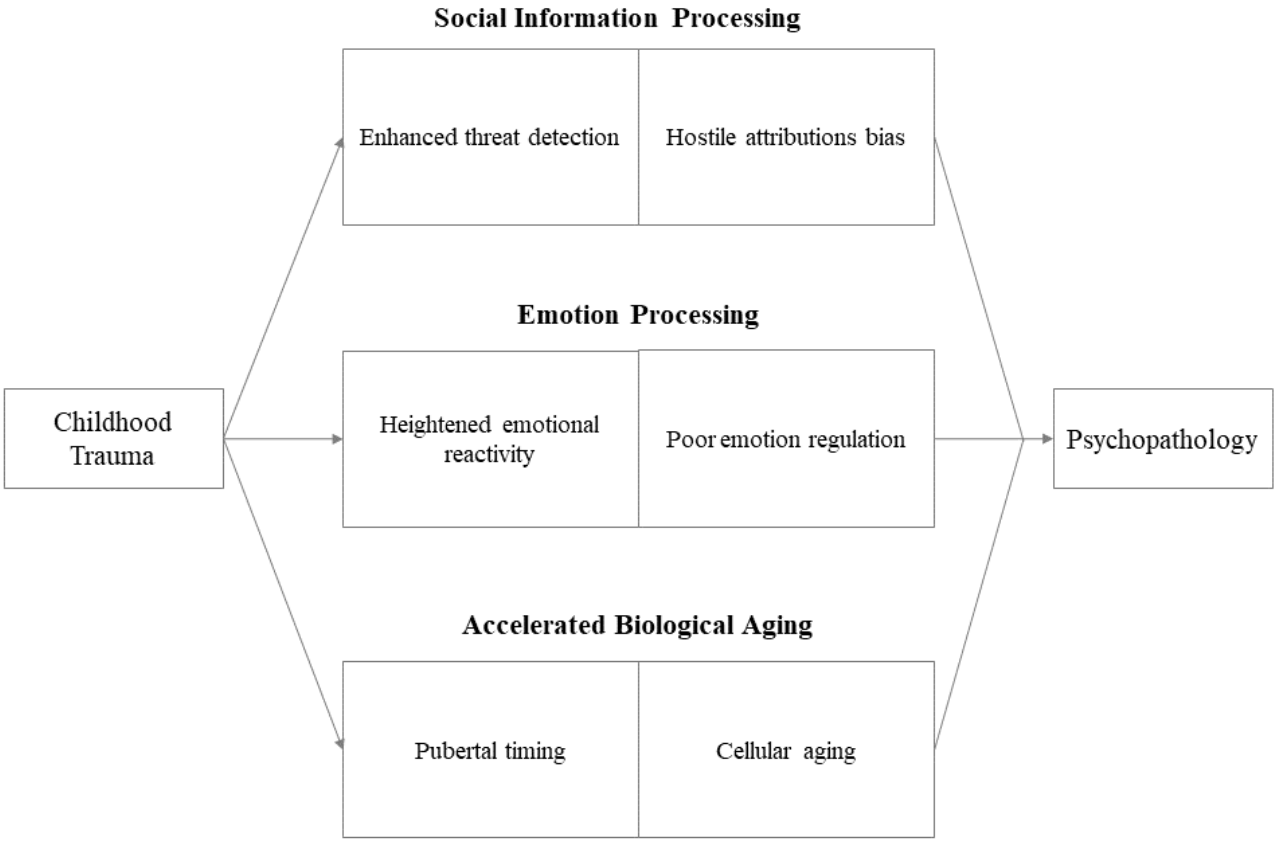
educational level, marital status). Furthermore, to develop trauma-related approaches for patient care, it is important to identify mechanisms mediating the relationship in order to explain how CM increases the vulnerability to PPD. Moreover, these mediating factors might represent prevention as well as intervention targets for parents with CM experiences.

Emotion Regulation: A Potential Mechanism Linking Childhood Maltreatment and Postpartum Depression

To date, many studies have explored the mechanisms underlying the relationship between CM and psychopathology. In their transdiagnostic model, McLaughlin et al. (2020) identify three mechanisms — accelerated biological aging, biases in social information processing, and impaired emotional processing — explaining how CM increases the risk of psychopathology in children and adolescents (see Figure 2).

Figure 2

Transdiagnostic Model linking Childhood Trauma to Psychopathology (adapted from McLaughlin et al., 2020, p.3)



Note. A transdiagnostic model of mechanisms linking childhood trauma to psychopathology spanning social, emotional, and biological domains (adapted from McLaughlin et al., 2020, p. 3).

Among these mechanisms, impaired emotional processing has emerged as particularly critical in the development and maintenance of psychopathology. Impaired emotional processing, defined as heightened emotional reactivity and difficulties in emotion regulation, has consistently been linked to psychopathology (Cludius et al., 2020; McLaughlin et al., 2020). In addition, studies have found an association between CM and increased emotional reactivity (McLaughlin et al., 2012; McLaughlin & Lambert, 2017). Furthermore, individuals

with experiences of CM tend to use more maladaptive emotion regulation strategies (e.g., rumination, suppression) and experience more difficulties in using adaptive emotion regulation strategies (Heleniak et al., 2016; McLaughlin & Lambert, 2017; Milojevich et al., 2019; Weissman et al., 2019). These findings have been observed in studies using different methodological frameworks (McLaughlin et al., 2020). Consistent with the transdiagnostic model from McLaughlin et al. (2020), studies have revealed impaired emotional processing as a mediator for the relationship between CM and psychopathology. For instance, Heleniak et al. (2016) identified increased emotional reactivity and maladaptive responses to distress as mediators for the association between CM and both internalizing and externalizing psychopathology in adolescents. In a study from Weissman et al. (2019), greater emotional reactivity and engagement in rumination mediated the longitudinal association between CM and increased psychopathology in children and adolescents aged 8-16 years.

Based on these findings and the transdiagnostic model, the question arises whether impaired emotional processing might serve as a mediator in the relationship between experiences of CM and PPD. Maternal CM has been linked to disruptions in postpartum maternal emotion regulation (England-Mason et al., 2017, 2018; Marysko et al., 2010; Souch et al., 2022). These difficulties include challenges in utilizing adaptive emotion regulation strategies and emotional awareness (England-Mason et al., 2017). Furthermore, CM was linked to attentional avoidance of both negative emotional and attachment-related negative emotional stimuli (England-Mason et al., 2018). Additionally, maternal CM has been connected to increased dissociative experiences during the first year postpartum, reflecting a lack of integration between thoughts, feelings, and memories (Marysko et al., 2010). However, no study has investigated difficulties in emotion regulation as a mediator for the relationship between experiences of CM and PPD, so far. Hence, examining this potential mediation could

offer valuable insights for the development of tailored interventions aimed at supporting mothers with CM experiences during the perinatal period.

1.2.2 Uncovering the Link Between Maternal Childhood Maltreatment and Impairments in Mother-Infant Bonding: The Mediating Role of Postpartum Depression

Despite the consequences for the mother's own health, experiences of maternal CM are also associated with negative consequences for their children. During the last years, theories linking maternal childhood experiences to their own parenting style emerged (Madden et al., 2015). Studies have supported these theories by showing a link between parenting styles mothers experienced during their own childhood and their own parenting behavior (Khoury et al., 2022; Moioli et al., 2022; Souch et al., 2022). Furthermore, research investigating the intergenerational transmission of abuse (also known as '*the cycle of abuse'*) showed an increased risk for maltreating one's own children when parents experienced forms of maltreatment during their own childhood (Altemeier et al., 1986; Bert et al., 2009). For instance, Möhler et al. (2009) found maternal CM exposure predicted more intrusive maternal behaviors. Furthermore, maternal experiences of CM were shown to reduce observed emotional availability, maternal sensitivity and increased maternal intrusiveness (Khoury et al., 2022; Moioli et al., 2022; Souch et al., 2022).

One mechanism underlying the link between CM and negative parenting outcomes like intrusive maternal behavior represent impairments in early mother-infant bonding (Mielke et al., 2020). During the first years of a child's life, mother-infant bonding represents a central psychological process building a functional mother-child relationship (Le Bas et al., 2020). Mother-infant bonding is defined as the emotional bond mothers develop towards their infant right after birth (Bicking Kinsey & Hupcey, 2013). Mother-infant bonding is characterized by positive feelings, emotional warmth, affection, and maternal behaviors such as cuddling or

smiling at the infant (Reck et al., 2016). From an evolutionary point of view, mother-infant bonding ensures a mother feels connected to her baby and spends time and energy to meet the baby's needs, assuring the baby's safety and healthy development. Reck et al. (2016, p. 473) describe the process of developing mother-infant bonding as “falling in love with the baby”. Strong and positive mother-infant bonding has been shown to promote both the children’s physical and mental health and laying the foundation for functional interpersonal relationships during adulthood (Puig et al., 2013). Conversely, impairments in mother-infant bonding (e.g., experiencing anger or anxiety towards the infant, being irritated by the infant; Brockington et al., 2001) can disrupt the mother-child interaction (e.g., reduced maternal emotional availability and sensitivity), increasing the risk of developmental problems (Tichelman et al., 2019). Most studies examining the association between maternal experiences of CM and impairments in mother-infant interaction show positive associations between maternal experiences of CM and impairments in mother-infant bonding, suggesting that maternal experiences of CM influence the quality of mother-infant bonding during the postpartum period (Bergunde et al., 2024; Lehnig et al., 2019).

Since many years pass between maternal experiences of CM and the birth of their children, it's important to find out which potentially intervening factors might influence the link between experiences of CM and impairments in mother-infant bonding. These factors could act as mediators, linking CM and mother-infant bonding in a causal way (Muzik et al., 2013). Understanding these mechanisms is crucial for identifying critical intervention points, as disrupting these processes may prevent the intergenerational transmission of maltreatment and promote healthier bonding experiences between mothers and their infants. By focusing on these mediating factors, preventive interventions could target not only the immediate effects of CM but also the underlying mechanisms maintaining the ‘*cycle of abuse*’ (Mielke et al., 2020).

One such potential intervening factor might be symptoms of PPD as maternal CM, symptoms of PPD and impairments in MIB show moderate to strong associations (see *chapter 1.1.2 & 1.2.1*). However, studies that examined the relationship of maternal CM and impairments in mother-infant bonding and controlled for symptoms of PPD revealed inconclusive findings (Bergunde et al., 2024; Lehnig et al., 2019; Muzik et al., 2013). Hence, studies examining PPD as a mediator for the relationship between maternal CM and PPD may shed a light on underlying mechanisms for this relationship, representing one aim of the current thesis. It is noteworthy, that one study emerged during the preparation of the thesis examining symptoms of PPD as a mediator for the relationship between maternal CM and impairments in mother-infant bonding (Chau et al., 2023). In this study, PPD partially mediated the relationship emphasizing PPD as an underlying mechanism for the intergenerational transmission of parenting. However, the study was cross-sectional and included only parents from Australia limiting its generalizability.

1.2.3 Summary

Chapter 1.2 highlights the profound impact of maternal experiences of CM on postpartum mental health (i.e., PPD) and mother-infant bonding. These intergenerational consequences emphasize the critical need for interventions aiming to mitigate the effects of CM and prevent adverse outcomes in the postpartum period. Previous research has already provided valuable insights into the associations between CM, PPD and mother-infant bonding. However, research gaps remain. For instance, the underlying mechanisms linking CM to PPD and to impairments in mother-infant bonding are not yet fully understood. Furthermore, when investigating the link between CM and PPD, it is important to consider additional risk factors potentially affecting maternal mental health. Given the far-reaching consequences of PPD, effective prevention strategies are essential. The next chapter explores preventive approaches targeting PPD, with a particular focus on innovative solutions such as digital interventions.

1.3 Targeting Postpartum Depression – A Promising Field for Prevention

Among mental health issues, PPD provides an "unique opportunity" for preventive strategies as PPD occurs within a specific period of time (i.e., perinatal period) following a specific event, the birth of a child (O'Hara & McCabe, 2013, p.397). Hence, the period of time women and men are at increased risk of developing depressive symptoms is predictable. Furthermore, the perinatal period represents a time when women are in frequent contact with the healthcare system, particularly with midwives and gynecologists (Pawils et al., 2022).

Prevention measures can be divided into three categories, universal (e.g., all pregnant women), selective (e.g., targeting women at-risk), and indicative (e.g., women with sub-clinical symptoms of PPD) prevention (O'Hara & McCabe, 2013). Current findings emphasize indicative and selective prevention as more promising approaches in preventing depression than universal approaches (Dennis, 2005; Hetrick et al., 2016; Loechner et al., 2018). In European countries, preventive interventions are recommended in five clinical practice guidelines for women with increased risk of depression (i.e., women with previous episodes or increased depressive symptoms in pregnancy; Motrico et al., 2022).

A comprehensive overview of prevention approaches for PPD can be found in a review of Werner et al. (2015). Overall, studies examining the efficacy of prevention programs for PPD revealed small to moderate effects for psychological (*SMD* = .28) and exercise-based (*SMD* = .43) interventions (Motrico et al., 2023; Yuan et al., 2022). Psychological interventions appeared to be more effective in primiparous women and those without prior episodes of depression (Martín-Gómez et al., 2022). Preventive approaches focusing on dietary supplements and pharmaceutical interventions are inconclusive or indicate no significant effects for the prevention of depression (Dowlati & Meyer, 2021; Motrico et al., 2023). However, results of the aforementioned meta-analyses should be considered with caution, since

they revealed high levels of heterogeneity across the different trials (e.g., timing of intervention, timing of follow-up, and the training of clinicians or different background of healthcare professionals delivering the intervention). Additionally, most randomized controlled trials (RCTs) insufficiently included high-risk populations, limiting the generalizability (Motrico et al., 2023).

1.3.1 Challenges in Preventing and Treating Postpartum Depression

Although PPD appears promising for psychological and exercise-based prevention measures, preventing and treating PPD poses several challenges. Many mothers at-risk remain undetected and mothers with PPD stay undiagnosed (Pawils et al., 2022). Furthermore, therapy or counseling services are often scarce (due to structural undersupply in rural areas or shortage of healthcare professionals), leaving numerous mothers who seek help without access to adequate treatment (Pawils et al., 2022). In addition, mothers with PPD often experience feelings of guilt and shame and are afraid of potential consequences when admitting their depressive symptoms (e.g., having their baby taken away, public humiliation, stigmatization; Zauderer, 2009).

Families with psychosocial burdens (e.g., low SES, traumatic life events, low educational level) are often disadvantaged by these shortages and tend to be overlooked within current healthcare systems (U. Bauer, 2005; Ulrich et al., 2022). However, as noted in *chapter 1.1*, women experiencing psychosocial burdens represent a particular vulnerable group during the transition to parenthood. The fact that healthcare measures and research aiming to prevent mental illness and alleviate stress often fail to reach those most in need has been the focus of ongoing scientific debates and is also known as the *prevention paradox* (U. Bauer, 2005; Rose et al., 2008). For instance, a German study from Ulrich et al. (2022) provides supporting evidence for the existence of inequalities within in the context of German prevention services

targeting individuals during the transition to parenthood: Families with high educational levels and poor child health are more likely to utilize services, while socio-economically disadvantaged families and families experiencing high levels of stress were predominantly found in the low-service user group (Ulrich et al., 2022).

The *prevention paradox* affects a large number of individuals during the transition to parenthood. A German representative study revealed that approximately 5% of all families with children aged zero to three years are considered as highly burdened, while 36% experience moderate levels of burden (Lorenz et al., 2020). Notably, the study was conducted before the COVID-19 pandemic, suggesting that the levels of burden, particularly in vulnerable families, may have increased significantly (Renner et al., 2023). With regard to the large number of psych-socially burdened families and the particularly high needs within this vulnerable group, strategies overcoming the *prevention paradox* are urgently needed.

1.3.2 The Potential of Digital Interventions in the Field of Postpartum Depression

Considering, today almost everybody owns a smartphone and particularly women use smartphone apps as a source of information about pregnancy and perinatal health, mobile health (mHealth) interventions represent a way to overcome bottlenecks in healthcare systems (Wallwiener et al., 2016). mHealth interventions offer numerous advantages such as low-threshold access, geographic independence, constant availability and potentially lower costs (Paganini et al., 2018; Seiferth & Vogel et al., 2023). Since the transition to parenthood is accompanied by limited time resources of parents, interventions that are flexible and independent of time and location may be particularly well-suited for parents facing psychosocial burdens. Furthermore, mHealth interventions potentially avoid the likelihood of experiencing mental health stigma and therefore might encourage help-seeking behavior. This could be an advantage, especially in the group of new mothers, who often experience

particularly great pressure from society, have an inhibition to admit feelings of depression and sadness, and struggle with feelings of guilt and shame (Zauderer, 2009). Digital interventions have proven to be effective and cost-effective in many areas of the prevention and treatment of mental illnesses (Paganini et al., 2018). Blended care, which combines digital interventions with counseling or face-to-face conversations with psychotherapists, is considered as particularly promising by showing lower attrition rates than self-guided digital interventions (Linardon et al., 2019). Hence, mHealth interventions do not only represent a solution for several shortages in our healthcare system but have the potential to reduce health inequalities, such as the *prevention paradox*.

To date, a large body of studies developed and evaluated mHealth interventions aiming to promote maternal mental health and to reduce parenting stress during the transition to parenthood (Carona et al., 2023; Chan et al., 2019; Daehn et al., 2023, 2024; Haga et al., 2019; Lin-Lewry et al., 2024; Schmidt-Hantke et al., 2024). While some studies offer universal preventive interventions aimed primarily at detecting mothers with depressive symptoms early and thus preventing the onset and a chronic course of PPD (Daehn et al., 2023; Haga et al., 2019), other digital interventions strive to reduce depressive symptoms in subclinical or clinically relevant cases (Carona et al., 2023; Chan et al., 2019; Daehn et al., 2024). However, these interventions were neither specifically tailored to nor adequately examined in psycho-socially burdened families, once again leaving this vulnerable group neglected in the research on prevention and treatment of PPD. Hence, developing and evaluating interventions specifically tailored to the needs of psycho-socially burdened families aiming to reduce parenting stress and to prevent PPD, remains a gap in the current field of e-mental perinatal health.

1.3.3 Summary

In sum, digital intervention, such as mHealth based interventions, represent a promising approach for preventing mental illness and overcoming health inequalities in our current healthcare system. Several mHealth interventions exist aiming to prevent maternal PPD during the transition to parenthood. However, mHealth based solutions aiming to prevent PPD are not specifically tailored to the needs of psycho-socially burdened mothers. Moreover, studies examining the efficacy of these interventions failed to provide evidence in psycho-socially burdened families (Brusniak et al., 2020). Hence, there is a high need for developing an mHealth based intervention for the prevention of PPD specifically tailored to the needs of psycho-socially burdened families.

Another research gap represents the lack of scientific recommendations and guidelines for the development, evaluation and implementation of digital assessments and interventions (Seiferth & Vogel et al., 2023). The outbreak of the COVID-19 pandemic significantly accelerated digitalization in the healthcare system. However, in society and especially among healthcare providers, there is still significant skepticism regarding digital interventions and healthcare professionals (i.e., physicians, psychotherapists) remain skeptical about prescribing these interventions as they often question their efficacy and security (Torous et al., 2018). Furthermore, a plethora of uncertified applications (apps) are available in the App Store and Google Play Store promising to improve mental health. However, most of these digital interventions have not been adequately evaluated and often lack evidence-based content (Lecomte et al., 2020). There are further issues limiting the effectiveness and use of digital interventions, such as limited knowledge about the side effects and risks and high attrition rates (Hennemann et al., 2018). In addition, there are also concerns regarding the security and transparency of digital interventions, particularly mHealth interventions that are offered free of charge and provided by free-enterprise companies (Torous et al., 2018). Due to these existing

concerns and challenges, guidelines and frameworks to enhancing the transparency of the development and content of digital interventions and to increase (methodological) quality of studies investigating the efficacy are needed.

1.4 Aims of the Thesis

The objective of the current thesis was to contribute to a better understanding of PPD by expanding research on risk factors and consequences of PPD, and to develop and evaluate an mHealth-based intervention specifically tailored to the needs of psycho-socially burdened families, a particularly vulnerable group during the transition to parenthood. The publications of the current thesis are based on data from the European project *I-PREGNO* ("Prevention of unhealthy weight gain in families in pregnancy and postpartum using a mHealth-enhanced intervention"; Henning et al., 2023; Vogel & Färber et al., 2023). The project consisted of four sites (National Center for Early Prevention [NZFH]/ German Youth Institute, University of Bamberg, University of Graz, and Vrije Univeristy of Brussels) and was funded by *European Joint Programming Initiative: A Healthy Diet for a Health Life* (JPI HDHL).

The first part of the presented publications (*Publication I* and *Publication II*) reflects my interest in the field of parents with experiences of CM as a subgroup of psycho-socially burdened parents. CM represents a powerful transdiagnostic risk factor for the development of psychopathology in the adulthood. During the transition to parenthood, experiences of CM might become particularly distressing negatively impacting parental well-being and the relationship to their new-born child. *Publication I* investigated the association between severity of CM and the severity of postpartum depressive symptoms by controlling for other potential influencing factors (e.g., educational level). Furthermore, exploratory analyses examined emotion regulation as a mediator for the association between severity of CM and postpartum depressive symptoms. Hence, *Publication I* contributes to the research investigating the impact of experiences of CM on the development of depressive symptoms during the postpartum period and identifies a potential target (emotion regulation) for interventions aiming to promote mental well-being in mothers and fathers during the transition to parenthood. *Publication II* examined symptoms of PPD as a mediator in the relationship between experiences of CM and

impairments in mother-infant bonding during the first year after birth. Hence, the study contributes to the research on the intergenerational transmission of parenting by uncovering the relationship between CM and impairments of mother-infant bonding, a mechanism associated with disturbances in mother-child interaction and negative parenting.

The second part of my thesis focused on the development and evaluation of the mHealth based intervention *I-PREGNO* specifically tailored to the needs of psycho-socially burdened families during the transition to parenthood. *Publication III* presents a description and evaluation of the development process of *I-PREGNO*. The objective of this paper was to increase the transparency of the content and the development process of mHealth interventions and to derive implications for research and practice for the development of mHealth interventions, especially with regard to interventions addressing psycho-socially burdened individuals. *Publication IV* presents the results of a cluster randomized controlled trial (cRCT) investigating the efficacy of *I-PREGNO* as a blended counseling intervention within an early childhood intervention program provided by the NZFH in Germany.

Through the process of developing and evaluating *I-PREGNO*, as well as the aforementioned lack of existing guidelines in the field of e-mental health (see *chapter 1.3.3*), the motivation arose to publish an international consensus statement in collaboration with a large group of scientist-practitioners and experts in the field e-mental health. Hence, *Publication V* provides an expert consensus for researchers and practitioners in the field of e-mental health covering the most important topics of the development, deployment and evaluation of e-mental health assessments and interventions.

2 Cumulative Publications of the Thesis

Publication I

Shadows of the past – Hierarchical regression analyses on the role of childhood maltreatment experiences for postpartum depression

This chapter is a post-peer-review, pre-copyedit version of an article published in Journal of Affective Disorders.

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Shadows of the past – Hierarchical regression analyses on the role of childhood maltreatment experiences for postpartum depression

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Abstract

Background: Postpartum depression (PPD) is one of the most common mental disorders in parents after birth. To develop tailored preventive programs, it is necessary to identify risk factors for PPD in parents. This study aimed to examine the impact of parental childhood maltreatment (CM) as a risk factor for PPD.

Methods: Data from a German study comprising $n = 349$ mothers and $n = 46$ fathers were used. Hierarchical regression models were performed to examine CM, educational background, single parenthood, emotion regulation and attachment style as predictors of symptoms of PPD. In exploratory analyses, potential mediators (i.e., parenting stress and emotion regulation) were investigated via a path model.

Results: CM, low level of education, difficulties in emotion regulation, and attachment anxiety were significant predictors for maternal PPD [$R^2 = .52$, $F\ (6, 305) = 57.99$, $p < .001$]. For fathers, difficulties in emotion regulation were identified as a predictor [$R^2 = .43$, $F\ (6, 24) = 4.78$, $p < .01$]. In exploratory analyses, emotion regulation served as a mediator for the link between CM and PPD as well as for the link between CM and parenting stress.

Limitations: The study design is cross-sectional and based on self-report questionnaires. Despite our attempts, only few fathers participated in the study, resulting in an underpowered sample for the regression analyses.

Conclusions: The study confirmed the assumption that CM experiences represent a risk factor for the development of maternal PPD. Emotion regulation might provide a pivotal target for interventions with parents at-risk.

Keywords: Childhood maltreatment, postpartum depression, emotion regulation

Introduction

Due to the numerous challenges and changes during the transition to parenthood (i.e., sleep deprivation, role changes), the postpartum phase represents a critical period for the development of psychopathology in life (Saxbe et al., 2018). With a prevalence of 17% worldwide (Wang et al., 2021), postpartum depression (PPD) is one of the most common mental disorders in women during the first year postpartum. In addition, the prevalence of PPD is also high in fathers with almost 10% three to six months postpartum (Rao et al., 2020). Being depressed right after giving birth does not only have a negative impact on the physical and emotional well-being of the parent (Huizink et al., 2017; Reck et al., 2016; Vismara et al., 2016), including suicidality (Chen et al., 2023), but interferes significantly with a healthy development of the new-born regarding parent-child-relationship, emotion regulation, and socio-emotional development (Erickson et al., 2019, Slomian et al., 2019). Given the high prevalence and the far-reaching potential consequences for those affected and their offspring, early detection of and the development of suitable preventive interventions for parental PPD are essential (Avalos et al., 2019). As part of this effort, identifying risk factors for PPD as potential targets for prevention programs is crucial.

Earlier research revealed a variety of social risk factors such as single parenthood (Wang et al., 2021), a low level of education (Cena et al., 2021), and economic deprivation (Ban et al., 2012) which can exacerbate (parenting) stress during the transition to parenthood and therefore increase the risk of developing depressive symptoms (Cornish et al., 2006; Vismara et al., 2016). Besides these recognized social risk factors, psychological factors may additionally elevate the risk of PPD by increasing parents' vulnerability. Insecure attachment – characterized by attachment avoidance and anxiety – represents a risk factor for maladaptive emotion regulation and psychopathology including PPD (Bifulco et al., 2004; Ikeda et al., 2014; Mikulincer & Shaver, 2016). Studies revealed heterogeneous findings regarding the

associations between attachment anxiety, avoidance and PPD with some studies identifying links between both types and PPD, while others report associations specifically between attachment anxiety and PPD (Bifulco et al., 2004; Warfa et al., 2014). In addition, dysfunctional emotion regulation also appears to elevate the risk for PPD, influencing how individuals cope with emotional distress and challenges (Aldao et al., 2010; Gross & Muñoz, 1995; Loechner et al., 2020). Earlier studies showed that maternal dysfunctional emotion regulation plays a key role in the etiology and maintenance of maternal PPD (Cardoso & Fonseca, 2023; Edwards et al., 2017; Haga et al., 2012). Alongside the aforementioned risk factors, childhood maltreatment (CM) comprising experiences of sexual, emotional and physical abuse as well as physical and emotional neglect during the parents' own childhood has been shown to be a serious risk factor for the development of depression across the lifespan (Felitti et al., 1998; Nelson et al., 2017). Parents with a history of CM may perceive more intense stress (McLaughlin et al., 2010; Thakkar & McCanne, 2000), have fewer coping strategies and therefore might be particularly vulnerable to develop PPD. In line with these findings, earlier research has identified early adverse childhood experiences (ACE; i.e., CM, parental mental illness, household dysfunction) as a risk factor for maternal PPD (Racine et al., 2021; Souch et al., 2022).

In sum, uncovering risk factors for PPD can be expected to be a crucial step enabling the development and further improvement of targeted prevention programs for high-risk groups during the transition to parenthood (Paul et al., 2023). In line with this perspective, international treatment guidelines recommend the systematic identification of parents at risk (NICE, 2014). Although it is conceivable that particularly parents who experienced CM have a high risk to develop PPD, there is still limited evidence for the association between CM and PPD, as the majority of studies assessed ACE in general instead of focusing specifically on CM. Moreover, no studies to date have investigated psychological mechanisms mediating the link between CM

and symptoms of PPD. Previous studies primarily investigated the relationship between maternal CM and depression during the antenatal period (Racine et al., 2021; Souch et al., 2022) with only few studies exploring the postpartum period (Nagl et al., 2017). Social factors as described above could also influence the relationship between CM and PPD (Metzler et al., 2017), and were not considered in previous studies investigating the link between CM and PPD. Additionally, to the best of our knowledge, no study has examined the relationship between CM and PPD in fathers.

To address the aforementioned limitations, the present study simultaneously explores the interaction between CM, psychological mechanisms (emotion regulation and attachment), social factors (i.e., educational level, single parenthood) and symptoms of maternal and paternal PPD. The study advances our understanding of the association between CM and PPD as both mothers and fathers are included in the present study.

Based on previous findings, we hypothesized that

(1) higher levels of CM are associated with more severe PPD symptoms.

(2) a lower level of education and being a single parent is associated with more severe PPD symptoms.

(3) greater difficulties in emotion regulation and an insecure attachment (anxiety and avoidance) are associated with more severe PPD symptoms.

Lastly, we hypothesize that CM significantly contributes to the explanation of the variance in PPD, even after controlling for risk factors like being a single parent, having a low level of education, difficulties in emotion regulation, and insecure attachment style.

Methods

The current manuscript represents a secondary analysis of pooled data from two randomized controlled trials (RCTs) conducted within the project "*I-PREGNO*" (trial I: Henning et al., 2023; trial II: Vogel et al., 2023). The common aim of the RCTs was to test the efficacy of a mobile health intervention to prevent unhealthy weight gain and psychosocial stress. Detailed procedural information is available in the study protocols for each trial (Henning et al., 2023; Vogel et al., 2023). The RCTs received ethical approval from the ethical committee of the University in Bamberg (nr. 2022-02/09). Both trials were registered at the German register for clinical trials (DRKS; DRKS00031067, DRKS00029673). The analyses and hypotheses of this paper were preregistered in the Open Science Framework (OSF; https://osf.io/s28n7).

Participants & Procedure

Mothers and fathers were recruited for the trials from September 2022 to August 2023 in Germany. In trial I, parents were recruited via social media and advertisements in daycare centers and medical practices. Inclusion criteria were owning a smartphone and having a child at the age between 0-12 months. Trial II was designed to recruit psycho-socially burdened parents. We therefore recruited mothers via healthcare professionals who work within an early childhood home-visiting program of the Federal Foundation for Early Childhood Intervention in Germany. For trial II, eligibility criteria were the experience of at least one psychosocial burden factor (see Vogel et al., 2023), receiving support from the home-visiting program for a minimum of 12 weeks, and owning a smartphone. In both trials, when the mother was registered and eligible for participation, fathers were also encouraged to participate. Exclusion criteria for both trials were: (1) < 16 years, (2) chronic condition influencing behavior related to energy balance such as diabetes, (3) lack of sufficient proficiency in German hindering app

usage and questionnaire completion, and (4) acute mental health issues hindering participation (e.g., acute suicidality, mania). A lifetime history of or a current mental disorder were not criteria for exclusion. Participants received 20 Euros after the second assessment.

Measures

All included variables were assessed online via Limesurvey (LimeSurvey Project Team / Carsten Schmitz, 2012) during the baseline-assessment (t0) with one exception. Attachment style was assessed in the post-assessment questionnaire (t1) 12 weeks after t0.

Childhood Maltreatment

CM was assessed using the Childhood Trauma Screener (CTS), a validated German short form of the Childhood Trauma Questionnaire (Bernstein et al., 2003; Grabe et al., 2012). The questionnaire consists of five items, each covering one form of CM (emotional, physical, and sexual abuse as well as emotional and physical neglect) on a 5-point-Likert scale ranging from 1 (not at all) to 5 (very frequently). The evaluation of the CTS is based on the sum score of the five items. In our sample, Cronbach's α was satisfactory (α = .74). Cut-off values were specified for the individual maltreatment experiences in order to assess the presence of CM subtypes: emotional and physical abuse ≥ 3, sexual abuse ≥ 2, and emotional and physical neglect ≥ 4 (Glaesmer et al., 2013). Due to a technical issue within the baseline assessment, physical neglect had to be assessed in a follow-up survey.

Postpartum depressive symptoms

To assess parental postpartum depressive symptoms, we used the German version of the Edinburgh-Postnatal-Depression-Scale (EPDS; Cox et al., 1987). The EPDS represents a 10-item self-report questionnaire that screens for PPD symptoms in mothers and fathers. Each item is rated on a 4-point Likert scale ranging from 0 to 3. A sum score higher than 9.5 indicates a diagnosis of PPD (Bergant et al., 1998). The questionnaires' psychometric properties have

been found to be satisfactory (Cox et al., 1987; Massoudi et al., 2013). Analyses of our data indicated good internal consistency (α = .87).

Sociodemographic Factors

Sociodemographic variables, including age, gender, education, and single parenthood, were measured through self-generated questions. For our analyses, we used dummy-coded variables for educational level and single parenthood (being a single parent = 1, high education = 1). High education was defined as a degree qualifying for university or university degree.

Emotion regulation

The German short form of the Difficulties in Emotion Regulation Scale (DERS) assesses emotional regulation strategies (Ehring et al., 2013; Gratz & Roemer, 2004). The questionnaire includes six subscales (non-acceptance of emotional responses, difficulty in engaging in goal-directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity). Each subscale comprises two to four items, making a total of 18 items, all of which are rated on a 5-point Likert scale, ranging from 1 (almost never) to 5 (almost always). The sum score of all subscales was used in the present analyses. Overall, the DERS has shown good psychometric properties (Victor & Klonsky, 2016). In our sample, internal consistency was good (α = .81).

Attachment style

The short form of the Experiences in Close Relationships-Revised questionnaire (ECR-R; Brennan et al., 1998; Ehrenthal et al., 2009) measures attachment style in adult partnerships on two dimensions (attachment anxiety and attachment avoidance). The questionnaire consists of nine items. Participants rate statements about their behavior in close relationships on a 7-point Likert scale, with 1 (strongly disagree) to 7 (strongly agree). For the evaluation, the mean values of the items were calculated for each of the two subscales. The psychometric properties

are reported as good (Ehrenthal et al., 2009). In our sample both subscales showed good internal consistencies (anxiety: α = .83; avoidance: α = .83).

Parenting Stress

The adapted German version of the Parenting Stress Index – Short Form (PSI; Abidin et al., 2006; German: Tröster, 2011) was conducted to assess parenting stress during the postpartum period. The questionnaire consists of 28 items divided into seven subscales with 4 items each (general health, role restriction, isolation, competence, attachment, partnership quality, and depression). Each subscale comprises four items rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), with higher scores indicating higher levels of stress. For the general parenting stress, a sum score of all subscales was calculated. We decided to exclude the subscale partnership quality, as this was only available fromx participants with a partnership. The studies indicate good psychometric properties (Abidin et al., 2006; Reitman et al., 2002; Tröster, 2011). Analyses of our sample indicated an excellent internal consistency (α = .91).

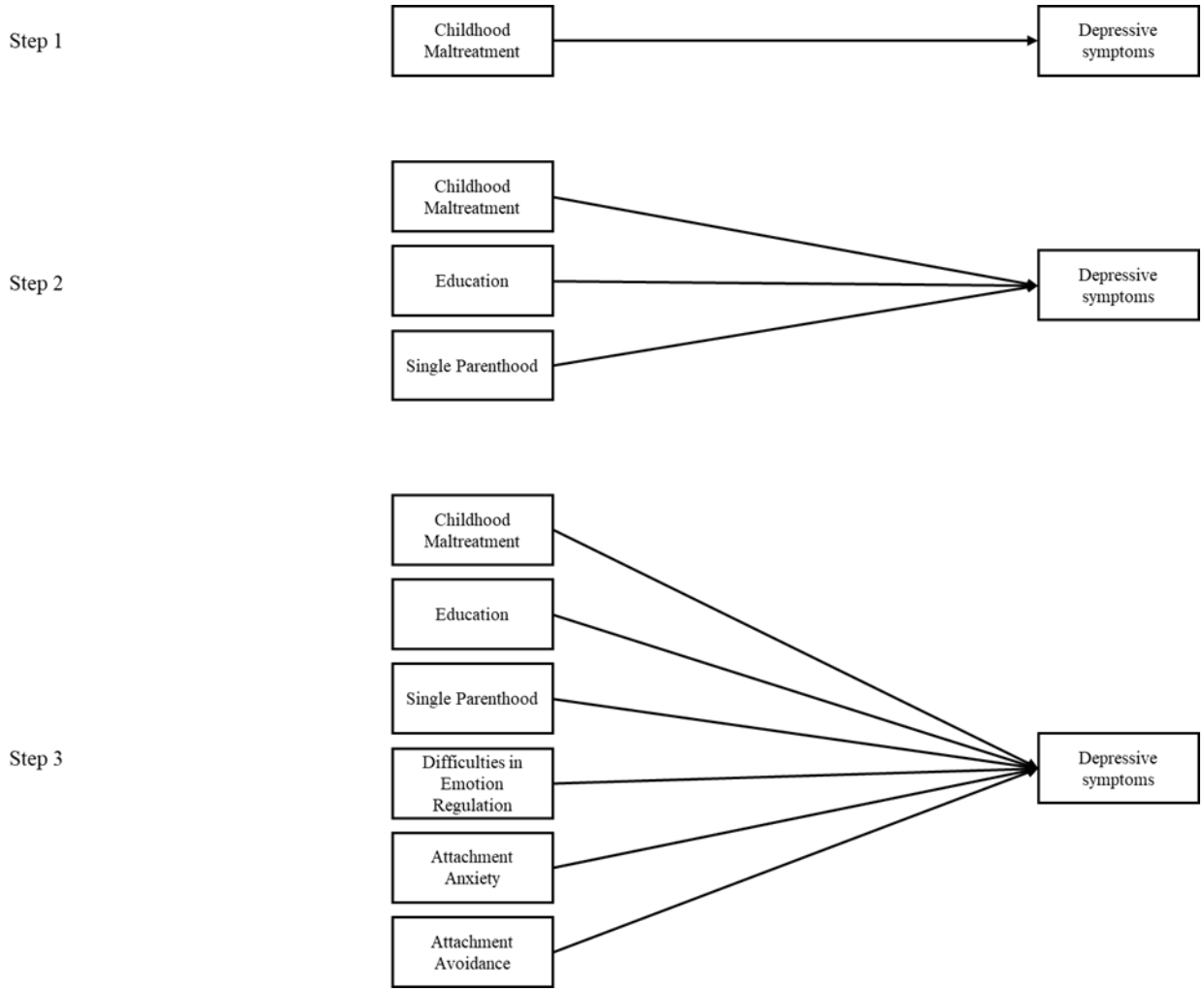
Data analytical strategy

Analyses were performed using SPSS 29 and RStudio version 2023.9.1.494. Two multiple hierarchical regression models (separate for mothers and fathers) were conducted with SPSS to examine whether parental CM predicted PPD during the first-year postpartum accounting for social and psychological variables. Both analyses involved three steps, with CM entered in step 1. Afterwards, dummy coded social variables (high level of education level and single parenthood) were added in a second step and psychological variables (difficulties in emotion regulation, attachment anxiety and attachment avoidance) added in the third step (see Figure 1). For the interpretation of our results we used the coefficient of determination (adjusted R^2), estimated regression coefficients (B), and - to compare the different coefficients

– standardized regression coefficients (ß). A priori power analysis was performed for the multiple hierarchical regression models using G*Power 3.1 (Faul et al., 2009). The required sample size was 347 participants, assuming an effect size of $f^2 = .06$ (see Racine et al., 2020) and aiming for a power of 1-ß = .95 (α = .05). When aiming for a power of 1-ß = .80 (α = .05) the required sample size resulted in 234 participants.

Figure 1

Step 1-3 of the Hierarchical Regression Models.

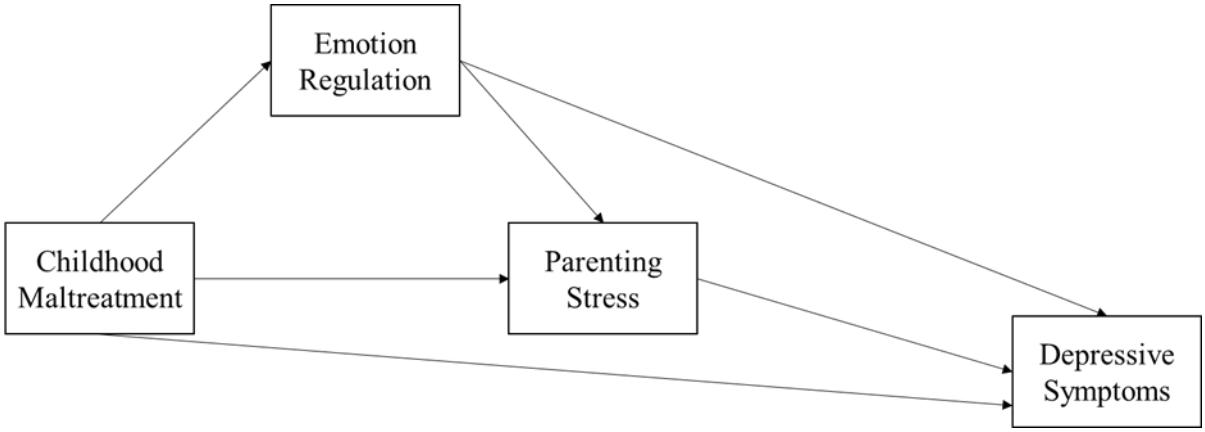


Note. Hierarchical regression analyses were performed separately for mothers (n = 312) and fathers (n = 31).

In addition, a multiple regression with the five subtypes of CM (items of the CTS) was conducted as predictors for postpartum depressive symptoms. In exploratory analyses, a path-analysis using the lavaan package in RStudio (v0.6-16) was performed to examine emotion regulation as a potential mediator for the association between CM and parenting stress, predicting the onset of PPD (Rosseel, 2012). Unfortunately, the sample size of fathers was too low for this kind of analyses. Figure 2 shows the assumed path model with the defined variables and paths.

Figure 2

Path Model with Emotion Regulation and Parenting Stress as Mediators for the Link Between Childhood Maltreatment and Postpartum Depression.



Note. The path model was only performed for mothers (n = 312).

Results

Altogether, n = 349 mothers and n = 46 fathers were included in the analyses. Due to missing data, a total of 343 participants (n(mothers) = 312; n(fathers) = 31) were included in the final regression models. On average, mothers were M = 32.63 (SD = 5.24) years and fathers M = 36.48 (SD = 4.93) years old. The baseline assessment was conducted at M = 5.11 (SD = 3.37) months postpartum. The frequencies, means, and standard deviations for all variables used in the analyses are reported in Table 1. In the sample, n = 102 (33 %) mothers and n = 7 (23 %) fathers had an elevated sum score on the EPDS (> 9.5), which indicates a diagnosis of PPD (Bergant et al., 1998).

Table 1

Overview about the Sociodemographic Variables and Social and Psychological Variables Used for the Analyses.

	Mothers	Fathers
	***n* (%)**	***n* (%)**

Citizenship		
German	273 (88 %)	2 (94 %)
Other citizenship	39 (13 %)	29 (7 %)
Education		
High	235 (75 %)	24 (77 %)
Low	77 (25 %)	7 (23 %)
Social welfare benefit	33 (11 %)	1 (3 %)
Single parenthood	32 (10 %)	1 (3 %)
Unplanned pregnancy	62 (20 %)	3 (10 %)
Primiparous parent	199 (64 %)	19 (61 %)
CM experiences (CTS items)		
Emotional Neglect	32 (10 %)	4 (13 %)
Physical Abuse	34 (11 %)	0
Emotional Abuse	69 (22 %)	5 (16 %)
Sexual Abuse	52 (17 %)	1 (3 %)
Physical neglect	10 (3 %)	1 (3 %)
	***M* (*SD*)**	***M* (*SD*)**
Total CM (CTS)	7.71 (3.32)	7.03 (1.89)
Depressive symptoms (EPDS)	7.82 (5.56)	5.87 (4.65)
Difficulties in emotion regulation (DERS)	36.04 (11.89)	34.39 (8.51)
Attachment		

Attachment anxiety (ECR-R)	2.84 (1.56)	2.66 (1.20)
Attachment avoidance (ECR-R)	2.52 (1.23)	2.28 (1.17)
Parenting stress (PSI)	69.51 (17.44)	68.68 (14.71)

Note. High education = degree qualifying for university or university degree; CM = Childhood maltreatment; CTS = Childhood trauma screener; EPDS = Edinburgh-Postnatal-Depression-Scale; DERS = Difficulties in emotion regulation scale; ECR-R = Experiences in close relationships – revised; PSI = parenting stress index.

Hierarchical multiple regression analyses

In both analyses of mothers and fathers, CM significantly predicted postpartum depressive symptoms (Step 1), even when including social factors (Step 2). Overall, the model of step 3 explained the most of the variance. For mothers, the change in R^2 was statistically significant in every step (see Table 2), indicating that the inclusion of level of education and psychological variables significantly improved the predictive power of the model. While a low level of education, difficulties in emotion regulation and attachment anxiety were significant predictors of depressive symptoms, single parenthood and attachment avoidance were not. The final model, including all predictors, explained 52 % of the variance in postpartum depressive symptoms.

Table 2

Results of Hierarchical Analyses in Mothers with Symptoms of Postpartum Depression as Dependent Variable.

	B	95% CI for *B*		*SE B*	*β*	*t*	R^2	ΔR^2
		LL	*UL*					
Step 1							.13	*N/A*
Constant	3.19	1.72	4.65	.75				

	Childhood maltreatment	.60	.43	.78	.09	.36	6.78***		
Step 2								.14	.02*
	Constant	5.34	3.06	7.61	1.16				
	Childhood maltreatment	.53	.34	.72	.10	.32	5.49***		
	High education	-1.88	-3.39	-.36	.78	-.15	-2.43*		
	Single parenthood	-1.64	-3.64	.37	1.02	-.09	-1.61		
Step 3								.52	.39***
	Constant	-3.78	-5.87	-1.69	1.06				
	Childhood maltreatment	.20	.06	.35	.08	.12	2.76**		
	High education	-1.67	-2.81	-.52	.58	-.13	-2.87**		
	Single parenthood	-1.47	-3.03	.09	.79	-.08	-1.86		
	Difficulties in emotion regulation	.28	.24	.32	.02	.59	13.56***		
	Attachment anxiety	.39	.04	.74	.18	.11	2.18*		
	Attachment avoidance	.13	-.30	.57	.22	.03	0.59		

Note. Postpartum depression was measured through the Edinburgh-Postnatal-Depression-Scale. Childhood maltreatment was measured through the childhood trauma screener, difficulties in emotion regulation through difficulties in emotion regulation scale, attachment style through questionnaire experiences in close relationships-revised. High education and single parenthood were implemented as dummy-coded variables. High education = degree qualifying for university or university degree. *B* = estimated regression coefficient; *CI* = confidence interval; *LL* = lower limit; *UL* = upper limit; *SE B* = standard error of *B*; ß = standardized regression coefficient; *t* = t-value of t-test; R^2 = adjusted R^2; ΔR^2 = change in R^2. *p<.05. **p<.01. ***p<.001.

For fathers, the change in R^2 was only significant in Step 3 (see Table 3), indicating that the inclusion of difficulties in emotion regulation and attachment style, but not level of education and single parenthood increased the predictive power of the model. More specifically, only difficulties in emotion regulation were a significant predictor in the final model, which explained 43 % of the variance in depressive symptoms.

Table 3

Results of Hierarchical Regression Analyses for Fathers with Symptoms of Postpartum Depression as Dependent Variable.

		B	95% CI for *B*		*SE B*	*β*	*t*	R^2	ΔR^2
			LL	*UL*					
Step 1								.17	*N/A*
	Constant	-1.90	-7.98	4.19	2.98				
	Childhood maltreatment	1.10	.27	1.94	.41	.45	2.70*		
Step 2								.11	.001
	Constant	-1.85	-10.86	7.17	4.39				
	Childhood maltreatment	1.10	.13	2.07	.48	.45	2.32*		
	High education	.02	-4.31	4.35	2.11	.002	.01		
	Single parenthood	-.77	4.49	-.03	4.49	-.03	-.17		
Step 3								.43	.34**
	Constant	-7.74	-15.99	.52	4.00				
	Childhood maltreatment	.87	-.002	1.74	.42	.35	2.06		
	High education	-1.73	-5.33	1.86	1.74	-.16	-1.00		
	Single parenthood	-3.55	-11.34	4.24	3.78	-.14	-0.94		

Difficulties in emotion regulation	.29	.10	.47	.09	.53	3.21**
Attachment anxiety	-.98	-2.34	.37	.66	-.25	-1.50
Attachment avoidance	.73	-.72	2.18	.70	.18	1.04

Note. Postpartum depression was measured through the Edinburgh-Postnatal-Depression-Scale. Childhood maltreatment was measured through the childhood trauma screener, difficulties in emotion regulation through difficulties in emotion regulation scale, attachment style through questionnaire experiences in close relationships-revised. High education and single parenthood were implemented as dummy-coded variables. High education = degree qualifying for university or university degree. B = estimated regression coefficient; *CI* = confidence interval; *LL* = lower limit; *UL* = upper limit; *SE B* = standard error of *B*; ß = standardized regression coefficient; *t* = t-value of t-test; R^2 = adjusted R^2; ΔR^2 = change in R^2. *p<.05. **p<.01. ***p<.001.

In-depth analysis of CM subtypes and psychological mechanisms

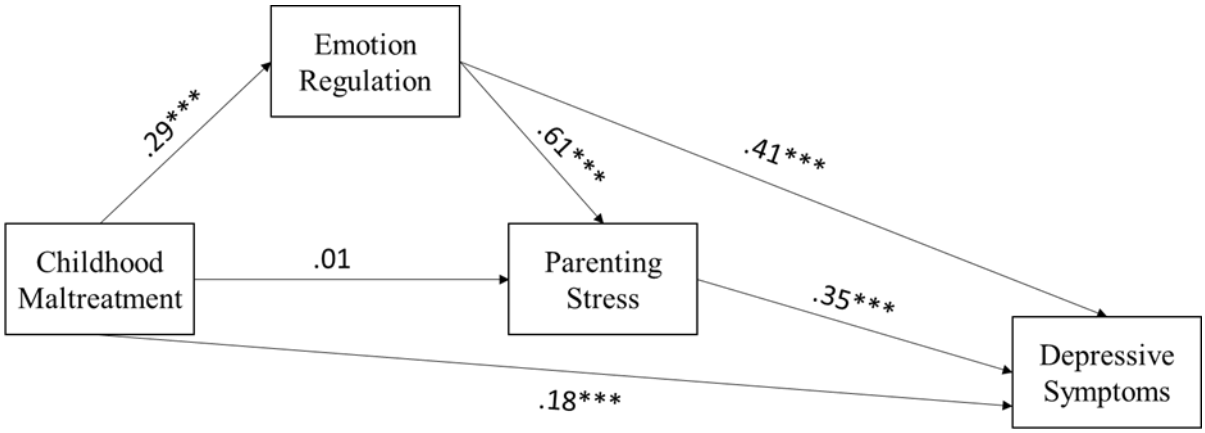
The exploratory analyses revealed that emotional abuse and emotional neglect in childhood served as significant predictors for higher scores in EPDS in mothers whereas physical neglect, physical abuse, and sexual abuse did not, $R^2 = 0.13$, F (5, 306) = 10.31, $p <$ .001 (see Table S1 in supplemental material).

The results of the path model are presented in Figure 3. Results showed a significant indirect effect of difficulties in emotion regulation mediating the link between CM and parenting stress, indicating a complete mediation of difficulties in emotion regulation between CM and parenting stress. Furthermore, we found a significant indirect effect with parenting stress mediating the link between emotion regulation and depression. The results indicate a partial mediation of parenting stress for the relationship between emotion regulation and

depression. Controlled for the aforementioned paths, indirect effect of parenting stress mediating the link between CM and depression was not significant, and the path between CM and PPD stayed significant. Overall, the path model explained 38% of the variance in parenting stress, 56% of the variance in depression and 9% of the variance in difficulties in emotion regulation.

Figure 3

Results of the Performed Path Model: Emotion Regulation and Parenting Stress as Mediators for the Link between Childhood Maltreatment and Postpartum Depression.



Note. N = 311 mothers. PPD = postpartum depression (measured through the Edinburgh-Postnatal-Depression-Scale). Childhood Maltreatment was measured through the childhood trauma screener, difficulties in emotion regulation through difficulties in emotion regulation scale, parenting stress through parenting stress index – short form.

Discussion

The current study aimed to examine experiences of CM as a predictor for symptoms of maternal and paternal PPD. In addition, we investigated the role of social factors (i.e., low education, single parenthood) and psychological mechanisms (i.e., emotion regulation, attachment) in this relationship. Furthermore, in in-depth analyses, we examined which subtypes of CM are associated with PPD and then investigated emotion regulation as a mediator for the relationship between CM and parenting stress leading to increased symptoms of PPD.

For mothers, our results confirmed the significant impact of CM on depressive symptoms during the first year after giving birth. Consistent with our hypotheses, low education, higher attachment anxiety, and greater difficulties in emotion regulation were associated with higher levels of depressive symptoms, with emotion regulation emerging as the predictor with the greatest influence on PPD (ß = .59). Further, the findings imply that despite controlling for social and psychological risk factors, experiences of CM affect maternal depressive symptoms during the first year postpartum. The results of the path model emphasize these findings, as the path between CM and PPD cannot be fully explained by the mediators (parenting stress and emotion regulation). Contrary to our hypothesis and existing studies, single parenthood and attachment avoidance were not associated with PPD. For fathers, we only found dysfunctional emotion regulation to be positively associated with the severity of symptoms of PPD, indicating that maladaptive emotion regulation strategies do have an impact on the development of symptoms of PPD in fathers after birth. However, due to the very low sample for fathers (n = 31) and the low prevalence rates of CM in this group, results need to be interpreted with great caution.

Overall, our study underscores the significance of the relationship between CM and depression during the postpartum period and thus contributes to the body of research focusing on CM as a risk factor for psychopathology in adulthood (Kessler et al., 2010). In line with most earlier studies investigating the association between ACE and PPD, our results confirmed CM as a risk factor for PPD (Racine et al., 2021; Souch et al., 2022).Yet, whereas earlier research has mostly used the broader concept of ACE, our results extend these findings by showing that CM in particular is associated with more severe symptoms of PPD. Hence, integrating systematic screening for CM in prenatal care could help identify vulnerable mothers. In contrast to other studies showing associations between PPD and sexual and physical abuse (Nagl et al., 2017; Souch et al., 2022), in-depth analyses conducted in our

sample indicated that only emotional abuse and neglect were significantly associated with PPD. This is in line with a meta-analysis investigating the link of CM and major depression in which emotional abuse and neglect emerged as predominant factors (Nelson et al., 2017). Future studies should investigate the association between different CM subtypes and PPD more in depth with longitudinal study designs.

Contrary to our hypothesis that single parents have an increased risk of PPD (Wang et al., 2021), our results did not confirm this assumption. One explanation for the increased risk for PPD in single parents may represent the lack of social support which could lead to an increase in depressive symptoms (Hitzler et al., 2022). Yet, since the majority of single mothers in our sample received help from an early childhood home-visiting prevention program, the effect of single parenthood on PPD could have been buffered by the received support. This assumption is in line with another study that investigated the effect of young maternal age and single status on maternal mental health (Agnafors et al., 2019). The authors point out that in the case of a single mother, the child's father or another caregiver who shares responsibility for the child is likely to reduce maternal stress, which in turn could lead to fewer symptoms of PPD in mothers. Furthermore, the number of single mothers was small (n = 32). A study with a greater number of single mothers and social support, and quality of relationships as control variables could provide more insight.

Regarding attachment style, our results support findings of previous studies showing that anxious attachment increases the risk for PPD in mothers (Bifulco et al., 2004). While evidence is mixed with respect to attachment avoidance, our results contribute to a larger group of studies showing no association between attachment avoidance and PPD (Warfa et al., 2014). An insecure attachment style is associated with less effective stress regulation and more difficulties to build, maintain and benefit from supportive relationships, which in turn might increase the likelihood of developing depressive symptoms. In times of heightened stress (e.g.,

during the transition to parenthood), where fears regarding the child and one's role as a parent possibly may exacerbate previous insecurities, individuals with more anxious attachment might feel more helpless and depressed. Our findings suggest that both CM and maternal anxious attachment independently predict the risk of PPD, with CM, especially emotional abuse and neglect, maintaining a significant association with PPD even when attachment style is added to the model.

This study found difficulties in emotion regulation to be highly associated with depressive symptoms during the first year postpartum for mothers as well as fathers. This aligns with research identifying dysfunctional emotion regulation strategies as a common risk factor for mental disorders (Gross & Muñoz, 1995) and initial studies investigating the link between difficulties in emotion regulation and PPD (Cardoso & Fonseca, 2023; Haga et al., 2012). In a longitudinal study from Haga et al. (2012), mothers who scored higher on emotion regulation strategies such as self-blame, rumination, and catastrophizing showed more severe symptoms of PPD, and women who tended to use more positive reappraisal and planning scored lower on measures of PPD. With respect to our findings, we assume that parents with dysfunctional emotion regulation strategies may be likely to have fewer resources coping with stress, which may result in an increase of depressive symptoms during the transition to parenthood. Consequently, our findings emphasize the assumption that dysfunctional emotion regulation should be considered as a key mechanism for the onset of PPD, which should be targeted in treatment and preventive interventions for PPD. In our path analysis examining the relationships between CM, emotion regulation, parenting stress, and PPD in mothers, we found several significant pathways. The path model indicates that mothers with CM experience more difficulties in emotion regulation. Difficulties in emotion regulation lead to increased parenting stress, which in turn is associated with higher levels of postpartum depressive symptoms. These results imply that experiences of CM in mothers might play a role in shaping emotion

regulation strategies, which in turn influences their mental well-being during the first year after birth of their own child. Hence, emotion dysregulation may not only be a general risk factor for PPD, but even serves as mediator in the relationship between CM and PPD. In line with our findings, individuals with CM were shown to have greater difficulties in emotion regulation (Heleniak et al., 2016). Results of previous studies showed that CM leads to disruptions in multiple processes involved in emotion regulation, including heightened emotional reactivity and increased maladaptive response focused emotion regulation strategies (e.g., rumination, suppression) to distress, which in turn function as vulnerability factors for internalizing and externalizing psychopathology in childhood, adolescence and adulthood (Heleniak et al., 2016; Weissman et al., 2019). With respect to these findings, our results of the current manuscript provide evidence for difficulties in emotion regulation representing an intrapersonal key mechanism for the link between CM and PPD (Heleniak et al., 2016; Klumparendt et al., 2019; Weissman et al., 2019). Since we observed a partial mediation between relationship of CM and PPD, it remains unclear which other psychological mechanisms might mediate this relationship.

Strengths and Limitations

The present study has some noteworthy limitations. First, we used self-report questionnaires, which introduces the possibility of response bias and may not fully capture the complexities of the assessed constructs. Due to the conceptualization of the study, the attachment style was assessed 12 weeks later than the other variables within the analyses. As adult attachment is considered to be a stable construct (Pinquart et al., 2013), we decided to include the variable in our analyses. Second, the cross-sectional nature of the data restricts causal inferences and emphasizes the need for longitudinal studies. Third, we were not able to include all possible risk factors for PPD in our analyses (e.g., family history of psychiatric disorders, other significant life events), as these variables were not collected in the studies we

used for the analyses. Although we pursued a holistic and dyadic approach in *I-PREGNO*, we did not succeed in recruiting many fathers for the studies. This is comparable with other research projects that focus on the transition to parenthood (Stahlschmidt et al., 2013; Yaremych & Persky, 2023). Since the power was very low, the results of the regression analysis with fathers should only be considered preliminary. However, the attempted and partially successful inclusion of fathers in the study represents a significant advancement in recognizing their role in child development and family dynamics, enhancing the comprehensiveness of the findings, even though we reached not enough fathers to perform full powered analyses.

The study possesses notable strengths that contribute to its importance. Firstly, the inclusion of a high-risk sample (psychosocial burdened parents) provides valuable insights into research neglecting populations facing heightened challenges. This is remarkable, since parents with high psychosocial stressors represent a particular hard-to-reach group, despite the need for understanding their burden and providing support. However, we cannot rule out whether this might overestimate the correlation between risk factors and PPD compared to the general population. Additionally, to our knowledge this is the first study disentangling the role of CM, as well as most salient social and psychological factors for PPD. The exploration of specific CM and mediation analysis of emotion regulation, CM and parenting stress for PPD are further novelties leading to important practical implications for parents-to-be.

Implications

The interpretation of the results from this study underscores several key points with clinical implications. First, the findings highlight the importance of parental mental well-being for preventive strategies for families during the transition to parenthood. Particularly, preventive interventions may benefit from enhancing emotion regulation skills to cope with the up-coming parenting stress in this period. Moreover, interventions aiming an early detection of

PPD (e.g., machine learning techniques; Paul et al., 2023) should not only screen for social and physical risk factors, but also for psychological risk factors including CM experiences, and difficulties in emotion regulation. Importantly, it is beneficial to extend support throughout the first year postpartum and not limit help to the late stages of pregnancy and the immediate postpartum period.

Based on the results of the path analyses, future research should examine CM and emotion regulation before birth, followed by postpartum parenting stress and PPD. If these findings are replicated in longitudinal studies, enhancing emotion regulation could serve as a significant preventive strategy. While the current study examined attachment and emotion regulation as mechanisms that influence parental PPD, it is advantageous to include other mechanisms discussed in the literature, such as the role of social support (Hitzler et al., 2022; Racine et al., 2020). Furthermore, future research would benefit from the involvement of fathers.

Conclusion

The current study confirmed that experiences of CM, low education, and attachment anxiety can be considered as a risk factors for maternal PPD. Mothers with experiences of CM should be recognized as mothers at-risk for PPD in the perinatal healthcare system. Furthermore, the results suggest that dysfunctional emotion regulation strategies might play a fundamental role in the development of maternal and paternal PPD. Emotion regulation offers a suitable tool for psychological interventions during the postpartum period. If findings can be confirmed in longitudinal studies, research should develop interventions focusing on enhancing emotion regulation strategies in parents during the transition to parenthood and investigate further mechanisms of PPD in parents with CM.

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Abbreviations

ACE: Adverse childhood experiences

CM: Childhood maltreatment

PPD: Postpartum depression

CTS: Childhood trauma screener

EPDS: Edinburgh-Postnatal-Depression-Scale

PSI: Parenting stress index

DERS: Difficulties in emotion regulation scale

ECR-R: Experiences in close relationships - Revised

OSF: Open science framework

RCT: Randomized controlled trial

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Ethical statement

The project received ethical approval from the ethical committee of the University in Bamberg (nr. 2022-02/09).

CRediT authorship contribution statement

LV: Conceptualization, Data collection, Analysis & Methodology, Writing – original draft, Writing – review & editing. JL: Conceptualization, Writing – review & editing, Supervision. TE, CW: Writing – review & editing, Supervision. CL, UL: Writing – review & editing. AO, CS, CH: Writing – review & editing, Data collection.

Declaration of competing interest

Authors have no conflict of interest to report.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used ChatGPT in order to improve the grammar, readability and language of the manuscript. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

Data availability

Due to ongoing analyses, data will not be publicly available prior to the year 2026. In 2026, the *I-PREGNO* data will be published on the OSF platform as part of the *I-PREGNO* project. If there is a legitimate interest in the data in advance, the data can be requested from the corresponding author.

Publication II

Understanding the Link Between Maternal Childhood Maltreatment and Mother-Infant Bonding: Postpartum Depression as a Mediator

This chapter is a pre-peer-review, pre-copyedit version of an article submitted in European Journal of Psychotraumatology.

Understanding the Link Between Maternal Childhood Maltreatment and Mother-Infant Bonding: Postpartum Depression as a Mediator

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Keywords

- Childhood Maltreatment
- Mother-infant Bonding
- Depression
- Mediation Analysis
- Intergenerational transmission of parenting

Highlights

- The current article examines the mediating effect of postpartum depression in the relationship between maternal experiences of childhood maltreatment and impairments in mother-infant bonding during the postpartum period.
- Postpartum depressive symptoms fully mediated the relationship between childhood maltreatment and impairments in mother-infant bonding.
- The results of the current article highlight the importance of addressing postpartum depression in mothers with childhood maltreatment experiences to promote mother-infant bonding and to support a healthy start for the child.

Abstract

Background. Impairments in mother-infant bonding during the postpartum period were shown to adversely affect a child's development. Research suggests that such impairments are associated with mothers' own childhood experiences of maltreatment. Hence, understanding factors that mediate this relationship is essential for developing targeted preventive interventions to support mothers who experienced maltreatment in their own childhood during the perinatal period.

Objective. As postpartum depression is associated with maternal experiences of childhood maltreatment and impairments in mother-infant bonding, we aimed to examine the mediating effect of postpartum depression in the relationship between maternal experiences of childhood maltreatment and impairments in mother-infant bonding.

Methods. Longitudinal data from N =128 mothers in the control group of an eHealth preventive intervention (*I-PREGNO*) were analyzed. Using a path model, we investigated whether the association between maternal childhood maltreatment (measured by the Childhood Trauma Screener) and mother-infant bonding (measured by the Postpartum Bonding Questionnaire) was mediated by postpartum depressive symptoms (measured by the Edinburgh Postnatal Depression Scale).

Results. Postpartum depressive symptoms fully mediated the relationship between maternal experiences of childhood maltreatment and impairments in mother-infant bonding (indirect effect [*ab*]: b= .44, p = .001, 95% *CI* [.18, .70]; direct effect [*c'*]: b = .01, p = .953, 95% *CI* [-.38, .41]; total effect [*c*]: b = .45, p = .041, 95% *CI* [.02, .89]).

Conclusion. Our results highlight the importance of addressing postpartum depression in mothers with childhood maltreatment experiences to promote mother-infant bonding and to support a healthy start for the child.

Background

Mother-infant bonding (MIB) during the first year postpartum is a crucial psychological process that has a significant impact on the infant's healthy cognitive, emotional, and social development (Le Bas et al., 2020). MIB is defined as the emotional and physical connection between a mother and her infant, fostering feelings of closeness and promoting the development of attachment (Bicking Kinsey & Hupcey, 2013; Nakić Radoš et al., 2024). MIB already begins during pregnancy (defined as the engagement in "behaviors that represent an affiliation and interaction with their unborn child"; Cranley, 1981, p. 282) and continues to develop after birth (Bicking Kinsey & Hupcey, 2013; Tichelman et al., 2019). A strong and positive MIB has been shown to promote both physical and mental health in infants while laying the foundation for functional interpersonal relationships until adulthood (Puig et al., 2013; Waters et al., 2000). Conversely, impairments in MIB (e.g., experiencing anger or anxiety towards the infant, being irritated by the infant; Brockington et al., 2001) after birth can disrupt the mother-child interaction (e.g., reduced maternal emotional availability and sensitivity), and increase the risk of problems in the infant's socio-emotional development (Lux et al., 2023; Mason et al., 2011). Research estimates that approximately 7% of women with new-born children experience MIB impairments in the first year postpartum, with prevalence rates rising to 17 - 29% in clinical samples (Brockington et al., 2001; Kerstis et al., 2016; Reck et al., 2006).

Parents' own childhood experiences evidently influence subsequent parenting styles, a process known as the intergenerational transmission of parenting (Madden et al., 2015). A well-known example of the intergenerational transmission is a phenomenon called 'cycle of abuse'. Mothers who have experienced maltreatment in their own childhood (maternal experiences of childhood maltreatment) show an increased risk of maltreating their own children (Savage et al., 2019). This is particularly meaningful given that childhood maltreatment represents a global problem with serious life-long consequences (Hillis et al., 2016). In Germany, for example, the

prevalence rates for experiencing at least one subtype of childhood maltreatment (emotional, physical, and sexual abuse, emotional, and physical neglect) range from 28 to 35% in the general population (Bernstein et al., 2003; Klinger-König et al., 2023; Witt et al., 2018).

Maternal experiences of childhood maltreatment are associated with negative parenting during the first year after birth (Fuchs et al., 2015; Souch et al., 2022) and later problems in caregiving (Dixon et al., 2005; Nuttall et al., 2012; Vaillancourt et al., 2017). Additionally, mothers who survived maltreatment during their own childhood often exhibit less sensitive behavior in interactions with their children (Bödeker et al., 2019; Rahma et al., 2018), a pattern that may be explained by impairments in MIB, and are considered as a potential mechanism underlying the intergenerational cycle of abuse (Mielke et al., 2020). Hence, experiences of maltreatment during one's own childhood may profoundly affect a mother's ability to form a connection with her own child (Leite Ongilio et al., 2023). Consistent with this theory, previous studies found a link between maternal childhood experiences of maltreatment and impairments in MIB during the first year postpartum (Lara-Cinisomo et al., 2018; Williams et al., 2022). In particular, emotional neglect and abuse in a mother's own childhood appear to contribute to difficulties in MIB during the first year postpartum (Bergunde et al., 2024; Lehnig et al., 2019).

Given the high prevalence of childhood maltreatment and existing evidence suggesting that experiences of childhood maltreatment can lead to substantial impairments in later MIB, the question arises as to which mechanisms might mediate this relationship. Postpartum depressive symptoms have been shown to be strongly associated with impairments in MIB (Tichelman et al., 2019), indicating that mothers experiencing depressive symptoms face several challenges in mother-infant relationships such as reduced emotional involvement (Goodman, 2007; Löchner, Ulrich, et al., 2024), and heightened negative parenting behavior (Lovejoy et al., 2000). These factors, in turn, may contribute to further impairments in MIB later on (Aran et al., 2022; De Palma et al., 2023; Wendelboe et al., 2021). Moreover, studies

have shown a relationship between experiences of childhood maltreatment and postpartum depressive symptoms in mothers (Racine et al., 2021; Vogel et al., 2025). Hence, postpartum depressive symptoms may act as a mediator in the relationship between experiences of childhood maltreatment and impairments in postpartum MIB. The results of a recent study by Bergunde et al. (2024) demonstrate that maternal experiences of childhood maltreatment lost significance as a predictor of impairments in MIB when considering postpartum depressive symptoms as a predictor in the regression model. In another study, mothers with a history of mental illness (i.e., a current or previous mental disorder) and experiences of childhood maltreatment showed reduced emotional availability compared to mothers with childhood maltreatment but without a history of mental illness and healthy controls (Mielke et al., 2020). Mothers without a history of mental illness did not differ from healthy controls (Mielke et al., 2020). The aforementioned findings were corroborated by a cross-sectional online study conducted in Australia, which identified postpartum depressive symptoms as a mediator in the relationship between psychological childhood abuse and impairments in MIB (Chau et al., 2023). However, the cross-sectional design of the study limits the ability to determine the direction of the relationships between the variables and hinders causal inferences.

Building on these findings, the current study aimed to deepen the understanding of the relationship between maternal childhood maltreatment and impairments in MIB by investigating postpartum depressive symptoms as mediator within a 12-week longitudinal study of mothers with infants up to 12 months postpartum. Based on previous findings, we hypothesized that

(1) maternal experiences of childhood maltreatment are significantly related to more impairments in MIB,

(2) maternal experiences of childhood maltreatment are significantly related to more postpartum depressive symptoms,

(3) postpartum depressive symptoms are significantly related to more impairments in MIB,

and (4) postpartum depressive symptoms significantly mediate the association between maternal experiences of childhood maltreatment and impairments in MIB.

Methods

The present study is a secondary analysis of a randomized controlled trial (RCT) conducted within the *I-PREGNO* project. A detailed description of the trial was published in a study protocol (Henning et al., 2023). The trial was preregistered at the German register for clinical trials (DRKS; DRKS00031067) and received ethical approval from the ethical committee of the University in Bamberg (No. 2022-02/09). *I-PREGNO* is an mHealth intervention developed to prevent unhealthy weight gain and to reduce postpartum stress and depression in parents during the transition to parenthood (Vogel & Färber et al., 2023, Vogel & Henning et al, 2024). For the current analyses, we used longitudinal data (comprising the baseline and post-assessment 12 weeks after baseline) of the RCT investigating the efficacy of *I-PREGNO* as a self-guided digital intervention in mothers during the first year postpartum. Maternal experiences of childhood maltreatment (assessed retrospectively) and symptoms of postpartum depression were measured at baseline, while impairments in MIB were assessed 12 weeks later at post-assessment. Analyses of the current manuscript included exclusively data from mothers receiving the control condition to rule out potential intervention effects. The analyses of the present manuscript were preregistered at Open Science Framework (OSF; https://doi.org/10.17605/OSF.IO/RZFJG).

Study Design & Participants

Recruitment for the two-arm RCT lasted from March 2023 until the end of July 2023. We recruited mothers and fathers of children aged between zero to 12 months using press

releases, social media advertisements, and the distributions of leaflets and posters at pediatricians, kindergartens, and child guidance counselling services. Interested mothers and their partners were able to register by completing an online questionnaire screening for inclusion and exclusion criteria. Parents were only included if they 1) had a child aged zero to 12 months, 2) owned a smartphone (android or iOS), 3) were at least 16 years old, and 4) had sufficient proficiency in German. Participants were excluded when they had severe mental health problems that hampered the ability of participating, or chronic diseases influencing behavior related to energy balance (e.g., diabetes, see Henning et al., 2023).

In case of inclusion, parents were randomly assigned to one of two study arms (either intervention group or control group) and informed regarding the study condition and study procedure via a telephone call lasting between 15 and 20 minutes. After the phone call, participants in the control group received an e-mail with an invitation to complete the online baseline assessment. Twelve weeks after the completion of the baseline assessment, participants in the control group were invited for the post-assessment via e-mail. They received shopping vouchers to the value of 20 Euros for the completion of the post-assessment. To prevent dropouts, participants were reminded via e-mail one, two, and three weeks following the initial invitation.

Measures

Amongst other measures, childhood maltreatment and postpartum depressive symptoms were assessed at baseline. MIB was assessed 12-weeks later at the post-assessment (t1). All assessments were performed online using self-reported questionnaires using Limesurvey version 5.6.57 (LimeSurvey Project Team / Carsten Schmitz, 2012). Sociodemographic variables were assessed within the baseline-questionnaire by self-generated questions. An overview of all the measurement instruments included in the study can be found in the study protocol (Henning et al., 2023).

Childhood Maltreatment

Mothers' childhood experiences of maltreatment were assessed with the Childhood Trauma Screener (CTS; Grabe et al., 2012), a validated German short form of the Childhood Trauma Questionnaire (CTQ; Bernstein et al., 2003). According to Bernstein et al. (2003) childhood maltreatment comprises five forms of neglect and abuse (emotional, physical, and sexual abuse, emotional, and physical neglect) experienced under the age of 18. The CTS consists of five items, each covering one form of childhood maltreatment on a 5-point Likert scale ranging from 1 ('not at all') to 5 ('very frequently'). The evaluation of the CTS is based on the sum-score of the five items. In our sample, Cronbach's α was satisfactory (α = .78). Cut-off values were specified for the subtypes of childhood maltreatment: emotional and physical abuse ≥ 3, sexual abuse ≥ 2, and emotional and physical neglect ≥ 4 (Glaesmer et al., 2013). Due to a technical issue in the baseline assessment, the physical neglect item had to be assessed in a follow-up survey.

Postpartum Depressive Symptoms

Maternal postpartum depressive symptoms were measured using the German version of the Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987). The EPDS represents a 10-item self-report questionnaire that screens for symptoms of postpartum depression in mothers after birth. Each item is rated on a 4-point Likert scale ranging from 0 to 3 and added together for a sum-score. The questionnaires' psychometric properties have been found to be good (Bergant et al., 2008; Cox et al., 1987; Massoudi et al., 2013). Analyses of our data indicated good internal consistency (α = .87).

Mother-Infant Bonding

Impairments in MIB were assessed by the German version of the Postpartum Bonding Questionnaire (PBQ-16; Brockington et al., 2001; German version: Reck et al., 2006). The

German version consists of 16 items. Each item is rated on a 6-point Likert scale ranging from 0 (‘always’) to 5 (‘never’). According to Reck et al. (2006), we calculated a sum-score of the 16 items, with higher scores indicating more problems. The 16-item version of the PBQ showed an internal consistency of α = .85 (Reck et al., 2006), which was replicated in our sample (α = .85).

Statistical Analyses

The purpose of the study was to investigate whether postpartum depressive symptoms mediate the association between maternal childhood maltreatment and impairments in MIB. Childhood maltreatment was retrospectively assessed at baseline, current levels of depression were also measured at baseline, and MIB was assessed 12 week later at the post-assessment, which is why we consider all time points as time-lagged. Statistical analyses were performed in R version 4.3.1. (R Core Team, 2021) with $\alpha = .05$ (one-sided). We handled missing data using Full Information Maximum Likelihood (FIML) estimation (Enders & Bandalos, 2001). After data inspection and quality checks, bivariate correlations among all variables of interest (i.e., sum score of CTS, EPDS, and PBQ) were examined using Pearson FIML correlations investigating hypotheses (1) to (3) (Baron & Kenny, 1986). In a next step, a path model was performed for the investigation of postpartum depressive symptoms (EPDS sum score) as a mediator for the relationship between childhood maltreatment (CTS sum score) and MIB (PBQ sum score) by using the delta-method and lavaan package (Rosseel, 2012).

Results

In total, we included $N = 128$ mothers in the current analyses (a study flowchart of the original RCT is provided in the supplementary material). Information of the sample description is presented in Table 1. On average, mothers reported a CTS sum-score of $M = 6.84$ ($SD = 2.69$). Out a total of 128 participants, 25% ($n = 32$) reported having experienced at least one subtype of childhood maltreatment (i.e., scored above the cut-off scores). Three percent ($n = 4$)

reported emotional neglect, 5% (n = 6) physical abuse, 15% (n = 19) emotional abuse, 14% (n = 18) sexual abuse, and 1% (n = 1) physical neglect. The average EPDS sum-score was M = 6.47 (SD = 5.05) and the average PBQ-16 sum-score was M = 11.31 (SD = 6.88).

Table 1

Sample's Descriptive Information

Mothers (N = 128)	
	M (SD)
Age (years)	33.41 (4.23) Range [22-48]
	***n* (%)**
Origin	
German speaking country (Austria & Germany)	122 (95 %)
Other	6 (5 %)
Educational level	
Graduation after 9 years of schooling	1 (1 %)
Graduation after 10 years of schooling	9 (7 %)
Degree qualifying for university or university of applied science	25 (20 %)
University degree	93 (73 %)
Receipt of social welfare	5 (4 %)
Primiparous	78 (61 %)
Planned Pregnancy	113 (88 %)
Infants	
	M (SD)
Age (months)	4.83 (SD = 3.39) Range [0-13]
	***n* (%)**
Sex	
Male	66 (52 %)
Female	61 (48 %)
Preterm birth (gestational age < 37 weeks)	5 (4 %)
Chronical disease	5 (4 %)

Note. Sample's description. The sample included N = 128 mothers. In one family, the information regarding the child's sex was unavailable. Age was rounded up to full months for analysis, meaning infants at the age of 12.5-12.9 months were recorded as 13 months old.

Correlations

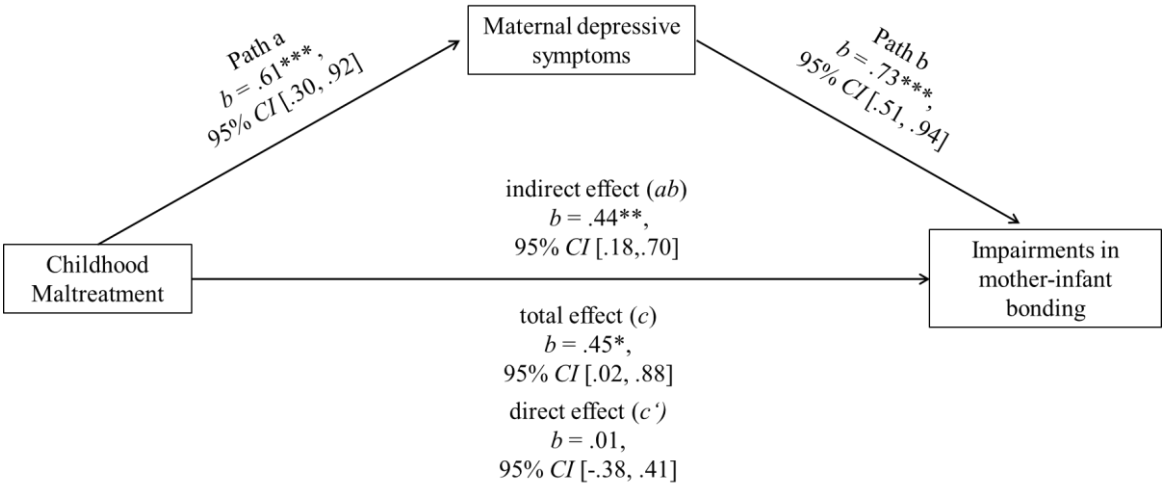
Testing hypothesis 1, correlation analyses revealed a significant small positive association between the CTS sum score and PBQ-16 sum-score (r = .18, p = .048, 95% *CI* [.01, .35]). In addition, the CTS sum score correlated significantly with the EPDS sum score (in line with hypothesis 2), showing a moderate correlation (r = .32; p < .001, 95% *CI* [.17, .48]). Lastly, there was a significant moderate to high positive correlation between EPDS and PBQ-16 sum score (hypothesis 3, r = .54, p < .001, 95% *CI* [.41, .66]).

Mediation Analysis

A mediation model was performed to investigate whether the association between maternal experiences of childhood maltreatment (indicated by the CTS sum score) and impairments in MIB (indicated by the PBQ-16 sum score) were mediated by postpartum depressive symptoms (indicated by EPDS sum score). Results are presented in Figure 1. The path model revealed a significant indirect effect (ab = .44, p = .001, 95% *CI* [.18, .70]) with postpartum depressive symptoms as a mediator between childhood maltreatment and MIB. The direct effect was not significant (c' = .01, p = .953, 95% *CI* [-.38, .41]) indicating a full mediation of the relationship between childhood maltreatment and MIB impairments. Overall, the model explained 29% of the variance of impairments in MIB (R^2 = .29).

Figure 1

Results of the Path-Model: Maternal Depressive Symptoms Mediating the Relationship Between Childhood Maltreatment and Impairments in Mother-Infant Bonding



Note. Childhood maltreatment was measured by the five-item Childhood Trauma Screener (Grabe et al., 2012); maternal depressive symptoms by the Edinburgh Postnatal Depression Scale (Cox et al., 1987); impairments in mother-infant bonding by the Postpartum Bonding Questionnaire (Reck et al., 2006). *b* = regression coefficient; *CI* = confidence interval. *** $p < .001$, ** $p < .01$, * $p < .05$.

Discussion

In the current study, we examined the mediating role of maternal depressive symptoms in the relationship between maternal experiences of childhood maltreatment and impairments in MIB during the postpartum period using data from the *I-PREGNO* project. In line with previous research (see Bergunde et al., 2024; Lehnig et al., 2019) and our hypotheses, our study showed a positive, although weak, association between childhood maltreatment and impairments in MIB, and a moderate positive association between childhood maltreatment and maternal postpartum depressive symptoms (see also Racine et al., 2021). Furthermore, a moderate to strong correlation between maternal depressive symptoms and impairments in MIB

was found, which is consistent with earlier findings (Doyle et al., 2023; Tichelman et al., 2019). This highlights the fundamental role of postpartum depressive symptoms for impairments in MIB. Due to our longitudinal design (postpartum depressive symptoms were measured 12 weeks before impairments of MIB), our results highlight the lasting negative influence of maternal symptoms of depression on MIB during the postpartum period. The quality of MIB during the first year of an infant's life plays a crucial role in shaping the overall mother-infant relationship and is considered as a fundamental component of healthy infant development (Brockington et al., 2001; Reck et al., 2006). Given this, our findings emphasize the importance of early identification and intervention for postpartum depression to support both maternal well-being and optimal child development.

Confirming our key hypothesis, postpartum depressive symptoms fully mediated the relationship between maternal experiences of childhood maltreatment and impairments in MIB. Consequently, the results of our study endorse findings from other studies in which experiences of childhood maltreatment lost significance as a predictor for impairments in MIB after controlling for maternal depressive symptoms (Bergunde et al., 2024; Mielke et al., 2020). Overall, the mediation model explained 29% of the variance in MIB, highlighting the substantial contribution of the examined factors to the understanding of MIB. Other factors, such as the infant's temperament or adverse experiences during birth may also play a role (Doyle et al., 2023; Junge-Hoffmeister et al., 2022). Since we included mothers during the entire postpartum phase (until 12.9 months after birth), our findings can be interpreted not only in the context of the first few weeks after birth but also across the entire first year of the child's life.

Overall, our model suggests that maternal mental health represents a key mechanism mediating the relationship between maternal experiences of childhood maltreatment and impairments in MIB. This insight is crucial for designing targeted preventive and therapeutic

interventions. First, the finding that experiences of childhood maltreatment may not directly lead to impairments in MIB offer reassurance to mothers who have experienced maltreatment during their own childhood. Therefore, incorporating this information into psychoeducational interventions for this target group could be beneficial. Second, interventions aiming to improve MIB in childhood maltreatment survivors should not only focus on MIB itself, but may benefit of treating co-occurring maternal depressive symptoms. Third, (preventive) interventions focusing on postpartum depressive symptoms in turn should also include the assessment of problems in MIB and consider adding interventions targeting MIB if necessary. Therefore, future studies on interventions targeting maternal postpartum depression should assess their efficacy in improving MIB.

Although our study has several strengths, such as disentangling the effect of childhood maltreatment on MIB and using longitudinal data, there are some important limitations. First, our sample was a highly educated community sample with low psychosocial burden and low symptoms of depression. As expected the prevalence rates of childhood maltreatment in mothers were lower than in the general German population (25% vs. 35%, Witt et al., 2018), potentially compromising external validity. This limitation has been noted in other studies as well (e.g., Bergunde et al., 2024), suggesting that reaching psycho-socially burdened parents represents a general challenge that should be carefully considered in future research. Due to the selective sample, which showed the abilities to enroll and participate in a longitudinal and self-guided eHealth study, the results of this study might underestimate the true effects. Participating mothers showed substantial self-organizational and motivational aspects, which is hardly seen in parents with more severe depressive symptoms. Future research within psycho-socially burdened families may further endorse such results (Löchner, Ulrich, et al., 2024; Ulrich et al., 2023). Second, we used self-reported questionnaires for the assessments of our variables which introduces the possibility of response bias and may not fully capture the complexities of the assessed constructs. Although the CTS is a common screening tool for childhood maltreatment

in Germany, it is retrospective and asks about events that, in most cases, occurred several years ago. In addition, parents with depressive symptoms were shown to be biased in assessing their children's psychopathology symptoms (Löchner et al., 2024). For this reason, influences of recall bias and state-dependent memory cannot be ruled out (Seizer et al., 2024). MIB was assessed by the PBQ-16 that represents a common measure for postpartum MIB. However, in the context of bonding and mother-child interaction, standardized observational instruments represent the gold standard of assessments. This was not possible due to our online recruitment throughout all of Germany. Third, although we found a full mediation of postpartum depression for the relationship between maternal experiences of childhood maltreatment and impairments in MIB, we cannot rule out the possibility that depressive symptoms reflect or overlap with other underlying factors. For instance, maternal post-traumatic stress disorder (PTSD) symptoms or other mental health conditions, which were not assessed and controlled for in our analysis, but might underlie or influence the observed mediation effect (Muzik et al., 2013). Therefore, future studies should investigate whether the mediation effect is specific to depressive symptoms or also applies to other psychological mechanisms and symptoms.

Since our analyses represent exploratory secondary analyses of an RCT with mostly high educated, low psychosocial burdened mothers, future studies should examine our model in larger, more representative samples using standardized observational tools to assess impairments in MIB. Since our model explains 29% of the variance of impairments in MIB, future studies should extend the model and include other factors affecting MIB (e.g., social support, temperament of the child) and investigate the interaction of these factors with childhood maltreatment and maternal depressive symptoms. Moreover, the identification of mechanisms mediating the relationship between postpartum depressive symptoms and MIB in maternal experiences of childhood maltreatment could improve interventions targeting MIB in mothers with postpartum depression. In the aforementioned cross-sectional study from Chau et al. (2023), maternal self-efficacy was found to mediate the relationship between postpartum

depressive symptoms and impairments in MIB. Thus, enhancing parenting competences of mothers and strengthening self-efficacy of mothers could represent a target within interventions aiming to prevent impaired MIB in mothers with histories of childhood maltreatment and depressive symptoms. Further potential psychological mediators could include maternal emotion regulation or sensitivity (Goodman, 2007).

With respect to maternal childhood experiences of maltreatment, it would be interesting to examine whether all five subtypes of childhood maltreatment correlate with impairments in MIB and whether depressive symptoms mediate the relationship for all five subtypes. Studies that investigated single subtypes are inconclusive on this question. However, there is emerging evidence that emotional abuse and emotional neglect in particular are associated with postpartum depressive symptoms (Vogel et al., 2025) and impairments in MIB (Bergunde et al., 2024; Chau et al., 2023; Lehnig et al., 2019). The involvement of fathers is another key element which is often neglected in perinatal research and in the development of interventions for parents – although it is demanded by the target group (Versele et al., 2022).

Conclusion

Our study revealed a positive correlation between maternal experiences of childhood maltreatment and impairments in MIB, with depressive symptoms fully mediating this relationship. This finding suggests that it is not the experience of childhood maltreatment itself that directly increases the risk of impairments in MIB, but rather the psychological consequences (i.e., the development of depressive symptoms) of mothers' childhood experiences of maltreatment. Preventive approaches during pregnancy and interventions aimed at fostering MIB should therefore address maternal depressive symptoms in order to break the cycle of intergenerational transmission of parenting and to ensure a healthy start in life for infants.

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Abbreviations

CTQ	Childhood Trauma Questionnaire
CTS	Childhood Trauma Screener
EPDS	Edinburgh Postnatal Depression Scale
FIML	Full Information Maximum Likelihood
MIB	Mother-Infant Bonding
OSF	Open Science Framework
PBQ-16	Postpartum Bonding Questionnaire - 16
RCT	Randomized Controlled Trial
DRKS	German Register for Clinical Trials

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Data availability statement

Due to ongoing analyses, data will not be publicly available prior to the year 2026. In 2026, the I-PREGNO data will be published on the OSF platform as part of the I-PREGNO project. If there is a legitimate interest in the data in advance, the data can be requested from the corresponding author.

Disclosure statement

The authors report there are no competing interests to declare.

Publication III

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

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

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DECLARATIONS

Data availability statement

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

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Conflict of interest disclosure

No competing interests were disclosed.

Ethics approval statement

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

Author contributions

L.V., C.H., and C.S. wrote the first draft including introduction, methods and discussion. L.V., T.S., A.O. conducted the focus group discussions, usability tests and analyzed the data. V.V. and T.D. contributed to the qualitative data analysis. C.S., C.H., T.F., J.W. were responsible for developing the app prototype and the final version of the app. M.v.P. and E.B. contributed to the development. K.S. conducted the coding of the behavior change techniques. J.L., U.L., J.W., T.D., M.v.P. supervised the app development process and made substantial contributions to the conception of this publication. C.S. created the figures for this publication. All authors reviewed and edited both the first and final draft and approved the final manuscript.

Abbreviations:

SES:	socioeconomic status
mHealth:	mobile health
BCT:	behavior change technique
HP:	healthcare professional
UCD:	user-centered design
CBT:	cognitive behavioral therapy

ABSTRACT

Introduction

Mobile health (mHealth) interventions are a promising approach to promote mothers' and fathers' health in the perinatal period. This may be particularly true for psychosocial 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.

Methods

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).

Results

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.

Conclusion

The *I-PREGNO* app development process was guided by an iterative and user-centered approach involving the target audience and a multidisciplinary team of experts. The findings provide valuable implications for the design and development of evidence-based self-guided mHealth for hard-to-reach groups during the transition to parenthood. The efficacy of the *I-PREGNO* intervention will be evaluated in randomized controlled trials in routine care.

KEYWORDS

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

INTRODUCTION

The transition to parenthood represents a critical period of time with physical, behavioral, psychological, and social changes (Saxbe, Rossin-Slater, & Goldenberg, 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, Contador, Tawfiq, Adamo, & Gaudet, 2015; Mannan, Doi, & Mamun, 2013; Versele et al., 2023) or perinatal psychopathology (e.g., depression, anxiety) (Leach, Poyser, & Fairweather-Schmidt, 2017; Smythe, Petersen, & Schartau, 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., low socio-economic 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, Alberdi, & McAuliffe, 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., 2023). 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, Walper, Renner, & Liel, 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 (socioeconomic) resources (U. 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, Fiedler, Wunsch, Woll, & Wollesen, 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, Nunes, Weiderpass, Santana, & Andersson, 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 et al. (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, Drozd, Lisøy, Wentzel-Larsen, & Slinning, 2019; Jannati, Mazhari, Ahmadian, & Mirzaee, 2020; Rhodes, Smith, Chadwick, Croker, & Llewellyn, 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, Hill, Pirotta, O'Reilly, & Moran, 2020). A meta-analysis has shown promising short- as well as long-term effects of BCTs on physical activity and nutrition (Samdal, Eide, Barth, Williams, & Meland, 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, Horey, Middleton, Boyle, & Flenady, 2018; Gilmore et al., 2017; Guerra-Reyes, Christie, Prabhakar, Harris, & Siek, 2016; Sherifali et al., 2017).

To address these gaps, we developed a multi-component 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.

METHODS

This paper was pre-registered 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. The latest version of the app is now being evaluated (stage V) in three (cluster-)randomized controlled trials (cRCT) in Austria and Germany (Vogel, Färber et al., 2023). The study has received ethical approval from the ethical committee of the University in Bamberg (nr. 2022-02/09).

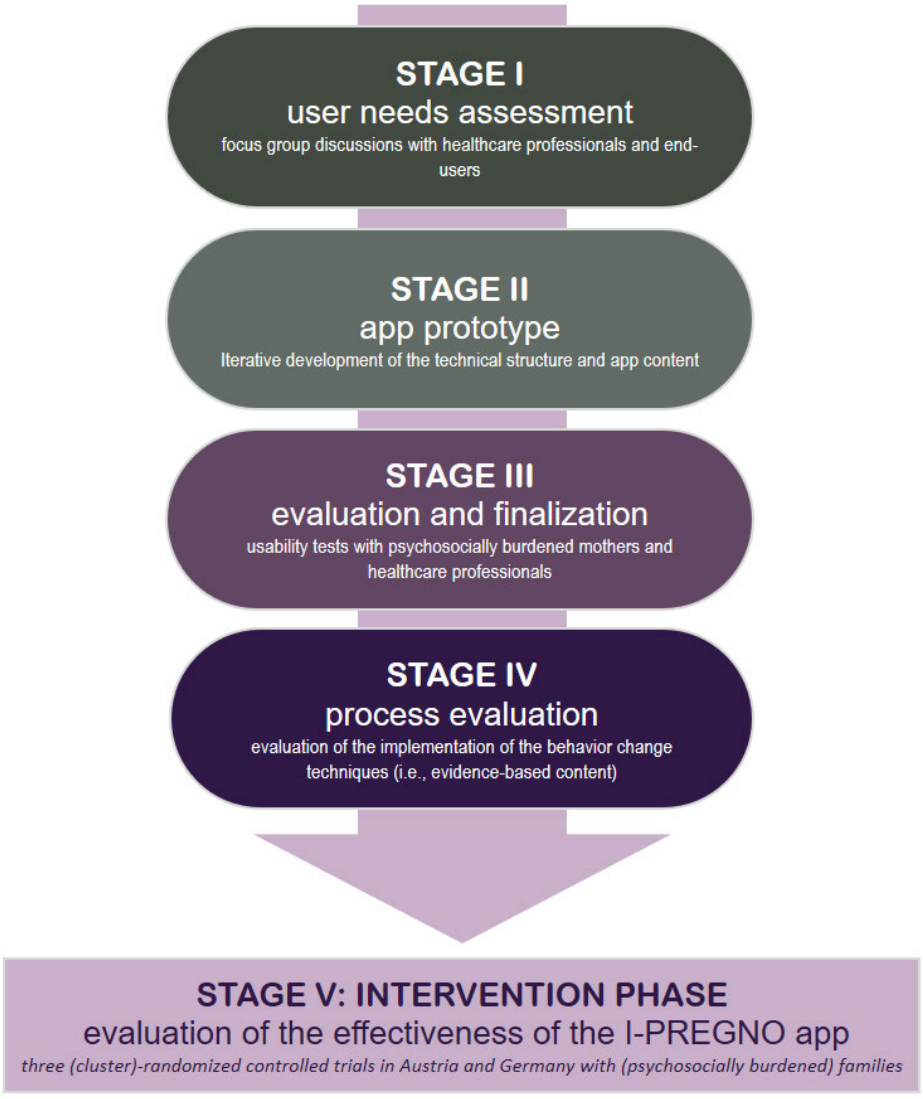

Figure 1. Overview of the intervention development process.

Stage I: User Needs Assessments

For the user needs assessments, we conducted focus group discussions in November and December 2021 with family nurses and 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 one 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. In order 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. In order 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 minutes) and two focus group discussions ($n = 3$; $n = 4$, duration = 120 minutes) 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.

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) midwive, 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) midwive	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 focus group discussions consisted of an explanation of the purpose, the discussion itself, and the completion of a short questionnaire including socio-demographics. 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 semi-structured interview guide, which is attached in the Supporting Information (Table S3). The focus group discussions were audiotaped and transcribed into minutes afterwards. 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 afterwards within the research team. Results were then formulated in guidelines for the app development (Stage II).

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).

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 prior to 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., 2017) 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).

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 non-native 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 minutes 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 minutes 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. Afterwards, 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.

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 afterwards. 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 (Figure S1). Intercoder reliability Cohen´s Kappa was in total .93, which can be interpreted as nearly perfect agreement (range: .67 to 1). Discrepancies were resolved via consensus discussion between the reviewers.

RESULTS

Stage I

Perspective of healthcare professionals

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	Module "nutrition" offers information about breastfeeding, further online sources for

		problems.	childcare are linked within the app.
	Provide tools	Include exercises and tips.	The app offers a variety of BCTs and CBT-based strategies, i.e. 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	Use of various multimedia elements (i.e., images, podcasts, mini games, input fields, links). The

		should be adapted to the language skills of the target group; only positive and non-stigmatizing terms should be included.	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.
	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.

Note. HP = Healthcare professionals.

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.

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			Development of specific content, i.e., self-efficacy, emotion regulation, introduction and self-esteem modules that focus on these topics and offer psychoeducation as well as exercises.
	Self-Esteem	Increase the user's self-esteem and self-care. This includes that the app promotes a positive attitude and convey positive feelings.	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 hiqh-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	The app does not provide concrete information, but encourages the users to ask for support and offers

		child.	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	The version for the partners includes information about the “role as a father” and which tasks and functions the partner can take over.

	fathers.	
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.	*This function was not implemented in the app due to limited technical and financial resources.*
Exchange	Promote exchange, by providing a forum with experts and a chat function for mothers and professionals.	*This function was not implemented in the app due to limited technical and financial resources.* Users were encouraged to get in touch with other individuals in similar situations (i.e., module social competences).
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	Exercises included in the module "social competences" which aim to increase social skills and

	to seek external support.	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), e.g.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 hours. 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 vs. cognitive aspects; breastfeeding yes/no).
	Seen critically	Families did not like gaming features and short videos (10-30 seconds). They explained that these features lead them to feel not being taken seriously.	Content was presented as podcast or text or mini game without an evaluation of the entered content, image. No videos were included.
	Anonymity	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 prior to 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 emphasis 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.

Stage II

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.

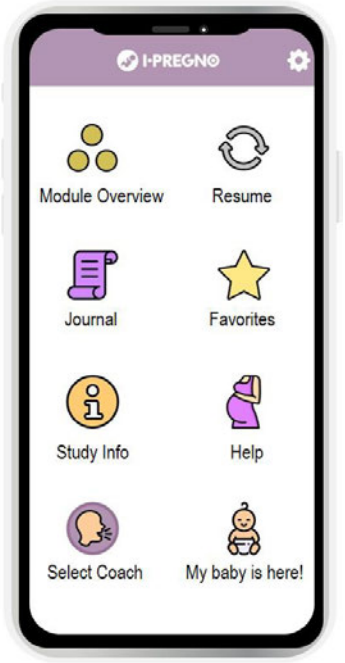

Figure 2. The *I-PREGNO* app interface.

The module-based intervention section represents the core of the app and comprises twelve 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.

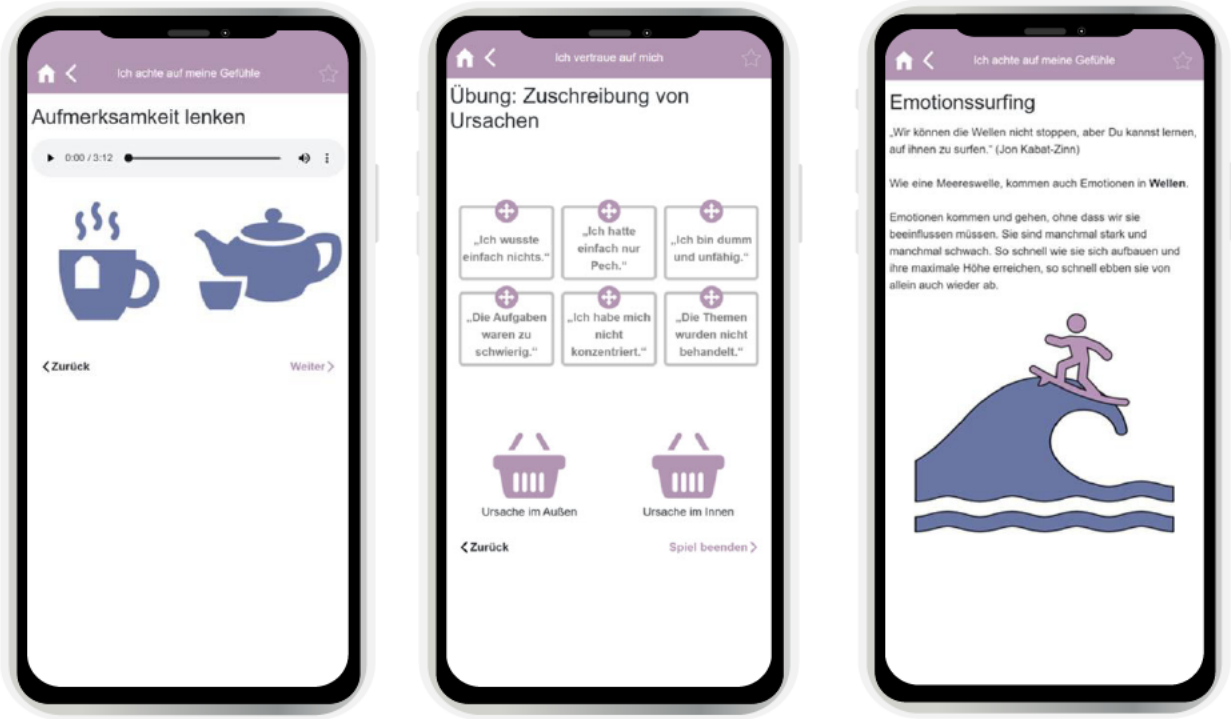

Figure 3. Exemplary screenshots of the module 'emotion regulation' illustrating the multimedia content implemented in the *I-PREGNO* app.

Individualization of the app content

In order 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. In order 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 72 hours. 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).

Stage III

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.

Stage IV

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 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 (Table S1, Supporting Information). In total, 1037 techniques were coded across all modules ($M = 86.42$ BCTs/module, range 2 - 225; Table S2, Supporting Information).

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 in order 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) 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 behaviour (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-	**Goals and planning (1.2)**

	choices e.g. 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.	**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)
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.

DISCUSSION

The objective of the paper was to describe and evaluate the development process of the multi-component *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.

Stage I - III: Development of the I-PREGNO app based on a user-centered design 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 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.

Stage IV: Implementation of Behavior Change Techniques

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, Taylor, & Lavender, 2016). More specifically, the following BCTs were marked as particularity 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 articifical 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 combinations 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 (Vogel, Färber et al., 2023) 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.

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. Secondly, 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 in order 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.

Conclusion

This study is a first step towards 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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Publication IV

Efficacy of a Blended Counseling Intervention (I-PREGNO) on Mental Well-being of Vulnerable Mothers Postpartum: Findings from a Cluster Randomized Controlled Trial

This chapter is a pre-peer-review, pre-copyedit version of an article currently being under revision in Journal of Consulting and Clinical Psychology.

Efficacy of a Blended Counseling Intervention (I-PREGNO) on Mental Well-being of Vulnerable Mothers Postpartum: Findings from a Cluster Randomized Controlled Trial

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Abstract

Objective. Parents face numerous changes and challenges during the postpartum period, increasing their risk of mental health issues, which can negatively impact family functioning**.** Parents with psychosocial burdens are particularly vulnerable to develop mental health issues postpartum and are in need of targeted intervention programs. This study examined the efficacy of the 12-week mobile application-based blended counseling intervention '*I-PREGNO*' on the well-being among psycho-socially burdened mothers during the postpartum period.

Methods. A two-arm parallel cluster randomized controlled trial was conducted in Germany with $N = 108$ mothers of children aged 0-12 months, recruited via a national early childhood intervention program. Assessments included one baseline assessment (T0), one post intervention assessment 12 weeks after baseline (T1), and one follow-up assessment 6 months after baseline (T2). Multi-level models were used to examine differences in well-being between the intervention group (IG) and the control group (CG), as measured by scores on the Parenting Stress Index (PSI) and the Edinburgh Postnatal Depression Scale (EPDS).

Results. No significant differences between the groups at T1 and T2 were observed on parenting stress. However, post-hoc tests revealed significantly reduced PSI scores for mothers in the IG who started the intervention within the first four months postpartum. No difference in EPDS score was found at T1 and T2.

Conclusion. While *I-PREGNO* showed promising results in managing parenting stress shortly after childbirth, it may not be sufficient for the prevention of postpartum depressive symptoms. For preventing postpartum depression, psycho-socially burdened mothers may require more comprehensive, personalized, and multifaceted interventions.

Public Health Significance Statement:

This paper examined the efficacy of the mHealth-based intervention named *I-PREGNO* on maternal mental well-being. The intervention was effective in reducing postpartum stress in psycho-socially burdened mothers who used the intervention during the first four months after childbirth. However, the study found no evidence for *I-PREGNO* sufficiently preventing depressive symptoms. Clinicians should consider integrating more comprehensive and personalized approaches to support mothers at-risk for postpartum depression, especially in case of using mHealth approaches.

Introduction

The transition to parenthood is accompanied by a multitude of changes and challenges for parents. Beyond the physical and biological alterations, the postpartum period involves substantial psychological (e.g., role changes) as well as behavioral (e.g., sleep disturbances, reduced physical activity, altered eating habits) changes, and sometimes social and personal challenges (e.g., financial pressure, social isolation; Saxbe et al., 2018). These changes and challenges often lead to increased levels of parenting stress among parents of newborns, adversely affecting their mental health and well-being (Chung et al., 2024; Hutchens & Kearney, 2020; Venkatesh et al., 2014). As a result, the perinatal period represents a critical window for parental well-being which, in turn, affects family functioning (Macdonald et al., 2020; Ulrich et al., 2021).

Prevalence rates of maternal postpartum depression range from 5 - 26% (Liu et al., 2022). This is particularly relevant since parental symptoms of psychopathology and parenting stress have an impact on the offspring's development (Chung et al., 2024; Crouch et al., 2019; Vismara et al., 2016). Parental psychopathology negatively affects the offspring's cognitive, emotional, and social development, which subsequently elevates the risk of future mental health problems in children and adolescents (Lux, Müller, et al., 2023; Slomian et al., 2019). In addition, Löchner et al. (2024) identified parents' stress level as an important contributing factor for problems in the offspring's affective development in families with children aged zero to three years.

Previous research identified psycho-socially burdened mothers as individuals at high risk for experiencing increased postpartum stress and developing postpartum depressive symptoms (Gastaldon et al., 2022; Hutchens & Kearney, 2020). Psycho-socially burdened families often face multiple psychological and social stressors, including (childhood) traumatic experiences, economic burden, a low level of education, illness of the child,

premature birth, dissatisfaction in relationships, or single parenthood (Goyal et al., 2010; Hutchens & Kearney, 2020; Lorenz et al., 2020; Racine et al., 2021). Studies that investigated this group at-risk underscore the need of targeted interventions for this vulnerable population during the transition to parenthood to promote their mental well-being (Löchner et al., 2024; Ulrich et al., 2021; Ulrich, Löchner, et al., 2022). However, preventive interventions often do not reach psycho-socially burdened families, a phenomenon which is also known as the prevention paradox (Bauer, 2005). Various barriers impede their access to necessary support services, including shortage in healthcare and social service systems, fear of being judged and logistical challenges such as time constraints, particularly in universal prevention services of the families (Lux, Entleitner-Phleps, et al., 2023; Ulrich et al., 2023). As a result, these families frequently remain underserved, highlighting the need for more inclusive and accessible preventive strategies tailored to their specific circumstances and needs (Hollis et al., 2015; Ulrich et al., 2023; Ulrich, Walper, et al., 2022). In sum, there is an urgent need for effective preventive measures to prevent parenting stress and postpartum depression during the transition to parenthood, specifically tailored to vulnerable families during this critical period.

In recent years, mobile health (mHealth) interventions have emerged in the field of prevention, and are considered as promising possibilities to address individuals that have not been reached through traditional approaches (Chua & Shorey, 2022; Seiferth & Vogel et al., 2023; Zhou et al., 2022). mHealth solutions offer a potentially low-cost, and accessible approach, particularly for parents during the transition to parenthood when they experience a variety of time restrictions. To counter the major problems of pure digital interventions (e.g., low adherence), meta-analyses show that the combination of digital features (e.g., apps) with face-to-face counseling enhances both the efficacy and adherence of interventions, and is therefore recommended for optimal outcomes (Santarossa et al., 2018; Wright et al., 2019). Recently, a substantial body of literature features studies that developed (Drissi et al., 2020)

and evaluated digital interventions to promote maternal well-being during the transition to parenthood (Lin-Lewry et al., 2024). However, these interventions were neither specifically tailored to, nor examined in psycho-socially burdened families. Evidence suggests that digital interventions, which are effective for participants with fewer burdens, do not achieve the same level of efficacy for individuals facing economic challenges (Western et al., 2021). Moreover, Brusniak et al. (2020) demonstrated that socioeconomic burdens as well as migration background reduced user engagement with digital interventions in mothers during the transition to parenthood. This raises the question of whether digital interventions are feasible and effective in promoting the mental well-being of psycho-socially burdened mothers during the postpartum period.

To address the question, an mHealth-based intervention, named *'I-PREGNO'* was developed. *I-PREGNO* represents a 12-week blended counseling intervention combining a self-guided mobile application (app) with counseling sessions that can be provided by healthcare professionals (e.g., regular midwives, family midwives, family nurses, social workers) within a nationwide early childhood intervention program in Germany that supports psycho-socially burdened families with children aged zero to three years (Vogel & Färber et al., 2023). The mHealth intervention focuses on specific parental psychological needs and health behavior to promote mental well-being during the first year after birth. *I-PREGNO* was developed following a user-centered design process from May 2021 to September 2022 ensuring it meets the needs of the target group (psycho-socially burdened families; Vogel & Henning et al., 2024).

The objective of the current paper was to investigate the effects of *I-PREGNO* on maternal mental well-being (in form of parenting stress and postpartum depressive symptoms). Therefore, we analyzed data of a cluster randomized controlled trial (cRCT) which examined the efficacy of *I-PREGNO* as a blended counseling intervention within the

aforementioned German early childhood intervention program. We hypothesized that mothers in the intervention group (IG) would show reduced parenting stress and fewer depressive symptoms compared to the control group (CG) after the intervention.

Methods

The authors confirm that the manuscript meets the TOP and CONSORT guidelines (Campbell et al., 2012; Eysenbach & CONSORT-EHEALTH Group, 2011; Schulz et al., 2010). The study was pre-registered on 07/19/2022 at the German Clinical Trials Register (https://drks.de/search/en/trial/DRKS00029673), received ethical approval from the ethics committee of the University in Bamberg (nr. 2022-02/09) and was conducted in line with the Helsinki Declaration. The reproducible code for all analyses is available on the Open Science Framework (OSF, https://osf.io/s28n7/). The data will not be publicly available prior to the year 2026 due to ongoing analysis. After 2026, the data will be available at OSF. Before 2026, data and intervention materials will be provided to readers upon reasonable request.

Study Design

I-PREGNO represents a blended counseling mHealth intervention aiming to promote the well-being of vulnerable families after birth. For the present secondary analyses, we used data from the German cRCT that was conducted from September 2022 to August 2023 by two sites (University of Bamberg and National Center for Early Prevention, German Youth Institute, Munich). The detailed methodology, including the rationale, design, sample size calculation for the primary outcome, and statistical analyses, has been described in the study protocol (see Vogel & Färber et al., 2023). No significant changes to the methods has been made after the trial commenced.

In a parallel two-arm cRCT design we compared effects of the IG receiving the *I-PREGNO* blended counseling intervention for 12 weeks and treatment as usual (TAU) against the CG with TAU alone. To prevent contamination between different conditions, cluster

randomization was chosen, ensuring that each healthcare professional delivered the same treatment to all families participating in the *I-PREGNO* study that they provided support for. The randomization was performed using a computerized random number generator provided by an external, independent expert from the Department of Computing in the Cultural Sciences at the University of Bamberg. All included families underwent an online baseline assessment (T0; start of intervention during the first year postpartum), post assessment (T1; after 12 weeks of intervention or TAU) and one follow-up assessment (T2; six months after the baseline assessment). Blinding of the participating parents and healthcare professionals was not feasible due to the real-life nature of the intervention. *I-PREGNO* was developed as a family-based intervention with the aim to involve both parents in the intervention, as a result of a preceding qualitative study with the target group (Versele et al., 2022). However, as only $n = 6$ fathers participated, we were not able to include fathers in the present analyses.

Participating healthcare professionals

Clusters were defined as healthcare professionals who worked within the national early childhood intervention program (described in a following section as the TAU) and were either in training or had a degree as a (family) midwife or family nurse. In addition, healthcare professionals had to have sufficient German language skills and support at least one family eligible for the trial. Eligible healthcare professionals could register online via Limesurvey (LimeSurvey Project Team / Carsten Schmitz, 2012). Healthcare professionals received €50 for every family they recruited who completed T0.

Participating families

Healthcare professionals recruited and screened mothers for inclusion and exclusion criteria. Inclusion criteria comprised a) showing at least one of the psychosocial burdens defined in Table 1, b) having a child at the age between 0-12 months, c) owning a smartphone, and d) receiving support through the healthcare professionals for a period of at

least 12 weeks. Exclusion criteria included a) mothers with an age younger than 16 years; b) acute mental health crisis that hampered the ability to participate (e.g., suicidality, mania); c) chronic disease that can influence behavior related to energy balance (diabetes, pre-eclampsia, etc.) or require a complex diet; d) insufficient knowledge of the German language (which does not allow the use of the app and the completion of the questionnaires); or e) other reasons that did not allow the correct use of the app, counseling or completion of the questionnaires. Each family received €50 in total for participating in all measurements (a €20 payment after T1 and a €30 payment after T2).

Procedure

Healthcare professionals registered online and completed an online survey comprising the consent to the study, the screening for inclusion and exclusion criteria for healthcare professionals, as well as information about their professional background. Following successful registration, healthcare professionals were randomized to one of the two study arms (see intervention section for details). The study team contacted the healthcare professionals via telephone and conducted a 20-30 minutes briefing with information about the randomization and instructions for the study. In addition, healthcare professionals in the IG received a five-hour online training for the *I-PREGNO* blended counseling. The goal of the training was to prepare the healthcare professionals to conduct the counseling sessions. The online training sessions had two main focuses. The first was to deliver key messages about diet and physical activity presented in the app (see interventions section), and the second was to teach and practice motivational interviewing skills by a trained instructor. Healthcare professionals had the opportunity to practice in small groups and ask questions. The training was made available to professionals in the CG after the finalization of data collection. Subsequently, healthcare professionals screened for inclusion criteria, and registered families for the study. Mothers who agreed to participate in the study and signed a consent form

provided to them by the healthcare professionals were registered online via Limesurvey (LimeSurvey Project Team / Carsten Schmitz, 2012). Registered parents received an individualized link for the baseline assessment (T0) via e-mail. Following the completion of the baseline assessment, the healthcare professional and the participant received a message to start the intervention phase and – if they were randomized to the IG – a download guide for the app. Twelve weeks (T1) and six months after baseline assessment (T2) the families received the link for the next measurement points' questionnaires via e-mail. The app account was deactivated after twelve weeks usage in the IG. In case of non-response to the questionnaires, participants were reminded via email and telephone as well as through the healthcare professional for up to four weeks. Mothers who did not complete the post-assessment (T1) were not marked as drop-outs but invited to the follow-up assessment (T2).

Interventions

Treatment as usual

TAU represents a nationwide established home-visiting program (called Early Childhood Intervention) conducted by healthcare professionals who support vulnerable families in their parent-child-relationship and parenting competences. The program usually starts during the postpartum period (Opitz et al., 2023). The program is primarily funded by the Federal Ministry of Family Affairs, Senior Citizens, Women and Youth (BMFSFJ) as part of the Federal Foundation for Early Childhood Intervention (Bundesstiftung Frühe Hilfen). Targeting all families with children aged zero to three years, the voluntary program is particularly tailored to psycho-socially burdened families. The service is mainly delivered by trained healthcare professionals (family midwives, family nurses) and strives to provide a low-threshold access for help. Regular home visits, typically occurring weekly for six to twelve months, are intended to provide comprehensive support for questions related to child development and coping with everyday family tasks. There is no standardized manual for

single sessions of the program. Instead, healthcare professionals adopt a general framework with specified guidelines to the individual needs of the families. In contrast, the counseling sessions regarding *I-PREGNO* were standardized, and the healthcare professionals were asked to address the key messages in each session.

I-PREGNO

I-PREGNO is a blended counseling intervention that combines a 12-week modular smartphone app with counseling sessions. In the current trial, *I-PREGNO* was integrated in the aforementioned TAU condition. The app was developed from April 2021 to August 2022 based on a qualitative analysis and an user-centered design process (Versele et al., 2022; Vogel & Henning et al., 2024). The interactive self-guided modular *I-PREGNO* app integrates basic principles of evidence-based Cognitive Behavioral Therapy (CBT) and behavior change techniques (Michie et al., 2013). The app aims to increase parental mental well-being and to broaden their knowledge about nutrition and physical activity via the completion of 12 modules (e.g., emotion regulation, stress regulation, self-esteem; Vogel & Henning et al., 2024). The development process of the app and the specific contents have been published in detail in a previous article (Vogel & Henning et al., 2024).

The face-to-face counseling is based on techniques of motivational interviewing, aiming to help families incorporating the app's information into their daily lives. It provides guidance on health behavior changes focusing on nutrition and physical activity based on seven key messages ([1] *'Make water YOUR drink of choice'*; [2] *'Diversity does not have to be a lot'*; [3] *'Colorful and healthy: plant-based foods'*; [4] *'Snacks & fast food: (un)canny seducers'*; [5] *'Finding the right amount of meat'*; [6] '*Finding joy in movement and sitting less'*; [7] *'Train your strength'*). More detailed descriptions of *I-PREGNO* as a blended counseling mHealth intervention can be found in the study protocol (Vogel & Färber et al., 2023).

Measures

As the paper presents analyses on secondary outcomes of the study *I-PREGNO*, we focused on the outcome of mental well-being via parenting stress and depressive symptoms.

Outcomes

Parenting stress was measured by the German version of the Parenting Stress - Index (Abidin et al., 2006; Tröster, 2011). The German version consists of 48 items comprising 12 subscales divided in seven subscales with parental outcomes and five subscales assessing the behavior of the child. Each subscale includes four items rated on a 5-point Likert-scale ranging from 1 ('strongly disagree') to 5 ('strongly agree') with higher scores indicating higher levels of stress. For our analyses, we used the sum score of six parental subscales (*attachment, social isolation, parental competence, depression, health, role restriction*), leaving out *partner relationship* as this subscale could not be answered meaningfully by single mothers, resulting in 24 items per person per assessment. Studies showed that the psychometric properties are good (Tröster, 2011). In our sample, internal consistencies of the PSI were excellent with α_{T0} = .93; α_{T1} = .94; α_{T2} = .94.

To measure *maternal postpartum depressive symptoms*, we used the sum score of the German version of the Edinburgh-Postnatal-Depression-Scale (EPDS; Bergant et al., 1998; Cox et al., 1987). The EPDS consists of 10 items measuring perinatal depressive symptoms and were rated on a 4-point-Likert scale ranging from 0 to 3. The overall score ranges from 0 ('no postpartum depression') to 30 ('severe postpartum depression'). Bergant et al. (1998) reported satisfactory psychometric properties. In our sample, internal consistency was very good (α_{T0} = .86; α_{T1} = .89; α_{T2} = .85).

Moderators

At post assessment (T1), mothers were asked about regular use of *psychopharmaceutical medication* and whether they received additional *psychological treatment* during the last 12 weeks. Both variables were binary-coded and used as a moderator for the intervention effects on EPDS and PSI.

To explore whether the *timing of the start of the intervention* moderates the effect of the intervention, we included the age of the child (in months) at baseline as a moderator.

Furthermore, we generated a variable for *app usage* that contains the sum of minutes mothers spent using the app within the 12 weeks of intervention. Usage was assessed by the apps´ meta-data logfiles, which were internally tracked within the app. For per protocol analyses, mothers who did not use the app once (i.e., app usage = 0 min.) were excluded.

Control variables

In addition, we included socioeconomic and psychological control variables which potentially affect the outcome variables. For *socioeconomic variables,* we assessed whether the families received social welfare through a self-generated, binary-coded item. The *educational background* was measured through an ordinal-scaled item [1 = 'no formal school diploma'; 2 = 'lower secondary school diploma (about nine years of schooling)'; 3 = 'intermediate secondary school diploma (about ten years of schooling)'; 4 = 'qualification for universities of applied sciences (about 12 years of schooling)'; 5 = 'qualification for universities'; 6 = 'university degree']. Furthermore, we assessed *single parenthood, German citizenship,* and *unintended pregnancy* through binary-coded variables. The items were adapted from a previous study that was conducted within the national early childhood intervention program by the National Center for Early Prevention at the German Youth Institute (Opitz et al., 2023). Maternal *experiences of childhood trauma* were measured using the Childhood Trauma Screener (CTS; Grabe et al., 2012), a German short version of the Childhood Trauma Questionnaire (CTQ; Bernstein et al., 2003).

Analyses

Analyses were conducted by a project independent researcher (LS) using *R* 4.4 (R Core Team, 2024). Main effect analyses were performed using multi-level models with random intercepts following a longitudinal analysis of covariance (Bates et al., 2015; Twisk et al., 2018). In this method the outcome variable measured at the different follow-up measurements is regressed on the interaction between the treatment (grouping) variable with a dummy time variable and the baseline value of the outcome.

Moderator analyses were performed by adding a three-way interaction between the moderator variable, the treatment variable, and the time variable to the regression formula, whereby the moderating influence on the treatment effect was estimated at both follow-up time points, respectively.

Results

Participants (i.e., mothers) were recruited between August 2022 and August 2023. The final follow-up assessment (T2) was completed in February 2024. Figure 1 shows the study-flow of the cRCT. Fifteen of the recruited 72 healthcare professionals withdrew their registration before completing the onboarding process, and an additional $n = 18$ dropped out due to limited time resources or a lack of eligible families during the study recruitment period. In total, $n = 39$ healthcare professionals recruited at least one mother for the study. On average, the 22 healthcare professionals in the IG recruited 1.91 ($SD = 1.38$) mothers while the 17 healthcare professionals of the CG recruited 3.18 ($SD = 2.48$) mothers for the study.

In total, $N = 108$ mothers were registered for the trial. Thirteen mothers were excluded by the study coordinators prior to baseline since they met one or more exclusion criteria (child was too old $n = 6$, moved to another district $n = 1$; lack of sufficient German language skills $n = 1$; no specific reason $n = 8$). As a result, $n = 95$ mothers were randomized to one of the

study conditions and included in the analyses for the current paper. Thirty-three mothers in IG and 45 mothers in CG completed the study. Table 2 displays socio-demographic characteristics of the sample. Both groups (i.e., IG and CG) did not differ significantly in any of the variables measured at baseline.

However, the number of contacts with healthcare professionals during the 12 weeks of intervention differed significantly between both groups ($t(53) = -1.90$, $p < .05$, $d = -1.46$, 95% CI [-3.01, .08]). On average, mothers in the IG received $M = 5.30$ ($SD = 2.32$) counseling appointments, while mothers in the CG received $M = 6.76$ ($SD = 3.52$) counseling appointments. App-usage of the IG for the 12 weeks was on average $M = 89.70$ ($SD = 146.71$) minutes. Five mothers in the IG did not use the app (i.e., app-usage of zero minutes). No harms were reported during the study.

Intervention effects on parenting stress

Table 3 lists the descriptive statistics of the PSI sum score across the three time points for the IG and CG. Our attempts to fit a three-level model with assessments nested within mothers and mothers nested within healthcare professionals did not converge, which may be due to the lack of variance at the healthcare professional level. In a two-level model (assessments nested within mothers), no significant differences between the groups were found at T1 (estimate = -4.42, $p = .19$; 95% CI [-10.85, 2.03]) or T2 (estimate = -0.37, $p = .91$; 95% CI [-6.88, 6.13]). However, in a model that included child age at the time of study enrollment as a moderator of the treatment effect, a significant interaction effect between child age and group was observed at T1 (see supplementary material). This indicates that mothers who started the intervention earlier after child birth scored significantly lower on the PSI than mothers in the CG over time (see Figure 2). Psychological and psychopharmaceutical treatments, app usage, and the number of counseling appointments showed no significant interactions (see supplementary material).

Intervention effects on postpartum depressive symptoms

Table 3 lists the descriptive statistics of the EPDS sum score over time for both groups. Our three-level-models with the sum score of the EPDS as independent variable showed no significant differences between the groups at T1 (estimate = -1.55, p = .19; 95% CI [-3.81, 0.73]) and T2 (estimate = 1.20, p = .31; 95% CI [-1.08, 3.50]). We found no significant interaction effects for psychological, psychopharmaceutical treatments, child age, app usage, and the number of counseling appointments (see supplementary material).

Sensitivity Analyses

Per-protocol analyses

Per-protocol analyses were conducted on an exploratory basis, excluding all participants in the intervention group with zero minutes of app usage (n = 10). The exclusion of these participants did not significantly alter the results (see supplementary material).

Influence of psychosocial burdens

In further exploratory analyses, we extended the primary multi-level models with the sum scores of the PSI and EPDS as dependent variables by including socioeconomic and psychological covariates (*childhood traumatic experiences, educational level, single parenthood, receipt of social welfare, unintended pregnancy, citizenship*) to examine their influence on the outcomes and the treatment effect. Detailed results of these analyses are provided in the supplementary material. When analyzing parenting stress as the dependent variable, no significant influence of the socioeconomic and psychological variables was found. However, when using EPDS as the dependent variable, a significant effect of social welfare status was identified (estimate = -3.39, SE = 1.39, $t(62)$ = -2.44, p = .018 ; 95% CI [-5.99; -0.79]), indicating that mothers who received financial aid from the state exhibited significantly lower depressive symptoms.

Discussion

The objective of this study was to evaluate the effect of *I-PREGNO* on mental well-being in mothers receiving support from a German early childhood intervention program. *I-PREGNO* represents a blended counseling preventive mHealth intervention tailored to the needs of psycho-socially burdened families during the transition to parenthood. The current manuscript focused on the efficacy of the intervention on parenting stress and postpartum depressive symptoms in mothers.

The statistical analysis on parenting stress initially showed no intervention effect of *I-PREGNO*. However, further analyses that considered the child's age at the start of the intervention phase revealed an interaction effect between parenting stress and the timing when the intervention was initiated, favoring an early start after birth. Mothers who started during the first four months postpartum experienced less parenting stress compared to the mothers in the CG immediately after intervention. Contrary to our hypotheses, we found no effects on postpartum depressive symptoms between the two groups at the end of the intervention (T1) and six months after baseline (T2).

To our knowledge, *I-PREGNO* is the first blended counseling intervention aiming to enhance postpartum mental well-being in psycho-socially burdened families. In sum, our analysis did not provide overall evidence for *I-PREGNO* decreasing levels of parenting stress and reducing symptoms of postpartum depression. Nevertheless, analyses on parenting stress revealed an interaction effect indicating decreased levels of parenting stress during the early stages of the postpartum period. Findings from a recently published meta-analysis support our results, as the authors observed a significant effect of digital interventions on stress-related outcomes only within the first three months postpartum (Lin-Lewry et al., 2024). With respect to this finding, we assume the content of our intervention being more relevant to the early postpartum period. Many of the topics addressed in the app focus on the challenges that come

along with the new role as a parent, highlighting the thoughts, emotions, behaviors, and stress experiences of parents during this initial stage (Saxbe et al., 2018; Ulrich, Walper, et al., 2022). In later stages of the postpartum period, issues related to the care and management of the child's needs are likely to become more prominent. These topics are not directly targeted by our app, which may explain the reduced efficacy observed in mothers that started the intervention after the first four months postpartum. The results of the current study, along with previous research, suggest that mHealth-based interventions aimed at reducing stress during the postpartum period should be tailored to the user's phase (the child's age) and provide content relevant to issues typically arising at that time.

While the app and accompanying counseling sessions may provide valuable support and coping strategies with occurring stress related depressive symptoms, they may not be sufficient to address the underlying causes or severity of depressive symptoms. Existing literature provides heterogeneous findings about the efficacy of mHealth interventions for the prevention of postpartum depression. Chua and Shorey (2022) identified ten studies investigating the efficacy of mobile applications on the course of depressive symptoms. From these ten studies, only five found a significant decrease in the IGs after the intervention phase compared to CGs. Another meta-analysis found that app-based interventions could decrease depressive symptoms with small to moderate effect sizes (Zhou et al., 2022). However, most of the identified studies included mothers with low psychosocial burden and used inactive or wait list control groups which limits the comparability of the results.

While the app and counseling sessions of *I-PREGNO* may offer initial relief during the first months postpartum, interventions aiming to prevent postpartum depressive symptoms may require a more personalized and comprehensive approach. The complexity and multifaceted nature of depression means that interventions need to be tailored to the individual's specific needs and may still be insufficient to fully prevent the onset of the

disease (Loechner et al., 2018). *I-PREGNO* focuses on the promotion of psychological competences (e.g., mindfulness, emotion regulation, and self-efficacy). For psycho-socially burdened mothers developing depressive symptoms, healthcare professionals highlighted that additional support for coping with social burdens (e.g., social or financial support) is necessary. This observation might be further supported by our sensitivity analyses indicating a positive effect of financial support on depressive symptoms. Furthermore, enabling mothers to interact with each other and the integration of providing feedback within the app might be a promising feature (Cook et al., 2010; Lin-Lewry et al., 2024). Another point to consider is the exclusive focus on health behavior in the counseling sessions of *I-PREGNO* may not effectively promote mental well-being. In line with this assumption, Shorey et al. (2019) who developed a similar CBT-based mHealth intervention found significantly decreased scores in EPDS in the IG compared to the CG. However, they integrated one antenatal educational session (30 minutes) and one postnatal educational session (60 minutes) that provided additional information about the parental mental well-being during the postpartum period (Shorey et al., 2019). Moreover, they integrated a digital discussion forum with one trained nurse answering parental queries once a day (Shorey et al., 2019). These features might represent a promising addition for the further development of *I-PREGNO*. In addition, many studies investigating mHealth-based interventions which reported significant effects included mothers during the antenatal period indicating preventive interventions might be more effective when they encompass the entire perinatal period (Carona et al., 2023; Chan et al., 2019; Shorey et al., 2018).

The observation that mothers in the IG tended to exhibit an increase in depressive symptoms six months after baseline (T2), while mothers in the CG showed a decrease, is challenging to interpret. One possible explanation for this finding is that sustained improvement in depressive symptoms may require continuous support over a period longer than 12 weeks. Additionally, mothers in the CG received more counseling sessions as part of

the TAU condition than those in the IG, which may have influenced the course of depressive symptoms. In line with these findings, Löchner et al. (2023) reported improvement in the TAU-CG in depressive symptoms in comparison with the IG that received a preventive intervention. The authors interpreted such result as potentially increased awareness for depression and increased help-seeking behavior after being allocated to the CG. This issue could have been overcome by blinding the participants, which is very difficult in a real-life intervention and was not possible for our trial. However, more research is needed to explore such beneficial findings for the CG. Another point to consider is that the sum of counseling appointments and app usage in the IG was lower than anticipated. Mothers who show levels of high parenting stress and are at risk of developing depressive symptoms may need more intensive, and more frequent support.

The range in app usage data indicates the presence of subgroups within the sample, with some mothers using the app frequently and others not using it regularly. Although initial analyses controlling for app usage did not reveal a significant difference on parenting stress and depressive symptoms, it is possible that further analyses could identify specific subgroups for whom these approaches are more suitable and effective. Therefore, future research should investigate the impact of adherence on psychological outcomes more in depth and identify subgroups of users. However, the dosage of an mHealth intervention is yet to be defined and probably characterized by great differences depending on target group and intervention (Boucher & Raiker, 2024).

Strengths and Limitations

The main strength of our current study represents the successful participation of psycho-socially burdened mothers during the postpartum period. This group has consistently been neglected in research on mHealth interventions and represents a classic example for the prevention paradox (Bauer, 2005). Hence, our results provide first evidence on the feasibility

and efficacy of smartphone-based interventions in psycho-socially burdened mothers. Second, the study flow shows relatively low drop-out rates (24 % for IG; 15% for CG) after allocation, limiting attrition bias. Moreover, we applied an user-centered design including healthcare professionals and psycho-socially burdened mothers when developing *I-PREGNO* (Vogel & Henning et al., 2024).

There are also some limitations to consider. Despite the success of reaching a substantial number of participants, the sample size still limits discovering small effects and subgroup analyses. Initially, we planned to enroll a larger sample size (Vogel & Färber et al., 2023); however, time constraints necessitated a termination after one year of recruitment. In addition to the time restriction, a large number of families could not be registered due to insufficient skills of the German language. A further limitation represents the assessment of numbers of counseling in both groups. Although we asked the healthcare professionals after the intervention phase how many appointments they conducted during the 12-weeks intervention phase per family, we did not receive many responses from the healthcare professionals (n = 58; 61%), resulting in a high missing rate in this variable for both groups. Furthermore, we have no information on the content and techniques used in the counseling sessions. In future studies, one should strive for a more standardized procedure, although this often means reduced feasibility. Furthermore, the counseling sessions were carried out by healthcare professionals who received a five-hour training for *I-PREGNO*. As the healthcare professionals of our study were not trained in the prevention of psychological disorders during their training as (family) midwives and family nurses, it is possible that, first, a longer training period for *I-PREGNO* could make our intervention more effective and, second, the involvement of psychologically trained professionals might be associated with greater efficacy.

Clinical and Practical Implications

Our results lead us to some clinical and practical implications. Since we found an effect on parenting stress in the IG in mothers that started during the first months postpartum, we highlight the potential of blended counseling interventions that support mothers with high levels of parenting stress during the early postpartum stage. This finding represents particularly relevant information for practice since increased levels of parenting stress are bi-directly correlated with maternal mood disorders (e.g., depression; Vismara et al., 2016) and have a negative impact on the emotional development of the offspring (Löchner et al., 2024).

However, our results suggest that the *I-PREGNO* intervention alone may not be sufficient for the prevention of postpartum depression, indicating that additional measures or more comprehensive approaches may be necessary to achieve this goal. We recommend several research questions which should be addressed in future studies developing and examining digital interventions for psycho-socially burdened parents during the transition to parenthood. We encourage researchers to develop more personalized interventions and examine which specific content is effective for whom. This could not only lead to more frequent usage but also increase the efficacy of mHealth-based interventions. In addition, it would be interesting to explore whether the use of *I-PREGNO* might be more effective if the intervention already begins during pregnancy (Vogel & Färber et al., 2023).

Previous research suggests that using a couple-based approach might be more effective for preventive interventions, especially during the transition to parenthood (Versele et al., 2022). However, including fathers might be a challenging objective as evidenced by our difficulties to include a sufficient number of fathers in our study. Our results indicate that the successful inclusion of fathers may need another methodology and materials compared to mothers.

Conclusion

The results of our study showed a beneficial effect on parenting stress for mothers who started *I-PREGNO* zero to four months after birth. However, we were unable to observe this effect for mothers in later stages during the first year postpartum. Additionally, we did not find a positive effect on maternal postpartum depressive symptoms. Our findings suggest that, although the intervention holds promise in managing parental stress right after giving birth, psycho-socially burdened mothers who are at risk to develop depressive symptoms may require more comprehensive, personalized and multifaceted interventions. Future studies should identify additional approaches that could reduce burdens in these families and prevent postpartum depressive symptoms.

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Table 1

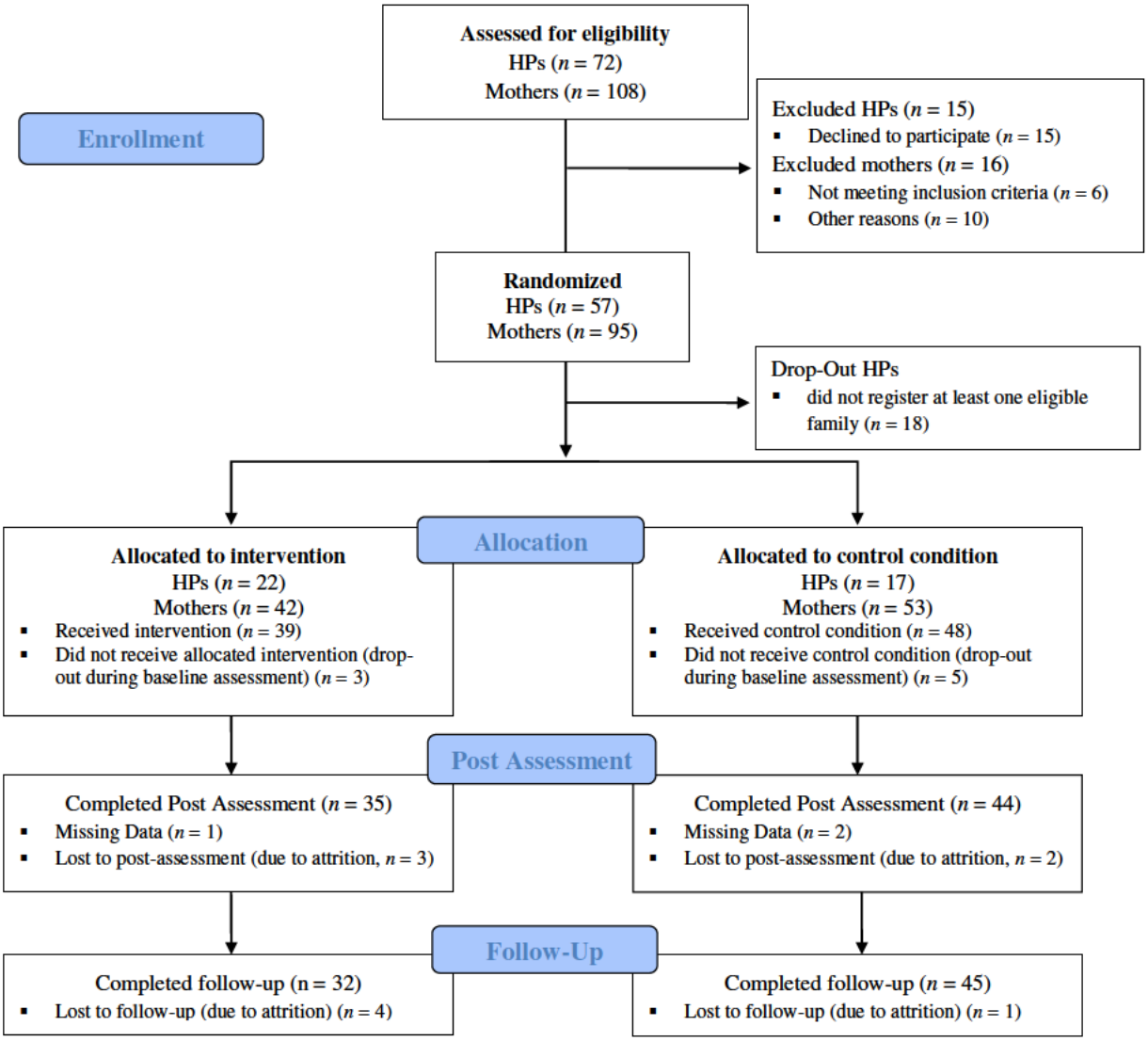
Psychosocial burdens as part of the inclusion criteria for participants

Psychosocial burden	· **financial problems** · **single parenthood** · **mental illness of one parent** · **underaged mother (≥ 16 years)** · **insecure living situation** · **traumatic life events in the past** · **social isolation / lack of integration** · **birth of multiples and rapid succession of births** · **premature birth of the child** · **regulatory disorder of the child** · **chronical illness, developmental delay and/or disability of the child** · **relationship distress**

Note. The Table was adopted from the Study Protocol (Vogel, Färber et al., 2023).

Figure 1

Consort Study Flow Chart of the cRCT in I-PREGNO



Note. Study Flow of mothers participating in the cRCT of *I-PREGNO* in Germany. Post assessment (T1) was conducted 12 weeks after baseline, follow-up (T2) six months after baseline; HPs = healthcare professionals.

Table 2

Baseline demographic and clinical characteristics of both groups and in total.

	Intervention group	**Control group**	**Total**
Mothers	***n* = 42**	***n* = 53**	***N* = 95**
Age, mean (SD)	30.48 (6.91)	28.75 (6.17)	29.52 (6.53)
Highest Level of education (%)			
University degree	7.1%	26.4%	17.9%
Qualification for universities	9.5%	5.7%	7.4%
Qualification for universities of applied sciences	7.1%	5.7%	6.3%
Intermediate secondary school diploma	38.1%	22.6%	29.5%
Lower secondary school diploma	31.0%	35.8%	33.7%
No formal school diploma	7.1%	3.8%	5.3%
Social welfare (%)	35.7%	30.2%	32.6%
Childhood traumatic experiences (CTS), mean (SD)	9.84 (4.41)	9.59 (3.80)	9.70 (4.06)
Single parenthood (%)	31.0%	34.0%	32.6%
Planned pregnancy (%)	40.5%	56.6%	49.5%
Primiparous (%)	59.5%	58.5%	58.9%
Depressive symptoms (EPDS), mean (SD)	11.85 (6.51)	10.44 (5.85)	11.07 (6.16)
Parenting stress (PSI), mean (SD)	72.54 (21.84)	72.60 (18.08)	72.57 (19.73)
Counseling appointments, mean (SD)	5.30 (2.32)	6.76 (3.52)	6.26 (3.21)
Psychotherapy (%)	11.9%	11.3%	11.6%
Psychopharmaceuticals (%)	9.5%	9.4%	9.5%

Children			
Age in months, mean (SD)	5.34 (3.16)	6.42 (3.49)	5.94 (3.37)
Severe illness	7.1%	3.8%	5.3%

Note. CTS = Childhood Trauma Screener; PSI = Parenting Stress Index – Short Form (sum score without the subscale relationship quality); EPDS = Edinburgh Postnatal Depression Scale.

Table 3

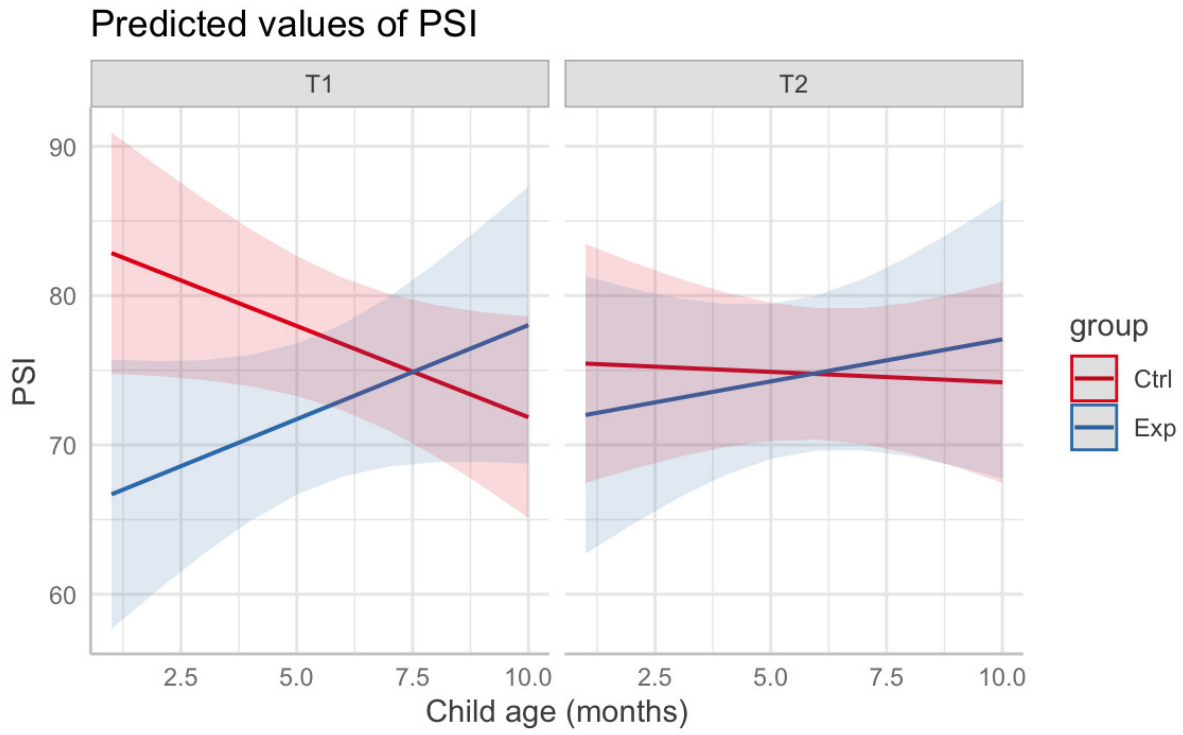
Descriptive Data and Model Parameters of Multi-level Models on Changes in Parenting Stress and Postpartum Depressive Symptoms across all Three Time Points.

	Baseline		Post assessment (T1)				6 months follow-up (T2)			
	IG	CG	IG	CG	Treatment effect		IG	CG	Treatment effect	
Outcome	**(*n* = 39)**	**(*n* = 48)**	**(*n* = 35)**	**(*n* = 44)**	***b [CI]***	***p***	**(*n* = 33)**	**(*n* = 45)**	***b [CI]***	***p***
PSI	72.54 (21.84)	72.60 (18.08)	72.71 (24.82)	76.32 (19.15)	-4.42 [-10.85; 2.03]	.19	74.39 (25.13)	75.18 (19.53)	-0.37 [-6.88; 6.13]	.91
EPDS	11.85 (6.51)	10.44 (5.85)	10.33 (7.01)	11.16 (5.52)	-1.55 [-3.81; 0.73]	.19	12.15 (6.26)	9.93 (5.63)	1.20 [-1.08; 3.50]	.31

Note. T1 = 12 weeks after baseline; IG = Intervention group; CG = Control group; CI = Confidence interval; PSI = Parenting Stress Index – Short Form (sum score without the subscale relationship quality); EPDS = Edinburgh Postnatal Depression Scale.

Figure 2

Interaction between time (T1 and T2) and Group in Parenting Stress for different starting points after birth (measured through the age of the newborn child).



Note. Child age reported in months, PSI = Parenting Stress Index – Short Form (sum score calculated without the subscale relationship quality); Ctrl = Control Group; Exp = Intervention Group.

Abbreviations.

CBT: Cognitive Behavioral Therapy
CG: Control Group
cRCT: Cluster Randomized Controlled Trial
CTS: Childhood Trauma Screener
EPDS: Edingburgh-Postnatal-Depression-Scale
IG: Intervention Group
mHealth: mobile Health
PSI: Parenting Stress Index – Short Form
TAU: Treatment As Usual

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Author contribution statement.

LV: Conceptualization, Data curation, Formal analysis, Methodology, Writing—original draft; LS: Formal analysis, Writing—review and editing; EB: Methodology, Writing—review and editing; TD: Conceptualization, Methodology, Funding acquisition, Writing—review and editing; TF: Methodology , Writing—review and editing; CH: Data curation, Writing—review and editing; CL: Conceptualization, Funding acquisition, Writing—review and editing; UL: Writing—review and editing; AO: Data curation, Methodology, Writing—review and editing; NS: Writing—review and editing; CS: Conceptualization, Data curation, Methodology, Writing—review and editing; MVP: Conceptualization, Methodology, Funding acquisition, Writing—review and editing; VV:; JW: Conceptualization, Methodology, Funding acquisition, Writing—review and editing; JL: Conceptualization, Methodology, Funding acquisition, Supervision, Writing—review and editing.

Conflict of interest.

The authors declare no conflict of interest.

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Ethics statement.

The study has received ethical approval from the ethical committee of the University in Bamberg (nr. 2022-02/09).

Transparency and Openness.

The code behind this analysis/simulation has been made publicly available at the Open Science Framework (OSF). The data will not be made publicly available prior to the year 2026 due to ongoing analysis. The data will then be made public within the project at the OSF-platform: https://osf.io/s28n7/ . If there is a legitimate interest in the data in advance, this can be requested from joerg.wolstein@uni-bamberg.de or mireille.van-poppel@uni-graz.at.

The data reported in this manuscript were collected as part of a larger data collection (at one or more points in time). Findings from the data collection have been reported in separate manuscripts. MS 1 (und. Rev.) investigated experiences of childhood trauma as a predictor for the depressive symptoms in mothers during the postpartum period. MS1 focuses on the following variables: childhood trauma, postpartum depression, attachment, and emotion regulation and only uses data from the baseline assessment. MS 2 (soon to be submitted) compares the app usage patterns between a sample with high psychosocial burdens in a blended care setting and a field study sample who used the *I-PREGNO* app on their own (self guided). The aim of this exploratory comparison is to provide insights into psychosocially burdened samples and to derive practical recommendations for the development and implementation of mHealth interventions that take into account usability, feasibility, and acceptability in a hard-to-reach group. MS2 only included data from the baseline assessments (i.e., age parents, age children, gender parents, gender children, sum of burdens and psychosocial burdens, socioeconomic demographics), data from the app (i.e., apps meta-data log files, number of logins, minutes spent in the app in total, minutes spent in each module, numbers of modules completed) and variables (i.e., MAUQ, mHealth App Usability Questionnaire for standalone mHealth apps, ‘ease of use’, ‘interface and satisfaction’, ‘usefulness’) from the post assessment that are not part of the current manuscript.

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How to e-mental Health? A Guideline for Researchers and Practitioners using Digital Technology in the Context of Mental Health

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How to *e-mental Health*? A Guideline for Researchers and Practitioners using Digital Technology in the Context of Mental Health

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ABSTRACT

Objective. Despite an exponentially growing number of digital or e-mental health services, methodological guidelines for research and practical implementation are scarce. We aim to promote methodological quality, evidence, and long-term implementation of technical innovations in the healthcare system.

Method. This expert consensus is based on an iterative Delphi adapted process and provides an overview of the current state-of-the-art guidelines and practical recommendations of the most relevant topics in e-mental health assessment and intervention.

Results. Covering three objectives i) development, ii) study specifics, iii) intervention evaluation, 11 topics were addressed and co-reviewed by 25 international experts and 1 think tank in the field of e-mental health.

Conclusion. As the first of its kind, this expert consensus provides a comprehensive essence of scientific knowledge and practical recommendations for e-mental health researchers and clinicians. This way, we aim to enhance the promise of e-mental health: a low-threshold access to mental health treatment worldwide.

INTRODUCTION

Mental illness is on the rise, and since the COVID-19 Pandemic, prevalence rates have significantly increased[1]. At the same time, healthcare systems around the world are challenged to provide adequate psychological help due to several (individual and social) barriers and challenges. These challenges include health disparities, insufficient infrastructure, workforce shortage, long waiting lists[2], stigmatization, and low perceived need[3]. The COVID-19 outbreak also resulted in an unexpected acceleration of digitalisation in different fields[4], as well as in the increased efforts in prevention, treatment and rehabilitation of mental disorders. There are numerous advantages that *e-mental health* may offer: low-threshold access, geographic independence, constant availability, and potentially lower cost[5].

Despite the increase and numerous advantages of e-mental health solutions, several shortcomings affect the development and delivery of e-mental health interventions. Firstly, therapists are still skeptical of prescribing digital mental health care because they perceive themselves as not sufficiently trained in this area and lack knowledge about which technologies are validated and affordable for various patient groups[6]. Furthermore, uncertainty exists regarding the impact that digital approaches might have on the therapeutic relationship[7]. Secondly, among other challenges (e.g. not being familiar with new technological developments), users face difficulties in distinguishing scarcer, evidence-based interventions among the plethora of health and well-being offers[8]. Thirdly, the field of research is also inconsistent regarding terminology[1], leading to miscommunication with users and stakeholders[9]. Finally, guidance and methodological advancements are not only necessary to

[1] see Smoktunowicz et al. (2020), for a "Consensus statement on the problem of terminology in psychological interventions using the internet or digital components"

improve user experience, but also to raise quality standards in development and evaluation. In meta-analytical reviews, most e-mental health apps were shown to perform badly regarding data security and transparency[10], methodological quality, and attrition rates[11]. However, the field is evolving and app evaluation frameworks (AEF)[12] and common glossaries[9] have been developed to overcome such limitations and increase methodological quality.

With this paper, we aim to provide current practical guidelines for researchers and practitioners in the field of e-mental health to cover the most important topics of the development, deployment, and evaluation of e-mental health assessments and interventions. The term *e-mental health* covers four types of digital services[13]: 1) information provision, 2) assessment for screening and monitoring, 3) intervention, and 4) social support. More specifically, this includes digital solutions in a comprehensive way, including mobile and web-based apps, digitally-delivered interactions with clients via e.g. video calls and chats, chatbots, and devices for assessing and monitoring health (e.g. wearables, smartwatches). Since the field is so dynamic, and constantly renews itself, we refrain from focusing on specific devices, data collection, analysis, or interaction methods, but aim to provide overarching and enduring recommendations.

METHOD

This is an expert consensus of the work of international researchers in the field of e-mental health aiming to promote methodological quality, evidence, and longer-term implementation of technical innovations in the healthcare system. For this purpose, the original author group from Germany investigated and contacted leading experts worldwide in the field of e-mental health based on Google Scholar profiles, groundbreaking publications and achievements, and personal recommendations. Thirty-six e-mental health experts were invited to contribute with their knowledge, provide an overview of the current state-of-the-art and give

practical suggestions resulting in 25 authors and a think tank contributing actively (see Figure 1). The author's expertise covers multiple disciplines (psychologists, psychiatrists, computer scientists, industry) with different working areas (clinical studies, (tele-)psychotherapy, mental health state assessment, development and conducting of digital interventions in the field of mental health, app development, artificial intelligence) in children, adolescents, and adults around the globe. We sought diversity in terms of research seniority, culture, and gender.

For finding consensus on relevant recommendations and guidelines for clinicians and for researchers, an adapted, structured Delphi procedure in nine steps based on iterative feedback and co-reviewing by the authors was implemented[14], guided by LV, CS, and JL. Firstly, a list of the three most important objectives was discussed within the authors and agreed on: i) development, ii) study specifics, and iii) evaluation of e-mental health assessments and interventions. A total of 15 topics were brainstormed within the objectives (Terminology, Where to start, Content, Participatory Research, Target group, Suicidality, Data protection and data security, Artificial intelligence in assessment and intervention, Sensing and wearables, Drop-out rates and compliance, Efficacy evaluation, Ecological Momentary Assessment, Transfer into (clinical) practice, App evaluation frameworks). Thereafter, the topic "Drop-out rates and compliance" was removed as a separate chapter, and the section "Where to start" and "Terminology" as well as "Target group" and "Participatory research" were combined. Secondly, authors were grouped into teams due to their expertise and preference (2-4 for each section). All author teams were asked to include the latest literature and findings, clear recommendations respecting their topic, potentially helpful links for further literature recommendations, and a list of do's and don'ts for each topic (see Supplementary Material). After all authors delivered their first drafts, LV, CS, and JL reviewed the content and checked redundancies, and synthesised all parts into one piece on an online document, accessible and editable for all authors. Consequently, all participating authors were asked to review the whole

manuscript and comment on each section regarding i) discrepancies, ii) agreement with their own experience, iii) literature recommendations, and iv) other comments. First-authors of each section finally discussed and/or integrated such comments with the support of CS, LV, and JL, who again developed a second clean version that was then handed over to more senior researchers in the field PC, EN, LN, and TR for a global check-up and proof of coherence. Minor issues (typos, references) were resolved by the first and last authors, specific comments were fed back to the author teams and either discussed, integrated, or dismissed. To achieve a final version and common “ground truth”, the last issues were syndicated, and all authors reviewed the again cleared manuscript and consented.

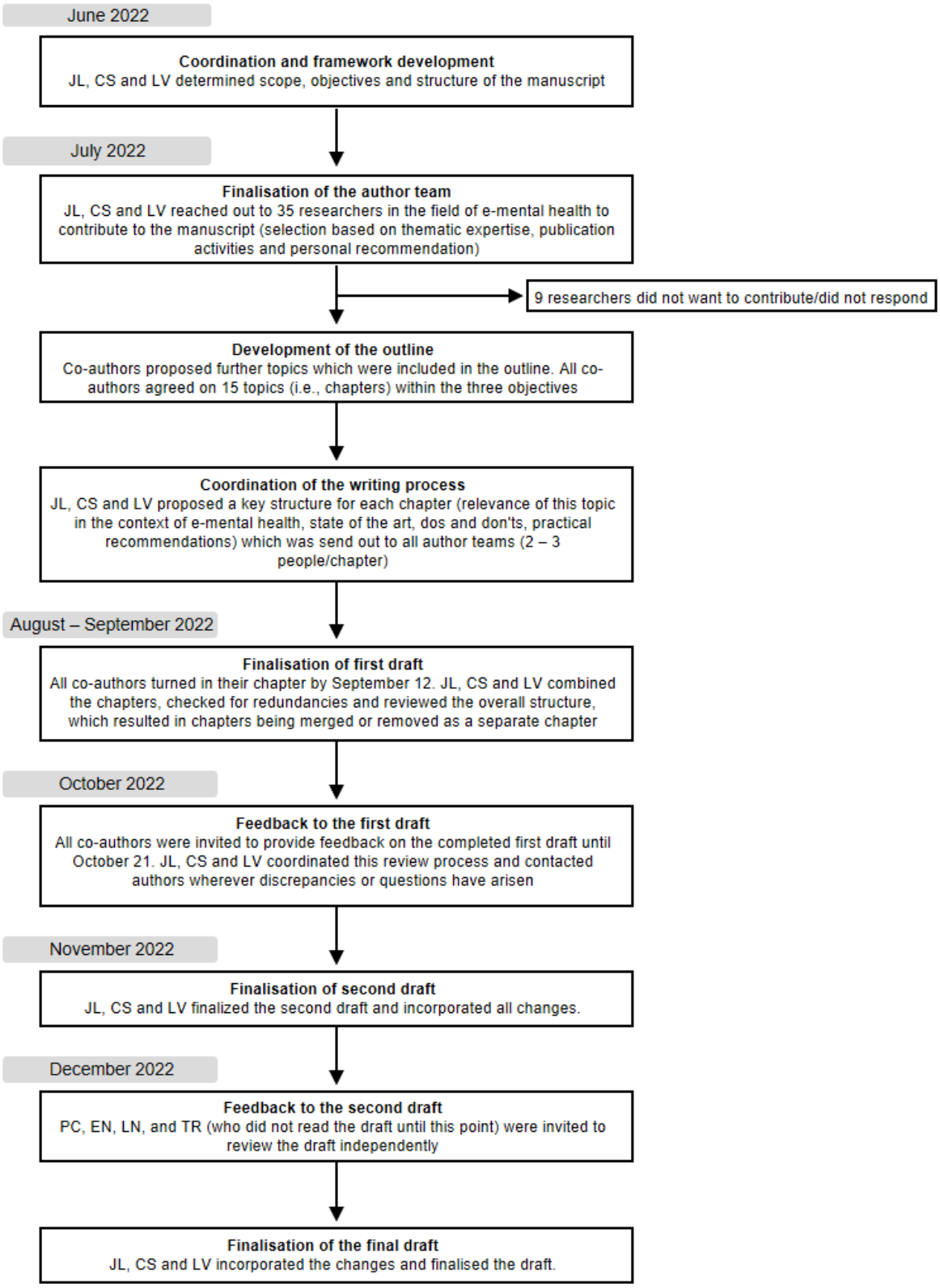

Figure 1. Flow diagram illustrating the manuscript creation process.

I E-MENTAL HEALTH DEVELOPMENT

1 Where to start?

The implementation of any e-mental health project - assessment or/and intervention - is preceded by the fundamental decision about whether a digital approach is appropriate to address the specific research issue. Researchers need to identify the characteristics of the problem that allow for a digital operationalisation (i.e., multi-faceted, context-sensitive, time-sensitive) and the specificities of applying technology (i.e., problem definition). Once it is established that a digital solution is the most appropriate approach, researchers can be clear about I) their **objectives, theory**, and **hypotheses**, which they aim to investigate. This may guide through several decisions that need to be taken throughout the process (see Figure 2). Furthermore, II) the specification of the main **target group** (i.e., demographics, mental disorder, cultural background) and the **target group involvement** (i.e., participatory research) is essential for following decisions, like III) the **extent** (e.g., self-guided, partly guided, blended counseling) and **nature** (e.g., on-demand, asynchronous, chat, video-based) of the delivered approach.

Digital technologies can be used to facilitate **communication** between practitioners and/or patients and can vary in their intensity of communication. Thus, the **level of interaction between users and providers** needs to be defined (e.g., guided by a research team for technical support, or therapists). Furthermore, content transfer may range from passively reading a text vs. clicking, and engaging more actively with the digital solution or with a coach/therapist. This, greatly depends on IV) the chosen **type of platform** that is used to deliver the e-mental health service (e.g., online and offline, browser or app). In this context, sensors can also be used (e.g., touch, motion, pulse, gaze) to provide direct feedback about physical and emotional responses. This decision also depends on budget and collaboration with (external, potentially

commissioned) tech companies, self-made toolkit supplies for e-health studies, in-house IT support, and/or cooperation within a project with a technical partner.

For high-quality assessment and interventions, V) **best-practice** and **evidence-based components** should show the foundation of digital solutions. Furthermore, the definition of VI) the **technical development process**, including different disciplines, experiences, work cultures, and (project) aims should not be underestimated. Ideally, an agile, iterative process in a multidisciplinary team is set up to develop and transfer psychological content into an attractive digital solution. Especially for the implementation of gamification features, interactive content and delivery logic, an interdisciplinary shoulder-to-shoulder working culture is most promising. Together with the technical experts, VII) decisions about **data flow, data storage, access**, and **transparency** need to be taken and the following procedure clearly defined. Study participants should be well informed about such details and comfy their trust in academic e-mental health research (as a quality criterion, diverging from more commercially driven supplies). Following these steps, the VIII) **risk management** strategies and drop-out prevention may be defined. As a final step, the research team may determine IX) what study design best suits the **proof of objective and hypotheses**. Naturally, those defined steps interact, are dynamic and need to be reconsidered during the whole process. In addition, other specific frameworks and guidelines may support researchers and clinicians in their project planning decisions[15–20].

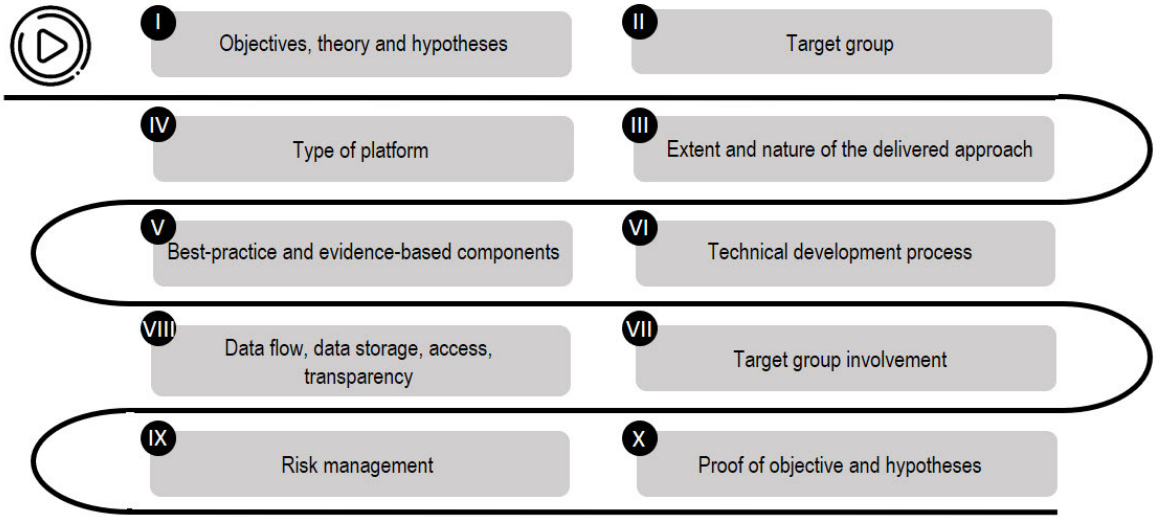

Figure 2. E-mental health study conceptualisation process

2 Intervention content development

The process of content development for a multicomponent e-mental health intervention is two-staged. First, researchers need to select psychological and psychotherapeutic strategies based on existing evidence or best-practice approaches for the selected target group and intervention aim. Second, the components of the intervention need to be transferred to the digital solution. This technical translation poses a range of pitfalls and therefore requires a highly iterative and dynamic research approach which should take place within a multidisciplinary team (e.g., mental health professionals, software engineers, design experts[6,21]).

A pragmatic approach comprises converting existing resources, such as applying psychological content from text-based manuals, exercises or questionnaires in agreement with the original authors. However, information displayed in digital solutions follows a rather different temporal and architectural structure and the user engages with the app with a different "user mindset" because app use occurs at varying times, with varying intensity, in varying contexts. To consider these peculiarities of the digital environment, a significant amount of

time, financial costs, perspectives, and tests must be dedicated to the process of transforming specific components of traditional health interventions. More concretely, this means that each piece of content must be condensed to the core aims and elements that are to be conveyed through the digital solution. It is important that the structure (e.g., division into modules, sessions/lessons, and exercises), delivery logic (e.g., temporal availability of content) and complexity of content is always set against the background of the targeted group, and outcomes of the intervention. Once the crucial elements and user needs are determined, a user experience story may be developed.

Engaging elements may enhance a positive and reinforcing environment (e.g., text, audiovisual, prompts, quizzes, self-report questions, gamification features). Although forced guidance through an assessment or intervention may be needed to address the research objectives, flexibility and the personalisation of features (i.e., Just-in-Time Adaptive Interventions[22]) are likely to be beneficial to increase the attractiveness of an app-based or smart-phone intervention[23]. In general, the content should match the "look and feel" of the digital format (e.g., length of a video, amount of text displayed[6,24]). It is also necessary to consider which resources are realistically available to the development team and if it is possible to develop new, customised multimedia elements. Finally, content development should be specifically focused on the target group.

3 User-centered design and participatory approaches

The implementation of user engagement participatory research within the development of e-health interventions is currently recognised as a way to increase the ease of use as well as the likelihood to fit the users' needs. It is therefore recommended to limit common problems like low uptake, high complexity, and poor fit to the user's needs. Participatory research actively involves end-users, healthcare professionals, and other stakeholders in all stages of the development and research process (including the formulation of the research question and goal,

planning research design, selection of research methods and outcomes, interpretation of results, and dissemination) by taking into account their views, needs, expectations, and cultural background[25,26]. For a participatory approach, it is mandatory that end-users also participate in the decision-making processes[27].

In the field of e-health intervention development, user-centered design (UCD) has been established in recent years[28,29]. UCD represents a systematic, iterative process with three phases during development[30]. First, an initial investigation of the users' needs should be conducted (e.g., differentiating children, adolescents, adults and elderly users). The purpose of the first phase is to identify the needs of the target group, and to identify features and characteristics of the intervention that would be acceptable and preferred. For example, strategies such as personalisation, gamification, and including a social component have been identified as important for the users' engagement[31,32]. Focus groups or interviews with future users or individuals in their environment (e.g., therapists) and/or open-ended written survey questions are suitable methods for user needs assessments. Qualitative research methods (e.g., thematic analyses) are suitable for establishing UCD guidelines[33]. Secondly, a prototype with key features of the intervention should be created, which can be used in usability tests[30]. During the third step, usability tests, researchers observe potential users interacting with the prototype in a controlled environment, while they are simultaneously thinking aloud[34]. Researchers take notes about the participant's behaviours, comments, and issues, to uncover and adapt functional and design flaws[29,30]. This phase is a balancing act between drawing evidence-informed strategies and content from the literature and combining them with ways of delivering this information in an acceptable and engaging way. Continuing to engage with the target group at this stage ensures that when the product is finalised, the target group has been involved and has provided continual feedback and guidance throughout the process, maximising the likelihood that the final product will meet the needs of the users. It must be noted that UCD represents a

preliminary stage of participative research as participation takes on a strictly consultative role and the project's decisions are still in the control of the researchers[35]. To achieve meaningful participation, it is necessary to involve end-users as early as possible in the research process and in all decision-making processes.

Focusing on the target group's specific needs is particularly important when it comes to digital interventions, with significant variability in the aspects of technology that will appeal to different groups of users[36]. Clinical observation shows less adherence when participants expressed a wide range of needs but the digital treatment addresses a single disorder[37]. When identifying the target group, specifics that should be considered include age, gender, cultural (racial and ethnic) background, delivery context, and delivery format. This information can guide the best ways to engage with the specific target groups at the outset of the project. Additional questions relate to the answer if it is recommended by the mental health professionals. In a UCD, all potential specificities must be explored together with the target group[38].

Once the specifics of the target group have been identified, the next step is to conduct an appropriate stakeholder engagement process with all parties involved in the delivery, dissemination, and implementation of the intervention, as well as the end-users. In addition, the examination of the usual consumer behaviour by the specific target group may be helpful, e.g., what kind of health apps are used, how often, and what features are more or less appealing.

II STUDY SPECIFICS

4 Managing suicidality

E-mental health research is often conducted with participants recruited via the internet without any face-to-face contact throughout the entire research process. As a result, both researchers and institutional review boards express great uncertainty about how to manage

participants who are experiencing severe mental health crises like suicidal thoughts or behaviour (STB)[39,40]. In common practice (not only in e-mental-health research), individuals with a history of suicidal behaviour or who affirm suicide-related questionnaire items (e.g., item nine of the PHQ-9) are often excluded from trials at baseline[40]. This practice, however, results in almost no increase in safety for participants, because it overlooks that suicidality often is a highly fluctuating symptom[41] and study participants may conceal their suicidal ideation in order to be admitted to the study[42]. Moreover, while there is an established association between suicidal ideation and previous suicidal attempts with subsequent suicidal behaviour, their practical predictive utility in differentiating individuals who are likely to exhibit suicidal behaviour from those who are not is limited[43]. Indeed, most people who die by suicide do not score in commonly used suicide risk assessments[44]. Thus, excluding participants who score on suicidality items primarily reduces the external validity of study results[45], which poses potential risks to users when these interventions are implemented in real-world care.

Given the impossibility of eliminating the risk of suicidality in e-mental-health research, we propose implementing the following measures to increase participant safety during the intervention, as it has been practiced in prior randomised controlled trials of digital interventions specifically designed for individuals with STB[46]. The assessment of STB should be expanded, including the use of specifically validated questionnaires[47]. At any point where patients may potentially report suicidality (e.g., in the intervention or questionnaires), it must be ensured that this is noticed by the study team. The study protocol should specify how to react to reports of STB, and these procedures should be trained and team members be supervised. This reaction can, but does not necessarily need to include a telephone or other contact by the study team. However, in case of a disclosed immediate and definite plan for suicide, the country-specific emergency services should be informed. Participants should be clear about these procedures as well as about the timeframe within which their entries will be

seen by a member of the study team. We recommend documenting this in the informed consent. When STB is reported, detailed and visible information on support and contact services (e.g., national emergency numbers and 24-hour help lines) should be provided automatically including low-threshold click-to-call links. The use of other forms of treatment should not lead to an exclusion from the trial. Instead, individual crisis plans should be developed together with the participant. For studies with particularly vulnerable study samples, a collaboration with local emergency centres should be arranged in advance. In intervention trials for mental disorders, optional modules that specifically target STB should be available[46,48]. In general, help options should be equally available to all participants, irrespectively of their group allocation and the type of intervention[35].

5 Data protection and data security

Significant deficiencies in data protection and data security may inhibit e-mental health assessment and intervention studies[49,50]. The focus of data security is to prevent unwanted data loss and the unauthorised manipulation of data. The protection of personal data (e.g., patient contact details) is of uttermost importance in e-mental health applications.

In the development of an e-mental health offering, it must be anticipated that users may unintentionally reveal their access data, lose their devices, or use the devices for other (harmful) actions (e.g., children visiting adult websites). To counter these problems, tools can be installed on devices that lock access to other content. Preconfigured and password-protected study smartphones should be used. Two-factor authentication prevents mass registrations by fake users that can lead to poor data quality. In any case, users should be thoroughly informed about typical problems and dangers. This also applies to harmful software that the user captured unintentionally (e.g., keyloggers and spyware spy on sensitive data).

Further challenges include incorrect programming, which can enable unauthorised access to sensitive data. Therefore, a quality-assured software development process is essential[51]. If a manufactured app is used, the data should be stored in the healthcare institution's storage facilities rather than in the manufacturer's cloud. An external data hosting service provider should be certified. No data should be stored permanently on the device of the user, and a virus and trojan scanner should be installed. Immediate data transfer instead of data storage on the device as well as automated data backups could also ensure data quality. To prevent an attack where data traffic is intercepted, manipulated, or deleted, an end-to-end encryption (via TSL/SSL) should be used to transfer data. There should be brute-force attack protection built into the platform and all information in the database should be encrypted using a high-end algorithm with separate keys for each study.

The most effective measure is the pseudonymisation of sensitive data, which makes it worthless for unauthorised persons without any additional information[52]. The process of pseudonymisation and internal de-pseudonymisation of the data must take place in a separate system[52] and be considered even before the selection or development of an e-mental health system. Data protection and transparency are especially relevant for the use of artificial intelligence (AI) methods.

6 Artificial Intelligence in assessment and intervention

AI holds great promise for e-mental health, largely owing to the advances in affective computing. The latter includes the analysis, synthesis, and reaction to the affect and emotions of humans using the former. The last decade has seen major progress thanks to the rise of deep learning as an enabler in (generative) AI[53].

Likewise, great progress has been made in the recognition of emotion (e.g., in categories or dimensions such as arousal and valence), depression (e.g., in "dimensions" such as

depression assessment questionnaires as the BDI-II or PHQ-9), or other mental disorders[54,55]. The means of assessment serve mostly audio (e.g., speech), video (e.g., facial expression, body posture, gait), text (written or spoken language), and physiology (e.g., via heart rate, skin conductance). A series of research competitions (e.g., AVEC[56]) have been benchmarking the progress of the community including tasks of the above from these modalities. Additionally, several reports exist on successful emotion and depression analysis from phone usage data, touch, and other information sources[57]. At the same time, readily available toolkits independent of the application domain and target tasks are sparsely available as "out-of-the-box" solutions. Usually, training these to match the target domain and target task is required. Also, robustness of real-world applications "in-the-wild" has increased notably over the last decade[58]. However, not all free-for-research and beyond solutions include state-of-the-art de-noising, target person verification, or features such as subject adaptation. In addition, while such solutions often work largely independently of the subject, most of these tools are mostly geared towards a specific culture or language, or another context, due to the data they were trained upon. For practical solutions, this requires usually to re-train such tools or "engines" on the target data.

Emotion can also be synthesised with increasing realism by AI and recently deep learning approaches – often reaching human-level or close-to-human-level quality for speech and image or even language rendering. This led to effective virtual agents such as the "sensitive artificial listeners" that may be implemented in clinical practice for assessment and interventions. Again, platforms are available open source and free for research, but usually require some adaptation to the target task. Most notably, the AVEC challenge series had recently hosted the first ever "AI only" depression challenge, where interviews were conducted by an AI, and the recognition of depression severity was also conducted by AI reaching competitive results concerning human assessment considering the subjective nature of the task.

The recent past brought further breakthroughs in AI and particularly Deep Learning by the advent of transformer architectures, and diffusion approaches enabling a next generation of abilities in recognition of affect, and generation. This era is also coined by the "foundation models": These extensive data pre-trained models are marked i) by convergence, i.e., rather than training "your own model" from scratch, the trend is to use these models and fine-tune them to one's needs, which led to considerable improvements in a field, where data is continuously (too) scarce; and ii) by emergence. The latter is fascinating, as, while these models may not have been trained on tasks in affective computing or such relevant to e-mental health, they may show emergent skills in these stemming from the sheer "big" quantities of data they were trained upon. In Amin et al (2023), it is shown that the well-known ChatGPT (a general pre-trained transformer (GPT)) can predict suicidal risk at competitive performance "out-of-the-box" levels. This is without fine-tuning and training on the task, when compared to traditional and deep approaches fully trained on the task[59]. Similarly, Dall-E 2 - also based on GPT - can paint emotional faces from verbal descriptions - arguably also emergent behaviour from the perspective of affective computing. In short, we seemingly enter an era where e-mental health relevant skills can emerge in AI of the present and the future, which are big-data trained in a more general manner, such as foundation models. Such models could render even explicit training of tasks increasingly obsolete. In combination with the increasing power of generative AI ("GenAI"), interventions could be produced in a rich manner including questioning and chatty communication, potentially including the audiovisual rendering of artificial therapists, which are highly personalised and socio-emotionally empowered. Current foundation models such as GPT-4 or Metaverse as virtual space may be only a sneak preview of the oncoming power and abilities, which may help overcome the uncanny valley of such artificial therapists and help AI get to know patients better than any human depending on their data access. Accordingly, they might also soon be able to influence us in strange ways.

Potential dangers may relate to AI-driven chatbots or generative AI such as ChatGPT, which can be charismatic and appear emotionally involved due to expressing emotions (with emojis or an empathic language)[60]. This interaction may implicate an image of being a friend or human but if assumed would be highly unethical. Since individuals with mental illness are a vulnerable group, often longing for appreciation and insecurity in social contacts, great emphasis must be put on ethical guidelines. Bot-based interaction must be recognised as non-human to minimize the possibility of manipulation and harm or even dependence on the interaction with such AI - potentially at the cost of human relationships[61]. Furthermore, such AI may find its ways of behaviour, which may be even more persuasive and change the human-to-human behaviour of such interacting with it in the long run. Asking participants to use sensing and wearable data collection tools can often provide supplementary data to support AI research methods.

7 Sensing and wearables

Historically, diagnosing mental health conditions has relied on thoroughly validated self-report questionnaires. While questionnaire-based assessments are an indispensable source of information in this context, they are purely based on introspection, can lack vital information that is systematically neglected by the patient (e.g., due to self-other knowledge asymmetry[62]), are temporally constrained (i.e., one-time, infrequent assessments), limited in granularity (i.e., in terms of a selection of questions in the anamnesis), and suffer from floor and ceiling effects (i.e., lack sensitivity to change at their scale's extremes). Foremost, it is becoming increasingly apparent that patients are likely to be not able to self-report the fine-grained and complex patterns of behaviours in various situations of daily life that characterise their physical and psychological traits, states, and changes in these.

The ongoing evolution in *mobile sensing* and *mobile computing and communication technologies* ameliorates this situation. More and more sophisticated and accurate sensors in consumer electronics (e.g., smartphones or wearables) allow for the unobtrusive and automated collection of high-frequency, objective, longitudinal data on human behaviours, states, and environmental conditions[63,64]. Figure 3 provides an overview of the variety of data that off-the-shelf consumer electronics sensors can provide.

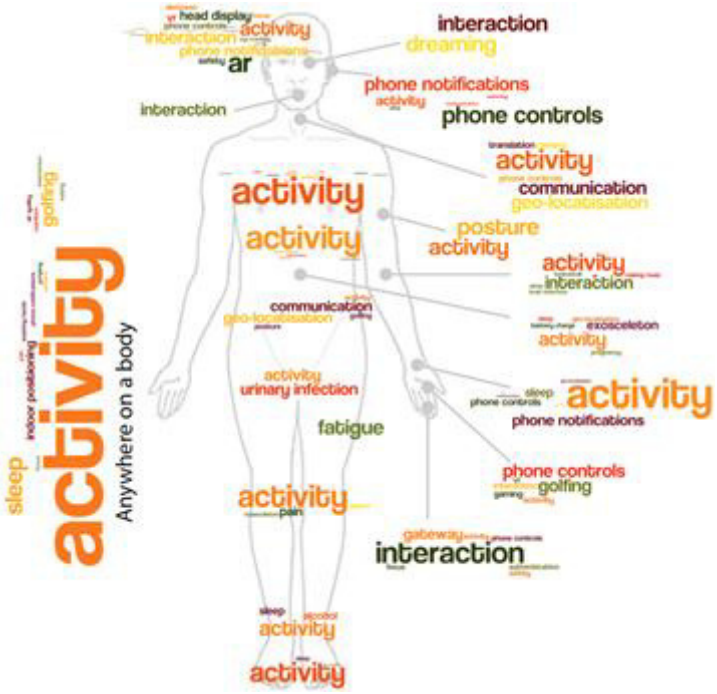

Figure 3. Overview of mobile sensors embedded in consumer electronics and variables they provide[65]

On a growing scale, mobile sensing data is increasingly being used throughout the health and behavioural sciences to understand behavioural aspects of mental health through digital biomarkers[66–68] to detect health conditions and deterioration[69,70] and improve conditions through behavioural interventions[71,72].

While mobile sensing is becoming increasingly established as a method in mental health research, its standardisation is challenging due to rapid and frequent changes in hardware,

operating systems, and ethical and legal frameworks, amongst others[12,73]. Participants should be aware of often liberal data storage and access policies of companies. While this circumstance has acted as a roadblock in the past, the main mobile operating systems have started to develop standardised so-called application programming interfaces (APIs) for researchers to access and use in empirical studies (e.g., Android Health Connect[2], Apple SensorKit[3] or HealthKit[4]).

However, the most innovative methods can be useless if they miss the mark. While offering specific new opportunities, e-mental health interventions need to be evaluated properly.

III EVALUATION

8 Efficacy evaluation, RCTs, and other methods

There is no shortage of available e-mental health interventions, most of which are not well-evaluated[74]. However, despite the young age of the field, high-quality evidence is needed from the start, as unreliable results can stick around in a classic canon of literature[75] and lead to low quality of developments, or even harm the patients. This section offers recommendations and ideas for how to produce this high-quality evidence. While there are some unique ways to evaluate e-mental health interventions, which will be addressed below, a good starting point for an evaluation study are the same principles that apply to classic interventions: Besides observational or case studies, the gold standard to evaluate (mental) health interventions are randomised controlled trials (RCT). First meta-analyses of e-mental health intervention RCTs show promising effects, even when compared to face-to-face treatments, but also that primary studies have been focussing on a small range of diagnoses and age groups[76]. A high variance

[2] https://android-developers.googleblog.com/2022/05/introducing-health-connect.html

[3] https://developer.apple.com/documentation/sensorkit

[4] https://developer.apple.com/documentation/healthkit

in types of control groups and interventions further reduces the amount of knowledge that can be gained from meta-analyses. Therefore, the field would benefit from further RCTs addressing these issues.

When setting up and selecting variables for an evaluation study of an e-mental health intervention, past studies of classical interventions can serve as an example. Researchers and practitioners still need to investigate any potential adverse treatment effects[77] and the importance of mediators and moderators of treatment effects that apply in face-to-face settings (i.e., symptom severity, self-efficacy, motivation, age or amount of therapist involvement). Special attention should be paid to therapist effects,which robustly explain a relevant amount of variance in classical treatment outcomes[78]. For the evaluation of e-mental health interventions the type of the application (stand-alone, prescribed after seeing a professional, continued blended care) can influence which therapist effects are present. There might be none if there is no therapist involved, they might be similar to classical mental care, or they might be even stronger, e.g., when negative biases of a professional towards digital solutions are present. Studies should aim for an extensive and diverse pools of therapists, also because estimates of the therapist-level random slope suffer from more bias when there are very few therapists in a study[79].

Going beyond these traditional evaluation standards, evaluations of e-mental health interventions offer exciting new possibilities: The underlying technological infrastructure has the potential to extend the classical outcome-oriented designs and measures as it becomes more achievable to measure various *process variables*. These can focus on psychological content, such as therapeutic relationships (e.g., rupture-repair[80]), sudden gains/losses[81] or personalised items and networks[82,83]. Time series data on an individual level will allow new hypotheses to be answered. Also, by using shifting time windows, one can produce a meta-time series of e.g.

dynamic variance or critical fluctuations and use their change as an outcome variable[81,84,85]. Another possibility is to evaluate individuals' network parameters (e.g., networks of symptoms) and their change over time or recurrence plot quantification[86,87]. In short, the type and amount of data from e-mental health studies can change the classical approach of *aggregating first (across participants) and analyse second* to *analyse first (on the individual level) and aggregate second*. Therefore, e-mental health studies have the huge potential to expand the concept of traditional RCTs. Going beyond RCTs, further methodological approaches (e.g., A/B testing, trials of principles) can be used to test small differences within an intervention or to test the efficacy of a general principle of an electronic solution (e.g., self-monitoring). These approaches of agile science might contribute to the reduction of the time discrepancies between technical development and evaluation results[21] which is especially important when working with fast-changing technologies. As a specific option for evaluation, Ecological Momentary Assessment (EMA) will be discussed in the next section.

9 Ecological Momentary Assessment

EMA (synonyms: ambulatory assessment, experience sampling method, real-time data capture) encompasses a range of methods that involve repeated assessments of individuals' dynamical experiences and behaviours in their natural habitat, thereby increasing both ecological validity and generalizability, while minimising recall biases[88,89]. This method can be used in various stages of the therapeutic process (e.g., diagnostic process, tracking the course of symptoms during treatment and, transfer of therapeutic effects thereafter).

EMA offers the possibility to combine subjective assessments with further methods (e.g., psychophysiological and physical activity assessments)[88]. EMA also allows for integrating continuous mobile sensing (i.e., digital phenotyping[90]) to predict critical phases[91] and to improve the timing of EMA inquiries[88]. By providing a detailed picture of mental state and functioning, EMA promises to be more sensitive to capturing change and, thereby,

improving the assessment of the therapeutic effects of interventions[92]. One of the most promising avenues of EMA is the opportunity to extend treatment beyond the clinical setting into real life using e-mental health applications[93].

When setting up a study, the following aspects are very important: There are various sampling designs (i.e., time-based, event-based, combined sampling schemes). Choose the one that fits your research question. Carefully balance the length of the questionnaire presented at each assessment, the number of assessments per day, and the assessment epoch to ensure high compliance rates[94]. Also, allow participants to delay or actively decline alarms. Choose an adequate time frame for the questions. Whereas questions referring to the present moment minimise retrospective bias, those with a specific time interval enhance representativity. When deciding on the order, group items with the same timeframes, and ask transitory constructs (e.g., emotions) first, questions that are not likely influenced by preceding questions (e.g., context) at the end. If you must develop new items, use two, or better three per construct, to be able to determine the items' reliability[95]. A crucial point is that the sampling strategy must fit the temporal dynamics of the underlying process; otherwise, results can be misleading[96].

Carefully determine the length of the EMA period that is needed to answer the research questions. However, balancing the lengths is key to ensuring participants' compliance[94,97]. Meta-analytic results revealed higher compliance rates in studies offering monetary incentives compared to other or no incentives[94]. Moreover, linking the incentives to a certain degree of compliance might reduce dropouts during the assessment period[97].

10 Transfer into (clinical) practice

To make e-health interventions feasible for real-world settings, the following criteria should be considered: (1) research should integrate follow-up measurements to assess long-term usage since there is a lack of meta-analysis on long-term benefits of mental health apps

as the handling of follow-up measurements and dropouts is inconsistent[76,98]. Indeed, reviews showed that too few studies used (long-term) follow-up measurements and many showed huge dropout rates of 47%[99,100]. (2) Researchers, developers and practitioners should consider relevant factors to improve adherence to digital health interventions in real-world contexts[101]. When looking into real-life settings, Fleming et al.[100] found in over 10,000 digital mental health apps only 11 peer-reviewed publications analysed uptake and usage data in such real-life settings. The completion rate was between 44-99% in RCTs but dropped to 1-28% when looking at real-world usage. Furthermore, new (machine learning) approaches showed that a distinction into user subtypes and, therefore personalisation of interventions could lessen the effects of interventions[102]. Thus, researchers and developers should consider relevant factors to improve adherence to digital health interventions in real-world contexts: (3) Integrate mood monitoring, feedback and human/automated support to lower dropout rates[103]. For example, dropout rates decreased by 46% when therapeutic support was provided and even minimal care with only administrative support resulted in a meaningful decline in dropout rates[104]. Further, it has been shown that when specific data of EMA is fed back to clients regularly, the number of missing EMA data is low (<10%) and reduces over time[85]. Digital health is a global challenge, but the implementation of digital health interventions is based on complex national and local economic and political processes. (4) Hence, when conceptualising and evaluating the implementation process of e-mental health interventions researchers and practitioners should always consider the integration of all relevant stakeholders that will be involved in the final roll-out of the digital interventions, such as lived experience users and beneficiaries, companies, health insurance, or other political institutions and decision-makers. We argue that for each digital intervention a unique approach for its roll-out should be considered and developed along with its scientific evaluation. Target groups, clinical scope (prevention or intervention), business models, funding strategies, long-term technical maintenance,

requirements for quality management, regularity frameworks, data safety, market access, and reimbursement schemes are only some examples to be considered. The exploitation of evidence-based interventions may further benefit significantly from the flexibility, variety of resources, and agile methods of industrial partners. Even where the process is successful, any on-going quality control in clinical practice is substantial and very challenging in a dynamic field of tech industries. Furthermore, potential side effects tend to be underestimated, leading to a broad supply of unapproved interventions.

11 App evaluation frameworks

As the number and diversity of e-mental health solutions increases, so does the need to evaluate which are most effective and safe. While regulatory bodies are beginning to approach the regulation of primarily mobile and web-based apps but also other sorts of digitally delivered interventions, most efforts remain nascent[105,106]. This means clinicians and patients must rely on tools like app evaluation frameworks (AEF) to help them make more informed decisions. While there are also an increasing number of AEF, there are differences in their approaches with some providing scales vs. ratings, subjective vs. objective metrics, and others information vs. databases. Each approach has a unique value depending on the use case and clinical needs.

Perhaps the largest category of app evaluation is scales or frameworks that provide guidance and information on how to consider an app. For example, the American Psychiatric Association's app evaluator framework[107] provides a four-step process with corresponding questions about privacy, efficacy, engagement, and clinical utility. While this framework does not provide scores or ratings, there are other frameworks such as the Mobile Application Rating Scale (MARS)[108] that do. Often these rating systems require training before they can be properly used. Ramos et al.[109] reviewed popular frameworks through the lens of diversity, equity, and inclusion and found that only 58% included related metrics which offer a target for future efforts and evaluation criteria whether subjective or objective.

A related consideration in app evaluation is the use of subjective vs. objective metrics. For example, questions about the aesthetics or usability are inherently subjective and will vary between users. Examples of objective metrics may include videos or music in an app. Each approach has merits and subjective evaluations, often in the form of user or expert reviews that can provide rich contextual information about an app. However, it can be challenging to keep these reviews updated and current in the rapid-paced world of apps[110]. Objective metrics may not offer such context but often provide easier-to-update approaches that may have higher inter-rater reliability by their very nature. One example of such an approach is the Mobile App Index and Navigation Database (MIND, mindapps.org) which rates apps across 105 criteria that are derived from largely objective criteria[111].

A further consideration is how users can engage with any AEF, whether it offers subjective or objective metrics, frameworks or ratings. Some approaches like Psyberguide, MIND, and UK's National Health Service Apps Library maintain websites that users can search while others provide only the rating scale or related educational material. The impact of either approach remains unstudied although recent research suggests that digital literacy and health app awareness are important related factors for app use[112]. Some newer approaches like the adapted Mobile Application Rating Scale (A-MARS) have been proposed with the authors suggesting the need for concomitant support from a coach or digital navigator[113].

DISCUSSION

The COVID-19 pandemic boosted the supply of digitally delivered assessments and treatments, along with the promise of increased availability of digital, low-threshold treatment for mental illness worldwide. However, e-mental health research and practice is still in an embryonal stage of development and evidence-base. As the first of its kind, this expert consensus provides a comprehensive essence of scientific knowledge and practical

recommendations for both practitioners and researchers (see Do's and Don'ts in Supplementary Material).

In summary, when researchers agree on using a digital approach, they should define the development and evaluation process carefully, guided by their main objective and theory. The technical transformation of psychological content requires a transdisciplinary, participative and highly iterative research process which swallows up a range of resources that need to be estimated when planning the project. Data protection and the inclusion of vulnerable groups pose challenges to the successful implementation and should be given special consideration while adhering to current standards during the development and implementation by a user-centered approach. AI holds great promises for e-mental health, largely owing to the advances in affective computing. Mobile sensing and EMA have a huge potential to enable accurate assessments of individuals' daily life states and behaviours, which can be used for diagnostics and evaluation of interventions. RCTs are one element of an evaluation strategy for e-mental health, but should expand their focus to a wider range of populations, control groups and investigation of process variables and individual data patterns. AEF offer useful heuristics to identify apps of interest, and to share data on privacy, efficacy, engagement, and clinical integration but cannot replace clinical judgment. In order to use e-mental health interventions in the context of prevention and intervention, it should be feasible for real world settings.

Despite all technical innovations and novel features, one should not neglect the final goal of all attempts: health that is defined as "the ability to adapt and self manage in the face of social, physical, and emotional challenges"[114] enabling an individual to work, have relationships, and express oneself in a society. Well-executed e-mental health assessments and interventions have the potential to be meaningful to individuals and their care teams. Rather than replacing health professionals, digital technologies have a potential to support the human therapeutic process in a scalable format (e.g., by providing interactive psychoeducation and

monitoring material). With this expert consensus, we aim to provide guidance on best practice when preventing or improving the state of mental illness using e-mental health interventions. The target group with its needs and wishes should be placed in the foreground to achieve this. Of paramount importance are high ethical standards, transparency, respect for patients' rights, data protection, the special consideration of vulnerable groups, and the explicit clarification of any non-human interactions. In the dynamic field, it is also necessary to rethink the classical statistical methods of development and evaluation of digital tools in order to not to lag behind the market in practice. It may be advisable to include flexible, iterative, built-in behavioural digital assessments and process monitoring and to collaborate with companies to provide exploitation and implementation with a viable business model, as digital intervention's availability and sustainable quality of digital intervention depend on it.

We further emphasize the need for feasibility and long-lasting usage based on long-term follow-up measurements, evaluation in real-world settings, considering factors that improve adherence, and integration of relevant stakeholders in the conceptualisation, implementation, exploitation, and roll-out process of the digital intervention as well as the integration of comprehensive process quality evaluation based on recognised international frameworks. Suicidality should not be an exclusion criteria, but it should be included once an adequate monitoring policy is established. Another groundbreaking development is generative AI outcomes such as GPT-4 or Metaverse, as virtual space may be only a sneak preview of the oncoming power and abilities supporting mental health aid. However, such AI, if not governed, might also soon have the ability to influence the mental health domain in unknown ways. Ethical considerations must be prioritised shielding potential harm and manipulation, especially in vulnerable groups such as individuals with mental illness.

To support the development and usage of high-quality e-mental health offers, the research field must be expanded, especially regarding long-term efficacy analysis, adherence,

patient satisfaction and improved uptake, cost-benefit analysis and a facilitated access for clinicians and patients to evidence-based interventions within the routine healthcare. We claim a proof of efficacy as a prerogative of transfer into clinical practice, since side effects of e-mental health intervention have not yet been studied comprisingly and may be underestimated.

This expert consensus is unsystematic, primarily based on the subjective experience of a selective group of clinical and scientific experts, mostly from Europe, the U.S., and Australia. This is noteworthy, since a key advantage of e-mental health is providing low-threshold access to mental health services in particular in more rural regions with a limited supply of health care services. Given the increasing number of smartphone users worldwide and the expanding reach of mental health apps within high-income countries[115], providing early scalable psychoeducation and online training in a stadium of mild symptoms or for early recognition, digital assessment, and intervention methods are especially promising in preventing more severe courses with low costs[116]. In addition, the geographical range and duration of treatment can be expanded e.g., by using video calls and chats to stabilize clients through follow-up sessions, preventing relapse, and providing care at a low cost. Moreover, cost-effectiveness studies are scarce and especially neglect low-income countries where e-mental health services may be particularly beneficial[116,117].

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Author contributions

JL, CS and LV conceptualised the study and supervised the writing process. JL, LV and CS wrote the first draft including Introduction, Method and Discussion. The chapters were written

in the following writing groups: *Where to start:* KH, IB, JL, CS; *Intervention content development*: CS, JL; *User-centered design and participatory approaches*: LV, LBS, AWS, JL; *Managing suicidality,* LBS, KH, *Data protection and data security:* HL, IB, AC; *Artificial Intelligence in assessment and intervention:* BS, JL; *Sensing and wearables:* KW, YT, RS, CST; *Efficacy evaluation, RCTs and other methods:* AO, BA, STT, AC; *Ecological Momentary Assessment*: PSS, MF; *Transfer into (clinical) practice*: SW, BA, EM, STT; *App evaluation frameworks*, JT. All authors commented on the first and final draft. PC, TJR, AN and NE reviewed the final version particularly. All authors share responsibility for the final version of the manuscript.

Competing interests

PC has received speaker fees from Angelini Pharma, Lundbeck and Koa Health within the past three years. JT is a scientific advisor for precision mental wellness. LBS reported receiving personal fees from Psychotherapy Training Insitutes, Health Insurances and Clinic Providers in the context of e-mental-health but outside the submitted work. All other authors have no interest no declare.

3 General Discussion

With a prevalence of 17 % worldwide, PPD represents one of the most common complications after birth (Wang et al., 2021). The consequences of PPD are far-reaching, impacting society as a whole, mothers, their families, and most notably, their children (Slomian et al., 2019). With respect to the high prevalence and the far-reaching consequences, the examination and development of effective preventive strategies represents an important aim for research and the healthcare systems around the world. Across all families, mothers with psychosocial burdens (e.g., stressful life events, low social status, experiences of violence) are at particularly high risk to develop depressive symptoms during the postpartum period (Hutchens & Kearney, 2020). One subgroup of psycho-socially burdened mothers includes those who experienced forms of maltreatment (emotional, physical and sexual abuse as well as physical and emotional neglect) during their own childhood (Souch et al., 2022). The examination of this subgroup has the potential to enhance preventive programs specifically tailored to the needs of mothers with experiences of CM. This might not only reduce the prevalence of PPD in mothers with CM, but also might address the intergenerational transmission of trauma, the so called '*cycle of abuse*'(Mielke et al., 2020; Slomian et al., 2019). Therefore, the first aim of the current thesis was to contribute to the examination of the link between CM and PPD and investigate emotion regulation and parenting stress as mediating mechanisms (*Publication I*). Furthermore, I aimed to disentangle the link between maternal experiences of CM and impairments in mother-infant bonding during the first year after birth by examining PPD as a mediator (*Publication II*).

Although psycho-socially burdened families are at particularly high risk of PPD, they are often neglected in existing research and often not reached through traditional preventive approaches (Ulrich et al., 2022). Hence, there is a high need on developing preventive strategies targeting psycho-socially burdened families. In recent years, digital interventions have been arising as promising tools in the field of healthcare. However, no mHealth based intervention existed targeting psycho-socially burdened families during the transition to parenthood.

Therefore, the second objective of the current thesis was the development and evaluation of an mHealth based intervention (*I-PREGNO*) aiming to promote the mental well-being of psychosocially burdened families in Germany during the transition to parenthood (*Publication III* and *IV*). As digital interventions still represent a relatively new type of intervention compared to traditional approaches, there was a lack of guidelines and recommendations for the development and evaluation of digital interventions at the beginning of *I-PREGNO*. *Publication V* therefore concludes by publishing guidelines and recommendations for the development, evaluation and implementation of digital interventions.

3.1 Summary of Findings

In *Publication I*, I investigated the link between experiences of CM and PPD while simultaneously controlling for other factors that could potentially influence the relationship (level of education, single parenthood, emotion regulation, insecure attachment). Furthermore, I performed a path model examining the mediating role of emotion regulation and parenting stress in the relationship between CM and PPD. The study confirms the significant impact of CM on depressive symptoms in mothers during the first year after giving birth. The findings imply that despite controlling for social and psychological risk factors, experiences of CM affect maternal depressive symptoms during the first year postpartum. In relation with the severity of postpartum depressive symptoms, emotional abuse and neglect turned out to be particularly relevant. Besides maternal experiences of CM, low education, higher attachment anxiety, and greater difficulties in emotion regulation were associated with higher levels of depressive symptoms. Contrary to our hypothesis and existing literature, single parenthood and attachment avoidance were not associated with PPD. Since fathers have often been neglected in previous studies, we aimed to investigate the link not only in mothers but also in fathers. However, due to the low number of fathers and the low prevalence rates of CM in this group, results need to be interpreted with great caution. Overall, our study underscores the significance of the relationship between CM and depressive symptoms during the postpartum period and thus contributes to the body of research focusing on CM as a risk factor for psychopathology in adulthood (Kessler et al., 2010). In my opinion, one main finding of *Publication I* was the pivotal role of emotion regulation for the development of postpartum depressive symptoms and should therefore be considered in treatment and preventive interventions for PPD. Consistent to the assumptions of the transdiagnostic model (McLaughlin et al., 2020), the path model indicates that experiences of CM might play a role in shaping emotion regulation strategies, which in turn influences their mental well-being during the first year after birth of their own child.

In *Publication II*, I examined the mediating role of maternal PPD in the relationship between maternal experiences of CM and impairments in mother-infant bonding during the first year postpartum using data from the *I-PREGNO* project. In the mediation analysis, postpartum depressive symptoms were found as mediator for the relationship between maternal experiences of CM and impairments in mother-infant bonding. The findings indicate that maternal experiences of CM increase the severity of postpartum depressive symptoms leading to impairments in mother-infant bonding. *Publication II* again highlights the fundamental role of maternal mental health, particularly symptoms of depression, during the transition to parenthood. Furthermore, the findings contribute to other studies identifying symptoms of psychopathology as a mediator in the link between maternal CM and negative parenting. Therefore, the study reveals further information uncovering the intergenerational transmission of parenting.

With *Publication III*, I aimed to contribute to the development frameworks that provide suggestions for the design and content of digital interventions tailored to the needs of psycho-socially burdened families during the transition to parenthood. By sharing our results of the development process, I further aimed to increase the transparency of our digital intervention *I-PREGNO*. We followed a participatory and theory driven approach that included an extensive literature review for effective evidence- and cognitive behavioral therapy (CBT)-based strategies as well as the involvement of the target group through usability tests and focus group discussions. Overall, the focus group discussions in stage I revealed that the app should provide psychoeducational material on parental mental and physical health, highlighting how these factors influence child development. Additionally, it should offer skills and exercises that promote mental well-being. According to healthcare professionals, the app should serve as a supportive tool in their work by providing modular content they can refer to, delegate, or assign as homework. The content should be presented in different ways: text by using easy language and pictures/ emojis facilitating the understanding, small podcasts or videos. Stigmatizing

language should be avoided. Mothers in the focus group discussions described the transition to parenthood as a period marked by a loss of control, insecurity, and feelings of anxiety. Hence, including strategies and skills increasing their autonomy, fostering self-esteem and reducing anxiety and self-doubts might be promising. Furthermore, features fostering the management of every-day tasks and personalized content might increase the fit to the users' needs leading to an increase in user engagement. Notably, in contrast to previous research features like gamifications and frequent reminders of using the app were not considered as suitable for the target group. In addition, *Publication III* provides an overview about the content of the app *I-PREGNO*. Besides strategies of CBT (e.g., psychoeducation, cognitive restructuring), the app contains various strategies of behavior change techniques within the different modules. Overall, *Publication III* highlights the complexity and time-consuming aspects of developing mHealth based interventions.

Publication IV presents initial results of the cRCT conducted in Germany. With this paper, I aimed to examine the efficacy of the 12-week blended counseling intervention *I-PREGNO* on the mental well-being among psycho-socially burdened mothers during the postpartum period. Contrary to our hypotheses, we found no significant differences in parenting stress or postpartum depressive symptoms between the intervention and control group at the end of the intervention (T1) or six months after baseline (follow-up, T2). However, when considering the child's age at the start of the intervention, analyses revealed an interaction effect between parenting stress and the timing of the intervention, favoring an early intervention start. These results suggest that starting the intervention during the early postpartum period may have a positive effect on parenting stress. Notably, controlling for the amount of counseling or app usage did not yield additional effects on the outcomes. Since we found no intervention effect in postpartum depressive symptoms, we suggest that interventions aimed at preventing postpartum depressive symptoms may require a more personalized and comprehensive approach. Although the findings of *Publication IV* may not seem promising initially, the interaction effect related

to the timing of the intervention suggests potential for the efficacy of the *I-PREGNO* intervention. Given that the sample size was smaller than originally planned in the study protocol (Vogel & Färber et al., 2023), a study with a larger sample could offer additional insights. Further potential adaptations for future studies are discussed in *Chapter 3.3 and 3.4*.

The last publication (*Publication V*) presents a consensus statement from experts in the field of e-mental health providing guidelines for the development, evaluation and implementation of e-mental health assessments and interventions. The objective of these guidelines was not only to assist researchers in planning and conducting studies but also to help practitioners to gain a better understanding of the quality of existing interventions. Overall, our paper highlights several substantial aspects for the development, evaluation and implementation of e-mental health interventions and assessments: The development process is characterized as time-consuming and resources intensive and requires a collaborative, multidisciplinary team, typically involving psychologists (as researchers and practitioners), computer scientists, software developers and graphic designers. An agile, iterative approach is recommended for transforming psychological content into a digital solution. The involvement of the target group and relevant stakeholder through participatory approaches is crucial and leads to an increase in usability by ensuring the fit to the users' needs. Key challenges include addressing suicidality in digital interventions and assessments, and ensuring data protection. Artificial Intelligence (AI) and mobile sensing show promise for enhancing (e-)mental health interventions, but it must be carefully managed to address ethical challenges. Mobile sensing and ecological momentary assessment (EMA) offer real-time, accurate data for diagnostics and intervention evaluation. While RCTs are valuable, they should be preceded by smaller feasibility studies and include diverse populations, process variables, and adverse effect assessments. Research should also focus on long-term outcomes, adherence, and dropout rates. Lastly, the feasibility of digital interventions in real-world settings must be considered, with implementation strategies and stakeholder involvement integrated from the start.

3.2 Strengths and Limitations of the Thesis

The current thesis provides important insights into the research on PPD in psycho-socially burdened families. In this context, several strengths and limitations must be highlighted. Since limitations and strengths of the different studies have already been discussed in the publications, this section will focus on overarching limitations and strengths that apply across all studies included in this thesis.

My thesis comprises several strengths. One of the key strengths is the focus on psycho-socially burdened families, a hard-to-reach group, which is underrepresented in research. In *Publication I*, *III* and *IV*, I successfully included psycho-socially burdened mothers and healthcare professionals supporting psycho-socially burdened families. Furthermore, by employing participatory approaches, I actively involved stakeholders, individuals with psychosocial burdens and healthcare professionals, ensuring interventions are relevant and fit to the target group. Moreover, my research adopts a holistic approach, integrating perspectives from an interdisciplinary team (consisting of psychologists, psychiatrists, social workers, midwives, nutritionists and exercise scientists) to comprehensively address the complexities of the perinatal period and PPD. By combining scientific methods and the expertise of practitioners, my research contributes to improving the care of high-risk mothers and bridging the gaps between research and clinical practice. The low dropout rate observed in *Publication II and IV* underscores the feasibility and acceptability of the intervention. Additionally, the use of a longitudinal design with one follow-up assessment allows a deeper understanding of long-term effects in *Publication IV*.

However, several limitations must be acknowledged. First, the small sample size constrained the ability to perform complex statistical models and limits the interpretability of the results. As mentioned before, the target group in studies *III*, and *IV* consisted of hard-to-reach groups. As a result, the recruitment process required substantial personnel and time

resources. Additionally, in *Publication III*, the recruitment process was further complicated by the fact that the focus group discussions and usability tests were conducted during the COVID-19 pandemic, making participant recruitment even more challenging. Future studies with larger samples can seek to replicate the findings of my publications.

Furthermore, since our studies were conducted within specific target groups, the results of my studies are limited in their generalizability. Another factor limiting the generalizability and making recruitment particularly challenging was that both, the questionnaires and the app, were only available in German. This led to a large number of exclusions, since many families receiving the German wide home-visiting program did not have enough skills in the German language. Therefore, translating the app into multiple languages and using different versions of the questionnaires could be valuable for future studies focusing on this target group and evaluating *I-PREGNO*.

The analyses of *Publication I* and *II* represent secondary analyses, meaning that the research questions and methodologies were, to some extent, constrained by the original study designs and data availability. While secondary analyses provide valuable insights, prospective studies with specifically tailored research designs and pre-calculated power for the specific research questions could address the limitations of these publications. Due to the study design (online, German-wide recruitment), it was only possible to assess self-report questionnaires. While self-reports are widely used in psychological research, there are some noteworthy limitations. Self-report questionnaires are subject to biases, such as social desirability and retrospective recall biases. Future studies should include objective measures (e.g., behavioral assessments or physiological data), real-time assessments (i.e., EMA), observatory assessments, and interviews.

Additionally, the inclusion of fathers remains a main challenge in research on perinatal mental health. Although the studies of the project *I-PREGNO* were designed to include mothers

and fathers and hence, the family as a whole system, we were not able to include enough fathers to perform full-powered analyses. Future studies should aim to better integrate fathers into research designs, as their role during the transition to parenthood is increasingly recognized as essential (Versele et al., 2022). With respect to the findings of *Publication III*, it is not surprising that only a few fathers were recruited, as healthcare professionals had noted in the focus group discussions, they rarely have contact with fathers during their work. According to *Publication V*, the inclusion of fathers from the beginning of projects, might be beneficial to gain more insights into effective recruitment strategies and enhancing the fit of interventions to this target group. Future research should consider tailored recruitment strategies to engage fathers more effectively.

Finally, the field of e-mental health is rapidly evolving. While this dissertation contributes to the understanding of the potential of mHealth based interventions, it is important to recognize that ongoing developments are continuously shaping the field. By the time of this dissertation's completion, new findings have already emerged that refine and expand existing guidelines. Future research should remain adaptive to these advancements to ensure that interventions remain evidence-based and technologically up-to-date.

3.3 Implications for Research and Practice

The following sections outline key implications for both research and practice based on the findings of the current thesis. A particular focus is placed on mothers with experiences of CM and challenges and potentials of digital technologies in the field of prevention of PPD.

3.3.1 Mothers with Experiences of Childhood Maltreatment as Vulnerable Group

Publication I and *II* emphasize mothers with experiences of CM as a vulnerable group during the transition to parenthood. Hence, preventive measures and interventions aiming to promote the mental well-being of mothers with CM experiences are in high demand. However, as outlined in the introduction, families with psychosocial burdens are often hard to reach (Ulrich et al., 2022). Thus, it may be crucial not only to develop tailored interventions, but also to find effective methods for identifying and reaching this subgroup during the transition to parenthood. One promising approach might be the integration of a systematic screening through self-report questionnaires (e.g., Childhood Trauma Screener or Childhood Trauma Questionnaire) in prenatal care (e.g., through gynecologists or midwives; Nagl et al., 2017; Racine et al., 2021). In recent years, machine learning has become established in research for predicting negative health outcomes. Regarding PPD, first studies in this field have primarily focused on sociodemographic and pregnancy-related data (Paul et al., 2023). With respect to our findings, it would be interesting to explore whether incorporating psychological variables could enhance predictive accuracy of these models. Additionally, examining whether mothers with experiences of CM use preventive measures - and if so, identifying which types of interventions they use more frequently - could help tailoring these to their needs.

Further implications for future research emerge through *Publication I* and *II*. First, studies investigating the association between different subtypes of CM and PPD, impairments in mother-infant bonding, and difficulties in emotion regulation could be useful in determining whether differences exist between subtypes of CM and whether interventions for this vulnerable

group should be further personalized with respect to CM profiles (Goerigk et al., 2023). Second, as the small sample size constrained the ability to perform more complex statistical models, future studies with a larger sample could replicate the findings of the mediation models in *Publication I* and *II* and expand these integrating other potentially relevant variables. For example, mediators of the transdiagnostic model (McLaughlin et al., 2020), such as impaired social information processing or social support, can be integrated in an expanded mediation model. This could help to develop more targeted and personalized interventions for mothers at-risk. Third, when conducting further research on CM and PPD, the involvement of CM survivors could be especially relevant for enhancing the relevance and acceptability of interventions and research.

Publication I revealed emotion regulation as a key mechanism in the relationship between CM, parenting stress and PPD. Consequently, emotion regulation should be considered in preventive interventions targeted at mothers with experiences of CM during the transition to parenthood. The development and implementation of interventions designed to promote emotion regulation can be achieved through various approaches. One possibility is the implementation of an mHealth-based intervention. In the *I-PREGNO* project, we have already developed a module that targets emotion regulation strategies for families facing psychosocial challenges (see *Publication III* and *IV*). In a next step, this module could be expanded and tailored to the specific needs of mothers with experiences of CM through a user-centered design approach. Moreover, other mHealth-based interventions exist that aim to enhance emotion regulation skills in individuals with a history of CM (Brodbeck et al., 2022). The content of these interventions could also be adapted to address the transition to parenthood. In case of proven efficacy, the intervention could then be recommended or prescribed by midwives and gynecologists who identify parents (to-be) during CM-screening.

3.3.2 Focusing on Emotion Regulation

Publication I has shown that emotion regulation is not only an important mediator in the relationship between CM and PPD, but also has a general significant influence on PPD in mothers after childbirth. Therefore, including a training on emotion regulation in universal preventive programs for pregnant women might be a valuable addition to the healthcare system. One opportunity could be the expansion of childbirth preparation courses, which are attended by most pregnant women and often also by fathers (Zauderer, 2009). Hence, adding an additional session to childbirth preparation courses focused on promoting emotion regulation in parents to-be could be promising. Furthermore, the session could be combined with the online emotion regulation module integrated in *I-PREGNO* which psycho-socially burdened parents could use as additional training after the birth of the child. Regarding the emotion regulation module integrated in the app *I-PREGNO*, one follow-up question to *Publication IV* could be whether *I-PREGNO* enhances emotion regulation in psycho-socially burdened mothers during the transition to parenthood. Additionally, it would be interesting to analyze how many mothers used the emotion regulation module.

3.3.3 Postpartum Depression and Its Consequences on Mother-Infant Bonding

Publication II provides additional implications regarding the intergenerational transmission of parenting. As we identified PPD as a mediator for the relationship between CM and impairments in mother-infant bonding, addressing symptoms of PPD in measures fostering mother-child interaction could potentially help to a) improve mother-infant bonding and b) break the intergenerational transmission of parenting (Erickson et al., 2019; Mielke et al., 2020). When supporting mothers with experiences of CM, healthcare professionals should provide information about the intergenerational transmission and potentially intervening mechanisms in psychoeducational sessions to a) create an understanding and awareness of the

intergenerational transmission and b) provide information about how to break the '*cycle of abuse*'.

Since *Publication II* highlights, consistent with a large body of research, the strong link between PPD and impairments in mother-infant bonding, one urgent implication of this thesis represents the need to combine counseling approaches aiming to foster mother-infant bonding, such as the home-visiting program of the NZFH in Germany, with medical or psychological interventions aiming to treat symptoms of maternal PPD. For this reason, this thesis underscores results of earlier studies highlighting need for an integrated approach, combining interventions for the treatment of maternal depressive symptoms with interventions fostering the mother-infant bonding (e.g., Tichelman et al., 2019). Hence, psychotherapeutic manuals developed in the field of PPD should include a module focused on the mother-infant bonding and incorporate strategies to support the infant's health and well-being during this vulnerable phase. Furthermore, investigating mediators and moderators for the relationship between PPD and impairments in mother-infant bonding can provide additional information for the development of interventions fostering mother-infant bonding in mothers managing PPD.

As noted earlier, *Publication II* highlights the importance of addressing depressive symptoms when promoting mother-infant bonding. Building on this, *Publication IV* aimed to develop an mHealth-based intervention, which was implemented within an early childhood intervention funded by the NZFH in Germany. Digital interventions offer numerous advantages, including their seamless integration into existing traditional interventions, commonly referred to as blended care approaches (Fenski et al., 2024). Therefore, the next chapter will explore the implications for future projects developing digital solutions for the prevention of PPD.

3.3.4 Prevention of Postpartum Depression through Digital Health

Digital interventions are often highlighted as promising tools overcoming shortages and problems of the healthcare systems (Seiferth & Vogel et al., 2023). In particular, they are described carrying the potential to reach people who have not been reached by previous traditional measures. However, this potential is not reflected in current research (Brusniak et al., 2020; Western et al., 2021). Digital interventions are often designed in a context of high educated researchers and practitioners by neglecting the needs and digital literacy of psycho-socially burdened individuals (Latulippe et al., 2017). Furthermore, the evaluation of digital interventions mostly involves participants with high educational levels and high SES (Brusniak et al., 2020; Chan et al., 2019). Thus, the question arises whether digital interventions really overcome the *prevention paradox* and combat the health inequalities in our society. As a result of my investigations I conclude, more research focusing on neglected subgroups by using participatory approaches is needed to really exploit this potential. As *Publication III* revealed high levels of interest among the target group and *Publication IV* revealed low drop-out during the trial, the approach of *I-PREGNO* can be considered as a successful and promising addition for the home-visiting early childhood intervention program in Germany. The current version of the intervention can be utilized for psycho-socially burdened mothers immediately after birth. However, as the sample of *Publication IV* was smaller than we expected and symptoms of PPD and parenting stress were secondary outcomes, future research on the efficacy of *I-PREGNO* is needed. Moreover, the intervention could benefit from being adapted to new advancements in the field of e-mental health and integrate more personalized content. Future studies should again involve the target group and healthcare professionals. The counseling sessions of *I-PREGNO* should incorporate more strategies for stress reduction and the prevention of PPD, while healthcare professionals should receive enhanced training in the field of perinatal mental health. For the personalization of *I-PREGNO*, more research is needed on the different subgroups of psycho-socially burdened families as highlighted by the healthcare professionals in *Publication*

III. The content of the app could be adapted even more to the individual needs depending on the life situation. For example, the app could provide different versions adapted to the age of the child. The progress made in e-mental health in recent years is suitable for such adaptations. For example, the expanding field of AI, could be especially promising for the personalization of mHealth based content by actively monitoring users and providing individualized information and feedback, providing just-in-time-adaptive interventions, and using chat-bots.

3.3.5 Proposal of a Stepped Care Approach for Identifying and Preventing Postpartum Depression

PPD provides great potential for prevention measures as the time women experience first symptoms of PPD is quite predictable and represents a time in which women are well integrated into the healthcare system with regular visits at their gynecologists or receiving support through midwives (O'Hara & McCabe, 2013). The prevention, early recognition and early treatment of PPD does not only improve maternal mental health but also has the potential to enhance mother-infant bonding (Slomian et al., 2019), parenting behavior (Löchner, Hämmerle, et al., 2024), and potentially reduces healthcare costs (Stentzel et al., 2024). However, the potential has not been exploited, yet. On the contrary, many of those affected remain undetected or are discovered too late, negatively affecting their children and resulting in various women needing elaborate treatment for which they often have to wait several weeks or even months (Pawils et al., 2022). Therefore, new approaches are being sought to enhance the detection of mothers at-risk and better reach families in need.

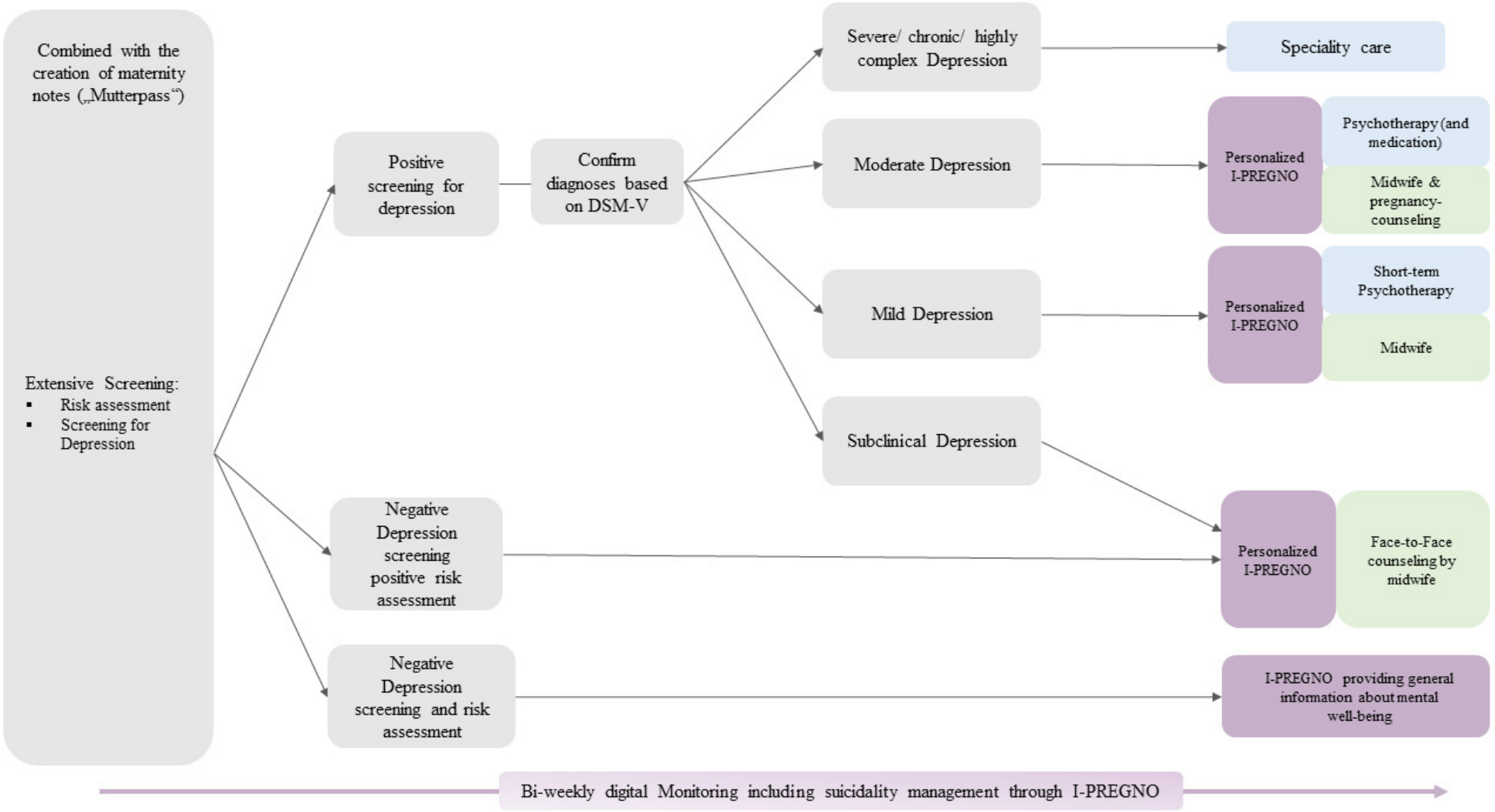
Throughout my Dissertation, I have frequently reflected on ways to enhance the current German healthcare system and implement a new nationwide strategy supporting mothers at-risk during the perinatal period. In this last chapter, I would like to take a look in the future and propose a model for the prevention and treatment of PPD in women within the German healthcare system during the transition to parenthood. The model is based on results of other prevention programs

in Germany (Daehn et al., 2023, 2024; Stentzel et al., 2024), the results and my learnings within the project *I-PREGNO* and uses a stepped care approach (Gjerdingen et al., 2008). Since e-mental health assessments and interventions offer many advantages, such as enabling accurate assessments, providing potentially low threshold and low-cost interventions (Seiferth & Vogel et al., 2023), the integration of digital technologies represents a key component of the model. The model could be developed and evaluated in a future research project by using an enhanced version of the *I-PREGNO* intervention. Therefore, the mHealth-based intervention representing a key component of my model is named *I-PREGNO*.

The foundation of this new stepped care approach should be a regular monitoring of depressive symptoms (e.g. through the EPDS) and risk factors occurring during this vulnerable period of time (e.g., stressful or traumatic events, such as traumatic birth, miscarriage, low social support, financial problems). The monitoring should be conducted by regularly assessments in the women's every-day life by using their smartphone (EMA). Furthermore, as smart sensing was identified as a promising tool predicting an increase of depressive symptoms by for example tracking GPS-data (Moshe et al., 2021), the app used for monitoring should be able to track passive data. The question whether the evaluation of passive data provides another possibility to identify women at-risk should then be examined. Feedback about the results of assessments should be given to mothers, as this can be assumed to increase compliance. Reflecting *Publication V*, suicidal thoughts should be an important component of the bi-weekly assessment (e.g., represented through item 10 of the EPDS). Also, the provider of the app should offer immediate support for women with suicidal thoughts by trained healthcare professionals. The model comprises two phases, the pregnancy and the postpartum period. Figure 3 presents the stepped care approach during pregnancy, Figure 4 during the postpartum period.

Figure 3

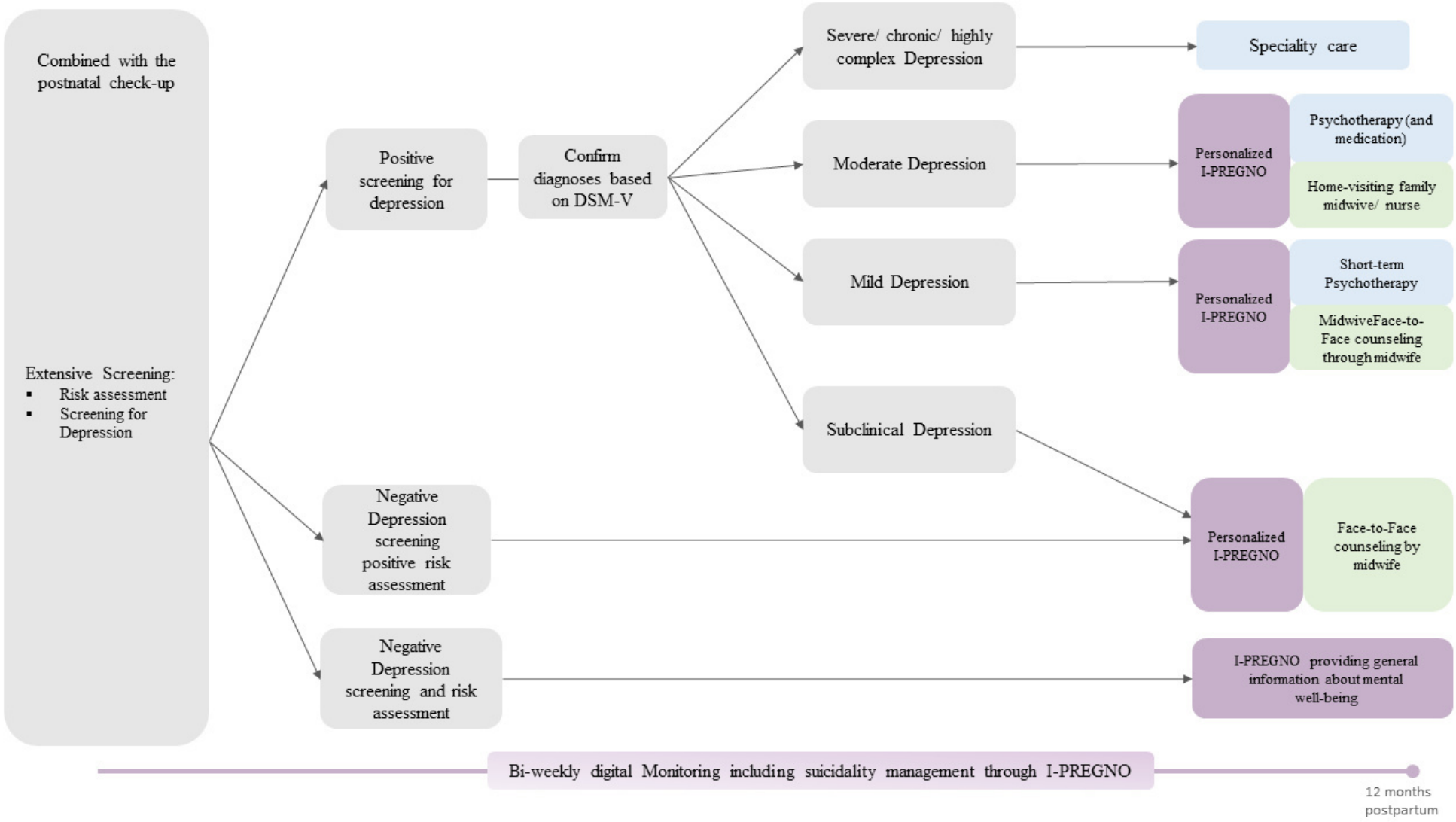
Stepped Care Approach for Preventing Postpartum Depression During Pregnancy



Note. I-PREGNO = digital intervention providing (personalized) information and monitoring of mental health in mothers. DSM-V = Diagnostic and Statistical Manual of Mental Disorders – fifth edition.

Figure 4

Stepped Care Approach for Identifying and Preventing Postpartum Depression During the Postpartum Period



Note. I-PREGNO = digital intervention providing (personalized) information and monitoring of mental health in mothers. DSM-V = Diagnostic and Statistical Manual of Mental Disorders – fifth edition.

At the beginning of pregnancy and shortly after birth, there should be an extensive assessment of risk factors for PPD including psychosocial lifetime risk factors (e.g., previous miscarriage, education, SES, CM, history of mental illness, traumatic birth related experiences). For the screening and monitoring of depressive symptoms, a questionnaire with a cut-off, indicating a probable diagnosis of depression, should be used (e.g., EPDS). In Germany, extensive screenings could be integrated with the first appointment at the gynecologist or midwife, where pregnancy is confirmed and the maternity notes (*"Mutterpass"*) are created. Additionally, the second extensive screening could be conducted again during the postnatal check-up, which is typically performed by the gynecologist or midwife shortly after birth. Ideally the extensive assessment will be conducted through their smartphone using the *I-PREGNO* app. Hence, downloading the app will represent an integral part of the first appointment with a midwife or gynecologist during pregnancy. An individual risk profile will then be created based on the risk factors. All mothers screened through the extensive pre- and postnatal screenings will be divided in three groups receiving different intervention conditions (i.e., positive screening for PPD, negative PPD screening/ positive risk screening, negative PPD screening/ negative risk screening). The following bi-weekly monitoring allows to control for the course of depressive symptoms and provides the opportunity to intervene in case of no improvement or a deterioration.

After the extensive screening at the beginning of pregnancy, women without risk factors (i.e., low risk of developing depressive symptoms) nor depressive symptoms receive the online intervention monitoring their depressive symptoms bi-weekly and providing general information about maternal health during pregnancy and birth. Women showing risk factors but do not have a depression score above the cut-off receive the online intervention with by-weekly monitoring and personalized content (divided in modules) relevant for their mental health (e.g., women with low social support receive a module about social support and competences, women

with difficulties in emotion regulation receive a module for enhancing emotion regulation strategies).

Women scoring above the cut-off score receive, in a first step, an online counseling conducted by a trained psychologist. During this appointment, information about their screening will be provided and, in a second step, a structured clinical interview will be conducted. After the interview, women will be divided in four groups: No diagnoses (i.e., subclinical group), mild depressive episode, moderate depressive episode, severe, highly complex or chronic depression. The intensity of the treatment varies depending on the group.

The subclinical group receives the personalized *I-PREGNO* app as well as an additional counseling through their midwives supporting them to transfer the content of *I-PREGNO* into their every-day life. Women with a mild depressive episode receive the personalized *I-PREGNO* app combined with additional counseling sessions through their midwives and an additional short-term psychotherapy conducted by psychotherapists. Since the German clinical practice guidelines recommend either psychotherapy or medication, medication therapy should be offered to women as an alternative (Bundesärztekammer (BÄK) et al., 2022). Women with a moderate depression receive the same treatment as women with mild depressive symptoms but either a combination of medication and psychotherapy or a more intense (i.e., more sessions or more frequent) psychotherapy. Furthermore, they should be connected to pregnancy counseling. Women showing severe, highly complex or chronic depression receive the "highest stage" of treatment named specialty care. This means that mothers to-be are admitted to specialized facilities or receive very intensive outpatient care. Care should be taken to ensure that mothers receive sufficient support after the birth and that a social network consisting of professionals and relatives is available.

After birth, the conditions of the different groups are similar. However, mothers with a moderate episode of depression should receive support through the home-visiting program

provided by the NZFH. Mothers with severe, highly complex or chronic depression should also receive support through a stay in a mother-child clinic or another mother-child facility combined with medical treatment integrating medical and psychological treatment with interventions aiming to enhance mother-infant bonding and to promote a healthy start of an infant's life.

Overall, the presented model carries the potential to enhance maternal healthcare in the perinatal period. The implementation of a stepped-care approach potentially facilitates an early identification of mothers at-risk (Gjerdingen et al., 2008; Stentzel et al., 2024). Furthermore, an early detection of postpartum depressive symptoms and the seamless provision of preventive measures may help to reduce chronic and severe courses of PPD. Additionally, by using a systematic monitoring and implementing low-threshold interventions, such as mHealth based interventions, this model offers the opportunity to reach a broader population and to overcome shortages within the current healthcare system (Seiferth & Vogel et al., 2023).

3.4 Conclusion

This doctoral thesis contributes to the expanding field of research on PPD by examining its risk factors, consequences, and prevention strategies. Regarding risk factors, CM was identified as a significant predictor for the development of PPD. Additionally, difficulties in emotion regulation were found to mediate the relationship between CM and PPD, highlighting a potential mechanism through which CM experiences increase vulnerability to postpartum mental health problems. In terms of consequences, the findings underscore the crucial role of PPD in the link between CM and impairments in mother-infant bonding. PPD mediates this relationship, suggesting that addressing maternal depressive symptoms may be key to improving bonding outcomes in mothers with a history of CM. With respect to prevention, this thesis presents two publications describing the development and evaluation of an mHealth-based intervention (*I-PREGNO*) designed to support psycho-socially burdened families during the transition to parenthood. While preregistered analyses did not find a significant effect of *I-PREGNO*, exploratory analyses, along with the low drop-out rate, indicate its potential and highlight the need for further adaptation and refinement in future research. To enhance the effectiveness of preventive efforts, participatory approaches should be further integrated into future projects, ensuring that interventions align with the needs of the target population.

In sum, this doctoral thesis provides new findings carrying the potential to develop innovative measures for the prevention, early identification and treatment of PPD. The development and advancement of (existing) prevention measures could not only contribute to enhance healthcare provision for vulnerable mothers during the transition to parenthood but also raise the awareness of the frequency and far-reaching consequences of PPD in society.

4 Deutsche Zusammenfassung

Mit einer Prävalenz von 17 % weltweit (Wang et al., 2021) gilt die Entwicklung einer postpartalen Depression als eine der häufigsten Komplikationen für Mütter nach der Geburt. Postpartale Depressionen sind mit weitreichenden Folgen für Mütter, ihre Familien und die Gesellschaft verbunden (O'Hara & Wisner, 2014). Vor diesem Hintergrund war es Ziel der vorliegenden Dissertation, offene Fragestellungen zu untersuchen, die zu einem besseren Verständnis der postpartalen Depression beitragen. Ein Schwerpunkt der Dissertation lag dabei auf der Untersuchung psychosozial belasteter Familien (z.B., Familien mit traumatischen Erlebnissen, einem niedrigen sozioökonomischen Status oder alleinerziehende Mütter), die ein besonders hohes Risiko für die Entwicklung einer postpartalen Depression aufweisen und deswegen als besonders vulnerabel im Übergang zur Elternschaft gelten (Hutchens & Kearney, 2020).

Als erstes wurde in der vorliegenden Arbeit der Zusammenhang zwischen mütterlichen und väterlichen traumatischen interpersonellen Erfahrungen in der Kindheit und Symptomen der postpartalen Depression untersucht (*Publikation I*). Für dieses Vorhaben wurden querschnittliche Daten aus zwei Studien, die in Deutschland durchgeführt wurden, zusammengeführt. Insgesamt umfasste der gepoolte Datensatz n = 349 Müttern und n = 46 Väter. Hierarchische Regressionsmodelle wurden berechnet, um Erfahrungen von frühen interpersonellen Traumata, Bildungsniveau, Alleinerziehendenstatus, Schwierigkeiten in der Emotionsregulation und einem unsicheren Bindungsstil als Prädiktoren für Symptome der Postpartalen Depression zu untersuchen. In explorativen Analysen wurden potenzielle Mediatoren (elterlicher Stress und Schwierigkeiten der Emotionsregulation) mittels eines Pfadmodells untersucht. Frühe interpersonelle Traumata, ein niedriges Bildungsniveau, Schwierigkeiten in der Emotionsregulation und ein ängstlicher Bindungsstil waren signifikante Prädiktoren für den Schweregrad der mütterlichen depressiven Symptomatik [R^2 = 0.52, $F(6, 305) = 57.99$, $p < .001$]. Bei Vätern wurden lediglich Schwierigkeiten in der Emotionsregulation als Prädiktor identifiziert [R^2 = 0.43, $F(6, 24) = 4.78$, $p < .01$]. In den explorativen Analysen

konnten Schwierigkeiten der Emotionsregulation als Mediator für den Zusammenhang zwischen Erfahrungen von Misshandlung in der Kindheit der Mütter und dem Schweregrad von Symptomen einer Postpartalen Depression sowie für den Zusammenhang zwischen Erfahrungen von Misshandlung in der Kindheit der Mütter und elterlichem Stress identifiziert werden. Als Limitationen der Studie lassen sich das querschnittliche Studiendesign und die Verwendung von Selbstberichtsfragebögen nennen. Trotz unserer Bemühungen nahmen nur wenige Väter an der Studie teil, was zu einer unzureichenden statistischen Power für die Regressionsanalysen der Väter führte. Zusammenfassend bestätigte die Studie die Annahme, dass frühe interpersonelle Traumata einen Risikofaktor für die Entwicklung einer postpartalen Depression bei Müttern darstellen. Darüber hinaus könnten Schwierigkeiten der Emotionsregulation einen zentralen Ansatzpunkt für Interventionen zur Prävention einer Postpartalen Depression darstellen.

In *Publikation II* wurden Symptome einer postpartalen Depression als Mediator für den Zusammenhang zwischen Erfahrungen früher interpersoneller Traumata der Mutter und Probleme in der Mutter-Kind-Bindung untersucht. Für dieses Forschungsvorhaben wurden longitudinale Daten von N = 128 Müttern einer Kontrollgruppe einer eHealth Interventionsstudie (*I-PREGNO*) analysiert. Mithilfe eines Pfadmodells untersuchten wir, ob der Zusammenhang zwischen dem Schweregrad von Misshandlung von Müttern in ihrer Kindheit und der Qualität der späteren Mutter-Kind-Bindung im ersten Jahr nach der Geburt durch postpartale depressive Symptome mediiert wird. Die Ergebnisse des Pfadmodells deuteten auf eine volle Mediation durch postpartale depressive Symptome hin (indirekter Effekt [*ab*]: b = .44, p = .001, 95 % *CI* [.18, .70]; direkter Effekt [*c'*]: b = .01, p = .953, 95 % *CI* [-.38, .41]; totaler Effekt [*c*]: b = .45, p = .041, 95 % *CI* [.02, .89]). Die Ergebnisse aus *Publikation II* unterstreichen die Bedeutung der Behandlung postpartaler Depression bei Müttern mit traumatischen Erfahrungen in der Kindheit, um die Mutter-Kind-Bindung zu fördern und einen gesunden Start für das Kind zu unterstützen. Des Weiteren deuten die Ergebnisse darauf hin,

dass nicht die traumatischen Erfahrungen der Mütter selbst für die Entstehung von Problemen in der Mutter-Kind-Bindung verantwortlich sind, sondern die psychologischen Folgen (depressive Symptome), die durch das Erleben von frühen interpersonellen Traumata entstehen können.

Darüber hinaus enthält die vorliegende Arbeit zwei Publikationen (*Publikation III, IV*) über die Entwicklung und Evaluation einer mHealth basierten Intervention (*I-PREGNO*), die speziell auf die Bedürfnisse psychosozial belasteter Familien zugeschnitten ist. *Publikation III* präsentiert die Ergebnisse eines iterativen Entwicklungsprozesses der App *I-PREGNO*. Für die Entwicklung der App *I-PREGNO* wurde ein Nutzer-orientiertes Design gewählt, das in vier Phasen unterteilt werden kann. In Phase I wurden die Bedürfnisse der zukünftigen Nutzerinnen und Nutzern durch Fokusgruppen mit psychosozial belasteten Müttern und Fachkräften der Frühen Hilfen ermittelt. In Phase II wurde ein Prototyp der App entwickelt, der in Phase III durch Usability-Tests in der Zielgruppe und einem Walkthrough mit den Fachkräften der Frühen Hilfen evaluiert wurde und Anpassungen in der App unternommen wurden. Schließlich wurden in Phase IV die in der App implementierten Behavior Change Techniques evaluiert (Michie et al., 2013). Durch die Fokusgruppendiskussionen in Phase I konnten unterschiedliche Bedarfe psychosozial belasteter Mütter und Väter im Übergang zur Elternschaft identifiziert werden. Die Inhalte der App sollten nach Angaben der Mütter und der Fachkräfte vor allem psychologische Mechanismen adressieren (z. B. Emotionsregulation, Stress, dysfunktionale Kognitionen) und neben Informationen auch Strategien und Übungen enthalten, um das Wohlbefinden zu stärken. Außerdem sollte die App über den Zusammenhang zwischen körperlicher und psychischer Gesundheit der Eltern und der Gesundheit und Entwicklung des Kindes aufklären. Die Entwicklung des Prototypens basierte auf den identifizierten Bedürfnissen der Zielgruppe in Phase I, weiteren qualitativen Studien zu diesem Thema (Versele et al., 2022), sowie der Integration bestehender evidenzbasierter Inhalte. Insgesamt umfasst *I-PREGNO* nach den vier Phasen der Entwicklung 12 Module in denen interaktive

Inhalte mit psychoedukativen Inhalten in Form von Audioaufnahmen, Bildern und Texten integriert sind. Als Stärken des Entwicklungsprozesses kann das iterative und Nutzer-zentrierte Design, der Einbezug der Zielgruppe sowie die Arbeit in einem multidisziplinären Team von Expertinnen und Experten genannt werden. Die Ergebnisse der *Publikation III* liefern wertvolle Erkenntnisse für die Entwicklung evidenzbasierter mHealth-Angebote für psychosozial belastete Eltern im Übergang zur Elternschaft.

Publikation IV präsentiert erste Ergebnisse der Evaluation von *I-PREGNO* als eine 12-wöchige „Blended Care" Intervention integriert in die langfristige aufsuchende Betreuung und Begleitung der Frühen Hilfen in Deutschland. Die zweiarmige, cluster-randomisierte kontrollierte Studie mit insgesamt $N = 108$ Müttern von Kindern im Alter von 0-12 Monaten umfasste eine baseline-Messung (T0), eine post-Messung (12 Wochen nach Start der Intervention, T1) sowie eine Follow-Up Messung sechs Monate nach Start der Intervention (T2). Unterschiede in der depressiven Symptomatik und der Ausprägung von Elternstress zwischen der Interventionsgruppe (IG) und der Kontrollgruppe (CG) wurden durch Mehrebenenmodelle berechnet. Während die Ergebnisse der präregistrierten Analysen keinen signifikanten Effekt von *I-PREGNO* auf das psychische Wohlbefinden von Müttern zeigen konnten, ließ sich in explorativen Analysen, in denen für den Startzeitpunkt der Intervention kontrolliert wurde, ein Interaktionseffekt in der Ausprägung des Elternstresses zwischen der IG und CG finden. In der Gruppe der Mütter, die in den ersten Monaten nach der Geburt mit an der Studie teilnahmen, zeigten Mütter in der IG signifikant geringere Werte im Bereich des Elternstress als Eltern in der CG. In Bezug auf die depressive Symptomatik lieferten auch die explorativen Ergebnisse keine signifikanten Unterschiede. Vor dem Hintergrund der Ergebnisse der Studie und vorheriger Befunde anderer Forschungsgruppen lässt sich vermuten, dass die Prävention von postpartalen Depressionen bei psychosozial belasteten Eltern einen umfassenderen Ansatz als *I-PREGNO* benötigt. Die explorativen Analysen und die niedrige Abbruchrate in der IG weisen dennoch auf das Potenzial von mHealth basierten Interventionen

in der Zielgruppe hin. Trotzdem unterstreichen die Ergebnisse der präregistrierten Analysen die Notwendigkeit einer weiteren Anpassung und Erweiterung von *I-PREGNO*.

Abschließend präsentiert *Publikation V* ein *Consensus Statement,* dessen Ziel es war, die methodische Qualität, Evidenz und langfristige Implementierung digitaler Innovationen im Gesundheitswesen zu fördern. Die Entstehung der *Publikation V* basierte auf einem iterativen, Delphi-adaptierten Prozess, an dem 25 internationale Expertinnen und Experten aus dem Bereich e-mental health und ein Think Tank teilnahmen. Insgesamt umfasst *Publikation V* 11 Kapitel mit Leitlinien im Bereich der Entwicklung, Evaluierung und Implementierung von digitalen Assessments und Interventionen.

Zusammenfassend schließt die vorliegende Dissertation bestehende Forschungslücken im Bereich der Prävention von postpartalen Depressionen durch die Untersuchung von Risikofaktoren, die Erforschung der Folgen von postpartalen Depressionen und die Entwicklung und Evaluierung einer mHealth basierten Intervention. Die Ergebnisse dieser Arbeit unterstreichen die Notwendigkeit präventiver Interventionen für Frauen, die in ihrer eigenen Kindheit interpersonelle Traumata erlebt haben, und nun selbst Eltern werden. Des Weiteren konnten Schwierigkeiten der Emotionsregulation als ein vielversprechender Ansatzpunkt für die Prävention von postpartalen Depressionen identifiziert werden. Diese Dissertation liefert erste wichtige Erkenntnisse über die Entwicklung und Evaluation einer mHealth basierten Intervention, die speziell auf die Bedürfnisse psychosozial belasteter Familien im Übergang zur Elternschaft zugeschnitten ist.

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Appendix

Appendix

Appendix A. Supplementary Material Publication I

Table S1

Result of an In-depth Multiple Regression Analysis in Mothers with Symptoms of Postpartum Depression as Independent Variable.

	B	95% CI for *B*		*SE B*	*ß*	*t*	R^2
		LL	*UL*				
PPD							$.13^{***}$
Constant	3.55	2.02	5.08	.78		4.56^{***}	
Emotional neglect	.72	.05	1.40	.34	.14	2.11^{*}	
Physical abuse	.14	-.70	.99	.43	.02	.34	
Emotional abuse	1.02	.37	1.68	.34	.21	3.06^{**}	
Sexual abuse	-.18	-1.11	.74	.47	-.02	-.39	
Physical neglect	.80	-.02	1.62	.42	.12	1.92	

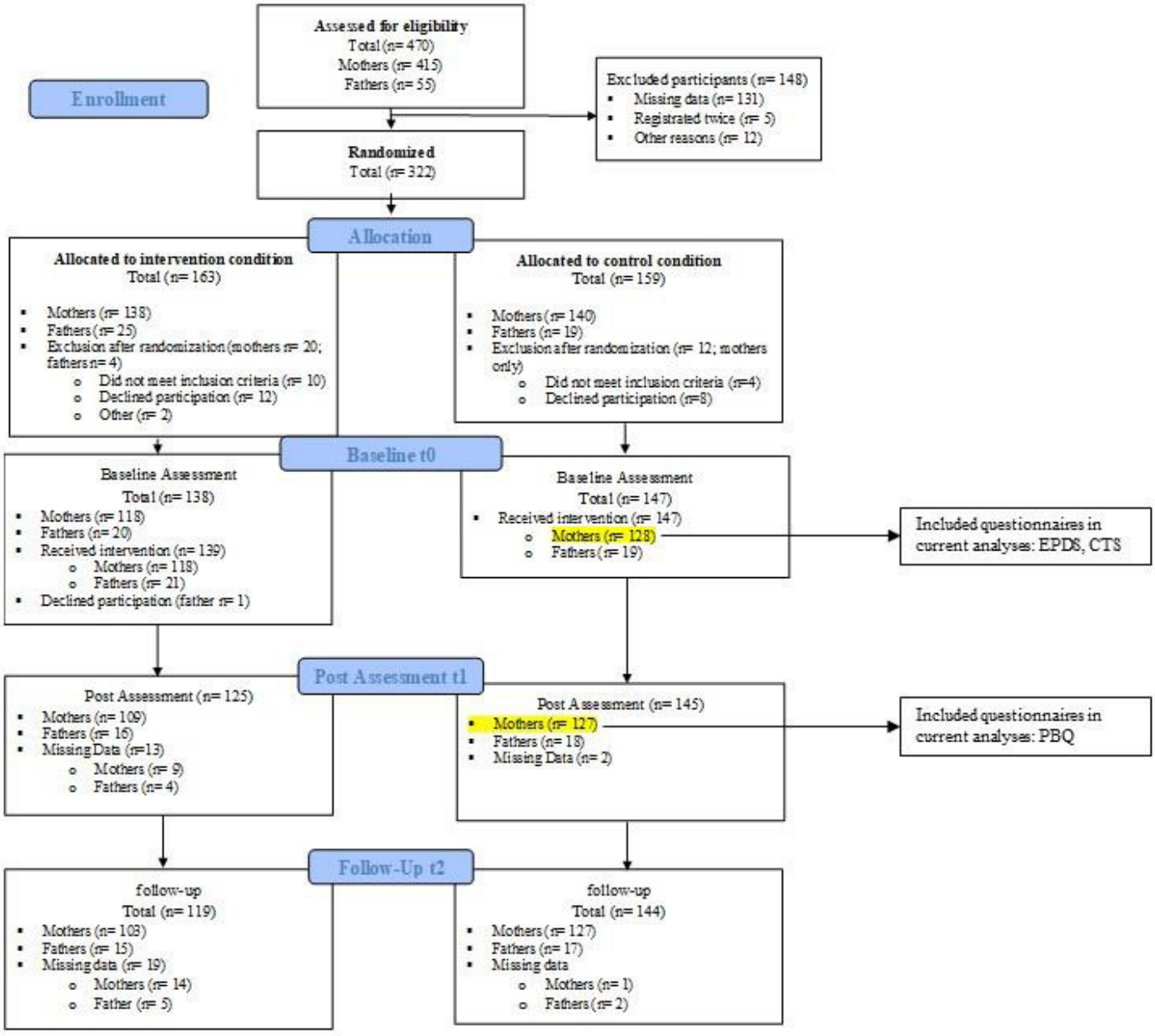
Note. Postpartum depression was measured through the Edinburgh-Postnatal-Depression-Scale. The subscales of childhood maltreatment were measured using the childhood trauma screener.

CI = confidence interval; *LL* = lower limit; *UL* = upper limit. *p<.05. **p<.01. ***p<.001.

Appendix B. Supplementary Material Publication II

Figure S1

Study Flow Chart of the Trial I-PREGNO



Note. Data used for the analyses of the paper are highlighted in yellow. CTS = Childhood Trauma Screener (Grabe et al., 2012); EPDS = Edinburgh Postnatal Depression Scale (Cox et al., 1987); PBQ = Postpartum Bonding Questionnaire (Reck et al., 2006)

Appendix C. Supplementary Material Publication III

Supplementary Material

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

Table S1. *Behavior Change Technique Taxonomy (Michie et al., 2013) and Frequency of Techniques Presented in the App (n)*

#	Behavior Change Technique	n
Cluster: Goals and planning		**245**
1.1	Goal setting (behavior)	6
1.2	Problem solving	136
1.3	Goal setting (outcome)	9
1.4	Action planning	28
1.5	Review behavior goal(s)	26
1.6	Discrepancy between current behavior and goal	14
1.7	Review outcome goal(s)	25
1.8	Behavioral contract	-
1.9	Commitment	1
Cluster: Feedback and monitoring		**92**
2.1	Monitoring of behavior by others without feedback	-
2.2	Feedback on behavior	-
2.3	Self-monitoring of behavior	85
2.4	Self-monitoring of outcome(s) of behavior	7
2.5	Monitoring of outcome(s) of behavior without feedback	-
2.6	Biofeedback	-
2.7	Feedback on outcome(s) of behavior	-
Cluster: Social support		**33**
3.1	Social support (unspecified)	20
3.2	Social support (practical)	10
3.3	Social support (emotional)	3
Cluster: Shaping knowledge		**220**
4.1	Instruction on how to perform the behavior	106
4.2	Information about Antecendents	111
4.3	Re-attribution	2
4.4	Behavioral experiments	1
Cluster: Natural consequences		**114**
5.1	Information about health consequences	33
5.2	Salience of consequences	7
5.3	Information about social and environmental consequences	33

#	Behavior Change Technique	n
5.4	Monitoring of emotional consequences	1
5.5	Anticipated regret	-
5.6	Information about emotional consequences	40
Cluster: Comparison of behavior		**30**
6.1	Demonstration of the behavior	27
6.2	Social comparison	3
6.3	Information about others' approval	-
Cluster: Associations		**4**
7.1	Prompts/cues	4
7.2	Cue signalling reward	-
7.3	Reduce prompts/cues	-
7.4	Remove access to the reward	-
7.5	Remove aversive stimulus	-
7.6	Satiation	-
7.7	Exposure	-
7.8	Associative learning	-
Cluster: Repetition and substitution		**73**
8.1	Behavioral practice/rehearsal	59
8.2	Behavior substitution	3
8.3	Habit formation	11
8.4	Habit reversal	-
8.5	Overcorrection	-
8.6	Generalisation of target behavior	-
8.7	Graded tasks	-
Cluster: Comparison of outcome		**17**
9.1	Credible source	13
9.2	Pros and cons	3
9.3	Comparative imagining of future outcomes	1
Cluster: Reward and thread		**25**
10.1	Material incentive (behavior)	-
10.2	Material reward (behavior)	2
10.3	Non-specific reward	2
10.4	Social reward	9
10.5	Social incentive	-
10.6	Non-specific incentive	-
10.7	Self-incentive	3
10.8	Incentive (outcome)	-
10.9	Self-reward	7
10.10	Reward (outcome)	2
10.11	Future punishment	-
Cluster: Regulation		**65**
11.1	Pharmalogical support	-
11.2	Reduce negative emotions	63
11.3	Conserving mental resources	2
11.4	Paradoxical instructions	-
Cluster: Antecedents		**51**
12.1	Restructuring the physical environment	1
12.2	Restructuring the social environment	-
12.3	Avoidance/reducing exposure to cues for the behavior	5
12.4	Distraction	2

#	Behavior Change Technique	n
12.5	Adding objects to the environment	3
12.6	Body changes	40
Cluster: Identity		**38**
13.1	Identification of self as role model	8
13.2	Framing/reframing	18
13.3	Incompatible beliefs	4
13.4	Valued self-identify	8
13.5	Identify associated with changed behavior	-
Cluster: Schedulded consequences		-
14.1	Behavior cost	-
14.2	Punishment	-
14.3	Remove reward	-
14.4	Reward approximation	-
14.5	Rewarding completion	-
14.6	Situation-specific reward	-
14.7	Reward incompatible behavior	-
14.8	Reward alternative behavior	-
14.9	Reduce reward frequency	-
14.10	Remove punishment	-
Cluster: Self-belief		**42**
15.1	Verbal persuasion about capability	9
15.2	Mental rehearsal of successful performance	5
15.3	Focus on past success	8
15.4	Self-talk	20
Cluster: Covert learning		1
16.1	Imaginery punishment	-
16.2	Imaginery reward	-
16.3	Vicarious consequences	1

Figure S1. *Coding Example for BCT "4.2 Information about Atecendents" coded over the Course of Two Screenshots.*

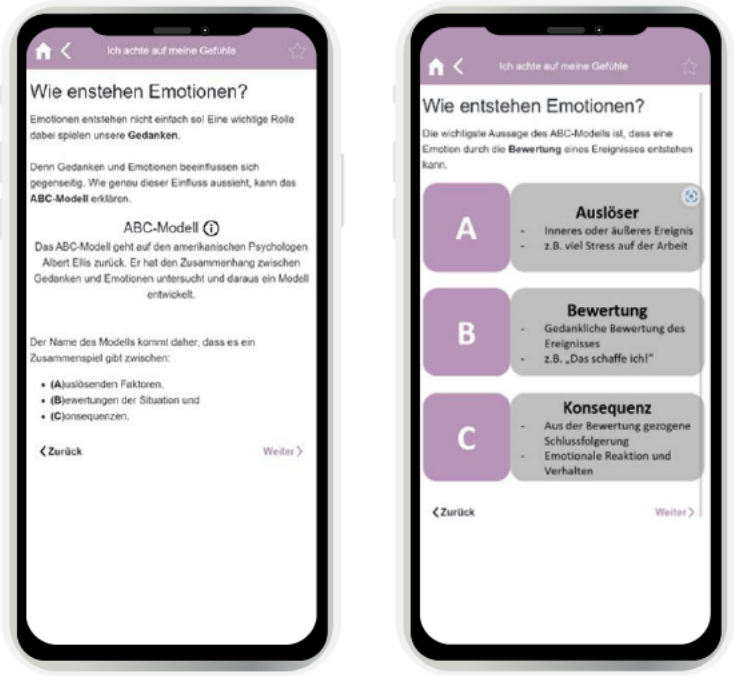


Table S2. *Overview of Intervention Content and Single BCTs Coded Within Each Module.*

Module (n total BCTs)	**Objectives and aims**	**Sessions within the module**	**BCTs within the module (number of codings)**		
Tutorial (3)	Users will be able to describe the structure of the app and use the features of the app.	1. Objectives and content of the app 2. Usage of the app	2.3 (1) 4.2 (1)	9.1 (1)	
Introduction (47)	Users can list the contents of the app and describe why these topics are relevant to parents. Users identified their personal goals for the intervention phase.	1. Psychoeducation "self-care as a parent-(to-be)" 2. Importance of self-care (i.e., mental wellbeing, nutrition, exercise behavior) for parents 3. Changes during the pregnancy and postpartum period 4. Goal setting	1.1 (1) 1.2 (7) 1.3 (1) 1.4 (3) 1.6 (1) 1.9 (1) 2.3 (6) 3.1 (1) 3.2 (1)	4.1 (6) 4.2 (4) 5.1 (1) 5.3 (1) 5.6 (1) 6.1 (1) 8.1 (1) 9.1 (1) 10.2 (1)	10.3 (1) 10.4 (1) 10.9 (1) 10.10 (1) 11.2 (1) 13.1 (1) 13.2 (1) 15.4 (1)
Self-Esteem (148)	Users can describe what self-esteem is, what it is based on and get to know exercises that can be used to strengthen their own and their child's self-esteem. Users can explain how the body changes during pregnancy and	1. Psychoeducation "self-esteem" 2. Identifying personal resources 3. Strengthening personal resources 4. Developing new personal resources 5. Developing self-esteem-enhancing cognitions	1.1 (2) 1.2 (17) 1.3 (2) 1.4 (5) 1.5 (3) 1.6 (1) 1.7 (3) 2.3 (7) 2.4 (1)	9.1 (2) 9.2 (1) 10.4 (1) 10.7 (3) 10.9 (4) 11.2 (13) 12.3 (1) 12.4 (1)	

	after childbirth and how this affects body image. They get to know exercises to strengthen their attitude towards their own body.	6. Implementing self-esteem-enhancing cognitions 7. Implementing a daily self-esteem journal 8. Psychoeducation "development of children's self-esteem"** 9. Changes of the body 10. Dealing with difficult situations in a self-assured manner 11. Introduction "body image" 12. Cognitive restructuring 13. Identifying cognitive distortions 14. Reducing avoidance behavior 15. Developing self-reward techniques 16. Preparing for the postpartum time* 17. Conclusion "personal learning in this module"	3.1 (3) 3.2 (1) 4.1 (9) 4.2 (7) 4.4 (1) 5.1 (4) 5.2 (1) 5.3 (6) 5.6 (12) 6.1 (1) 8.1 (9) 8.2 (2)	13.1 (1) 13.2 (4) 13.3 (1) 13.4 (7) 15.1 (2) 15.3 (1) 15.4 (9)	
Stress – management (225)	Users learn what stress is and develop their own stress model. They learn about parental stress and the consequences of stress for the child. They get to know different exercises to cope with stress.	1. Psycho-education "stress" 2. Identifying individual stressors 3. Identifying individual stress reactions 4. Introduction of stress management skills 5. Problem solving exercise 6. Time management exercise 7. Breath relaxation exercise 8. Meditation exercise "walking" 9. Meditation exercise "sitting" 10. Mindfulness exercise "sense of touch" 11. Mindfulness exercise "tasting" 12. Mindfulness exercise "sense of smell" 13. Cognitive exercise "packing parcels" 14. Radical acceptance 15. Sleep as a special stressor 16. Taking responsibility for tasks 17. Handing over responsibility for tasks 18. Conclusion „personal learning from this module"	1.1 (2) 1.2 (21) 1.4 (6) 1.5 (4) 1.6 (1) 1.7 (3) 2.3 (13) 2.4 (1) 3.1 (7) 3.2 (5) 4.1 (19) 4.2 (32)	5.1 (14) 5.2 (3) 5.3 (11) 5.6 (12) 6.1 (7) 7.1 (2) 8.1 (14) 8.2 (1) 8.3 (7) 9.1 (2) 9.2 (1) 9.3 (1)	10.4 (1) 11.2 (11) 11.3 (1) 12.1 (1) 12.3 (4) 12.5 (2) 12.6 (6) 13.1 (2) 13.2 (2) 15.2 (1) 15.3 (2) 15.4 (3)
Emotion regulation (198)	Users learn what emotions are, why they are important and how emotions can be regulated. They learn about the link between emotions and hormones in the transition to parenthood and how children regulate emotions. They try out different exercises to regulate emotions.	1. Psychoeducation "functions of emotions" 2. Psychoeducation "development of emotions" 3. Relation between emotions and cognitions 4. Recognizing and defusing cognitive distortions 5. Introduction of emotion regulation skills 6. Emotion surfing exercise 7. Psychoeducation "emotions and hormones"	1.2 (30) 1.4 (4) 1.5 (3) 1.7 (3) 2.3 (13) 2.4 (1) 3.1 (2) 4.1 (22) 4.2 (23) 5.1 (3)	5.2 (2) 5.3 (4) 5.4 (1) 5.6 (7) 6.1 (7) 8.1 (20) 8.3 (4) 9.1 (1) 10.4 (1)	11.2 (21) 12.4 (1) 12.6 (5) 13.1 (2) 13.2 (7) 13.3 (3) 15.1 (3) 15.2 (1) 15.4 (4)

		8. Dealing with depressive moods 9. Emotion regulation in infants 10. Relation between physical activity and emotions 11. Mindfulness exercise "walking" 12. Mindfulness exercise "Five senses" 13. Focused attention exercise 14. Developing helpful emotional beliefs 15. Promoting self-compassion 16. Behaving contrary to the emotion 17. Implementing distraction 18. Identifying positive activities 19. Conclusion "personal learning from this module"			
Self-Efficacy (101)	Users learn what self-efficacy is and why it is relevant for coping with parental tasks and the child's development. They can try different exercises to increase their self-efficacy in everyday life.	1. Psychoeducation "self-efficacy" 2. Identifying sources of self-efficacy 3. Identifying daily personal achievements 4. Coping with success and failure 5. Personal attribution of success and failure 6. Identifying role models 7. Discovering personal resources 8. Improving self-efficacy of children 9. Conclusion "personal learning from this module"	1.1 (1) 1.2 (12) 1.4 (4) 1.5 (5) 1.6 (1) 1.7 (5) 2.3 (8) 2.4 (1) 4.1 (8) 4.2 (15) 4.3 (2)	5.1 (2) 5.2 (1) 5.3 (3) 5.6 (2) 6.1 (5) 6.2 (3) 7.1 (1) 8.1 (4) 9.2 (1) 10.4 (1) 11.2 (1)	12.5 (1) 12.6 (1) 13.1 (1) 13.2 (2) 15.1 (3) 15.2 (2) 15.3 (3) 15.4 (1) 16.3 (1)
Social competences (55)	Users identify their social relationships and learn how these may change in the transition to parenthood. They are introduced to communication strategies that they can use in social situations to communicate their feelings and needs.	1. Psychoeducation "social relations", identifying social resources 2. Psychoeducation "change in social relationships within and after the pregnancy" 3. Observing without judging 4. Recognizing and expressing feelings 5. Recognizing and communicating personal needs 6. Asking other people for something 7. Conclusion "personal learning from this module"	1.2 (7) 1.4 (1) 1.5 (3) 1.7 (3) 2.3 (3) 2.4 (1) 3.1 (2)	3.2 (2) 3.3 (2) 4.1 (5) 4.2 (7) 5.1 (1) 5.3 (2)	5.6 (1) 6.1 (2) 8.1 (5) 9.1 (2) 11.2 (5) 12.6 (1)
Mindfulness (74)	Users learn about the basic assumptions of mindfulness and how these can be relevant to parental behavior. They can try different mindfulness exercises.	1. Psychoeducation "mindfulness" 2. Identifying relations between mindfulness and mental health 3. Meditation exercises for the pregnancy and postpartum period 4. Introduction of further mindfulness exercises	1.2 (12) 1.4 (1) 1.5 (3) 1.7 (3) 2.3 (11) 2.4 (1)	4.1 (8) 4.2 (2) 5.1 (1) 5.3 (5) 5.6 (3) 8.1 (3)	11.2 (10) 11.3 (1) 12.6 (8) 15.1 (1) 15.4 (1)

		5. Conclusion "personal learning from this module"			
Nutrition (41)	Users get to know five key messages on nutrition and given examples of how to implement this behavior in everyday life.	1. Psychoeducation "Nutrition and weight development" 2. Finding out why water is valuable 3. Discovering how a diverse plate looks like 4. Discovering vegetable food 5. Dealing with sweets and fast-food 6. Finding the good portion of meat 7. Breastfeeding**	1.2 (8) 2.3 (6) 4.1 (10) 4.2 (8)	5.1 (3) 7.1 (1) 8.1 (1)	9.1 (3) 13.2 (1)
Physical Activity (48)	Users are given information on two key points about exercise and are presented with a range of strength exercises that they can try in their everyday lives.	1. Psychoeducation "physical activity during the pregnancy/postpartum period" 2. Monitoring and altering sitting behavior 3. Psychoeducation "weight training during the pregnancy/postpartum period" 4. Strength exercises: training notes 5. Strength exercises "upper body" 6. strength exercises "full body" 7. strength exercises "lower body" 8. strength exercises "pelvic floor"	1.2 (9) 1.4 (1) 2.3 (4) 3.1 (1) 4.1 (9)	4.2 (4) 5.1 (2) 6.1 (4) 6.2 (1) 8.1 (2)	9.1 (1) 12.6 (8) 13.1 (1) 15.3 (1)
Self-monitoring (2)	Users can record different emotion and behavior-related entries on a daily basis. Self-observation encourages introspection and self-reflection.	Continuous daily self-monitoring of – Mood *"how did you feel today?"* – Physical activity *"how satisfied were you with your exercise behavior today?"* – Nutrition *"how satisfied were you with your eating behavior today?"* – Sleep *"how satisfied were you with your sleeping behavior today?"* – Reflection of the past day *"did something happen today that had an impact on your mood, exercise, nutrition or sleeping behavior?"* – Outlook for the following day *"What are you resolving to do tomorrow to take care of yourself?"* – Other notes on the day *"What else was important to you today?"*	2.3 (1) 2.4 (1)		
Conclusion (95)	Users reflect on the topics they have worked on with the app and record what they have learned from the app.	1. Summarizing and reflecting on the app content 2. Review of goal achievement 3. Sticking to the personal goals 4. Dealing with setbacks	1.2 (13) 1.4 (3) 1.5 (5) 1.6 (10) 1.7 (5)	4.1 (10) 4.2 (9) 5.1 (2) 5.3 (1) 5.6 (2)	10.9 (2) 10.10 (1) 11.2 (1) 12.6 (2) 13.2 (1)

	They compare their progress with the goals set at the beginning of the app. They are encouraged to set rewards for goals achieved, make concrete plans for next steps and a plan for dealing with setbacks.		2.3 (12) 3.1 (4) 3.2 (1) 3.3 (1)	10.2 (1) 10.3 (1) 10.4 (3)	15.2 (1) 15.3 (1) 15.4 (2)

Notes. *pregnancy only; **postpartum only

Table S3. *Interview Guide of the Focus Groups With Professionals and Psychosocially Burdened Mothers.*

Focus groups with healthcare professionals	**Focus groups with potential users**
In your experience, what apps do psychosocially burdened families use and what are your experiences with these apps?	What kind of apps do you usually use? When and how much time do you spend with apps?
Which (mental) health topics do you perceive as relevant for psychosocially burdened families during the transition to parenthood?	Do you use any apps related to (mental) health and health behavior during the transition to parenthood?
Which of them could be included in an app?	What are topics or questions that people are interested in during the transition to parenthood?
What features would the app need to fit into families' everyday life?	How could an app support people during the transition to parenthood? How could an app support the parents' well-being and physical health?
In your opinion, how exactly does an app look like that enhances your work and does not make your daily work routine more difficult?	What kind of app features do you (not) like?
How can fathers (to-be) be included in the intervention?	What kind of strategies could be used to help parents who need support to avoid dropping the use of the app once they have started it?

Appendix D. Supplementary Material Publication IV

i-Pregno

Procedure

Main effect analyses are performed using multi-level models with random intercepts following a longitudinal analysis of covariance. In this method the outcome variable measured at the different follow-up measurements is adjusted for the baseline value of the outcome:

Y_t = b_0 + b_1 * X + b_2 * Y_0 + b_3 * time + b_4 * X * time

where, Y_t = the outcome measured at the two follow-up measurements and X = the treatment (grouping) variable. The regression coefficient for the treatment variable reflects the treatment effect at the first follow-up measurement. The treatment effect at the second follow-up measurement is calculated as the sum of the regression coefficient for the treatment variable and the regression coefficient for the interaction between the treatment variable and time (b_1 + b_4).

Moderator analyses are performed by adding a three way interaction with the moderator variable Z to the above formula, whereby the term 'X * Z' and 'X * time * Z' represent the moderating influence of Z on the treatment effect at timepoint 1 and 2 respectively.

Data layout:

id	outcome	time	group	baseline
1	Y_t1	0	1	Y_t0
1	Y_t2	1	1	Y_t0
2	Y_t1	0	2	Y_t0
2	Y_t2	1	2	Y_t0

Prep

```
# group and time as factors
data$group[data$group == 1] <- "Exp"
data$group[data$group == 3] <- "Ctrl"
data$group <- factor(data$group)

data$time[data$time == 0] <- "T0"
data$time[data$time == 1] <- "T1"
data$time[data$time == 2] <- "T2"
data$time <- factor(data$time)

# t0 as covariate, t1 and t2 as outcome
data2 <- data[!data$time == "T0",]
data2$epds_pre <- rep(data$epds[data$time == "T0"], each = 2)
data2$psi_pre <- rep(data$psi[data$time == "T0"], each = 2)
```

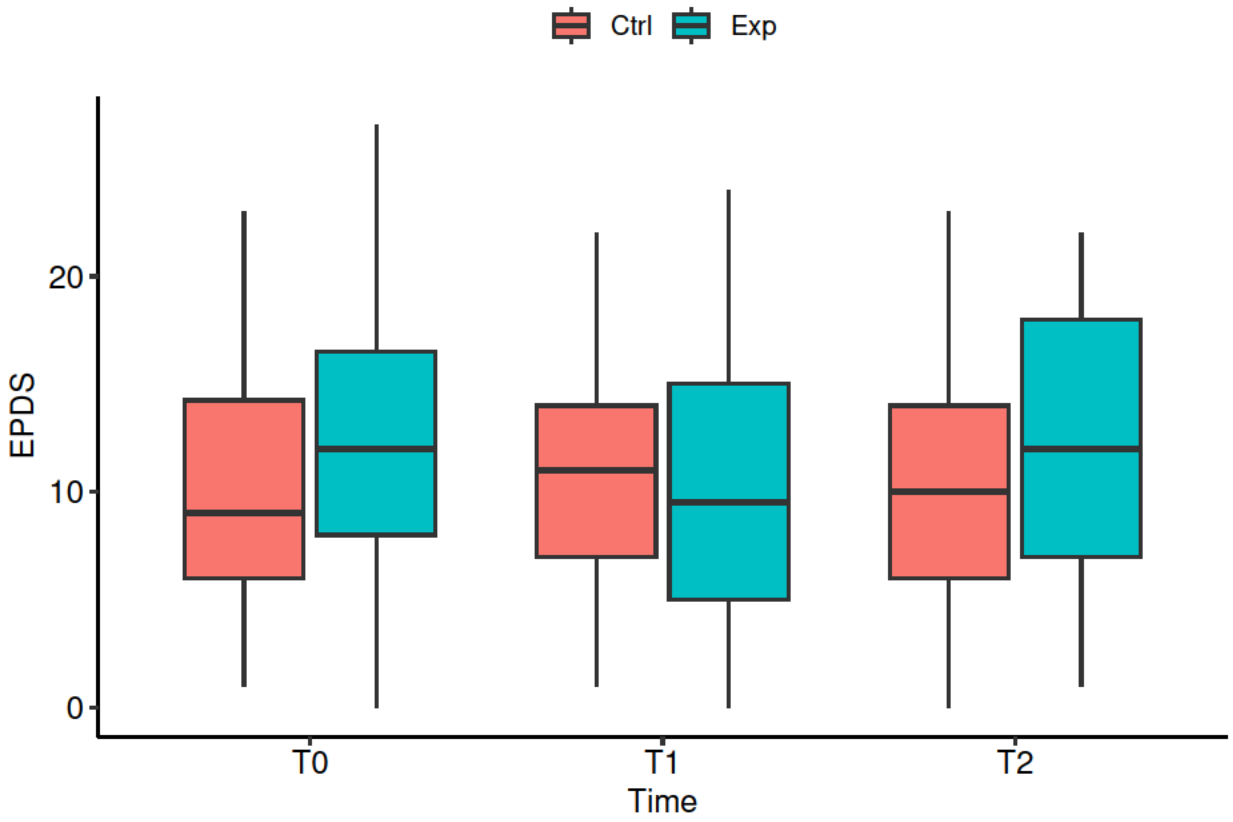
```r
# take a look
summary(data2)
```

```
##            id      time          hp         group        citizen
##  FK_001_01_A:  2   T0: 0   Min.   : 1.00   Ctrl:106   Min.   :0.0000
##  FK_001_02_A:  2   T1:95   1st Qu.:17.00   Exp : 84   1st Qu.:1.0000
##  FK_004_01_A:  2   T2:95   Median :31.00              Median :1.0000
##  FK_004_02_A:  2           Mean   :33.60              Mean   :0.8421
##  FK_004_03_A:  2           3rd Qu.:48.75              3rd Qu.:1.0000
##  FK_004_04_A:  2           Max.   :71.00              Max.   :1.0000
##  (Other)    :178
##       edu            finaid             SP             age_c
##  Min.   :1.000   Min.   :0.0000   Min.   :0.0000   Min.   : 0.000
##  1st Qu.:2.000   1st Qu.:0.0000   1st Qu.:0.0000   1st Qu.: 3.000
##  Median :3.000   Median :0.0000   Median :0.0000   Median : 6.000
##  Mean   :3.305   Mean   :0.3263   Mean   :0.3263   Mean   : 5.942
##  3rd Qu.:4.750   3rd Qu.:1.0000   3rd Qu.:1.0000   3rd Qu.: 8.000
##  Max.   :6.000   Max.   :1.0000   Max.   :1.0000   Max.   :13.000
##                                                    NA's   :18
##   preg_planned        ill_c           contact_hp          cts
##  Min.   :0.0000   Min.   :0.00000   Min.   : 0.000   Min.   : 5.000
##  1st Qu.:0.0000   1st Qu.:0.00000   1st Qu.: 4.000   1st Qu.: 6.000
##  Median :1.0000   Median :0.00000   Median : 6.000   Median : 9.000
##  Mean   :0.5341   Mean   :0.05814   Mean   : 6.259   Mean   : 9.704
##  3rd Qu.:1.0000   3rd Qu.:0.00000   3rd Qu.: 8.000   3rd Qu.:12.000
##  Max.   :1.0000   Max.   :1.00000   Max.   :15.000   Max.   :21.000
##  NA's   :14       NA's   :18        NA's   :74       NA's   :28
##      treat             med             appuse            psi
##  Min.   :0.0000   Min.   :0.0000   Min.   :  0.00   Min.   : 24.00
##  1st Qu.:0.0000   1st Qu.:0.0000   1st Qu.: 18.25   1st Qu.: 63.00
##  Median :0.0000   Median :0.0000   Median : 33.32   Median : 75.00
##  Mean   :0.1341   Mean   :0.1098   Mean   : 89.70   Mean   : 74.78
##  3rd Qu.:0.0000   3rd Qu.:0.0000   3rd Qu.: 77.14   3rd Qu.: 89.00
##  Max.   :1.0000   Max.   :1.0000   Max.   :643.75   Max.   :120.00
##  NA's   :26       NA's   :26       NA's   :112      NA's   :33
##       epds          epds_pre        psi_pre
##  Min.   : 0.00   Min.   : 0.00   Min.   : 27.00
##  1st Qu.: 6.00   1st Qu.: 6.25   1st Qu.: 60.00
##  Median :10.00   Median :10.00   Median : 74.00
##  Mean   :10.83   Mean   :11.07   Mean   : 72.57
##  3rd Qu.:15.00   3rd Qu.:15.00   3rd Qu.: 83.50
##  Max.   :24.00   Max.   :27.00   Max.   :118.00
##  NA's   :32      NA's   :16      NA's   :16
```

EPDS as outcome

```r
# plot by design
ggplot(data,aes(x = time, y = epds, fill = group)) +
  geom_boxplot() + ylab("EPDS") + xlab("Time") + theme_pubr() +
  theme(legend.title=element_blank())
```

```
## Warning: Removed 40 rows containing non-finite outside the scale range
## (‘stat_boxplot()‘).
```




```
# estimation
lme_epds1 <- lmer(epds ~ time * group + epds_pre + (1|hp/id), data = data2)
summary(lme_epds1)
```

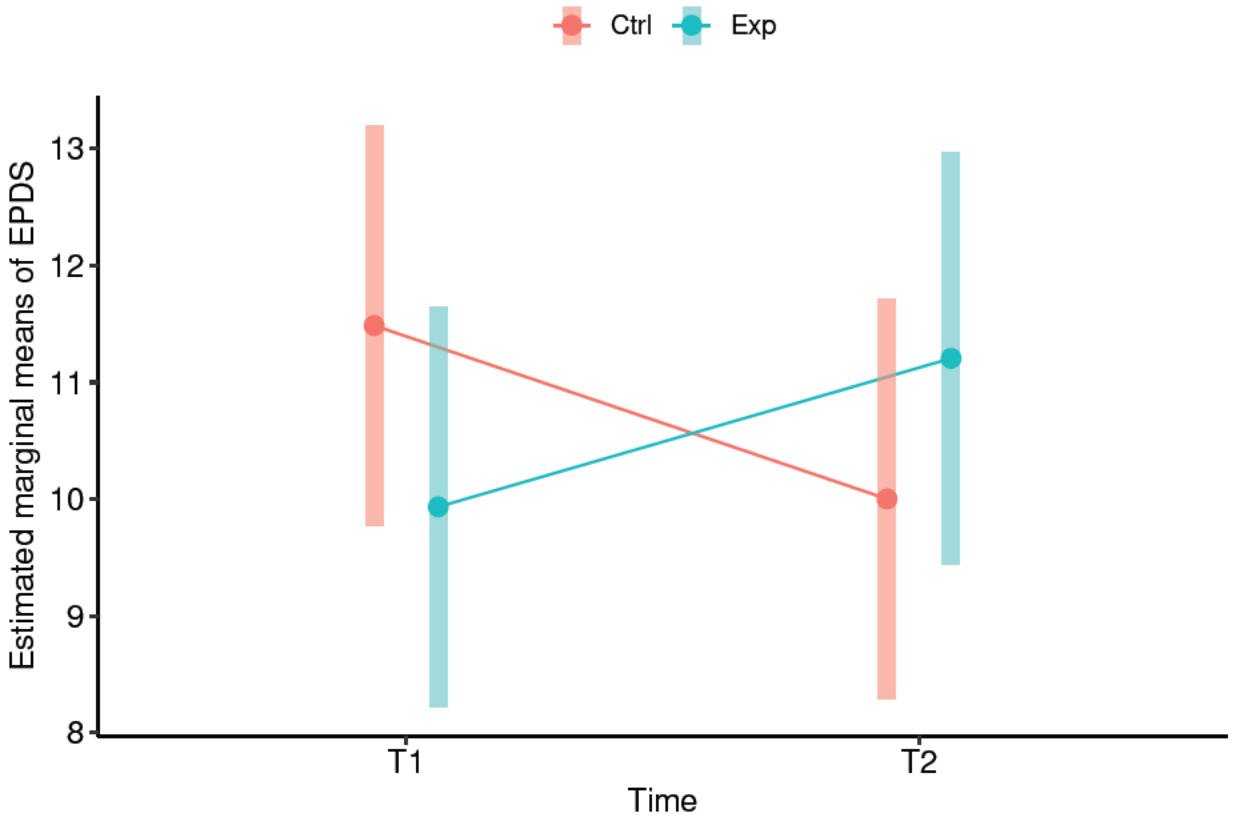
```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: epds ~ time * group + epds_pre + (1 | hp/id)
##    Data: data2
##
## REML criterion at convergence: 908.1
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -1.79199 -0.49024 -0.05465  0.39643  2.57814
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id:hp    (Intercept) 13.390   3.659
##  hp       (Intercept)  1.485   1.219
##  Residual              9.222   3.037
## Number of obs: 158, groups:  id:hp, 83; hp, 38
##
## Fixed effects:
##                Estimate Std. Error       df t value Pr(>|t|)
```

```
## (Intercept)      4.88218    1.16858 41.43790   4.178 0.000148 ***
## timeT2          -1.48402    0.65057 72.60939  -2.281 0.025476 *
## groupExp        -1.55212    1.16759 38.39698  -1.329 0.191583
## epds_pre         0.59933    0.08059 75.25352   7.437 1.37e-10 ***
## timeT2:groupExp  2.75492    0.99155 73.70208   2.778 0.006925 **
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp epds_p
## timeT2      -0.266
## groupExp    -0.407  0.285
## epds_pre    -0.727 -0.023 -0.089
## tmT2:grpExp  0.183 -0.656 -0.411  0.003
```

```
# marginal means
lme_epds1_em <- emmeans(lme_epds1, specs = ~ time:group)
summary(lme_epds1_em)
```

```
##  time group emmean    SE   df lower.CL upper.CL
##  T1   Ctrl   11.49 0.827 21.7     9.77     13.2
##  T2   Ctrl   10.00 0.822 21.0     8.29     11.7
##  T1   Exp     9.93 0.856 59.3     8.22     11.6
##  T2   Exp    11.21 0.880 63.8     9.45     13.0
##
## Degrees-of-freedom method: kenward-roger
## Confidence level used: 0.95
```

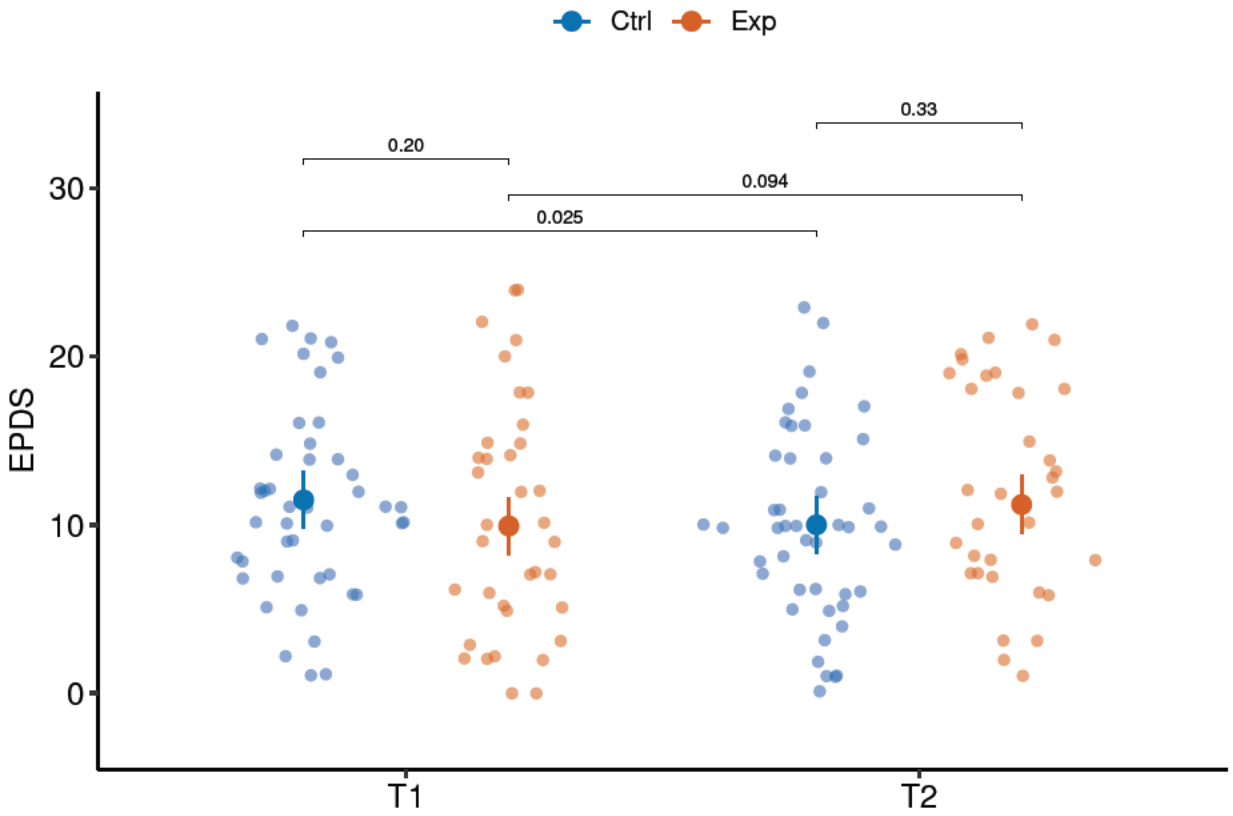
```
# plot marginal means
ggplot(data = as.data.frame(lme_epds1_em), aes(y = emmean, x = time, col = group)) +
  theme_pubr() + xlab("Time") + ylab("Estimated marginal means of EPDS") +
  geom_line(aes(group = group), position=position_dodge(0.25)) +
  geom_point(position=position_dodge(0.25), size = 3) +
  geom_linerange(data = as.data.frame(lme_epds1_em),
                 aes(y = emmean, ymin = lower.CL, ymax = upper.CL, x = time, group = group),
                 position=position_dodge(0.25), lwd=3, alpha=.5) +
  theme(legend.title=element_blank())
```



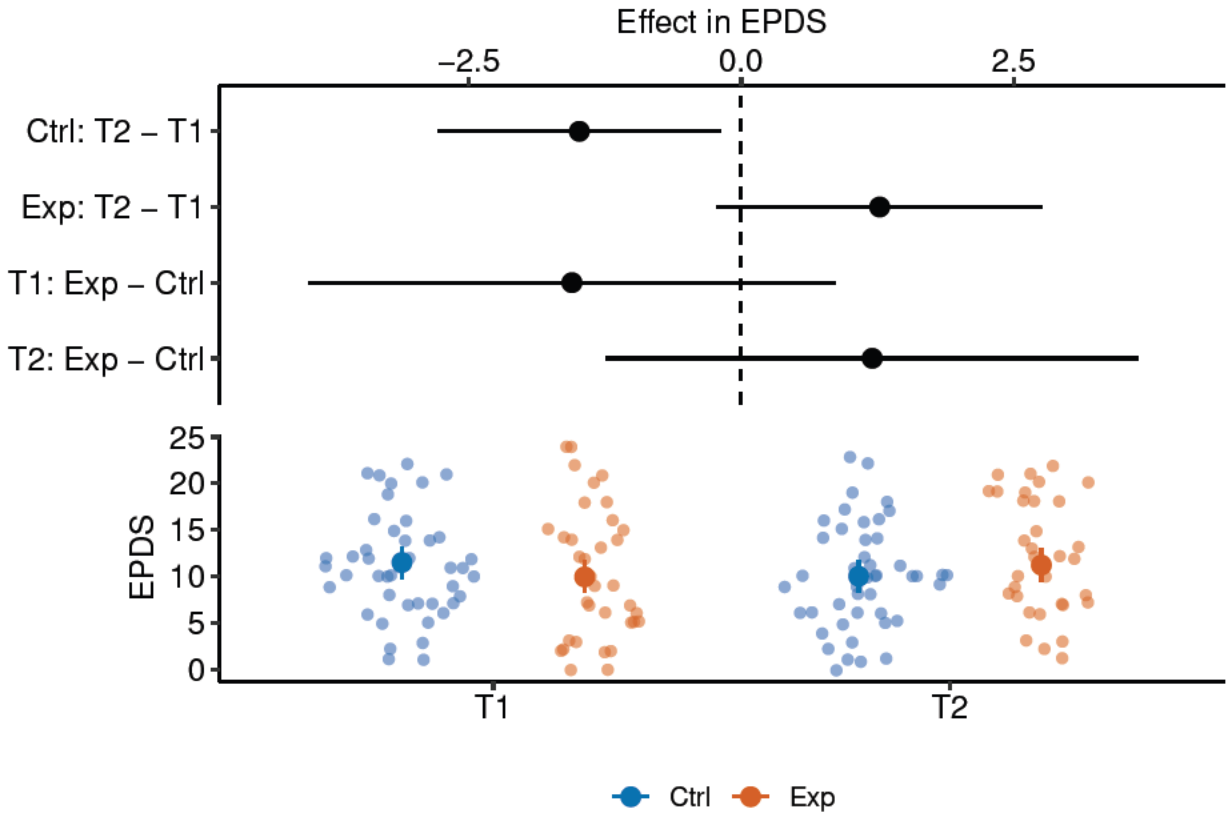

```
# pairwise comparisons
lme_epds1_simple <- contrast(lme_epds1_em,
                     method = "revpairwise",
                     simple = "each",
                     combine = TRUE,
                     adjust = "none")
summary(lme_epds1_simple)
```

```
##  group time contrast   estimate    SE   df t.ratio p.value
##  Ctrl  .    T2 - T1       -1.48 0.651 74.9  -2.280  0.0255
##  Exp   .    T2 - T1        1.27 0.750 76.8   1.695  0.0940
##  .     T1   Exp - Ctrl    -1.55 1.193 36.1  -1.301  0.2014
##  .     T2   Exp - Ctrl     1.20 1.206 37.2   0.997  0.3251
##
## Degrees-of-freedom method: kenward-roger
```

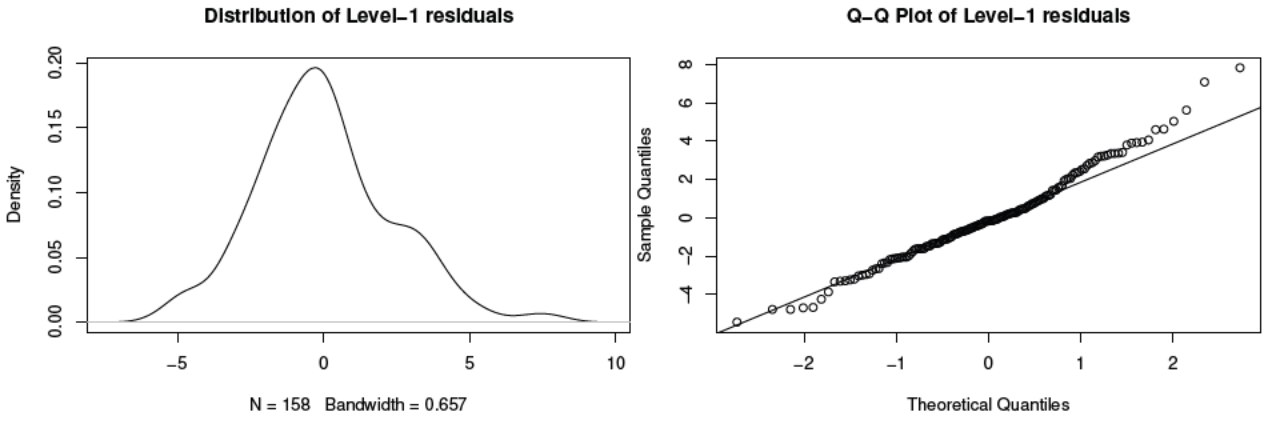
```
# plot pairwise comparisons
ggplot_the_response(
  fit = lme_epds1,
  fit_emm = lme_epds1_em,
  fit_pairs = lme_epds1_simple,
  palette = pal_okabe_ito_blue,
  y_label = "EPDS",
  g_label = "none")
```

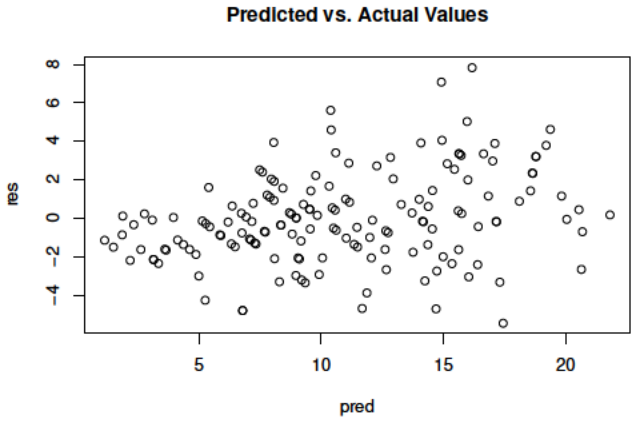



```
# go crazy with plotting
ggplot_the_model(
  fit = lme_epds1,
  fit_emm = lme_epds1_em,
  fit_pairs = summary(lme_epds1_simple, infer=T),
  palette = pal_okabe_ito_blue,
  y_label = "EPDS",
  g_label = "none",
  effect_label = "Effect in EPDS",
  show_p = F
)
```

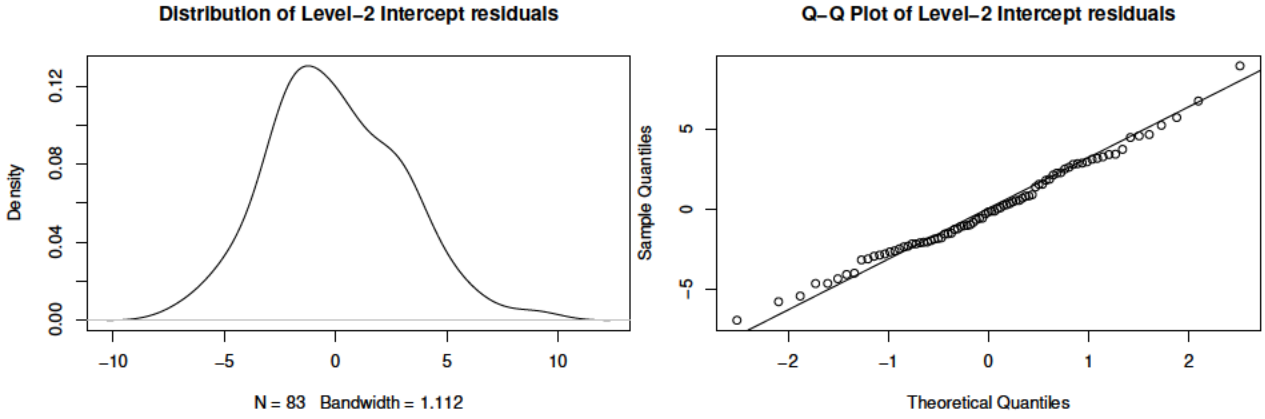



```r
# diagnostics for lme
# level-1 residuals
res <- resid(lme_epds1)
pred <- fitted(lme_epds1)
plot(density(res), main = "Distribution of Level-1 residuals")
qqnorm(res, main = "Q-Q Plot of Level-1 residuals")
qqline(res)
plot(pred, res, main='Predicted vs. Actual Values')
```






```
# level-2 residuals
res_int <- ranef(lme_epds1)$id[,1]
plot(density(res_int), main = "Distribution of Level-2 Intercept residuals")
qqnorm(res_int, main = "Q-Q Plot of Level-2 Intercept residuals")
qqline(res_int)
```



LME w/ control variables

```
lme_epds1_cont <- lmer(epds ~ time * group + epds_pre + SP + edu + citizen +
                  finaid + cts + preg_planned + (1|hp/id), data = data2)
summary(lme_epds1_cont)
```

```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: epds ~ time * group + epds_pre + SP + edu + citizen + finaid +
##     cts + preg_planned + (1 | hp/id)
##    Data: data2
##
## REML criterion at convergence: 804.9
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -1.79709 -0.47047 -0.05238  0.39741  2.48370
```

```
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id:hp    (Intercept) 13.825   3.718
##  hp       (Intercept)  1.428   1.195
##  Residual              8.759   2.960
## Number of obs: 143, groups:  id:hp, 75; hp, 35
##
## Fixed effects:
##                   Estimate Std. Error        df t value Pr(>|t|)
## (Intercept)       7.143635   3.068913 67.450652   2.328   0.0229 *
## timeT2           -1.240024   0.667297 64.370539  -1.858   0.0677 .
## groupExp         -1.397846   1.264616 26.477874  -1.105   0.2789
## epds_pre          0.567041   0.088125 61.625028   6.435 2.07e-08 ***
## SP                0.007175   1.442194 62.731666   0.005   0.9960
## edu              -0.254144   0.404691 62.948931  -0.628   0.5323
## citizen           0.616699   1.450890 59.770538   0.425   0.6723
## finaid           -3.395482   1.392681 61.957493  -2.438   0.0176 *
## cts               0.022870   0.135963 63.611499   0.168   0.8670
## preg_planned     -1.360806   1.283330 57.860957  -1.060   0.2934
## timeT2:groupExp   1.909173   1.016011 65.649526   1.879   0.0647 .
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp epds_p SP     edu    citizn finaid cts
## timeT2      -0.124
## groupExp    -0.262  0.264
## epds_pre    -0.072 -0.017 -0.106
## SP          -0.281 -0.009  0.162  0.052
## edu         -0.685  0.016  0.063 -0.079 -0.013
## citizen     -0.474  0.023 -0.049 -0.190  0.083  0.240
## finaid      -0.197  0.020 -0.001 -0.017 -0.450  0.266 -0.102
## cts         -0.582  0.003  0.038 -0.215  0.081  0.327  0.083  0.030
## preg_plannd -0.329  0.005  0.222 -0.141  0.381 -0.070  0.062  0.118  0.085
## tmT2:grpExp  0.079 -0.657 -0.382  0.003  0.027 -0.009 -0.008 -0.017 -0.006
##             prg_pl
## timeT2
## groupExp
## epds_pre
## SP
## edu
## citizen
## finaid
## cts
## preg_plannd
## tmT2:grpExp -0.004
```

Moderation by treat

```
# look into data
data2$treat <- factor(data2$treat)
```

```r
table(data2$treat)
```

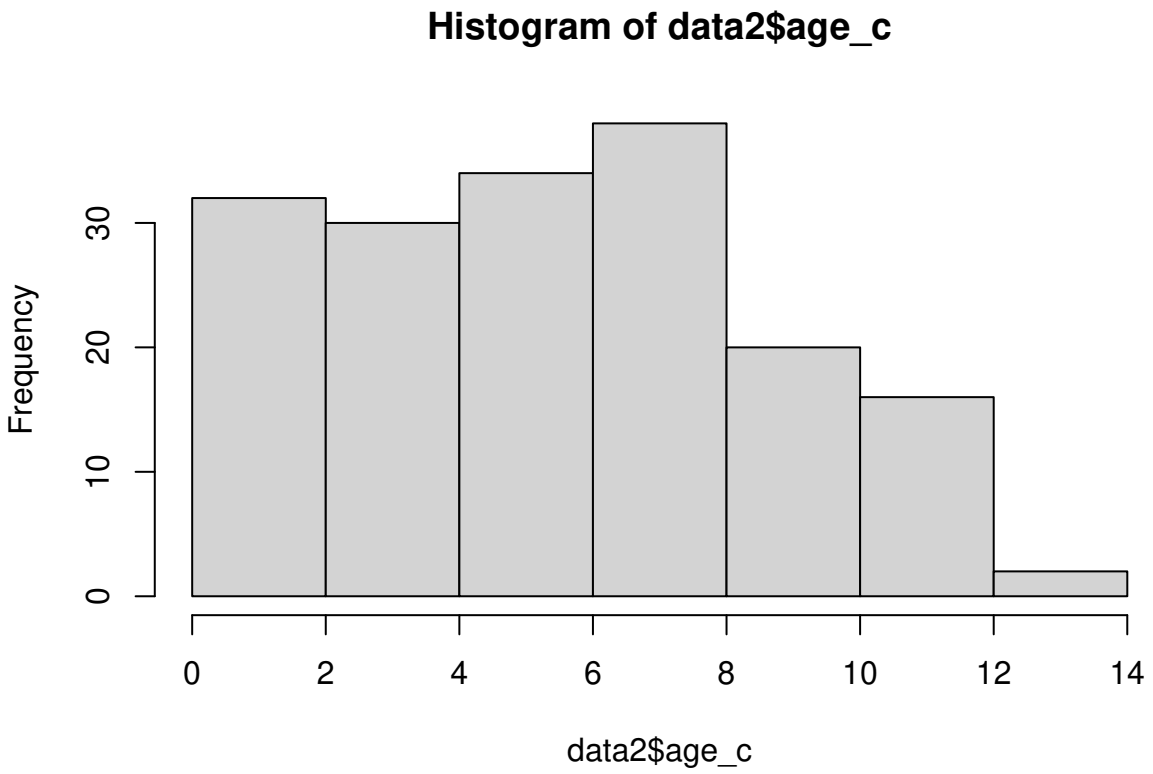
```
##
##   0   1
## 142  22
```

```r
# lme
lme_epds3 <- lmer(epds ~ time * group * treat + epds_pre + (1|hp/id), data = data2)
summary(lme_epds3)
```

```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: epds ~ time * group * treat + epds_pre + (1 | hp/id)
##    Data: data2
##
## REML criterion at convergence: 884.2
##
## Scaled residuals:
##     Min      1Q  Median      3Q     Max
## -1.6896 -0.4741 -0.0503  0.4145  2.5830
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id:hp    (Intercept) 13.3461  3.6532
##  hp       (Intercept)  0.9335  0.9662
##  Residual              9.3389  3.0560
## Number of obs: 157, groups:  id:hp, 82; hp, 38
##
## Fixed effects:
##                         Estimate Std. Error       df t value Pr(>|t|)
## (Intercept)               5.0789     1.1528  35.7159   4.406 9.20e-05 ***
## timeT2                   -1.5002     0.7067  70.9437  -2.123   0.0373 *
## groupExp                 -1.9166     1.2214  40.5059  -1.569   0.1244
## treat1                    0.6017     2.2075 106.7233   0.273   0.7857
## epds_pre                  0.5847     0.0846  70.3870   6.911 1.77e-09 ***
## timeT2:groupExp           2.5571     1.0806  72.5595   2.366   0.0206 *
## timeT2:treat1             0.6669     1.9006  69.8687   0.351   0.7267
## groupExp:treat1           1.8314     3.1644 108.4774   0.579   0.5640
## timeT2:groupExp:treat1    0.6762     2.8313  70.1070   0.239   0.8119
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp treat1 epds_p tmT2:E tmT2:1 grpE:1
## timeT2      -0.295
## groupExp    -0.405  0.291
## treat1      -0.073  0.164  0.267
## epds_pre    -0.694 -0.016 -0.121 -0.255
## tmT2:grpExp  0.202 -0.654 -0.422 -0.104 -0.002
## timeT2:trt1  0.110 -0.372 -0.108 -0.432  0.006  0.243
## grpExp:trt1  0.131 -0.113 -0.364 -0.668  0.063  0.163  0.301
## tmT2:grpE:1 -0.077  0.250  0.161  0.289  0.001 -0.382 -0.671 -0.444
```

Moderation by child age

```
# look into data
hist(data2$age_c)
```




```
# lme
lme_epds4 <- lmer(epds ~ time * group * age_c + epds_pre + (1|hp/id), data = data2)
summary(lme_epds4)
```

```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: epds ~ time * group * age_c + epds_pre + (1 | hp/id)
##    Data: data2
##
## REML criterion at convergence: 887.6
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -1.68317 -0.51687 -0.09285  0.42441  2.49459
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id:hp    (Intercept) 13.314   3.649
##  hp       (Intercept)  1.511   1.229
##  Residual              9.444   3.073
## Number of obs: 154, groups:  id:hp, 81; hp, 37
##
```

```
## Fixed effects:
##                         Estimate Std. Error       df t value Pr(>|t|)
## (Intercept)              6.31758    1.75812 70.35390   3.593 0.000601 ***
## timeT2                  -0.92274    1.36688 67.61350  -0.675 0.501934
## groupExp                -2.67861    2.30640 80.27041  -1.161 0.248928
## age_c                   -0.19156    0.22529 96.92556  -0.850 0.397274
## epds_pre                 0.59434    0.08523 68.15808   6.973 1.57e-09 ***
## timeT2:groupExp          0.85308    2.02837 68.37000   0.421 0.675385
## timeT2:age_c            -0.09843    0.19554 67.61682  -0.503 0.616337
## groupExp:age_c           0.15789    0.34816 99.77700   0.453 0.651179
## timeT2:groupExp:age_c    0.32550    0.30814 68.46495   1.056 0.294534
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp age_c  epds_p tmT2:E tmT2:_ grpE:_
## timeT2      -0.390
## groupExp    -0.647  0.301
## age_c       -0.721  0.386  0.584
## epds_pre    -0.420 -0.013  0.045 -0.124
## tmT2:grpExp  0.266 -0.674 -0.428 -0.259  0.002
## timeT2:ag_c  0.343 -0.873 -0.262 -0.437  0.001  0.588
## gropExp:g_c  0.551 -0.247 -0.855 -0.622 -0.120  0.374  0.283
## tmT2:grpE:_ -0.219  0.554  0.371  0.277  0.001 -0.864 -0.635 -0.434
```

Moderation by medication

```
# look into data
data2$med <- factor(data2$med)
table(data2$med)
```

```
##
##   0   1
## 146  18
```

```
# lme
lme_epds4 <- lmer(epds ~ time * group * med + epds_pre + (1|hp/id), data = data2)
summary(lme_epds4)
```

```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: epds ~ time * group * med + epds_pre + (1 | hp/id)
##    Data: data2
##
## REML criterion at convergence: 883.7
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -1.73151 -0.47256 -0.08523  0.36932  2.56664
##
## Random effects:
```

```
##  Groups   Name        Variance Std.Dev.
##  id:hp    (Intercept) 13.444   3.667
##  hp       (Intercept)  1.174   1.083
##  Residual              9.225   3.037
## Number of obs: 157, groups:  id:hp, 82; hp, 38
##
## Fixed effects:
##                       Estimate Std. Error        df t value Pr(>|t|)
## (Intercept)            4.64525    1.16478  34.30406   3.988 0.000331 ***
## timeT2                -1.17932    0.69318  70.87234  -1.701 0.093269 .
## groupExp              -1.64804    1.22136  36.44686  -1.349 0.185547
## med1                   1.84223    2.32404 104.61641   0.793 0.429756
## epds_pre               0.61253    0.08166  72.92957   7.501 1.22e-10 ***
## timeT2:groupExp        2.23409    1.05744  72.39445   2.113 0.038072 *
## timeT2:med1           -2.02068    2.04220  69.80845  -0.989 0.325854
## groupExp:med1         -0.27210    3.47140 106.77051  -0.078 0.937669
## timeT2:groupExp:med1   3.71591    3.06935  69.98856   1.211 0.230101
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp med1   epds_p tmT2:E tmT2:1 grpE:1
## timeT2      -0.287
## groupExp    -0.400  0.286
## med1        -0.138  0.151  0.237
## epds_pre    -0.699 -0.015 -0.126 -0.134
## tmT2:grpExp  0.198 -0.655 -0.414 -0.097 -0.004
## timeT2:med1  0.097 -0.339 -0.097 -0.440  0.005  0.222
## gropExp:md1  0.087 -0.101 -0.332 -0.670  0.097  0.146  0.295
## tmT2:grpE:1 -0.068  0.226  0.143  0.292  0.001 -0.345 -0.665 -0.440
```

Moderation by app usage

```
# lme
lme_epds5 <- lmer(epds ~ time * appuse + (1|id), data = data[group=="Exp",])
summary(lme_epds5)
```

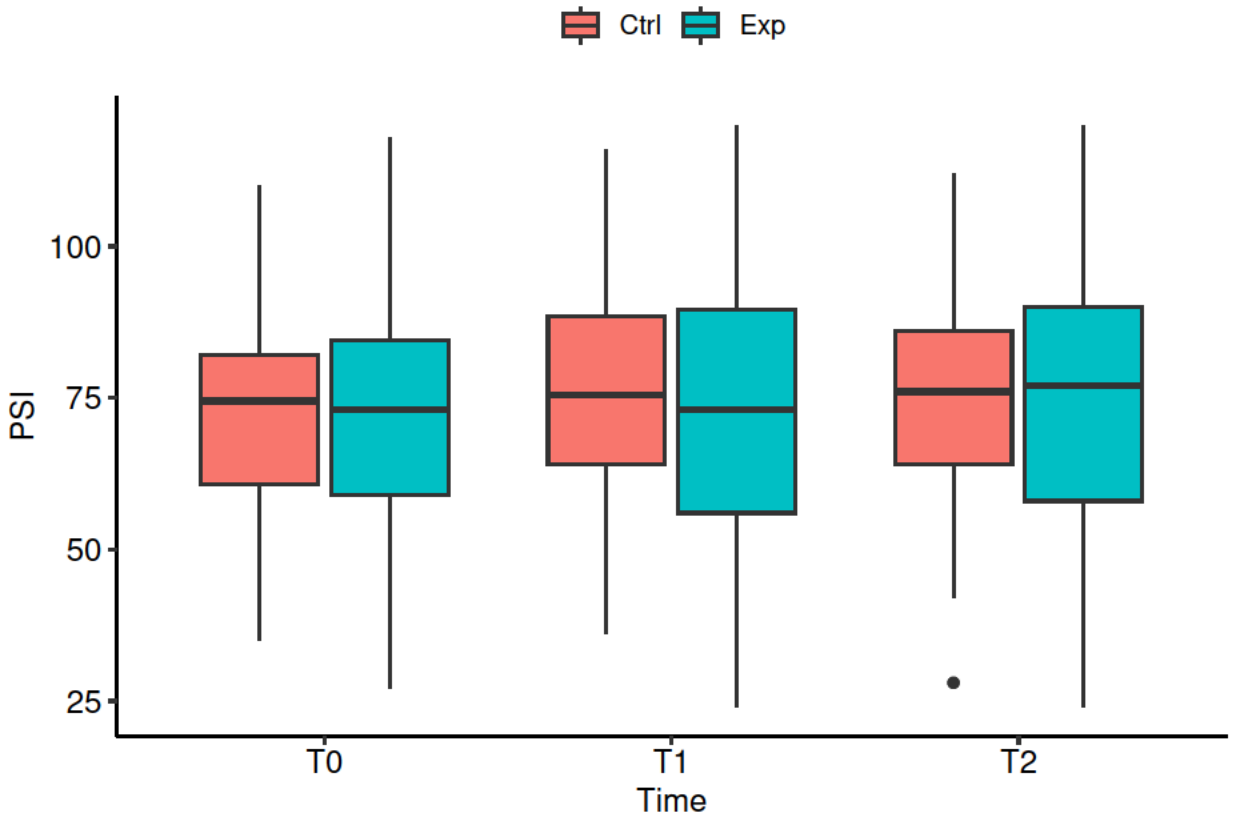
```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: epds ~ time * appuse + (1 | id)
##    Data: data[group == "Exp", ]
##
## REML criterion at convergence: 671.4
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -2.17435 -0.49037 -0.07235  0.53548  2.20177
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id       (Intercept) 29.30    5.413
##  Residual             12.35    3.514
```

```
## Number of obs: 108, groups:  id, 39
##
## Fixed effects:
##                Estimate Std. Error        df t value Pr(>|t|)
## (Intercept)   10.912648   1.215643 54.529095   8.977 2.48e-12 ***
## timeT1        -1.644238   0.976012 66.898019  -1.685   0.0967 .
## timeT2         0.294999   1.016318 67.403199   0.290   0.7725
## appuse         0.010407   0.007136 54.529095   1.458   0.1505
## timeT1:appuse  0.002005   0.005551 65.978814   0.361   0.7191
## timeT2:appuse -0.003941   0.005600 66.106590  -0.704   0.4840
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT1 timeT2 appuse tmT1:p
## timeT1      -0.369
## timeT2      -0.355  0.464
## appuse      -0.527  0.194  0.187
## timeT1:apps  0.201 -0.539 -0.253 -0.381
## timeT2:apps  0.199 -0.261 -0.550 -0.378  0.493
```

PSI as outcome

```
# plot by design
ggplot(data,aes(x = time, y = psi, fill = group)) +
  geom_boxplot() + ylab("PSI") + xlab("Time") + theme_pubr() +
  theme(legend.title=element_blank())
```

```
## Warning: Removed 41 rows containing non-finite outside the scale range
## (`stat_boxplot()`).
```



LME

```
# estimation
lme_psi1 <- lmer(psi ~ time * group + psi_pre + (1|hp/id), data = data2)
```

```
## boundary (singular) fit: see help('isSingular')
```

```
lme_psi1 <- lmer(psi ~ time * group + psi_pre + (1|id), data = data2)
summary(lme_psi1)
```

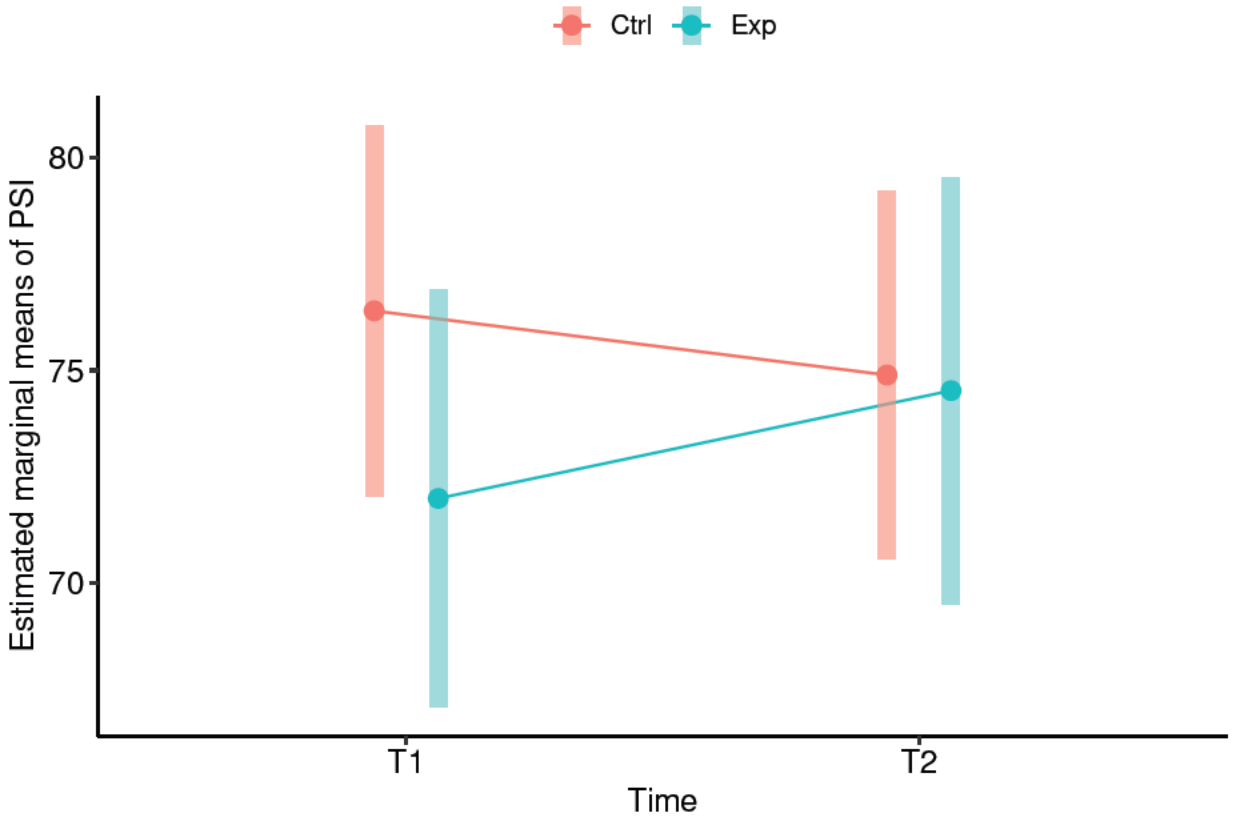
```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: psi ~ time * group + psi_pre + (1 | id)
##    Data: data2
##
## REML criterion at convergence: 1255.5
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -2.63916 -0.40529  0.04263  0.46137  2.36294
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id       (Intercept) 102.4    10.12
```

```
##  Residual             114.0    10.68
## Number of obs: 157, groups:  id, 82
##
## Fixed effects:
##                 Estimate Std. Error        df t value Pr(>|t|)
## (Intercept)      17.78845    5.54484  75.98785   3.208  0.00196 **
## timeT2           -1.51042    2.28167  66.64343  -0.662  0.51027
## groupExp         -4.41510    3.31956 122.11907  -1.330  0.18599
## psi_pre           0.81164    0.07067  69.04018  11.485  < 2e-16 ***
## timeT2:groupExp   4.04775    3.48062  67.45887   1.163  0.24895
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp psi_pr
## timeT2      -0.201
## groupExp    -0.246  0.349
## psi_pre     -0.917 -0.009 -0.020
## tmT2:grpExp  0.112 -0.656 -0.516  0.027
```

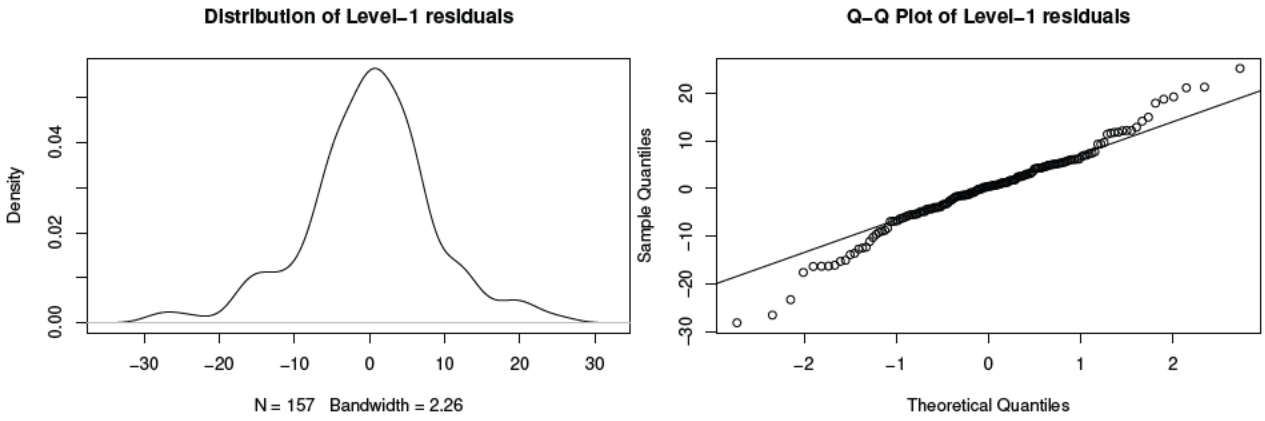
```r
# marginal means
lme_psi1_em <- emmeans(lme_psi1, specs = ~ time:group)
summary(lme_psi1_em)
```

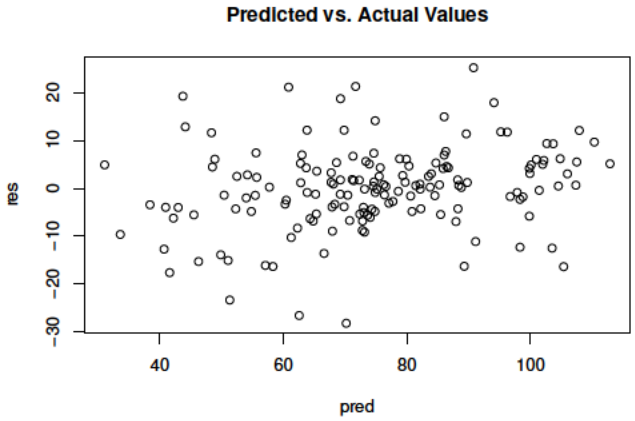
```
##  time group emmean   SE  df lower.CL upper.CL
##  T1   Ctrl    76.4 2.21 128     72.0     80.8
##  T2   Ctrl    74.9 2.19 126     70.6     79.2
##  T1   Exp     72.0 2.48 127     67.1     76.9
##  T2   Exp     74.5 2.54 131     69.5     79.5
##
## Degrees-of-freedom method: kenward-roger
## Confidence level used: 0.95
```

```r
# plot marginal means
ggplot(data = as.data.frame(lme_psi1_em), aes(y = emmean, x = time, col = group)) +
  theme_pubr() + xlab("Time") + ylab("Estimated marginal means of PSI") +
  geom_line(aes(group = group), position=position_dodge(0.25)) +
  geom_point(position=position_dodge(0.25), size = 3) +
  geom_linerange(aes(y = emmean, ymin = lower.CL, ymax = upper.CL, x = time, group = group),
                 position=position_dodge(0.25), lwd=3, alpha=.5) +
  theme(legend.title=element_blank())
```

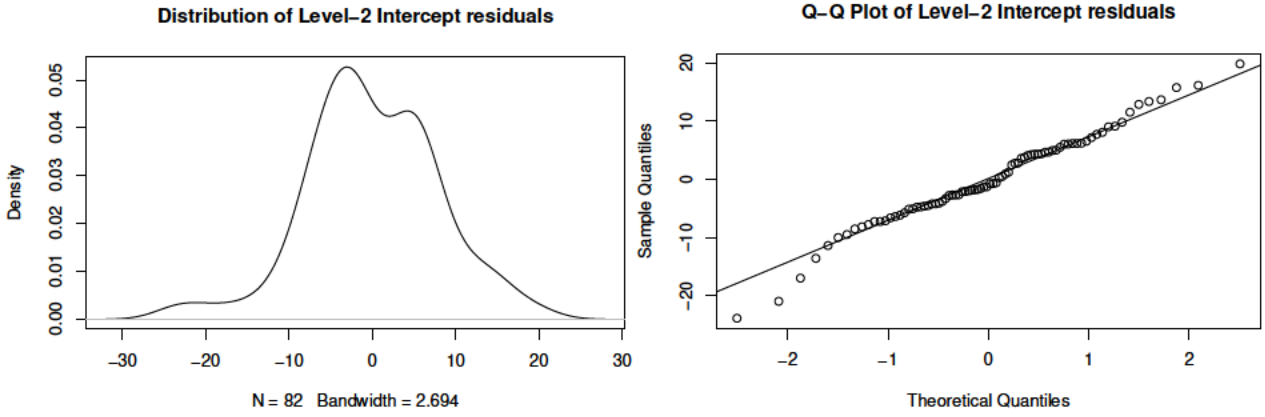



```r
# diagnostics for lme
# level-1 residuals
res <- resid(lme_psi1)
pred <- fitted(lme_psi1)
plot(density(res), main = "Distribution of Level-1 residuals")
qqnorm(res, main = "Q-Q Plot of Level-1 residuals")
qqline(res)
plot(pred, res, main='Predicted vs. Actual Values')
```






```
# level-2 residuals
res_int <- ranef(lme_psi1)$id[,1]
plot(density(res_int), main = "Distribution of Level-2 Intercept residuals")
qqnorm(res_int, main = "Q-Q Plot of Level-2 Intercept residuals")
qqline(res_int)
```



LME w/ control variables

```
lme_psi1_cont <- lmer(psi ~ time * group + psi_pre + SP + edu + citizen +
                      finaid + cts + preg_planned + (1|id), data = data2)
summary(lme_psi1_cont)
```

```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: psi ~ time * group + psi_pre + SP + edu + citizen + finaid +
##     cts + preg_planned + (1 | id)
##    Data: data2
##
## REML criterion at convergence: 1099.2
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -2.01047 -0.36420  0.01524  0.40435  2.57214
```

```
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id       (Intercept) 119.84   10.947
##  Residual              95.55    9.775
## Number of obs: 142, groups:  id, 74
##
## Fixed effects:
##                 Estimate Std. Error      df t value Pr(>|t|)
## (Intercept)       5.3760     9.7348 65.3813   0.552    0.583
## timeT2           -0.4211     2.2023 63.1245  -0.191    0.849
## groupExp         -4.5971     3.5989 92.7686  -1.277    0.205
## psi_pre           0.7807     0.0773 60.0585  10.100 1.45e-14 ***
## SP               -1.1125     4.2662 60.7099  -0.261    0.795
## edu               2.0442     1.2457 63.3566   1.641    0.106
## citizen           3.1943     4.2630 61.1583   0.749    0.457
## finaid            0.7442     4.1285 61.8407   0.180    0.858
## cts               0.5149     0.3963 60.4250   1.299    0.199
## preg_planned     -0.3620     3.7746 59.5623  -0.096    0.924
## timeT2:groupExp   2.2917     3.3561 64.1626   0.683    0.497
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp psi_pr SP     edu    citizn finaid cts
## timeT2      -0.125
## groupExp    -0.181  0.305
## psi_pre     -0.353 -0.012 -0.063
## SP          -0.210 -0.007  0.163 -0.076
## edu         -0.569  0.018  0.031 -0.219 -0.010
## citizen     -0.445  0.022 -0.061 -0.108  0.108  0.256
## finaid      -0.185  0.020  0.014 -0.012 -0.443  0.256 -0.106
## cts         -0.568  0.001 -0.030 -0.045  0.076  0.352  0.072  0.026
## preg_plannd -0.226  0.006  0.223 -0.218  0.384 -0.038  0.074  0.122  0.046
## tmT2:grpExp  0.065 -0.656 -0.453  0.029  0.022 -0.005 -0.009 -0.020  0.001
##             prg_pl
## timeT2
## groupExp
## psi_pre
## SP
## edu
## citizen
## finaid
## cts
## preg_plannd
## tmT2:grpExp -0.012
```

Moderation by treat

```
# look into data
data2$treat <- factor(data2$treat)
table(data2$treat)
```

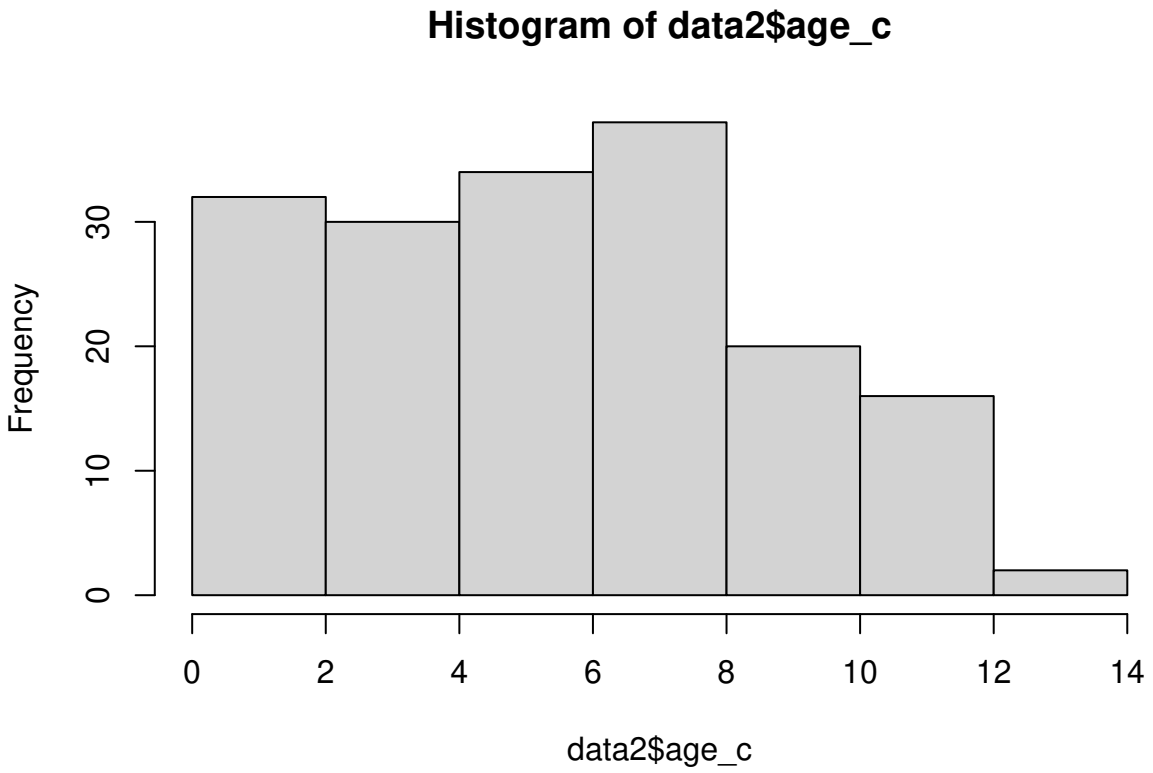
```
##
##   0   1
## 142  22
```

```r
# lme
lme_psi2 <- lmer(psi ~ time * group * treat + psi_pre + (1|id), data = data2)
summary(lme_psi2)
```

```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: psi ~ time * group * treat + psi_pre + (1 | id)
##    Data: data2
##
## REML criterion at convergence: 1213
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -2.71391 -0.42521  0.03269  0.48620  2.39399
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id       (Intercept)  91.38    9.559
##  Residual             110.99   10.535
## Number of obs: 156, groups:  id, 81
##
## Fixed effects:
##                          Estimate Std. Error       df t value Pr(>|t|)
## (Intercept)               20.4090     5.5225  77.8049   3.696 0.000406 ***
## timeT2                    -1.6051     2.4316  67.7886  -0.660 0.511443
## groupExp                  -6.9272     3.4652 121.5644  -1.999 0.047829 *
## treat1                    -2.6249     6.2652 119.4672  -0.419 0.675994
## psi_pre                    0.7865     0.0706  70.5034  11.140  < 2e-16 ***
## timeT2:groupExp            5.4480     3.7197  69.1964   1.465 0.147549
## timeT2:treat1              4.7717     6.5507  66.4630   0.728 0.468905
## groupExp:treat1           14.7425     9.3467 119.0368   1.577 0.117383
## timeT2:groupExp:treat1 -13.6147     9.7587  66.6728  -1.395 0.167605
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp treat1 psi_pr tmT2:E tmT2:1 grpE:1
## timeT2      -0.209
## groupExp    -0.300  0.351
## treat1      -0.084  0.195  0.242
## psi_pre     -0.909 -0.012  0.026 -0.076
## tmT2:grpExp  0.113 -0.654 -0.520 -0.129  0.034
## timeT2:trt1  0.078 -0.371 -0.130 -0.523  0.004  0.243
## grpExp:trt1  0.207 -0.129 -0.373 -0.658 -0.115  0.189  0.350
## tmT2:grpE:1 -0.043  0.249  0.198  0.352 -0.013 -0.381 -0.671 -0.518
```

Moderation by child age

```r
# look into data
hist(data2$age_c)
```




```r
# lme
lme_psi3 <- lmer(psi ~ time * group * age_c + psi_pre + (1|id), data = data2)
summary(lme_psi3)
```

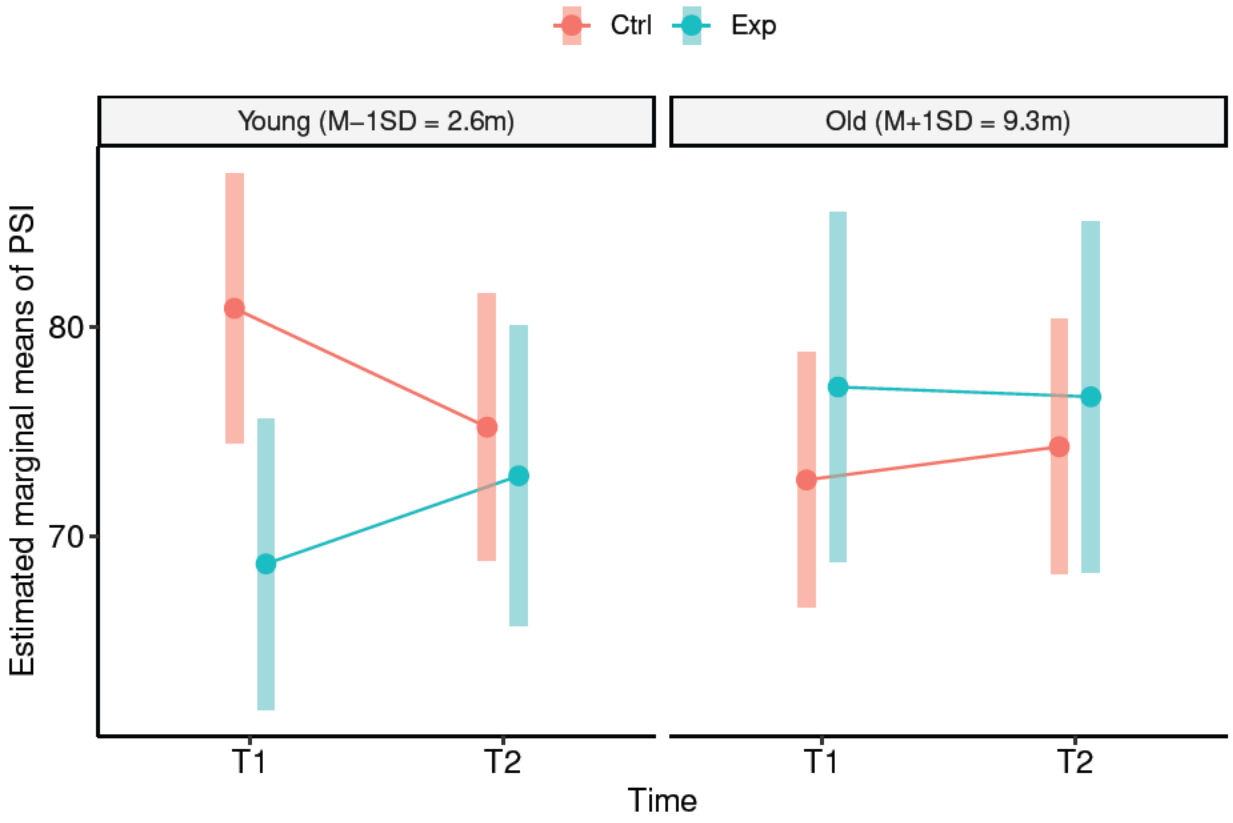
```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: psi ~ time * group * age_c + psi_pre + (1 | id)
##    Data: data2
##
## REML criterion at convergence: 1214.7
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -2.48920 -0.39758  0.05369  0.45515  2.06132
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id       (Intercept) 108.1    10.40
##  Residual             111.1    10.54
## Number of obs: 153, groups:  id, 80
##
## Fixed effects:
```

```
##                         Estimate Std. Error        df t value Pr(>|t|)
## (Intercept)             28.69137    7.51130  82.98088   3.820 0.000257 ***
## timeT2                  -8.48408    4.68580  62.36612  -1.811 0.075021 .
## groupExp               -18.64525    7.08740 108.80764  -2.631 0.009755 **
## age_c                   -1.22195    0.66445 112.69827  -1.839 0.068543 .
## psi_pre                  0.76781    0.08003  67.51313   9.593 3.11e-14 ***
## timeT2:groupExp         14.49818    6.95891  62.90930   2.083 0.041284 *
## timeT2:age_c             1.08251    0.67046  62.33944   1.615 0.111451
## groupExp:age_c           2.48164    1.09411 108.00082   2.268 0.025307 *
## timeT2:groupExp:age_c   -1.77945    1.05575  63.26654  -1.685 0.096822 .
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp age_c  psi_pr tmT2:E tmT2:_ grpE:_
## timeT2      -0.316
## groupExp    -0.620  0.336
## age_c       -0.568  0.446  0.584
## psi_pre     -0.785 -0.001  0.271  0.032
## tmT2:grpExp  0.200 -0.673 -0.478 -0.300  0.017
## timeT2:ag_c  0.279 -0.874 -0.293 -0.508 -0.004  0.588
## gropExp:g_c  0.587 -0.271 -0.877 -0.617 -0.329  0.404  0.310
## tmT2:grpE:_ -0.174  0.555  0.417  0.322 -0.001 -0.864 -0.635 -0.475
```

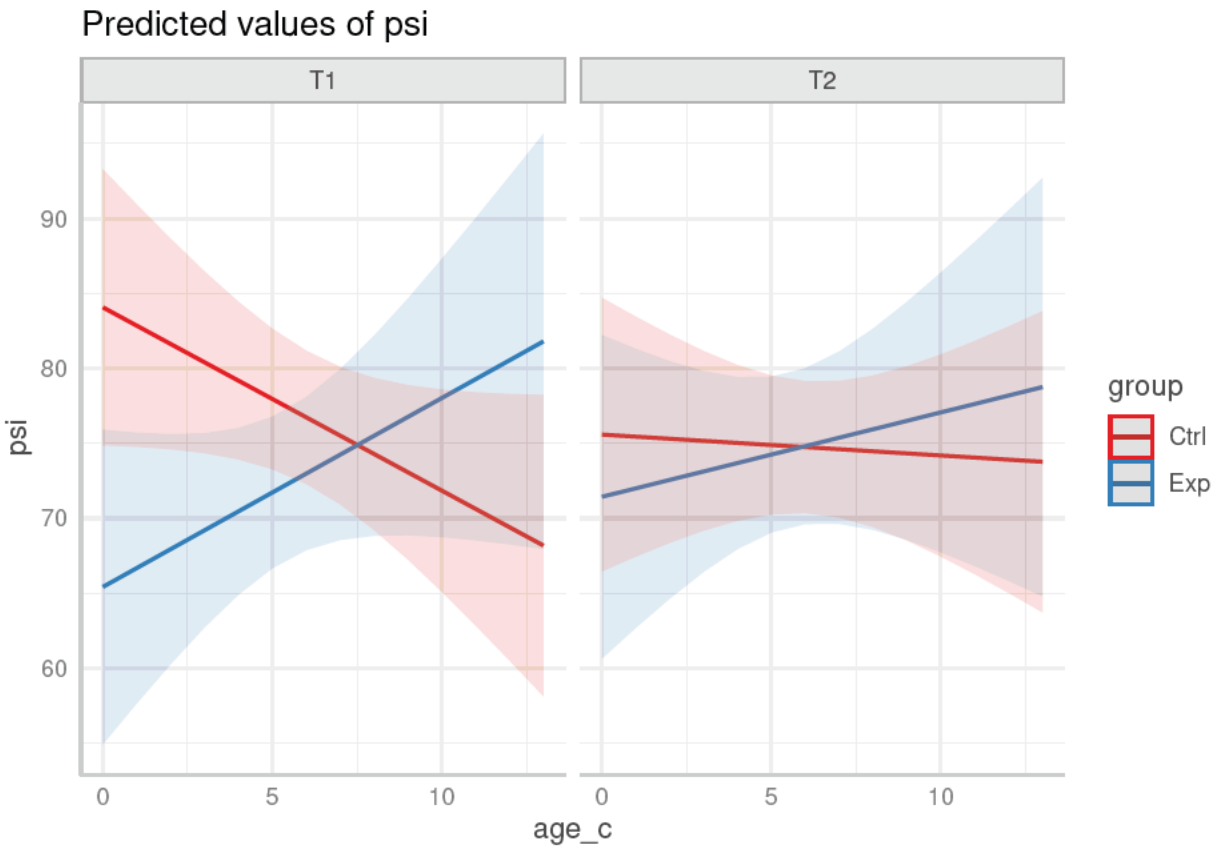
```
# marginal means
lme_psi3_em <- emmeans(lme_psi3, ~group*time*age_c, at = list(age_c=c(9.3, 2.6)))
summary(lme_psi3_em)
```

```
##  group time age_c emmean   SE  df lower.CL upper.CL
##  Ctrl  T1     9.3   72.7 3.08 119     66.6     78.8
##  Exp   T1     9.3   77.1 4.20 116     68.8     85.5
##  Ctrl  T2     9.3   74.3 3.07 118     68.2     80.4
##  Exp   T2     9.3   76.7 4.22 117     68.3     85.0
##  Ctrl  T1     2.6   80.9 3.25 119     74.5     87.3
##  Exp   T1     2.6   68.7 3.50 114     61.8     75.6
##  Ctrl  T2     2.6   75.2 3.21 117     68.9     81.6
##  Exp   T2     2.6   72.9 3.62 120     65.7     80.1
##
## Degrees-of-freedom method: kenward-roger
## Confidence level used: 0.95
```

```
# plot three way interaction
ggplot(data = as.data.frame(lme_psi3_em), aes(y = emmean, x = time, col = group)) +
  theme_pubr() + xlab("Time") + ylab("Estimated marginal means of PSI") +
  geom_line(aes(group = group), position=position_dodge(0.25)) +
  geom_point(position=position_dodge(0.25), size = 3) +
  geom_linerange(aes(y = emmean, ymin = lower.CL, ymax = upper.CL, x = time, group = group),
                 position=position_dodge(0.25), lwd=3, alpha=.5) +
  theme(legend.title=element_blank()) +
  facet_grid(.~age_c, labeller = as_labeller(c("2.6" = "Young (M-1SD = 2.6m)",
                                               "9.3" = "Old (M+1SD = 9.3m)")))
```




```
# alternative plot
pred_df <- predict_response(lme_psi3, terms = c("age_c [0:13]", "group","time"))
plot(pred_df)
```



Moderation by medication

```
# look into data
data2$med <- factor(data2$med)
table(data2$med)
```

```
##
##   0   1
## 146  18
```

```
# lme
lme_psi4 <- lmer(psi ~ time * group * med + psi_pre + (1|id), data = data2)
summary(lme_psi4)
```

```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: psi ~ time * group * med + psi_pre + (1 | id)
##    Data: data2
##
## REML criterion at convergence: 1214.6
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
```

```
## -2.76718 -0.45613  0.03343  0.47585  2.17716
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
##  id       (Intercept)  92.91    9.639
##  Residual             112.62   10.612
## Number of obs: 156, groups:  id, 81
##
## Fixed effects:
##                       Estimate Std. Error        df t value Pr(>|t|)
## (Intercept)           17.90654    5.44042  77.48315   3.291   0.0015 **
## timeT2                -0.19978    2.41744  67.55401  -0.083   0.9344
## groupExp              -4.74794    3.43981 121.42312  -1.380   0.1700
## med1                   1.64558    6.83823 119.08658   0.241   0.8102
## psi_pre                0.81356    0.06953  70.01339  11.701   <2e-16 ***
## timeT2:groupExp        3.37305    3.68850  68.90751   0.914   0.3637
## timeT2:med1           -6.60022    7.13395  66.23023  -0.925   0.3582
## groupExp:med1         -1.05039   10.21724 119.51432  -0.103   0.9183
## timeT2:groupExp:med1   1.67695   10.72220  66.39075   0.156   0.8762
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT2 grpExp med1   psi_pr tmT2:E tmT2:1 grpE:1
## timeT2      -0.212
## groupExp    -0.271  0.351
## med1        -0.056  0.178  0.224
## psi_pre     -0.907 -0.011 -0.010 -0.094
## tmT2:grpExp  0.117 -0.656 -0.522 -0.119  0.031
## timeT2:med1  0.072 -0.339 -0.119 -0.522  0.004  0.222
## gropExp:md1  0.118 -0.118 -0.336 -0.661 -0.026  0.175  0.349
## tmT2:grpE:1 -0.040  0.226  0.179  0.348 -0.011 -0.344 -0.665 -0.523
```

Moderation by app usage

```
# lme
lme_psi5 <- lmer(psi ~ time * appuse + (1|id), data = data[group=="Exp",])
summary(lme_psi5)
```

```
## Linear mixed model fit by REML. t-tests use Satterthwaite's method [
## lmerModLmerTest]
## Formula: psi ~ time * appuse + (1 | id)
##    Data: data[group == "Exp", ]
##
## REML criterion at convergence: 904.6
##
## Scaled residuals:
##      Min       1Q   Median       3Q      Max
## -2.57828 -0.46965  0.01722  0.45364  2.40798
##
## Random effects:
##  Groups   Name        Variance Std.Dev.
```

```
##  id       (Intercept) 432.7    20.80
##  Residual             112.8    10.62
## Number of obs: 107, groups:  id, 39
##
## Fixed effects:
##                Estimate Std. Error        df t value Pr(>|t|)
## (Intercept)   70.657229   4.399407 48.600167  16.061   <2e-16 ***
## timeT1        -1.404627   2.996355 66.047430  -0.469    0.641
## timeT2         1.950475   3.086948 66.267233   0.632    0.530
## appuse         0.020972   0.025826 48.600167   0.812    0.421
## timeT1:appuse  0.011227   0.016815 65.113528   0.668    0.507
## timeT2:appuse  0.003123   0.016943 65.183963   0.184    0.854
## ---
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
## Correlation of Fixed Effects:
##             (Intr) timeT1 timeT2 appuse tmT1:p
## timeT1      -0.304
## timeT2      -0.295  0.469
## appuse      -0.527  0.160  0.155
## timeT1:apps  0.167 -0.541 -0.256 -0.318
## timeT2:apps  0.166 -0.262 -0.551 -0.315  0.494
```

Appendix E. Supplementary Material Publication V

nature mental health

Consensus Statement

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How toe-mental health: a guideline for researchers and practitioners using digital technology in the context of mental health

In the format provided by the authors and unedited

SUPPLEMENTARY INFORMATION

How to e-mental health: a guideline for researchers and practitioners using digital technology in the context of mental health

Table S1. Do's and don'ts researchers should consider when implementing an e-mental health intervention and/or assessment.

I. DEVELOPMENT	
Where to start?	
• Examine the context of use and identify the digital specifics to solve the problem • Involve the target group (and other important stakeholders) in the development of the application from the beginning and tailor it to it/them (i.e., selection of the features) • Get expert advice on data protection and privacy while writing the funding proposal • Obtain quotations from several external IT partners at an early stage in order to structure the budget accordingly • Check similar solutions in the field beforehand and identify well-evidence based open access material (e.g., no-code software development) • Consider budget for the support of the digital solution after completion (e.g., installing updates, fixing bugs)	• Do not assume a priori that a digital health solution is the most appropriate approach for every problem/context of use, but explore if this approach is best (or at least better than existing ones) • Avoid developing the application purely from a researchers point of view (potential driver for low user engagement) • Avoid having a static mindset and a finished technical solution in your mind, but engage in an iterative process (guided by your objectives and the target group) • Do not discard your project timeline too easily but try to use resources proactively and continuously monitor the project to anticipate delays
Intervention content development	
• Plan sufficient resources (i.e., financial, time, personnel) for the technical translation of therapeutic content when planning the project • Put together a transdisciplinary team (e.g. mental health professionals, software engineers, design experts) and plan time for the development of a mutual understanding and finding a common ground • Define features or content which allow for personalization of the e-mental health intervention (i.e., just-in-time adaptive interventions, self-monitoring tools, notification) • Ensure that different multimedia elements are implemented and that there is some variety across the intervention (i.e., gamification)	• Do not take elements of existing static, text-based psychotherapeutic manuals and implement it one-to-one without considering the characteristics of the digital environment and the target group • Avoid following a linear development process, but rather an agile iterative research process • Do not adopt a 'one design fits all' approach • Avoid modifying the core principles of the evidence-based intervention, but identify possibilities to transfer them into the digital environment
User-centered design and participatory approaches	
• Plan sufficient financial and time resources for users' inclusion throughout the study/development • Define the target groups as precisely as possible • Include the environment of your target group (e.g., professionals, therapists, relatives) • Involve the target group as early as possible	• Do not overlook that various subgroups are represented within focus group/selected advisory group/stakeholder (i.e., equal gender, ethnic minorities, age) • Avoid neglecting awareness of who is conducting the interviews (i.e., should they be part of the development/research team and final product or do they face the risk of being biased?)

• Involve target users/ stakeholders also in decision-making processes • Identify key needs and preferences of specific target groups • Identify access routes and potential barriers of your target group • Conduct focus groups and qualitative interviews • Include advisory board with all needed stakeholders	• Do not presume what the target group might want and do not confirm assumptions on ready-made interventions • Avoid conducting few focus groups only and do not present only finalised material

II. STUDY SPECIFICS	
Managing Suicidality	
• Incorporate separate modules with specific content for people with suicidal ideation (i.e., emergency contact details) • Routinely include a measure of suicidal thoughts and behaviours • Assist participants with moderate to severe suicidal ideation to develop an individual crisis plan • Train and supervise team members who provide guidance to participants to ensure qualified patient support and the well-being of the staff • Rigorously assess reasons for dropout (i.e., include third persons to follow-up on participants who cannot be reached)	• Avoid excluding participants with suicidal ideation from trials • Do not exclude suicide-related items from other scales (e.g., PHQ-8). • Do not offer the intervention group better crisis support than the control group • Do not prohibit co-interventions for people with suicidal thoughts or behaviours • Do not start trials without a pre-specified crisis support plan • Do not obtain contact information of participants and/or their general practitioners, although the study design would allow this
Data protection and data security	
• Pseudonymizise sensitive data wherever possible • Consider a two-factor-authentification if appropriate • Let the app be developed under your control, avoid commercial manufacturer apps if possible • Demand a quality-assured software development process (i.e., thorough analysis of requirements, detailed specification of data flows, data processing and data storage, precise test strategy) • Involve your data protection officer in the project at an early stage and establish in-depth technical know-how in your own institution • Use open source libraries in software development if possible • Use a research database developed for this purpose which is separated from other institutional information systems • Educate the users about dangers	• Do not upload data in the vendor's public cloud or in an unknown destination • Do not save sensitive data on the smartphone permanently • Do not rely on external IT partners only • Do not keep the de-pseudonymization list in the same database as the e-mental data • Avoid commercial manufacturer apps if possible • Do not start without any risk assessment • Do not neglect the national protection laws
Artificial intelligence in assessment and intervention	
• Recognise emotions in different categories, modalities and sources (i.e., clearly define input and output vocabulary/data model)	• Do not neglect validation and robustness test in the target population (including e.g. culture, language, age)

• Train toolkits or "engines" on target data • Use open source AI tools (algorithms, syntax) adapted to the target task • Validate AI for bias in your population (e.g., use model evaluation cards or similar to check for fairness issues and others)	• Do not use features of self-fulfilling predictions
Sensing and wearables	
• Define device type (unisensory vs. multi-sensory, smartphone vs. wearable, operating system: e.g., iOS vs. Android) • If possible, try to incorporate the user's usual devices (smartphone and wearable) • Consider evidence for the device's reliability/validity and contact manufacturer in case of evidence is not clear • Wearing wearables should be enjoyable, even fashionable • Decide whether to use in-house vs. outsourced mobile-sensing platform • Assess if you have the raw data or features • Assess ethics of data capture • Consider details of the back-end (e.g., reliability, geographical location, security) • Chose a sufficient time interval for piloting and plan time to improve things after the piloting • Prepare communication channels with participants in case of data loss/technical errors • Assure enough time to acquire ethical study approval(s) and to design data privacy concepts in advance • Transparently document your device choice and study setup (e.g., device firmware /software version; sources of potential biases, including study-unrelated behaviours that might influence the collected data quality; nested structure of measurements such as within days/weeks) • Have a procedure of "sensing device hard reset" to return to default configuration • Report the process of the data access in studies (raw data, processed data via dedicated webs, mobile platforms, APIs) and clarify the details with the manufacturer if necessary • Watch out for dependencies: behavioural interventions (e.g., drug trials) may affect device performance due to the dependency of device accuracy on features that will change as a result of the manipulation (e.g., accelerometer, heart rate and its variability, temperature) used by these devices • Adhere to established reporting guidelines depending on your study design (following the	• Do not assume that devices are always sufficiently charged (i.e., assure no less than a day of battery lifetime) and 'always on'/connected • Do not assume manual synchronisation (if required) more than once a day • Do not use devices that are potentially unsafe (e.g., invoking an allergy), hard to use or malfunctioning (require a specific interaction to function accurately) • Do not use devices that require participants to use large screens/laptops or PCs • Do not use devices which costs are disproportionate with the usual devices the population is using • If wearables: do not use obstructive or stigmatising devices • If wearables: do not use devices that are not waterproof • Avoid developing new software and use existing frameworks whenever possible • Do not outsource it to locations where privacy/security laws and practices are different (EU vs. USA vs. China) • Do not assume the data is synchronising without errors • Avoid convenience sampling of a pilot population unrelated to the intended target population (e.g., students vs seniors) • Do not involve team members without adequate ethical training • If possible, avoid accepting device software updates along study duration (unless the security may be compromised) • Avoid using pre-defined data processing pipelines / algorithms that are poorly documented • Avoid overwhelming the study participants with large selections of own raw data presented to them

EQUATOR and/or STROBE guidelines for observational studies and for diagnostic/prognostic studies: STARD and TRIPOD) • Conduct and report reliability and validation analysis (e.g., Bland-Altman analysis if multiple devices are used simultaneously; nomological net analysis to check construct validity) • Share early your algorithms for data processing and algorithm design	

III. EVALUATION	
Efficacy evaluation, RCTs and other methods	
• Especially in the early stages of development, use different forms of evaluation before moving on to an RCT, including qualitative analyses, such as focus groups with target groups or short interventional studies • Before you begin an RCT, preregister your study, including all planned measurements; this avoids non-significant studies to vanish • Think about how to measure processes and to go beyond RCTs when evaluating your intervention • If you are using high-frequency assessments (e.g. EMA), consider how this might influence the effects of the intervention • Consider different study populations and control groups and also blended designs including elements of e-mental health and traditional face-to-face elements	• Do not include variables in your study without a clear theoretical rationale for why these variables are important for the success of the intervention or as control variables • Do not just publish the measures for which you have obtained significant results in favour of your intervention while not reporting other measures that failed to produce significant results • Do not confuse correlation with causality • Do not assume that the effects of moderators and mediators in traditional settings transfer automatically to an e-mental health setting; do not automatically exclude these variables
Ecological Momentary Assessment (EMA)	
• Choose an adequate sampling design (i.e., time-based, event-based, combined sampling schemes) • Balance the lengths (i.e., number of questions at each assessment, number of assessments per day, and the assessment epoch) • Use automatic repeated prompts/alarms and allow participants to delay alarms • Determine the order of items considering the different timeframes of items (e.g., “right now” or ”since the last prompt”) • Use items with good psychometric properties. In EMA, Mc Donald´s omega is the currently most often used measure of reliability. • Consider the temporal dynamics: make sure that the sampling rate matches the temporal dynamics of the underlying target process. For example, a sampling rate that is too infrequent might miss the dynamics of interest, whereas a sampling rate that is too frequent to accurately assess the target process poses unnecessary burden on the participants	• Do not overdo the assessments but carefully determine the length of the EMA period needed to answer the research questions • Do not be a miser. Offering monetary incentives seems to positively affect adherence rates

Transfer into (clinical) practice	
• Assess the long-term usage and feasibility of digital interventions • Evaluate the implementation of the digital intervention in real-world settings • Integrate intervention uptake, ongoing use and impact when assessing in real-world settings • Use proven factors to improve adherence, e.g. mood monitoring or human support • Integrate recognised international frameworks to identify relevant process evaluative indicators (acceptance, liability, functionality) • Consider all relevant stakeholders in the conceptualization and evaluation process • Develop a unique roll-out strategy and consider national/regional requirements such as regulatory frameworks, data safety, business models, long term technical maintenance, funding, market fit etc.	• Avoid efficacy studies without the consideration of process evaluation and a unique roll-out strategy • Do not ignore relevant stakeholders in the public health system • Do not assume that scientific evidence automatically leads to market acceptance
App evaluation frameworks	
• Ensure recommendations are up to date • Assess assumptions and cultural bias in some recommendations, e.g., such as those that score "ease of use" • Verify through your own testing that app recommendations appear accurate and in line with the needs of your populations • Assess for any bias in app recommendation systems	• Do not assume app recommendations have taken into account cultural needs of your population • Do not ignore patient preferences and needs in light of any app recommendation • Avoid offering patients lists of 'top' apps without plans to discuss and/or incorporate into treatment

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