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Using an Electronic Mindfulness-based Intervention (eMBI) to improve maternal mental health during pregnancy: Results from a randomized controlled trial

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ABSTRACT

Prevalence rates of peripartum depression and anxiety are high and correlate with adverse maternal and neonatal outcomes. Mindfulness-based interventions (MBI) have been shown to reduce mental distress during pregnancy.

A multicenter, randomized controlled study was conducted after screening for depressive symptoms. The intervention group (IG) was given access to an 8-week supervised eMBI between weeks 29 and 36 of pregnancy and followed up to 5 months postpartum. Psychometric data were collected using the Edinburgh Postnatal Depression Scale (EPDS), the State-Trait Anxiety Inventory (STAI), the Pregnancy-Related Anxiety Questionnaire (PRAQ-R), the Freiburg Mindfulness Inventory (FMI-14) as well as the Patient Health Questionnaire (PHQ).

Out of 5299 pregnant women, 1153 scored >9 on the EPDS and $N = 460$ were included in the RCT. No significant interaction effects for depressive symptoms and anxiety were found. Pregnancy- and birth-related anxiety decreased significantly in the IG and 6 weeks after birth, the rate of women at risk for adverse mental outcome was significantly lower compared to the CG. Mindfulness scores improved significantly in the IG.

The eMBI program did not show effective regarding general depressive or anxiety symptoms, however, positive results were demonstrated regarding pregnancy and birth-related anxiety and the prevention of postpartum depression.

1. Introduction

Depression and anxiety rank among the most common mental disorders during pregnancy (Babb et al., 2015). Depressive symptoms occur in up to 16 % of pregnant women and major depression is diagnosed in up to 5 % (Leight et al., 2010) . This rate remains high after childbirth with a prevalence of postpartum depression of 10–19 % (O'Hara and McCabe, 2013). Anxiety is observed at rates as high as 39 % during the antepartum and 16.5 % in the postpartum period (Goodman et al., 2014).

The increased vulnerability of pregnant women is presumably due to multifactorial causes, including physiological and hormonal changes (Szpunar and Parry, 2018). Stress, fear, and uncertainty play an important role for expectant mothers as they need to adjust to their new life situation (Di Florio et al., 2013).

It has been shown that impaired mental health in the peripartum period can have a negative impact on mental, fetal, and neonatal outcomes in the short and long term. A meta-analysis by Grigoriadis et al. found associations between antepartum depression and preterm birth as well as low infant birth weight, higher rates for pregnancy-related

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hypertensive disorders, postpartum intensive care surveillance, and difficulties in breastfeeding (Grigoriadis et al., 2013). The rising rate of cesarean sections is also associated with maternal mental disorders. Around 80 % of all surgical indications are presumably relative indications, 10 % being due to pregnancy-related anxiety. (Krankenkasse, 2017). However, 62 % of these women reconsidered their initial demand for a primary cesarean section after adequate treatment of pregnancy-related anxiety (Saisto and Halmesmäki, 2003).

However, about 80 % of women with peripartum depression the condition remains undetected and thus only 20 % receive appropriate treatment (Goodman et al., 2014; Marcus, 2009; O'Connor et al., 2016; Patel and Wisner, 2011).

Several earlier studies have found mindfulness-based interventions to be effective in reducing mental distress in pregnant women, especially in those at risk for depression and anxiety (Byrne et al., 2014; Duncan et al., 2017; Dunn et al., 2012; Hofmann et al., 2010). As pregnant women in particular are open to using digital resources in the field of medical health care (Bert et al., 2013), rising eHealth and mHealth technologies may be used to identify women at risk (Rathbone and Prescott, 2017; van den Heuvel et al., 2018; Van Dijk et al., 2016). Combined electronic-based mindfulness interventions provide easily accessible, cost-effective, and anonymous treatment and prevention tools in pregnancy applying cognitive behavioral and psychoeducational approaches (Kersting et al., 2013) (Wagner et al., 2006).

Most studies published to date have not been randomized controlled trials (RCTs) and have not focused on women at risk who might benefit the most (Dimidjian et al., 2016). Thus, with our RCT we investigated the clinical effectiveness of an eMBI in a sample of pregnant women who screened positive for emotional distress.

2. Methods

2.1. Study design

This prospective study was a multicenter RCT as part of the Innovation Fund Project Mind:Pregnancy (01NVF17034) in the state of Baden-Württemberg, Germany. Participating centers included the maternity departments of the University Hospitals of Heidelberg and Tübingen as well as more than 200 gynecological practices.

Screening for mental distress took place routinely from February 2019 to October 2020 either at the gynecological practices or at the coordinating university hospitals as part of a selective contract between statutory health insurance providers and panel doctors. Women who screened positive for mental distress based on a score >9 on the EPDS were invited to a multidisciplinary psychological assessment to determine whether they were in acute need of treatment. The assessments were conducted either in person or via video consultation using a short version of the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (SCID-5-CV) (American Psychiatric Association, 2013). Methodological recommendations as well as a clinimetric approach as suggested and published by Guidi et al. and Carrozzino et al. were followed in terms of focusing on health-related changes over time and primarily clinical validity of rating scales (Carrozzino et al., 2021; Guidi et al., 2018).

2.2. Participants

Screened patients who were not in acute need of psychiatric treatment were eligible for trial participation if they met the following eligibility criteria: age 18 years or older, adequate proficiency in German, singleton pregnancy, no known neonatal malformations, anomalies or underlying risk factors for preterm birth, <29 weeks of gestation at screening, health insurance coverage by one of the participating statutory health insurance providers, and residency within the state of Baden-Württemberg. Further details have been previously published in the study protocol (Müller et al., 2020).

Study participants were randomly assigned at a ratio of 1:1 to the intervention group (IG) or the control group (CG). The IG was given access to the eMBI with 8 weekly sessions lasting 45 min, whereas the CG received treatment as usual (TAU) without any restrictions or regulations within the study period. Both groups completed the questionnaires digitally via an application and had access to an online pregnancy guided book. The randomization list was generated by an independent scientific assistant using the R package "blockrand" (R v. 3.4.2). Participants each received 100 € as financial compensation.

The individual study period for each patient was 13 months. As shown in Fig. 1, 1153 out of 5299 (21.76 %) screened pregnant women exhibited an EPDS score above the cutoff value of 9. Out of 547 women evaluated at the coordinating centers, 460 (84.10 %) were enrolled in the study.

2.3. Ethics

The study was approved by the ethics committee of the Medical Faculty of the Universities of Heidelberg (S-744/2018) and Tübingen (952/2018BO2) and conducted in accordance with the ethical standards of the Declaration of Helsinki and subsequent amendments. All personal data were collected and processed subject to confidentiality and the European General Data Protection Regulation (EU-GDPR). This study follows the CONSORT statement (Consolidated Standards of Reporting Trials, (https://www.equator-network.org/reporting-guidelines/consort/) and the SPIRIT guidelines (Standard Protocol Items: Recommendations for Intervention Trials) (Additional file 1) (Moher et al., 2012). The study was registered with the German Clinical Trials Registry (DRKS 00,017,210).

2.4. Clinical intervention

2.4.1. Electronic mindfulness-based intervention (eMBI)

All participants randomized to the IG were granted access to a supervised eMBI, which was specifically developed for this study, available through Apple iTunes and the Google Play Store. Data submitted was carefully viewed by the study staff with the possibility to interact with the patient if necessary. The intervention consisted of eight weekly sessions lasting 45 min involving psychoeducational and obstetrical content, mindfulness exercises, and cognitive behavioral approaches. Exemplarily, the first session addressed "Fears and worries about birth and parenting". The psychoeducational content encompassed the occurrence of pregnancy-related stress, emergence of mental vicious circles, and individual sources of strength. Mediated skills comprised how to exit from the vicious circle of fear and the use of mindful breathing and mindful body scans. Content was delivered in the form of audio files, videos, written content, a personal skills box, and interactive worksheets. Full details have been published elsewhere (Müller et al., 2020).

2.4.2. Outcome measures

Both groups were asked to complete questionnaires digitally every 2 weeks during the 8-week intervention (assessments T1–T5) and at 1 and 5 months postpartum (assessments T6 and T7).

2.4.3. Primary outcomes

2.4.3.1. Choice of primary measures. Primary outcome measures were selected according to the respective prevalence and clinical significance within the general population. Primary outcomes measures used in the mindmom study encompassed:

2.4.3.2. Edinburgh postnatal depression scale (EPDS). The EPDS (Cox et al., 1987) is a 10-item self-rating scale that assesses depressive symptoms during the peripartum period over the past 7 days by rating

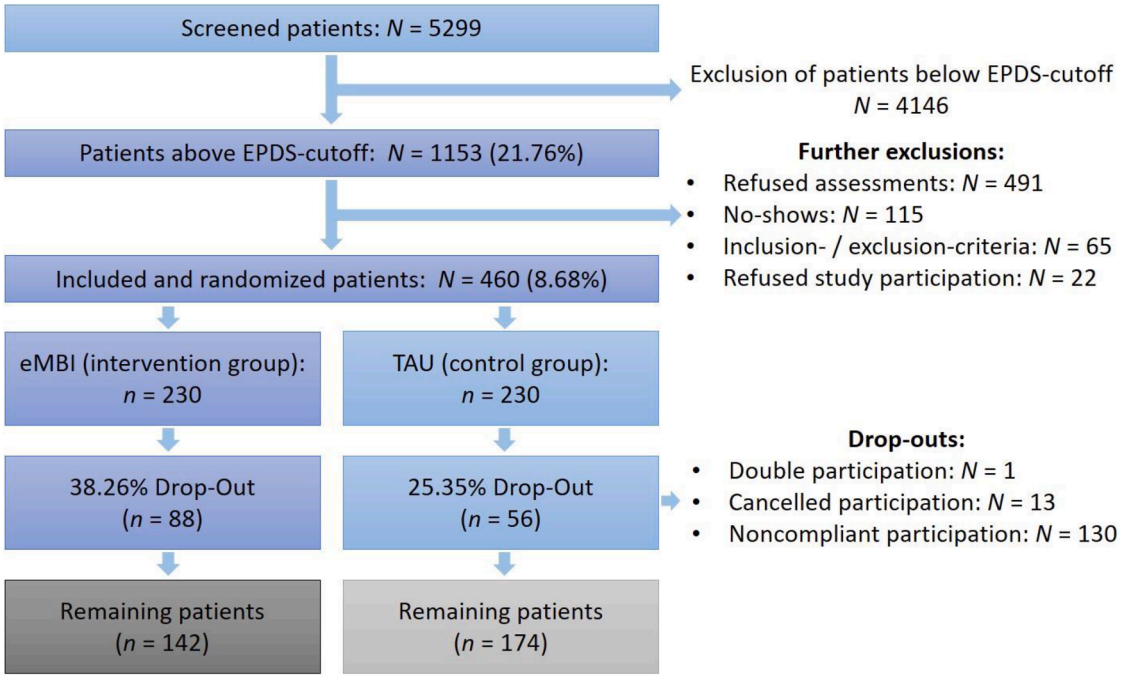

Fig. 1. Participant flowchart.

them on a Likert scale (0–3). A recently published systematic review has shown that the EPDS is the best available patient-reported outcome measure (PROM) for screening perinatal depression. (Sultan et al., 2022) The most commonly used cut-off value of 9 (EPDS score > 9) showed a sensitivity of 0·96 and specificity of 1·00 in earlier research. (Wisner et al., 2013) A cutoff value of > 12 indicates an elevated risk for a major depressive episode.

2.4.3.3. State-Trait anxiety inventory (STAI). Anxiety was measured using the STAI. The questionnaire consists of two 20-item scales: the STAI-S evaluates anxiety as a state, encompassing feelings of tension, nervousness, and worry, whereas the STAI-T refers to anxiety as a trait. Each of the 20 items is measured using a Likert Scale (1–4) (Newham et al., 2012).

2.4.3.4. Pregnancy-Related anxiety questionnaire – revised (PRAQ-R). The PRAQ-R is an abridged 10-item version of a self-report instrument assessing pregnancy- and birth-specific anxiety. The PRAQ-R has been psychometrically validated and has proven to be a valid predictor for birth and childhood outcomes (Huizink et al., 2016, 2014; Reck et al., 2013).

2.4.4. Secondary outcomes

2.4.4.1. Freiburg mindfulness inventory (FMI-14/FFA-14). The Freiburg mindfulness questionnaire (FMI-14, in German "Freiburger Fragebogen zur Achtsamkeit" or hereinafter referred to as FFA-14) was developed according to the Buddhist rules of life (Buchheld et al., 2001). Mindfulness is measured as a personal characteristic, which is seen as the tendency to act in a mindful way (Sauer et al., 2011). We used the abridged German version consisting of 14 Likert-scaled (1–4) items (Walach et al., 2006).

2.4.4.2. Patient health questionnaire (PHQ-D). The PHQ-D was developed for the practical screening of mental disorders for primary care and directly measures the diagnostic criteria of DSM-IV (Spitzer et al., 1999). It proved as a valid and well-accepted self-rating instrument for use in research and clinical practice and has been validated in German (Gräfe et al., 2004). The PHQ-D measures the following scales with 78 items: somatoform, depressive, anxiety, eating disorders and alcohol abuse. In addition, items on psychosocial functioning, stress experience and critical life events are included.

2.4.5. Adverse events

Adverse events were predefined as suicidal ideation (indicated by the answer to EPDS item 10 "Yes, very often" or "sometimes"), worsening of depressive symptoms (indicated by an increase in the EPDS above the cutoff value of 12 after study entry), or study termination due to negative effects or admission to inpatient treatment during the period of the study (Jacobson and Truax, 1991; Woud et al., 2021).

2.5. Statistical analyses

All analyses were conducted using SPSS® Statistics for Windows (IBM® version 27.0.0) (Müller et al., 2020) Little's MCAR test was used to assure that missing data due to drop-outs and missing values were valid for our analyses (Little, 1988). Moreover, the groups were tested for comparability regarding sociodemographic and medical third variables by means of *t, U,* and χ^2 tests. If differences were significant, the respective variables were analyzed for associations with the outcome variables and included as covariates.

The manipulation check (analyses regarding mindfulness as indexed by the FFA-14 scores) and the confirmatory research hypotheses were analyzed using (multivariate) analysis of variance (ANOVA) with repeated measurements corrected for significant confounders. Mauchly's sphericity test was used to determine whether the sphericity assumption had been violated. If significant, repeated measures *df*s were corrected using the Huynh–Feldt correction. The critical, local α-errors were Bonferroni-adjusted to $\alpha_{local} = \frac{0.05}{3} = 0.01\overline{6}$ for three confirmatory tests. For the manipulation check, the critical, local α-errors are not adjusted and set to a conventional level of $\alpha_{local} = 0.05$. Partial η^2 and ω^2 are used as effect sizes. These are sample-based or population-based estimators of explained variances, respectively. According to Cohen (Cohen, 1977), $\eta^2 / \omega^2 = 0.01$ represents small, $\eta^2 / \omega^2 = 0.06$ represents medium, and $\eta^2 / \omega^2 = 0.14$ represents large effects. Dunn's multiple comparison procedure (Dunn, 1961) was performed as a post hoc test for

significant effects relevant to the hypotheses. This procedure results in a minimum significant difference (ψ).

Estimation of sample size was calculated with G*Power (Version 3.1.9.7), (Faul et al., 2009, 2007) For details, see (Müller et al., 2020). The initial sample size estimation was conducted prior to the first study inclusions.

At that point, we aimed to reach a sample size which would enable an exclusion of small between-subject effects, i.e., $N = 822$ subjects plus 20 % dropouts (total $N = 1028$). However, during recruitment, these numbers proved to be unrealistic. Thus, we adapted the final sample size estimation to $N = 196$ (plus 30 % dropouts (total $N = 280$), which would enable us to exclude small within-between-subject effects. According to this calculation, $N = 196$ cases were needed to reach a power of 1- = 0.99 and 0.98 for large ($f = 0.40$) and medium-sized ($f = 0.25$) effects, respectively. However, we tried to increase recruitment as much as possible to further increase the statistical power regarding between-subject effects and to counterbalance missing values regarding non-mandatory measures. The $N = 460$ is the result of this endeavor. However, due to drop-outs (see Fig. 1) and further missing values, the number of valid cases varies. Post-hoc power calculations for nonsignificant results are indicated and reported in the results section. However, in all our ANOVAS, the power was virtually 1-β = 1.0 for large ($f = 0.40$) within- and between-subject effects as well as for medium-sized within-subject effects ($f = 0.25$).

3. Results

3.1. Descriptive characteristics

All descriptive characteristics are demonstrated in Table 1. Descriptive statistics of outcome measures can be found as online supplementary material (Table S1). The MCAR test including sociodemographic, pregnancy-, birth-, and infant-related, medical, and psychological data was nonsignificant ($\chi^2 = 25\,104.74$, $df = 25\,073$, $p > 0.442$).

The IG and the CG statistically significantly differed regarding the PHQ score, the number of children at home, and the educational level (see Table 1): the IG scored lower in the PHQ stress evaluation, had more children at home, and had a lower educational level than the CG.

These potential confounders were correlated with the outcome variables: The PHQ stress evaluation was significantly associated with every outcome at every measurement point. The associations ranged between $r = [0.201;0.479]$ ($p < 0.001$), showing the highest association with the STAI-T at T6 and the lowest association with the PRAQ-R at T5. The numbers of children at home were significantly associated with the FFA-14, the STAI-S and -T, as well as the PRAQ-R, ranging between ρ = [−0.241;0.173] for the highest positive association with the STAI-S at T1 and the highest negative association with the PRAQ-R at T1 (levels of significance ranging between $p = [< 0.001; 0.048]$). The level of education was significantly associated with the EPDS as well as with the STAI-S and -T, ranging between ρ = [0.171; −0.122] for the highest negative association with the STAI-S at T6 and the lowest negative association with the EPDS at T1 (levels of significance ranging between $p = [< 0.017; 0.041]$). Consequently, we controlled these variables as covariates in the respective analyses.

3.2. Manipulation check (FFA-14)

A 2 (group) x 3 (time) – ANOVA with PHQ stress evaluation, and the number of children at home as covariates was used. The assumption on sphericity was significantly violated ($p < 0.001$) and thus Huynh-Feldt-corrected (ε = 0.925). There was a significant main effect of time ($F(1.850, 344.164) = 6.543$, $p = 0{\cdot}002$, $\eta^2 = 0.034$, $\omega^2 = 0.018$), indicating an increase in FFA-14 scores between T1 ($M = 33.0$, $S.E. = 0.5$) and T7 ($M = 35.6$, $S.E. = 0.6$). Moreover, there was a significant interaction effect between group and time ($F(1.850, 344.164) = 3.351$, $p = 0.040$, $\eta^2 = 0.018$, $\omega^2 = 0.008$), indicating that the FFA-14 scores increased in the IG between T1 and T7 (see Fig. 2). Dunn's post-hoc test ($\Psi_{Dunn} = 1.9$) also revealed a significant difference between T1 and T5 in the IG.

Furthermore, a significant main effect of the PHQ stress evaluation ($F(1, 186) = 12.417$, $p < 0.001$, $\eta^2 = 0.06$, $\omega^2 = 0.057$) was observed, referring to the negative association between this measure and the FFA-14 scores. There were no other significant main ($p \geq 0.287$) or interaction effects ($p \geq 0.339$).

We calculated a power of 1-β = 0.940 for medium-sized between-subject effects ($f = 0.25$) and 1-β = 0.852 for small within-subject effects ($f = 0.10$). Only small between-subject effects cannot be ruled out sufficiently with 1-β = 0.205.

3.3. Primary outcomes

3.3.1. Depressive symptoms (EPDS)

A 2 (group) x 7 (time) – ANOVA with PHQ stress evaluations, and the highest school educational level as covariates was used. The assumption on sphericity was significantly violated ($p < 0.001$) and thus Huynh-Feldt-corrected (ε = 0.781).

We found significant main effects of the PHQ stress evaluation ($F(1, 149) = 36.861$, $p < 0.001$, $\eta^2 = 0.198$, $\omega^2 = 0.189$) and maternal education ($F(1, 149) = 7.231$, $p = 0.008$, $\eta^2 = 0.046$, $\omega^2 = 0.039$), referring to the significant associations of these measures and the EPDS scores. The main effect of group was not significant ($F(1, 149) = 5.334$, $p = 0.022$, $\eta^2 = 0.035$, $\omega^2 = 0.028$).

Overall, the interaction effect between group and time was not significant ($F(4.684, 697.908) = 1.972$, $p = 0.086$, $\eta^2 = 0.013$, $\omega^2 = 0.004$) (see Fig. 3).

Findings were negative for all other main ($p = 0.820$) and interaction effects ($p \geq 0.544$). The power was 1-β = 0.988 for medium-sized between-subject effects ($f = 0.25$). Only small within-subject and between-subject effects ($f = 0.10$) cannot be ruled out sufficiently with 1-β = 0.653 and 1-β= 0.293.

3.3.2. State-Trait-Anxiety (STAI)

A 2 (group) x 7 (time) – MANOVA with PHQ stress evaluations, the number of children at home, as well as the highest educational level as covariates was used. There was a significant main effect of PHQ stress evaluations ($F(2141) = 28.562$, $p < 0.001$, $\eta^2 = 0.288$, $\omega^2 = 0.273$), referring to the significant positive associations of this measure and the STAI scores.

Findings were negative for all other main ($p \geq 0.122$) and interaction effects ($p \geq 0.218$). The power was 1-β = 0.986 for medium-sized between-subject effects ($f = 0.25$). Only small within-subject and between-subject effects ($f = 0.10$) cannot be ruled out sufficiently with 1-β = 0.702 and 1-β= 0.287.

3.3.3. Pregnancy- and birth-related anxiety (PRAQ-R)

A 2 (group) x 5 (time) – ANOVA - with PHQ stress evaluation, and the number of children as covariates was used. Huynh-Feldt correction was applied (ε = 0.802).

A significant interaction effect was observed between group and time ($F(3.208, 741.004) = 3.558$, $p = 0.012$, $\eta^2 = 0.015$, $\omega^2 = 0.007$), indicating a decrease in PRAQ-R scores for the IG between T2 and T4 (see Fig. 4). Dunn's post-hoc test ($\Psi_{Dunn} = 1.4$) did not reveal any further significant differences.

Furthermore, we found significant main effects of the PHQ stress evaluation ($F(1, 231) = 18.277$, $p < 0.001$, $\eta^2 = 0.073$, $\omega^2 = 0.069$) and number of children ($F(1, 231) = 12.438$, $p < 0.001$, $\eta^2 = 0.051$, $\omega^2 = 0.046$), referring to the significant associations of these measures and the PRAQ-R scores.

No other significant main ($p \geq 0.832$) or interaction effects ($p \geq 0.263$) were found. In this analysis, the power was additionally virtually 1-β = 1.0 for small within-subject effects ($f = 0.10$). Furthermore, it was 1-β = 0.967 for medium-sized between-subject effects ($f = 0.25$). Only

Table 1
Demographics and tests on comparability of subgroups.

	General	TAU	eMBI	$\|t\|$ (p)		General	TAU	eMBI	$\|t\|$ (p)
Maternal age (years)[a] *M (SD)*	32.6 (4.3)	32.8 (4.6)	32.3 (4.7)	0.95 (0.35)	**Infant body weight** (grams) [b] *M (SD)*	3370.4 (475.9)	3411.8 (438.6)	3319.4 (515.3)	1.70 (0.09)
Gestation age at study inclusion (weeks) [c] *M (SD)*	21.2 (4.3)	21.4 (4.2)	21.0 (4.3)	0.78 (0.43)	**Infant body length** (cm) [d] *M (SD)*	51.5 (2.6)	51.7 (2.5)	51.2 (2.6)	1.52 (0.13)
Gestation age at birth (weeks) [e] *M (SD)*	39.2 (1.7)	39.2 (1.7)	39.2 (1.6)	−0.14 (0.89)	**PHQ stress evaluation** (points)[f] *M (SD)*	6.8 (3.4)	7.2 (3.7)	6.3 (3.0)	2.28 (0.02)
Maternal education (frequencies)	General[g]	TAU[g]	eMBI[h]	*U (p)*	**Household netto income** (frequencies)	General[i]	TAU[i]	eMBI[i]	*U (p)*
University entrance qualification	149 (51.4)	97 (58.1)	52 (42.3)	8396.5 (<0·01)	< 1500 €	70 (24.8)	36 (21.8)	34 (29.1)	8744.5 (0.15)
University of applied sciences entrance qualification	48 (16.6)	29 (17.4)	19 (15.4)		1500 - 2999 €	128 (45.4)	76 (46.1)	52 (44.4)	
High secondary qualification	78 (26.9)	32 (19.2)	46 (37.4)		3000 - 4999 €	62 (22.0)	39 (23.6)	23 (19.7)	
Low secondary qualification	14 (4.8)	8 (4.8)	6 (4.9)		5000 - 8000 €	21 (7.4)	13 (7.9)	8 (6.8)	
No school leaving qualification	1 (0.3)	1 (0.6)	0 (0.0)		> 8000 €	1 (0.4)	1 (0.6)	0 (0.0)	
Level of maternal occupation frequencies (%)	General[k]	TAU[k]	eMBI[k]	*U (p)*	**Civil status** (frequencies)	General	TAU	eMBI	χ^2 (p)
Prohibition notice	113 (40.9)	68 (42.5)	45 (38.8)	9150.0 (0.84)	married	192 (65.8)	113 (67.3)	79 (63.7)	5·35 (0.34)
unemployed	35 (12.7)	16 (10.0)	19 (16.4)		partnership	94 (32.2)	53 (31.5)	41 (33.1)	
part-time employed	60 (21.7)	33 (20.6)	27 (23.3)		single	5 (1.7)	1 (0.6)	4 (3.2)	
full-time employed	68 (24.6)	43 (26.9)	25 (21.6)		divorced	1 (0.3)	1 (0.6)	0 (0.0)	
Country of origin (frequencies)	General	TAU	eMBI	χ^2 (p)	**Current psychotherapy** (frequencies)	General	TAU	eMBI	χ^2 (p)
Germany	249 (85.3)	140 (83.3)	109 (87.9)	19.17 (0.17)	False	55 (17.5)	30 (17.3)	25 (17.7)	0.01 (0.99)
Other	43 (14.7)	28 (16.7)	15 (12.1)		True	259 (82.5)	143 (82.7)	116 (82.3)	
Gravidity (frequencies)	General[l]	TAU[l]	eMBI[l]	*U (p)*	**Parity** (frequencies)	General[m]	TAU[m]	eMBI[m]	*U (p)*
1st pregnancy	143 (45.3)	82 (47.1)	61 (43.0)	11,822.0 (0.48)	1st birth	177 (56.0)	102 (58.6)	75 (52.8)	11,675.5 (0.35)
2nd pregnancy	85 (26.9)	44 (25.3)	41 (28.9)		2nd birth	103 (32.6)	53 (30.5)	50 (35.2)	
3rd pregnancy	47 (14·9)	29 (16·7)	18 (12·7)		3rd birth	30 (9.5)	15 (8.6)	15 (10.6)	
≥ 4th pregnancy	41 (13.0)	19 (10.9)	22 (15.5)		≥ 4th birth	6 (1.9)	4 (2.3)	2 (1.4)	
Number of children at home (frequencies)	General[m]	TAU[m]	eMBI[m]	*U (p)*	**Birth mode** (frequencies)	General	TAU	eMBI	χ^2 (p)
no child	167 (57.4)	105 (62.5)	62 (50.4)	9075.5 (<0.05)	Spontaneous	179 (57.9)	103 (60.6)	76 (54.7)	5.35 (0.34)
one child	96 (33.0)	49 (29.2)	47 (38.2)		Primary c-section	42(13.6)	23 (13.5)	19 (13.7)	
two children	25 (8.6)	12 (7.1)	13 (10.6)		Secondary c-section	64 (20.7)	30 (17.6)	34 (24.5)	
three or more children	3 (1.0)	2 (1.2)	1 (0.8)		Vaginal-operative	24 (7.8)	14 (8.2)	10 (7.2)	
Infant sex (frequencies)	General	TAU	eMBI	χ^2 (p)	**Infant APGAR values after 10 min**. (frequencies)	General[n]	TAU[n]	eMBI[n]	*U (p)*
Female infants	126 (40.6)	72 (42.1)	54 (38.8)	0.34 (0.64)	10	279 (92.7)	154 (92.2)	125 (93.3)	11,053·0 (0.69)
					9	16 (5.3)	8 (4.8)	8 (6.0)	
Male infants	184 (59.4)	99 (57.9)	85 (61.2)		8	5 (1.7)	4 (2.4)	1 (0.7)	
					7	1 (0.3)	1 (0.6)	0 (0.0)	

Notes. t = t-value; p = empirical α-error; M = mean; SD = standard deviation; U = statistical value of *U test*; χ^2 = statistical value of χ^2-test;.

[a] . min = 20·0; max = 45·0;.
[b] . min = 1790·0; max = 4550·0;.
[c] . min = 12·4; max = 29·1;.
[d] . min = 41·0; max = 60·0;.
[e] . min = 30·0; max = 41.9;.
[f] . min = 0·0; max = 20·0;.
[g] . median = university entrance qualification;.
[h] . median = university of applied sciences entrance qualification;.
[i] . median = 1500 - 2999 €;.
[k] . median = unemployed;.
[l] . median = 2;.
[m] . median = 0;.
[n] . median = 10.

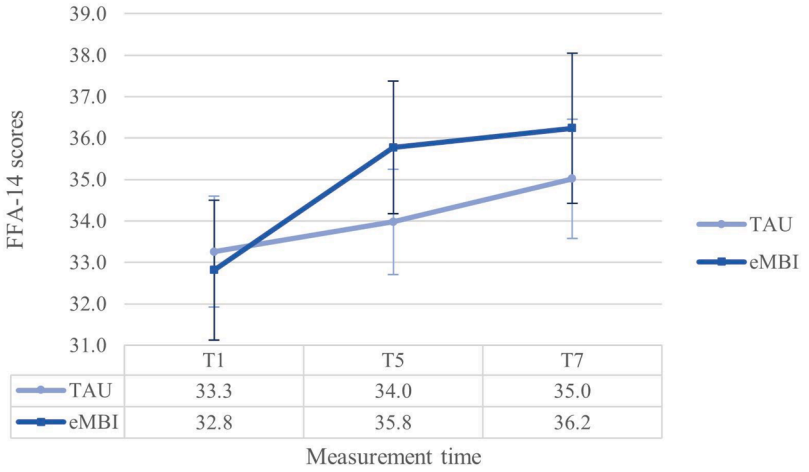

Fig. 2. Within-between-interaction effect regarding FFA-14 scores.
T1 = 28th Gestational week (GW), T3 = 32nd GW, T5 = 36th GW, TAU = treatment as usual, eMBI = electronic mindfulness-based intervention.

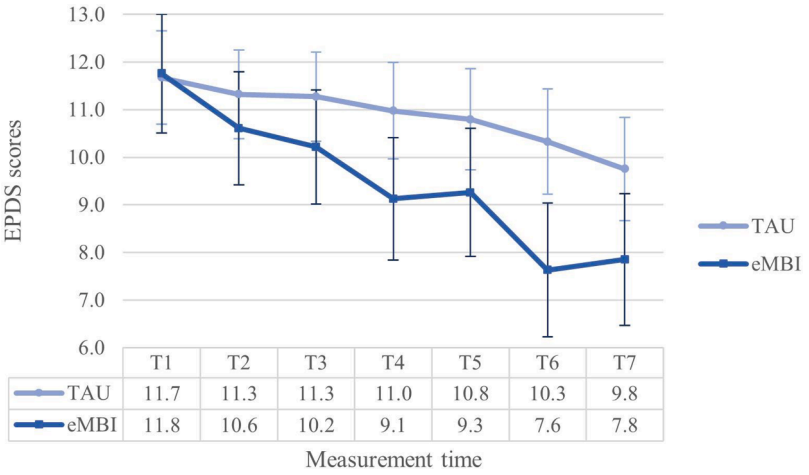

Fig. 3. Within-between-interaction effect regarding EPDS scores
T1 = 28th Gestational week (GW), T2 = 30th GW, T3 = 32nd GW, T4 = 34th GW, T5 = 36th GW, T6 = 1 month postpartum (pp), T7 = 5 months pp, TAU = treatment as usual, eMBI = electronic mindfulness-based intervention.

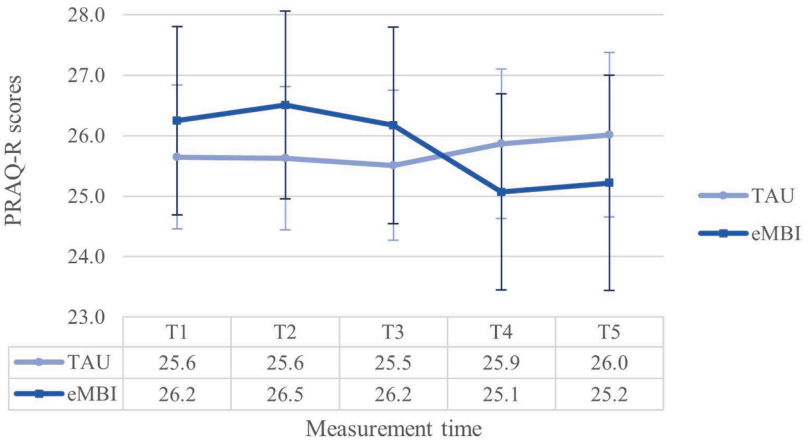

Fig. 4. Within-between-interaction effect regarding PRAQ-R scores
T1 = 28th Gestational week (GW), T2 = 30th GW, T3 = 32nd GW, T4 = 34th GW, T5 = 36th GW, TAU = treatment as usual, eMBI = electronic mindfulness-based intervention.

small between-subject effects cannot be ruled out sufficiently with 1-β = 0.239.

3.3.4. Adverse events

No serious adverse events were recorded. There were $n = 23$ out of $n = 142$ valid cases (16.20 %) in the IG and $n = 41$ out of $n = 174$ (23.56 %) in the CG with an increased cutoff value of > 12. The number of these events did not differ significantly between the two groups ($\chi^2 = 2.63$, $p = 0.11$). Regarding suicidal ideation, there were $n = 9$ out of $n = 142$ valid cases (6.34 %) in the IG, while there were $n = 20$ out of $n = 174$ valid cases (11.49 %) in the CG, with no significant difference between the groups ($\chi^2 = 2.49$, $p = 0.11$). On further evaluation, none of these responses was judged to be acutely dangerous.

4. Discussion

The present study constitutes the first randomized controlled trial (RCT) to investigate the effectiveness of a supervised 8-week electronic mindfulness-based intervention in a sample of pregnant women screened for psychological distress. Although our findings regarding two of the primary outcomes depression and general anxiety were negative, our results indicate a significant reduction in pregnancy and birth-related anxiety in the IG. Additionally, self-perceived mindfulness and self-awareness also increased significantly in the IG. Our results are important as demand for psychotherapy and therapy for fear of childbirth far exceeds availability of clinicians.

The vast majority of published studies regarding the effects of a mindfulness-based intervention used face-to-face interventions, whereas digital interventions are still scarce so far. (Alsubaie et al., 2017; Goldberg et al., 2018).

Similar study concepts with face-to-face mindfulness interventions were able to show significant reductions in depression and anxiety. However, the trial by Pan et al. did not report any significant effect for mindfulness scores (Pan et al., 2019). Our study also demonstrates a significant, positive impact on improving mindfulness over the whole study period. These findings are important as mindfulness, in turn, is demonstrably beneficial in terms of optimized health outcomes in mothers and their children (Beattie et al., 2014). A 2017 review analyzing RCTs investigating the use of MBIs during pregnancy found no significant reduction in mental distress in these studies but did suggest MBIs had a positive effect on mental health (Dhillon et al., 2017).

By providing evidence that some benefits of the eMBI last up to several months postpartum, our study – unlike previously published research (Vieten and Astin, 2008; Zhang and Emory, 2015) – suggest long-term advantageous effects on maternal mental health. To our knowledge, the present study is the first to demonstrate significant postintervention benefits in between-group analyses, even when the mindfulness interventions are delivered electronically. Not least in view of the lack of adequately powered RCTs, we consider our work a significant contribution to the body of data on the even though partial usefulness of eMBIs in the treatment of mental health during pregnancy.

Previous literature suggests that psychoeducational treatment approaches appear to be beneficial by improving health-related behavior and, consequently, support better overall maternal and fetal health outcomes as well as providing optimized cost-efficiency (2015). A 2020 review encompassing 22 studies highlights the importance of mHealth tools in clinical routine and the chances their implementation offers. However, the results point to major gaps in currently available mHealth tools, including the absence of active psychological support such as by implementing mindfulness-based interventions (Hussain-Shamsy et al., 2020).

Implementing MBI at an early stage can encourage these women to adopt favorable habits and health behavior (Bischoff et al., 2019). Furthermore, potential geographic, financial, and psychological barriers could be reduced to a minimum. Failure to show effectiveness in lowering depression and general anxiety in contrast to face-to-face interventions might suggest that in order to positively impact general mental health, a personal component needs to be added, whereas the positive effects on birth anxiety may be achieved digitally.

4.1. Strengths and limitations

The main strength of our study lies in its prospective, longitudinal design with a follow-up period of up to 5 months after childbirth and the inclusion of a CG. The intervention and the peripartum assessments were provided as part of an application and are thus easily and universally applicable and cost-effective. Another strength of our study is that mental health was examined according to a multidimensional approach based on DSM/ICD criteria. Anxiety, and specifically pregnancy-related anxiety and depression, which often occur as comorbidities (Masi et al., 2004; Skouteris et al., 2009), and mindfulness were assessed. In addition, a broad range of confounders were considered. The large number of screened and included patients contribute to the high power of our RCT while in many cases other comparable research lacks an active CG (Sado et al., 2020). The multidimensional approach of our intervention offers not only mindfulness-based training but also psychoeducational and obstetrical content as well as cognitive behavioral therapy approaches. Lastly, the 8-week duration was selected based on considerations of potentially greater effectiveness than shorter interventions programs used in earlier research (Subnis et al., 2020). Compared to a previously published trial, completion and compliance rates among our study cohort were relatively high and contribute to the high power of this RCT (Krusche et al., 2018).

However, some limitations should be considered. The results should be interpreted cautiously, as the effectiveness of the intervention is not fully supported by our data. Furthermore, it is not clear whether the improvement in mental distress can be attributed solely to the eMBI or whether specific circumstances, for example, the social environment, progression of pregnancy, or unforeseen events, might have had an influence on both the control as well as the IG. Moreover, we were unable to further distinguish between normal-risk and high-risk pregnancies that might have required extended hospitalization, causing another major risk factor for impaired mental health (Goetz et al., 2020). The question also remains as to why women in the IG did not show greater changes on all psychometric questionnaires compared to women in the CG. Possibly, with study eligibility requiring high levels of depression (EPDS > 9) and the willingness to attend weekly mindfulness sessions, women in both groups may have been motivated to actively improve their mental health. Future studies should also include pregnant women at low risk for anxiety and depression as mindfulness is known to be effective in reducing stress in a healthy population, too (Chiesa and Serretti, 2009).

5. Conclusions

Our study is the first to evaluate the effectiveness of an electronic-based mindfulness intervention on different dimensions of mental health outcomes during pregnancy and up to 5 months postpartum. Even though our intervention could not prevent depression and general anxiety, our study shows that an 8-week electronic intervention can impact pregnancy- and birth-related anxiety and mindfulness significantly and supports applying electronic-based intervention tools in a pregnant population. This eMBI may complement existing recommendations and clinical routines in prenatal care, thus optimizing maternal and fetal outcomes in the long-term.

Statement of ethics

The study protocol has been approved by the Ethics Committees of the Universities of Heidelberg (approval number S-744/2018) and Tübingen (approval number 952/2018BO2), Germany, and follows the guidelines of the Declaration of Helsinki and current German and

European Union legislation on data protection. The study participants signed a written informed consent form before randomization. Participation could be terminated at any time. The study was registered with the German Clinical Trials Registry (DRKS 00,017,210).

Role of the funding source

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Author contributions

All the authors participated in the design and planning of the intervention presented here. Specifically, Stephanie Wallwiener and Mitho Müller designed and planned the trial, Stephanie Wallwiener coordinated the study and has the scientific responsibility, and Mitho Müller planned and performed the necessary statistical analysis and controls for data monitoring. Kathrin Haßdenteufel, Stephanie Wallwiener and Mitho Müller were responsible for data management as well as manuscript writing and editing. Harald Abele, Sara Yvonne Brucker, Johanna Graf, Stephan Zipfel, Armin Bauer, Peter Jakubowski, Jan Pauluschke-Fröhlich were responsible for data and study management as well as manuscript editing. Johanna Grad and Stephan Zipfel supervised the psychotherapeutic elements of the eMBI. All authors read and approved the final manuscript.

Data sharing statement

All data analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

Declaration of Competing Interest

Stephanie Wallwiener is a medical advisor to the Institute of Digital Women's Health. All other authors have no conflicts of interest to declare.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2023.115599.

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