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mHealth Mindfulness Intervention for Women with Moderate-to-Moderately-Severe Antenatal Depressive Symptoms: a Pilot Study Within an Integrated Health Care System

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Abstract

Objectives Traditional mindfulness-based interventions have been shown to reduce depression symptoms in pregnant women, although in-person classes may pose significant accessibility barriers, particularly during the COVID-19 pandemic. Mobile technology offers greater convenience, but little is known regarding the efficacy of self-paced, mobile-delivered (mHealth) mindfulness interventions in this population. This study tested the feasibility and acceptability of offering such an intervention for pregnant women with moderate-to-moderately-severe depression symptoms.

Methods We conducted a single-arm trial within Kaiser Permanente Northern California (KPNC). Participants were identified through KPNC's universal perinatal depression screening program. Eligible participants included English-speaking pregnant women (<28 weeks of gestation) with moderate-to-moderately-severe depressive symptoms without a regular (<3 times/week) mindfulness/meditation practice. Participants were asked to follow a self-paced, 6-week mindfulness meditation program using a mobile app, Headspace™, 10–20 min/day. Outcome measures included feasibility, acceptability, and patient-reported outcomes (e.g., depression symptoms).

Results Of the 27 women enrolled, 20 (74%) completed the study. Over half (55%) of participants used the app ≥50% of the days during the 6-week intervention. Responses to the semi-structured interviews indicated that women appreciated the convenience of the intervention and the ability to engage without having to attend classes or arrange childcare. We observed significant improvements in pre-postintervention scores for depression symptoms, perceived stress, sleep disturbance, and mindfulness.

Conclusions Our study demonstrates the feasibility and acceptability of an mHealth mindfulness intervention for women with moderate-to-moderately-severe antenatal depression symptoms. The preliminary data further suggest that an efficacy trial is warranted.

Keywords Depression · Mindfulness · Mobile health · Pregnancy · Intervention · Prenatal · Mental health · Maternal health · Perinatal

Antenatal depression is a debilitating and costly mood disorder that affects approximately 12% of pregnant women (Gavin et al. 2005). It is the most prevalent complication of pregnancy and is associated with significant health consequences for mothers and children (Avalos et al. 2015; Badon et al. 2019; Grigoriadis et al. 2013; Szegda et al. 2014).

Though antenatal depression is the strongest predictor of postpartum depression, impacting up to 20% of postpartum women (Gavin et al. 2005; Gaynes et al. 2005), half of all women with antenatal depression do not receive treatment (Ko et al. 2012).

There are several barriers to current treatment options for women with antenatal depression. First, citing concerns over the safety of antidepressant medication use during pregnancy, most pregnant women (83–95%) prefer non-pharmaceutical treatments (Dimidjian and Goodman 2009, 2014). Second, while psychotherapy is an effective non-pharmacological treatment option, numerous barriers to receiving care exist, including the shortage of mental health care providers

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(Kaiser Family Foundation n.d.), limited access to care, financial constraints, and lack of time, transportation, and childcare (Goodman 2009). Further, the current COVID-19 pandemic is posing a significant impact on the mental health of pregnant and postpartum women: a recent study reported a near tripling of the rate of perinatal depression since the pandemic began (15% pre-pandemic versus 41%) (Davenport et al. 2020). While rates of perinatal depression have increased, access to in-person delivered health care is drastically diminished (Li 2020; Panchal et al. 2020). Therefore, it is critical to identify safe, remotely-delivered, effective, and scalable intervention options for pregnant women with depression.

Mindfulness, a psychological process of bringing one's attention to the present moment (Creswell 2017; Kabat-Zinn 1990; Pagnini and Philips 2015), is an effective intervention for reducing symptoms of depression in many populations (Dimidjian et al. 2016; Guardino et al. 2014; Khoury et al. 2015; Lever Taylor et al. 2016; Vieten and Astin 2008). Despite the promising evidence of mindfulness-based interventions in reducing depression symptoms, logistical requirements of currently available mindfulness training such as mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT) (Kabat-Zinn 1990; Segal et al. 2002) often include over 30 h of *in-person* instruction together with 45 min of home practice daily, which severely restricts its accessibility for pregnant women. Women of reproductive age are often too busy to attend regular in-person sessions, particularly if they have other children at home and/or a full-time job. In fact, a recent in-person mindfulness pilot study for pregnant women reported that the recruitment was challenging for these reasons and that a more practical intervention was needed (Guardino et al. 2014). Logistical barriers such as distance, lack of transportation, childcare, and scheduling conflicts have been reported as reasons for non-adherence or refusal to participate in behavioral intervention research studies (Eyles et al. 2015; Schapira et al. 2014; Wahbeh et al. 2014a; Wahbeh and Oken 2016). In addition, in-person classes are costly for the patients and the health care system and not readily available in rural areas, preventing wide dissemination.

The widespread use of smartphones has led to a proliferation of behavioral Internet-based or mobile application (mHealth) interventions that fit the lifestyles of individuals who are unable to attend in-person classes and offer potential for improving adherence and efficacy. Remotely delivered interventions are also urgently needed as underscored by the COVID-19 pandemic. Recent studies report that many Americans suffering from depression, stress, or anxiety prefer online mindfulness training over in-person sessions (Wahbeh and Oken 2016; Wahbeh et al. 2014a, b). A recent meta-analysis of online, webinar versions of traditional mindfulness-based intervention (MBI) (e.g., MBSR) has demonstrated significant beneficial impact on depression, anxiety,

and well-being in various populations (Spijkerman et al. 2016). However, studies on Internet-based mindfulness interventions are extremely limited among perinatal women with depression symptoms, and accessibility challenges remain. While the introduction of technology for delivery of MBI is a major advancement, these studies use online versions of the traditional MBIs in a webinar format with a trained facilitator. Thus, participants are still required to log on at a specified weekly time and there are the same extensive training durations (e.g., 30+ h total, 2.5 h a session) and homework (45 min/day) over 8 weeks, just as the in-person versions. A self-paced, mHealth MBI with smaller dosage has high potential as a scalable and effective intervention with greater accessibility. Emerging studies have documented the efficacy of self-paced, smaller dosage digitally-delivered MBIs in reducing depression symptoms and stress in the general population (Economides et al. 2019; Ritvo et al. 2019; Yang et al. 2018) and among those with debilitating illnesses such as cancer (Bruggeman-Everts et al. 2017; Compen et al. 2018; Lengacher et al. 2018; Zernicke et al. 2014). However, little is known regarding the efficacy of self-paced mHealth mindfulness interventions among women with antenatal depression symptoms. As a first step, we conducted a feasibility study of such an intervention for pregnant women with moderate-to-moderately-severe depression symptoms within an integrated health care delivery system.
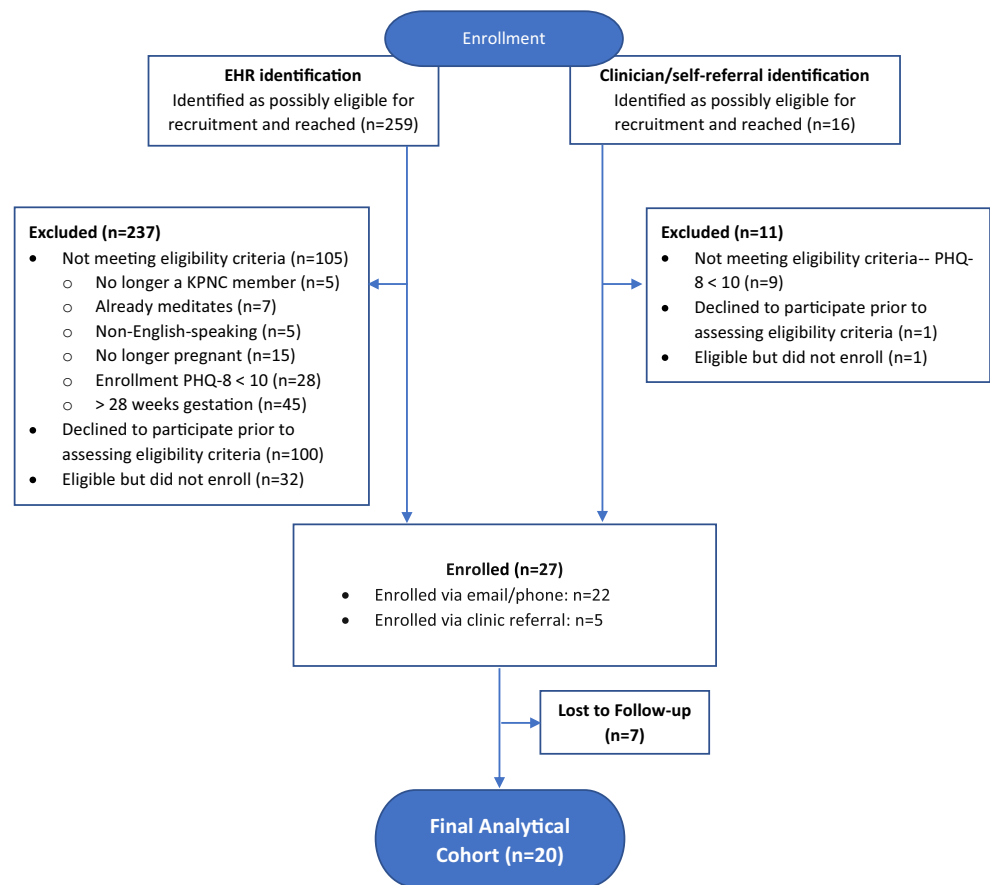
Method

Participants

We conducted a single-arm trial between March 2018 and May 2019. Women seeking antenatal care were recruited from 7 of the 44 Kaiser Permanente Northern California (KPNC) obstetrics and gynecology (OBGYN) clinics. Eligibility criteria included the following: age ≥18 years, Patient Health Questionnare-9 (PHQ-9) score 10–19 (indicating moderate-to-moderately-severe depression symptoms), <28 weeks of gestation, English-speaking, and access to a smartphone, tablet, and/or computer with Internet connection. Women who engaged in a regular mindfulness or meditation practice three or more times per week or were enrolled in a mindfulness program were ineligible.

A total of 531 women were identified to have a PHQ-9 score between 10 and 19 in the seven clinics. Among those, 275 were reached as potentially eligible participants ($n = 259$ through EHR databases, $n = 16$ from clinician referral) (Fig. 1). The primary reasons for exclusion were not meeting eligibility criteria ($n = 114$, 41%) and declining to participate ($n = 101$, 37%). The most common reasons for ineligibility were gestational age >28 weeks, current pregnancy ended in miscarriage, PHQ-8 score out of the eligible range, and existing meditation

Fig. 1 Overall flow of
participants through the study

Enrollment

EHR identification
Identified as possibly eligible for
recruitment and reached (n=259)

Clinician/self-referral identification
Identified as possibly eligible for
recruitment and reached (n=16)

Excluded (n=237)
- Not meeting eligibility criteria (n=105)
  - No longer a KPNC member (n=5)
  - Already meditates (n=7)
  - Non-English-speaking (n=5)
  - No longer pregnant (n=15)
  - Enrollment PHQ-8 < 10 (n=28)
  - > 28 weeks gestation (n=45)
- Declined to participate prior to
  assessing eligibility criteria (n=100)
- Eligible but did not enroll (n=32)

Excluded (n=11)
- Not meeting eligibility criteria-- PHQ-
  8 < 10 (n=9)
- Declined to participate prior to
  assessing eligibility criteria (n=1)
- Eligible but did not enroll (n=1)

Enrolled (n=27)
- Enrolled via email/phone: n=22
- Enrolled via clinic referral: n=5

**Lost to Follow-up
(n=7)**

**Final Analytical
Cohort (n=20)**

practice. The most common reasons for declining participation
were being too busy and lack of interest. A total of 27 partic-
ipants enrolled in the study.

Procedures

Setting

The study was conducted within KPNC, an integrated
health care delivery system serving over 4.4 million
racially- and socioeconomically-diverse members who are
representative of the Northern California population
(Gordon 2012, 2015). Standard antenatal care includes
screening for depression at two points during pregnancy
(first antenatal visit and glucola visit at 26–28 weeks of
gestation) using the PHQ-9 (Kroenke et al. 2001).

Recruitment

Potential participants were identified using two strategies: (1)
a universal perinatal depression screening PHQ-9 score of 10–
19 during pregnancy identified through the KPNC electronic
health records (EHRs) and (2) clinician referral or self-referral
from KPNC OBGYN clinical staff or study brochures.
Potential participants were contacted about the study via email

and phone by a research assistant and rescreened for depres-
sion symptoms using the PHQ-8 (see below for more infor-
mation). Women who met all eligibility criteria and had a
PHQ-8 score of 10–19 were enrolled. Informed consent was
obtained from all individual participants included in the study.
Participants then completed the baseline survey and received
access to the mHealth mindfulness program (details below).
Participants were asked to complete an online follow-up sur-
vey immediately after the intervention to assess patient-
reported outcomes, in addition to semi-structured interviews
within 3 weeks after the intervention to assess acceptability of
the intervention. Women who completed both baseline and 6-
week follow-up surveys received a $25 gift card and an addi-
tional year-long subscription to the mindfulness app. The
KPNC Institutional Review Board approved the study.

Intervention

The intervention used a commercially available mindfulness
program, Headspace™, which provides self-paced, guided
mindfulness meditations through a website or mobile applica-
tion (iOS and Android). Women were asked to use the app for
10–20 min a day over the 6-week study period. Each partici-
pant was given a study-specific log-in ID and instructed to
first complete the 30-day "Basics" course, which teaches users

the basics of mindfulness meditation. After that, they could choose other 10- to 30-day courses that are condition- or situation-specific, such as "Pregnancy," "Anxiety," "Relationships," or "Sleep," or single meditation sessions for the remainder of the 6-week study period. All Headspace courses teach mindfulness using various basic techniques, including breathing exercises, body scan, noting (being aware of any emotions that may be arising at the moment), and visualization (visualizing images such as sun shining on the entire body). In addition to the daily, progressive audio instruction, there are occasional short (1–2 min) lecture videos designed to increase the understanding of mindfulness and to encourage its integration into daily life. Headspace can be set up to send reminders using push notifications.

Measures

Feasibility

We assessed the feasibility of the intervention on the criteria outlined by Bowen et al. (2009). *Demand* was evaluated by calculating the number of women with a positive antenatal PHQ-9 screening score assessed by KPNC clinicians via routine screening and identified from the EHR. *Acceptability* was assessed through responses in a semi-structured interview. Women were asked open-ended questions about their experience with the study and with Headspace, recommended changes to the study procedures, and perceived need for additional health system support for pregnant women. Participants' responses were written down as close to verbatim as possible by the interviewer. *Implementation* was evaluated by measuring retention, which was calculated as the proportion of enrolled participants who completed both the baseline and post-intervention surveys. *Practicality* was operationalized as adherence to the mindfulness program. Date, duration, and name of each meditation were ascertained from Headspace for each participant using the study-specific log-in ID, enabling us to calculate adherence. *Integration* was assessed by asking participants during the semi-structured interview about perceived effects/benefits of practicing mindfulness and intention to continue using the Headspace program. *Expansion* focuses on the scalability of the intervention. *Preliminary efficacy* was evaluated by assessing change in patient-reported outcomes.

Depression

The 8-item PHQ-8 (Kroenke et al. 2009) depression screener is a validated instrument adapted from the PHQ-9 and was used to assess current depression symptoms at recruitment and follow-up. The PHQ-8 excludes the question regarding suicidal thoughts. PHQ-8 scores range from 0 to 24. A score of 1–4 suggests minimal depression, 5–9 mild depression, 10–

14 moderate depression, 15–19 moderately severe depression, and 20–24 severe depression. The PHQ-8 has been validated and reported to have an alpha coefficient of 0.82 (Pressler et al. 2011).

Stress

The 10-item Perceived Stress Scale (PSS-10) (Cohen and Williamson 1988) assesses to what degree a respondent perceives situations in his or her life in the past month as stressful through a 5-point Likert scale (0 = "Never" to 4 = "Very Often"). The scores are summed to give a total score ranging from 0 to 40. The PSS-10 has been demonstrated as having high internal consistency ($\alpha = 0.85$) (Smith et al. 2014).

Sleep Quality

The 19-item Pittsburgh Sleep Quality Index (PSQI) (Buysse et al. 1989) asks about sleep quality during the past month, including questions on sleep duration, sleep disturbance, and use of sleep-inducing medications. A global score, ranging from 0 to 21, is calculated using seven components of sleep. Higher scores indicate poorer sleep quality. In a study of pregnant women, the PSQI was validated at two time points: 15-23 weeks, and 29–39 weeks of gestation. Alpha coefficients were 0.70 and 0.76, respectively (Skouteris et al. 2009).

Mindfulness

The 24-item Five Facet Mindfulness Questionnaire short form (FFMQ-SF) (Bohlmeijer et al. 2011) uses a 5-point Likert scale to measure five factors representing elements of mindfulness: observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience. Responses vary between 1 ("never or very rarely true") and 5 ("very often or always true"). Higher scores indicate greater mindfulness. The FFMQ-SF has good reliability with alpha coefficients ranging from 0.80 (nonreactivity) to 0.90 (acting with awareness, describing, nonjudging) (Pelham et al. 2019).

Data Analyses

Baseline differences between completers and non-completers were assessed using ANOVA for continuous variables and Fisher's exact test for categorical variables. Mean and standard deviations were calculated for all participant-reported outcome measures. Change in score and *p* values were derived using paired *t* tests. Cohen's *d* effect sizes were calculated by dividing change in score by the standard deviation of change in score. All analyses were conducted using SAS v. 9.4 (Cary, NC).

Data from semi-structured interviews were uploaded into NVivo qualitative data analysis software (QSR International Pty Ltd., version 12, 2018.). Inductive thematic analysis was used to identify and develop codes on themes related to mindfulness benefits, the interface experience, experience with the study, and suggested changes. Two primary coders (MM and LN) coded each interview. A third coder (EK) reviewed all coded transcripts to ensure accuracy of codes.

Results

Baseline Characteristics

Patients who completed the study were more likely to be White (65%) and less likely to be Black (10%) or multiracial (5%), more likely to have at least a college degree (75%), less likely to be primigravid (65%), and more likely to be married (80%) compared to the women who did not complete the study (Table 1). Women who completed the study were slightly older than those who did not complete the study. Noncompleters had higher baseline PHQ-8 scores (15.7) compared with completers (13.5) and were slightly farther along in pregnancy (17.7 weeks of gestation) compared with completers (16.3 weeks of gestation). However, these differences were not statistically significant.

Demand

The number of women with moderate depression symptoms was high. Over 500 women in seven clinics had a PHQ-9 score of 10–19, among approximately 6400 pregnant women who were screened during the study period.

Acceptability

Fifteen participants (75%) completed a brief, post-intervention telephone interview. Ten participants (67%) who responded reported that they were either "very" or "extremely satisfied" with the Headspace app. Overall, participants felt it was easy to use, appreciated the convenience of the app (e.g., able to use at any time and any location), and liked the variety of meditation packs available. Some participants disliked the meditation facilitator's voice and reported they would have liked to have different voice options.

Implementation

The study had a high retention rate. Of the 27 participants, 20 (74%) completed the baseline and follow-up survey.

Practicality

Among the women who completed the study, 19 (95%) used Headspace at least once. Of the 19 participants, 11 (58%) practiced meditation ≥50% of the days during the 6-week study period, and five (26%) practiced ≥70% of the days. In addition, 53% of participants used Headspace at least once during the month after the intervention period ended. In addition to the Headspace "Basics" packs, the most frequently used packs included "Pregnancy," a 30-day program that uses a visualization technique to cultivate connection with the newborn, as well as to prepare for change in life; "Managing Anxiety," a 30-day program that uses "noting" and "body scan" techniques to manage anxiety; and other programs that help with sleep. Study staff called 18 women (67%) at least once during the study to remind them to engage in the intervention due to failure to complete at least three Headspace sessions in the previous week.

Integration

The most commonly reported perceived benefits of the meditation program were decreased anxiety, increased calmness, improved sleep, and being able to set aside time for themselves and to quiet their minds. Most felt that the first trimester was the best time to start the meditation program, preferably as early as possible after learning about the pregnancy. All participants interviewed said they were planning to continue using Headspace after the end of the study.

Expansion

The intervention used a commercially available mindfulness app. This makes the intervention scalable and widely implementable in a wide range of health care settings as it does not require training of facilitators or fidelity control.

Preliminary Efficacy

Compared to baseline, at the 6-week post-intervention follow-up, participants experienced significant improvements in depression symptoms ($-6.0, p \leq .01$), perceived stress ($-5.6, p \leq .01$), and sleep quality ($-1.9, p \leq .05$; with these findings indicating less sleep disturbance) (Table 2). Participants also achieved greater levels of mindfulness in four of five mindfulness domains (observing: $+1.4, p \leq .05$; describing: $+2.1, p \leq .01$; acting with awareness: $+3.2, p \leq .01$; nonreactivity: $+2.1, p \leq .05$) and significant improvements in overall mindfulness ($+10.6, p \leq .01$).

Table 1 Baseline demographic and clinical characteristics of participants

Baseline characteristics	Total n = 27	Completed n = 20	Not completed n = 7
Gestation (weeks), mean (range)	16.7 (9–30)	16.3 (9–29)	17.7 (13–30)
Parity, n (%)			
0	19 (70.4)	13 (65.0)	6 (85.7)
1+	8 (29.6)	7 (35.0)	1 (14.3)
Depression diagnosis[a], n (%)			
Pre-pregnancy	4 (14.8)	2 (10.0)	2 (28.6)
Pregnancy	3 (11.1)	2 (10.0)	1 (14.3)
Both	7 (25.9)	6 (30.0)	1 (14.3)
Neither	13 (48.2)	10 (50.0)	3 (42.9)
Baseline PHQ-8 score, mean (range)	14.0 (10–22)	13.5 (10–21)	15.7 (11–22)
Age, mean (range)	31.0 (19–39)	31.4 (19–39)	29.9 (20–39)
Race/ethnicity, n (%)			
White	16 (59.3)	13 (65.0)	3 (42.9)
Black or African American	3 (11.1)	2 (10.0)	1 (14.3)
Asian	1 (3.7)	1 (5.0)	0 (0.0)
Hispanic	4 (14.8)	3 (15.0)	1 (14.3)
Multiracial	3 (11.1)	1 (5.0)	2 (28.6)
Education, n (%)			
High school or less	3 (11.1)	2 (10.0)	1 (14.3)
Some college/vocational school	6 (22.2)	3 (15.0)	3 (42.9)
College graduate	18 (66.7)	15 (75.0)	3 (42.9)
Household income, n (%)			
<$100,000	15 (55.6)	11 (55.0)	4 (57.1)
≥$100,000	12 (44.4)	9 (45.0)	3 (42.9)
Medicaid status, n (%)			
Yes	5 (20.0)	4 (22.2)	1 (14.3)
No	20 (80.0)	14 (77.8)	6 (85.7)
Marital status, n (%)			
Married	20 (74.1)	16 (80.0)	4 (57.1)
Never married	7 (25.9)	4 (20.0)	3 (42.9)
Primary device used for mindfulness program, n (%)			
Android	6 (26.1)	6 (31.6)	0 (0.0)
iOS	15 (65.2)	13 (68.4)	2 (50.0)
Desktop	2 (8.7)	0 (0.0)	2 (50.0)

[a] Depression diagnosis codes were ascertained from the electronic health records for the period of 1 year prior to their pregnancy through study recruitment. Participants were categorized as having pre-pregnancy depression, antenatal depression, both, or neither based on the dates of the diagnosis and dates of current pregnancy

Discussion

Findings from this study using criteria from Bowen et al. (2009) suggest feasibility and acceptability of a self-paced mHealth mindfulness intervention for pregnant women with moderate-to-moderately-severe levels of depression. Participants appreciated the convenience of the intervention, and many learned mindfulness skills using mHealth technology. Although this study was not designed as an efficacy trial, the preliminary results of self-reported outcomes as well as semi-structured interviews suggest improvement in depression symptoms, stress, sleep, and mindfulness. These findings are important given the potential impact that this mHealth mindfulness intervention may have on reducing health care costs. Further, effective mHealth interventions for antenatal depression may help address the severe shortage in mental health care resources, which has been exasperated during the COVID-19 pandemic. The methods used provide a practical strategy for conducting a larger, fully powered trial, and information gained from this feasibility study will provide

Table 2 Baseline and post-intervention outcome measures

Outcome	Possible score range	Baseline Mean (SD)	Post-intervention Mean (SD)	Change Mean (SD)	Cohen's d	p value
Patient Health Questionnaire (PHQ-8)	0–24	13.5 (3.5)	7.5 (4.4)	−6.0 (5.5)	−1.1	<.001
Perceived Stress Scale (PSS-10)	10–40	24.5 (5.7)	18.9 (6.4)	−5.6 (7.3)	−0.8	.0027
Pittsburgh Sleep Quality Index (PSQI)	0–21	10.9 (3.8)	9.1 (3.9)	−1.9 (3.3)	−0.6	.0224
Five Facet Mindfulness Questionnaire (FFMQ)						
Observing	4–20	13 (3.8)	14.1 (3.5)	1.4 (2.8)	0.5	.0467
Describing	5–25	17.4 (3.7)	19.5 (3.7)	2.1 (2.3)	0.9	<.001
Acting with awareness	5–25	14.1 (2.9)	17.3 (3.8)	3.2 (3.4)	0.9	<.001
Nonjudging of inner experience	5–25	13.2 (3.5)	14.9 (4.1)	1.8 (4.5)	0.4	.0987
Nonreactivity	5–25	12.7 (3.9)	14.8 (3.2)	2.1 (3.5)	0.6	.0184
Total	24–120	70.3 (11.3)	80.6 (13.1)	10.6 (11.7)	0.9	.001

important insights to increase the likelihood of a successful future study.

Mindfulness is a mental state achieved by focusing one's awareness on the present moment with an attitude of non-judgment (Kabat-Zinn 1990). The theoretical basis for mindfulness derives from a model based on studies of the influence of mindfulness on brain regions involved in learning and memory processes, emotion regulation, self-referential processing, and perspective taking (Holzel et al. 2011a, b). A recent meta-analysis of nine studies targeting depressed adults (75% women) reported that those who received the mindfulness-based intervention had a significantly reduced risk of depression relapse (5-year follow-up period) compared with those in the control group (hazard ratio, 0.69; 95% CI, 0.58–0.82) (Kuyken et al. 2016). Similar to our findings, a recent meta-analysis of eight randomized controlled trials of pregnant women concluded that women in the in-person mindfulness arm experienced significant reductions in depression, anxiety, and other quality of life measures with small to medium effect sizes (Lever Taylor et al. 2016). Thus, mindfulness programs have promise as non-pharmacological interventions to help women suffering from depression.

The accessibility challenges of in-person mindfulness training and the recent COVID-19 pandemic underscore the need for accessible and robust resources for mental health, with high priority in an extremely vulnerable population—pregnant women. A recent survey found that the COVID-19 pandemic has had a significant impact on the mental health of pregnant and postpartum women with over a third of women reporting significant depression symptoms (American Psychiatric Association 2020). This increase in the number of women with antenatal depression symptoms is coupled with a surge in demand for mental health care. The mental health care system nationwide was suffering from a shortage of providers prior to the COVID-19 pandemic (Andrilla et al. 2018; Kaiser Family Foundation n.d.; Walker et al. 2015). Now, months into the COVID-19 outbreak, mental health care

providers are in extreme shortage (Li 2020; Panchal et al. 2020). The pandemic has also forced health care services, including mental health care, to be delivered remotely (Bojdani et al. 2020). Thus, there is an urgent and critical need for the identification of remotely-delivered, scalable, and effective interventions.

There have been a limited number of studies that have used the Internet to deliver mindfulness interventions to pregnant women. A study conducted in China that targeted pregnant women with mild or moderate symptoms of depression and anxiety found that an Internet-based mindfulness intervention improved depression and anxiety (Yang et al. 2019), while a UK-based study did not find a significant benefit of a Web-based intervention, mainly due to high attrition rates (22 out of 107 in intervention arm completed the study) (Krusche et al. 2018). There are also a few other studies using Web-based mindfulness interventions that are currently underway, though the results are not yet available (Cohen and Dimidjian 2018; Hulsbosch et al. 2020). The present study differs from these studies because we used a self-paced, mobile-based intervention that does not require logging into sessions at specified time. To our knowledge, there has not been any mHealth mindfulness study targeting pregnant women with depressive symptoms. Other studies that used Headspace have demonstrated a reduction in stress and improvement in well-being in general populations (Champion et al. 2018; Economides et al. 2018). Further, research has demonstrated a reduction in distress and improvement in quality of life for cancer patients using the Headspace intervention (Kubo et al. 2018, 2019, 2020).

In the present study, the participants appreciated the intervention because of the ease of using the program and the short dosage (10–20 min a day). They also welcomed the fact that they could use their mobile phone or computer to engage in the intervention without having to leave home or work to attend in-person classes. Most women we reached had access to the technology to receive the mHealth intervention, and

among those who enrolled, very few participants had trouble downloading or using the app. Nearly a quarter of our sample received Medicaid benefits at study baseline, highlighting the potential for mHealth mindfulness-based interventions to reach women of low socioeconomic status with moderate-to-moderately-severe antenatal depression symptoms. This is important as these women often do not have access to more traditional treatment options (e.g., psychotherapy) for antenatal depression. Mobile devices are increasingly used by all segments of the population, with approximately 90% of Americans of reproductive age owning a smartphone (PEW Internet and American Life Project 2017). If this mHealth mindfulness intervention is found to be effective, it may serve as a low-cost strategy to help a large number of women suffering from antenatal depression with limited access to care. Lastly, half our sample experienced moderate-to-moderately-severe depression symptoms that did not reach the threshold for a clinical diagnosis. The US Preventive Services Task Force's recent recommendation to refer all women at increased risk of perinatal depression to counseling services will be met with the patient-level barriers (e.g. costs, time) as well as challenges from the health care system, which is already suffering from a shortage of mental health care providers (Avalos et al. 2019; Felder 2019; Freeman 2019; O'Connor et al. 2019; Wisner et al. 2019). Findings from this study suggest the feasibility of an mHealth mindfulness-based intervention for women at increased risk of perinatal depression if future studies provide evidence of efficacy of mHealth mindfulness-based interventions in this population.

Although this was a feasibility study that was not designed to be an efficacy study, we observed a reduction in depression scores after the intervention. The decrease in mean post-PHQ-8 scores to below the threshold for a positive screen (PHQ-8 score of 10 or greater) accompanied by a nearly 50% reduction in symptoms highlight the clinical significance of the improvement in depression symptom burden (Kroenke et al. 2009). Although the pre- and post-perceived stress scores both correspond to a moderate level of stress (PSS scores between 14 and 26), we documented a reduction in symptoms of perceived stress of nearly a quarter (24%) (Cohen et al. 1983). A 20% reduction in the sleep quality score was noted, although the mean post-score did not fall below the threshold of 5, and scores were still indicative of poor sleep quality (Akman et al. 2015).

A few lessons were learned from this feasibility study. First, the recruitment rate was higher when clinicians referred patients to the study compared to when study staff reached out about the study. This underscores the importance of engaging clinicians when conducting intervention studies to maximize recruitment rates. Second, we tracked participants' app usage and reached out when there was an extended period of inactivity (i.e., <3 sessions in the past week). This helped remind some participants to get back on track with the app. Using the

reminder features and push notification built into the app may also be useful as a reminder given the proportion of women our study team reached out to with reminder calls. Additionally, automatic tracking of progress can be used as a source of motivation to continue using the program. Such interactive features of a mobile app can increase its adherence and effectiveness, and ease of using the app can facilitate widespread, efficient implementation (Hebden et al. 2012).

Limitations and Future Research Directions

The present study has several limitations. First, since it is a small single-arm feasibility study, we cannot draw conclusions regarding the efficacy of the intervention on participant-reported outcomes or assess dose-response relationships. However, the purpose of the study was to determine feasibility and acceptability, which we were able to demonstrate. The preliminary efficacy results on patient-reported outcomes were promising and provided tentative effect size estimates to conduct an empirically informed power analysis for a larger randomized control trial. Second, because we required the use of technology as part of the intervention, the study findings may not be generalizable to the general population due to the "digital divide." However, as noted, the majority of the women we attempted to recruit owned mobile devices or computers with an Internet connection, and a quarter of our sample were on Medicaid. The main reasons reported for declining to participate were lack of time or interest, not lack of access to technology. Third, as in most intervention studies, the women who completed and those who dropped out were slightly different from each other, potentially affecting the generalizability of the results. However, unlike most previous studies of mindfulness interventions which tend to be predominantly among Whites, this study enrolled women of minority backgrounds as well as low-income women. Future studies focusing on these vulnerable populations would help reduce health disparities with regard to access to mental health care. Fourth, non-English speakers were ineligible because the intervention is only offered in English. Future mindfulness-based studies should incorporate other languages given the high burden of depression among minority populations (Mukherjee et al. 2016).

Given the promising results from this feasibility study, larger-scale randomized trials are needed to establish the efficacy and durability of mHealth mindfulness interventions in this population. Pragmatic trials of this type of intervention within large health care systems will help provide evidence regarding the effectiveness of implementing a low-cost, technology-based program for pregnant women suffering from moderate-to-moderately-severe depression symptoms, with a goal of improving the health of both mothers and the offspring.

Declarations

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