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Mindfulness yoga during pregnancy for psychiatrically at-risk women: Preliminary results from a pilot feasibility study

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ABSTRACT

Keywords: Yoga Mindfulness Depression Pregnancy Maternal-fetal attachment

Prenatal psychopathology may have an adverse impact on mother and baby, but few women receive treatment. We offered a 10-week mindfulness yoga (M-Yoga) intervention to psychiatrically high-risk pregnant women as an alternative to pharmacological treatment. Participants (N=18) were primiparous, 12-26 weeks pregnant, and had elevated scores (>9) on the Edinburgh Postnatal Depression Screen at baseline. In addition to a baseline diagnostic assessment, women completed self-ratings on depression, mindfulness, and maternal-fetal attachment before and after M-Yoga. Findings suggest that M-Yoga was feasible, accepted and effective. Symptoms of depression were significantly reduced (p=0.025), while mindfulness (p=0.007) and maternal-fetal attachment (p=0.000) significantly increased. Overall, this pilot study is the first to demonstrate that M-Yoga may be an effective treatment alternative or augmentation to pharmacotherapy for pregnant women at high risk for psychopathology.

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1. Introduction

Psychopathology during pregnancy is a serious health concern^{1–3} with perinatal major depression (MDD) impacting 1 in 5 women and⁴ perinatal anxiety affecting 1 in 10 women.⁵ Cooccurrence of MDD and anxiety is high and treatment is complex with modest success rates.^{5,6} Hormonal changes, genetic predisposition and social factors can set up an expectant mother for many debilitating symptoms, including persistent depressed mood or irritability, feelings of being easily overwhelmed, and decreased ability to cope with stress.⁷ Untreated antenatal psychopathology bears major health risks for both mother and unborn child such as poor weight gain, preeclampsia, premature labor and trouble bonding with the unborn baby.^{2,3,8–10} Thus, from a public health perspective, development of feasible treatment modalities for pregnant women suffering psychiatric conditions is critical.

Unfortunately, few women suffering from perinatal mental health disorders receive treatment, leaving them and their children exposed to the negative impact of psychiatric illness during this vulnerable period. ^{11–14} While antidepressant medications have been proven effective to treat antenatal mood disorders, ¹⁵ many

pregnant women are reluctant to take these drugs due to concern for their infant's safety. ^{16,17} In fact, up to 50% of women taking antidepressants prior to conception choose to discontinue medication, creating risk for relapse of symptoms during their pregnancy. ¹⁵ Many women prefer psychosocial treatments, but face psychological and practical barriers to treatment initiation and adherence while pregnant. ¹⁸

When traditional treatments are rejected or feared, there is evidence ¹⁹ to suggest that women may feel more comfortable with the options offered by complementary and alternative medicine (CAM), including herbal medicine, relaxation techniques, and mind-body work. Despite limited empirical research, CAM methods are becoming more popular²⁰ among pregnant women, suggesting that pregnancy may be a time when CAM is more acceptable to the average women, possibly serving as a gateway to effective treatments for women who may have never considered CAM before becoming pregnant.

1.1. Why mindfulness yoga?

Yoga is an ancient practice that originated in India thousands of years ago, and involves meditative focus combined with physical poses. Kabat-Zinn²¹ defines the practice of mindfulness as being fully present in the moment, without judgment or correction, starting with simple awareness of one's body and thoughts. Inherently, the human mind judges each experience we have as positive or negative, while striving for a particular outcome and becoming disappointed if that outcome is not achieved.

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Mindfulness practice gently pulls the mind out of this pattern by observing each experience with an attitude of curiosity, nonjudgment, and patience, focusing on what is happening in the present moment, instead of worrying about the future or regretting the past. Yoga alone has been shown to have many positive health effects, from reducing stress and improving chronic pain to decreasing the incidence of symptoms associated with psychiatric illnesses.^{22–26} In addition, mindfulness practice alone has been shown to successfully decrease perceived stress and depressive symptoms while increasing energy and psychological wellbeing.^{27–29} In the United States, yoga is frequently taught in gymlike settings, resulting in an epidemic of classes that omit mindfulness and concentrate on yoga as "exercise" meaning that "yoga and mindfulness" are often not synonymous for a beginning yoga student. Thus, the intentional combination of yoga and mindfulness practice can be powerful, increasing stress tolerance and sleep quality and decreasing psychological distress and chronic pain intensity.^{30–33} Mindfulness and yoga are natural partners during times of stress and physical pain, and may be particularly useful as the body progresses through the normal physical and emotional changes of pregnancy.

Research on the impact of mindfulness yoga on pregnant women is limited, but encouraging. Several studies support the acceptability of prenatal yoga among women seeking treatment for antenatal depression. S4-37 Mindfulness practice and yoga have been shown to decrease the perception of pain during labor, reduce physical discomfort during pregnancy and significantly reduce stress. S6.38.39 In addition, Vieten and Astin²⁹ found that a prenatal mindfulness-based intervention alone significantly reduced anxiety and negative emotions.

To date, no research has examined yoga as a treatment for antenatal psychopathology. Only one study 40 examined the impact of mindfulness yoga (M-Yoga) on the emotional and physical distress of healthy pregnant women in the United States, finding that an intervention combining Iyengar yoga and mindfulnessbased stress reduction (MBSR⁴¹;) significantly decreased emotional stress and physical pain. However, since women meeting criteria for current psychopathology were excluded in this study, it is unclear whether benefits of M-Yoga are limited to healthy women or can be generalized to pregnant women with psychiatric illness. The present study is the first attempt to close this gap in the literature; we explore the feasibility, acceptability, and efficacy of M-Yoga in reducing symptoms of depression among pregnant women with current and lifetime psychiatric diagnoses in an open trial format using a convenience sample. We hypothesize that prenatal yoga will improve antenatal depression through the following mechanism: M-Yoga will enhance women's mindfulness and maternal-fetal attachment, which in turn will lead to an empowered and positive feeling towards pregnancy and motherhood and subsequently contribute to reduced symptoms of depression.

2. Materials and methods

2.1. Recruitment

All study procedures were approved by the institutional review board of the University of Michigan Medical School. Informed consent, including an explanation of potential risks and benefits, was obtained from all subjects prior to data collection. Participants were recruited through a university-based perinatal psychiatry clinic and flyers posted in the community. Women were invited to participate in a free 10-week prenatal "Mindfulness Yoga" class to improve wellbeing and decrease stress. Forty-nine women were screened for eligibility within a 4-week period in the fall of 2009,

and 22 met eligibility requirements for the study. Eligible women were primiparous, age \geq 18, English-speakers, not taking psychotropic medications, \leq 26 weeks gestation and scored 9 on the EPDS depression screen. Women in psychotherapy, practicing yoga or those with medical problems (pre-existing or pregnancy-related) were not excluded from the sample. Each eligible woman underwent a psychiatric diagnostic interview at baseline to assess both past and present DSM-IV diagnoses. Exclusion criteria included active substance abuse, psychosis and suicidality.

Of the initial 22 women entering the study, two dropped out after attending only one class; one due to transportation problems and the other due to back problems unrelated to yoga; thus only 20 women participated in the intervention. Lastly, for the final outcome measures, two more women did not complete surveys after the last yoga class (premature delivery; relocation) reducing the sample size to n = 18.

2.2. Participants

Women enrolled in the study were predominantly Caucasian, partnered, college-educated and carried low socioeconomic risk (Table 1). Half of the sample had an active Axis I diagnosis at baseline according to DSM-IV-TR, ⁴⁴ and over 85% had a lifetime psychiatric diagnosis, as assessed by the SCID⁴³ (Table 1). Depression symptom severity at baseline and post-intervention was assessed using the Beck Depression Inventory-II (BDI-II). ⁴⁵ Nine participants were also engaged in outside psychotherapy while undergoing the M-Yoga class. There were no adverse events related to study participation.

Table 1Participant demographic and mental health baseline characteristics.

| Participant characteristics ($N = 22$) | % Frequency |
|--|---------------|
| | (N) or M (SD) |
| Age | 32.41 (4.98) |
| Gestational age at baseline (in weeks) | 21.80 (5.96) |
| Ethnicity | |
| Minority | 27% (6) |
| Caucasian | 72% (15) |
| Education | |
| <bachelors degree<="" td=""><td>14% (3)</td></bachelors> | 14% (3) |
| Bachelors degree only | 32% (7) |
| Masters degree or higher | 60% (12) |
| Marital status | |
| Single | 28% (5) |
| Living with partner | 72% (17) |
| Income | |
| Under 25,000 | 0% (0) |
| 25,000-50,000 | 15% (3) |
| More than 50,000 | 45% (9) |
| Refused/missing | 40% (10) |
| Current psychopathology ^a | |
| No diagnosis | 50.0% (11) |
| Major depression | 9.1% (2) |
| Post-traumatic stress disorder | 18.2% (4) |
| Anxiety disorder (GAD, Phobias, Panic Disorder) | 45.5% (10) |
| Substance abuse/dependence | 0% |
| Past psychopathology ^a | |
| No diagnosis | 13.6% (3) |
| Major depression | 54.5% (12) |
| Post-traumatic stress disorder | 36.4% (8) |
| Anxiety disorder (GAD, Phobias, Panic Disorder) | 9.1% (2) |
| Substance abuse/dependence | 45.5% (10) |

Note: Income is measured in categories 1-21 in 4 k increments: 18 = 85-89 k, 12 = 55-59 k.

Minorities included: 2 Latinas, 1 African-American, 1 Bi-racial, 1 Native-American, 1 Other.

^a Axis I diagnosis assessed with SCID, 73% of participants had more than one diagnosis.

2.3. Design

The M-Yoga open feasibility trial was facilitated by two instructors, both Master's level clinicians, certified in prenatal yoga and experienced in mindfulness techniques. Each 90-min session focused on a variety of poses, all taught specifically for the pregnant body, with awareness of the baby and modified for any level of experience or gestational age. Classes met once per week. Two 10 session mindfulness yoga classes ran consecutively, each with 10 participants who completed the full series of sessions; one class took place during evening hours and the other during the day. Both classes received the same intervention, taught by the same instructors. Materials used during M-Yoga, such as mats, bolsters and straps, were provided by the research study.

The M-Yoga curriculum differed from typical prenatal hatha yoga classes by highlighting mindfulness practice, with targeted instructions, reminders, and readings. Participants were taught mindfulness techniques including breathing, guided visualization and relaxation. The instructors consciously made it a part of class to continually remind women to focus inward toward the sensations of their body, listen to the feedback of body during asana, and be aware of how their bodies are changing to support their growing baby. A significant aspect of the intervention was being "mindful" of the baby, to sense its unique persona, which in turns facilitates the attachment process. In addition, having the word "mindfulness" in the title of the class/ study continually brings that awareness to the forefront.

Sessions opened with a 10-15 min check-in, allowing each woman to share how she was feeling physically and emotionally with the group. Teachers customized the poses and instruction to address participants' current issues, cultivating a supportive atmosphere. For example, if irritability was an issue, instructions included finding compassion towards oneself as the body experiences the hormonal changes of pregnancy. If heartburn was an issue, poses were taught with an emphasis on creating more space between the chest cavity and throat. Each class included seated, kneeling, standing, and restorative poses. The instructors demonstrated each pose while including descriptions of Kabat-Zinn's⁴⁶ seven qualities of mindfulness: allowing presence, non-judging, patience, beginner's mind, non-striving, acceptance and letting go. The instructors used directives, such as "Practice the pose for your body without judgment" and "Bring your attention to your breath, always practicing with awareness of your growing baby". See Table 2 for more examples. Techniques supported women's comfort with their changing body, prepared the body and mind for the birthing

Table 2 Examples of M-Yoga instructor's language.

Bring your awareness and focus inward to your breath Watch your inhalation and your exhalation Allow your inhalation to bring an extension to your spine Allow your exhalation to bring a release of your shoulders Observe the base of your posture equally balancing your weight on the four corners of each foot Move into the posture without jerking or forcing Observe your breath and body without commenting or analyzing Observe and accept where your body is today, moving with awareness and modifying the pose as necessary Bring your attention to your breath and to your center where your baby is, always practicing with awareness of your growing baby Inhale the breath and lengthen the spine, on your exhalation move into Start the pose from afresh as we repeat it on the second side Practice the pose for your body today without judgment Observing if you need to come of a pose, and coming out of the pose with the same awareness and attention as we had going into the pose Release more completely into the pose with each exhalation Relinquish your will to do, and allow yourself to be in the pose

experience, and focused awareness on the fetus. To ensure women's safety, modifications for all poses were offered and participants were reminded throughout the practice to listen to the body's cues, when to move deeper in a pose and when to slow down. Classes ended with a 15–20 min restorative pose, including a full-body relaxation exercise, along with a reading from a text such as *Everyday Blessings: The Inner Work of Mindful Parenting.*⁴⁷ Finally, sessions concluded with a 5–10 min informal interaction while participants prepared to leave. Instructors and participants did not interact outside the class context, and we did not facilitate peer interactions among participants outside the M-Yoga class. Women were encouraged to also practice at home, but compliance was not assessed.

2.4. Measures

Participating women underwent an initial psychiatric interview, and completed self-report questionnaires about depression, mindfulness, and maternal-fetal attachment, at baseline and after the final yoga class.

- 1. The Structured Clinical Interview for DSM Disorders (SCID I N-P)⁴³ is a clinician-based diagnostic interview deriving a DSM-IV Axis I diagnosis,⁴⁴ administered prior to the intervention. The SCID modules assess the presence of current and past psychopathology, specifically Mood Disorder, Psychotic Symptoms, Eating Disorders, Anxiety Disorders, and Substance Disorders. Available data suggest good inter-rater reliability for Major Depressive Disorder ($\alpha=0.61-0.80$) and PTSD ($\alpha=0.77-0.88$) and is seen as the "gold standard" among diagnostic interviews.^{48,49}
- 2. The *Edinburgh Postnatal Depression Scale* $(EPDS)^{50}$ was used to determine eligibility; a cut-off score of ≥ 9 was used.⁴² Items are scored on a 4-point scale (0-3), and scores ranged from 0-30.⁵¹ Available data suggest good reliability $(\alpha=0.87)$ and positive predictive value (83%).⁵¹
- 3. The *Beck Depression Inventory (BDI-II)* is a 21-item survey designed to measure the severity of symptoms of depression, such as loss of interest, guilty feelings and worthlessness. ⁴⁵ Items are scored on a 4-point scale (0–3), ranging from 0 to 63, with higher scores indicating greater symptomatology. A score of 0–13 indicates minimal depression, 14–19 mild depression, 20–28 moderate depression and 29–63 severe depression. ⁵² Among psychiatric samples, the internal reliability of the BDI-II has ranged from a = 0.89 to a = 0.92. ⁴⁵
- 4. The *Five Facet Mindfulness Questionnaire-Revised (FFMQ-Revised)* assesses for elements of mindfulness in five areas: Observing (paying attention to stimuli), Describing (labeling the sensation of stimuli), Acting with awareness (purposefully attending to stimuli), Non-Judging (not criticizing one's inner experience), and Non-Reactivity (allowing thoughts and emotions to come and go, without reaction).⁵³ Items are scored on a 5-point scale (1−5), ranging from 39 to 195, with higher scores reflecting greater mindfulness. The FFMQ-Revised has shown good internal consistency in several samples, with Chronbach's alphas ≥0.80.⁵³
- 5. The *Maternal Fetal Attachment Scale (MFAS)* is a 24-item scale that assesses for maternal-fetal attachment during pregnancy, made up of five factors, Role Taking ("I picture myself feeding the baby"), Differentiation of Self from Fetus ("I enjoy watching my tummy jiggle as the baby kicks inside"), Interaction with Fetus ("I poke the baby to get him/her to poke back"), Not Attributing Characteristics to the Fetus ("It seems the baby kicks and moves just to keep me from resting") and Giving of Self ("I feel all the trouble of being pregnant is worth it"). Available data suggests good reliability, with subscale

- Cronbach's alphas ranging from 0.52 to 0.73, and a total score alpha of 0.85. 54
- 6. Women completed a brief feedback survey regarding acceptability of the intervention.

3. Results

3.1. Psychopathology and baseline characteristics

Women with and without current psychopathology did not differ on demographic characteristics (Table 1). Thus, we did not control for demographics in all subsequent analyses. The eighteen participants attended on average 7.83 sessions (SD = 1.62); eleven (55%) participants attended at least 8 or more groups, and 3 (16%) only attended 5 groups.

3.2. Acceptability

Overall, women felt M-Yoga was a helpful coping strategy and benefited the child as well ("Yoga helped me to cope with a high-risk pregnancy—and my son is the most calm and gentlest of souls. The stress reduction REALLY helps the baby, too"). Social support of group was highlighted ("Hearing from the other moms made me feel much less alone,"and "I really benefitted emotionally from sharing with the other participants and benefitted physically from breathing and relaxation exercises.") Teaching content and instructors were perceived positively ("The breathing and mindfulness exercises allowed me to have the delivery I wanted. It was perfect." or "I loved all of it—the readings were excellent and the instructors have a true passion for helping pregnant women".)

3.3. Stability and treatment effects from before to after M-yoga intervention

We calculated the correlation coefficients from pre-to postintervention for all measures (Table 3), demonstrating a negative correlation between baseline depression symptoms (BDI-II) and post-intervention mindfulness skills as well as negative correlations between both baseline mindfulness and maternal-fetal attachment with post-intervention depression symptoms (BDI-II). Futhermore, we calculated the stability coefficients from pre-to postintervention for mindfulness (r(18) = 0.85, p < 0.001), maternal-fetal attachment (r(18) = 0.62, p < 0.01), and depression (BDI-II) (r(18) = 0.64, p < 0.01). Postintervention BDI-II depression scores were significantly and inversely related with baseline mindfulness (r(18) = -0.470, p < 0.05) and maternal-fetal attachment (r(18) = -0.549, p < 0.05); these associations were even stronger for concurrent postintervention mindfulness (r(18) = -0.547, p < 0.05) and maternal-fetal attachment (r(18) = -0.591, p < 0.05).

3.4. Intervention effects

Eighteen women provided post-intervention assessments. Using paired *t*-tests, we explored changes on all outcome variables

Table 3 Correlations between pre and post group measures.

| Measures | Post depression (BDI-II) | | Post maternal- fetal attachment |
|--|-----------------------------|--------------------|------------------------------------|
| Pre depression (BDI-II) Pre mindfulness | 0.642** -0.470* | -0.556* 0.853** | -0.272 0.234 |
| Pre maternal-fetal attachment | -0.549* | 0.004 | 0.623** |

p < .05 and p < .01.

Table 4 Intervention effects.

| | Time point | | | | | | | |
|-------------------------------|------------------------|--------------------|-------|----|-------------|--|--|--|
| | Before intervention | After intervention | t | df | р | | | |
| Maternal psychopathology | | | | | | | | |
| BDI score | 13.95 (6.84) | 9.63 (6.99) | 2.40 | 17 | 0.025* | | | |
| EPDS score | 12.45 (3.41) | 7.60 (4.16) | 4.41 | 19 | 0.000** | | | |
| Mindfulness | | | | | | | | |
| Total | 131.17 (14.23) | 137.56 (16.79) | -3.09 | 17 | 0.007** | | | |
| Observe | 27.78 (3.95) | 29.28 (3.56) | -1.92 | 17 | 0.072^{a} | | | |
| Describe | 27.06 (4.00) | 27.61 (3.68) | -1.13 | 17 | ns | | | |
| Awareness | 27.50 (3.76) | 28.11 (4.57) | 65 | 17 | ns | | | |
| Non-judgment | 28.89 (6.25) | 28.94 (6.76) | -2.20 | 17 | 0.042* | | | |
| Non-react | 21.94 (4.76) | 23.61 (5.29) | -1.71 | 17 | ns | | | |
| Maternal-fetal attachment | | | | | | | | |
| Total | 83.56 (10.12) | 95.50 (10.53) | -5.65 | 17 | 0.000** | | | |
| Role taking | 17.39 (2.45) | 18.23 (2.08) | -2.30 | 17 | 0.035* | | | |
| Diff of self from fetus | 14.17 (2.96) | 17.06 (2.41) | -4.96 | 17 | 0.000** | | | |
| Interaction with fetus | 16.67 (3.16) | 19.22 (3.42) | -4.21 | 17 | 0.001** | | | |
| Not attrib. char. to fetus | 17.72 (3.34) | 22.67 (4.33) | -3.99 | 17 | 0.001** | | | |
| Giving of self | 19.78 (3.00) | 22.22 (2.05) | -3.04 | 17 | 0.007** | | | |

p < 0.05 and p < 0.01.

from pre-to post-intervention (Table 4). As 9 women were enrolled in outside psychotherapy, we investigated treatment effects based on psychotherapy; psychotherapy enrollment did not affect M-Yoga outcomes, and thus was not controlled for in analyses. There was a significant reduction in depressive symptoms as measured by both the BDI-II and EPDS. Mindfulness skills (FFMQ-Revised) total score improved significantly over the intervention. This result was mainly driven by significant results on the Non-Judgment subscale. Finally, maternal-fetal attachment (MFAS) significantly increased overall and on all five subscales.

4. Discussion and conclusion

While conventional treatments for psychopathology are well researched and many are widely accepted, pregnant women may be reluctant to utilize standard treatment modalities due to possible risks to the unborn child. It is crucial to explore more acceptable treatments. Our findings suggest that the M-Yoga intervention is acceptable to the target population. We found that M-Yoga reduced depressive symptoms in pregnant women. Given small sample size, we did not have adequate representation of mildly, moderately or severely depressed women and thus were unable to make inferences about the efficacy of M-Yoga based on depression severity. However, we speculate that M-Yoga may prove beneficial if offered as an adjunctive treatment mode in combination with traditional pharmacotherapy or psychotherapy for pregnant women struggling with symptoms of depression. Future studies should include a sufficiently large sample with a wide range of depression severity in order to make more concrete conclusions.

As predicted, the intervention appeared to positively impact participants' mindfulness skills, helping them to experience the present moment with an attitude of curiosity instead of judgment. This was expected as the intervention specifically targeted the capacity for mindfulness through selected readings and the guided focus on body awareness. Finally, it appeared that a potentially positive impact of M-Yoga was in the maternal-fetal attachment domain, with improvement in overall total score as well as all five

 $^{^{}a}$ p < 0.10.

subscale scores. The MFAS measured how often mothers engage in behaviors that indicate interaction and connection with their unborn child,⁵⁴ meaning that women who completed the intervention became more comfortable assuming the role of a mother, enjoyed interaction with the fetus and were more likely to engage in healthy behaviors because of the pregnancy. This increase in fetal attachment suggests that M-Yoga provided a supportive environment in the transition to motherhood, as well as an opportunity to engage in healthy behaviors for the group as a whole.⁵⁵ The improvements in maternal-fetal attachment were independent of depression symptom level and current psychopathology.

Limitations of this study include the small sample size, the homogeneity of the sample population and the lack of a control group. In addition, we relied upon self-report of symptoms after the intervention rather than interviewer-rated assessment of some key outcomes (BDI-II). Finally, we did not measure symptoms of anxiety, which would have been useful considering that nearly half our sample (45.5%) met criteria for an anxiety disorder at baseline. However, the majority of our participants (54.5%) met criteria for past MDD and all participants scored ≥9 on the EPDS at baseline, indicating they were at-risk for developing MDD during pregnancy, we feel that depression is an appropriate primary outcome variable. Despite a small sample size, data collected provides a solid foundation for future research in terms of documenting feasibility and acceptability of this intervention. It is notable that we were able to recruit our sample very quickly due to tremendous response and in fact were required to turn away several women after meeting our recruitment goal. Verifying our results with a larger, more diverse sample will be important; given the interest we observed during the recruitment phase, obtaining such a sample appears realistic. Our sample consisted primarily of white, highly educated, partnered, and financially comfortable women open to alternative treatments for psychopathology. While we attempted to make the classes accessible to women of different socioeconomic backgrounds and employment status by offering classes during the day and evening, enrollment in the classes was determined in part by distance traveled and was thus limited to women who had reliable transportation. More research is needed to explore the effects of M-Yoga on pregnant women who are unpartnered, under age 25, from diverse ethnic backgrounds and with fewer resources (education, income, etc). Finally, the lack of a control group does not allow us to separate the effects of M-Yoga and the social support created by meeting weekly with other pregnant women and two familiar instructors. Future research would benefit from recruiting a group who practices yoga at home using a DVD or a group that meets weekly for group exercise such as walking to use as a control in order to determine which mechanism has the greatest impact on outcomes.

Our work provides promising first evidence that mindfulness yoga may improve depression symptoms, promote a mindful stance towards pregnancy and enhance mother's attachment towards her child, which in turn, is a long-term gain promoting child wellbeing. This study builds on the work of Beddoe et al, 40 Vieten & Astin²⁹ and Battle et al, 35 demonstrating the feasibility and acceptance of mindfulness yoga during pregnancy, yet for the first time targeting a high-risk population with historical and active psychiatric disorders.

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Conflict of interest statement

The authors declare that they have no conflict of interest.

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