Mindfulness for Pregnancy: A Randomised Controlled Study of Online Mindfulness During Pregnancy

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**Abstract**

Objective

Prenatal depression, stress and anxiety are significant predictors of postnatal depression and also have a direct negative impact on the family. Helpful psychological interventions during pregnancy are scarce and expensive, and usually only available for a small percentage of those suffering or deemed to be at risk. The aim of this study was to evaluate the potential of an online mindfulness course for expectant mothers.

Design

A randomised study was conducted to explore differences between control and active participants allocated to take an online mindfulness course, offered free to research participants, or wait.

Setting

The course provided was online and already available but given to study participants for free. Measures were also taken online using a secure site to collect the data.

Participants

185 mothers were recruited and randomised to the online course (*n* = 107) or a waitlist control (*n* = 78), with 72 completers at post-course (*n* = 22 active, *n* = 50 control) and 48 completers at postnatal follow-up (*n* = 16 active and *n* = 32 control).

Intervention

The online mindfulness course is available at www.bemindfulonline.com and comprises a four-week, condensed version of an eight-week mindfulness course, with videos and written instructions for guided meditation and other mindfulness-based exercises.

Measurements and findings

A number of psychological well-being measurements were taken including stress, anxiety, depression and pregnancy-specific measure such as labour worry. Intention to treat analysis (baseline carried forwards) showed no group difference in stress from pre to post intervention or control.

Key conclusions

Results indicated that the course was potentially beneficial for those who completed it, but levels of drop out from the course were very high.

Implications for practice

Although outcomes for mothers completing the intervention were improved relative to a waitlist control, high rates of drop out indicate that the online course has low completion rates for pregnant women in its current format.

*Keywords: Mindfulness, Pregnancy, Prenatal Mood, Online Interventions, e-health*

Perinatal maternal depression (DSM-V; American Psychiatric Association 1994, American Psychiatric Association 2013) is disabling and widespread (Cox et al. 1993, Cooper and Murray 1998, Oates et al. 2004, Ramchandani et al. 2005). The prevalence rate of maternal depression during pregnancy has been estimated to be between 8.5% and 11% (Gaynes et al. 2005). Stress, anxiety and depression during pregnancy are associated with later impairments in behavioural, social and cognitive development in the child, (Ramchandani et al. 2005, Talge et al. 2007, Brand and Brennan 2009, Deave et al. 2008).

Pregnancy-focused mindfulness-based interventions may be beneficial for clinical (Muzik et al. 2012, Dimidjian et al. 2014, Goodman et al. 2014, Miklowitz et al. 2015) and non-clinical samples (Beddoe et al. 2009, Duncan and Bardacke 2010, Byrne et al. 2013, Woolhouse et al. 2014). However, existing studies are preliminary, with small samples, limited follow-up, and rarely include randomised controlled designs (Vieten and Astin 2008, Dunn et al. 2012, Guardino et al. 2013, Chan 2014, Gambrel and Piercy 2014, Woolhouse et al. 2014, Zhang and Emory 2015). Preliminary evidence also suggests that generic mindfulness training (i.e. mindfulness training not aimed at preparation for parenthood) may have beneficial effects on mood during and after pregnancy, see table 1. A pilot evaluation of Mindfulness-Based Cognitive Therapy (MBCT) delivered at 12-28 weeks of pregnancy to a mixed sample of expectant mothers with and without histories of anxiety or depression showed clinically reliable declines in depression, stress and anxiety and this decline remained at 6 weeks postpartum (Dunn et al., 2012). A randomised controlled pilot trial of mindfulness for stress during pregnancy showed a decrease in pregnancy-related stress and anxiety following a generic 6-week mindful awareness programme (Guardino et al., 2013). One study examining the potential benefits of MBCT for currently well women with major depressive disorder or bipolar disorder who were either pregnant (up to 32 weeks), trying to conceive, or had recently had a baby (up to one year postpartum) found reduced rates of depression which were maintained at follow-up (Miklowitz et al., 2015).

Online interventions provide accessible mental health resources at reduced cost to health services and patients, across a range of conditions (Clarke et al. 2009, Powell et al. 2013). Such interventions may be particularly useful in the perinatal period given the accessibility issues faced by this population and because recent findings suggest that many pregnant women search the internet for health information (Drozd et al. 2015, Sayakhot & Carolan-Olah, 2016).

*Study Aims*

This pilot randomised controlled study examined the effects of participation in a generic online mindfulness course during pregnancy compared with a waitlist condition. The primary outcome was change in perceived stress from pre- to post intervention. Secondary outcomes were changes in general mood (anxiety and depression), pregnancy-related distress and labour worry. The study also considered whether any differences in mood identified were maintained postpartum. It was hypothesised that relative to the waitlist group, course completers would have improved levels of perceived stress from pre to post-course and at two months postnatal follow-up, and that a similar pattern of improvements would be observed for secondary measures.

**Methods**

*Participants*

Pregnant women were recruited online via email lists (University departments, colleges, postgraduate mailings), Facebook, Twitter, Google advertising and posts in pregnancy and new mother forums and other community sites. Posters were also sent to schools, churches, community centres and shops around Oxfordshire. Expectant mothers were invited to sign-up to the study from 12 weeks gestation. The minimum age for participants was 18 years. The exclusion criteria were completion or current attendance of a mindfulness course and current suicidal ideation.

*Procedure*

Recruitment took place over the course of a year. Participants were directed to a secure website, where they provided informed consent and submitted their due-date and contact details. At 12-34 weeks gestation participants were emailed and directed to a separate website for baseline data collection.

Following this participants were randomly allocated to take the online mindfulness course immediately or to wait until after their baby was born, with the aim of a 1:1 ratio. Participants were stratified by perceived stress score (high/low, with a cut point of 15 or less (low) based on population norms (Cohen and Williamson 1988)) and previous children (yes/no). Randomisation was conducted using an online randomisation tool (www.randomization.com) by the first author who was not blind to stress and parity study data for the purposes of randomisation. Where a course participant withdrew from the study or was withdrawn having been lost to follow-up their random allocation was re-assigned to the next participant recruited to the study to maintain balance across study arms.

Participants were invited to log in to the course website regularly to follow assigned activities (see below). Those who had not logged on for more than a week were reminded (via email) to login or contact the research team. Up to three reminders were sent, the last one informing the participant they would be assumed withdrawn. Upon course completion, participants were sent the study follow-up measures via a new secure survey link in an email. Participants in the control condition were asked to complete the 'post-course' (T1) measures 45 days after baseline survey completion to match previously found approximate times for participants to complete the course (approximately six and a half weeks). Participants who were assigned to the no-intervention group were offered access to the online mindfulness course in the postnatal period.

*Intervention*

The ‘Be Mindful Online’ general mindfulness course consists of ten interactive sessions (see [www.bemindfulonline.co.uk](http://www.bemindfulonline.co.uk) for further details) Participants learn to use formal and informal meditation practices such as body scan, mindful movement, breathing space and mindful eating, through videos and assignments. The online course follows the same class sequence as an eight-week mindfulness course, condensed to a four-week format, allowing participants to stop and start as required. See Table 2 for an outline of course content. Participants were given free course membership.

*Measures*

Measures were taken at baseline (T0), post-course (T1), and at eight weeks postpartum (T2, except where noted):

*The Perceived Stress Scale* (PSS; (Cohen et al. 1983, Cohen and Williamson 1988)) measures how uncontrollable and overwhelming events are perceived to have been during the past month. Scores range from 0-40. Cronbach's α for this sample was .91.

*The General Anxiety Disorder-7* (GAD-7; Spitzer, Kroenke, Williams & Löwe 2006) measures general anxiety over the previous two weeks. Scores range from 0-21. Cronbach's α for this sample was .89.

*The Edinburgh Postnatal Depression Scale* (EPDS; Cox, Holden, & Sagovsky, 1987) measures levels depressive symptoms over the previous week and can be used in the prenatal and postnatal phases (Edmondson et al. 2010, Pearson et al. 2013). Scores range from 0-30 (scores >8 indicates possible depression; >11 likely depression). Cronbach's α for this sample was .88.

*The Tilburg Pregnancy Distress Scale* (TPDS; Pop, Pommer, Pop-Purceleanu, Wijnen, Bergink & Pouwer, 2011) measures pregnancy-related distress for the previous 7 days and ranges from 0-48. Cronbach's α for this sample was .81.

*The Oxford Worries about Labour Scale* (OWLS; Redshaw, Martin, Rowe & Hockley, 2009) is a 10-item scale that measures worry about labour. The scale has a range of 10-40 with 10 being the highest level of worry. Cronbach's α for this sample was .83.

*Mindfulness practice* The amount of mindfulness practice completed was determined by weekly self-report. Participants were asked to complete three questions each week. The first question concerned frequency of formal practice, the second, informal practice and the third, another practice for the week, for example, bringing attention to a chosen activity (each rated *'Every day, Most days, One or Twice or Never'* to *'Every day, 4-5 days, 2-3 days, 1 day, Never or Not at all')*. If a score was missing, no practice was assumed.

*Sample Size Calculations for Randomised Study*

Owing to the limited research (and particularly randomised controlled studies where there are few studies using the PSS and studies show mixed results) surrounding mindfulness courses for pregnancy, a conservative effect size of 0.25 (*f*) (Cohen, 1992) was used to determine a robust sample size, using G\*Power software (Erdfelder, Faul, & Buchner, 1996). The sample size required for a repeated measures within-between interaction design with 95% power was 54 participants (27 per group). Accounting for attrition, the aim was to recruit a sample of at least 80 participants completing the course.

*Analysis plan*

The success of random allocation was analysed with t-tests for continuous data and chi-square tests for categorical data. Variables where significant group differences were found between participants at baseline were used as covariates for subsequent analyses. Mixed factorial repeated measures ANCOVAs were used to investigate change in mood over time (T0 to T1) between and within groups comparing active and control participants, controlling for potential confounders. For the postnatal follow-up analysis, pre-course and postnatal time points were used, omitting post-course scores.

## Results

*Participant Flow*

Of the 237 participants enrolled in the study, 185 completed the initial survey (T0) and 107 were randomised to active and 78 to control. Twenty-two active (21%) and 50 (64%) control participants completed the post-course measures (39% overall completion rate), and 16 active (15%) and 32 control (41%) completed postnatal measures, see Figure 1 for a CONSORT diagram showing the flow of participants through the study. These participants are the focus of the main study analyses. However a comparison of course completers and course drop-outs (those who withdrew or were lost to follow-up) is provided below.

*Withdrawal / Drop-out and Adherence*

Of the 107 participants allocated to take the online mindfulness course, 4 participants withdrew due to premature delivery or miscarriage and 81 were lost to follow-up. Of these, 42% (*n =* 34) did not begin the course, 17.3% (*n =* 14) discontinued at week one, 24.7% (*n =* 20) at week two, 12.3% (*n =* 10) at week three and 3.7% at week four (*n =* 3). The mean time to complete the course for those who did complete it (*n =* 22) was 8.41 weeks and the mode completion time was 6 weeks.

*Comparing course completers and non-completers*

Baseline data was examined comparing those allocated to the immediate course who completed it (*n =* 22) and those who did not (*n =* 85). Significantly more course completers practiced yoga (41%, *n =* 9,14% *n =* 12), [χ2 (1) = 7.95, *p<*.01]. Course completers were also significantly older (mean age 33.59 years, *SD* 4.73,mean age 30.67 years, *SD* 4.98), [*t*(105) = 2.47, *p<*.05]. Furthermore, course completers reported significantly more perceived partner support (mean 3.05, *SD* 2.48) on the TPDS than non-completers (mean 4.93, *SD* 3.43), [*t*(44.30) = -2.92, *p<*.01] (equal variances not assumed). There were no other significant differences between the groups.

*Baseline Characteristics of Retained Participants*

Sociodemographic characteristics for study participants who provided both pre and post intervention data, (or equivalent for the waitlist group) are shown in Table 3 with baseline mood in Table 4. Overall, at study entry participants’ average scores showed high stress, moderate general anxiety and depression, and a TPDS score that met the cut-off for pregnancy-related 'distress' (M = 17).Participants allocated to the immediate course reported less TPDS distress, [*t*(70) = -2.28, *p<*.05] (equal variances not assumed). Subsequent analyses controlled for baseline TPDS distress.

*Changes in mood T0 to T1*

*Perceived Stress*

To test the hypothesis that completing the online mindfulness course would result in a reduction in PSS score post-course, relative to the waitlist control group a mixed factorial repeated measures ANCOVA was conducted. The within-subjects variable was time (T0, T1); between-subjects variable was group (active, waitlist control) and baseline TPDS distress was a covariate.

Consistent with the hypothesis, there was a significant time x group interaction, [*F*(1,69) = 7.78, *p<*.01, η2=.10]. Post-hoc comparisons examining stress over time were significant for immediate participants (*n =* 22), [*F*(1,69) = 33.36, *p<*.001, η2=.33] (mean difference -8.10) and waitlist participants (*n =* 50), [*F*(1,69) = 13.39, *p<*.001, η2=.16] (mean difference -3.36) but with a greater decrease for immediate participants. The difference in scores between groups at T1 was significant, [*F*(1,69) = 4.26, *p<*.05, η2=.058].

*Anxiety*

A mixed factorial ANCOVA was conducted examining GAD-7 anxiety over time, controlling for TPDS distress. There was no effect of time, group or interaction, [*F*(1,69) = 2.26, *p>*.05].

Pairwise comparisons showed a decrease in anxiety for immediate, [*F*(1,69) = 18.42, *p<*.001), η2=.21] (mean difference -3.88) and waitlist participants, [*F*(1,69) = 14.27, *p<*.001, η2=.17] (mean difference -2.23). There was a trend for immediate participants to have lower anxiety at T1 compared to waitlist controls, [*F*(1,69) = 3.15, *p=*.08, η2=.04]. *Depression*

A mixed factorial ANCOVA showed a significant time x group effect for EPDS depression pre-post controlling for TPDS distress, [*F*(1,69) = 11.25, *p<*.005, η2=.14]. Pairwise comparisons showed that immediate participants decreased in depression, [*F*(1,69) = 28.64, *p<*.001, η2=.29] (mean difference -5.97) with a trend for waitlist participants, [*F*(1,69) = 3.85, *p*=.054, η2=.05] (mean difference -1.43). There was a significant difference in scores at T1 between groups, [*F*(1,69) = 10.06, *p*<.005, η2=.13].

*Pregnancy Distress and Labour Worry*

A mixed factorial ANCOVA examining the change in TPDS distress over time showed a time x group interaction, [*F*(1,70)=4.27, *p<*.05, η2=.057].

Pairwise comparisons showed a difference over time for immediate participants, [*F*(1,70) = 19.36, *p<*.001), η2=.22] (mean difference -5.64) and waitlist participants, [*F*(1,70) = 8.38, *p<*.01, η2=.11] (mean difference -2.46). Immediate participants had significantly lower distress scores at T1 than waitlists, [*F*(1,70) = 5.19, *p<*.05, η2=.17].

A mixed factorial ANCOVA was conducted for (reverse scored) labour worry from T0 to T1, controlling for baseline TPDS distress. There was a trend towards a significant time x group interaction, [*F*(1,69) = 3.73, *p=*.058, η2=.051].

Pairwise comparisons showed a significant difference in labour worry over time with waitlist participants showing no improvement, [*F*(1,69) = 0.00, *p*>.05] (mean difference -.02) and immediate participants improving, [*F*(1,69) = 5.42, *p<*.05, η2=.07], (mean difference 3.14). At T1, the difference between waitlist and immediate groups showed a trend, [*F*(1,69) = 3.53, *p=*.065, η2=.05].

*Changes in Perceived Stress T0 to T2(postnatal follow-up)*

Comparing levels of perceived stress in immediate (*n =* 16) and waitlist (*n =* 32) participants from T0 to T2, the time x group interaction was not present, [*F*(1,45) = 0.70, *p>*.05]. Immediate, [*F*(1,45) = 10.57, *p<*.005, η2=.19], and waitlist, [*F*(1,45) = 10.06, *p<*.005, η2=.18], participants both decreased in PSS from T0 to T2. There were no significant time by group interactions for any of the secondary outcomes from T0 to T2 and given the very low sample sizes at T2 these data are not reported further.

*Intention to Treat Analysis*

Because of the significant and differential drop out from the immediate and waitlist control arms of the study we repeated the above analysis including all randomised participants and carrying forward baseline data where the participant did not provide follow-up data due to drop out. Analysis of the primary outcome of perceived stress (*n* = 107 Active and *n* = 78 Control) showed no significant effect of group on stress *F*(1, 182) = 0.3, *p* >.05 and no significant time x group interaction effect, *F*(1,182) = .80, *p>*.05.

## Discussion

This study examined the impact of participation in an online mindfulness course, compared to waitlist control, on perceived stress and mood during pregnancy. The main finding of the study is that the course had very low rates of completion, only 21% of participants randomised to the course completed it, and intention to treat analysis showed no benefit of allocation to immediate course access relative to a waitlist control condition on the primary outcome of perceived stress.

Although the reasons for non-completion are not fully understood, these findings suggest that relatively few women allocated to receive a generic online mindfulness course during pregnancy find it sufficiently engaging to continue to participate in online sessions. The drop-out rates observed are consistent with other research evaluating online courses, which tend to have particular difficulties with retention (van Ballegooijen et al. 2014, Karyotaki et al. 2015), although other studies examining face-to-face mindfulness courses for pregnancy have demonstrated good levels of retention (e.g. Dimidjian et al. 2014, who report an 86% completion in a sample of 49 women enrolled in an open trial of MBCT for depression prevention in pregnancy). Features of the online delivery of the mindfulness course including the absence of an instructor to consult about difficulties, low levels of contact with the researchers, a lack of social support from other participants, and the fact that the course did not require any financial commitment on the part of participants may all have contributed to lower levels of motivation. General service users of the be Mindful Online course show an approximate attrition rate of 67% overall (the exact figure is difficult to establish due to people returning and completing the course at later dates in some cases), so whilst the 79% attrition rate observed in this study is higher, the broader findings suggest that it is important to explore the reasons that people do not complete the online mindfulness course, and how these might be addressed to increase potential benefit. It might be valuable in future to conduct mixed methods research to address some of these open questions such that participants could be asked about the time intensity of the course, the mode of delivery or specific course elements which may prove off-putting and whether this had any bearing on completion. It would also be interesting to evaluate further demographics such as whether working part-time, full-time, in or outside of the home makes a difference, which could feasibly have a bearing on completion.

Data obtained from those participants who did complete the course and provided T1 data suggested these participants had a significant improvement in general stress compared with their waitlist peers. Similarly course completers reported greater improvements in mood, from T0 to T1, including reduced depression, pregnancy-related distress and labour worry, compared to waitlist controls. Whether these findings can be attributed to the course itself, or to other variables that might relate both to course adherence and changes in mood state (e.g. social circumstances, the progress of the pregnancy, conscientious attendance at other pregnancy preparation activities) is unclear. There were no differences between course completers and non-completers in baseline mood, although those who went on to complete the course were older, reported more partner support and had greater prior experience of yoga, which suggests that they may have been both more familiar with the general approach of the course, and more supported in their pregnancy. Interestingly all participants who provided baseline and post-intervention (ore equivalent) data reported improved functioning over time, with the exception of labour worry, which only diminished in course completers. Unfortunately the high rates of attrition from the online course, combined with the very low rates of follow-up data at the postnatal assessment make it difficult to draw any conclusions about any sustained effects of course completion. However previous research suggests that benefits of mindfulness programmes in this population are not always maintained postpartum (e.g. (Vieten and Astin 2008, Zhang and Emory 2015) and this is certainly an area for future enquiry.

One significant limitation of this study was the failure to obtain follow-up data from participants who discontinued the course prior to its completion. Such data would have provided a much clearer picture of any potential benefits of the course in pregnancy, as well as the reasons participants had for dropping out. In particular, 33 people partially completed the course and previous studies of mindfulness based programmes have often considered those people who have completed at least 50% of sessions as having completed an adequate minimum amount of the course. However, despite this limitation, the study does provide useful information, suggesting that although those who successfully complete an online mindfulness course report better mood than those allocated to a waitlist condition, feasibility/acceptability is poor. As a precursor to future studies, the analyses here do show promise and the necessity for future investigation for this sample to ascertain the most practical way of implementing a course to improve mood in pregnant women Thus, whilst an online course may provide a valuable opportunity for expectant mothers to access mindfulness training, particularly if they are unable or unwilling to access such a course in person, significant further research needs to be carried out to understand more about the barriers to course completion, and the outcomes for women who discontinue such courses mid intervention.

**References**

American Psychiatric Association (1994). Diagnostic and statistical manual of mental disorders: (DSM-IV), American Psychiatric Publishing Inc.

American Psychiatric Association (2013). Diagnostic and statistical manual of mental disorders, (DSM-V), American Psychiatric Publishing Inc.

Beddoe, A. E., C. P. Paul Yang, H. P. Kennedy, S. J. Weiss and K. A. Lee (2009). "The Effects of Mindfulness‐Based Yoga During Pregnancy on Maternal Psychological and Physical Distress." Journal of Obstetric, Gynecologic, & Neonatal Nursing **38**(3): 310-319.

Brand, S. R. and P. A. Brennan (2009). "Impact of antenatal and postpartum maternal mental illness: how are the children?" Clinical obstetrics and gynecology **52**(3): 441-455.

Byrne, J., Y. Hauck, C. Fisher, S. Bayes and R. Schutze (2013). "Effectiveness of a Mindfulness‐Based Childbirth Education Pilot Study on Maternal Self‐Efficacy and Fear of Childbirth." Journal of Midwifery & Women’s Health.

Chan, K. P. (2014). "Effects of perinatal meditation on pregnant Chinese women in Hong Kong: A randomized controlled trial." Journal of Nursing Education and Practice **5**(1): p1.

Clarke, G., C. Kelleher, M. Hornbrook, L. DeBar, J. Dickerson and C. Gullion (2009). "Randomized Effectiveness Trial of an Internet, Pure Self-Help, Cognitive Behavioral Intervention for Depressive Symptoms in Young Adults." Cognitive Behaviour Therapy **38**(4): 222-234.

Cohen, S., T. Kamarck and R. Mermelstein (1983). "A global measure of perceived stress." Journal of Health and Social Behavior **24**(4): 385-396.

Cohen, S. and G. Williamson (1988). Perceived stress in a probability sample of the United States. The social psychology of health: Claremont Symposium on applied social psychology. S. Spacapan and S. Oskamp**:** 31-67.

Cooper, P. J. and L. Murray (1998). "Postnatal depression." BMJ **316**(7148): 1884-1886.

Cox, J. L., J. M. Holden and R. Sagovsky (1987). "Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale." The British Journal of Psychiatry **150**(6): 782-786.

Cox, J. L., D. Murray and G. Chapman (1993). "A controlled study of the onset, duration and prevalence of postnatal depression." The British Journal of Psychiatry **163**(1): 27-31.

Deave, T., J. Heron, J. Evans and A. Emond (2008). "The impact of maternal depression in pregnancy on early child development." BJOG: An International Journal of Obstetrics & Gynaecology **115**(8): 1043-1051.

Dimidjian, S., S. H. Goodman, J. N. Felder, R. Gallop, A. P. Brown and A. Beck (2014). "An open trial of mindfulness-based cognitive therapy for the prevention of perinatal depressive relapse/recurrence." Archives of women's mental health **18**(1): 85-94.

Drozd, F., S. M. Haga, H. Brendryen and K. Slinning (2015). "An Internet-Based Intervention (Mamma Mia) for Postpartum Depression: Mapping the Development from Theory to Practice." JMIR Research Protocols **4**(4): e120.

Duncan, L. and N. Bardacke (2010). "Mindfulness-Based Childbirth and Parenting Education: Promoting Family Mindfulness During the Perinatal Period." Journal of Child and Family Studies **19**(2): 190-202.

Dunn, C., E. Hanieh, R. Roberts and R. Powrie (2012). "Mindful pregnancy and childbirth: effects of a mindfulness-based intervention on women’s psychological distress and well-being in the perinatal period." Archives of Women's Mental Health **15**(2): 139-143.

Edmondson, O. J., L. Psychogiou, H. Vlachos, E. Netsi and P. G. Ramchandani (2010). "Depression in fathers in the postnatal period: Assessment of the Edinburgh Postnatal Depression Scale as a screening measure." Journal of Affective Disorders **125**(1): 365-368.

Gambrel, L. E. and F. P. Piercy (2014). "Mindfulness‐Based Relationship Education For Couples Expecting Their First Child—Part 1: A Randomized Mixed‐Methods Program Evaluation." Journal of marital and family therapy.

Gaynes, B. N., N. Gavin, S. Meltzer-Brody, K. N. Lohr, T. Swinson, G. Gartlehner, S. Brody and W. C. Miller (2005). "Perinatal depression: prevalence, screening accuracy, and screening outcomes." Evidence Report: Technology Assessment (Summary)(119): 1-8.

Goodman, J., A. Guarino, K. Chenausky, L. Klein, J. Prager, R. Petersen, A. Forget and M. Freeman (2014). "CALM Pregnancy: results of a pilot study of mindfulness-based cognitive therapy for perinatal anxiety." Archives of Women's Mental Health **17**(5): 373-387.

Guardino, C. M., C. Dunkel Schetter, J. E. Bower, M. C. Lu and S. L. Smalley (2013). "Randomised controlled pilot trial of mindfulness training for stress reduction during pregnancy." Psychology & health **3**: 334-349.

Karyotaki, E., A. Kleiboer, F. Smit, D. Turner, A. Pastor, G. Andersson, T. Berger, C. Botella, J. Breton and P. Carlbring (2015). "Predictors of treatment dropout in self-guided web-based interventions for depression: an ‘individual patient data’meta-analysis." Psychological medicine: 1-10.

Löwe, B., O. Decker, S. Müller, E. Brähler, D. Schellberg, W. Herzog and P. Y. Herzberg (2008). "Validation and Standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the General Population." Medical Care **46**(3): 266-274 210.1097/MLR.1090b1013e318160d318093.

Miklowitz, D., R. Semple, M. Hauser, D. Elkun, M. Weintraub and S. Dimidjian (2015). "Mindfulness-Based Cognitive Therapy for Perinatal Women with Depression or Bipolar Spectrum Disorder." Cognitive Therapy and Research: 1-11.

Muzik, M., S. E. Hamilton, K. L. Rosenblum, E. Waxler and Z. Hadi (2012). "Mindfulness yoga during pregnancy for psychiatrically at-risk women: Preliminary results from a pilot feasibility study." Complementary Therapies in Clinical Practice(0).

Oates, M. R., J. L. Cox, S. Neema, P. Asten, N. Glangeaud-Freudenthal, B. Figueiredo, L. L. Gorman, S. Hacking, E. Hirst, M. H. Kammerer, C. M. Klier, G. Seneviratne, M. Smith, A.-L. Sutter-Dallay, V. Valoriani, B. Wickberg, K. Yoshida and T. P. Group (2004). "Postnatal depression across countries and cultures: a qualitative study." The British Journal of Psychiatry **184**(46): s10-s16.

Pearson, R. M., J. Evans, D. Kounali, G. Lewis, J. Heron, P. G. Ramchandani, T. G. O'Connor and A. Stein (2013). "Maternal depression during pregnancy and the postnatal period: Risks and possible mechanisms for offspring depression at age 18 years." JAMA Psychiatry **70**(12): 1312-1319.

Pop, V., A. Pommer, M. Pop-Purceleanu, H. Wijnen, V. Bergink and F. Pouwer (2011). "Development of the Tilburg pregnancy distress scale: the TPDS." BMC pregnancy and childbirth **11**(1): 80.

Powell, J., T. Hamborg, N. Stallard, A. Burls, J. McSorley, K. Bennett, K. M. Griffiths and H. Christensen (2013). "Effectiveness of a web-based cognitive-behavioral tool to improve mental well-being in the general population: randomized controlled trial." Journal of Medical Internet Research **15**(1): e2.

Ramchandani, P., G., A. Stein, J. Evans and T. G. O'Connor (2005). "Paternal depression in the postnatal period and child development: a prospective population study." The Lancet **365**(9478): 2201-2205.

Redshaw, M., C. Martin, R. Rowe and C. Hockley (2009). "The Oxford Worries about Labour Scale: Women's experience and measurement characteristics of a measure of maternal concern about labour and birth." Psychology, Health & Medicine **14**(3): 354-366.

Sayakhot, P., & Carolan-Olah, M. (2016). Internet use by pregnant women seeking pregnancy-related information: a systematic review. BMC pregnancy and childbirth, 16(1), 65.

Talge, N. M., C. Neal, V. Glover, T. R. Early Stress, F. Prevention Science Network, C. Neonatal Experience on and H. Adolescent Mental (2007). "Antenatal maternal stress and long-term effects on child neurodevelopment: how and why?" Journal of Child Psychology & Psychiatry & Allied Disciplines **48**(3-4): 245-261.

van Ballegooijen, W., P. Cuijpers, A. van Straten, E. Karyotaki, G. Andersson, J. H. Smit and H. Riper (2014). "Adherence to Internet-based and face-to-face cognitive behavioural therapy for depression: a meta-analysis."

Vieten, C. and J. Astin (2008). "Effects of a mindfulness-based intervention during pregnancy on prenatal stress and mood: results of a pilot study." Archives of Women's Mental Health **11**(1): 67-74.

Woolhouse, H., K. Mercuri, F. Judd and S. J. Brown (2014). "Antenatal mindfulness intervention to reduce depression, anxiety and stress: a pilot randomised controlled trial of the MindBabyBody program in an Australian tertiary maternity hospital." BMC pregnancy and childbirth **14**(1): 369.

Zhang, H. and E. Emory (2015). "A Mindfulness-Based Intervention for Pregnant African-American Women." Mindfulness **6**(3): 663-674.

Signed-up to study (*n =* 237)

Excluded (*n =* 52)

  Declined to participate (*n =* 2)

  Incorrect contact details (*n* = 2)

  Did not begin survey (*n =* 31)

  Did not complete survey (*n =* 17)

Analysed (*n* = 16)

Analysed (*n =* 22)

**Allocated to course (*n* = 107)**

 Completed allocated intervention (*n* = 22)

 Lost to drop-out or withdrawal (*n =* 85)

* premature birth or miscarriage *(n =* 4)
* course unavailable on phone (*n =* 3)
* cannot find time/moved abroad (*n =* 3)
* no wish to continue course (*n =* 3)
* discontinued course- no further contact (*n =* 72)

Analysed (*n* = 50)

**Allocated to waitlist control (*n =* 78)**

 Lost to follow-up (no further contact) (*n=*28)

Analysed (*n* = 32)

**Allocation (T0)**

**2m Postnatal Follow-up (T2)**

**Post-course (T1)**

## Follow-Up

Randomized (*n* = 185)

**Recruitment**

*Figure 1 CONSORT diagram of participant flow through study*

Table 1 Studies examining generic mindfulness courses for use during pregnancy

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Authors | Year | Study type | Intervention | Sample | *N* | Measures | Outcomes | Post-assessment time | Follow-up | Limitations |
| Dunn, Hanieh, Roberts & Powrie | 2012 | RCT | 8-wk MBCT | Expectant mothers. 1st & 2nd trimester Non-clinical | 10 vs 9 | DASS-21 depression, anxiety, stress, EPDS depression SCS self-compassion MAAS mindfulness | Clinically reliable declines in depression, stress & anxiety | Post-course & 6 week postnatal | Maintained & change in compassion | Small sample 9/10 ppts in active group reported histories of anxiety or depression All participants were receiving outpatient care but there is no description |
| Guardino, Dunkel Schetter, Bower, Lu & Smalley | 2013 | RCT (reading control) | 6-wk MAPS (Mindful Awareness Practice classes) | Expectant mothers, 1st & 2nd trimester. Highly stressed or anxious  Non-clinical | 24 vs 23 | PSA pregnancy stress PRA pregnancy anxiety PSS perceived stress STAI anxiety FFMQ mindfulness | Pregnancy-related stress & anxiety declined. General stress, anxiety declined & mindfulness increased for both groups | Post-course & 6 week (prenatal) | Decrease (difference) not maintained at follow-up | No control group-reading control group given pregnancy book Small sample 30% reading control group did yoga |
| Miklowitz, Semple, Hauser, Elkun, Weintraub & Dimidjian | 2015 | Pre-post | 8-wk MBCT | Expectant mothers, trying to conceive or =< 1 yr postpartum, with MDD or bipolar history (sub threshold at baseline) | 31 post-course & 6m fu, 32 1m fu | Client satisfaction questionnaire BDI depression Hamilton depression STAI anxiety LIFE for relapses FFMQ mindfulness | BDI depression decreased (no diff with perinatal status) Hamilton depression decreased No change in anxiety Mindfulness increased  High treatment satisfaction | Post-course, 1 month, 6 month | Hamilton & BDI depression decrease maintained at 6m An increase in mindfulness resulted in BDI decrease at all time points 21.9% relapsed by 6m (30% norm) | No control group Sample size meant previous number of depressive episodes could not be analysed Half of the sample were taking medication but no analysis |

Table 2 Be Mindful Online Course Content

|  |  |
| --- | --- |
| Week number | Focus of week |
| 0 | **Introduction** |
|  | Course preparation and orientation |
|  | Stress, anxiety and depression assessment |
| 1 | **Stepping out of Automatic Pilot** |
|  | Online sessions include: Dealing with Barriers |
|  | Assignments: Routine Activity, Mindful Eating, Body Scan |
|  | Emails: Practising at Home, Mindful Meal Anecdote |
| 2 | **Reconnecting with Body & Breath** |
|  | Online sessions include: The Physical Barometer |
|  | Assignments: Mindful Movement, Event Awareness, Mindful Breathing |
|  | Emails: Breathing Tips, Remember your Intentions |
| 3 | **Working with Difficulties** |
|  | Online sessions include: On Negative Thoughts |
|  | Assignments: Breathing Space, Stress Awareness, Sitting Meditation |
|  | Emails: The Guest House Poem, 3 minute Breathing Space |
| 4 | **Mindfulness in Daily Life** |
|  | Online sessions include: Mindful Walking |
|  | Assignments: Activity Awareness, Breathing Space and Action Step, Stress Strategies |
|  | Emails: Preparing for Stress, Fear and Fearless Quote |
| 5 | **Going Forward** |
|  | Online session includes: Completion Certificate and Additional Resources |

Table 3

*Participant Characteristics for those with pre and post intervention data ( n =72)*

|  |  |  |
| --- | --- | --- |
| Participant Characteristics | *%* | *n* |
| Age (range 22-40 years) | mean: 32.7 years,  mode: 34 years | |
| UK residents | 90.3% | 65 |
| Ethnicity British/White-British/White | 88.9% | 64 |
| Currently married or cohabiting (other *n =* 1; partner sectioned) | 95.8% | 69 |
| Living separately from partner | 2.8% | 2 |
| Relationship length (range 6 months - 17 years) | mean: 6.67 years | |
| Educated to high school/college level1 | 15.3% | 11 |
| Educated to degree level | 40.3% | 29 |
| Educated to postgraduate level | 40.3% | 29 |
| Currently employed | 76.4% | 55 |
| Unemployed status-homemaker | 19.4% | 14 |
| Planned pregnancy2 | 76.4% | 55 |
| Months trying to conceive (range 0-60 months) | mean: 5.13 months,  mode: 1 month | |
| Multiparous | 54.2% | 39 |
| One child (two *n* = 4, three *n* = 1, four *n* = 1, six *n* = 1) | 40.3% | 29 |
| First trimester | 12.5% | 9 |
| Second trimester | 76.4% | 55 |
| Third trimester | 11.1% | 8 |
| Physical ailments (non-perinatal; asthma, heart & blood pressure, diabetes, joint problems, IBS, hypothyroidism) | 26.4% | 19 |
| Mental health problems | 13.9% | 10 |
| Mental health: Depression | 5.6% | 4 |
| Mental health: Anxiety | 2.8% | 2 |
| Mental health other or comorbid (bipolar, OCD, GAD, panic disorder, PT*SD*, phobias, depression, anxiety) | 5.6% | 4 |
| Practice yoga (daily-monthly, mode: 15.3% weekly *n* = 11) | 29.2% | 21 |
| Practice meditation (daily-monthly) | 6.9% | 5 |
| Note: 1One participant is missing education data due to survey glitch; two participants stated 'other' education: 'Vocational' and 'HND'. 2One participant was expecting twins; the rest of the sample had singleton pregnancies. | | |

Table 4

*Baseline Mood for those with pre and post intervention data (n =72)*

|  |  |  |  |
| --- | --- | --- | --- |
| Measure | Mean | *SD* | Research Norms |
| PSS Stress | 21.65 | 8.02 | 11.9-14.71 |
| GAD-7 Anxiety | 9.10 | 5.56 | 2.7-3.82 |
| EPDS Pregnancy Depression | 12.33 | 6.48 | 7.63 |
| TPDS Pregnancy Distress | 21.85 | 8.97 | 10.674 |
| OWLS Labour Worry | 27.31 | 7.13 | 25.155 |
| FFMQ Mindfulness | 115.04 | 22.50 | 119.64-121.556 |

Note: 1(Cohen and Williamson 1988), 2(Löwe et al. 2008), 3(Cox et al. 1987, Cox et al. 1993) 9/10 potential need for further screening; 12/13 possible depression, 4 (Pop et al. 2011) , 5(Redshaw et al. 2009) Non-clinical sample of new mothers using the scale retrospectively, 6(Guardino et al. 2013, Woolhouse et al. 2014).