

Manuscript Details

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Abstract

Background and purpose: Women's health behaviours during pregnancy can affect their children's lifetime outcomes. Inactivity, poor diet, alcohol, and smoking during pregnancy are linked to maternal stress and distress. Mindfulness-based interventions can improve health behaviours and mental health. The purpose of the study was to develop and evaluate the feasibility of a mindfulness-based maternal behaviour change intervention. Materials and methods: The eight-week 'Mind the Bump' intervention integrated mindfulness training with behaviour change techniques. It aimed to improve mindfulness, mental health, and adherence to UK maternal health behaviour guidance. Acceptability, practicability, effectiveness/cost-effectiveness, affordability, safety/side-effects, and equity were evaluated from baseline to post-course and follow-up. Results: Mindfulness, positive affect, and wellbeing improved. Stress, negative affect, depression, anxiety, and adherence to guidance did not improve. The intervention was practicable and safe, but the other implementability criteria were not satisfied. Conclusion: The intervention was not fully feasible; recommendations to address its limitations are discussed.

Keywords	Behaviour change; feasibility; intervention; maternal health; mindfulness.
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Suggested reviewers	Madelynne Arden, Lou Atkinson

Submission Files Included in this PDF

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Dear Assistant Professor, Dr S. Afshin Shorofi, Associate Editor, *Complementary Therapies in Clinical Practice*

Thank you very much for the opportunity to make revisions to our paper '*The feasibility of 'Mind the Bump': a mindfulness-based maternal behaviour change intervention*'. We would like to thank the reviewers for their constructive comments. Please find my response to the comments set out below and within the revised version of the paper, tables, and figures. We hope that you will find these revisions acceptable, but please let us know if you require any further information or points of clarification prior to making a final decision about this paper

Reviewer comment

@@@ responses

.....

Abstract

"Results: Mindfulness. ?? positive affect, and wellbeing improved."

@@@ The full stop has been changed to a comma in the Abstract.

Figures/Tables

Figure 1: Arrows should be well positioned.

@@@ I have reorganised the Figure so that the arrows are in line.

Figure 2 & 3: bar legends should be well positioned on the right side of the graph.

@@@ I have moved the legends, and changed all the fonts to Times New Roman.

At the bottom of the table define the acronyms.

@@@ I have defined p/w underneath Table 6 and SD underneath Table 11.

Additional comments

You interchange between ante-natal and antenatal. Please be consistent in terms used.

@@@ I have changed ante-natal to antenatal on page 9.

- Mind the Bump, a mindfulness-based behaviour change intervention, was not feasible
- Recruitment was not representative
- No change in adherence to UK health behaviour guidance
- No change in negative mood, stress, or clinical mental health scores
- Adherence and retention issues

Title: The feasibility of ‘Mind the Bump’: a mindfulness based maternal behaviour change intervention

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Authors’ contributions

SH designed and conducted the study. LS and DF supervised the PhD.

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ABSTRACT

Background and purpose: Women's health behaviours during pregnancy can affect their children's lifetime outcomes. Inactivity, poor diet, alcohol, and smoking during pregnancy are linked to maternal stress and distress. Mindfulness-based interventions can improve health behaviours and mental health. The purpose of the study was to develop and evaluate the feasibility of a mindfulness-based maternal behaviour change intervention. **Materials and methods:** The eight-week 'Mind the Bump' intervention integrated mindfulness training with behaviour change techniques. It aimed to improve mindfulness, mental health, and adherence to UK maternal health behaviour guidance. Acceptability, practicability, effectiveness/cost-effectiveness, affordability, safety/side-effects, and equity were evaluated from baseline to post-course and follow-up. **Results:** Mindfulness, positive affect, and wellbeing improved. Stress, negative affect, depression, anxiety, and adherence to guidance did not improve. The intervention was practicable and safe, but the other implementability criteria were not satisfied. **Conclusion:** The intervention was not fully feasible; recommendations to address its limitations are discussed.

Key words

Behaviour change; feasibility; intervention; maternal health; mindfulness.

1. Introduction

Women's physical activity, nutrition, gestational weight gain, alcohol consumption, smoking, and mental health before and during pregnancy can affect children's lifetime developmental, cognitive, behavioural, and health outcomes via biopsychosocial mechanisms and stress-induced epigenetic changes [1–8]. United Kingdom (UK) pregnancy health behaviour guidelines aim to protect women's health by reducing the risk of conditions such as high blood pressure and gestational weight gain, pre-eclampsia, and gestational diabetes. They also aim to protect against foetal defects, miscarriage, prematurity, and lifetime risks to children [9]. The National Institute for Health and Care Excellence (NICE) and UK Chief Medical Officers advise pregnant women to do five 30-minute sessions of moderate activity each week (150 minutes total). They should follow the “Eatwell Plate” diet, including “5 a day” portions of fruit and vegetables; not exceed 2000 calories per day until the third trimester, when the daily limit is 2500 calories. Conception body mass index (BMI) should be in normal range (18.5 kg/m^2 to 25 kg/m^2). Women should take folic acid in early pregnancy, and vitamin D throughout. They should not drink alcohol or smoke [10–13]. Adherence to activity, diet, and weight gain guidance is not routinely monitored during pregnancy, but fewer than half of women of reproductive age are sufficiently active, and only a third eat five or more daily portions of fruit and vegetables. More women of reproductive age are underweight (2%), overweight (30%) or obese (20%) than in normal BMI range (48%). During pregnancy, 42% supplement vitamin D, 41% drink some alcohol, and 12% smoke [14–16]. Co-occurrence of these behavioural risks is not established.

Maternal stress, distress, and trauma can directly affect the infant via the placenta, resulting in foetal hyperactivity and cardiac irregularity, higher amygdala reactivity, and abnormal development of the hypothalamic–pituitary–adrenal axis, predisposing children to inter-generationally transmitted stress, distress, and illness [17–23]. The majority of British women (78%) report at least some stress during pregnancy, and around 20% have a diagnosable antenatal mental health condition: 3% clinical depression; 3% post-traumatic stress disorder; 10% to 15% mild to moderate depression and anxiety [24,25]. Whilst some women experience a continuation or re-occurrence of earlier anxiety and depressive disorders, around half are diagnosed for the first time during pregnancy [24].

Antenatal mental health conditions predict poorer self-care and non-adherence to guidance for conception BMI, physical activity, and quitting alcohol and smoking [26–28]. Thus,

targeting maternal mental health and health behaviours together might have potential to improve adherence to guidance.

Mindfulness is an inherent psychological characteristic trait typified by an ability to be lucidly aware of present moment experience, an open, accepting, and curious engagement with present moment experience, and a non-judgemental, accepting, and self-compassionate attitude to oneself [29]. Naturally occurring ‘trait’ mindfulness is positively related to higher physical activity and healthy eating, lower alcohol consumption, higher positive affect and wellbeing, and lower perceived stress, antenatal depression, pregnancy-related distress, and general anxiety in pregnancy [27,30].

Mindfulness-based interventions (MBIs) are structured programmes that teach mindfulness skills and psychoeducation. Adaptations to the original clinical programme, mindfulness-based stress reduction (MBSR) [31] target specific mental health and health behaviours. MBIs are typically delivered over an eight-week period and involve daily practice of formal meditations, including paying attention to the physical sensations of breathing, and informal practices such as noticing how it feels to do daily tasks, alongside self-monitoring psychological and behavioural patterns. There has been an uptake of MBIs for health and wellbeing in the general public, with beneficial effects on burnout, stress and distress, depression, anxiety, and relaxation [32].

Pregnancy-specific MBIs, such as mindfulness-based childbirth education (MBCE) [33] and mindfulness-based childbirth and parenting (MBCP) [34], target the mental health of pregnant women, and are shown to alleviate antenatal anxiety, depression, and perceived stress across the intervention period and at follow up [33-34]. Systematic reviews do not find consistent positive effects of non-pregnancy programmes, such as MBSR, on maternal mental health [35–38], highlighting the importance of pregnancy-specific adaptation.

There is a paucity of research on maternal health behaviour change MBIs. One that targeted weight management in obese pregnant women showed small beneficial correlations between changes in mindfulness and awareness of eating and eating due to external cues rather than hunger, but not on gestational weight gain [39,40]. Non-pregnancy MBIs have beneficial effects on weight reduction, obesity-related eating behaviours, alcohol and other drug post-rehabilitation cravings, cutting down, quitting, and maintaining abstinence from smoking, and physical activity levels [41–44]. Effective interventions integrate mindfulness training with

recognised behaviour change techniques of goal setting, planning, and self-monitoring [45] to capitalise on participants' motivation to change.

The potential of MBIs for improving maternal mental and behavioural health together has not been explored. The current study aimed to develop and evaluate the feasibility of a mindfulness-based behaviour change intervention that targeted single and co-occurring physical activity, diet, alcohol consumption, and smoking behaviours during pregnancy by integrating mindfulness skills for stress and distress reduction with health behaviour change techniques.

1.1 Theories used in designing the intervention

Intervention design was informed by the Medical Research Council (MRC), National Institute for Health and Care Excellence (NICE), and the Behaviour Change Wheel (BCW) guide [45–49] recommendations for developing complex behaviour change interventions. Step one of the BCW is to define the behavioural problem in terms of the 'Capability', 'Opportunity', 'Motivation' and 'Behaviour' model (COM-B), including physical and psychological capabilities, social and environmental opportunities, and reflective and automatic motivations. This process identifies behaviour change targets, which determines the intervention's components, behaviour change techniques (BCTs), and mode of delivery. Goal setting and self-monitoring components are recommended by the MRC [47].

The aim was to develop a deliverable mindfulness-based maternal behaviour change intervention with potential for low-cost implementation. A non-clinical programme that targets general population sub-clinical mental health symptoms and general wellbeing, "Mindfulness: A Practical Path to Finding Peace in a Frantic World" (MaPP) [50], was adapted for pregnancy and health behaviour change. This paper describes the content and feasibility of the intervention.

2. Materials and methods

2.1 Participants

This was a single-arm exploratory study conducted with a convenience sample of pregnant women. The participants were self-selecting volunteers who verbally conveyed that they met the inclusion criteria and did not meet the exclusion criteria (Table 1) during telephone screening.

[Insert Table 1]

Recruitment approaches focused on the Oxford region to reduce cost/time barriers to attendance. Posters were displayed on local community and university noticeboards. Dedicated Facebook and Twitter accounts were used to advertise the study, and information was shared to Facebook pages of local pregnancy exercise and interest groups. Contact was made with local antenatal exercise teachers who agreed to disseminate email and paper-based information to women who attended their classes. Two teachers invited the researcher to make face-to-face presentations to their yoga classes.

Women who expressed an interest in participating after reading the participant information sheet were screened by telephone. Eligible women were sent a formal invitation letter. Baseline data collection occurred during the introductory session (week 0) on campus, and informed consent was obtained from all individual participants included in the study. Week 8 post-intervention data were collected from paper surveys given to participants at the final taught session and returned by post. Week 16 follow-up data were collected using paper questionnaires sent and returned by post.

2.2 Intervention

The intervention was named “Mind the Bump”. It spanned 17 weeks, beginning with an introductory 90-minute session in week 0. The session included information about the potential effects of alcohol, smoking, high gestational weight gain, nutrition, supplements, and physical activity on pregnant women and their children’s immediate and lifetime outcomes, and the relevant UK guidance. A list of local free and paid pregnancy exercise classes was provided. The study materials (included in Table 2) were the ‘Mindfulness: Finding Peace in a Frantic World’ book and compact disc (CD) [51], and a paper diary. The women were invited to set their autonomous SMART (specific, measurable, achievable, realistic, and time-framed) goals [52] for their own leisure time physical activity, nutrition, alcohol consumption, smoking, and mindfulness practice over the next 16 weeks, and to record them in the study diary. Each 90-minute session of the week 1 to 8 MBI ran twice per week (one weekday evening, Saturday morning) to optimise opportunity to attend. Each session was followed by an email that summarised the session and the home practice recommendation, which were also shown in the diary.

The eight week face-to-face MBI was followed by an eight week self-led period (week 9 to 16). The rationale for this follow-up period, which went beyond the typical eight weeks of an

MBI, was that health behaviours and mental health are important throughout pregnancy [12]. It was therefore important to assess whether mindfulness practice was sustainable, and whether any changes in mindfulness, mental health, or adherence to health behaviour guidance were maintained, augmented, or diminished after the taught course.

Week 1 to 8 recommendations were to use the CD to practice ‘formal’ mindfulness five times each week between sessions, to practice informally by paying attention to daily tasks, and to use regular short ‘breathing space’ practices. The self-led period home practice recommendations were to continue to use the CD and/or other preferred resources, such as local drop-in mindfulness practice groups and MaPP author Mark Williams’ Mindfulness Based Cognitive Therapy practice recordings on YouTube [e.g. 53], to maintain their formal practice. Total contact time during week 1 to 8 was 13.5 hours, including four hours of formal mindfulness practice. Recommended formal home practice using the CD was 20 to 23 hours in weeks 1 to 8, and at least seven hours in weeks 9 to 16. The target for formal practice from week 1 to 16 was at least 31 hours. The women were recommended to use the study diary to self-monitor their autonomous health behaviour and mindfulness practice goal achievement each week from weeks 1 to 16.

Pregnancy specific additions to the MaPP programme included:

1. Focusing on the sensations of the baby during the Body and Breath, Body Scan, and Breath and Body practices.
2. Breath and Body acceptance practices included invitations to explore and accept neutral, pleasant and unpleasant sensations of being pregnant.
3. Substituting the Mindful Movement practice with Mindful Walking.
4. Focusing on the baby during the compassion practice.
5. Advising women to sit or to lie on their side to do the Body Scan, as lying on the back is not recommended after 16 weeks gestation [54].
6. Intentions for mindful parenting in the week eight reflective task.

Pregnant women’s views of the structure and format were obtained from a discussion with a group attending Oxford Brookes University’s pregnancy exercise sessions. They said that Mind the Bump appeared to be acceptable. The materials, behaviour change, and mindfulness practice aspects of the intervention are outlined in Table 2.

[Insert Table 2]

The anticipated impacts of Mind the Bump's components on capability, opportunity, and motivation to change health behaviours and to develop a mindfulness practice within the BCW's intervention functions [45] are shown in Table 3. There appeared to be potential to increase capability, opportunity, and motivation for maternal health behaviours, although the possible challenges of the impact of pregnancy on physical capabilities, and tension between making time for one self-care activity and not having time for another were acknowledged.

[Insert Table 3]

The mapping of Mind the Bump to the BCW's behaviour change techniques taxonomy (BCTT v.1) [55] is available here: bit.ly/396h5Qr.

2.3 Objectives

The purpose of the study was to evaluate the feasibility of delivering Mind the Bump, a mindfulness-based behaviour change intervention for pregnant women. The objectives were to report the following feasibility criteria:

1. The effectiveness of different recruitment strategies.
2. Participants' socio-demographic and pregnancy characteristics and their baseline health behaviour and psychological characteristics.
3. Retention at weeks 8 and 16.
4. Adherence to the intervention.
5. Mindfulness and mental health outcomes.
6. Per capita cost of the intervention.
7. Indicative safety of the intervention.

2.4 Outcomes

Recruitment, retention, attendance, costs, and safety data were collected in weeks 0 to 16. The researcher monitored her fidelity to the weekly session plans. Self-report data were collected using anonymous paper questionnaires in weeks 0 (baseline), 8, and 16. Pregnancy physical activity, alcohol consumption, mindfulness, and mental health were measured using reliable and validated self-reported measures. Unless otherwise stated, these were five point Likert Scale questionnaires. Idiosyncratic measures were created for adherence to the intervention, diet, and smoking. Higher scores indicated higher hours of exercise, alcohol consumption, mindfulness, positive mood, compassion, distress, and mental health symptoms. The study did not have the scope to collect data about calorie intake or dietary

composition, or to use physiological smoking measures. Where possible, short form measures were selected to reduce participant burden.

2.4.1 Pregnancy characteristics

At baseline, women provided information about their parity, gestation, pregnancy recognition, whether pregnancy was planned or assisted with in-vitro fertilisation (IVF), their age group, employment, family income, education, and ethnicity. *Pregnancy symptoms:* Women reported the frequency with which they experienced tiredness, nausea, and illness or pain on a scale of *not at all* to *all the time*, and completed an open text response on the type of illness/pain.

2.4.2 Adherence to the intervention

The participants reported their frequency of mindfulness practice and the extent to which they met the autonomous SMART goals they set in week 0 on a scale of *no days* to *every day*.

2.4.3 Health behaviours

Activity levels: Activity levels were measured using the Pregnancy Physical Activity Questionnaire (PPAQ) [56]. It is a valid and reliable measure of sedentary, light, moderate and vigorous activity in pregnant women (Cronbach's alpha = 0.78). *Diet:* The women indicated whether they were taking pregnancy-specific multivitamins or vitamin D supplements. They indicated the frequency with which they would describe their diet as "healthy and balanced", how often their diet conformed to the Eatwell Plate (starchy carbohydrates, "5 a day" portions of fruit and vegetables, protein-rich foods, dairy products, and high fat/sugar foods and drinks) on a scale of *every day* to *never*. *Alcohol consumption:* Pre-pregnancy and current alcohol consumption was measured using the three item Alcohol Use Disorders Identification Test Consumption scale (AUDIT-C) [57]. It asks about the frequency and quantity of alcohol consumption. *Smoking:* Smoking was measured by asking how many cigarettes they smoked each day.

2.4.4 Psychological measures

Mindfulness: Mindfulness was measured using the Five Facet Mindfulness Questionnaire (Short Form) (FFMQ-SF) [58]. *Affect:* Affect was measured using the Positive and Negative Affect Schedule (PANAS) [59], which asks how frequently participants experience 10 positive and 10 negative mood states. *Wellbeing:* Wellbeing was measured using the

Warwick-Edinburgh Mental Well-being Scale (WEMWBS) [60], which asks about the frequency of experiencing 14 positive states. *Perceived stress*: Stress was measured using the Perceived Stress Scale (PSS) [61], which evaluates tendency to view life events over the previous month as stressful and beyond ability to cope using 10 questions. *General anxiety*: The Generalised Anxiety Scale (GAD-7) [62] measured symptoms of anxiety over the week using seven questions on a four point scale. *Antenatal depression*: The Edinburgh Postnatal Depression Scale (EPDS) [63] measured symptoms of antenatal depression using 10 questions on a four item scale about how women have felt over the last two weeks. *Pregnancy-related distress*: Tilburg Pregnancy-Related Distress Scale (TPRDS) [64] evaluated the way women felt about their pregnancy during the last seven days using 16 items. *Compassion*: The Self-Compassion Scale - Short form (SCS-SF) [65] measured compassion towards the self with six positively and six negatively worded questions. The Compassion Scale [65] measured compassion for other people using 12 positively and 12 negatively worded questions.

2.4.5 Adherence to the intervention

The women self-reported health behaviour measured adherence to UK guidance for maternal health behaviours. They self-reported their adherence to the recommendations for mindfulness practice, the frequency with which they had achieved their lifestyle goals, and the frequency with which they had used the diary at weeks 8 and 16, on a scale of *no days* to *every day*.

The questionnaires were anonymous and each woman had her own ID number. Completed questionnaires were returned in sealed blank envelopes into an unsorted pile at taught sessions, or by post in pre-paid printed envelopes. The researcher did not read the questionnaires until the week 16 data collection was complete.

2.5 Sample size

The target sample was a group of 30 pregnant women. This was sufficient to evaluate the feasibility of the intervention, and was consistent with other feasibility studies of mindfulness-based interventions for antenatal mental health, smoking cessation, and weight management [36,43,66].

2.5.1 Assignment method

The unit of assignment was the group, which was the intervention condition.

2.5.2 Blinding

The nature of the intervention meant that blinding was not possible.

2.5.3 Unit of Analysis

The group was the smallest unit used to assess intervention effects.

2.6 Statistical Methods

Attendance and self-report adherence data were entered into and checked in Excel. Descriptive and inferential statistics for the quantitative data were created in SPSS 25 [67]. 50% attendance of the eight-week mindfulness course counted as completion, which is typical in antenatal mindfulness studies [68,69].

Leisure time physical activity (LTPA) hours were calculated by adding together the time spent on moderate and vigorous leisure time (classified in the PPAQ) [56]. Conception BMI was calculated using pre-pregnancy weight and height (kg /m²). AUDIT-C scores above zero indicated alcohol consumption [57]. Some women who were drinking small amounts had written notes on the pregnancy alcohol scale as it did not allow them to accurately report amounts of less than one unit. Consequently, pregnancy alcohol consumption was assessed in fractions of units. Women who had consumed alcohol or smoked pre-conception but were now abstinent were identified as quit.

Adherence to guidance was defined by at least five 30 minute sessions of moderate activity each week (2.5 hours in all); regular (*most days* or *all days*) healthy and balanced diet, regular 5 a day fruit and vegetables, supplementing vitamin D; no alcohol; no smoking; and normal range BMI at conception [10–13]. Non-adherence to guidance was classified as a health behaviour risk. Adherence to health behaviour and mindfulness goals on *most days* or *all days* was classified as regular. Pregnancy symptoms *a lot* or *all of the time* was classified as frequent.

Descriptive summary data was reported. Independent *t*-tests were conducted on the baseline characteristics of the retained and withdrawn groups at weeks 8 and 16. Effect sizes were calculated using the formula $d = (M_2 - M_1) / \sqrt{((SD_1^2 + SD_2^2) / 2)}$ and were categorised as < 0.1 = trivial; 0.1 to 0.3 = small; 0.4 to 0.5 = moderate; > 0.5 = large [70]. Mindfulness and mental health scores were not consistently normally distributed, so Wilcoxon signed rank and Friedman repeated measures tests were used to assess changes in median scores from baseline to week 8 and week 16.

Ethical permission to conduct the research was granted by Oxford Brookes University Ethics Committee.

3. Results

3.1 Recruitment strategies

Table 4 illustrates the success of the recruitment approaches. No expressions of interest were generated by posters displayed in the more deprived areas, whereas posters in more affluent and university areas led to expressions of interest. Translation of expressions of interest into recruitment was highest from women who were already engaged in antenatal exercise classes or were signed up to Facebook pregnancy groups.

[Insert Table 4]

3.2 Participant flow

Fifty women expressed interest in participating in the study between September 2013 and January 2014. Nine decided not to proceed after reading the information sheet, six were unable to commit the time, one miscarried, and two did not respond to further email correspondence. Six women were not eligible after screening: five were high gestation, and one was higher risk pregnancy. Three eligible women withdrew prior to the introductory session: one decided on “hypnobirthing”, and two suffered bereavements. Thirty-two women participated, and the intervention was delivered to two consecutive groups. There were thirteen women in-group one, and nineteen in-group two. Six women (19%) withdrew between weeks one and three, having attended one or two mindfulness sessions: five due to lack of time, one due to family illness. Twenty-six (81%) were retained at week eight; 22 (69%) were retained at week 16. Figure 1 summarises participant flow.

[Insert Figure 1]

All retained participants were included in the analyses at each time point. Data were collected from group one on 15th October 2013, 15th December 2013, and 3rd February 2014, and from group two on 25th January 2014, 29th March 2014, and 19th May 2014.

3.2.1 Baseline socio-demographic characteristics

The majority of women were in their thirties, were UK nationals, employed, graduates, and had family income of £40,000 or more (Table 5). All were either married to or cohabiting with the father of the baby, and spoke fluent English. Most were in the second trimester

(weeks 14 to 27) with planned and naturally conceived singleton pregnancies. More than half the women were nulliparous (first child). Two women were expecting twins, and one of these pregnancies was assisted with IVF.

[Insert Table 5]

3.2.2 Baseline pregnancy symptoms

Just over half of the women ($n = 17$, 53%) reported frequent (a lot, or all of the time) tiredness, and 10 (31%) reported frequent morning sickness. Six women reported frequent pelvic girdle pain, and three experienced it occasionally.

3.2.3 Baseline health behaviours

The majority of women were sufficiently active, had a regularly healthy and balanced diet including five portions of fruit and/or vegetables, were in the normal BMI range at conception, and were not drinking alcohol; no-one was smoking (Table 6). Two women were underweight at conception ($<18.5 \text{ kg/m}^2$), two were overweight (25 to 29.9 kg/m^2), and three were obese (30 kg/m^2 and over). Twenty-eight had consumed alcohol prior to pregnancy; 17 had quit. The one woman who smoked prior to pregnancy had quit. Eleven women (34%) had nil health behaviour risks; 16 (50%) had one risk; five (16%) had co-occurring risks, of whom three (10%) had two, and two (6%) had three risks.

[Insert Table 6]

3.2.4 Baseline mental health

Low mood and perceived stress were highly prevalent, and a number of women scored above the clinical cut-off for antenatal depression, general anxiety, and pregnancy distress (Table 7).

[Insert Table 7]

3.2.5 Comparison between study population at baseline and target population of interest

In comparison to national norms, the women were more likely to be well-educated, relatively affluent, older first-time mothers who had planned their pregnancies with their husbands or co-habiting partners. Adherence to UK guidance was higher than normal, other than for alcohol consumption, which was lower than population prevalence [14,15]. Inactive, overweight, and obese women were under-represented. Mean mental health scores were

above population medians. Low mood and perceived stress were highly prevalent, and a number of women scored above the clinical cut-off for antenatal depression, general anxiety, and pregnancy distress.

3.2.6 Baseline comparisons of those lost to follow up and retained

There were no differences between the socio-demographic characteristics of the retained and withdrawn groups at weeks 8 and 16. Withdrawal was more common amongst the women who were obese at conception and/or had health risks. Two of the women who were obese at conception withdrew by week 8; the third was lost at week 16. (No risks: One of 11; single: five of 16; co-occurring: four of five.)

T-tests indicated that the mean total mindfulness, positive affect, negative affect, wellbeing, pregnancy distress, and compassion scores of the week 8 withdrawal group were not different to the retained group. Perceived stress was higher in the withdrawal group ($M = 24.33$, $SD = 4.72$) than the retained group ($M = 21.54$, $SD = 2.16$) ($t(30) = 2.24$, $p = .001$, $95\% CI = 0.25, 5.34$, $d = 0.76$). Antenatal depression was higher in the withdrawal group ($M = 11.00$, $SD = 5.73$) than the retained group ($M = 6.79$, $SD = 4.00$) ($t(30) = 2.12$, $p = .043$, $95\% CI = 0.13, 8.28$, $d = 0.85$). General anxiety was higher in the withdrawal group ($M = 9.33$, $SD = 4.46$) than the retained group ($M = 4.82$, $SD = 3.80$) ($t(30) = 2.49$, $p = .019$, $95\% CI = 0.79, 8.24$, $d = 1.09$). T-tests showed similar differences in the baseline and week 16 perceived stress, antenatal depression, and general anxiety scores of the retained and the lost to follow up groups. These were large effects, and indicate that the women who withdrew by week 8 and 16 had significantly higher stress, depression, and anxiety at baseline than those who were retained.

The analysis was for ‘intention to treat’, and women who did not complete due to low attendance, and/or did not adhere to the mindfulness practice or self-monitoring aspects of the Mind the Bump intervention were not treated differently in the feasibility analyses.

3.3 Adherence to the intervention

3.3.1 Deliverability

The researcher was able to deliver the intervention in accordance with the content and timing plan. Each session was delivered four times. The core aspects were the same each time. There was some variation in the reflection and discussion aspects, depending on the participants’ experiences. This is typical in MBIs [71]. **However, the initial intention was to deliver the**

programme once, to a group of 30 women. The pattern of recruitment, the women's availability, and the researcher's capacity to teach the programme meant that two consecutive courses were taught. There was no capacity to run a rolling programme that allowed women to join immediately.

3.3.2 *Home practice*

Adherence to the home mindfulness practice element of the intervention was low to moderate during the taught course, and reduced in the self-led period. Preference switched from formal practice in the taught period to the breathing space practice in the self-led period. Figure 2 illustrates formal, informal, and breathing space practice in the taught period. Only three women (12%) engaged in formal home practice five or more times per week during the taught course. Over half ($n = 15$, 58%) did so three to four times, seven (27%) did so once or twice per week, and one (4%) did not practice. Figure 3 shows practice frequency in the self-led period. No one engaged in formal practice at recommended levels, and 11 women (35%) did no formal practice.

[Insert Figures 2 and 3]

3.3.3 *Health behaviour guidance*

Table 8 illustrates adherence to UK guidance for pregnancy health behaviours. An increasing proportion became less active than recommended (week 0: 16%, week 8: 35%, week 16: 41%). A caveat is that nine women (28%) reported Pelvic Girdle Pain at baseline; this condition can limit mobility and ability to exercise. One or two women were not taking vitamin D at each time point. The majority of the women described their diet as regularly healthy and balanced at baseline and week 8, and this improved at week 16, but the proportion regularly consuming five daily portions of fruit and vegetables reduced from baseline to week 8 and to week 16. More than half the women adhered to guidance not to drink alcohol, but abstinence reduced slightly from baseline to weeks 8 and 16. All the women complied with guidance to not smoke during pregnancy. Other than for alcohol, adherence to guidance was higher than UK norms [10–13] throughout the intervention. Ten of the women had given birth at week 16, meaning that vitamin D guidance no longer applied. Table 9 shows leisure time physical activity hours and alcohol units at each time point; they were consistent from week 0 to week 8 to week 16.

[Insert Table 8]

[Insert Table 9]

3.3.4 Goal attainment

At least half the women regularly attained their baseline goals for physical activity (50%), diet (54%), and alcohol (54%) during the eight week taught course, but exercise goals became less achievable in the self-led period (23%) as pregnancy progressed. The woman who smoked prior to pregnancy attained her goal not to smoke.

3.3.5 Self-monitoring

Adherence to the self-monitoring recommendation was low. From week 1 to 8, two women (8%) used the diary sometimes, 18 (69%) used it occasionally and six (23%) did not use it in the week 1 to 8 period. Nine (41%) women used it occasionally in the follow-up period, the remainder ($n = 13$, 59%) did not use it.

3.3.6 Attendance

The number who attended each session is shown in Table 10. Mean attendance was 5.17 (SD = 1.77) sessions. Reasons for non-attendance included illness, fatigue, lack of childcare, academic conferences, and social commitments. Twenty-one women attended four sessions, meeting the completion criterion. All returned week 8 data; 17 returned follow up data, of whom 10 were still pregnant.

[Insert Table 10]

3.4 Mindfulness and mental health outcomes

Table 11 illustrates the means, standard deviations, and ranges of physical activity hours, alcohol units, mindfulness, and mental health scores at baseline, week 8 and week 16. Mindfulness scores increased from baseline to week 8, and there were further small changes at week 16. Mental health scores improved from baseline to week 8, and there were further small gains at week 16. Mean perceived stress, antenatal depression, general anxiety, and pregnancy distress reduced from baseline to week 8, but gains were partially lost by week 16. Self-compassion increased from baseline to week 8 and week 16. Compassion for others was stable throughout.

Wilcoxon signed rank tests on baseline to week 8 data showed that there were large, highly significant increases in total mindfulness, the non-reactivity, observing, acting with awareness, and describing subscales, and positive affect. There was a moderate significant

increase in wellbeing. There was no change in negative affect, perceived stress, antenatal depression, general anxiety, pregnancy distress, and compassion. Friedman repeated measures found the same pattern of changes and stability across the baseline to week 16 period; post-hoc tests showed that gains occurred during the taught course.

This means that mindfulness and positive aspects of psychological health improved during the taught course. Mindfulness subscale changes indicated that emotional reactivity and habit-driven ‘autopilot’ patterns reduced, and awareness of and ability to articulate thoughts, feelings, and behaviours increased. However, negative and clinical aspects of antenatal mental health were not alleviated. Maternal health behaviours were stable, so analyses of relationships with mindfulness and mental health were not conducted.

[Insert Table 11]

3.5 Per capita cost of the intervention

The material costs were £8.11 per book and £100 catering. There were no venue costs, and no payments were made to the women. No costs were incurred in the follow-up period. The per capita materials cost was £11 for the cohort, not accounting for losses at weeks 8 and 16. A PhD award covered £4000 for the researcher’s mindfulness teacher training and £7000 development and delivery costs. The inclusive per capita cost was £355 per person for the cohort of 32 women, rising to £437 and £494 for the groups retained at weeks 8 and 16.

3.6 Indicative safety of the intervention

No intervention-related incidents were reported during the mindfulness course or self-led period.

3.7 Implementability

Table 12 indicates that Mind the Bump did not adequately fulfil the BCW’s APEASE (Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects, and Equity) implementability criteria [45].

[Insert Table 12]

4. Discussion

The objective of the current study was to report the feasibility of Mind the Bump, a novel complex mindfulness-based maternal behaviour change intervention. It combined

mindfulness training with behaviour change techniques to target adherence to maternal health behaviour guidance alongside mindfulness and mental health.

4.1 The effectiveness of different recruitment strategies

General recruitment advertising using posters attracted most interest, but lowest translation into recruitment, and there was no response to posters in economically deprived areas. Selective targeting of pregnancy interest or exercise group on social media and via pregnancy yoga teachers yielded the highest translation into recruitment. This reflected recruitment patterns in other pregnancy MBIs [35–38], and suggests that women who are already actively engaged in self-care are more likely to be interested in MBI studies.

4.2 Participants' socio-demographic and pregnancy characteristics and their baseline health behaviour and psychological characteristics

Recruitment suggested that the intervention appealed more to older, higher income, highly educated women who were in stable relationships. This reflected the profile of women who take part in maternal mental health focused MBIs [38]. A university-based study may have deterred women who had not attended university. Whilst the aim was to recruit women under 26 weeks gestation, the timing of the intervention delivery meant that some of the women were in the third trimester at baseline, and 10 gave birth during the follow up period. First time mothers were over-represented. There was no potential to provide childcare, which may have constrained its accessibility to women with children. The study was able to recruit women who were less active than advised, were overweight or obese at conception, did not adhere to five a day recommendations, and were drinking alcohol, but not women who were smoking. However, despite telephone screening, 11 women were adhering to the guidance for exercise, diet, alcohol and smoking at baseline, thus there was no potential to improve their adherence to guidance. There was low prevalence of co-occurring risks. The study attracted a relatively high number of women who were suffering from pelvic girdle pain, which can inhibit exercise, limiting the potential of the intervention to improve their activity levels. These women were perhaps interested in taking part because they were aware that mindfulness could alleviate pain-related stress [72]. Despite efforts to screen out clinically diagnosable women by telephone, a number of women self-reported clinical levels of anxiety, pregnancy-specific distress, and depression at baseline. They were neither diagnosed nor receiving medical support. A previous non-clinical antenatal mindfulness study also attracted a higher than typical proportion of pregnant women who scored above clinical cut-off for

depression and anxiety [73]. It may be that women who are aware of their low mood, and that mindfulness training can be helpful, are attracted to MBI studies. The failure of telephone screening to detect ineligible participants might be overcome by women completing online health behaviour and clinical mental health measures as part of the screening process.

Overall, the Mind the Bump group were not representative in terms of their socio-demographic and pregnancy characteristics, or their baseline health behaviour and psychological characteristics, which suggests low “goodness of fit” and appeal to the general population.

4.3 Response and retention at weeks 8 and 16

The response rate was high: 100% at week 8 and 84% at week 16. This was no worse than the 72% to 84% retention rate in other antenatal mindfulness studies [e.g. 69,73]. The withdrawal rate was also consistent with 12% to 23% withdrawal in non-clinical maternal mindfulness studies [34,73]. The pattern of early drop out, and the reason of time commitment, are common in MBI studies [74].

It was notable that the women who withdrew had higher mental health symptoms and more health behaviour risks than the retained cohort. Whilst women with higher mental health symptoms were not the target group, the loss of those with health behaviour risks, particularly the three obese women, was a significant feasibility issue. Offering mindfulness groups for obese pregnant women might increase retention, but Mind the Bump was designed as a universal intervention.

4.4 Adherence to the intervention

The intervention was deliverable, and flexible to the attendees’ experiences, but there were no external fidelity checks. Adherence to home practice recommendations is regarded as the elusive “Holy Grail” of MBIs, but there is a lack of consensus on dose effects and adherence to recommendations [75]. Nearly all the women used all or some parts of the portfolio of formal, informal, and breathing space practices, but none practiced mindfulness at recommended levels during the week 1 to 8 period, suggesting that this was too onerous. It appears that three to four days per week is the typical frequency [76]. Practice rates reduced during the self-led period. This pattern reflected the common tendency of practice to diminish after the face-to-face course is complete, and it may be associated with whether or not participants believe that the practices are a plausible way of maintaining their health [75]. There was a switch from longer to shorter practices during the self-led period. The women

were provided with information about public mindfulness practice sessions at Oxford Mindfulness Centre, but this was not taken up. This is understandable, given that 10 women had given birth at week 16. Formal practice was not sustainable after the face-to-face period, and overall rates reduced. Whilst this suggests that contact with the teacher was important in maintaining motivation and opportunity, it may be that the course was too short.

Adherence to guidance for maternal health behaviours was high throughout the intervention. This was not surprising as it was apparent that the women who volunteered to take part in this study had generally healthy lifestyles, and 11 women were adhering to recommendations at baseline. This constrained the potential to improve adherence to maternal health behaviour guidance. Overall, the retained women were more active than pregnant population norms, and moderate activity levels remained consistent throughout the intervention. Whilst this study did not evaluate the natural trajectory of health behaviours during pregnancy, the finding differs to the general trend for exercise levels to diminish [77], and might suggest that Mind the Bump had a protective effect. However, the withdrawal of the three women with obesity health risk meant it was not possible to assess any potential gains or protective effects for this group.

Whilst the majority of women adhered to their own exercise goals, this became less achievable as pregnancy progressed. Adherence to diet goals was more consistent across time, and it seems reasonable to suggest that diet is less subject to the effects of progressing pregnancy than exercise.

Most of the women who did not adhere to guidance to avoid alcohol at baseline continued to drink small amounts throughout. The literature on antenatal alcohol interventions draws contradictory conclusions. Some find that educational antenatal alcohol interventions do not significantly reduce consumption even though they improve knowledge, whereas others find that brief interventions can be effective [78]. Mind the Bump was not a brief intervention, and its alcohol message was probably obscured by the focus on mindfulness.

Low adherence to the recommendation to use the diary for self-monitoring might suggest that this aspect of the intervention was not salient, that the diary was poorly designed, or that the weekly handouts negated its utility. It might be that, despite the primary aim of the intervention, health behaviour change was not a priority for the participants, or that the impact of pregnancy and daily commitments on ability to fulfil intentions led to disengagement with self-monitoring.

Attendance was moderate, but the completion rate of 66% for the baseline cohort was lower than the 86% to 88% completion rate in antenatal MBIs [68]. Running each session twice a week, in response to participants' availability, improved accessibility and attendance. Group size tended to be no more than 10, whereas the capacity was 30 women. This is unlikely to be feasible in a larger evaluation or rollout.

4.5 Mindfulness and mental health outcomes

There were beneficial effects on mindfulness and positive aspects of antenatal mental health. Scores increased significantly during the mindfulness course, and were largely maintained during the self-led period despite mindfulness practice levels falling considerably. This suggests that factors which may underpin adverse antenatal health behaviours, such as emotional and behavioural reactivity, automaticity, inability to articulate thoughts and emotions, and harsh self-judgement reduced during the mindfulness course. This indicates that Mind the Bump was at least as effective as higher-dose pregnancy specific MBIs in improving trait mindfulness and positive mental health [79]. That gains were largely constrained to the taught course period indicates that the mindfulness sessions were likely to have been a key component.

The women's baseline mental health characteristics suggested that there was potential for improvement, but the intervention was not related to any changes in antenatal stress, distress, depression, or anxiety. This reflects a later review's conclusion that the current evidence base is not sufficient to assert that MBIs improve clinical aspects of pregnancy mental health [35]. However, the current study did not compare the intervention group's mindfulness and mental health outcomes to natural changes.

4.6 Per capita cost of the intervention

The costs of delivering the intervention were low, and no costs were accrued during the follow-up period. Whilst the development and mindfulness teacher training costs were met by PhD funding, this increased the per capita cost considerably. Other antenatal mindfulness studies have not reported costs, other than one that reported the costs of advertising [73], which were not incurred in the current study. Per capita development and training costs would potentially reduce over time if the intervention were delivered to more women. However, the lack of impact on negative aspect of mental health and health behaviours meant that the current version of the intervention was not cost-effective.

4.7 Indicative safety of the intervention.

No harms were reported, which indicated that the intervention appeared to be safe.

4.8 Impact on anticipated mechanisms of change

Mindfulness and some aspects of mental health improved, suggesting that the mindfulness training may have improved the women's capability to regulate their health behaviours. However, given the lack of actualised impact on the behavioural outcomes, there was no evidence that the intervention successfully impacted on the other anticipated capability, opportunity, and motivation mechanisms in a way that changed their adherence to health behaviour guidance. Low adherence to the intervention may have affected its potential to improve health behaviours, but the women were already adherent to maternal lifestyle guidance at baseline, thus constraining any potential to improve capability, opportunity, and motivation for health behaviours.

There was no evidence that education about health behaviours during pregnancy, goal setting, or increased mindfulness and wellbeing made a difference to capability, opportunity, or motivation, as adherence to guidance did not increase. There was no evidence that modelling by the trainer or peers affected capability or opportunity to improve health behaviours, and it may be that sharing experiences of the barriers to change reinforced challenges. Low self-monitoring meant that this consistently effective component of behaviour change programmes [47,80] had very limited potential to impact capability, opportunity, or motivation.

4.9 The success of and barriers to implementing the intervention, fidelity of implementation

There were no evident barriers to implementing the intervention, but failure to recruit the target group and low adherence to the intervention constrained any potential to improve maternal health behaviours. The withdrawal of women who were obese at conception indicated barriers to delivering it to this group. Feedback was that the gestational weight gain education component was not acceptable.

4.10 Research, programmatic, or policy implications

Overcoming these issues would require more stringent screening of potential participants, and reconsidering the contents. It may be that pregnancy specific mindfulness practices are more acceptable for home practice. The pregnancy-specific meditations on the Headspace app and

accompanying book, “The Headspace Guide to a Mindful Pregnancy” [81], which post-dated the current intervention development, may be a more suitable companion to Mind the Bump. The Headspace practices are tailored to pregnancy, and the app is less repetitive than the MaPP CD, so it may be more likely to create and sustain engagement in home practice.

Paper based self-monitoring has been superseded by app based approaches, and can be more effective in behaviour change [82]. Thus, future mindfulness-based behaviour change interventions should integrate digital goal setting and self-monitoring content where possible. The feasibility of digital, face-to-face, or blended delivery of mindfulness-based behaviour change interventions should be evaluated. Co-producing interventions with women from target groups is likely to support goodness of fit to their needs and preferences [83].

This feasibility study did not have a control group, thus curtailing the detection of any beneficial or iatrogenic effects in comparison to normal trajectories. Whilst there are practical and ethical issues around wait-list controls during time-limited periods such as pregnancy [84], intervention outcomes should be evaluated against natural changes or existing where possible [47]. As such, it may be useful to discover whether mindfulness-based behaviour change programmes have potential to impact the health behaviours of women of reproductive age in comparison to matched control groups, or to compare pregnancy MBIs to other structured programmes, such as pregnancy yoga [85]. It would be useful to measure birth and short term infant outcomes, such as birth weight and attachment, to assess any indicative effects. It is important to recognise that intervening in mental and lifestyle health prior to, not after, conception could reduce the likelihood of early foetal exposure to stressors [2,5,7], although the impact of any such pregnancy health programmes would be predicated on planned pregnancy and women’s capability, opportunity, and motivations to change [86].

4.11 Generalisability: external validity

The current findings were not generalisable to the general population of pregnant women. Whether it would be any more feasible for different types of women, i.e. lower adherence to health behaviour guidance, different socio-demographics, different mental health, or even for women from the same backgrounds but who fully met the inclusion criteria, cannot be inferred. Follow-up data validity was reduced by 10 women giving birth.

5. Conclusion

This novel mindfulness-based maternal behaviour change intervention, Mind the Bump, aimed to improve pregnant women's mindfulness, mental health, and adherence to UK health behaviour guidance. Low adherence indicated acceptability problems, and the drop-out of women with more health risks implied a poor fit for this group. The intervention was deliverable, although recruitment patterns and optimising opportunities to attend meant that each session was taught four times instead of once. There were some benefits, as mindfulness and positive aspects of maternal mental health improved, but negative aspects of mental health, including affect, stress, depression, and anxiety did not improve. There was no change in adherence to guidance, although the potential for this was constrained by the generally healthy lifestyles of the women who chose to take part in the study, so it was not consistently effective. Although it was affordable and safe, further development was required, and the lack of impact on anticipated mechanisms of change and health behaviours meant that it was not cost-effective. The intervention attracted women who were university educated, affluent, and co-habited, and seemed to have no appeal to other women, so it was not equitable. Overall, the intervention did not meet the implementability criteria. There may be potential to adapt the target, delivery, and content of the intervention to address its limitations, in consultation with the target group.

Compliance with Ethical Standards

Conflict of Interest

The authors declare that they have no conflict of interest.

Research involving Human Participants and/or Animals

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Oxford Brookes University and the British Psychological Society) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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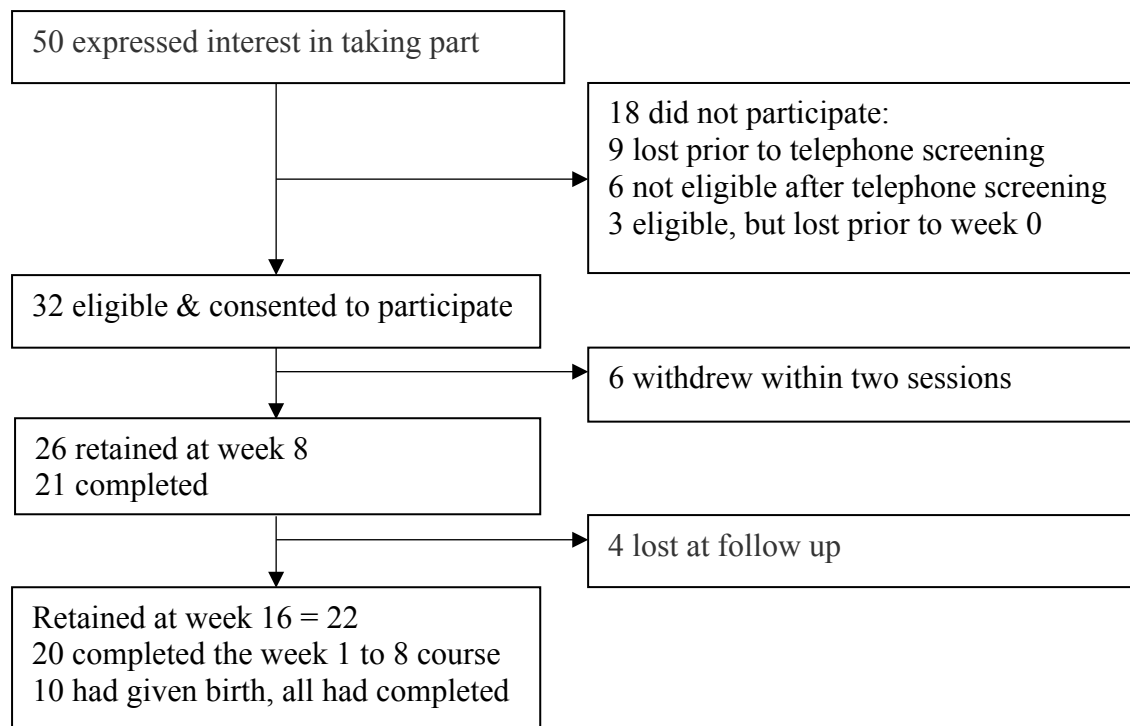


Figure 1 Participant flow.

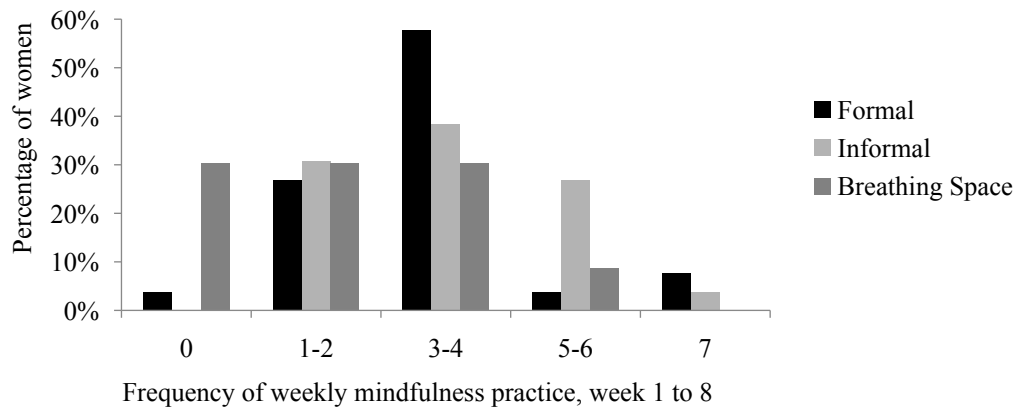


Figure 2 Practice frequencies during the taught course.

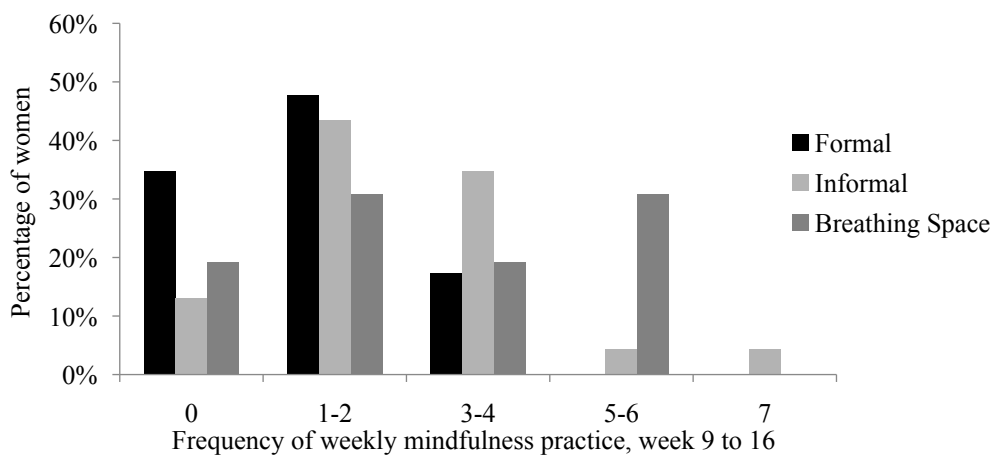


Figure 3 Practice frequencies during the self-led period.

Table 1 Inclusion and exclusion criteria for Mind the Bump

Inclusion	Reason for the criterion	Exclusion	Reason for the criterion
Up to 26 weeks gestation	To evaluate intervention within pregnancy timeframe.	Current mindfulness practice.	To evaluate the feasibility of developing a mindfulness practice.
Age 16 years and over	Women could provide their own informed consent.	Diagnosis of current mental illness.	The intervention was not designed for a clinical population.
Not adhering to recommendation for maternal health behaviours.	To measure the indicative effects on health behaviours.	Required significant specialist obstetric care	The intervention was not designed for women with high-risk pregnancies.
Available to attend nine concurrent weekly sessions at Oxford Brookes University.	To evaluate attendance and attrition.	Taking part in another health behaviour intervention	To avoid confounding effects.

Table 2 Mind the Bump content

Materials	Behaviour change components	Formal mindfulness practices	Brief/Informal mindfulness practices	Psychoeducation
‘Mindfulness: Finding Peace in a Frantic World’ book and Compact Disc. Paper study diary: weekly guidance, goal setting, and self-monitoring of goals.	Education. Goal setting. Self-monitoring. Planning how to overcome barriers to goal achievement.	Breath and body. Body scan. Mindful movement. Sounds and thoughts. Exploring difficulties. Befriending.	Breathing space. Mindful eating. Mindfulness of daily activities.	Automatic thoughts and behaviours. Attitudes to experience. The present moment. Embodied experience. Self-criticism. Depleting and nurturing activities.

Table 3 Anticipated impacts of Mind the Bump on capability, opportunity, and motivation factors in maternal health behaviours and mindfulness practice

Component	Intervention Function	Capability	Opportunity	Motivation
Education	Education	Understanding the potential benefits of establishing a mindfulness practice and the reasons for health behaviour change: knowing about UK maternal health behaviour guidance, and possible consequences of non-adherence.	Knowing about local antenatal exercise classes.	Accurate health behaviour risk appraisal. To engage in self-care by choosing health behaviour change and mindfulness practice.
Goal setting	Enablement			Reflective motivation about the potential benefits of health behaviour change and mindfulness practice. Autonomous SMART goals.
Mindfulness training	Training	Greater awareness of health behaviours. Improved mental health and mindfulness. Reduced reactivity, and greater ability to notice and tolerate urges to be sedentary, eat unhealthily, to drink alcohol, to smoke, and to avoid mindfulness practice. Developing practical skills to cope with emotional and physical difficulties.	Making time for self-care: to engage in health-promoting behaviours and mindfulness practice. Opportunity to attend the weekly mindfulness sessions, and to access peer support and mindfulness practice resources.	Reminders and reflections on reasons for health behaviour goals and mindfulness practice. Increasingly automatic motivations for positive health behaviours and mindfulness practice. Awareness of peers' self-care behaviours.
	Enablement	Improved physical and psychological capability to engage in in positive health behaviours and mindfulness practice.	Planning how to overcome barriers to goals.	Improved reflective and automatic motivations for health behaviours and mindfulness practice.

	Modelling	“Walking the talk” – trainer embodied mindfulness and adhered to her own health behaviour goals.	To discuss barriers and enablers for health behaviours and mindfulness practice, to share experiences of health behaviours, mindfulness, and pregnancy with other pregnant women.	
Self-monitoring and planning	Enablement	Improved health behaviour, mindfulness, and emotional regulation, self-efficacy, and self-regulation. Transformation of conscious health behaviour change into healthier automatic habits. Establishment of a sustainable mindfulness practice.	Observing and reflecting on self-care through health behaviour and mindfulness goal achievements, and barriers and enablers to this.	Greater self-determination, self-efficacy, and perceived control of health behaviours, mindfulness practice, and mental health

UK: United Kingdom. SMART: specific, measurable, achievable, realistic, time-framed.

Table 4 The effectiveness of different recruitment methods

Method	Forum	Interest n (%)	Translation into recruitment n (%)	Contribution to recruitment %
Poster	Noticeboards	26 (52)	13 (50)	41
Online	University website	-	-	-
	Local news website	-	-	-
Social Media	Facebook	9 (18)	7 (78)	22
	Twitter	-	-	-
Email	University research group	2 (4)	1 (50)	3
	Antenatal teachers	7 (14)	7 (100)	22
Face-to-face	Antenatal exercise	6 (12)	4 (67)	12

Table 5 Participant socio-demographics, N = 32

Characteristic	Group	Baseline n (%)	National norms (%)
Age group	20-30	8 (25)	51
	31-40	23 (72)	45
	41 and over	1 (3)	4
Nationality	White British	22 (69)	74
	Asian British	1 (3)	
	White European	6 (19)	26
	White North American	2 (6)	
	Chinese	1 (3)	
Native English speaker		27 (84)	N/A
Employment	Full-time	28 (88)	66
	PhD student	2 (6)	
	Full-time mother	2 (6)	
Highest level of education	Secondary school	1 (3)	15
	University Bachelor's degree	14 (44)	
	Master's degree	9 (28)	} 37
	Doctorate	8 (25)	
Annual Family Income	£10,000 to <£40,000	13 (41)	60
	£40,000 to <£80,000	14 (43)	30
	£80,000 & over	5 (16)	10
Married to or cohabiting		32 (100)	53
Trimester	First	2 (6)	
	Second	23 (72)	
	Third	7 (22)	
Expecting twins		2 (6)	2
Nulliparous		19 (59)	37
Planned pregnancy		28 (88)	83
Natural conception		31 (97)	84

Norms [14-16].

Table 6 Baseline adherence to maternal health behaviour guidance, N = 32

Health behaviour	Guidance	Adherent n (%)	Non- adherent n (%)	National norm for adherence %
Physical activity	2.5 hours p/w	27 (84)	5 (16)	50
Healthy balanced diet	Regular	24 (81)	8 (19)	??
5 a day	Regular	28 (88)	4 (12)	53
Folic Acid	To week 13	32 (100)	-	94
Vitamin D	Daily	31 (97)	1 (3)	58
Conception BMI	18.5 to <25 kg/m ²	25 (78)	7 (22)*	50
Alcohol consumption	Nil	20 (63)	12 (37)	59
Smoking	Nil	32 (100)	-	88

p/w: per week. BMI: body mass index. *Underweight (<18.5 kg/m²) n = 2 (6%); Overweight (25 to <30 kg/m²) n = 2 (6%); Obese (≥30 kg/m²) n = 3 (10%). 'Healthy balanced diet' was self-defined. Regular = most or all days. Guidance [10-13]; Norms [14-16].

Table 7 Psychological scores at baseline, N = 32

Variable	Mean (SD)	Population median/ clinical level scores	> median or clinical level	
			n	%
Total mindfulness	73.13 (11.41)			
Non-reactivity	13.69 (2.82)	-		
Observing	13.31 (3.01)	-		
Awareness	13.81 (3.30)	-		
Describing	16.66 (3.40)	-		
Non-judging	15.66 (4.14)	-		
Positive affect	29.63 (6.48)	31 *	19	59
Negative affect	21.13 (8.34)	15 *	24	75
Wellbeing	47.56 (7.68)	51 *	16	50
Perceived stress	22.06 (2.93)	20 **	23	72
Antenatal depression	7.63 (4.61)	13 **	4	13
General anxiety	5.79 (4.30)	10 **	3	9
Pregnancy distress	15.00 (8.09)	18 **	9	28
Self-compassion	14.75 (4.17)	-	-	
Social compassion	26.16 (2.34)	-	-	

SD: standard deviation. *Population median. **Indicates clinical level.

Table 8 Adherence to maternal health behaviour guidance at baseline N = 32; week 8 n = 26, week 16 n = 22

Behaviour	Pregnancy guidance	Adherence		Week 8		Week 16		National norm, %
		Baseline		n	(%)	n	(%)	
Exercise	At least 2.5 hours of moderate intensity per week	27	(84)	17	(65)	13	(59)	50
Diet	Regular healthy, balanced	24	(81)	21	(81)	19	(86)	-
	Regular 5 a day	28	(88)	21	(81)	17	(77)	53
Vitamin D	Daily supplement	31	(97)	23	(88)	18	(81)	42
Alcohol	Abstain	20	(63)	20	(63)	11	(55)	72
Smoking	Abstain	32	(100)	26	(100)	22	(100)	88

‘Healthy balanced diet’ was self-defined. Regular = most or all days. Guidance [10-13]; Norms [14-16].

Table 9 Mean moderate leisure time physical activity and alcohol units; baseline N= 32; week 8 n = 26; week 16 n = 22

Variable	Baseline			Week 8			Week 16		
	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range
LTPA (hours)	4.43	2.72	0.5 - 10	4.92	3.70	0 - 13.5	4.75	3.16	0 - 12
Alcohol (units)	0.26	0.50	0 - 2	0.28	0.55	0 - 2	0.57	1.33	0 - 2

LTPA: leisure time physical activity. SD: standard deviation.

Table 10 Mind the Bump attendance, withdrawal, and completion. N = 32

Number of sessions	1	2	3	4	5	6	7	8	Total n	% retained	% completed
	Non completion				Completion						
Attended	5	3	3	1	9	6	2	3	32		
Withdrew	4	2	-	-	-	-	-	-	6	19	
Retained at week 8	1	1	3	1	9	6	2	3	26	81	66
Retained at week 16	1	1	3	1	6	5	2	3	22	69	53

Table 11 Mindfulness and mental health from baseline N= 32 to post course week 8 n = 26, and follow up week 16 n = 22

Variable	Baseline		Week 8		Change in median			Week 16		Change in median	
	Mean	SD	Mean	SD	Z	p	r	Mean	SD	χ^2	p
Total mindfulness	73.13	11.41	83.00	10.99	3.88	<.001	.77	83.77	11.95	16.09	<.001
Non-reactivity	13.69	2.82	15.88	3.23	3.33	.001	.65	16.18	3.45	9.07	.011
Observing	13.31	3.01	14.35	3.02	2.83	.005	.55	14.00	3.52	9.38	.009
Awareness	13.81	3.30	16.00	3.20	3.78	<.001	.74	17.00	3.09	20.66	<.001
Describing	16.66	3.40	19.27	2.79	3.48	.001	.68	18.95	3.00	12.49	.002
Non-judging	15.66	4.14	17.50	2.66	1.68	.093		17.64	4.05	5.61	.060
Positive affect	29.63	6.48	33.38	6.01	2.94	.003	.58	34.27	7.79	11.05	.004
Wellbeing	47.56	7.68	50.62	7.06	2.06	.039	.40	49.82	9.00	2.16	.339
Negative affect	21.13	8.34	19.62	8.08	-0.70	.482		19.50	10.00	1.54	.463
Perceived stress	22.06	2.93	20.88	2.14	-1.58	.115		21.68	3.64	3.98	.137
Antenatal depression	7.63	4.62	6.12	3.71	-1.00	.316		7.09	5.32	0.29	.867
General anxiety	5.59	4.36	3.65	2.93	-1.59	.119		3.77	4.62	0.70	.703
Pregnancy distress	15.00	8.09	13.08	7.69	-1.41	.159		2.53	9.05	0.31	.859
Self-compassion	14.75	4.17	16.62	4.11	1.62	.105		18.36	4.59	5.57	.062
Social compassion	26.16	2.34	26.65	2.48	1.28	.199		26.32	2.64	1.62	.446

SD: standard deviation.

Table 12 Mind the Bump implementability according to APEASE criteria

Criterion	Condition	Mind the Bump
Acceptability	To recipients, and in wider social and political contexts.	Low adherence, not known in other contexts.
Practicality	The intervention can be delivered as designed.	Yes.
Effectiveness/cost effectiveness	The indicative outcomes suggest that the intervention will change health behaviours and targeted factors.	No impact on primary health behaviour target. Positive changes in mindfulness and positive aspects of mental health, none on negative or clinical aspects. Not cost-effective.
Affordability	Reasonable costs.	Low material costs, but high development and potential rollout costs.
Safety/side effects	Assess potential harms.	None reported.
Equity	The intervention reaches its intended recipients. Does not disadvantage particular groups.	Not possible to recruit higher risk women. Appeal may be limited to women who are similar to this sample.

APEASE: Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects, Equity.

Sarah Hennelly: Conceptualisation, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Programme administration, Resources, Software, Validation, Visualisation, Roles/Writing – original draft, Writing – review & editing. **David Foxcroft:** Supervision. **Lesley Smith,** Supervision. **Parvati Penman-Howe:** Writing – review & editing.