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MINDFULNESS IN THE PERINATAL PERIOD

Section A: Brief mindfulness-based interventions in the perinatal period: A systematic narrative review

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Section B: Acceptability and feasibility of an online brief mindfulness-based intervention for first time mothers within the postpartum period.

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Summary of Major Research Project

Section A:

Researchers have suggested that mindfulness may be a supportive intervention for perinatal women. This review evaluated studies to establish the strength of evidence and feasibility of digital, brief mindfulness-based interventions within this population. A systematic search yielded 13 papers meeting inclusion criteria. The review found promising support for the acceptability of interventions and cultivating mindfulness with tentative support for psychological wellbeing. Strength of support is limited by study design and quality. Controlled trials of brief mindfulness-based interventions are required to better assess the role of mindfulness in supporting psychological well-being for perinatal women.

Section B:

Research on mindfulness-based interventions within the postpartum period is currently scarce. New interventions to support mothers' psychological wellbeing have been called for, with mindfulness-based interventions showing promise. This study explored the acceptability, feasibility, and preliminary efficacy of an online, brief mindfulness-based intervention for first-time mothers within the postpartum period. Mothers of infants under one year (*n*=112*)* participated in a pilot randomised controlled trial. Findings suggest the intervention was acceptable and feasible. Analysis of covariance revealed a statistically significant between-group difference in perceived stress at post-intervention, with the intervention group reporting reductions in comparison to the control group, supported further by reliable change indices.

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Major Research Project (MRP) Section A: Literature Review Paper

Brief mindfulness-based interventions in the perinatal period: a systematic narrative review

Word count: 7996 (plus 11)

Abstract

Background: The perinatal period is a time associated with joy but also increased physical and mental stress for women. Due to the evidence base within the general population, mindfulness-based interventions may be one possible source of support for perinatal women.

Aims: This review aimed to evaluate empirical studies exploring the preliminary efficacy, acceptability, and engagement of digitally delivered brief mindfulness-based interventions for perinatal women.

Methods: A systematic search of six databases and open grey literature yielded 13 papers meeting inclusion criteria, which were narratively synthesised. Studies included single arm studies (*n*=6), non-randomised controlled trials (*n*=1), pilot randomised controlled trials (*n*=3) and full randomised controlled trials (*n*=3).

Results: Tentative support was found for mindfulness-based interventions decreasing psychological distress and moderate support for cultivating mindfulness. Acceptability was high across studies and supported via qualitative feedback. Engagement varied with daily use - a particular challenge for mothers. Study design and quality was mixed. Sample characteristics identified several under-represented groups, limiting generalisability of findings.

Conclusion: Digitally delivered brief mindfulness-based interventions appear acceptable for women within the perinatal period and provide tentative support for psychological wellbeing. Further research is required to fully establish benefits of brief mindfulness-based interventions in this population.

Keywords:
Mindfulness, perinatal, brief, online

Introduction

Research into mindfulness-based interventions (MBIs) has grown considerably within recent years. MBIs have been shown to be supportive in managing and preventing psychological distress within the general population (Kuyken et al., 2016), and thus may be supportive for perinatal women as they may be at an increased risk of experiencing or re-experiencing mental health problems (Dimidjian et al., 2016; Howard et al., 2014). More recently, researchers have questioned the practicality of traditional 8-week formats, which may be a barrier for engagement for perinatal women (Dhillon et al., 2017). MBIs have been reviewed within the perinatal period (Lever Taylor et al., 2016; Badker & Misri, 2017), however briefer formats are yet to be reviewed. This review seeks to establish the state of the empirical evidence to date, and to explore participant engagement in digital, brief MBIs delivered within the perinatal period.

The perinatal period

This review defines the perinatal period as covering both pregnancy and the postpartum period (the twelve months following birth) which is a definition used previously (Loughnan et al., 2018).

Approximately 15% of women experience depression within the perinatal period (Pearlstein et al., 2009) which can be a destabilizing time for women (and their families). Women who are vulnerable because of pre-existing mental health problems may be at particular risk (Byrnes, 2018). Poor mental health can impact both on the mother and their infant's social, emotional, and cognitive development (Kurstjens & Wolke, 2001), suggesting effective and timely interventions are crucial.

Mindfulness-based interventions

Mindfulness can be defined as 'awareness that emerges through paying attention in a particular way on purpose, in the present moment, and non-judgementally to the unfolding of experience moment by moment' (Kabat-Zinn, 2003 p.145). The most evaluated MBIs are mindfulness-based stress reduction (MBSR; Kabat-Zinn, 1998) and mindfulness-based cognitive therapy (MBCT; Segal et al., 2002). MBSR was developed at the University of Massachusetts by Kabat-Zinn in 1979. MBSR was seen as an intervention that could cultivate non-judgemental self-awareness and was seen as acceptable to support individuals to manage physical health conditions such as chronic pain and cancer (Grossman et al., 2004), and mental health conditions such as depression and anxiety (Segal et al., 2018). A meta-analysis showed improvements on anxiety and stress within non-clinical populations after completing an MBSR course (Sharma et al., 2014).

MBCT was developed to reduce depression relapse (Segal et al., 2013) and encompasses a blend of meditative practices and cognitive therapy to cultivate awareness of thoughts, feelings and explore individuals' relationship to emotions. The National Institute of Clinical Excellence guidelines (NICE, 2009) recommended MBCT for depression relapse with further interventions across various mental health conditions being developed since (Piet & Hougaard, 2011). Both MBCT and MBSR have shown effectiveness in reducing symptoms within clinical and non-clinical populations (Khoury et al., 2015; Kuyken et al., 2016), with higher mindfulness levels at baseline being associated with increased change in clinical outcomes (Khoury et al., 2015).

MBIs focus on increasing acceptance and non-judgemental awareness of the present moment. Within MBCT, this is achieved by combining elements of cognitive behaviour therapy (e.g., the interlink between thoughts, emotions, and physical sensations) alongside mindfulness meditation (Teasdale et al., 1995). One hypothesis about the mechanisms of

change within mindfulness comes from Teasdale's (1999) modes of being. Teasdale specifies three distinct modes of human processing, which includes a 'mindless emotive mode' (e.g. engaging in rumination on the content of thoughts), a 'conceptualising/doing mode' (e.g. engaging in a practical task such as grocery shopping) and a 'being or experiencing mode' (e.g. attending to bodily sensations, whilst being aware of worry and negative thoughts rather than engaging with them). It is hypothesised that we move our processing mode from the 'doing' to 'being' mode as we engage in mindfulness.

Adaptations to mindfulness-based interventions

Traditional MBI courses are time intensive for therapists and participants. Typically, they consist of 8 weekly two-hour sessions and up to an hour of daily home practice. Time commitment is one potential barrier to engagement (Chen et al., 2014) with concerns that traditional MBIs may not be suitable for all populations and might lead to higher drop-out rates in those who cannot commit to the recommended engagement time (Dobkin et al., 2012).

Time commitment may be one reason standard MBIs are challenging to implement within clinical settings, with briefer formats increasing their accessibility. Currently there are varied definitions of brief MBIs (bMBIs), including fewer weeks (Lan et al., 2015) or shorter sessions (less than 30 minutes on one occasion, totalling no more than 100 mins per week) (Howarth et al., 2019). Even ultra-brief single sessions of less than five minutes showed increases in global mindfulness and positive affect (Cavanagh et al., 2013). Support for brief MBIs increasing wellbeing is backed by evidence that even small behaviour changes can impact on complex health outcomes (Davis et al., 2015).

Recent systematic reviews exploring bMBIs have shown efficacy on health outcomes after one session (Howarth et al., 2019), and promise in supporting acute pain management

(McClintok et al., 2019) and reducing negative affectivity (Schumer et al., 2018). However, further research is needed to explore their feasibility and efficacy across different settings.

Online MBIs

Online MBIs have become more popular in recent years with Segal (2011) suggesting that MBIs will likely move towards this format due to a greater reach and cost-effectiveness. However, this area is still within its infancy (Ahmed et al., 2018). Digital MBIs (d-MBIs) allow for greater availability and accessibility with a variety of delivery methods including online programmes, mobile applications, and audio guides (Cavanagh et al., 2018). Systematic reviews have shown support for d-MBIs in improving mental health symptoms, particularly stress (Jayawaredene et al., 2017), with guided formats yielding higher effect sizes than unguided meditations (Spijkerman et al., 2016). The authors hypothesised that d-MBIs may be more convenient and cost-effective in comparison to traditional formats, especially within busy, hard to reach but digitally adept populations, which perinatal women may fall into. To date no systematic reviews have explored brief d-MBIs in clinical or non-clinical populations.

Feasibility studies exploring digital bMBIs (dbMBIs) indicate following regular practice, mindfulness may improve distress, perceived stress, and negative affect (Glück & Maercker, 2011). Others have reported reductions in stress at post-intervention and one month follow-up (Krusche et al., 2012). A randomised control trial (RCT) exploring a self-guided d-bMBI with students reported increased mindfulness skills and decreased perceived stress, anxiety, and depression after completion of the d-bMBI (Cavanagh et al., 2013).

Mindfulness-based interventions in the perinatal period

Theoretical background and support. Dimidjian and colleagues (2016) hypothesised that MBCT could be particularly helpful for women within the perinatal period

given the increased rates of depression seen in women during this period. MBIs within the perinatal period have been associated with less emotional distress prenatally and postnatally for mothers and increased infant social-emotional development (Braeken et al., 2017). It is thought that being able to shift awareness back to the present moment is a key parenting skill (Dumas, 2005) that can help reduce maladaptive parenting behaviours (e.g avoidance or withdrawal) stemming from automatic cycles (Duncan et al., 2009).

Duncan and colleagues (2009) introduced a model of 'mindful parenting' whereby parents intentionally bring awareness to the moment-to-moment interactions with their child. This encourages the parent to focus on the context of their relationship with their child and attend to their child's needs whilst enhancing and attending to their own emotional self-regulation. This allows parents to move away from automatic, self-focused motivations which often reduce the quality of the parent-child relationship (Dumas, 2005; Duncan et al., 2009), instead, mindful parenting may promote healthy psychosocial development of the child (Baumrind, 1989). This further encourages reflective functioning, whereby the parent can reflect on the internal experience of themselves and their child (Fonagy & Target, 1997).

MBIs adapted for perinatal women. One of the first pilot studies exploring MBIs for perinatal women was the mindful motherhood programme (Vieten & Astin, 2008) Mindful motherhood incorporated aspects of yoga, meditation, and relaxation training alongside aspects from MBSR and MBCT. A total of 31 pregnant women who self-identified as having depression and/or anxiety took part in the study, with 13 being randomised to the MBI. When compared against the wait list, women who attended the MBI experienced a significantly greater decline in depression, anxiety, and negative affect. Similarities have been found elsewhere, with reductions in depression, stress, and anxiety continuing after birth and when the intervention was delivered during pregnancy (Dunn et al., 2012).

Preventatively, a study examining MBIs has shown positive results for a reduction in depression relapse for perinatal women (Dimidjian et al., 2015), with 18% of women in the MBI group experiencing relapse, compared to 50% of . women in the control group. Research focusing on anxiety has also shown promise. Goodman and colleagues (2014) reported a clinically and statistically significant reduction in anxiety and worry for women after completion of an MBI.

It is hypothesised that benefits of bMBIs within the general population may be particularly relevant for perinatal women (Dimijian et al., 2016). The flexibility of engagement, reduction in commitment demands and benefits seen on anxiety, worry and stress, as well as the increase in distress tolerance and non-judgement of experiences, make them a good option for increasing psychological wellbeing and reducing distress.

A consideration required for perinatal women is the feasibility of engagement. Many interventions have limited effects due to poor implementation - for example, consideration for population-specific contextual factors such as time limits for new mothers, (Moore et al., 2015). Mixed results are reported for attendance at d-bMBIs, with some finding similar results to traditional delivery formats in the general population (Farver-Vestergaard et al., 2019) and others finding only 20% completion rates within pregnant women (Krusche et al., 2018). Due to the demands faced within the perinatal period, acceptability of interventions and engagement rates are important to ensure implementation of a meaningful, realistic intervention.

The present review

The aim of this paper was to review empirical studies investigating d-bMBIs within the perinatal period, drawing together emerging evidence of effectiveness, acceptability, and adherence rates. To date, no review has solely explored d-bMBIs within the perinatal period.

Whilst reviews have been undertaken for web-based interventions (Ashford et al., 2016; Loughnan et al., 2019) and mindfulness-based interventions within the perinatal period (Lever Taylor et al., 2016) this review aimed to combine both areas to explore alternative delivery formats. Within the general population, d-bMBIs have been incorporated into bMBI systematic reviews, yet not explored separately (Gilmartin et al., 2017; Schumer et al., 2018). The review questions were therefore:

- Given the potential suitability of d-bMBIs for perinatal women, is there evidence for preliminary efficacy of d-bMBIs for supporting perinatal mothers with managing or reducing psychological distress (defined here as depression, anxiety, and stress) and in increasing wellbeing and cultivating mindfulness?
- Given the engagement issues with traditional formats of MBIs for perinatal women, are d-bMBIs feasible and/or acceptable for these women (with feasibility being measured via engagement with the intervention, and acceptability being assessed through user feedback.)

The review further sought to clarify gaps in understanding and to suggest recommendations regarding further research and clinical practice.

In this review, d-bMBIs are defined as interventions with less than an hour per session, for up to eight weeks. As there is currently no standard definition of ‘brief’ MBIs, this definition was chosen as it covers approximately half of a standard course and included most of the MBI’s described as ‘brief’ in the literature. This review follows PRISMA (2020) guidance for systematic reviews (See Appendix A for PRISMA checklist)

Methodology

Information sources, search strategy and selection process

Search terms were developed using Boolean operators ‘OR’ and 'AND' to combine terms, as follows:

(perinatal OR peri-natal OR postpartum OR post-partum OR pregnan* OR maternity OR antenatal)

AND

(mindful* OR MBCT OR MBSR OR MBI)

A systematic literature search was conducted on 13th February 2022 using the databases PsycINFO, Medline, Web of Science, Cochrane library and Applied Social Sciences Index and Abstracts (ASSIA). Grey literature was searched using Open Grey. Databases were searched from 1979 (when the first MBI was created; Kabat-Zinn, 1998). Reference lists of relevant systematic reviews and studies were also hand searched.

Eligibility criteria

Studies were only included if they met eligibility criteria listed in Table 1.

See Figure 1 for a summary of the inclusion process. Potentially relevant studies (after duplication removal) were initially screened by title and abstract by the review author. Remaining relevant articles were then retrieved, and full texts were assessed for eligibility.

Quality assessment

To assess the quality of the studies, the Oxford Centre for Evidence based medicine (OCEBM) level of evidence scale (Marx et al., 2015) was used in conjunction with the Standard Quality Assessment Criteria for Primary Research (SQACPR; Kmet et al., 2004) by the review author (see Appendices B and C for full details).

Table 1
Inclusion and exclusion criteria for studies

Inclusion criteria	Exclusion criteria
• Participants were women within the perinatal period (defined as pregnancy up to a year after childbirth) • The study described an intervention with pre and post participant outcome measures • The study had at least one intervention arm which was mindfulness-based. • Mindfulness exercises and/or formal sessions were delivered through a mobile application, website, or audio file (podcast or CD) • The intervention period was up to 8 weeks in duration • Each single session was able to be completed in less than an hour. • The study was published or translated into English	• The study participants were women who had had a miscarriage, or death of their infant. • Interventions with a predominant focus on yoga or self-compassion, including mindfulness-based self-compassion. • Studies in which details of the participants or intervention was not specified with enough detail to allow for judgement of eligibility.

Note: Perinatal defined as pregnancy and up to 12 months following birth. This definition was taken from previous studies (Austin et al., 2008; Loughnan et al., 2018).

The OCEBM level of evidence scale has been used widely to explore perceived treatment benefits and evidence strength (Kranz & Eastwood, 2009). Studies may be upgraded with dramatic effect sizes, and downgraded based on study quality, indirectness, or very small effect sizes. The SQACPR was chosen as it allows for quality appraisals across research designs, including uncontrolled, open studies, and has been validated within published systematic reviews (Ashford et al., 2016). This combination allows for a complete assessment of quality of individual studies and to evaluate evidence strength, with higher scoring studies being given larger weighting in the synthesis of results.

Data extraction

Data were extracted on intervention characteristics, population characteristics, and outcome measures (depression, anxiety, stress, subjective wellbeing, positive affect) at each time point. Data on engagement rates, acceptability scores and qualitative themes were also

extracted. Results were pooled into a tabular format and compared against other studies for synthesis and result convergence. A narrative synthesis rather than meta-analysis was produced due to the area being relatively new, consisting of several feasibility, underpowered studies with different designs.

Results

The original search yielded 1352 references. 321 duplicates were removed, resulting in 1031 references. 80 were retrieved for full text review following title and abstract screening. A further 11 were incorporated following manual searching of references of full text studies. Figure 1 details the PRISMA flowchart (Page et al., 2021). Thirteen studies met criteria for inclusion within the review (summarised in table 2).

Methodological quality

OCEBM levels of evidence

Table 3 reports the levels of evidence for each included study. 'High quality' RCTs should have at least 80% follow-up data, blinding to researchers and true randomisation (Marx et al., 2015). Two RCTs achieved all aspects at post-intervention (Yang et al., 2019; Zhang et al., 2021). Sun and colleagues (2021) reported blinding of assessors and true randomisation processes, however, only achieved 66.5% follow-up data at post-intervention. Each of these studies achieved 'step 1' in the levels of evidence with two being deemed as 'high quality'.

Three studies were downgraded based on quality. Two were downgraded due to insufficient randomisation and blinding information (Carossoli et al., 2021; Shreffler et al., 2019). One was downgraded due to a lack of information on attrition rates and overall quality (Bublitz et al., 2019). No studies were upgraded.

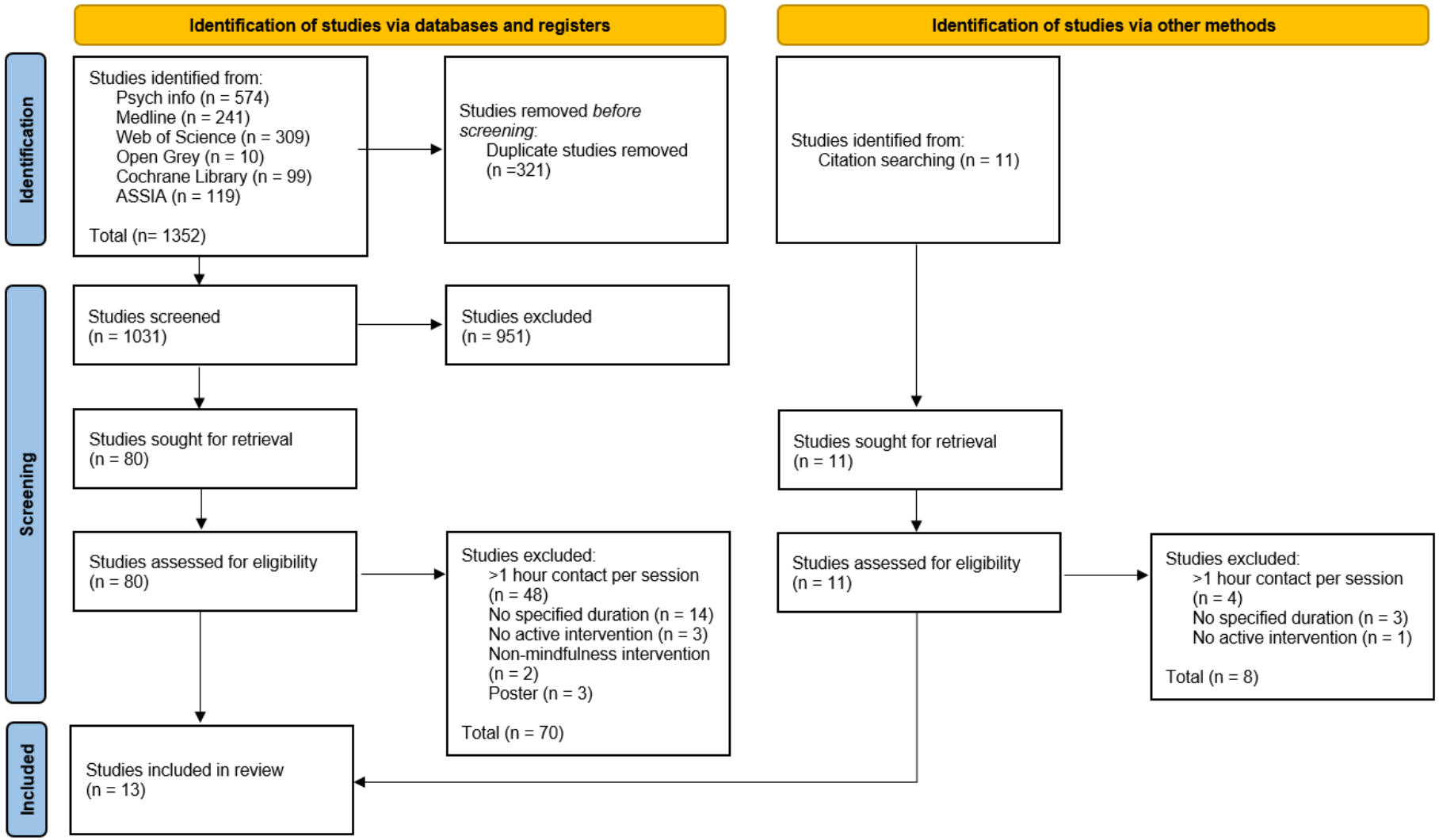

Figure 1. *PRISMA 2020 Flow diagram for Systematic reviews (Page et al., 2020)*

Table 2

Summary of included studies

Citation and study location	Population	Sample characteristics	Relevant measures	Main findings
Single Arm Pre/Post test				
Avalos et al., 2020 Northern California, United States;	Clinical sample: 27 postpartum women (<6 months post birth) Inclusion criteria: • ≥18 years of age • Within 6 months of giving birth • PHQ score of 10-19 (moderate to modestly severe depression) • No formal mindfulness practice	Age (years): 30.9 (SD=5.2) Ethnicity: Hispanic (33%), White (30%), Black (19%). Education and income: More than half (15/27, 56%) of the participants did not have a college degree, and most (20/27, 74%) had household income <US $100,000. Relationship status: No details	T0 = Baseline T1 = Post intervention • Depression (PHQ-8) • Stress (PSS) • Sleep quality (Pittsburgh sleep quality index) • Mindfulness (FFMQ-SF)	Significant improvement in depressive symptoms (-3.8, SD 5.0) Perceived stress (-6.0, SD=7.9), sleep quality (-2.1, SD 3.4). Increased mindfulness in 3/5 of the domain and overall (10.9 DS 16.8). There were trends for women who meditated for at least 50% of the days for greater improvements but this was not statistically significant.
Bublitz et al., 2019 Rhode Island, United States;	Nonclinical sample: 10 pregnant women Inclusion criteria: • ≥18 years of age • Pregnant with only one foetus • Risk of Pre-term birth • Free from severe depression and psychosis	Age (years): 34 (SD=3.16) Ethnicity: Hispanic (1%), non-Hispanic white (42%), Black (14%), and Asian (14%). Education and income: 71% had an annual income of >$50K Relationship status: Not reported	T0= Baseline T1 = Post intervention Scales not specified • Pregnancy anxiety • Depression • Post-traumatic stress disorder • Perceived stress •	Following mindfulness, reductions were found in symptoms of pregnancy anxiety 16% (*d*= 0.50), depression 26% (*d*= 0.43), posttraumatic stress disorder 40% (*d*= 0.61), and perceived stress 14% (*d*= 0.32).
Goetz et al., 2020 University Women's Hospital in Heidelberg, Germany	Nonclinical sample: 68 pregnant women Inclusion criteria: • Admitted to hospital due to high-risk pregnancy • ≥18 years of age • German speaking • gestational age of ≥24 and ≤34 weeks • Single foetus	Age (years): 32.07 (4.74); Range 22-41 Ethnicity: not reported Education and income: 60% bachelor's degree or above. 73% had >€1500 per month Relationship status: 73% Married and living together	T0= Baseline (day 1) T1 = Post intervention (day 7) • Depression: EPDS • Anxiety: STAI & PRAQ	No significant change was found in the EPDS, STAI-T, or PRAQ-R scores (P>.20) STAI-S scores significantly declined for these patients between the first and the second assessments (P=.03) If participants completed more than 50% of all the modules, they had significantly lower PRAQ-R scores than those with low app engagement at the second assessment.

Citation and study location	Population	Sample characteristics	Relevant measures	Main findings
Kubo et al., 2021 Northern California, United States;	Clinical sample: 27 Pregnant women Inclusion criteria: • ≥18 years of age • PHQ score of 10-19 (moderate to modestly severe depression) • <28 weeks of gestation • No formal mindfulness practice	Age (years): 31; range 19-39 Ethnicity: White (59.3%), Black or African American (11.1%), Asian (3.7%), Hispanic (14.8%), multiracial (11.1%) Education and income: 66.7% college graduates. 44.4% >$100,000 annual income Relationship status: 74.1% married; no details on other relationship forms	T0= Baseline T1 = Post intervention • Depression: PHQ-8 • Stress: PSS-10 • Sleep quality: PSQI • Mindfulness – FFMQ-SF	Significant improvements in depressive symptoms, perceived stress, and sleep quality. Participants also achieved greater levels of mindfulness in four of the five domains (observing, describing, acting with awareness, non-reactivity) and overall.
Maher, 2022 Worcester, Providence, Rhode Island, United States;	Nonclinical sample:18 postpartum women. Inclusion criteria: • Biological mothers between 6 weeks and 6 months postpartum • No history of mania, psychosis, and no active suicidal ideation	Age (years): 33.94 (SD = 3.75) Ethnicity: White (77.8%), Asian (11.1%), Hispanic/Latinx (5.6%), biracial (Hispanic/Latinx and White) (5.6%) Education and income: All participants held at least an undergraduate degree, with 72.3% holding a master's degree or above Relationship status: All women were currently in a relationship, and 94.4% were married.	T0 = baseline T1 = post intervention • Self-efficacy: (KPCS) • Postpartum anxiety (PSAS) • Generalised anxiety (GAD-7) • Depression (EPDS) • Mindfulness (FFMQ)	Anxiety: A statistically significant decrease in postpartum specific anxiety between baseline and post intervention. Self-efficacy: A statistically significant increase in self-efficacy and mindfulness between baseline and post intervention. No significant changes in depression
Mendelson et al., 2017 Johns Hopkins Children Centre; Baltimore, United States	Nonclinical sample: 27 postpartum women Inclusion criteria: • Their infants require a stay in NICU hospital for at least 2 weeks • Infants were not experiencing medical crisis or imminent risk of death	Age (years): 30.96, SD = 5.38 Ethnicity: African American or Black (41.7%), White (54.2%), Asian or Pacific islander (4.2%) Education and income: 50% college graduate or above Relationship status: 78.3% cohabiting with partner	T0= baseline T1= post intervention • Depression: PHQ-8 • Anxiety: GAD-7 • Trauma: SASRQ • Sleep: PSQI • NICU stress: PSS-NICU • Coping skills: brief COPE • Mindfulness: FFMQ-39 • Compassion: SCS	Significant pre-post improvements were identified in maternal depressive symptoms, anxiety symptoms, trauma symptoms involving anxiety/arousal, negative coping, sleep quality, number of hours slept per night, and NICU-related stress (see Table 3). No significant differences were found for positive coping, mindfulness, attachment to the infant, compassion, or the remaining sleep or trauma scales.

Citation and study location	Population	Sample characteristics	Relevant measures	Main findings
Nonrandomised control trial				
Wang et al., 2021 Guangzhou, China	Non-clinical sample: 158 pregnant women Inclusion criteria: • Admitted to hospital • ≥18 years of age • Pregnant women before 14 weeks gestation • History of 2 spontaneous miscarriages • Not currently receiving psychological treatment • No family history of psychiatric diagnosis	Age (years): 33.12 (SD=4.35) Ethnicity: Not reported Education and income: 65.8% University degree or higher. 58% Family income of >6000 RMD Relationship status: Not reported	T0= baseline T1= post intervention • Perceived stress: CPSS • Anxiety: SAS • Depression: EPDS • Positive Negative Affect: PANAS-R	Depression: Significant group × time interaction was found for depression with a small effect size with significant decreases being found following the intervention Positive affect: There was no significant group × time interaction for positive affect a significant time effect was found for positive affect with a medium effect size with significant increases being found following the intervention. Negative affect: A significant group × time interaction was found for negative affect with a medium effect with significant increases being found following the intervention
Pilot RCT				
Carissoli et al., 2021 Italy	Non-clinical sample: 108 Italian pregnant women Inclusion criteria: • ≥18 years of age • First pregnancy • Third trimester • Low risk pregnancy at the start of intervention	Age (years): 33.3 (SD= 4.2). Ethnicity: Not reported Education and income: 48.6% Bachelor's degree or higher Relationship status: 95.9% 'in a stable relationship'	T0 = Baseline, T1 = Post intervention (4 weeks later) T2 = Follow up (Within 3 months post birth) Psychological wellbeing scale separated into subscales: 1. Autonomy 2. Environmental mastery 3. Personal growth 4. Positive relations 5. Purpose in life 6. Self-acceptance	Post intervention: Sense of autonomy showed a significant increase in mindfulness group compared to control Follow-up (Postpartum): Sense of autonomy and self-acceptance showed significant time x group effects with increases in the MI group in comparison to the control.

Citation and study location	Population	Sample characteristics	Relevant measures	Main findings
Matvienko-Sikar & Dockray, 2016 Ireland, United Kingdom	Nonclinical sample: 46 pregnant women Inclusion criteria: • ≥18 years of age • Between 10-22 weeks gestation • Not received a diagnosis of depression, anxiety, or other wellbeing issues in the last 2 years	Age (years): 33.87, SD = 3.04 Ethnicity: 97.2% Irish, 2.8% non-Irish Education and income: 91.7% held at least an undergraduate degree Relationship status: All either in a relationship (11.1%) or married (88.9%)	T0 = Baseline T1 = Mid-intervention (1.5 weeks later) T2 = post-intervention (3 weeks later) • Prenatal distress: PDQ • Depression: EPDS • Gratitude during pregnancy scale: GDP • Mindfulness: MAAS • Satisfaction with life: SWLS • Cortisol levels	Stress: A significant effect of time was observed indicating that the group demonstrated reductions in stress. There were no significant intervention effects for any secondary outcome measures; a significant effect of time was observed for mindfulness, depression, and SWL
Shreffler et al., 2019 Oklahoma, United States	Nonclinical sample: 34 pregnant women Inclusion criteria: • In their second trimester • Planning to take baby home following birth	Age (years): Mean not reported; range 15-40 Ethnicity: Not reported Education and income: Not reported Relationship status: Not reported	T0= baseline T1= post intervention Attachment: MFAS	After adjusting for baseline MFAS, women in the Doppler + Mindfulness group had significantly higher levels of MFAS Controlling for baseline scores, results indicate a significant increase in MFAS scores for the Doppler + Mindfulness group
RCT's Sun et al., 2021 Shangdon, China	Clinical sample: 168 pregnant women Inclusion criteria: • ≥18 years of age • Between 12-20 weeks gestation • Single foetus • Completed junior high school education or above • Mild to moderate depressive symptoms (>9 on EPDS; or >4 on PHQ-9)	Age (years): 29.21 (SD=4.02) Ethnicity: 100% Chinese; Han (99.4%), Hui (0.6%) Education and income: 78.3% had a family income of >$618 per person Relationship status: All women were married	T1: Baseline T2: Mid-intervention (4 weeks after group allocation) T3: Post intervention (8 weeks after group allocation) T4: Follow up 1 (18 weeks post allocation)	Depression: Significant time effect and group × time interaction effect on the change of the EPDS scores. Both groups showed decrease scores at T2, and the mindfulness group continued to decline at T3 and T4 but increased at T5. For the binary EPDS variable at T3, fewer participants reported positive depressive symptoms (EPDS>9) in the mindfulness training group than in the attention control group.

Citation and study location	Population	Sample characteristics	Relevant measures	Main findings
	• Not at risk of suicide or self-harm • Not currently receiving psychiatric care • No history of substance use in past 6 months		T5: Follow up 2 (6 weeks post birth)Depression: EPDS • Anxiety: GAD-7 • Stress: PSS • Positive and negative affect: PANAS • Sleep quality: PSQI • Subjective prospective and retrospective memory • Wijma Delivery Expectancy questionnaire	Anxiety: Significant group x time interaction for anxiety: The anxiety score decreased at T2 and remained low in the mindfulness training group thereafter but increased at T3 and T4 in the attention control group. Positive affect: Significant group × time interaction. The mindfulness training group maintained higher positive affect scores than the attention control group in the prenatal period, and reached a statistically significant mean difference at T3 Other: No significant between-group intervention effect was found on stress, log-transformed negative affect, log-transformed sleep, fatigue, log-transformed prospective memory, retrospective memory, and fear of childbirth.
Yang et al., 2019 Zhejiang, China	Clinical sample: 123 pregnant women Inclusion criteria: • ≥18 years of age • Between 24-30 weeks gestation • Low risk pregnancy at the start of the intervention • Elevated depression or anxiety symptoms (≥4 on PHQ-9 and/or ≥4 on GAD-7) • Currently not experiencing high levels of depression or anxiety (≥14 on PHQ-9 and/or ≥14 on GAD-7) • Not currently using substances • Women who had a regular mind-body practice	Age (years): 30.98 (SD=4.21) Ethnicity: Not reported Education and income: 61.3% held a bachelor's degree or higher Relationship status: Not reported	T0= baseline T1= post intervention • Depression: PHQ-9 • Anxiety: GAD-7 • Mindfulness: FFMQ-39	Depression and anxiety: Postintervention scores of both PHQ-9 and GAD-7 were significantly lower in the intervention group than in the control group. In addition, a larger proportion of women in the intervention group had no symptoms of depression or anxiety after the intervention. Mindfulness: FFMQ scores and scores for the observing subscale (corresponding to attention monitoring) and the nonjudgment and nonreactivity subscales (corresponding to acceptance) significantly improved in the intervention group over the 8-week mindfulness intervention.

Citation and study location	Population	Sample characteristics	Relevant measures	Main findings
Zhang et al., 2021 Shandong, China	Clinical sample: 108 pregnant women. Inclusion criteria: • ≥18 years of age • 12-24 weeks gestation • EPDS scores >9 and/or GAD-7 scores >5. • Completed junior high school education or above • Not currently accessing psychological treatment • No current suicidal ideation • No current severe mental disorders or physical diseases • No prior mindfulness experiences	Age (years): 28.98 (SD=3.62) Ethnicity: Not reported Education and income: 66.7% had an income of >4000 Relationship status: 96.3% were married	T1 = baseline T2 = post intervention T3 – follow up (15 weeks after intervention) • Depression: EPDS • Anxiety: GAD-7 • Stress: PSS • Fatigue: FSS • Positive and negative affect: PANAS • Mindfulness: FFMQ-20	A significant time and group interaction for depression but non-significant time x group. Significant time x group interaction for stress, fatigue, positive affect, negative affect, and mindfulness. Tests of interaction for baseline mindfulness scores revealed evidence of an interaction among perceived stress, fatigue, positive affect, negative affect, and mindfulness scores, with higher mindfulness scores resulting in greater change but not for depression or anxiety.

Note: brief COPE= brief coping measure; CPSS= Chinese perceived stress scale; d = Cohens d statistic; EPDS = Edinburgh post-natal depression scale; FFMQ-SF=Five facet mindfulness questionnaire short form; FFMQ-39= Five facet mindfulness questionnaire 39 item (full form); FFMQ-20 = five facet mindfulness questionnaire 20 items; FSS= fatigue severity scale; GAD-7 = generalised anxiety disorder questionnaire 7 item; GDP=Gratitude during pregnancy scale; KPCS = Karitane parenting confidence scale; MAAS= Mindfulness attention awareness scale; MFAS = Maternal-Fetal attachment scale; NICU = Neonatal intensive care unit; PANAS; Positive Affect and Negative Affect Scale- Revised; PDQ=Prenatal distress scale; PHQ-9 = Patient health questionnaire 9 item scale; PRAQ-R: Pregnancy-Related Anxiety Questionnaire abridged version; PSAS = Postpartum specific anxiety scale; SAS=Self-rating anxiety scale; SASRQ=Stanford Acute Stress Reaction Questionnaire; SCS = Self compassion scale; SATI-S = State-Trait Anxiety Inventory (State scale). STAI-T: State-Trait Anxiety Inventory Trait scale; SCS = Self compassion scale; SWLS=Satisfaction with life scale.

Table 3

Levels of Evidence for Primary Research[1´2]

Study Type	Question	Step 1	Step 2	Step 3	Step 4	Step 5
Therapeutic—Investigating the results of a treatment	Does this treatment help? What are the harms?	Randomised controlled trial	Prospective[3] cohort[4] study Observational study with dramatic effect	Retrospective[5] cohort study Case-control [6]study	Case-series, historically controlled study	Mechanism-based reasoning
		Matvienko-Sikar & Dockray, 2016	Avalos et al., 2020	↓ Bublitz et al., 2019		
		Sun et al., 2021	↓ Carossoli et al., 2021			
		Yang et al., 2019	Gotez et al., 2020			
		Zhang et al., 2021	Kubo et al., 2021			
			Maher, 2022			
			Mendelson et al., 2017			
			↓ Shreffler et al., 2019			
			Wang et al., 2021			

1. This chart was adapted from OCEBM Levels of Evidence Working Group, "The Oxford 2011 Levels of Evidence," Oxford Centre for Evidence-Based Medicine, http://www. cebm.net/ocebm-levels-of-evidence/. A glossary of terms can be found here: http://www.cebm.net/glossary/. 2. Level-I through IV studies may be graded downward based on study quality, imprecision, indirectness, or inconsistency between studies or because the effect size is very small; these studies may be graded upward if there is a dramatic effect size. For example, a high-quality randomised controlled trial (RCT) should have ‡80% follow-up, blinding, and proper randomisation. The Level of Evidence assigned to systematic reviews reflects the ranking of studies included in the review (i.e., a systematic review of Level-II studies is Level II). A complete assessment of the quality of individual studies requires critical appraisal of all aspects of study design. 3. Investigators formulated the study question before the first patient was enrolled. 4. In these studies, "cohort" refers to a nonrandomised comparative study. For therapeutic studies, patients treated one way (e.g., cemented hip prosthesis) are compared with those treated differently (e.g., cementless hip prosthesis). 5. Investigators formulated the study question after the first patient was enrolled. 6. Patients identified for the study on the basis of their outcome (e.g., failed total hip arthroplasty), called "cases," are compared with those who did not have the outcome (e.g., successful total hip arthroplasty), called "controls." 7. Sufficient numbers are required to. ↓ indicates a downgrade in level.

SQACPR

An overall quality rating was derived for each study and presented in table 4 (possible range 0-1, with 1 being a perfect score). A range of scores from 0.43 to 0.95 were found across studies. Kemet et al. (2004) suggest a stringent cut-off score of 0.75, with three out of 13 studies falling below (Bublitz et al., 2019; Shreffler et al., 2019; Wang et al., 2021), and two scoring on the cut-off (Carissoli et al., 2021; Matvienko-Sikar & Dockray, 2016).

Methodological considerations

Design

Six studies employed a single-arm, uncontrolled design (Avalos et al., 2020; Bublitz et al., 2019; Gotez et al., 2020; Kubo et al., 2021; Maher, 2022; Mendelson et al., 2017), one study employed a non-randomised controlled trial design (Wang et al., 2021), three were described as pilot RCTs (Carissoli et al., 2021; Matvienko-Sikar & Dockray, 2016; Shreffler et al., 2019), and the remaining three were described as fully powered RCTs (Sun et al., 2021; Yang et al., 2019; Zhang et al., 2021). Four studies included qualitative analysis, analysed via inductive thematic analysis (Avalos et al., 2020; Kubo et al, 2021; Maher, 2022; Mendelson et al., 2017).

Seven studies employed control conditions which consisted of treatment as usual (Carissoli et al., 2021; Matvienko-Sikar & Dockray, 2016; Shreffler et al., 2019; Yang et al., 2019), other courses with the same duration (Sun et al., 2021; Zhang et al., 2021) or access to health information (Wang et al., 2021). Two studies altered the structure of the d-bMBI, by either engaging with a gratitude diary before or after meditation (Matvienko-Sikar & Dockray, 2016) or including foetal heart rate monitoring in addition to the d-bMBI (Shreffler et al., 2019).

Table 4

Scores for included papers on the Standard Quality Assessment Criteria for Primary Research (Kmet et al., 2004)

Study	1. Aims	2. Design	3. Recruitment and selection	4. Sample description	5. Randomisation	6. Blinding of researchers	7. Blinding of participants	8. Measures	9. Number	10. Analysis	11. Variance	12. Confounders	13. Results	14. Conclusions	Summary Score
Avalos et al., 2020	2	2	2	2	N/A	N/A	N/A	2	1	2	1	2	2	2	20/22 = **0.91**
Bublitz et al., 2019	2	1	1	1	N/A	N/A	N/A	1	1	1	1	1	1	1	12/22 = **0.55**
Carossoli et al., 2021	2	2	1	2	1	0	0	2	2	2	1	2	2	2	21/28 = **0.75**
Gotez et al., 2020	2	2	2	2	N/A	N/A	N/A	2	2	2	2	1	2	2	21/22 = **0.95**
Kubo et al., 2021	2	2	2	2	N/A	N/A	N/A	2	1	2	1	1	2	2	19/22 = **0.86**
Maher, 2022	2	2	2	1	N/A	N/A	N/A	2	1	2	2	2	2	2	20/22 = **0.91**
Matvienko-Sikar & Dockray, 2016	1	2	2	1	2	1	0	2	1	2	2	1	2	2	21/28 = **0.75**
Mendelson et al., 2017	2	2	2	2	N/A	N/A	N/A	2	1	1	1	1	2	2	18/22 = **0.82**
Shreffler 2019	2	2	1	1	0	0	0	1	1	1	0	1	1	1	12/28 = **0.43**
Sun et al., 2021	2	2	2	2	1	2	1	1	2	2	2	2	2	2	25/28 = **0.89**
Wang et al., 2021	2	2	1	2	0	0	0	2	2	2	2	1	2	2	20/28 = **0.71**
Yang et al., 2019	2	2	2	2	2	2	0	2	2	2	1	1	2	2	24/28 = **0.86**
Zhang et al., 2021	1	2	1	2	2	2	2	2	2	2	2	2	2	2	26/28 = **0.93**

Nine studies examined outcome measures at pre- and post-intervention (Avalos et al., 2020; Bublitz et al., 2019; Gotez et al., 2020; Kubo et al., 2021; Maher, 2022; Mendelson et al., 2017; Shreffler et al., 2019; Wang et al., 2021; Yang et al., 2019). Four included follow-up data at three weeks post-intervention (Matvienko-Sikar & Dockray, 2016), eight weeks post-intervention (Sun et al., 2021), 15 weeks post-intervention (Zhang et al., 2021) or following birth (Carissoli et al., 2021, Sun et al., 2021).

Intervention characteristics

Table 5 summarises intervention characteristics. Eight studies were self-guided d-bMBIs accessed through an app (Avalos et al., 2020; Carissoli et al., 2021; Gotez et al., 2020; Kubo et al., 2021; Matvienko-Sikar & Dockray, 2016; Shreffler et al., 2019; Yang et al., 2019;) or audio files (Mendelson et al., 2017). Three studies were semi-guided d-bMBIs (Maher 2022; Wang et al., 2021; Zhang et al., 2021) where sessions and/or audio files were sent directly to participants. The final two studies were fully therapist guided either via the phone (Bublitz et al., 2019) or through an online group (Sun et al., 2021). Interventions ranged from 1-week to 8-weeks in duration with a range of 10-15 to 60 minutes per session.

Formal sessions were offered in five studies (Bublitz et al., 2019; Gotez et al., 2020; Sun et al., 2021; Yang et al., 2019; Zhang et al., 2021). Three studies used an introductory session when the concept of mindfulness was discussed before continuing with meditation audios (Maher, 2022; Mendelson et al., 2017; Wang et al., 2021). The remaining five studies consisted solely of mindfulness exercises (Avalos et al., 2020; Carissoli et al., 2021; Kubo et al., 2021; Matvienko-Sikar & Dockray, 2016; Shreffler et al., 2019). Seven studies included information around the perinatal period (Carissoli et al., 2021; Gotez et al., 2020; Sun et al., 2021; Yang et al, 2019; Zhang et al., 2021) or adapted mindfulness exercises to include perinatal specific tasks such as noticing the babies' movements (in utero) (Maher, 2022; Shreffler et al., 2019).

Table 5

Overview of mindfulness-based intervention and control groups

Citation	Mindfulness-based intervention	Guidance level	Duration	Expected adherence	Adherence results	Control group
Avalos et al., 2020	Headspace App: Provides a self-paced, guided mindfulness meditation(s) through a website or mobile app. Participants were encouraged to follow the 'basic' 30-day introductory course	Self-help	6 weeks	10 to 20 minutes a day	Those who completed the study (19/27) 9/19 practiced at least half the days (47%) 5/19 practiced at least 70% of the days (26%) 58% used the app at least once in the month after the 6-week intervention period.	N/A
Bublitz et al., 2019	30-minute weekly phone-delivered mindfulness guided by a mindfulness instructor. Mindfulness sessions included standard components of traditional mindfulness-based stress reduction (body scan, awareness of breath, mindful activities of daily life, and open awareness).	Therapist-guided	8 weeks	Attendance at weekly sessions Participants were encouraged to practice mindfulness exercises for 15min each day using recordings provided at enrolment.	No details given	N/A
Carissoli et al., 2021	BenEssere Mamma App 20 daily exercises lasting from 3 to 20 minutes each consisting of: breathing meditation, body scan meditation, connection with unborn baby & inner smile meditation, savouring in the moment activities.	Self-help	4 weeks	Participants were encouraged to engage in daily mindfulness practices (ranging from 10-15 minutes) 5 times a week. A total of 20 meditations during the intervention period (4 weeks x 5 meditations)	86.1% of participants completed the practice report. *Women's adherence to daily practice was lower than requested: they did not follow the prescription of one meditation a day (20 meditations suggested in four weeks). The mean (SD) number of practice sessions per week was 3.00 (2.39) and the calculated median of exercises practised during the four-week intervention was about 9 exercises.*	4 Birth control classes

Citation	Mindfulness-based intervention	Guidance level	Duration	Expected adherence	Adherence results	Control group
Goetz et al., 2020	Through mediation of psychoeducational content and cognitive behavioural therapy-related approaches, the app teaches participants how to deal with stress, pregnancy-related anxiety, and symptoms of depression. Three 45-minute sessions consisting of: Module 1: Fears and worries about birth and parenting Module 2: Coping with stress Module 3: Me and my baby	Self-help	1 week	Engagement with the modules; no practice required between sessions	39/68 = 57% completed all three modules Separated into low and high engagement; no details on number in each	N/A
Kubo et al., 2021	Headspace App: Provides a self-paced, guided mindfulness meditation(s) through a website or mobile app. Participants were encouraged to follow the 'basic' 30-day introductory course	Self-help	6 weeks	10 to 20 minutes a day.	Of the participants that completed the study (20/27): 19 (95%) used the app once. 55% used the app on more than 50% of the days. 5/20 (26%) used it over 70% of the days. All interviewed stated they were planning on using the app after.	N/A
Maher, 2022	Initial meeting covering an overview of mindfulness, discuss common barriers and misconceptions and a brief mindfulness exercise and debrief. Audio files were uploaded to streaming applications and written handouts for each exercise was provided.	Self-help following initial meeting	4 weeks	Initial 1.5-hour meeting Two audio guided practices per day. Participants were asked to complete one seated 12-minute mindfulness session per day and one applied mindfulness practice (e.g. mindfully breastfeeding or mindful walking).	Participants were sent a form each day to say what they had engaged with in the last 24 hours. Participants averaged 1.26 mindfulness practices per day (63% of the recommendation) and 8.28 practices per week (59% of recommendations). Participants engaged more with applied mindfulness practices with applied practices accounting for 57.79% of total practices recorded.	N/A

Citation	Mindfulness-based intervention	Guidance level	Duration	Expected adherence	Adherence results	Control group
Matvienko-Sikar & Dockray, 2016	Participants used an online mindfulness and gratitude intervention 4 times a week for 3 weeks. Two mindfulness conditions: 1. Mindfulness audio (body scan, 5 mins) then gratitude exercise 2. Gratitude exercise then mindfulness audio (body scan, 5 mins) 3.	Self-help	3 weeks	4 times a week A total of 11 gratitude entries were asked for throughout the intervention	The average number of diary entries was 7.88/11 (71.6%). 21/32 participant provided more than 6 entries (65%)	TAU; prenatal care as usual
Mendelson et al., 2017	Participants went through a 20-minute introductory video explaining the programmes approach and practices. Four mindfulness practices were created. Audio files of mindfulness practice each available in 5- and 10-minute versions 1. Just breathe and be 2. Arriving 3. Well wishes 4. Self-kindness	Self-help	2 weeks	None specified	24/27 participants completed the study. 8/24 (33.3%) reported listening to the recordings four or more times per week, 5/24 (20.8%) reported listening at least 1–2 times per week, and 11/24 (45.8%) reported listening at least 1–2 times over the intervention period.	N/A
Shreffler et al., 2019	Participants were sent texts four times per week where they were asked to "take a few moments alone and complete the following task" Tasks included deep breathing, meditation, prenatal massage, telling the baby about a cherished person in their life, planning an activity, reading to baby.	Self-help	2 weeks	Not specified	Not reported	Control – not specified

Citation	Mindfulness-based intervention	Guidance level	Duration	Expected adherence	Adherence results	Control group
Sun et al., 2021	An 8-week mindfulness programme: 25-minute group sessions: Week 1: Understand mindfulness. Week 2: Be in the present. Week 3: Be mindful of negative emotions. Week 4: Accept difficulties. Week 5:Thoughts are just thoughts Week 6: Enjoy daily happiness. Week 7: Mindful pregnancy, and childbirth. Week 8: Continued mindfulness practice	Therapist guided	8 weeks	Attendance at the 8 weekly sessions Formal practice for 15-25 mins each day for 6 days a week Informal practice for 3-5 minutes each day for 6 days a week	10/84 did not activate the app 44/84 participants completed at least 4 weeks of training and the total completion rate was 52.4%. 7/84 (8%) participants completed the entire 8-week training program	Attention control – an 9 week regular weChat health consultations. *The content of the consultations included discussion on recent medical examinations, health appointments and assistance with arrangements for inpatient care.*
Wang et al., 2021	The average amount of times the mindfulness exercises were performed was 14.66 (SD=7.33). Overall, 65 women (83%) in the intervention group completed the intervention; 14 dropped out of the study along with 13 women in the control group due to a lack of interest (n = 4) or miscarriage (n = 23) during the study period. No details surrounding daily usage in comparison to days in hospital.	Self-guided	Varied; less than 3 weeks (average 18 days +/- 8.29)	Participants were asked to follow the audio every day that they were in hospital	The average amount of times the mindfulness exercises were performed was 14.66 (SD=7.33). Overall, 65 women (83%) in the intervention group completed the intervention; 14 dropped out of the study along with 13 women in the control group due to a lack of interest (n = 4) or miscarriage (n = 23) during the study period. No details surrounding daily usage in comparison to days in hospital.	Received information on recurrent miscarriage.
Yang et al., 2019	An 8-week, 4 sessions group; each session was 40 minutes in duration. Session 1: Anchors and staying present Session 2: The link between emotions, thoughts, and bodily sensations	Semi-guided	8 weeks	Completing the 4 sessions within the 8-week period Homework referred to but no further details	52/32 (83.9%) of women completed at least 3 sessions. Daily adherence to mindfulness practices was 'fairly low'. The mean number of mindfulness practices per week was 3.25 (SD=1.45). The mean number of minutes spent on meditation was 21.23 (SD=16.16)	Routine care and referred for psychological support if mild to moderate symptoms were exhibited.

Citation	Mindfulness-based intervention	Guidance level	Duration	Expected adherence	Adherence results	Control group
	Session 3: Physiological changes during pregnancy and mindfulness as a global relaxation strategy Session 4: Mindfulness acceptance Additional text, pictures, and audios related to the course were available for participants to review.					
Zhang et al., 2021	The 4-week mindfulness-based program: Week 1: To understand prenatal stress and their effects to pregnant women; into the mindfulness Week 2: Learn and become aware of yourself in your emotions Week 3: Live in the present Week 4: Embrace a new life Participants underwent a 20-minute face-to-face pre-intervention guidance session. Subsequently, they were required to listen to a program-related audio file sent over WeChat every day of approximately 30-45 minutes.	Semi-guided	4 weeks	Completion of the 4 x 30-minute sessions and 30–45 minutes per day of mindfulness practice.	88.9% (48/54) in the MBI group completed 14 or more days of homework. No further details on adherence.	Health Education (HE): *The HE participants also received a 20-minute face-to face pre-intervention introduction to HE courses. Later, they received antenatal care-related educational material through WeChat every day. Again, WeChat was used to urge participants to complete the courses and receive feedback*

Participant characteristics

Studies mainly focused on d-bMBI delivery in pregnancy, with only three studies exploring d-bMBIs in the postpartum period (Avalos et al., 2020; Maher, 2022; Mendelson et al., 2017). Participants' ages ranged from 15 to 40 years old (Shreffler et al., 2019), with the average age of participants being twenty-nine (Zhang et al., 2021) to thirty-four years old (Bublitz et al., 2019). No study specified first time mothers with only one including pregnancies with multiple babies (Yang et al., 2019).

Four studies focused on clinical populations, defined by mild to moderate anxiety and/or depression (Kubo et al., 2021; Sun et al., 2021; Yang et al., 2019; Zhang et al., 2021). In all four studies the Patient Health Questionnaire nine item scale (PHQ-9; Kroenke, 2001) or the Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987) was used to screen depressive symptom severity alongside the Generalised Anxiety Disorder scale (GAD—7; Spitzer, 2006) for anxiety symptoms. Studies predominantly focused on community samples with only two studies utilising samples from hospital admissions, either due to a high-risk pregnancy (Gotez et al., 2020) or a neonatal intensive care unit (NICU) admission post birth (Mendelson et al., 2017).

Sample sizes ranged from 10 (Bublitz et al., 2019) to 168 (Sun et al., 2021). The research was primarily conducted with participants from high income families, with limited representation from non-white women, except for Mendelson and colleagues (2017). Participants were predominantly in heterosexual relationship and cohabiting and/or married. Many studies reported over 50% of their sample having a degree or above and were mainly planned pregnancies.

Outcome measure reliability

Table 2 reports the measures used across the included studies. One study (Bubiltz et al., 2019) reported on pregnancy-specific anxiety, depression, posttraumatic stress disorder (PTSD), and perceived stress, but did not provide details of scales used and thus reliability cannot be reported.

Ten studies included a measure of depression, with validity of measures provided. Six used the EPDS (Cox et al., 1987) (Gotez et al., 2020; Maher 2022, Matvienko-Sikar & Dockray, 2016; Sun et al., 2021; Wang et al., 2021; Zhang et al., 2021), three used the PHQ-8 (Kroenke, 2001) (Avalos et al., 2020; Kubo et al., 2021; Mendelson et al., 2017) and one used the PHQ-9 (Kroenke, 2001) (Yang et al., 2019).

Eight studies included a measure of stress. Six used the Perceived Stress Scale (PSS; Cohen & Williamson, 1998)(Avalos et al., 2020; Kubo et al., 2021; Mendelson et al., 2017; Sun et al., 2021; Wang et al., 2021; Zhang et al., 2021). One study (Matvienko-Sikar & Dockray, 2016) used the Prenatal Distress Scale (PDQ; Yali & Lobel, 1999) to assess pregnancy specific stress and reported high scale reliability. Mendelson and colleagues (2017) employed a NICU specific stress scale, tailored to the participants' circumstances via the Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU, Miles et al., 1993) which showed good construct validity during creation.

Seven studies explored mindfulness traits. Five used a format of the Five Factor Mindfulness Questionnaire (Bare et al., 2008) including the full 39-item version (Maher, 2022; Mendelson et al., 2017; Yang et al., 2021) the 20-item version (Zhang et al., 2021) or the short form (Avalos et al., 2020; Kubo et al., 2021). Matvienko-Sikar & Dockray (2016) used the Mindfulness Attention Awareness Scale (Brown & Ryan, 2003). The FFMQ is seen

as a more adaptive mindfulness measurement in comparison to the MAAS due to measuring more than one facet of mindfulness, allowing independent exploration (Bear et al., 2008).

Seven studies included a measure of anxiety. Five (Maher, 2022; Mendelson et al., 2017; Sun et al., 2021; Yang et al., 2019) used the GAD-7 (Spitzer et al, 2006) which is validated within pregnant women (Zhong et al., 2015). Two studies included population specific anxiety measurements, either relating to pregnancy (Gotez et al., 2020) via the Pregnancy Related Anxiety Questionnaire (Van den Bergh, 1990) or postpartum (Maher, 2022) through the Postpartum Specific Anxiety Scale (Fallon et al., 2016). Population specific psychometrics are seen as preferable as they are psychometrically reliable instruments for the intended populations and hold increased instrument sensitivity (Ferketich et al., 1991).

Only two studies included a measure of subjective wellbeing (Carasolli et al., 2021; Matvienko-Sikar & Dockray, 2016) using the Subjective Wellbeing Scale (Ruini et al., 2003; Ryff & Keyes, 1995) or the Satisfaction with Life scale (Diener et al., 1985). Reliability and validity of both scales were reported and showed good psychometric properties.

Engagement and adherence with the d-bMBI

Eleven studies reported on participants' engagement with the d-bMBI. There was considerable variation in engagement measurement across the studies (see table 5). Six studies were able to calculate engagement with the intervention through their app or website (Avalos et al., 2020; Gotez et al., 2020; Kubo et al., 2021; Sun et al., 2021; Wang et al., 2021; Yang et al., 2019), whilst others used ‘homework’ completion (Matvienko-Sikar & Dockray, 2016; Zhang et al., 2021), attendance at sessions (Bublitz et al., 2019) and self-report measures (Carissoli et al., 2021; Maher, 2022; Mendelson et al., 2017). One study stated engagement was an outcome, yet gave no details of engagement (Shreffler et al., 2019).

Five studies included separate modules or sessions over the course of the intervention (Bublitz et al., 2019; Gotez et al., 2020; Sun et al., 2021; Yang et al., 2019; Zhang et al., 2021). When specified, a completion rate of ≥50% was used to define completion of the intervention (Gotez et al., 2020; Sun et al., 2021; Yang et al., 2019), with the remaining studies not reporting on attendance at specific modules.

Seven studies used mindfulness meditations delivered through an app (Avalos et al., 2020; Carissoli et al., 2021; Kubo et al., 2021; Wang et al., 2021), audio files (Maher, 2022; Matvienko-Sikar & Dockray, 2016; Mendelson et al., 2017) or texts (Shreffler et al,. 2019). Where there was scripted mindfulness, pre-defined levels of daily use included 10-20 minutes per day (Avalos et al., 2020; Kubo et al., 2021), 10-15 minutes daily for five times per week (Carissoli et al., 2021) or six days per week (Sun et al., 2021), two meditations per day (Maher, 2022), using the app four times per week (Mendelson et al., 2017) or completing daily homework (Zhang et al., 2021).

Synthesis of findings

Findings will be reported in relation to the original review question and separated between study designs. Findings explore preliminary efficacy, engagement, acceptability ratings and finally qualitative feedback.

Preliminary efficacy

Depression. For studies with control groups, five studies reported significant outcomes of reductions in depression for the d-bMBI group in comparison to the control group. Two of these studies had active controls and found an improvement from baseline to post-intervention, with either a small effect size (Wang et al., 2021) or medium effect size (Sun et al., 2021). One study had a TAU control group and reported significant reductions in depression but did not report effect size (Yang et al., 2019). Sun and colleagues (2021)

matched their control intervention in duration and therapist involvement, allowing for increased reliability of findings of the d-bMBI. Wang and colleagues (2021) used a non-randomised control trial, which may have led to selection bias or confounding of variables thus these results are less generalisable than other controlled studies. Zhang and colleagues (2021) reported significantly lower depression scores within the d-bMBI group at post-intervention in comparison to control, however this did not significantly change between baseline and post-intervention.

Of the six uncontrolled studies, all explored depression outcomes. Three reported significant reductions in depression symptoms following the d-bMBI (Avalos et al., 2020; Kubo et al., 2021; Mendelson et al., 2017). Bublitz and colleagues (2019) reported a reduction in depressive symptoms by 26%, however no further statistical testing was reported and therefore the reduction could be due to chance.

Anxiety. Two out of four controlled studies which included a measure of anxiety reported significant reductions in anxiety following the d-bMBI in comparison to controls (Sun et al., 2021; Yang et al., 2019) with a medium effect size reported at 10-weeks post-intervention (Sun et al., 2021). Wang and colleagues (2021) found no significant treatment effects for anxiety, however reported a significant increase over the study duration for the control group, who received information on reoccurring miscarriage.

Four uncontrolled studies included a measure of anxiety, with three reporting significant reductions. Maher (2022) reported a significant reduction in postpartum specific anxiety. Mendelson and colleagues (2017) focused on parents of infants admitted to the NICU, which may limit generalisability of findings to other perinatal women. State anxiety significantly declined after the d-bMBI with a small effect size (Gotez et al., 2020). Bublitz

and colleagues (2019) reported a reduction of 16%. No statistical testing was undertaken thus the reduction could be due to chance.

Stress. Three out of the four controlled studies which included a measure of perceived stress found a significant reduction for the d-bMBI group in comparison to the control between baseline and post-intervention measures (Matvienko-Sikar & Dockray, 2016; Wang et al., 2021; Zhang et al., 2021). Only one reported on effect size, finding a medium effect size (Wang et al., 2021).

For uncontrolled studies, four included a measure of stress. Significant reductions in perceived stress were reported in two studies (Avalos et al., 2020; Kubo et al., 2021) and a significant decrease in NICU related stress was found following a d-bMBI (Mendelson et al., 2017). Bublitz and colleagues reported a decrease in perceived stress by 14% following the d-bMBI. However no statistical testing was undertaken thus reductions could be due to chance.

Perceived wellbeing and positive affect. Two controlled studies included a measure of subjective wellbeing (Carissoli et al., 2021; Matvienko-Sikar & Dockray, 2016). Carissoli and colleagues (2021) reported a significant increase at post-intervention for the sense of autonomy subscale for d-bMBI participants in comparison to controls. Furthermore, sense of autonomy and self-acceptance were significantly higher at postpartum follow-up for those within the d-bMBI group in comparison to control. The control group was matched for the childbirth class aspects of the study, allowing for results to be attributed to the d-bMBI more reliably. Matvienko-Sikar & Dockray (2016) reported a significant increase between baseline and post-intervention measures for those within the d-bMBI group, however a non-significant difference between the groups. Both studies lacked statistical power and scored on the cut-off on the SQACPR, therefore conclusions should be treated with caution.

Two out of the three controlled studies incorporating positive affect reported significant increases over time between the two groups (Sun et al., 2021; Zhang et al., 2021) with those in the bMBI groups showing an increase in positive affect at post-intervention in comparison to controls. Wang and colleagues (2021) reported a significant main effect of time for positive affect; however, this did not significantly differ between the groups. No uncontrolled studies reported on subjective wellbeing or positive affect.

Mindfulness. Two of the four controlled studies including a mindfulness measurement reported significant increases after the d-bMBI in comparison to control groups (Yang et al., 2019; Zhang et al., 2021). Zhang and colleagues (2021) reported medium-large effect sizes which were maintained after sensitivity analyses and matching groups for engagement and contact time. Furthermore, moderator effects were explored with mindfulness scores being separated into 'high' and 'low' at baseline. Evidence was found for an interaction between higher levels of mindfulness at baseline leading to greater change on perceived stress, fatigue, positive affect, and mindfulness scores. No other study completed a moderation analyses with baseline mindfulness scores.

Three out of four uncontrolled studies which included a measure of mindfulness reported significant increase following the d-bMBI (Avalos et al., 2020; Kubo et al., 2021; Maher, 2022). Due to the lack of control group and emphasis on mindfulness during the d-bMBI these results are held lightly as demand characteristics may have been a factor in increased scores.

Summary. Results described above from both controlled and uncontrolled trials offer mixed preliminary evidence for d-bMBIs. Half of the included studies were uncontrolled studies with small sample sizes. The lack of control group limits the ability to draw meaningful conclusions on the d-bMBI specifically. Within depression, anxiety, stress, and

mindfulness one of the 'high quality' RCTs using active controls (Sun et al., 2021; Zhang et al., 2021) reported significant between-group effects. Studies with active and inactive controls found significant results on each outcome, increasing evidence strength and generalisability over uncontrolled study findings. For subjective wellbeing, results are weak due to the lack of power within the two studies and therefore conclusions cannot be drawn. Evidence for increased mindfulness following a d-bMBI appears the most robust finding, with medium to large effect sizes being maintained following sensitivity analyses and both 'high standard' RCTs yielding significant increases within the d-bMBI group. All outcomes were measured via self-report questionnaires which may influence results (as presumably participants were not blind to condition), as well as participants being aware of studies were exploring mindfulness-based interventions, leading potentially to biases when undertaking mindfulness outcome measures. The variation in methodologies and intervention design may limit the generalisability of results.

Engagement with the d-bMBI

Due to variations in delivery format and engagement measurements it is challenging to fully compare studies included within this review. Where *a priori* expectations were identified, engagement with the d-bMBI was lower than pre-specified. Studies with specific modules or sessions reported completion rates (defined as ≥50% attendance) between 83.9% (Yang et al., 2019) and 52.4% (Sun et al., 2021), with only 8% completing all modules (Sun et al., 2021).

Within meditation only studies (i.e., not a specific session or module) engagement, and measurements of engagement varied considerably. Engagement rates ranged from 45% of the requested amount (Carissoli et al., 2021) to 71.6% (Mendelson et al., 2017). No details

surrounding engagement were reported within one study (Bublitz et al., 2019) and thus cannot be explored.

Three studies commented specifically on challenges with daily practice (Carissoli et al., 2021; Avalos et al., 2020; Kubo et al., 2021). Another reported more ease with daily informal practice, with formal meditations being less likely to be undertaken daily (Maher, 2022).

Acceptability of the intervention

Six studies reported on acceptability of the d-bMBIs. One study explored acceptability of the study, rather than the intervention which, whilst supportive for future research, limits information surrounding user experience (Zhang et al., 2021). Overall high levels of satisfaction, ease of use and acceptability were found across the studies (Avalos et al., 2020; Carissoli et al., 2021; Kubo et al., 2021; Maher, 2022; Yang et al., 2019) with several studies reporting high levels of participants suggesting they would continue to use the apps. Participants reported on difficulties with daily meditation (Yang et al., 2019).

Qualitative feedback

Four uncontrolled studies incorporated qualitative feedback. Inductive thematic analysis was used to explore themes from semi-structured interviews. Further support for intervention satisfaction was found in each study. Participants commented on the ease of use (Avalos et al., 2020; Kubo et al., 2021; Mendelson et al., 2017), the accessibility due to the range of meditations available (Avalos et al., 2020; Kubo et al., 2021, Maher, 2022), and perceived benefits from engaging in the d-bMBI. Benefits included reduced anxiety, improved sleep, improved prioritising of uninterrupted time for self (Avalos et al., 2020; Kubo et al., 2021), improved stress management (Avalos et al., 2020), and increased calmness (Kubo et al., 2021). Adaptability of mindfulness skills into other areas of daily lives

was another consistent theme across studies as well as attending to the present moment more easily.

One study (Maher, 2022) occurred during COVID-19 pandemic, with participants reporting decreased social contact and heightened anxiety. Some participants reported finding it harder to engage with the d-bMBI because of the pandemic, whilst others reported increased coping skills with pandemic related distress.

Discussion

Overview

To the author's knowledge, this is the first systematic review of d-bMBIs delivered within the perinatal period. This review assessed the preliminary efficacy, engagement, and acceptability of d-bMBI interventions. Thirteen studies were identified, of which ten focused on delivery during pregnancy and three during the postpartum period. There was a range of study designs and quality, with half the studies using uncontrolled designs, and only three being fully powered RCTs.

Specific findings

Is there evidence for preliminary efficacy of d-bMBIs for supporting mothers during the perinatal period?

Mixed results were found for d-bMBIs in improving psychological symptoms, with tentative support in reducing depression and stress. This is in line with previous studies reporting significant reductions in depression, anxiety, and stress (Hall et al., 2016). This review further showed this findings held true in higher quality RCTs. In previous systematic and meta-analyses within the perinatal period only pre-post studies showed significant

decreases (Dhillon et al., 2017). This may be due to more RCTs being published in recent years, or the specific inclusion criteria used within this review.

Furthermore, there was some evidence to suggest increased mindfulness following engagement with a d-bMBI in both uncontrolled and controlled studies with qualitative data further supporting this finding.. Other systematic reviews have reported similar results (Corbally & Wilkinson, 2021; Dhillon et al., 2017) with increases in mindfulness following bMBIs in populations without pre-existing conditions.

Although a recognised potential problem for this population, subjective wellbeing was only explored in two studies which showed mixed results. Further exploration is warranted within this area as mindfulness could increase subjective wellbeing by facilitating present moment awareness, symptom reduction, relapse prevention and distress decrease (Cavanagh et al., 2018). Importantly, no harm effects were found within the studies included in this review. Similar to the conclusions of Babbar and colleagues (2021), (although the delivery and format of interventions varied), d-bMBI's potential for psychological support, and reduction in depression and stress in particular, may be beneficial to women within the perinatal period and were deemed acceptable by participants.

Are d-bMBIs feasible and/or acceptable for women within the perinatal period?

In previous systematic reviews study-defined criteria or engagement for completion was reported at approximately 74% (Lever Taylor et al., 2016). Similar results were found within this review with a range of 52.4% to 88.9%. Challenges in comparing engagement results occurred due to variation in study-defined engagement and was challenged further by the differences in interventions (modular vs daily meditations). Feedback from participants was supportive of d-bMBIs being acceptable and satisfactory for their needs however, tentative conclusions are drawn about acceptable engagement within d-bMBIs due to the

variability. Four studies commented on difficulties in engaging in daily mindfulness practices for perinatal women, which may be a barrier to future engagement.

One challenge within this review arises from inconsistencies within intervention design and the problem of reliably measuring the amount of mindfulness-based interventions engaged with, which is a common feature in systematic reviews (Del Re et al., 2013). Currently, researchers are unsure about the most influential part of mindfulness practices to enact greater change in wellbeing and psychological distress (Crane et al., 2014). Research has shown mixed results for intervention duration, with some suggesting increased duration yields higher symptom reduction (Shapiro et al., 2003), whilst others have not supported this finding (Carmody & Baer, 2009). Only two studies employed a therapist-guided intervention, and one did not report on engagement rates. Qualitative feedback obtained indicates that variety in both where and when the mindfulness exercise can be undertaken is important in maintaining engagement and increasing satisfaction, as well as having a variety of practice options. There was a consistent theme of daily meditation being a challenge for this population.

In summary, the studies reviewed offer promising evidence for the acceptability and satisfaction of d-bMBI interventions for perinatal women. Mixed results were found for reducing depression, stress, and anxiety, with medium support for increasing mindfulness in pregnant women. Weaker evidence was found for their use in the postpartum period. No adverse effects were reported in any study.

Implications for clinical practice

The findings from this review suggests that d-bMBIs may be a helpful intervention for clinical and non-clinical populations of perinatal women. Acceptability for d-bMBIs was high, although challenges were reported with daily practice due to limited time. It

appeared important for women to have flexibility in when they could complete exercises, which has been highlighted elsewhere for perinatal interventions (Millet et al., 2017). With traditional MBI formats, this level of flexibility is challenging to implement within clinical settings, thus d-bMBIs may be useful for providing flexibility to meet peoples' needs more effectively and reduce the demand placed on clinicians.

Furthermore, d-bMBIs have the possibility to reach and engage a range of individuals who may not be able to access traditional formats. This may impact on cost savings for services due to reduced therapist commitment, increased demand capacity and reduction of more intensive, traditional formats being delivered (Babbar et al., 2021).

Within qualitative feedback women often reported on being able to be attuned to the present moment following the d-bMBI, which is a key aspect of mindful parenting theories (Duncan et al., 2009). Maternal attachment was only reported in one study in this review, which was of poor study quality. It is known that maternal wellbeing can impact on an infant's social, cognitive, and behavioural wellbeing (Kurstjens & Wolke, 2001; Steine et al., 2014) and thus should be an area for exploration within clinical practice for mothers and their children. This review suggests that mindfulness can be cultivated through d-bMBIs, however, the evidence surrounding mindful parenting theories or infant development is limited.

Whilst it is important for treatments to adhere to manualised therapies to ensure efficiency, the development of tailored interventions for perinatal women is also important. Having interventions which explore aspects relevant to their lives and specific challenges may support engagement. Relevant training and information should be provided to those who are offering support, for example mindfulness teachers, to tailor interventions more suitably to perinatal women.

Implications for research

An initial step forward with d-bMBIs within a clinical setting may be as a preventative intervention. Studies within this review consisted of both clinical and non-clinical populations, showing support for reducing psychological distress. Hypotheses have been made surrounding the preventative nature of MBIs within perinatal mental health (Dimjiman et al., 2016) and this would be worthy of further investigations for d-bMBIs.

While this review supports acceptability and feasibility of d-bMBIs within the perinatal period, with no harm effects being reported, further RCTs exploring psychological distress and wellbeing would be the most robust way of exploring this promising avenue and further clarify evidence. Studies matched on intervention aspects would be beneficial to support conclusions on evidence strength, for example, having more formal weekly sessions or modules along with daily practice. This would also align the d-bMBIs more closely with more traditional formats of MBIs and form a more consistent definition of bMBIs.

The use of qualitative data was limited within this review, with only three studies incorporating it within their study. Qualitative research will be an important feature to enable further understanding engagement barriers and aspects that aid engagement with non-traditional delivery formats, especially when research is limited within specific areas or populations. In relation to the perinatal period, qualitative research would be valuable in further understanding the mechanisms of change within bMBIs, aspects that were helpful or hindersome for engagement, as well as strengthening quantitative results. Quantitatively, more research exploring the mediatory and moderator relationship of mindfulness, psychological distress and wellbeing would be beneficial.

Based on this review, it may be valuable for trials to explore the acceptability and feasibility of d-bMBIs within the postpartum period, due to the limited research within this

area. Further research is needed surrounding therapist led vs self-help programmes, group vs individual interventions and flexibility in delivery times, which would be supportive for accessibility of d-bMBIs for women within the perinatal period.

To address some of the methodological limitations it would be pertinent for future studies to attempt to recruit participants from a greater range of backgrounds in relation to cultural background, relationship status and socio-economic status. Longer term follow-up data would also be beneficial to ascertain clinical relevance for d-bMBIs' supportiveness for maternal attachment and infant development with more research being required before d-bMBIs can be recommended for perinatal mental health.

Limitations

There are several limitations of this review:

As usual within perinatal literature, included studies focused predominantly on d-bMBI delivery during pregnancy, rather than postnatally (Lever Taylor et al., 2016) meaning generalisability of results to postpartum women is limited.

Homogeneity of interventions across the review was limited. Most studies employed their own programmes; therefore, a variety of interventions were evaluated, meaning results cannot be fully generalised to d-bMBIs more widely.

Half of the studies were uncontrolled and RCTs included within this review varied in using non-active controls and active controls. The mixture of study designs and small number of fully powered RCTs mean findings are tentative. Only two studies matched their control group to the treatment group for aspects of group cohesion, therapist input and duration, increasing reliability of treatment effects. Although active controls may have led to a reduction in potential between-group differences, they are seen as 'gold standard' when

undertaking RCTs, increasing the reliability of findings associated with the d-bMBI. Demand characteristics are also lessened to an extent with active controls (Baer, 2003).

A potential risk of bias in each study comes from the use of self-reported measures for preliminary efficacy and engagement. This should not be overlooked, as it may lead to shared method variance (Podsakoff et al., 2003) and may be subject to demand characteristics (McCambridge et al., 2012), leading to decreased validity of findings.

Generalisability of findings to broader populations also needs to be considered. With one exception (Mendelson et al., 2017), the mothers included within the studies generally were well-educated, white, heterosexual and from high-income families, limiting generalisability to different ethnicities, cultures, religions, lower-educated, lower-income, non-heterosexual, and single parent families. This is important to consider as non-heterosexual parents may encounter discrimination or face stigma when having a child (Goldberg & Smith, 2011), and single mothers may face increased demands which may require additional support when delivering an intervention such as a d-bMBI. Furthermore, children from single-parent families are more likely to experience social and emotional problems than children from two parent families (McLanahan & Sandefur, 1994), which warrants consideration to ensure reliable, valid interventions are tailored to specific needs.

A further limitation is the exclusion of fathers, meaning results cannot be generalised to males. This is a common issue in parent-focused research (Phares et al., 2005), especially with research within the perinatal period (Alio et al., 2011). Mindfulness has begun to show promise for support for fathers (Rayburn et al., 2021), and couples when transitioning to parenthood (Canfield, 2021).

Although this review included two measures to assess study quality, no assessment of publication bias was included, and only one unpublished study met inclusion criteria (Maher,

2022). Only a limited search of grey literature was conducted. Although grey literature is not peer-reviewed and thus may not meet the standards required of peer-reviewed publications (Pappas & Williams, 2011), it allows for inclusion of studies that are awaiting publication and important research that is not published. These limitations need to be considered with respect to the findings and conclusions drawn, as results may not be a true representation of all literature and selection bias may be present.

Furthermore, no study examined treatment fidelity which is lacking with bMBIs more widely (Crane et al., 2018), potentially reducing the validity of findings. Without treatment fidelity ensuring adherence to true mindfulness practices, cohesion of interventions is limited, reducing generalisability of findings. This was further exacerbated by vast intervention variations within studies, with some using sessions or modular based approaches, and others using only meditation-based approaches.

Further limitations come from the conduct of the review. Similar definitions of brief interventions have been used previously, with 50% less contact than standard MBIs (Howarth et al., 2019) however different definitions of weekly duration was incorporated (up to 8 weeks, rather than 2 weeks), limiting generalisability of results to other systematic reviews.

Study inclusion, quality scoring and synthesis was undertaken by one reviewer and thus all aspects of the review are potentially biased. A lack of transparency in study findings may be a further limitation due to the narrative synthesis approach (Dixon-Woods et al., 2005). Literature was searched from the creation of MBIs in 1979 to ensure a link to a formalised intervention, however mindfulness practices have been a part of Buddhism prior to this, and relevant literature may have been missed, limiting validity of findings.

Conclusions

To the author's knowledge, this is the first systematic review of empirical literature of d-bMBIs within the perinatal period. Based on the 13 studies that met inclusion criteria, this review offers support for the acceptability of d-bMBIs for perinatal women and mixed results surrounding psychological distress and wellbeing. Stronger support for d-bMBIs cultivating mindfulness was found, extending the small, but promising, body of research suggesting d-bMBIs may offer benefits for perinatal women. Study quality, sample sizes and variations in d-bMBIs reduce the extent that conclusions can be made, however, perinatal women who engaged with d-bMBIs found them acceptable and supportive. Delivery formats of d-bMBIs needs consideration for perinatal women, with the likelihood of daily engagement being an area of difficulty. Future research should focus on the postpartum experience, specifically surrounding the feasibility and acceptability of a d-bMBI during a critical timepoint in mothers' lives when they may be at increased risk of psychological distress.

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Major Research Project (MRP) Section B: Empirical Research Paper

Acceptability, feasibility and preliminary efficacy of an online brief mindfulness-based intervention for first time mothers within the postpartum period.

Word count: 7951 (plus 290)

Abstract

Objectives: An 8-week brief mindfulness-based intervention (bMBI) for first-time mothers within the postpartum period (<12 months post birth) was examined for acceptability, feasibility, and preliminary efficacy in comparison to a control group.

Methods: One hundred and twelve postpartum mothers recruited via social media were randomly assigned to either a digitally delivered bMBI (<20 minutes weekly sessions and <5 minutes daily home practice) or a control group (received course materials at study completion). Participants completed self-report measures at baseline, post-intervention and 4-weeks follow-up to assess perceived wellbeing, stress, anxiety, depression, maternal attachment, mindfulness, and sleep quality. A mixed methods approach was used to explore descriptive statistics, preliminary efficacy via analysis of covariance (ANCOVAs), reliable change indices (RCI) and thematic analysis.

Results: Findings suggest the bMBI was acceptable and feasible. On average participants engaged with meditations 2.92 times per week (48% of the recommended 6 times). ANCOVAs revealed a significant difference in stress between the two groups at post-intervention and follow-up with intervention group reporting reduced stress, supported further by RCIs.

Conclusion: The bMBI was acceptable and feasible, with preliminary evidence tentatively suggesting bMBIs may support stress reduction within this population. Importance of flexible delivery is highlighted with recommendations for future research.

Keywords: Postpartum, mothers, perinatal, mindfulness, online, brief intervention.

Introduction

"I'm a mother now.

I run to the bathroom, run

to the kitchen, run to the crib

and I'm not even running.

These places just scare up as needed,

the wires that move my hands

to the sink, to the baby,

to the breast are electrical.

I'm in shock."

Credit: Brenda Shaughnessy, excerpt from "Liquid Flesh" from *Our Andromeda.* Copyright © 2012 by Brenda Shaughnessy. Reprinted with the permission of The Permissions Company, LLC on behalf of Copper Canyon Press, coppercanyonpress.org.

Postpartum period

Becoming a mother is often portrayed as a transformational process associated with increased life satisfaction and joy. However, this time may also bring potential losses, challenges, and negative experiences (Cree 2010; Harwood et al., 2007). Within the postpartum period (defined here as up to 12 months following birth), elevated stress, anxiety, and emotional dysregulation can be experienced by psychologically healthy and well supported mothers (Farr et al., 2014). Some women experience emotional difficulties for the first time, for others pregnancy or birth may act as a trigger for previous mental health difficulties (Goebert et al., 2007). Approximately 10-15% of women will meet the diagnostic criteria for an anxiety and/or depressive disorder within the postpartum period (Woody et al.,

2017) and without further support, adverse effects may occur for mother and infant, as well as maternal-infant attachment (Steine et al., 2014).

The evidence-base for non-pharmacological interventions in the UK is currently scarce for perinatal women (pregnancy and up to 12 months following birth) (National Institute of Clinical Excellence, NICE, 2014). Women may be reluctant and cautious about taking medicines as they may impact on the baby during pregnancy or breastfeeding (Battle et al., 2013; Dimidjian & Goodman, 2009). Current UK guidelines state that mental health symptoms should be assessed and discussed during routine contacts (NICE, 2021) self-help materials or Cognitive Behavioural Therapy being recommended based on severity of symptoms. Presently, there are no recommended preventative targeted interventions for maternal mental health which is concerning considering the potential associated challenges (Hughes et al., 2009). NICE (2014) called for developments and evaluations for new, non-pharmacological, theoretically grounded interventions for prevention of mental health difficulties in new parents.

One promising approach comes from the theoretical area of mindfulness. Mindfulness-based interventions (MBIs) are gaining interest within the perinatal population due to their evidence of effectiveness within the general population. Several systematic reviews found support for MBIs reducing symptoms of anxiety and depression, as well as increasing quality of life and subjective wellbeing (Khoury et al., 2015; Gu et al., 2015). MBIs are evidenced for effectiveness in reducing the risk of developing depression (Paul et al., 2013) and preventing depressive relapse within the general population (Segal et al., 2013). As perinatal women are at risk of developing depression, MBIs may be well suited to their needs and reduce the likelihood of depression (Dimidjian et al., 2016).

Mindfulness-based interventions

Mindfulness is defined as 'the awareness that emerges through paying attention in a particular way on purpose, in the present moment, and non-judgementally to the unfolding of experience moment by moment' (Kabat-Zinn, 2003 p.145). The most researched MBIs (representing the largest evidence base and seen as the 'first generation' interventions) are mindfulness-based stress reduction, introduced in 1979 (MBSR) and mindfulness-based cognitive therapy, introduced in 2002 (MBCT) (Crane et al., 2017). These interventions compromise of mindfulness practices, mindfulness principles and group discussion of experiences (Baer, 2003). Courses typically consist of eight, 2–3-hour weekly groups and encouragement of daily home practice of up to an hour. MBCT was first developed to prevent relapse in depression (Segal, et al., 2002) and was found to reduce relapse rates in recurrent depression when compared to treatment as usual (TAU), with findings continuing into long-term follow-up (McCartney et al., 2020; Piet et al., 2011). MBIs other than MBCT have shown promise in: helping to alleviate symptoms of anxiety and depression (Hofmann et al., 2010); increasing positive emotions including an increase in overall quality of life (Brown et al., 2007); and increasing trait mindfulness, which in turn results in an increase in health and wellbeing benefits (Gu et al., 2015).

Mechanisms of change in MBIs

MBIs aim to create personal change by promoting a non-judgemental and compassionate attitude to one's experiences (Baer, 2009). They cultivate meta-awareness techniques to observe changes in the present moment, with these being seen as temporary events that come and go, rather than static facts (Shahar et al., 2010) supporting behavioural self-regulatory abilities (Bishop et al., 2004).

Whilst mechanisms of change for MBIs have been explored within the literature, further clarification is required (Alsubaie et al., 2017). Teasdale's (1999) theory surrounding the mechanisms of change suggests three distinct modes of being. These include the 'mindless emotive mode', a 'conceptualising/doing mode', and a 'being/experiencing' mode. By engaging in mindfulness there is a move towards the 'being/experiencing' mode and away from the 'conceptualising/doing' mode enabling us to become more aware of the present moment and bring awareness to our internal experiences with a non-judgemental attitude.

Adaptations to MBIs

Traditional formats of MBCT and MBSR require a high level of commitment from participants which may be a barrier to engagement (Chen et al., 2014) particularly for women within the postpartum period (Evans et al., 2021). Introducing briefer MBIs (bMBI) may overcome this barrier, support engagement, and increase access to such interventions.

A variety of definitions are used to describe bMBIs with interventions being shorter in terms of weeks (Lan et al., 2015), duration of formal sessions (Howarth et al., 2019) or even single 5-minute sessions (Cavanagh et al., 2013). Systematic reviews exploring bMBIs have used different definitions. Schumer and colleagues (2018) found support for bMBIs (defined as <2 weeks in duration) reducing negative affect within clinical and non-clinical populations. Others have explored bMBIs (defined as <1.5 hours contact time) in pain management (McClintok et al., 2019). Mixed results were reported due to variation in intervention delivery, however support for bMBIs delivered in a particular format, specifically therapist guided <5-minute meditations showed promise for pain management. Howarth and colleagues (2019) further supported the positive impact of 5-minute meditations on health-related outcomes.

The reason why even very brief MBIs may be supportive is that even small behaviour changes can impact on complex health and wellbeing outcomes (Davis et al., 2015). Bailey and colleagues (2018), for example, suggested that 10-minute daily guided meditations improved wellbeing, with those engaging in daily practice showing greater improvement than those who were unable to practice daily.

Online delivery of MBIs

Segal (2011) noted the evolution of MBIs moving towards online delivery formats due to the greater reach and cost-effectiveness. Digital MBIs (d-MBIs) have be delivered digitally through apps, websites, and audio-files and shown promise for improving perceived stress and positive and negative affect, whilst increasing mindfulness and self-compassion (Bailey et al., 2018). Single session guided mindfulness sessions are reportedly supportive of reducing concerns within a global pandemic, momentary anxiety, and perceived stress (Farris et al., 2021). Self-guided d-bMBIs within non-clinical groups seeking stress-reduction strategies have also shown promise on psychological wellbeing (Cavanagh et al., 2013; Glück and Maercker, 2011; Krusche et al., 2012).

MBIs within the perinatal period

Duncan and colleagues (2009) introduced the ‘mindful parenting’ theory which brings the mindfulness notion of intentionally paying attention, non-judgementally to moment-to-moment interactions to the parent-child relationship. It is hypothesised that this intentional awareness increases the parents’ ability to attend to their child’s needs and their own emotional self-regulation, moving away from automatic, self-focused motivations (Dumas, 2005).

To date, MBIs within the perinatal period have predominantly focused on interventions during pregnancy (Hughes & Ensor, 2009; Lever Taylor et al., 2016). When

interventions are delivered at postpartum, lower response rates and higher attrition rates are reported in comparison with pre-birth interventions (Haga et al., 2013; Lever Taylor, 2016; Vesga-Lopez et al., 2008).

Typically, interventions consist of minimal modifications to the traditional 2 hour-weekly session, eight-week courses (Duncan & Bardacke, 2010; Dunn et al., 2012; Vieten & Astin, 2008). In 2017, two reviews of MBIs in the perinatal period (Badker & Misri, 2017; Shi & Macbeth, 2017) identified one study within the postpartum period out of a total of 17 (Perez-Blasco et al., 2013). Since these reviews, further studies have explored MBI's within the postpartum period (Ahamadpanah et al., 2018, Potharst et al., 2017, Zeegers et al., 2019; Maher, 2022) with one exploring self-compassion, a construct relating to mindfulness (Gammer et al., 2020).

Traditional delivery formats may be challenging for perinatal women for various reasons. Mothers may be required to find childcare and have time restraints and unpredictability in their schedules due to having an infant (Goodman, 2009; Howard et al., 2006). To overcome these barriers, d-bMBIs may be well suited to the restraints of time and commitment during new motherhood. Within the last few years d-bMBIs have begun to be tested for their acceptability and feasibility within the perinatal period, with more recent randomised controlled trials (RCTs) being conducted. Sun and colleagues (2021) compared a d-bMBI against an attention control group within clinically anxious and/or depressed pregnant women. Significant reductions were reported for depression and anxiety, with significant increases in positive affect in comparison to the control group. Furthermore, depression decreased throughout pregnancy – although depression increased following birth in relation to post-intervention. Further support for d-bMBIs has been suggested for reducing depression and anxiety (Yang et al., 2019) and stress (Zhang et al., 2021). Zhang and colleagues found evidence for moderator effects of mindfulness levels, with increased

mindfulness yielding greater change in stress, positive affect, and negative affect following the d-bMBI but did not impact on change for depression or anxiety.

Engaging with MBIs within the perinatal period has been associated with less emotional distress prenatally and postnatally for mother and increased social-emotional development for infants (Braeken et al., 2017). One hypothesis for this stems from the idea that shifting awareness back to the present moment is thought to be a key parenting skill (Dumas, 2005) as it leads to avoidance of cycles of maladaptive parenting behaviours stemming from automatic behaviours (Duncan et al., 2009) and may increase sensitivity to the infants' needs. New mothers may benefit from MBIs to increase their parenting skills, attachment behaviours, sensitivity to their baby, and to support their own wellbeing including reducing the likelihood of depression, which is known to be a risk factor within this population (Dimijian et al., 2016).

The current study

In summary, there is a need for psychological interventions to support mothers in the postpartum period. MBIs offer promise as one such intervention for numerous reasons, including evidence of effectiveness in preventing relapse in depression, improving wellbeing and reducing anxiety. However, engagement in standard MBIs may be challenging for first-time mothers due to the required time commitment. As such, d-bMBIs may provide a solution to this barrier to engagement. To date, to the author's knowledge, no studies have examined the acceptability and feasibility of d-bMBIs in first-time mothers within the postpartum period. As this research was examining a new population and intervention, this study aimed to: i) provide information about the feasibility and acceptability of the intervention; and ii) identify a possible signal of efficacy with respect to estimates of changes in mood and

wellbeing. Signals of efficacy are used in feasibility studies and pilot RCTs to indicate whether future larger-scale RCTs of clinical effectiveness are warranted (Brown et al., 2012).

Aims and objectives

The current study aimed to test the hypotheses that the d-bMBI would:

1. Be acceptable to new mothers within the postpartum period.
2. Be feasible for new mothers within the postpartum period.
3. Show preliminary efficacy for increasing subjective wellbeing, mindfulness, maternal attachment, and sleep quality in comparison to a control group.
4. Show preliminary efficacy for decreasing symptom severity of depression, anxiety, and stress, in comparison to a control group.

Method

Design

This study was a mixed-methods pilot RCT. Participants were randomly assigned to either a d-bMBI (10 of zen) or a delayed course materials group (referred to as control group). Prior to the start of recruitment, the RCT was registered with clinicaltrails.gov (registration number: NCT04674124; Protocol ID: UPID1920-0332, see Appendix D). All reporting is in accordance with the Consolidated Standards of Reporting Trials guidelines for pilot and feasibility studies (CONSORT; Eldridge et al., 2016) and Template for Intervention Description and Replication guidelines (TIDieR; Hoffmann et al., 2014). CONSORT and TIDieR checklists are presented in appendices E and F.

Sample size justification

A sample size of 88 participants was identified following previous recommendations for pilot studies (Teare et al., 2014; Lancaster et al., 2004). Sample sizes recommendations ranged from 60 to 90; with a minimum of 30 participants required per group when estimating the standard deviation (SD) of continuous outcomes. This sample size was increased to account for a 31% attrition rate based on the average attrition rate for online interventions (Melville et al., 2009; Meyerowitz-Katz et al., 2020). As per National Institute of Health Research Evaluation (NIHR) guidance, power calculations were not undertaken as the study was a pilot RCT and was primarily a feasibility and acceptability study (Lee et al., 2014).

Participants

Inclusion and exclusion criteria are presented in table 1.

Table 1
Self-reported inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Women (over 18 years of age) who identify as a first-time mother (biological, adoptive, or foster carer) and have a child under 12 months. • Basic English reading and writing abilities	• Previous completion of a formal 8-week mindfulness course or current mindfulness/meditation practice • Currently pregnant • Severe levels of depression and/or anxiety as measured by >15 on Patient Health Questionnaire 9 item and/or > 15 on Generalised Anxiety Disorder -7 item scales. • Suicidal or thoughts of self-harm within the last 2 weeks. • Currently experiencing symptoms of psychosis. • Diagnosis of Post-traumatic stress disorder. • Bereavement within the last 6 months which they still feel affected by.

Data collection

Data collection was conducted at T0 (up to 2 weeks prior to the intervention beginning; randomisation took place following T0), T1 (10 weeks post randomisation, after the intervention had completed) and T2 (14 weeks post randomisation). Participants were

asked to complete 17 questions about themselves and their baby at T0. This included information about their self-identified ethnicity, education level, marital status, and current healthcare support (medical intervention and psychological support), see appendix G.

Intervention

The facilitator had completed a certified MBSR teacher training course in 2017 and had facilitated mindfulness courses aimed at mothers for over three years. The intervention was set up with minimal teacher contact and less intensive resources than the traditional format of mindfulness-based interventions. All live sessions were audio recorded by the facilitator. The intervention, called '10 of zen', was an 8-week b-MBI. The course was compiled using feedback from mothers who had previously completed the course collected by the facilitator. Planning was carried out with the research supervisors (both knowledgeable in this area) to adapt the course specifically for new mothers within the postpartum period.

Table 2 offers a breakdown of the themes and meditations used within the intervention each week. The intervention comprised 15–20-minute weekly sessions delivered online via zoom as well as daily 'micro' meditations sent three times per week with a duration of three to five minutes. Participants were encouraged to engage in daily mindfulness practices by repeating micro-meditations for two consecutive days.

All sessions and meditations were recorded and could be accessed via an online platform at any point in the study enabling participants to 'catch up' on the weekly session if they were unable to attend the live session.

Control

At study completion, intervention and control group participants gained access to study materials consisting of audio files for the weekly sessions, all micro-meditations and addition resources. For written materials please see appendix H.

Table 2

Summary of 10 of zen intervention

Week	Title	Focus of session	Description of mindfulness exercise and micro meditations
1	Feeling distracted	Beginning to bring awareness to the present moment and normalise attention shifting from one thing to another. Incorporating non-judgemental approaches to experiences.	Main meditation: *Body Scan:* Participants are invited to scan individual parts of their body and focus in on what may be occurring at each. At points participants are encouraged to gently return their attention back to their body if their minds have wandered, whilst trying to not judge themselves if they attention has wandered. Micro meditations: 1. *Mindfulness in everyday life:* Participants are invited to bring deliberate awareness to one moment of their daily life; this may be brushing teeth, showering, eating etc. 2. *Being mindful with baby – focus on holding:* Participants are invited to be curious to the sensations in their body as they are holding their baby and tune in to different movements and actions.
2	Breathe and come back	Using the breath to anchor themselves within the present moment and becoming conscious about breathing.	Main meditation: *Mindful Breath:* Participants are invited to bring awareness to their breath and to begin to exhale longer than they inhale. They are then invited to notice where they feel the breath most and use this to bring themselves back to the moment if their minds begin to wander. Micro meditations: 1. *Being with baby – focus on breath*: Participants are invited to take some purposeful breaths with exhalations being elongated. They are then invited to notice their baby's breathing patterns and noticing theirs and their baby's breath as an exchange. 2. *Friendly awareness of breath:* Participants are invited to be playful with their breath and to observe their breathing without trying to alter it.
3	Week Three: Opening Awareness	Sitting in the present moment and bringing a curiosity and a non-judgemental approach to what may be found.	Main meditation: *Opening Awareness:* Participants are invited to explore what is going on within their stress spots (brow, shoulders, temple) and then around them at the present time through sounds and visions. Participants are then invited to bring their awareness to their body and notice what part it is drawn to. Micro meditations: 1. *3 Step breathing space:* Participants are invited to notice what is happening right now for them, and then within their body using the physical sensations of the breath and finally expanding their awareness to the whole body and beyond. 2. *Baby play time:* Participants are invited to bring their awareness to their baby whilst they are playing. They are invited to notice what the baby is noticing and what they are attending to.

Week	Title	Focus of session	Description of mindfulness exercise and micro meditations
4	Week Four: Mindful movement	Using awareness of the present moment whilst walking to bring mindfulness to different parts of life.	Main meditation: *Mindful walking*: Participants are invited to undertake different movements including walking around whilst bringing their attention to different sensations that may be occurring for them at the time. Micro meditations: 1. Stretching with baby: Participants are invited to engage in stretches with baby close and to attend to their reactions and their baby's reactions. 2. The 3 F's: Participants are invited to pay attention to different parts of their body as they are walking with three main areas: feet, fanny, and face.
5	Week Five: Barriers	The normalisation that engaging in a course can be difficult and engagement may fluctuate which may influence emotions and actions. Attempting to be present instead of perfect.	Main meditation: *Present instead of perfect:* Participants are invited to pay attention to their breath and then attune to the words 'present instead of perfect'. The notion of choice and control as well as normalising feelings are encompassed within the meditation. Micro meditations: 1. *Mindful baby massage:* Participants are invited to give their baby a foot massage and bring their awareness to the physical sensations that they have as well as the emotions that occur during the meditation. 2. *3 step breathing space and action step:* Participants are invited to undertake the 3-step breathing space as outlined above, with the additional aspect of thinking about one small thing they could do to look after themselves.
6	Week Six: Welcoming discomfort	Normalisation of different emotions, including anger. Bringing in the idea that all emotions are helpful in some way and do not define us as human beings.	Main meditation: *Its real to feel:* Participants are invited to bring to mind an event that happened recently that was difficult and where they then notice this in their body. They are then invited to repeat the words 'it's real to feel' whilst holding the memory in mind. Participants are then invited to bring to mind people close to them and to offer these words to them and repeating the phrase 'our thoughts and feelings do not define who we are'. Micro meditations: 1. *Being with baby when baby is crying:* Participants are invited to bring a colour that represents compassion, kindness and warmth to a moment where their baby is crying and to expand this to themselves. 2. *Outside/Inside:* Participants are invited to pause for a moment and to bring awareness to the outside of their body using their senses. They are then invited to bring awareness to inside their body and notice whatever arises repeating 'its okay, let be, this belongs'.

Week	Title	Focus of session	Description of mindfulness exercise and micro meditations
7	Week Seven: The loving stuff	Participants are invited to bring some of the love and care that they have for others back to themselves – being aware of internal dialogues that may occur and the impact they may have.	Main meditation: *I heart you and me:* Participants are invited to bring awareness to their body and then bring to mind someone who they have a good relationship with and wish them well. They are then invited to bring the same thoughts and feelings back on themselves Micro meditations: 1. *Heart centre:* Participants are invited to lift their hands onto their chest and pause and notice what is happening. Participants are invited to say words like 'you've got this' or 'you have everything you need' whilst engaging in this meditation. 2. *Loving kindness to self and baby:* Participants are invited to find a time where they and baby are quite settled and to hold them near their heart centre. They are then invited to repeat phrases to themselves and be curious about what this brings up.
8	Week Eight: Gratitude	Bringing awareness to biases that we may and the negative biases that happen in our minds at times. Thinking about how bringing awareness to things we are grateful for may help to shift this bias and move into a positive frame.	Main meditation: *10 times grateful:* Participants are invited to take some purposeful breaths and move through 10 things that they are grateful for using their fingers as a guide. Micro meditations: 1. *I am grateful for _____:* Participants are invited to share a photo or write something down in the group chat (or response to facilitator) to something they are grateful for on that day. 2. *Mindful walk with baby, gratefulness in nature:* Participants are invited to take a walk with baby in nature and notice what is happening around them.
9	Week Nine: Forming habits	Thinking about how to implement mindfulness in everyday life without the structure of the course and setting realistic goals for themselves.	Main meditation: *Coping with tiredness:* Participants are invited to complete a small body scan and bring to mind two affirmations: initially 'I surrender to my tiredness and it's okay', secondly 'I hold myself in this moment' and finally a visualisation of releasing weighs from their hands. Micro meditations: N/A

Outcome measures

The following section describes the outcome measures used in the study. Appendix I contains copies of measures. This data was collected via an electronic questionnaire sent out to participants at T0, T1 and T2.

Engagement in the d-bMBI was measured by participants reporting on weekly engagement in micro-meditations and attendance at either 'live' sessions or through the catch-up facility. This data was collected via an electronic questionnaire sent out to participants weekly.

Satisfaction, helpfulness, and likelihood to recommend was measured at post-intervention by participants completing a satisfaction questionnaire (Appendix J). This questionnaire was created by the research team and 10 of zen facilitator. The questionnaire contained Likert scale questions ranging from 1 (not at all) to 10 (extremely) and open-ended questions. This questionnaire was added to gain further detail on participants experiences of the intervention, qualitative feedback and ratings of acceptability.

Acceptability was measures by:

1. Rate of participant attendance at the live sessions or their use of 'catch up'.
2. Number reporting daily engagement with micro-meditations.
3. Feedback ratings of the intervention measured at post-intervention and via open ended questions.

Feasibility was measured by:

1. Ease of recruitment of participants to reach target sample.
2. Number of participants completing the follow-up questionnaires.
3. Participant dropout rates where feasibility issues were given as a reason.

Secondary outcome measures: Patient reported outcome measures (PROMS)

Subjective wellbeing was measured through The Short Warwick-Edinburgh Mental Well-Being Scale (SWEMBS; Stewart-Brown et al., 2009) The SWEMBS is a 7-item, 5-point rating scale ranging from 1 (none of the time) to 5 (all of the time), with higher scores indicating higher levels of perceived wellbeing. Participants are asked to complete the scale based on their experience within the last two weeks. The SWEMBS has been found to be highly correlated with the long version of the scale and shows good construct validity (Ng Fat et al., 2016). Baseline measures within this study showed a Cronbach alpha value of $\alpha = .8$.

Attachment was measured through the Maternal Postnatal Attachment Scale (MPAS; Condon, 1993) was used to examine changes in**.** The MPAS is a 19-item Likert self-report questionnaire assessing emotional quality of bonding, hostility towards the infant and the degree of pleasure in interaction. The number of items for each question varies ranging from 2 to 5 response options. Eight items were reversed, and responses were recorded to ensure equal weighting for each response. Higher scores on the MPAS indicate a higher level of maternal attachment. The MPAS has shown acceptable psychometric properties (Condon & Corkindale, 1997). Baseline measures within this study showed a Cronbach alpha value of $\alpha = .86$.

Depression, stress, and anxiety were measured via the Depression Anxiety Stress Scale – 21 (DASS-21; Lovibond & Lovibond, 1995). The DASS-21 is a 21-item measure with a 4-point Likert scale. Participants are asked to indicate the presence of symptoms within the last seven days, with higher scores indicating higher levels of symptomology. The DASS-21 has been found to have good internal consistency and convergent and discriminant validity both as a whole and across the three subscales (Henry & Crawford, 2005). Baseline measures within this study showed a Cronbach alpha value of $\alpha = .87$.

Mindfulness was measured via the 15-item Five Facet Mindfulness Questionnaire (FFMQ-15; based on the FFQM-39; Baer et al. 2008). The FFMQ-15 measures the 5 aspects of mindfulness: observation, description, aware actions, non-judgemental inner experience, and non-reactivity via a 5-point Likert scale ranging from 1 (never or very rarely true) to 5 (very often or always true), with higher scores indicating a higher level of mindfulness. The factor structure of the FFMQ-15 is consistent with the longer form with no significant differences in convergent validity (Gu et al., 2016). Previous research within non-meditator samples has found that a four-factor structure (omitting the observing facet) has provided a superior fit in comparison to the five-factor structure. Within the current sample it is likely that participants have limited experiences of meditative practices due to the eligibility criteria and therefore a four-factor hierarchical structure without the 'observing' facet was used within analysis. Baseline measures within this study showed a Cronbach alpha value of $\alpha = .81$.

Sleep Quality: Sleep Quality was measured via the Sleep Quality Scale (SQS; Capperlleri et al., 2009). Participants were asked to rate their quality of sleep over the last seven days on a single item with an 11-point Likert scale ranging from 0 (terrible) to 10 (excellent). Reproducibility and convergent validity were shown to be acceptable within the development of the measure.

Procedure

Participants were recruited via convenience sampling following online advertisements on social media sites (see Appendix K). Advertisements were aimed at mothers from a variety of ethnic and cultural backgrounds by speaking to various social media sites aimed at these groups when advertising. Snowballing was also used as a recruiting method by asking recruited mothers to pass the information on to friends who may be interested in joining.

The study was carried out online via a computer, tablet and/or a mobile phone. Screening and questionnaire responses were collected via Qualtrics, a secure online data collection platform, and the intervention was delivered through a blend of online platforms including Zoom, WhatsApp, and text messages.

Interested participants were invited to read study information, complete a short screening eligibility questionnaire and to sign consent forms if eligible. Eligibility criteria was assessed via self-reported yes/no questions (see appendix L to N for information sheet, eligibility, and consent). Those not meeting criteria were sent an explanation about why they were not being invited to participate. Additional resources for support were provided as well as contact details for the researcher. Those deemed eligible after screening were invited to complete demographic questions and baseline measures. Following completion, they were subsequently randomised via the Qualtrics secure online platform via block randomisation in blocks of four without any attempt to match groups. Participants were notified of their group allocation and the next steps via an email sent by the researcher. Participants and the lead researcher were not blind to group membership.

Participants were asked their preference for joining a WhatsApp group with other participants, or for receiving individual messages. Recommendations for the WhatsApp group were made due to previous research reporting on the group element being an important feature for interventions (Dunn et al., 2012; Goodman et al., 2014; Woolhouse et al., 2014).

Participants were emailed details about the start of the course and were added to the WhatsApp groups on the morning of the first session if they had agreed. Post-intervention and follow-up measures were requested from all participants via automated emails at 10 weeks and 14 weeks post-randomisation - with reminders being send one week after following no response.

To support retention, participants were invited entry into a prize draw to win one of four £25 shopping vouchers after they had completed the follow-up measures. Prize draw entry was based on measure completion and not on intervention engagement. The prize draw aimed to recognise the time and effort spent by participants in completing the measurements (Ryan & Deci, 2000).

Treatment integrity

Currently, no integrity measure for bMBIs has been formally created (Crane & Hecht, 2018). Inclusion of treatment integrity measures have been firmly recommended for RCTs to draw valid conclusions on treatment effects (Perepletchikova et al., 2007). Therefore, two integrity measures were used (See appendix O and P). Firstly, an adapted version of the MBCT adherence scale (MBCT-AS; Segal et al., 2002) was used to rate 50% of sessions and micro-meditations. Ratings were completed by an independent assessor who had completed a mindfulness parenting teacher training in 2018 at the Oxford Mindfulness Centre. Furthermore, the 15- item checklist for MBIs (Kechter et al., 2019) was used to further examine treatment fidelity at the end of the study.

Ethical considerations

Ethical approval was granted by the Salomon's Ethics Panel, Canterbury Christ Church University for this study (see Appendix Q). The project adhered to the British Psychological Society's Code of Human Research Ethics (2014).

Within the postpartum period there is an elevated risk of depression and/or other mental health difficulties (Woody et al., 2017). Screening measures and study information contained links and information to the NHS information about postnatal depression and included contact numbers for support. Participants were directed to seek support if they began to experience distressing symptoms and encouraged to speak to the facilitator or researcher if

any concerns occurred. No participant reported concerns about their mental health during the study period.

Data analysis

The pilot RCT utilised a mixed methods approach including exploration of descriptive statistics, thematic analysis, and preliminary efficacy via analysis of covariance (ANCOVAs) and reliable change indices (RCI).

Quantitative:

Guidance for evaluating pilot RCTs suggests hypothesis testing cannot be carried out due to a lack of power to detect statistically significant effects (Leon et al., 2011) with best practice being to report only descriptive statistics (Lee et al., 2014). Descriptive statistics were reported for all participant characteristics and clinical outcomes in the form of means, standard deviations and 95% confidence intervals. However, as this was a new treatment it was felt important to explore preliminary efficacy to provide a 'signal of efficacy' and give guidance for any future RCTs. Therefore, further ANCOVAs were carried out using IBM SPSS version 26. Dependent variables were subjective wellbeing, depression, stress, anxiety, maternal attachment, mindfulness, and sleep quality. The independent variable was the assigned group (intervention vs control). Preliminary data checks were undertaken to ensure statistical assumptions of ANCOVA were met. This included homogeneity of variances and regression slopes, linearity of covariate and dependent variable, and correlation of covariates. If assumptions were met, dependent variables were submitted to separate two-way mixed ANCOVA, with group as a between-subjects variable (intervention vs. control) and time as a within-subjects variable (post-intervention vs. 4-week follow-up). Baseline scores for the relevant dependent variable were included as a covariate to control for initial individual differences at baseline, which also allowed for individual differences of the COVID-19

experience to be captured. Mothers' age was included as a covariate due to its known association with maternal psychological distress (Emmanuel & St John, 2010). Baseline sleep quality was also included due to the known relationship between sleep quality, wellbeing, and mindfulness (Howell et al., 2008). Listwise deletion was undertaken for missing data as these analyses were exploratory (Kang, 2013). To further explore preliminary efficacy, Reliable change indices were calculated using the Jacobson and Traux method (1991).

Qualitative analysis:

As this study was interested in participants' general experiences of the intervention and was not looking to map results onto a pre-existing framework or structure, inductive qualitative analysis was conducted using thematic analysis (Clarke et al., 2013; Braun & Clarke, 2006). This approach allowed for flexibility during analysis to provide a more detailed account of the data. A semantic approach, (which analysed what was said by participants) was carried out and responses were analysed across the data rather than question by question.

Participant answers to the open-ended questions were read several times with specific events, thoughts and/or actions being noted to capture something related to the overall research question. Codes were generated and compared against the data. Overarching themes were generated and composed of subthemes that were derived from the initial codes. Themes were considered in the context of the dataset as a whole and were edited and changed where necessary. The credibility and coherence of findings was discussed with the research team and resulted in some changes of subthemes after discussion.

Results

Participant recruitment and flow

As shown in Figure 1, 141 mothers expressed interest in the study and completed screening. Of these, 122 participants (84.7%) were deemed eligible and provided consent, 112 (91.8%) went on to complete baseline measures within the agreed time frame and were then placed randomly into either the intervention group (10 of zen) or control group (delayed course materials). This resulted in 56 participants per group, with five participants in the intervention group opting out of WhatsApp groups. Thirty-four participants (30.4%) were lost to follow-up at post-intervention, with an additional seven participants (6.3%) being lost at 4-week follow-up. Total attrition rates for the study were 41 (36.7%).

Table 3 summarises means and standard deviations for baseline characteristics. Participants age ranged from 20 to 45 years with their babies age ranging from 0.7 months to 11.9 months. Participants were mostly heterosexual, currently on maternity leave and either married, cohabiting or in a civil partnership. Baseline measure differences between groups were not explored due to previous research suggesting that baseline comparison is unnecessary and can be misleading (Schulz et al., 2010). Instead, baseline measures were included as a covariate, where necessary, which is preferable due to the prognostic value (De Boer et al., 2015). Three participants were later excluded from the analysis, one as their child was over 12 months of age when completing baseline measures despite indicating at screening that their child was younger, and two participants withdrew from the study due to work commitments: one at week four of the intervention and one following reminders for T1.

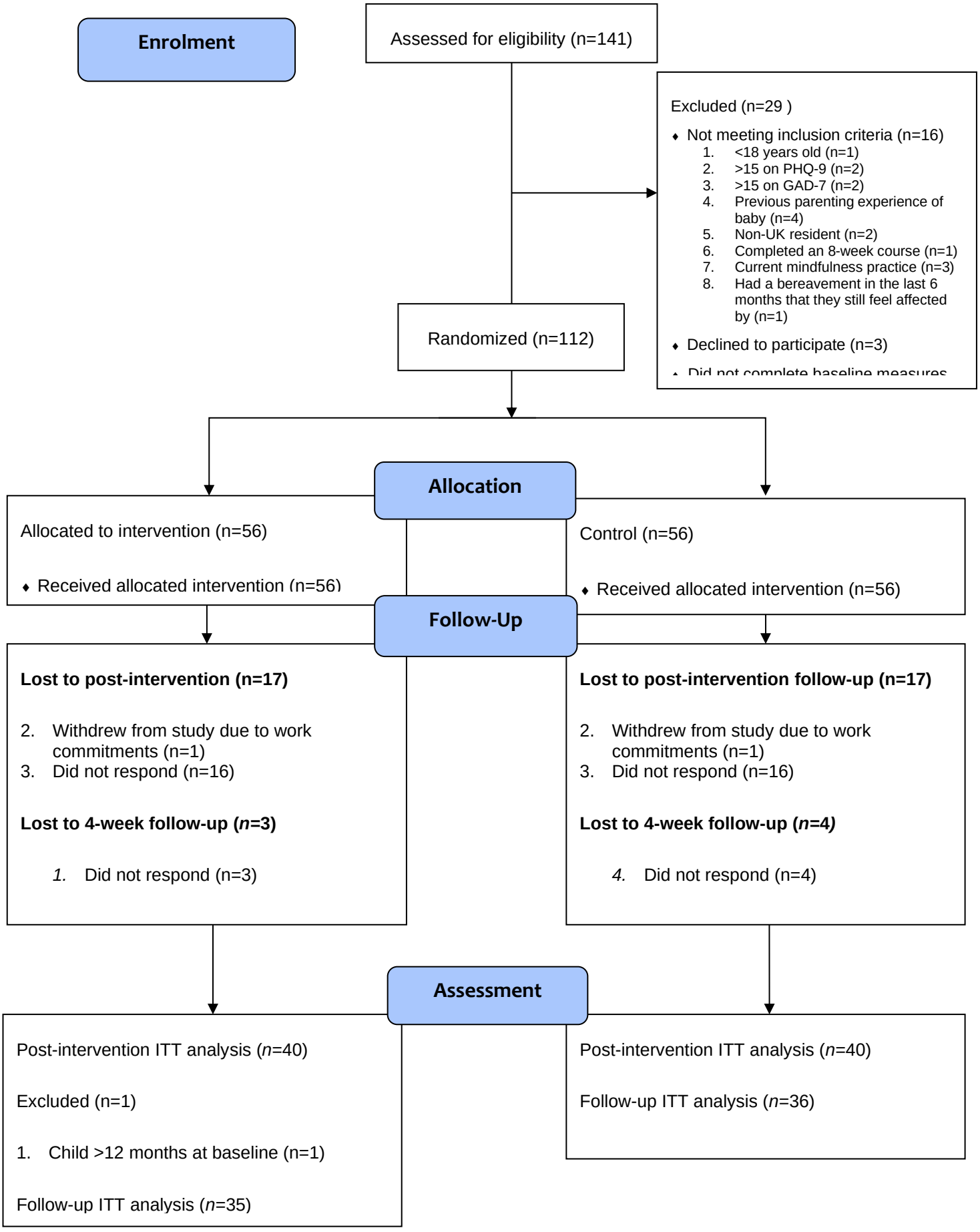

Figure 1. *CONSORT (2010) diagram of articipant flow*

Acceptability

Participant attendance at the live sessions or their use of 'catch up'. Table 4 highlights participant attendance at the weekly live sessions or via 'catch up'. Of those randomly allocated to the intervention, thirty-four (60.7%) participants completed at least six sessions, with sixteen (28.6%) completing all nine sessions. Three participants (5.3%) did not attend any sessions. The average number of sessions completed was 6.64 (SD=2.61), with an average of 4.88 (SD=2.78) being accessed live and 1.91 sessions (SD=2.07) being accessed via the catch-up facility.

Numbers reporting daily engagement with micro-meditations. Micro-meditations were sent to participants three times per week, with participants encouraged to engage in one micro-meditation daily when no live session occurred. Table 4 reports engagement with the micro-meditations which ranged from an average of 2 to 5 times per week (*M*=2.92, *SD* = 0.9). No participant engaging in daily mindfulness practice throughout the intervention.

'Satisfaction' ratings of the intervention as measured at post-intervention via open ended questions. Thirty-eight participants gave ratings of satisfaction using a 10-point scale. Satisfaction ratings ranged from 5 to 10 (*M*=8.97, *SD*=1.31).

'Helpfulness' ratings of the intervention measured at post-intervention and via open ended questions. Thirty-six participants gave ratings of helpfulness using a 10-point scale with results ranging from 4 to 10 (*M*=8.35, *SD*=1.55). Participants were asked to rate how likely they would be to recommend the course using a 10-point scale. Thirty-eight participants responded with ratings ranging from 5 to 10 (*M*=9.04, *SD*=1.42).

Table 3

Summary of baseline characteristics

Variable	Intervention (*n* = 54)	Control (*n* = 55)
	M (SD)	*M (SD)*
Mothers Age (Years)	33.55 (4.7)	32.05 (3.55)
Child age (Months)	4.7 (2.18)	4.6 (2.69)
	n (%)	*n (%)*
Mother		
Biological	54 (100)	54 (100)
Highest Qualification		
O-Levels, GCSE's or equivalent	1 (1.9)	4 (7.3)
BTEC or Diploma	3 (5.6)	3 (5.5)
A Level or equivalent	5 (9.3)	7 (12.7)
Undergraduate/Bachelor's degree	23 (42.6)	16 (29.1)
Postgraduate certificate or diploma	6 (11.1)	11 (20)
Master's degree	12 (22.2)	11 (20)
Doctorate or PhD	4 (7.4)	3 (5.5)
Family status		
Single parent household	1 (1.9)	0
Married/Civil partnership/Co-habiting	53 (98.1)	55 (100)
Ethnicity		
White British	49 (90.7)	51 (92.7)
White Irish	1 (1.9)	0
White Other	2 (3.7)	3 (5.5)
White and Black Caribbean	1 (1.9)	0
Indian	0	1 (1.9)
Chinese	1 (1.9)	0
Religion		
Christian	22 (40.7)	22 (40)
Hindu	0	1 (1.8)
Spiritual	1 (1.9)	0
No Religion	31 (57.4)	32 (58.2)
Sexual orientation		
Heterosexual	51 (94.4)	55 (100)
Bisexual	1 (1.9)	0
Gay/Lesbian	1 (1.9)	0
Prefer not to say	1 (1.9)	0

Variable	Intervention (*n* = 54) *n (%)*	Control (*n* = 55 *n (%)*
Working Status		
Currently on maternity leave	51 (94.4)	45 (81.8)
Working part time	1 (1.9)	4 (7.3)
Working full time	1 (1.9)	0
Not currently employed	1 (1.9)	6 (10.9)
Disability		
Yes	1 (1.9)	0
No	53 (98.1)	55 (100)
Previous informal mindfulness experience		
Yes	23 (42.6)	22 (40)
No	31 (57.4)	32 (58.2)
Prefer not to say	0	1 (1.8)
Currently prescribed medication		
Yes	6 (11.1)	6 (10/9)
No	48 (88.9)	49 (89.1)
Accessing Psychological therapy		
Yes	3 (5.6)	1 (1.8)
No	51 (94.4)	53 (96.4)
Prefer not to say	0	1 (1.8)
Previous parenting experience (>12 months of age)		
Yes	4 (7.4)	0
No	50 (92.6)	55 (100)
Baby Gender		
Male	23 (42.6)	34 (61.8)
Female	31 (57.4)	21 (38.2)
Multiple babies		
Single birth	54 (100)	55 (100)

Note: Disability: Fibromyalgia, Myalgic Encephalomyelitis (ME), and Narcolepsy. M = Mean. SD = Standard deviation.

Table 4

Summary of course engagement

	Mean (SD)	95% CI
Average total number of sessions completed (*n=48)*	6.64 (2.78)	5.88-7.40
Average number of 'live sessions' attended (*n=48)*	4.87 (2.78)	4.07-5.68
Average number of catch-up sessions attended (*n=48)*	1.92 (2.61)	1.33-2.52
Average number of micro meditations completed throughout the week (*n=38)*	2.92 (0.9)	2.63;3.21

Feasibility

Ease of recruitment of participants to reach target sample. Recruitment exceeded expectations, with 112 (127% of target sample) participants being recruited and undertaking baseline measures in a five-week period between 13th December 2020 and 16th January 2021.

Number of participants completing the follow-up questionnaires. Thirty-four participants (30.25%) did not complete measures at post-intervention and forty-one (36.65%) did not complete measures at the four-week follow-up. Retention was closely matched within each group.

Participant dropout rates where feasibility issues were given as a reason. One participant (1.8%) dropped out of the intervention group and gave feasibility as their reason for this as they had recently returned to full time employment and thus found it difficult to find time. One participant (1.8%) dropped out of the delayed materials group and gave time commitments as their reason.

Qualitative feedback

All participants who had access to the 10 of zen intervention were invited to complete a questionnaire at the end of the course. Forty participants completed this questionnaire which asked for comments about their satisfaction with the intervention, its perceived

usefulness and perceived helpfulness. Exploring the responses for open ended questions, three distinct themes were identified: embodying mindfulness traits, factors impacting on engagement and contextual factors. Each theme had a set of sub-themes, details of which can be found in table 5.

For embodying mindfulness traits, participants reported the ability to be in the present moment without thinking about the future, notice their thoughts and emotions without necessarily engaging with them and incorporating mindful activities throughout their day either by utilising techniques taught, or bringing practices to other activities. Participants commented on feeling calmer and relaxed following sessions and appreciated having time for themselves without feeling guilty.

For engagement factors, participants commented on difficulties in making time for the course due to the unpredictability of their schedules with a new-born. Having the catch-up facility appeared helpful, although mothers commented on finding self-motivation difficult. Several commented about the helpfulness of reminders and the accountability from the group. Some wished for more group engagement and felt group interaction could be emphasised more. The variety of meditations (audio/text and length of meditations) allowed for increased ease of integration and variability. Several participants commented on the course facilitators supportive, caring, and non-judgemental approach.

Contextually, the course ran within the COVID-19 pandemic with participants commenting on the isolation, loneliness, and difficulties period this brought. Participants felt a sense of being together with others with similar experiences during the course and reported on the helpfulness of this. Participants felt that the course was well tailored to new mums, with comments on the relevance of course content.

Table 5

Themes, emergent subthemes, and quotes

Theme	Subthemes	Quotes (participant ID)
Embodying mindfulness traits	Being more in the present moment	"[The course] made me feel more aware of my own body and senses" (62192)
		"I found myself more in the moment than worrying about what needed to be done next" (24846)
	Doing activities in a more mindful way	"I now do certain activities in a more mindful way. I regularly "take 5" for gratitude and feel a lot happier in myself" (27927)
		"I can take a breath and focus easier especially when I find things getting tough" (75072)
	Feeling calmer or more relaxed	"The live [sessions] and when I did take part in the micro zens made me feel much calmer, more relaxed and helped me to get to sleep." (15456)
		"Calmer, more relaxed, more confident, able to sleep easier (when baby allows!) (61301)
	Noticing thoughts and emotions	"[I am] more aware of my feelings… [I am] able to let thoughts pass rather than acknowledging and playing on them" (12921)
		"Noticing sensations around me and being able to sit with and accept difficult feelings rather than brushing them off. (94727)
	Taking a moment for self	"The course helped me introduce some 'me time' into my week for the first time since having my baby. It was the first opportunity I had had to relax and do something for myself" (36738)
		"Found it so amazing to have the structure of a few minutes each week to reflect on everything and appreciate how much I had achieved since giving birth." (72178)
	Recognising that it's okay to feel emotions and not to be perfect:	"The phrase I remember most is "no judgement" …it triggered something in me that it's okay to feel a certain way … It's okay to just be. … it doesn't make you a bad person or a good person It just meant that you're a person with feelings and it took away this crazy notion that mothers are always feeling guilty..." (69398)

Theme	Subthemes	Quotes (participant ID)
Factors impacting on engagement	Making time to do the course:	"Just life with a baby! I wasn't always able to join the lives and didn't always remember to do a micro zen every day." (15456)
		"I just struggled to attend at that time of day and found it hard to motivate myself to catch up" (22036)
	Ease of use and integration of the course:	"The small meditations were achievable, and I like the variety as some weeks suited me more than others" (96913)
		"I loved all the short micro meditations, they felt really easy to use day to day. Just easy to fit in and be more present" (94727)
	Group support and connection	"I liked having the small WhatsApp group to support and feel accountable" (96913)
		"I wish the WhatsApp group had been more chatty, or there was an option for breakout rooms to speak to the other Mums" (67285)
	Supportive and non-judgemental teacher	"There was no pressure at all to complete activities, so it didn't add any extra stress to life…. [Teacher] was so brilliant - kind and caring and I really felt like she cared about us all even though we were just names on a screen." (99246)
Contextual factors	Relevance of the course to new mums:	"It was great to have something to focus on and I found the content very relevant to my emotions and mental state as a new Mum." (15456)
	Helpfulness of the course during the COVID-19 pandemic	"The emotional content around becoming a mum and navigating difficulties of the pandemic was really helpful and made me feel I wasn't alone." (15456)
		"The course was wonderful and a huge help to me through what was a very difficult time" (36738)

Statistical analyses

Data checking

Data were checked to explore assumptions for the planned ANCOVA. In total, 71 cases were included within the analysis (treatment *n=35*, delayed *n*=36). An outlier was identified with a z-score of +3.29 (Tabachnick & Fidell, 2013) at post-intervention for DASS depression and was removed due to the influence on normality distributions (Field, 2013). Normality checks were undertaken via standardised skewness, kurtosis, and Shapiro-Wilk *p* values. All measures fell within the recommended values for skewness (≤2, George & Mallery, 2019) and kurtosis (≤3, Kallner, 2018). However, Sharpio-Wilk p values suggested anxiety, depression and sleep were non-normally distributed. This is common in moderate sample sizes (Field, 2013) and therefore was taken into consideration alongside histograms, kurtosis, and skewness. As these fell within the recommended ranges, analysis proceeded as planned.

Homogeneity of regression slopes and the independence of covariate and treatment effects were explored for each outcome (see appendix R). For subjective wellbeing, anxiety and stress, baseline sleep was correlated with baseline scores and thus removed as a covariate from these ANCOVAs. Age was removed as a covariate for anxiety as linearity of regression slopes were violated.

Patient Recorded Outcome Measures

Table 6 displays the unadjusted means, standard deviations, and confidence intervals for PROMs at baseline, post-intervention and 4-week follow-up. At baseline severe, or extremely severe ranges for depression, anxiety, and stress were reported. As predicted, from baseline to post-intervention subjective wellbeing, maternal attachment and sleep quality increased in the treatment group, whereas depression, anxiety and stress decreased.

Table 6

Observed and adjusted means, standard deviations and standard errors for patient reported outcome measures

	Intervention					*Control*				
	Observed Mean			*Adjusted Mean*		*Observed Mean*			*Adjusted Mean*	
	n	*M (SD)*	*CI (95%)*	*M (SE)*	*CI (95%)*	*n*	*M (SD)*	*CI (95%)*	*M (SE)*	*CI (95%)*
SWEMBS: Subjective wellbeing (possible range of scores 0-35)										
Baseline	54	21.41 (2.81)	20.64; 22.18			55	21.23 (3.33)	20.33; 22.13		
Post-intervention	40	22.52 (2.38)	21.76; 23.28	22.67 (.43)	21.81-23.54	40	21.9 (3.47)	20.74; 22.96	22.15 (.43)	21.3-23
Follow-up	35	23.19 (2.8)	22.23; 24.15	23.24 (.47)	22.3-24.18	36	22.31 (3.56)	21.11; 23.51	22.26 (.47)	21.33-23.19
DASS Depression (possible range of scores 0-42)										
Baseline	54	22.85 (5.96)	21.23; 24.48			55	22.8 (6.41)	21.07; 24.53		
Post-intervention	39	19.79 (4.22)	18.43; 21.16	19.71 (.74)	18.23-21.19	40	22 (6.53)	19.91; 24.09	21.2 (.73)	19.74-22.66
Follow-up	35	20.69 (4.39)	19.18; 22.19	20.2 (.74)	19.04-22	36	20.94 (5.98)	18.92; 22.97	20.64 (.73)	19.18-22.1
DASS Anxiety (possible range of scores 0-42)										
Baseline	54	20.37 (5.29)	18.93; 21.81			55	18.91 (5.32)	17.47; 20.35		
Post-intervention	39	18.82 (4.58)	17.34; 20.31	17.45 (.64)	16.17-18.73	40	19.85 (6.98)	17.61; 22.08	19.89 (.63)	18.6-21.13
Follow-up	35	18.68 (4.28)	17.21; 20.16	18.14 (.66)	16.83-19.46	36	19.56 (6.22)	17.45; 21.66	20.08 (.65)	18.79-21.38
DASS Stress (possible range of scores 0-42)										
Baseline	54	30.04 (6.88)	28.16; 31.91			55	29.16 (7.13)	27.24; 31.09		
Post-intervention	39	27.74 (6)	25.79; 29.67	26.81 (.95)	24.91-28.71	40	29.8 (7.95)	27.26; 32.34	30.77 (.94)	28.9-32.64
Follow-up	35	26.86 (4.83)	25.2; 28.52	26.34 (.95)	24.43-28.24	36	27.06 (6.9)	24.72; 29.39	27.56 (.94)	25.67-39.44
MPAS; Maternal Attachment (possible range of scores 0-95)										
Baseline	54	73.98 (8.81)	71.57; 76.39			55	76.07 (10.31)	73.28; 78.85		
Post-intervention	40	77.33 (8.81)	74.52; 80.15	78.78 (1.14)	76-80.55	40	77.75 (9.49)	74.71; 80.78	76.53 (1.12)	74.29-78.77
Follow-up	35	76.98 (8.51)	74.06; 79.9	78.4 (.99)	76.42-80.38	36	80.48 (7.19)	78.05; 82.91	79.1 (.98)	77.15-81.05
FFMQ: Mindfulness (possible range of scores 0-75)										
Baseline	53	38.26 (7.02)	36.33; 40.2			55	37.84 (7.33)	35.85; 39.82		
Post-intervention	39	37.44 (6.21)	35.42; 39.45	37.15 (.88)	35.4-38.9	39	34.46 (6.16)	32.47; 36.46	34.86 (8.5)	33.16-36.56
Follow-up	35	40.94 (5.72)	38.98; 42.91	40.91 (.77)	39.39-42.44	36	37.69 (6.58)	35.47; 39.92	37.69 (.74)	36.21-39.17
Sleep quality (possible range of scores 0-10)										
Baseline	53	4.57 (1.87)	4.05; 5.08			54	4.44 (2.05)	3.88; 5.00		
Post-intervention	39	5.17 (2.06)	4.51; 5.85	5.14 (.37)	4.41-5.87	39	5.10 (2.28)	4.36; 5.84	5.21 (.35)	4.5-5.91
Follow-up	34	5.44 (2.05)	4.73; 6.16	5.72 (.39)	49.4-6.51	36	5.28 (2.78)	4.34; 6.22	5.15 (.38)	4.39-5.9

Note: CI = Confidence interval; M = Mean; n = Number of participants; SD= Standard deviation; SE = Standard error;

Contrary to predictions, mindfulness decreased slightly following the intervention, however, increased at follow-up, over and above the baseline average.

Analysis of covariance

A significant group x time interaction was found for stress F(1,67)= 6.1, *p*=.016 after controlling for age and baseline stress scores, with an adjusted mean difference of 3.96 between the two groups at post-intervention (see table 7). Significant group effects were found for anxiety and mindfulness. No other statistically significant results were found for subjective wellbeing, depression, anxiety, mindfulness, and sleep. Table 7 displays the group, time, group x time interaction effects, and effect sizes for all ANCOVAs.

Table 7
ANCOVA Results

Patient recorded outcome measure	*df*	*F*	*p*	Effect size *(d)*
Subjective Wellbeing				
Group	1, 67	1.7	.197	.25
Time	1, 67	5.99	.16	.29
Group x time	1, 67	.55	.461	.11
Depression				
Group	1, 64	.75	.39	.14
Time	1, 64	.2	.66	.07
Group x time	1, 64	1.82	.18	.26
Anxiety				
Group	1, 68	6.08	.016*	.76
Time	1, 68	.088	.768	.27
Group x time	1, 68	.000	.984	.08
Stress				
Group	1, 67	4.18	.45	.52
Time	1, 67	10.19	.002*	.88
Group x time	1, 67	6.1	.016*	.68
Maternal Attachment				
Group	1, 67	.142	.707	.07
Time	1, 67	.063	.803	.057
Group x time	1, 67	3.14	.081	.42
Mindfulness				
Group	1, 65	6.72	.012*	.72
Time	1, 65	.036	.85	.05
Group x time	1, 65	.863	.356	.15
Sleep				
Group	1, 65	.287	.594	.08
Time	1, 65	2.428	.124	.34
Group x time	1, 65	1.656	.203	.25

Note:. Covariate sleep removed from subjective wellbeing, stress, anxiety, and maternal attachment models due to correlation with baseline measures. Covariate age removed from anxiety due to linearity of regression slopes being violated. Bonferroni corrections undertaken on all models due to multiple comparisons

Reliable change indices (RCIs)

Preliminary efficacy of the intervention was further explored through RCIs using the Jacobson and Truax method (1991). This criterion was used to calculate reliable improvement alongside reliable deterioration as a measure of possible harm effects, with results being displayed in table 7. Results appeared to support ANVOCA findings with the largest between-group difference in reliable improvement appearing to be found for stress. Importantly, there was no evidence of greater reliable deterioration in the intervention vs control group.

Table 8

Reliable change from baseline measures

Patient reported outcome measure (reliable change criterion)	**Reliable deterioration** *n* (%)	**No reliable change** *n (%)*	**Reliable improvement** *n (%)*
Subjective Wellbeing (3.81)			
Post-intervention			
Intervention	0 (0)	32 (80)	8 (20)
Control	0 (0)	33 (80)	7 (20)
Follow-up			
Intervention	1 (2.9)	26 (74.3)	8 (22.8)
Control	4 (11)	25 (72.3)	7 (16.7)
Stress (6.99)			
Post-intervention			
Intervention	0 (0)	27 (77.8)	12 (22.2)
Control	0 (0)	36 (92.7)	4 (7.3)
Follow-up			
Intervention	0 (0)	22 (75.9)	13 (24.1)
Control	0 (0)	28 (85.5)	8 (14.5)
Anxiety (5.83)			
Post-intervention			
Intervention	1 (2.5)	30 (77)	8 (20.5)
Control	3 (7.5)	36 (90)	1 (2.5)
Follow-up			
Intervention	3 (8.5)	25 (71.5)	7 (20)
Control	4 (11)	30 (83.5)	2 (5.5)
Depression (6.17)			
Post-intervention			
Intervention	0 (0)	31 (79.5)	8 (20.5)
Control	1 (2.5)	33 (82.5)	6 (15)
Follow-up			
Intervention	2 (5.7)	26 (74.3)	7 (20)
Control	1 (2.8)	28 (80)	6 (17.2)

Patient reported outcome measure (reliable change criterion)	**Reliable deterioration** *n (%)*	**No reliable change** *n (%)*	**Reliable improvement** *n (%)*
Mindfulness (8.66)			
Post-intervention			
Intervention	2 (5.2)	34 (89.5)	2 (5.3)
Control	7 (17.9)	30 (76.9)	2 (5.2)
Follow-up			
Intervention	1 (2.8)	26 (74.3)	8 (22.9)
Control	0 (0)	35 (97.2)	1 (2.8)
Maternal Attachment (9.97)			
Post intervention			
Intervention	0 (0)	36 (90)	4 (10)
Control	0 (0)	35 (87.2)	5 (12.5)
Follow-up			
Intervention	0 (0)	29 (85.7)	6 (14.3)
Control	0 (0)	28 (77.8)	8 (22.2)

Treatment integrity

Fifty percent of sessions and micro-meditations were rated for treatment integrity using an adapted MBCT-AS (Segal et al., 2002) with ratings from 0 (no evidence) to 2 (definite evidence) on 10 items. For live sessions, a score of 1.42 (SD=0.08) was reported and 1.08 (0.2) for mini meditations suggesting satisfactory treatment integrity. Lower scores were reported for the provision of MBIs during micro meditations, home practice setting and commitment to practice.

Triangulation of findings

As this study used a mixed methods approach, Table 9 presents the triangulation of qualitative and quantitative results (convergence and complimentary) aiming to increase validity, reliability, and credibility of findings (Erzberger & Prein, 1997). Triangulated data was confirmatory for and expansive for acceptability, whilst feasibility was partially confirmatory as whilst recruitment rates exceeded expectations, qualitative feedback suggested mothers often found it challenging to find the time to complete the course, mainly due to life with a new-born. Furthermore, stress reduction following the d-bMBI was confirmatory across the analyses, with increases in mindfulness being confirmed further.

Table 9
Triangulation of mixed method findings showing convergence codes as assigned

Research question	Quantitative findings	Qualitative findings	Convergence code
Acceptability	34/56 completed at least 6 sessions (60.7%) 16/56 completed all 9 sessions (28.3%) Average micro meditation completion was 2.92 (48.7% of recommendation) Perceived helpfulness (1-10; M=8.35, SD=1.55) Satisfaction with the course (1-10; M= 8.97, SD=1.55) Likely to recommend (1-10); M=9.04, SD=1.42)	Subtheme of relevance of the course to new mums and helpfulness of the course during the COVID-19 pandemic.	Confirmatory; convergent and expansion
Feasibility	Recruitment rate: 112/88 (127%) Dropout rate: Post intervention (30.4%) Follow up: (36.65%) One participant in each arm dropped out of the study citing time commitments as their rationale (3.6%) Average treatment integrity rating (TBC)	Subtheme of supportive and non-judgemental teacher and group connection. Subtheme of making time to do the course	Partially confirmatory
Subjective wellbeing	Non-significant group, time, or group x time interactions Reliable improvement was similar across both groups. At follow up, 1 individual showed reliable deterioration in subjective wellbeing within the intervention group, with 4 in the control showing reliable deterioration.	None	Not codable
Anxiety	Significant group interaction at post intervention to follow up when controlling for baseline measures. At Post-intervention the intervention group was on average 1.03 points less on the anxiety scale than the control group.	None	Not codable

Research question	Quantitative findings	Qualitative findings	Convergence code
	Non-significant time or group x time interactions At post intervention 8 individuals in the intervention group showed reliable improvement with 1 in the control group. At follow up this was 7 in the intervention group and 2 in the control.		
Depression	Non-significant group, time, or group x time interactions	None	Not codable
Stress	Significant time and group x time interaction after controlling for baseline stress. No individuals showed reliable deterioration at post intervention or follow up. 12 participants in the intervention group showed reliable improvement at post intervention compared to 4 in the control. At follow up this increased to 13 in comparison to 8.	Subtheme of feeling calmer or more relaxed following meditations/engaging in course material	Confirmatory; convergent and expansion
Mindfulness	Significant group interaction with the intervention group scoring on average higher on mindfulness than the control at post intervention (+2.98) and at follow up (+3.25). Nonsignificant time or group x time interactions. At follow up, 8 individuals in the intervention group showed reliable improvements in mindfulness in comparison to 1 in the control group.	Theme of embodying mindfulness traits with subthemes of: Being more in the present moment, doing activities in a more mindful way, noticing thoughts and emotions, recognising that it is okay to feel emotions and not to be perfect	Confirmatory; convergent and expansion
Maternal Attachment	Non-significant group, time, or group x time interactions No individuals showed reliable deterioration and groups were closely matched for reliable improvements.	None	Not codable
Sleep	Non-significant group, time, or group x time interaction	Three comments on sleeping easier within the theme of feeling calmer and more relaxed.	Not codable

Discussion

The ‘10 of zen’ course was developed as a d-bMBI for first-time mothers within the postpartum period. To the authors knowledge, this is the first pilot RCT of a d-bMBI for this group. In line with predictions, participants found the course acceptable and feasible. Furthermore, those with access to the intervention reported significantly greater decreases in perceived stress in comparison to control, when controlling for baseline stress scores. Contrary to hypothesis, there were no significant differences between the intervention group and control in change scores for all other outcome measures, although all changes were in the expected direction.

COVID-19 Pandemic

The study took place during the COVID-19 pandemic in 2020-2021. It is important to note that baseline measures coincided with the UK’s third lockdown being announced whereby people were asked to stay at home with no household mixing. Post-intervention and follow-up measures were completed around step 2 and 3 of ‘unlocking’ whereby individuals were able to mix with other households and support groups were able to commence.

Within the general population, anxiety and depression severity has increased during the pandemic (Boden et al 2021; Santabarbara et al., 2020), with similar trends being seen for perinatal women (Hessami et al., 2020; Kotlar et al 2021). Participants within this study averaged in the severe or extremely severe ranges for anxiety, depression, and stress which may have been influenced by the pandemic.

Recruitment, engagement levels and retention rates may have also been influenced by the pandemic. New mothers found themselves without their usual support networks, meaning they may have been searching elsewhere for support, leading them to this study and boosting recruitment. The reduction in activities may have meant mothers had more time than usual to

engage in the study and complete questionnaires. It is thus likely that COVID-19 impacted on results found and brings difficulty when generalising results outside of a pandemic.

Acceptability

Overall participants found the d-bMBI acceptable with high levels of perceived helpfulness, satisfaction with the course and being likely to recommend the course. Participants commented on the relevance of the course and how it was supportive for them in being a new mother within the COVID-19 pandemic.

In total 60.7% of participants completed at least six sessions out of nine, with 28.3% completing all nine. This is higher than previous studies finding that 52.4% of participants completed half of the intervention and only 8% completed every session (Sun et al., 2021) and lower than others with 83.9% of participants completing over half (Yang et al., 2019). The catch-up facility appeared important to increase acceptability with support from both the number accessed (on average 1.91 sessions) and qualitative feedback. Suggesting having flexibility of times is important for women with new-borns.

Participants commented on the difficulty of daily meditations, even when reduced to brief (less than 3-minute practices). This finding is similar to previous studies (Carissoli et al., 2021; Sun et al., 2021; Yang et al., 2019) suggesting that for the perinatal population, daily mindfulness is difficult to engage withe. On average, participants in this study completed 2.92 micro meditations per week which is a slightly less than previous studies who reported an average of 3-3.25 practices per week (Carissoli et al., 2021; Yang et al., 2019). This suggests that within the postpartum period, daily mindfulness may also be particularly difficult.+

Feasibility

Recruitment and retention rates would suggest that the 10 of zen course is a feasible intervention to implement within this population. The study reached 127% of the target recruitment number (112/88). Previous studies have required longer recruitment periods to reach similar levels (Sun et al., 2021; Zhang et al., 2021), suggesting that women within the postpartum period were keen to engage in a mindfulness-based intervention at the time this study was advertised.

Attrition rates for this study (36.65% overall at follow-up) are similar to other studies exploring d-bMBIs in the perinatal period who reported a 33.3% attrition rate at follow-up (Zhang et al., 2021). Attrition is lower than more intensive MBIs within this population (Krusche et al., 2018) and higher than single arm studies, reporting 25% (Felder et al., 2017). This suggests that the d-bMBI used within this study is feasible for postpartum women.

Two participants dropped out of the study citing returning to work as the reason for this, suggesting time commitment is difficult for this population or that engagement is only feasible for those working part-time or on maternity leave. This is further supported by engagement in daily mindfulness being lower than expected. Of those that entered the study, the majority (92%) were on maternity leave or not presently in employment which may have enabled them to engage more easily with intervention requirements due to time commitments. Supportive aspects for feasibility of the d-bMBI include the non-judgemental and supportive approach from the mindfulness teacher, which several participants commented on, as well as having a group connection via the weekly ‘live’ sessions and WhatsApp groups as this enabled them to feel accountable and have a shared experience with individuals in similar circumstances.

Preliminary efficacy

Stress

Preliminary efficacy using the intention-to-treat principle indicated that mothers who undertook the intervention reported significant lower stress levels at post-intervention to follow up in comparison to the control group, when controlling for baseline stress. This result appears to be promising, particularly given that the study was not powered to examine efficacy, and Bonferroni corrections were applied due to multiple comparisons being undertaken, reducing the likelihood of a type I error. Participants commented on feeling calmer or more relaxed when completing or following a mindfulness practice, supporting the finding further. This is similar to previous d-bMBIs within the perinatal period who found significant reductions for stress after engaging in a d-bMBI (Matvienko-Sikar & Dockray, 2016; Zhang et al., 2021). The lack of other statistically significant findings may have been influenced by the impact of the COVID-19 pandemic. Stages of lockdown and unlocking during measure completion and inflation found in depressive and anxious symptoms at baseline may have influenced the results in this study. However, promisingly no detrimental impact of engaging in the intervention was found, even in the context of the pandemic, as evidenced by means, standard deviations, confidence intervals and reliable change indices.

Mindfulness

Within qualitative data, several participants reported on various aspects of mindfulness which enabled them to bring more awareness to the present moment (such as anchoring with the breath, noticing bodily sensations). Similar themes have been found previously (Carissoli et al., 2021; Maher, 2022). It is known that attention to the present moment is one of the foundational aspects of mindfulness practices (Kabat-Zinn, 2003) as well as mindful parenting theories (Duncan et al., 2009). This finding suggests that the

intervention succeeded in supporting participants to cultivate and apply present-moment awareness, noticing the tendency to judge internal states and acting with increased awareness. These findings may influence wellbeing, as well as increase maternal sensitivity which has been linked to infant wellbeing (Leerkes et al., 2012).

Furthermore, changes in feelings and actions were observed when approaching certain situations and experiencing emotions. This is consistent with prior quantitative and qualitative research exploring the impact of MBIs within the postpartum period (Kantroqitz-Gordon et al 2018., Malis et al., 2017, Potharst et al., 2017) who reported participants had a sense of observing their feelings, rather than reacting. Presently, while these findings do not directly link to theories of mindful parenting, results appear promising for cultivating key aspects required, such as present moment awareness to child-parent relationship and awareness of own emotional regulation.

Clinical Implications

While this study did not actively seek to recruit a clinical sample, with exclusions being placed around anxiety and depression severity, participants within this sample reported severe and extremely severe levels of depression, anxiety, and stress at baseline measures. This is not surprising given the research suggesting elevated anxiety and depression levels have been seen within the general population and perinatal women during COVID-19. It is promising that this study found no harm effects following the intervention, even with elevated psychological distress. Previous studies have explored effectiveness of a d-bMBI for clinical perinatal women, with promising results being found (Sun et al., 2021; Zhang et al., 2021). It would be paramount to ascertain the impact of the intervention used within this study on a clinical population outside of a global pandemic, and with those who may be at risk of relapse, which is a known risk for this group (Dimjiman et al., 2016). Furthermore,

parents who may be the primary care giver and primary wage earners, such as single mothers, may require further consideration for these forms of intervention due to the increase in parenting demands (Taylor & Conger., 2017). It would be important for considerations to be made for these mothers and adaptations to the intervention made as required also.

This intervention was set up with minimal teacher contact. This, alongside the digital format and ability to catch-up on sessions, may be important features to aid in the acceptability of the intervention and to increase access and reach of such an intervention to those who may find it difficult to engage in the more intensive, traditional mindfulness formats. It appears important for settings offering interventions such as this to build in flexibility surrounding delivery, and consider access to technology required for engagement, for example providing such equipment if participants have limited access to funds.

Furthermore, it is paramount that considerations to these types of interventions are culturally sensitive. Mindfulness originates from Buddhist traditions and includes experiences and social references predominantly to White culture (Proulx et al., 2017). It may be that even the title or phrasing of such interventions may deter certain individuals these types of interventions, thus being able to promote access and create tailored interventions suited to a variety of cultures and backgrounds is important for future dissemination of these types of interventions with treatment modifications beginning to be explored (Watson-Singleton et al., 2019).

Limitations

The study had several limitations. First, the control group was wait-list, rather than an active comparison meaning factors around engagement, expectations and peer support were not controlled for, limiting interpretation of findings. Secondly, the lack of long-term follow-up limits our understanding of the extent to which benefits are sustained over time. Third,

despite efforts to recruit mothers from a variety of backgrounds and experiences via social media outlets targeting these individuals, the sample was predominantly White-British, highly educated and cohabiting with a partner. These demographics are not representative of the social and ethnic backgrounds of mothers within the UK, limiting generalisability to a broader population. Fourth, data collection methods hold limitations with qualitative being collected via questionnaires rather than semi-structured interviews which may have provided richer data. Furthermore, outcome measures were self-reported and likely influenced by social desirability, particularly maternal attachment which is known to hold perceived social pressures (Condon & Corkindale, 1998). Finally, this study only included new mothers. Research has begun to expand interventions to new fathers (Rayburn et al, 2021) and couples (Canfield, 2021) as they transition to parenthood. It is acknowledged that the homogenous female sample within this review limits the generalisability of findings to fathers as they transition to parenthood for the first time.

Another limitation comes from assessing treatment fidelity. Currently there is no fidelity measure for d-bMBIs and therefore a previous measure, the MBCT-AS (Segal et al., 2002) was adapted. This measure was not designed for the purpose of assessing treatment fidelity in this context and therefore was not applicable in some areas. Future work should look to develop an appropriate fidelity measure for bMBIs.

Future research

Future work should seek to explore generalizability to a variety of cultural groups particularly when exploring engagement barriers, acceptability, and feasibility of online MBIs due to cultural variations. This is especially important when considering the context of mindfulness-based interventions with their Buddhist roots and delivery within different cultures and religions (Davis, 2015). Exploring interventions outside of a global pandemic

and subsequent influence on engagement and patient outcomes would also be of benefit, as well as undertaking a fully powered RCT with the 10 of zen intervention. Future studies should aim to have an active control group, whereby aspects of the intervention are matched to allow for specific conclusions to be drawn with longer term follow ups (e.g. six or 12 months) to explore benefit sustainability and impact on infants. Further research exploring the group experience and impact on MBIs would also be of benefit. Future work would be beneficial in exploring preventative aspects of d-bMBIs in high risk, non-clinical groups and to widen inclusion to incorporate fathers' experiences.

Conclusion

This is the first pilot RCT to explore the acceptability and feasibility of a d-bMBI developed for first-time mums in the postpartum period. There was good evidence of acceptability and feasibility within the context of the COVID-19 pandemic, whereby new mothers were expressing elevated levels of anxiety, depression, and stress. Preliminary efficacy for stress reduction was found between the intervention and control group at post intervention to follow up.

The intervention was set up with minimal teacher contact and less intensive resources than the traditional format of mindfulness-based interventions, lending itself to the potential for widespread access without the need for intensive resources. Further research would benefit from exploring engagement and effects outside of a global pandemic, preventative aspects of the intervention with a long-term follow-up and barriers to daily engagement.

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7. Appendices

Section A: Literature Review

Appendix A: PRISMA checklist

Appendix B: OBECM levels of evidence

Appendix C: SQACPR

Section B: Empirical Research Paper

Appendix D: Clinical Trials registration

Appendix E: CONSORT Checklist

Appendix F: TIDieR checklist

Appendix G: Demographic questionnaire

Appendix H: End of study materials

Appendix I: Patient Recorded Outcome Measures

Appendix J: Satisfaction questionnaire

Appendix K: Recruitment materials

Appendix L: Information sheet

Appendix M: Eligibility

Appendix N: Consent form

Appendix O: MCT-AS Scale

Appendix P: 15-item checklist for MBIs

Appendix Q: Ethical approval

Appendix R: ANCOVA assumption checks

Appendix S: Mindfulness Journal Submission guidelines

Appendix T: Update to ethics committee

Appendix U: Update to participants

Appendix A: PRISMA checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	P.10
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	P.11
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	P.12
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	P.18
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	P.19/20
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	P.19
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	P.19
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	P.22
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	P.20/21
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	P.20/21
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	P.20/21
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	P.19
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	P.21
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	P.21

Section and Topic	Item #	Checklist item	Location where item is reported
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	P.21
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	P.21
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	P.21/30
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	P.22
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	P.22
Study characteristics	17	Cite each included study and present its characteristics.	P.23-28
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	N/A
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	N/A
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	P.29/31
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	P.41-46
	23b	Discuss any limitations of the evidence included in the review.	P41-48
	23c	Discuss any limitations of the review processes used.	P.54
	23d	Discuss implications of the results for practice, policy, and future research.	P.49-52

Section and Topic	Item #	Checklist item	Location where item is reported
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	N/A
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	N/A
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	N/A
Competing interests	26	Declare any competing interests of review authors.	N/A
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

Appendix B: Oxford Centre for Evidence-Based Medicine 2011 Levels of evidence

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non -randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

*** Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.**

**** As always, a systematic review is generally better than an individual study.**

Appendix C: Standard Quality Assessment Criteria for Primary Research (Kmet, Lee & Cook, 2004) Quality Scoring of Quantitative Studies

Definitions and Instructions for Quality Assessment Scoring

How to calculate the summary score

Total sum = (number of "yes" * 2) + (number of "partials" * 1)

Total possible sum = 28 – (number of "N/A" * 2)

Summary score: total sum / total possible sum

Quality assessment

- *Question or objective sufficiently described?*
    - **Yes:** Is easily identified in the introductory section (or first paragraph of methods section). Specifies (where applicable, depending on study design) all of the following: purpose, subjects/target population, and the specific intervention(s) /association(s)/descriptive parameter(s) under investigation. A study purpose that only becomes apparent after studying other parts of the paper is not considered sufficiently described.
    - **Partial:** Vaguely/incompletely reported (e.g. "describe the effect of" or "examine the role of" or "assess opinion on many issues" or "explore the general attitudes"...); or some information has to be gathered from parts of the paper other than the introduction/background/objective section.
    - **No**: Question or objective is not reported or is incomprehensible.
    - **N/A**: Should not be checked for this question.

- *Design evident and appropriate to answer study question?* (If the study question is not given, infer from the conclusions).
    - **Yes:** Design is easily identified and is appropriate to address the study question / objective.
    - **Partial:** Design and /or study question not clearly identified, but gross inappropriateness is not evident; or design is easily identified but only partially addresses the study question.
    - **No**: Design used does not answer study question (e.g., a comparison group is required to answer the study question, but none was used); or design cannot be identified.
    - **N/A**: Should not be checked for this question.

- *Method of subject selection (and comparison group selection, if applicable) or source of information/input variables (e.g., for decision analysis) is described and appropriate*.
    - **Yes**: Described and appropriate. Selection strategy designed (i.e., consider sampling frame and strategy) to obtain an unbiased sample of the relevant target population or the entire target population of interest (e.g., consecutive patients for clinical trials, population-based random sample for case-control studies or surveys). Where applicable, inclusion/exclusion criteria are described and defi ned (e.g., "cancer" -- ICD code or equivalent should be

provided). Studies of volunteers: methods and setting of recruitment reported. Surveys: sampling frame/ strategy clearly described and appropriate.
    - **Partial**: Selection methods (and inclusion/exclusion criteria, where applicable) are not completely described, but no obvious inappropriateness. Or selection strategy is not ideal (i.e., likely introduced bias) but did not likely seriously distort the results (e.g., telephone survey sampled from listed phone numbers only; hospital based case-control study identified all cases admitted during the study period, but recruited controls admitted during the day/evening only). Any study describing participants only as "volunteers" or "healthy volunteers". Surveys: target population mentioned but sampling strategy unclear.
    - **No:** No information provided. Or obviously inappropriate selection procedures (e.g., inappropriate comparison group if intervention in women is compared to intervention in men). Or presence of selection bias which likely seriously distorted the results (e.g., obvious selection on "exposure" in a case-control study).
    - **N/A**: Descriptive case series/reports.

- *Subject (and comparison group, if applicable) characteristics or input variables/information (e.g., for decision analyses) sufficiently described?*
    - **Yes**: Sufficient relevant baseline/demographic information clearly characterizing the participants is provided (or reference to previously published baseline data is provided). Where applicable, reproducible criteria used to describe/categorize the participants are clearly defi ned (e.g., ever-smokers, depression scores, systolic blood pressure > 140). If "healthy volunteers" are used, age and sex must be reported (at minimum). Decision analyses: baseline estimates for input variables are clearly specified.
    - **Partial:** Poorly defi ned criteria (e.g. "hypertension", "healthy volunteers", "smoking"). Or incomplete relevant baseline / demographic information (e.g., information on likely confounders not reported). Decision analyses: incomplete reporting of baseline estimates for input variables.
    - **No:** No baseline / demographic information provided. Decision analyses: baseline estimates of input variables not given.
    - **N/A:** Should not be checked for this question.

- *If random allocation to treatment group was possible, is it described*?
    - **Yes:** True randomization done - requires a description of the method used (e.g., use of random numbers).
    - **Partial:** Randomization mentioned, but method is not (i.e. it may have been possible that randomization was not true).
    - **No:** Random allocation not mentioned although it would have been feasible and appropriate (and was possibly done).
    - **N/A:** Observational analytic studies. Uncontrolled experimental studies. Surveys. Descriptive case series / reports. Decision analyses.
- *If interventional and blinding of investigators to intervention was possible, is it reported?*
    - **Yes:** Blinding reported.
    - **Partial:** Blinding reported but it is not clear who was blinded.
    - **No:** Blinding would have been possible (and was possibly done) but is not reported.

  - **N/A:** Observational analytic studies. Uncontrolled experimental studies. Surveys. Descriptive case series / reports. Decision analyses.

- *If interventional and blinding of subjects to intervention was possible, is it reported?*
  - **Yes**: Blinding reported.
  - **Partial:** Blinding reported but it is not clear who was blinded.
  - **No:** Blinding would have been possible (and was possibly done) but is not reported.
  - **N/A:** Observational studies. Uncontrolled experimental studies. Surveys. Descriptive case series / reports.

- *Outcome and (if applicable) exposure measure(s) well defi ned and robust to measurement / misclassification bias? Means of assessment reported?*
  - **Yes:** Defi ned (or reference to complete definitions is provided) and measured according to reproducible, "objective" criteria (e.g., death, test completion – yes/no, clinical scores). Little or minimal potential for measurement / misclassification errors. Surveys: clear description (or reference to clear description) of questionnaire/interview content and response options. Decision analyses: sources of uncertainty are defi ned for all input variables.
  - **Partial:** Definition of measures leaves room for subjectivity, or not sure (i.e., not reported in detail, but probably acceptable). Or precise definition(s) are missing, but no evidence or problems in the paper that would lead one to assume major problems. Or instrument/mode of assessment(s) not reported. Or misclassification errors may have occurred, but they did not likely seriously distort the results (e.g., slight difficulty with recall of long-ago events; exposure is measured only at baseline in a long cohort study). Surveys: description of questionnaire/interview content incomplete; response options unclear. Decision analyses: sources of uncertainty are defi ned only for some input variables.
  - **No:** Measures not defined or are inconsistent throughout the paper. Or measures employ only ill-defi ned, subjective assessments, e.g. "anxiety" or "pain." Or obvious misclassification errors/measurement bias likely seriously distorted the results (e.g., a prospective cohort relies on self-reported outcomes among the "unexposed" but requires clinical assessment of the "exposed"). Surveys: no description of questionnaire/interview content or response options. Decision analyses: sources of uncertainty are not defi ned for input variables.
  - **N/A:** Descriptive case series / reports

- *Sample size appropriate?*
  - **Yes:** Seems reasonable with respect to the outcome under study and the study design. When statistically significant results are achieved for major outcomes, appropriate sample size can usually be assumed, unless large standard errors (SE > ½ effect size) and/or problems with multiple testing are evident. Decision analyses: size of modeled cohort / number of iterations specified and justified.
  - **Partial:** Insufficient data to assess sample size (e.g., sample seems "small" and there is no mention of power/sample size/effect size of interest and/or

variance estimates aren't provided). Or some statistically significant results with standard errors > ½ effect size (i.e., imprecise results). Or some statistically significant results in the absence of variance estimates. Decision analyses: incomplete description or justification of size of modeled cohort / number of iterations.
    - **No:** Obviously inadequate (e.g., statistically non-significant results and standard errors > ½ effect size; or standard deviations > _ of effect size; or statistically non-significant results with no variance estimates and obviously inadequate sample size). Decision analyses: size of modeled cohort / number of iterations not specified.
    - **N/A:** Most surveys (except surveys comparing responses between groups or change over time). Descriptive case series / reports.

- *Analysis described and appropriate?*
    - **Yes:** Analytic methods are described (e.g. "chi square"/ "t-tests"/"Kaplan-Meier with log rank tests", etc.) and appropriate.
    - **Partial:** Analytic methods are not reported and have to be guessed at, but are probably appropriate. Or minor flaws or some tests appropriate, some not (e.g., parametric tests used, but unsure whether appropriate; control group exists but is not used for statistical analysis). Or multiple testing problems not addressed.
    - **No:** Analysis methods not described and cannot be determined. Or obviously inappropriate analysis methods (e.g., chi-square tests for continuous data, SE given where normality is highly unlikely, etc.). Or a study with a descriptive goal / objective is over-analyzed.
    - **N/A:** Descriptive case series / reports.

- *Some estimate of variance (e.g., confidence intervals, standard errors) is reported for the main results/outcomes (i.e., those directly addressing the study question/ objective upon which the conclusions are based)?*
    - **Yes:** Appropriate variances estimate(s) is/are provided (e.g., range, distribution, confidence intervals, etc.). Decision analyses: sensitivity analysis includes all variables in the model.
    - **Partial:** Undefined "+/-" expressions. Or no specific data given, but insufficient power acknowledged as a problem. Or variance estimates not provided for all main results/outcomes. Or inappropriate variance estimates (e.g., a study examining change over time provides a variance around the parameter of interest at "time 1" or "time 2", but does not provide an estimate of the variance around the difference). Decision analyses: sensitivity analysis is limited, including only some variables in the model.
    - **No:** No information regarding uncertainty of the estimates. Decision analyses: No sensitivity analysis.
    - **N/A:** Descriptive case series / reports. Descriptive surveys collecting information using open-ended questions.

- *Controlled for confounding?*
    - **Yes:** Randomised study, with comparability of baseline characteristics reported (or non-comparability controlled for in the analysis). Or appropriate control at the design or analysis stage (e.g., matching, subgroup analysis,

multivariate models, etc). Decision analyses: dependencies between variables fully accounted for (e.g., joint variables are considered).
    - **Partial:** Incomplete control of confounding. Or control of confounding reportedly done but not completely described. Or randomised study without report of comparability of baseline characteristics. Or confounding not considered, but not likely to have seriously distorted the results. Decision analyses: incomplete consideration of dependencies between variables.
    - **No**: Confounding not considered, and may have seriously distorted the results. Decision analyses: dependencies between variables not considered.
    - **N/A:** Cross-sectional surveys of a single group (i.e., surveys examining change over time or surveys comparing different groups should address the potential for confounding). Descriptive studies. Studies explicitly stating the analysis is strictly descriptive/exploratory in nature.

- *Results reported in sufficient detail?*
    - **Yes:** Results include major outcomes and all mentioned secondary outcomes.
    - **Partial:** Quantitative results reported only for some outcomes. Or difficult to assess as study question/objective not fully described (and is not made clear in the methods section), but results seem appropriate.
    - **No:** Quantitative results are reported for a subsample only, or "n" changes continually across the denominator (e.g., reported proportions do not account for the entire study sample, but are reported only for those with complete data -- i.e., the category of "unknown" is not used where needed). Or results for some major or mentioned secondary outcomes are only qualitatively reported when quantitative reporting would have been possible (e.g., results include vague comments such as "more likely" without quantitative report of actual numbers).
    - **N/A**: Should not be checked for this question.

- *Do the results support the conclusions?*
    - **Yes:** All the conclusions are supported by the data (even if analysis was inappropriate). Conclusions are based on all results relevant to the study question, negative as well as positive ones (e.g., they aren't based on the sole significant finding while ignoring the negative results). Part of the conclusions may expand beyond the results, if made in addition to rather than instead of those strictly supported by data, and if including indicators of their interpretative nature (e.g., "suggesting," "possibly").
    - **Partial:** Some of the major conclusions are supported by the data, some are not. Or speculative interpretations are not indicated as such. Or low (or unreported) response rates call into question the validity of generalizing the results to the target population of interest (i.e., the population defi ned by the sampling frame/strategy).
    - **No:** None or a very small minority of the major conclusions are supported by the data. Or negative findings clearly due to low power are reported as definitive evidence against the alternate hypothesis. Or conclusions are missing. Or extremely low response rates invalidate generalizing the results to the target population of interest (i.e., the population defi ned by the sampling frame/ strategy).
    - **N/A:** Should not be checked for this question.

Appendix D – Clinical Trials Registration

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 12, 2021

ClinicalTrials.gov ID: NCT04674124

Study Identification

Unique Protocol ID:	UPID1920-0332
Brief Title:	Evaluation of an Online Mindfulness-based Course for New Mothers
Official Title:	Feasibility and Acceptability of an Online Mindfulness-based Intervention for Mothers Within the Postpartum Period
Secondary IDs:	

Study Status

Record Verification:	October 2021
Overall Status:	Completed
Study Start:	December 13, 2020 [Actual]
Primary Completion:	June 1, 2021 [Actual]
Study Completion:	July 1, 2021 [Actual]

Sponsor/Collaborators

Sponsor:	Canterbury Christ Church University
Responsible Party:	Sponsor
Collaborators:	University College, London

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: ETH1920-0332 Board Name: Salomons Institute for Applied Psychology Ethics Panel Board Affiliation: Canterbury Christ Church University Phone: +44 (0)1227 927166 Email: Address: Salomons Institute for Applied Psychology Lucy Fildes Building 1 Meadow Road TUNBRIDGE WELLS, KENT TN1 2YG

Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary:	This research study is aiming to explore whether an online mindfulness programme is accessible and supportive for first time mothers who has a child who is less than 12 months old.
Detailed Description:	This study is a randomised controlled trial (RCT) comparing an online mindfulness based course (10ofZen) with a treatment as usual group (delayed 10ofZen course materials). Participants will be informed about the study and asked to undertake a screening questionnaire to ensure the eligibility criteria is met. Following this, participants will be invited to give online consent. A battery of self-report measures will be administered online at baseline (week 0), post-intervention (week 10) and at follow-up (week 14). A sleep measure will also be undertaken and used as a co-variate during data analysis. At the end of participation in the research study, all participants will gain access to the course materials, including audio recordings of meditations and any written materials used within the course.

Conditions

Conditions:	New Mothers Well-being Mindfulness
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	None (Open Label)
Allocation:	Randomized
Enrollment:	112 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Online Mindfulness Course Participants will be enrolled on a 9 week online mindfulness course.	Behavioral: Brief Online Mindfulness Intervention A nine-week mindfulness course compromising of 9x weekly 15 minute group sessions which will be on an online platform and daily micro meditations for participants to undertake. Other Names: • 10ofZen
No Intervention: Delayed course materials	

Arms	Assigned Interventions
Participants will have access to the course materials at the closure of their involvement in the study.	

Outcome Measures

Primary Outcome Measure:

1. Differences in scores between groups at post intervention (10) and follow up (14) on the Short Warwick-Edinburgh Mental Well-Being Scale
   Self-report measure of perceived well-being. Scores can range from 0-35. Higher scores are indicative of higher levels of subjective wellbeing.

   [Time Frame: Post-intervention and follow up (i.e 10 & 14 weeks post baseline)]

Secondary Outcome Measure:

2. Differences in scores between groups at post intervention (10) and follow up (14) on the Maternal Postnatal Attachment Scale
   Self-report measure of maternal emotional bond to the infant. Scores range from 0-95. Higher scores are indicative of higher levels of maternal emotional attachment.

   [Time Frame: Post-intervention (i.e 10 & 14 weeks post baseline)]
3. Differences in scores between groups at post intervention (10) and follow up (14) on the Depression Anxiety Stress Scale - 21
   Self-report measure of depression, anxiety and stress. Scores range from 0-63 with higher scores being indicative of higher levels of depression, anxiety and/or stress.

   [Time Frame: Post-intervention (i.e 10 & 14 weeks post baseline)]
4. Differences in scores between groups at post intervention (10) and follow up (14) Five Facet Mindfulness Questionnaire - 15
   Self-report measure of mindfulness traits. Scores can range between 15-75 with higher scores being indicative of higher levels of mindfulness traits.

   [Time Frame: Post-intervention (i.e 10 & 14 weeks post baseline)]
5. Differences in scores between groups at post intervention (10) and follow up (14) on sleep quality
   Self report measures on sleep quality ranging from 0 (very poor) to 10 (excellent)

   [Time Frame: Post-intervention (i.e 10 & 14 weeks post baseline)]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	Female
Gender Based:	Yes Women who identify as a mother (Biological, adoptive, foster-carer or step-mum)
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria: • Women who identify as a mother (Biological, adoptive, foster-carer or step-mum) • Have an infant under the age of 12 months at baseline measures • Sufficient English reading and listening abilities • Access to the internet via an electronic device (phone, tablet, laptop or computer)

- Access to a mobile phone
- No prior experience of parenting a baby (under 12 months of age)

Exclusion Criteria:

- Previous completion of a formal 8-week mindfulness course or current mindfulness/meditation practice
- Currently pregnant
- Severe levels of depression and/or anxiety as measured by 15+ point on the Generalised Anxiety Disorder-7 and Patient Health Questionnaire-9 (NICE, 2011).
- Suicidal ideation or thoughts of self-harm in the last two weeks
- Currently experiencing symptoms of psychosis
- Diagnosis of Post Traumatic Stress Disorder (PTSD)
- Bereavement within the last six months which they still feel affected by.

Contacts/Locations

Central Contact Person: [redacted]

Central Contact Backup: [redacted]

Study Officials: [redacted]

Locations: **United Kingdom**
Canterbury Christ Church University
Tunbridge Wells, United Kingdom, TN1 2YG
Contact: [redacted]
Contact: [redacted]

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information:

Appendix E – CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	73
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	74
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	75
	2b	Specific objectives or research questions for pilot trial	82
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	87
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	83
	4b	Settings and locations where the data were collected	83
	4c	How participants were identified and consented	87
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	88

Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	84
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	82
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	87
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	87
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	87
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	87
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	87
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	93
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	96
	13b	For each group, losses and exclusions after randomisation, together with reasons	96
Recruitment	14a	Dates defining the periods of recruitment and follow-up	100
	14b	Why the pilot trial ended or was stopped	100

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	97
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	105
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	105
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	105/107
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	116
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	116
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	114
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	117
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	82
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	N/A
	26	Ethical approval or approval by research review committee, confirmed with reference number	89

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

Appendix F – TIDieR Checklist

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	88	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	81	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	184	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	87	_____
	WHO PROVIDED		

5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	88	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	88	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	88	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	88	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	88	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	89	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	89	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

ǂ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendix G: Demographic questionnaire

1. What category best describes you?
    a. Biological mum
    b. Adoptive mum
    c. Step-mum
    d. Full-time foster carer
2. What is your date of birth? ____DD/MM/YYYY__
3. Which of the following best describes your highest level of educational qualifications?
    a. No formal qualifications
    b. O-Levels, GCSE's or equivalent
    c. BTEC or diploma
    d. A Levels or equivalent
    e. Undergraduate/Bachelor's degree
    f. Postgraduate certificate or diploma
    g. Masters degree
    h. Doctorate or PhD
    i. Other, please specify: _____-
    j. Prefer not to say
4. Which of the following best describes your family structure?
    a. Single parent household
    b. Married/civil partnership/co-habiting
    c. Prefer not to say
5. Which of the following best describes your ethnic origin…?
    a. White British
    b. White Irish
    c. White Other
    d. White and Black Caribbean
    e. White and Black African
    f. White and Asian
    g. Any other mixed background
    h. Indian
    i. Pakistani
    j. Bangladeshi
    k. Any other Asian Background
    l. Chinese
    m. Other Ethnic background, please specify _____
    n. Prefer not to say
6. How would you describe your religious background?
    a. Baha'i
    b. No religion
    c. Christian
    d. Jewish
    e. Muslim
    f. Sikh
    g. Buddhist
    h. Hindu
    i. Jain
    j. Pagan
    k. Zoroastrian

l. Other (please give details) _____
m. Prefer not to say

7. How would you describe your sexual orientation?
    a. Heterosexual
    b. Gay/lesbian
    c. Bi-sexual
    d. Other (please give details): _____
    e. Prefer not to say
8. Which of the following would best describe you?
    a. Currently on maternity leave
    b. Working full-time
    c. Working part-time
    d. Not currently employed
9. Would you describe yourself as having a disability?
    a. Yes (please give details if you're happy to) _____
    b. No
    c. Prefer not to say
10. Would you describe any of the children in your household as having a disability?
    a. Yes (please give details if you're happy to)
    b. No
    c. Prefer not to say
11. Do you have any previous experiences of mindfulness approaches or interventions?
    a. Yes (please give details if you're happy to)
    b. No
    c. Prefer not to say
12. Are you currently prescribed an anti-depressant or anti-anxiety medication for a mental health issue?
    a. Yes
    b. No
    c. Prefer not to say
13. Are you currently receiving psychological therapy or counselling for a mental health issue?
    a. Yes
    b. No
    c. Prefer not to say
14. Have you had any previous parenting experience before your baby?
    a. Yes please give details if you're happy to
    b. No
    c. Prefer not to say

Information about your baby

When was your baby born? ____DD/MM/YYYY__

What is the sex of your baby?

d. Female
e. Male
f. Prefer not to say

15. Is your baby one of multiple babies from the same birth? (if YES) please state (e.g twins/triplets)
    a. Yes _____
    b. No

Appendix H – End of study materials

An Online Mindfulness Course for New Mums

10 of zen

Course Materials and Further Resources

Thank you for taking part in the research study. Your involvement in the research study has now come to an end.

The following pages contain information on how to access the 10 of zen course materials and further resources which may be of interest to you.

The 10 of zen course:

The 10 of zen course covers different themes each week including learning how to meditate, slow down, feel less distracted and find comfort with difficult emotions. The themes are:-

- Week 1: Feeling distracted
- Week 2: Breathe and come back
- Week 3: Opening awareness
- Week 4: Mindful movement
- Week 5: Barriers
- Week 6: Welcoming discomfort
- Week 7: The love stuff
- Week 8: Gratitude
- Week 9: Forming habits

Each week consists of one audio recorded zoom call for approximately 15 minutes, followed by three different micro meditations lasting around 3 minutes each. The training plan is listed on the next two pages.

Accessing audio files:

You can download the audio files from the course using the link below:

https://cccusocialsciences.az1.qualtrics.com/jfe/form/SV_cSj8AtqWC3LlygS

On the website, you can download the audiofiles and save them to your own computer by clicking the three vertical dots next to the audio file.

10 of zen course: Training plan

The training plan for the 10 of zen course is listed in the table below. If you would like to follow the plan then download the files with the corresponding names from the following link:

https://cccusocialsciences.az1.qualtrics.com/jfe/form/SV_cSj8AtqWC3LlygS

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Week 1	Take 10 as a team: Feeling distracted Meditation: Body scan	Practice Micro Meditation: Body Scan		Micro Meditation: Mindfulness in everyday life		Micro Meditation: Being mindful with baby – focus on touch and bodily sensations	
Week 2	Take 10 as a team: Breathe and come back Mindful breath	Practice Micro Meditation: Mindful breath		Micro Meditation: Being with baby – focus on breath		Micro Meditation: Friendly awareness of breath	
Week 3	Take 10 as a team: Opening awareness Opening awareness	Practice Micro Meditation: Opening awareness		Micro Meditation: 3 step breathing space		Micro Meditation: Baby play time	
Week 4	Take 10 as a team: Mindful movement Mindful walking	Practice Micro Meditation: Mindful walking		Micro Meditation: Stretching with baby/baby yoga		Micro Meditation: Feet, Fanny and Face	
Week 5	Take 10 as a team: Present not perfect – Barriers	Practice Micro Meditation: Present instead of perfect		Micro Meditation: Mindful baby massage		Micro Meditation: 3 step breathing space plus action step	

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	Present instead of perfect practice						
Week 6	Take 10 as a team: It's real to feel/ welcoming discomfort It's real to feel meditation	Practice Micro Meditation: It's real to feel		Micro Meditation: Being with baby/when baby is crying		Micro Meditation: Outside/inside	
Week 7	Take 10 as a team: The loving stuff I heart you and me	Practice Micro Meditation: Love me more meditation		Micro Meditation: Heart Centre		Micro Meditation: Loving kindness to self and baby	
Week 8	Take 10 as a team: Gratitude 5 times grateful meditation	Practice Micro Meditation: 10 times grateful		Micro Meditation: I am grateful for _____		Micro Meditation: Mindful walk with baby – gratefulness in nature	
Week 9	Take 10 as a team: Tiredness Tiredness meditation						

Further resources:

Nikki W has several meditations in her 10 of zen library that are available to listen to. Some of these were used in the course and some are additional meditations for you to try out as you wish. These can be accessed using the link below:

https://www.10ofzen.com/welcometothelibrary

10 of zen Squad:

Nikki W runs a 10 of zen squad that involves an ongoing weekly 15 minute zoom call with other mums (with a catch up option if you miss the session) and one micro meditation per week. The 10 of zen squad also has a whatsapp group for mums to connect too.

You can find out more about the Zen Squad on the 10 of zen website:

https://www.10ofzen.com/zen-squad

Free video and audio resources:

- "Healing and the Mind – Healing from within" video with Jon Kabat-Zinn: https://vimeo.com/39767361
- Oxford Mindfulness Centre audio resources: https://www.youtube.com/channel/UCkvTP_x8sburMgYSMjYnNHw
- UCLA Mindful Awareness Research Center audio resources: http://marc.ucla.edu/body.cfm?id=22
- Finding Peace in a Frantic World audio resources: http://franticworld.com/free-meditations-from-mindfulness/

Social media pages:

- Nikki Wilson, 10 of zen founder: https://www.instagram.com/tenofzen/
- Dr Emma Svanberg, psychologist: https://www.instagram.com/mumologist/
- Dr Martha Deros Collado, Clinical Psychologist: https://www.instagram.com/dr.mdc_psychologist/

Free meditation/mindfulness apps:

- Insight Timer
- MyLife Meditation
- UCLA Mindful
- Smiling Mind
- The Mindfulness App
- Oxford Mindfulness Centre

Books:

- "Mindfulness for Mums: Simple Ways to Help You and Your Family Feel Calm, Connected and Content" by Izzy Judd
- "Mindful Birthing: Training the Mind, Body, and Heart for Childbirth and Beyond" by Nancy Bardacke
- "Mindfulness. A Practical Guide to Finding Peace in a Frantic World" by Mark Williams and Danny Penman
- "Get Some Headspace : 10 Minutes Can Make All the Difference" by Andy Puddicombe
- "Wherever You Go, There You Are" by Jon Kabat-Zinn

Appendix I – Patient Recorded Outcome Measures

Subjective Wellbeing: Short Warwick-Edinburgh Mental Well-Being Scale (SWEMBS)

[Questionnaire removed from electronic copy]

Maternal Attachment: The Maternal Postnatal Attachment Scale (MPAS)

[Questionnaire removed from electronic copy]

Depression, Anxiety and Stress: The Depression Anxiety and Stress Scale -21 (DASS-21)

[Questionnaire removed from electronic copy]

Mindfulness: 15-Item Five-Facet Mindfulness Questionnaire (FFMQ-15)

[Questionnaire removed from electronic copy]

Sleep: Sleep quality scale

[Questionnaire removed from electronic copy]

Appendix J: Satisfaction questionnaire

'10 of Zen course' condition:

1. How would you describe your experience of 10 of Zen?

2. How helpful did you find 10 of Zen?
- **1.** 10 point likert scale from 0= not at all to 10 = extremely
- **1.** Further comments on the helpfulness of the intervention:

3. On average throughout the intervention, how often did you engage in a micro meditation?
- **1.** Daily
- **2.** Three to four times a week
- **3.** Twice a week
- **4.** Once a week
- **5.** Less than once a week.
- **6.** What, if anything, made it easier or harder to engage in the regular micro meditations?

4. Overall, how satisfied are you with 10 of Zen?
- **1.** 10 point likert scale from 0= not at all to 10 = extremely
- **2.** What was it about the intervention that helped you feel satisfied/unsatisfied?

5. Have you noticed any changes as a result in taking part in 10 of Zen?
- **1.** Yes or No
- **2.** If yes, what changes did you experience?

6. To what extent do you think that 10 of Zen met your needs?

7. Did you experience any difficulties when taking part in 10 of Zen?
- **1.** Yes or No
- **2.** If yes, what difficulties did you experience?

8. How did you find the delivery of 10 of Zen?

9. What changes, if any would you make to 10 of Zen?
- **1.** Are there any practical changes to it that you think we should make?

10. Did you feel involved in 10 of Zen?
- **1.** Yes or No

2. If yes, what supported you to feel involved in 10 of Zen? If no, what do you think would help to make you feel more involved? Was there anything that made it difficult?

11. How likely would you be to recommend 10 of Zen to a friend who is a mum or soon to be a mum?

1. 10 point likert scale from 0= not at all to 10 = extremely

12. Any other feedback around your experience of the intervention:

‘Delayed 10ofZen materials’ condition:

1. Are you currently receiving any support with respect to your mental health and emotional wellbeing from your GP or other services?
    1. Yes or No
    2. If yes, what and who is it being provided by?

2. Overall how satisfied are you with how your mental health and emotional wellbeing is being supported by your GP or other services?
    1. 10-point likert scale from 0= not at all to 10 = extremely
3. If you are receiving support with respect to your mental health and emotional wellbeing, how useful is this?
    1. 10-point likert scale from 0= not at all to 10 = extremely

4. If you are receiving support with respect to your mental health and emotional wellbeing, how suitable or acceptable is this to you? How much is it meeting your needs?
    1. 10-point likert scale from 0= not at all to 10 = extremely

5. If you are receiving support with respect to your mental health and emotional wellbeing, how easy is it for you to receive this support from a practical point of view?
    1. 10-point likert scale from 0= not at all to 10 = extremely

6. If you are not receiving any support with respect to your mental health and emotional wellbeing, what kind of support would you like to receive? What would this look like?

Appendix K- Recruitment materials

"We are interested in whether an online mindfulness programme for mums (10 of Zen) is accessible and supportive for first-time mothers. If you decide to take part in the study, you will be chosen at random to either have access to the 10 of Zen course or delayed 10 of Zen materials, which you will get for free!

10 of Zen is an 8-week online programme that contains weekly 15-minute sessions and brief daily exercises for you to try out. The course aims to help you:

1. Cope with feelings of stress or worry;
2. Look at things in different ways;
3. Increase wellbeing.

You will also be asked to complete some questionnaires (which will take approximately 15 minutes) three times during your participation in the study.

By completing the questionnaires, you will be placed into a prize draw of 4 x £25 vouchers, and if you complete them on all three occasions, you'll be entered twice!

By participating you will also be helping us to potentially support mums in the future!

For more information or to take part, please visit [link]

or email [Trainee's email]"

Appendix L– Information Sheet

Information Sheet
Online mindfulness course for new mums

Hello. My name is [Trainee] and I am a trainee clinical psychologist at Canterbury Christ Church University. I am working with [Supervisor] (DClinPsy), [Supervisor] (PhD, DClinPsy) and [Course creator] (10 of Zen Founder) on a research project looking at an online mindfulness course for new mums. We would like to invite you to take part in the research study.

Before you decide whether to take part, it is important that you understand why the research is being done and what it would involve for you. You are welcome to talk to others about the study, or a member of the research team before deciding to take part.

(Part 1 tells you the purpose of this study and what will happen to you if decide to take part. Part 2 gives you more detailed information about how the study will be conducted).

What is the purpose of the study?

This research study is aiming to explore whether an online mindfulness programme (10 of Zen) is accessible and supportive for first-time mothers (biological, adopted, foster carer or Step-mum) who have a child who is less than 12 months old.

Who can take part in the study?

We are asking approximately 88 people who meet the following criteria to take part in this study:

If:

1. **They identify as a mother (biological, adopted, foster carer or step-mother)**
2. **They are aged 18+**
3. **They are living in the UK**
4. **They have sufficient ability to read and understand English to complete questionnaires and engage in an online course**
5. **They have no prior experience of parenting a baby (under 12 months of age)**
6. **They have access to a mobile phone**
7. **They have access to the internet via an electronic device (phone, tablet, laptop or computer)**

To also ensure the course is suitable for people participating, we are asking that people do not take part in the study if:

1. They have previously completed a formal 8-week mindfulness course or have a current mindfulness/meditation practice
2. They are currently pregnant
3. They are currently experiencing symptoms of psychosis (e.g. hearing voices or experiencing hallucinations)

4. They are currently experiencing high levels of depression or anxiety
5. They have had thoughts of harming themselves within the last two weeks
6. They have a diagnosis of Post-Traumatic Stress Disorder.
7. They have had a bereavement within the last 6 months which they still feel affected by

Do I have to take part?

No, you do not have to take part if you do not want to. It is up you to decide whether you want to join the study. If you agree to take part, you will be asked to fill in a short screening questionnaire to make sure you are suitable for the study.

You are free to withdraw at any time, without giving a reason or without it affecting your medical or legal rights.

If you are not sure whether it would be best to take part or would like more information, you are welcome to contact the study team on [trainee email]

What do you mean by 'mindfulness' and '10 of Zen'?

Mindfulness is a technique which supports us to notice our thoughts, feelings and sensations as they occur in the here-and-now, without judgement. Mindfulness is a form of meditation which has been found to help reduce low mood, stress, and anxiety, and support people's sense of wellbeing.

The online course used within this research study is called "10 of Zen". 10 of Zen has been running since 2018 and was created by [Course creator]. The idea of 10 of Zen is to take 10 minutes out of your day to practice meditation. We appreciate that the word 'zen' may have different meanings to different people depending on their religious background. However, this study focuses on meditation techniques and how we can use them to support our wellbeing in everyday life and is not aligned to any particular religion.

What will happen to me if I take part?

1. You will be asked to complete some brief questionnaires online to see if the course may be suitable for you.

If we think it is suitable for you to take part:

1. You will be sent an email asking you to complete some additional questionnaires online. We will ask you for some information about you; for example, your age, ethnicity, as well as some basic questions about your baby. This information will help us know more about the characteristics of who is taking part in the study. In addition, you will be asked to complete a set of questionnaires which includes questions about your experiences e.g. symptoms of depression, anxiety and stress within the last two weeks and your relationship with your baby. These will take approximately 15-20 minutes of your time.

2. Once you have completed these questionnaires, you will be chosen at random to either have:
    1. Access to the 10 of Zen course;
    2. Have access to the 10 of Zen course materials at the end of your involvement in the study

Participants who have access to the 10 of Zen course will also be able to gain access to course materials at the end of the study. This will include MP3's of daily 'micro' meditations and any written materials given throughout the course.

If you are selected at random to the '10 of Zen course' condition:

1. You will be sent an email to let you know that you have been assigned to the '10 of Zen course' condition, along with details about the course and how to access information you may need. You will also be given contact details for the facilitator of the group and a member of the study team.
2. If you've consented for your mobile number to be added to a WhatsApp group, you will be added to a group chat. Although you don't have to be part of the group chat, this is advised by the study team as it can help with a sense of being part of a group and it may provide additional support.
3. Through either the group chat or individual texts, you will be sent reminders for the weekly online group, as well as reminders throughout the week for the mini 'micro' meditations.
4. After the final session of the group, you will be asked to complete the online questionnaire again, and a short survey about your experiences of the group.
5. After completing the questionnaire about your experiences, you can choose to be entered into a prize draw to win one of four £25 Amazon or love to shop vouchers.
6. There will be an option for a second survey to be sent to you in four weeks' time. If you choose to take part in the second survey, you will be entered into the prize draw for a second time and therefore double your chances of winning a prize.
7. There will also be an option to choose whether you wish to be sent an email with the findings of this study once it is complete.

If you are selected at random to the 'delayed 10 of Zen materials' condition:

1. You will be sent an email to let you know that you have been assigned to the 'delayed 10 of Zen materials' condition. There will be a wait before you gain access to materials from the course.
2. Whilst you are waiting, after a few months you will be asked to complete a short online questionnaire about your experiences of being part of the research study and not having access to the course, in addition to a set of questionnaires that will ask you about your experiences in the past two weeks e.g. symptoms of depression, anxiety and stress.
3. After completing the questionnaire about your experiences, you can choose to be entered into a prize draw to win one of four £25 Amazon or love to shop vouchers.
4. You will be sent details on how to access course materials, including MP3's and any written materials from the 10 of Zen course once the research study has completed.

What will the 10 of Zen course involve?

1. The course is anticipated to start on the 17th of January.
2. During the course, you will be asked to take part in the following activities:
3. A weekly 15-minute online session hosted by a qualified mindfulness teacher. It is anticipated that the sessions will run on a Sunday evening at 8.30pm-8.45pm. The session includes a 5-minute introduction and discussion about mindfulness principles, followed by a 10-minute meditation exercise which changes each week.
4. Daily 'micro' meditations which can be undertaken at any time throughout the day. The 'micro' meditation will take no longer than 10 minutes and will vary from week to week.
5. You will receive reminders for both the weekly session and 'micro' meditations through a WhatsApp group chat or text message.

Are there any risks in taking part?

Mindfulness makes us more aware of our thoughts, emotions, bodily sensations and behaviours. Most people find this helpful, however, for some people it can lead to an increase in distress. We cannot guarantee that the 10 of Zen course will benefit everyone who receives it. However, you will be given the opportunity to discuss how you are feeling throughout the study with a member of the study team (as per below), and you will be provided with information about sources of support should you need this.

Some people can sometimes find it upsetting to answer questions in relation to their experience of motherhood or their mood. If you find a particular question upsetting, you can choose not to answer it and move on to the next question, have a break from answering questions and return later or to stop altogether. Your participation in this research study is voluntary and you are free to withdraw at any point. An example of the type of questions we will ask in relation to your experience of motherhood is:

When I interact with the baby I feel:

1. *Very incompetent and lacking in confidence*
2. *Moderately incompetent and lacking in confidence*
3. *Moderately competent and confident*
4. *Very competent and confident*

If you find yourself becoming upset or concerned whilst filling in the questionnaires or during the 10 of Zen course, please contact a member of the study team (as per below). You are able to save your progress and take a break from questions if you wish. If you start to experience discomfort or distress while completing the survey, we would advise you to stop. You might wish to talk to your GP about what further support may be helpful or contact NHS 111, by dialling 111 or using https://111.nhs.uk/.

What are the possible benefits of taking part?

Everyone who completes a questionnaire will be entered into a prize draw of 4 x £25 vouchers.

There is also an opportunity to be entered into the prize draw twice if you complete both questionnaires and therefore doubling the chances that you would win a prize.

It is hoped that the findings of this study will help us to develop and deliver future online courses for mothers with young babies. Although we cannot guarantee that you will personally benefit from the 10 of Zen course, mindfulness-based interventions have been found to:

1. Help with feelings of stress or worry;
2. Increase positive thinking;
3. Increase wellbeing.

If you wish to receive the findings from the study, please tick the option after completing the questionnaires. You will then be contacted at the end of the project and sent a summary of the findings.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed in part 2 of this information sheet.

Will information from or about me from taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. There are some rare situations in which information would have to be shared with others. Details about this are discussed in Part 2.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the information sheet

What will happen if I don't want to carry on with the study?

You are free to ask for your data to be removed up until September 2021 and you do not need to give us a reason for this. If you wish to withdraw from the study prior to the September 2021, your data can be destroyed and will no longer be used in the research. After this, we would have run tests on the data and so we would be unable to remove your data. This is because there are points at the analysis stage of the study where your data might have helped with the forming of key concepts or themes. At this point, it is difficult to remove all data if it has influence over the findings.

What if there is a problem?

If you have a problem, concern or complaint about any aspect of the study or your participation in it, please discuss this with [Trainee] in the first instance. She will do her best to address your concerns. You can contact her by leaving a message on the 24-hour voicemail phone number 01227 927070. Please leave a contact number and say that the message is for [Trainee] and she will get back to you as soon as possible. You can also email her on [Trainee email].

If following this you don't feel your concern has been adequately resolved or you remain dissatisfied, you can make a formal complaint by contacting:

Dr Fergal Jones, Clinical Psychology Programme Research Director, Salomons Institute for Applied Psychology, One Meadow Road, Tunbridge Wells, Kent, TN1 2YG. You can also email him at fergal.jones@canterbury.ac.uk.

Will information I give when taking part in the study be kept confidential?

Yes, all of the information collected in the study will be kept strictly confidential. All data will be anonymised using a unique identification number so that it will not be possible to personally identify you from any of your information. You will not be identifiable in the final write up of the study. Each person taking part in the study will have a unique ID code allocated so that individuals are not identifiable. These codes will be used for any quotes taken from the feedback given within the formal write up. You have the right to check whether the information collected from you is accurate.

During the completion of the project, any data we collect about you will be kept on password protected computers, in password protected files. Other people might ask to look at the data in an anonymised format. This may include the project supervisors: [Supervisors names]

The only time when we would have an obligation to pass on information about you to a third party would be if we had concerns about your safety or the safety or someone else, as the result of something you told us.

What will happen to the results of the research study?

Results from the study will be written up in the format of a doctoral thesis. This will be marked by internal examiners at Canterbury Christ Church University, as well as by an external examiner/s, arranged by the University. Results of the research may also be published in a research journal. You will not be identifiable in either the doctoral thesis or publication. If we decide to use quotes from the open-ended questionnaires within the write up, we will use pseudonyms to ensure that individual responses are anonymised.

You will also be offered the opportunity to receive feedback about the findings of the research study. If you would like to receive the findings, you will be asked to provide an email address which you would be happy to be contacted on. A summary of the key findings would then be emailed to you upon completion of the study.

We will keep your anonymous survey answers for 10 years after the study is complete. For more information about data protection, please see the university's research privacy notice: https://www.canterbury.ac.uk/university-solicitors-office/docs/research-privacy-notice.docx. This privacy notice explains your rights and the legal basis on which we process research

data. It also provides contact details in case you have any questions or complaints about how we handle your data.

Who is sponsoring and funding the research?

The research is being funded as part of the Clinical Psychology Doctorate Programme, Canterbury Christ Church University.

The main organiser of the research is [Trainee], trainee clinical psychologist at the Salomons Institute for Applied Psychology [trainee email]

She is supervised by the following members of staff:
[Supervisor name and details]

Other contact details:

Research department at Salomons Institute for Applied Psychology contact number: 01227 927110

Address: Salomons Institute for Applied Psychology, One Meadow Road, Tunbridge Wells, Kent, TN1 2YG

Who has reviewed the study?

This study has been reviewed and given favourable opinion by The Salomons Ethics Panel, Salomons Institute for Applied Psychology, Canterbury Christ Church University [REF: ETH1920-0332].

Further information and contact details

If you would like to find out more about the study and/or have any questions that you would like answering, please feel free to leave [Trainee] a message on a 24-hour voicemail phone line (01227 927070); Please say that the message is for [Trainee], and leave a contact number so that she can get back to you. Alternatively, you may email her at [Trainee email] to arrange a phone call or to ask questions.

Thank you for taking the time to read this information sheet. If you have any questions, please let [Trainee] know. If you are happy to continue and see if the research study and online mindfulness course would be suitable or helpful for you at this time, please click the arrow below.

Appendix M – Eligibility

[Information sheet displayed before]

Page 1: Thank you for your interest in our research study.

This research study is designed to investigate an online mindfulness course for new mums. The research study and online course will not be suitable or helpful for everyone.

To help us understand if it would be suitable or helpful for you at this time, we have a few questions for you. This will take approximately **10-15 minutes** of your time. Please click the box below to begin.

Page 2: Please indicate yes or no for the following statements and complete the questionnaires on the next page.

1. I am over 18 years or over [Yes/No]
2. I live in the UK [Yes/No]
3. I identify as a mother (biological, adoptive, step-mum or full-time foster carer) of a baby who is under one year of age [Yes/No]
4. I confirm that I have not previously had experiences of parenting a baby (under 12 months of age)
5. I confirm that I have regular access to a computer, laptop, tablet or mobile device [Yes/No]
6. I am comfortable reading, listening and writing in English [Yes/No]
7. I have previously completed a formal 8-week mindfulness course [Yes/No]
8. I have a current mindfulness/meditation practice. [Yes/No]
9. I have had a bereavement in the last six months and feel affected by this [Yes/No]
10. I have a diagnosis of Post-Traumatic Stress Disorder [Yes/No]
11. I am currently experiencing symptoms of psychosis (e.g. auditory/visual hallucinations) [Yes/No]
12. I am currently pregnant. [Yes/No]

[In order to process to the next screen (PHQ-9 Measures) individuals need to click 'Yes' to questions 1, 2, 3, 4, 5 and ' No' to 6, 7, 8, 9, 10, 11]

Page 3.1: Shown if participant answers 'No' to question 1, 2, 3, 4, 5, 6 or 'Yes' to 7, 8, 9, 10, 11, 12

Thank you for taking the time to answer the questions.

You have indicated that one or more of the criteria for taking part in the study does not apply to you at the present time. Therefore, we are not able to ask you to take part in the research at this time as it may not be suitable or helpful for you.

If you would like to speak to a member of the team about your responses, please contact n.pitman263@canterbury.ac.uk who will be willing to discuss this with you further.

Page 3.2 – Shown if participant meets inclusion criteria

Patient Health Questionnaire (PHQ-9) *[Questionnaire removed from electronic copy]*

Page 4.1: Shown if participants score equal to or higher than 15 on the PHQ-9 whilst scoring 0 on item 9.

Thank you for taking the time to answer the questions.

Your responses have indicated that you may be experiencing symptoms of depression. These experiences are not uncommon; however, the study aims to investigate a course that is not designed as a treatment for depression.

For this reason, we are not able to ask you to take part in the study at this time as it may not be suitable or helpful for you. We suggest you seek support from your general practitioner (GP) or mental health team if you have one.

If you would like to know more about the signs and symptoms of post-natal depression, you can find out more information here: https://www.nhs.uk/conditions/post-natal-depression/.

If you have had thoughts that you would be better off dead, or have had thoughts about hurting yourself or someone else in some way then you should:

1. Telephone or visit your GP as soon as possible and explain your experiences to them;
2. If your GP is closed, call 111 or access it here: https://111.nhs.uk/;
3. If it is an emergency or there is an immediate risk of harm, call 999 or go to your nearest Accident and Emergency (A&E) Department at a hospital;
4. For a 24 hour confidential listening service call the Samaritans on 116 123 or email jo@samaritans.org.

Page 4.2: If the response 2, 3 or 4 is chosen to item 9 on the PHQ-9, the following message will be displayed (this will be shown regardless of PHQ-9 scoring):

Thank you for taking the time to answer the questions.

You have indicated that you have been having thoughts that you would be better off dead or have had thoughts about hurting yourself in recent weeks. Having these thoughts are not uncommon, however, it can sometimes be a sign that someone is experiencing high levels of distress or depression.

This research study aims to investigate a course that is not designed as a psychological treatment for depression. As it is a web-based study we are unable to provide additional support to those who are experiencing higher levels of distress. For this reason, we are not able to ask you to take part in the study at this time as it may not be suitable or helpful for you.

If you would like to know more about the signs and symptoms of post-natal depression you can access information here: https://www.nhs.uk/conditions/post-natal-depression/.

We suggest that you seek support from your general practitioner (GP) or a member of a mental health team, if you have one. If you feel that you are at risk of harming yourself or you feel you are at risk of harming others then you should:-

1. Telephone or visit your GP as soon as possible and explain to them how you are feeling
2. If your GP is closed, call NHS 111 or access it here: https://111.nhs.uk/
3. If there is an emergency or an immediate risk of harm, please call 999 or visit your nearest accident and emergency (A&E) Department in hospital

4. For a 24 hour confidential listening service, you can contact the Samaritans on 116 123 or email jo@samaritans.org

4.3 Shown if participant meets all inclusion criteria and scores are below 15 on PHQ-9

Generalized Anxiety Disorder 7-item (GAD-7) *[Questionnaire removed from electronic copy]*

5.1 Shown if participant scores are equal to or above 15 on the GAD-7

Thank you for taking the time to answer the questions.

Your responses have indicated that you may be experiencing severe symptoms of anxiety. These experiences are not uncommon; however, the study aims to investigate a course that is not designed as a treatment for anxiety.

For this reason, we are not able to ask you to take part in the study at this time as it may not be suitable or helpful for you.

We suggest you seek support from your general practitioner (GP) or mental health team if you have one.

If you have had thoughts that you would be better off dead, or have had thoughts about hurting yourself or someone else in some way then you should:

1. Telephone or visit your GP as soon as possible and explain your experiences to them;
2. If your GP is closed, call 111. If it is an emergency or there is an immediate risk of harm, call 999 or go to your nearest Accident and Emergency (A&E) Department at a hospital;
3. For a 24 hour confidential listening service call the Samaritans on 116 123 or email jo@samaritans.org.

5.2 Shown if participant meets all inclusion criteria and scores fall below 15 on BOTH the PHQ-9 and GAD-7

Thank you for taking the time to answer the questions above. Your responses have indicated that the study may be suitable and helpful for you at the current time. We would like to invite you to take part in the study.

Please enter your email below and a member of the research team will contact you with the details for registration within the next two days: _____

Appendix N - Consent form

Please read the following statements and tick the corresponding box if you agree with them. Due to GDPR regulations for research studies there are quite a few statements below, so please bare with us.

		Tick here
1.	I confirm that I have read the information sheet provided [insert version and date] for the above research study. I have had an opportunity to consider the information and what will be expected of me. I have also had the opportunity to ask questions which have been answered to my satisfaction.	
2.	I understand that my personal information (basic demographic information and responses to questionnaires about depression and anxiety symptoms) will be used for the purposes explained to me. I understand that according to data protection legislation, 'public task' and 'research purposes' will be the lawful bases for processing.	
3.	I understand that no personal information (such as my name) will be shared outside of the research team.	
4.	I understand the potential risks of participating and that my participation is entirely voluntary. I understand that I can stop at anytime and that I am free to withdraw from the study without giving a reason.	
5.	I understand that I am able to ask for my data to be withdrawn up until the 1st September 2021, after which data analysis will be occurring shortly after.	
6.	I understand that I am free to refrain from answering questions that I do not wish to.	
7.	I understand that no promise or guarantee of benefits have been made to encourage me to participate in the above study.	
8.	I understand that relevant sections of data collection during the research study may be looked at by the supervisors of the project, Dr Rebecca Gould and Dr Rachel Whatmough.	
9.	I agree for my contact information to be passed onto the facilitator(s) of the 10ofZen course.	
10.	I understand that I do not have to agree to my mobile number being shared with other study participants in a Whatsapp group chat, although this is advisable.	

11.	I understand that the information that I provide will be written up and submitted for a doctoral thesis and pubication. It will not be possible to identify me in any publications or formal write ups. I am aware that if I would like a copy of the research findings then I will need to email Nikki Pitman (n.pitman263@canterbury.ac.uk).	
12.	I am aware of who I should contact if I wish to lodge a complaint.	
13.	I agree for the data I provide in the online surveys to be electronically archived and securely stored at Salomons Institute for Applied Psychology, Canterbury Christ Church University for 10 years, after which they will be securely destroyed.	
14.	I acknowledge that if I disclose any information about criminal offences, or present a risk to myself or others, the researchers are obliged to inform the university.	
15.	I agree for my anonymous data to be used in future research studies.	
16.	I voluntarily agree to take part in the research study.	

Please enter your name

_____

Please enter your email address

_____

Please tick one of the following:

I do want to be involved in the WhatsApp group chats (advisable) ☐

I do not want to be involved in the WhatsApp group chat ☐

Please enter your mobile number

_____

Appendix O – MBCT-AS Adherence scale adapted

MBCT Adherence Scale-Adapted

The Mindfulness-Based Cognitive Therapy Adherence Scale (Segal et al., 2002) has been adapted so that it can apply to broader mindfulness-based interventions. It is composed of 10 items, each of which is rated on a 2-point scale from 0 (no evidence for item) to 2 (definite evidence), as follows:

0 - no evidence
1- slight evidence
2 - definite evidence

Items	**Rating**
1. PROVISION OF RATIONALE FOR MINDFULNESS-BASED INTERVENTIONS: To what extent does the therapist provide patients with an explanation for why the completion of mindfulness-based tasks will help them learn to cope with the challenges of parenthood?	
2. SYSTEMATIC AWARENESS EXERCISES: To what extent does the therapist use systematic awareness exercises?	
3. CONVEYS CORE THEMES METAPHORICALLY: To what extent does the therapist use metaphors and narratively-oriented material to communicate the core themes of mindfulness-based interventions (such as MBCT and MBSR) to participants?	
4. HOME PRACTICE SETTING: To what extent does the therapist assign home practice to group participants?	
5. THOUGHTS AND FEELING LINKAGE: To what extent does the therapist convey the link between thinking and feeling?	
6. MOVEMENT-BASED AWARENESS EXERCISES: To what extent does the therapist use awareness exercises that are based on movement rather than sitting?	
7. 3-MIN BREATHING SPACE: To what extent does the therapist use 3-min breathing spaces during the group session?	
8. RELATE TO EXPERIENCE THROUGH ACCEPTANCE – AVERSION: To what extent does the therapist introduce the differences between relating to one's experiences from the standpoint of acceptance as opposed to aversion?	
9. BEHAVIOURAL STRATEGIES FOR MOOD REGULATION: To what extent does the therapist describe different behavioural strategies for mood regulation?	
10. COMMITMENT TO PRACTICE: To what extent does the therapist address the relevance of group members' commitment to practice as a way of coping with the challenges of parenthood?	

Total score: _____

References:

Segal, Z.V., Teasdale, J.D., Williams, J.M. and Gemar, M.C. (2002), The mindfulness-based cognitive therapy adherence scale: inter-rater reliability, adherence to protocol and treatment distinctiveness. Clin. Psychol. Psychother., 9: 131-138. https://doi.org/10.1002/cpp.320.

Appendix P - Treatment Fidelity Tool for Mindfulness-Based Interventions

Treatment Fidelity Tool for Mindfulness-based Interventions

Fidelity Component		15-Item Checklist		Author Comments
Design: ensure a study can adequately test its hypotheses in relation to underlying theory and clinical processes	1.	☑Theoretical/substantive rationale for any adaptations from established MBI (e.g., meet target population needs, exclusion of retreat)	1.	The 10 of Zen manual was created for first time new mums within the postpartum period.
			2.	No comparator used; course materials given at the end
	2.	☒MBI and comparison program matched for dosage within and across conditions (e.g., number of sessions, hours per session, number of weeks, days per week)	3.	The 10 of zen group had a backup facilitator
	3.	☑ Plan for implementation setbacks (e.g., back-up facilitators)		
Training: ensure treatment providers are satisfactorily trained to deliver the intervention	1.	☑ All facilitators received formal training (e.g., MBSR certified)	5.	10 of zen facilitator trained in MBSR and had 5+ years of experiencing running mindfulness for mums.
	2.			
	3.	☒ All facilitators received standardized program-specific training on curriculum manual (e.g., week-long training retreat)	6.	Standardized programme-specific training was not undertaken due to facilitator being the main contributor to the manual
	4.	☒ All facilitators were observed and received constructive feedback during initial phases (e.g., weekly phone calls with PI/supervisor)	7.	Prior to the course similar sessions were observed by the research team; no specific feedback was given. Support was offered if required.
Delivery: ensure intervention is delivered as intended	1.	☑All program sessions recorded via audiotape or videotape	5.	All sessions were audiotaped
	2.		6.	50% of sessions rated via an adapted MBCT-AS scale
	3.	☑Program sessions rated using a calibrated codebook (e.g., Mindfulness-Based Relapse Prevention Adherence and Competence Scale [MBRP-AC])	7.	Feedback was given after the intervention group completed; only one intervention group ran thus there were no differences in curriculum.
	4.	☒ All facilitators received ongoing, real-time constructive feedback, and inter-rater reliability assessments to minimize drift from curriculum and contamination between intervention groups		
Receipt: monitor and improve ability of participants to understand and perform treatment-related skills and strategies during delivery	1.	☑ Participant attendance recorded (e.g., session sign-in sheets)	5.	Participants names were recorded at 'live' sessions
	2.			
	3.	☑Measure of program acceptability collected	6.	Participants rated satisfaction and perceived helpfulness at the end of the intervention. Acceptability was also measured through an online questionnaire.

	4.	☒Measure of comprehension and ability to perform the intervention skills and strategies collected	7.	Feedback was sought via the online questionnaire; this was not formally assessed, however.
Enactment: monitor and improve the ability of participants to perform treatment-related skills and strategies in real-life settings	1.	☑ Measure of practice collected (e.g., daily practice logs for minutes and types of practice used)	6.	Participants filled in a weekly feedback form to record which days they completed a mini meditation. Minutes of meditations and types were not logged
	2.			
	3.	☒ Measure of intervention skills and strategies used in real-life settings collected (e.g., Applied Mindfulness Process Scale [AMPS])	7.	Not collected
			8.	The FFMQ-15 was used at baseline, post intervention and 4 week follow up.
	4.			
	5.	☑ Measure of dispositional mindfulness collected (e.g., Five-Facet Mindfulness Questionnaire [FFMQ])		

Notes. This list encompasses recommendations for MBI treatment fidelity adapted from NIH's BCC Guidelines (Bellg et al. 2004; Resnick et al. 2005). Instructions for use are threefold. First, researchers can use this list to develop a treatment fidelity plan for MBIs. Second, researchers can complete the center column by placing a checkmark next to the action completed. Third, researchers can detail their strategies in the space provided under the far-right column. By completing and including this checklist in main outcome papers, readers can understand how treatment fidelity was conducted when interpreting trial results.

Appendix Q: Ethical Approval

[Approval letter removed from electronic copy]

Appendix R – ANCOVA Checks

Descriptive Statistics

Group assigned		N	Minimum	Maximum	Mean	Std. Deviation	Skewness		Kurtosis	
		Statistic	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
Treatment	SWEMBS_BASELINE	54	16.36	28.13	21.4144	2.81676	.459	.325	-.478	.639
	SWEMBS_POST	40	17.43	29.31	22.5205	2.38277	.370	.374	.746	.733
	SWEMBS_FU	35	16.36	29.31	23.1906	2.79777	.132	.398	.295	.778
	MPAS_BASELINE	54	52.30	90.20	73.9833	8.81047	-.277	.325	-.263	.639
	MPAS_POST	39	54.90	89.40	77.3897	8.91276	-.545	.378	-.574	.741
	MPAS_FU	35	52.90	90.20	76.9800	8.51344	-1.158	.398	1.658	.778
	BASELINE_DASS_STRESS	54	16.00	44.00	30.0370	6.87891	-.089	.325	-.597	.639
	POST_DASS_STRESS	39	18.00	42.00	27.7436	6.00315	.438	.378	-.227	.741
	FU_DASS_STRESS	35	16.00	42.00	26.8571	4.83336	.961	.398	2.193	.778
	BASELINE_DASS_ANXIETY	54	14.00	38.00	20.3704	5.28542	1.091	.325	1.289	.639
	POST_DASS_ANXIETY	39	14.00	34.00	18.8205	4.58184	1.402	.378	2.349	.741
	FU_DASS_ANXIETY	35	14.00	30.00	18.6857	4.28246	1.011	.398	.397	.778
	BASELINE_DASS_DEPRESSION	54	14.00	38.00	22.8519	5.96343	.735	.325	.046	.639
	POST_DASS_DEPRESSION	39	14.00	32.00	19.7949	4.22511	1.042	.378	1.063	.741

	FU_DASS_DEPRESSION	35	14.00	32.00	20.6857	4.39098	.666	.398	.132	.778
	BASELINE_FFMQ	53	22.00	53.00	38.2642	7.02236	.083	.327	-.129	.644
	POST_FFMQ	39	25.00	48.00	37.4359	6.21033	.062	.378	-.889	.741
	FU_FFMQ	35	31.00	54.00	40.9429	5.71861	.055	.398	-.528	.778
	BASELINE_Sleep	53	2.00	10.00	4.5660	1.86578	.705	.327	.492	.644
	POST_Sleep	39	2.00	9.00	5.1795	2.06311	.012	.378	-.828	.741
	FU_Sleep	34	1.00	8.00	5.4412	2.04778	-.754	.403	-.141	.788
	Valid N (listwise)	32								
Delayed	SWEMBS_BASELINE	55	15.32	30.70	21.2325	3.33246	.765	.322	.684	.634
	SWEMBS_POST	40	15.84	29.31	21.8553	3.46517	.238	.374	-.879	.733
	SWEMBS_FU	36	15.32	29.31	22.3103	3.55708	.192	.393	-.540	.768
	MPAS_BASELINE	55	51.30	95.00	76.0727	10.31005	-.469	.322	-.340	.634
	MPAS_POST	40	51.00	93.60	77.7450	9.49234	-.573	.374	.215	.733
	MPAS_FU	36	64.40	93.60	80.4806	7.19336	-.255	.393	-.294	.768
	BASELINE_DASS_ STRESS	55	14.00	48.00	29.1636	7.12524	.281	.322	.264	.634
	POST_DASS_STRESS	40	14.00	50.00	29.8000	7.94597	.388	.374	-.214	.733
	FU_DASS_STRESS	36	14.00	44.00	27.0556	6.90319	.562	.393	.149	.768
	BASELINE_DASS_ANXIE TY	55	14.00	34.00	18.9091	5.31689	1.127	.322	.521	.634
	POST_DASS_ANXIETY	40	14.00	40.00	19.8500	6.97817	1.606	.374	2.071	.733
	FU_DASS_ANXIETY	36	14.00	40.00	19.5556	6.21723	1.567	.393	2.531	.768

	BASELINE_DASS_DEPRESSION	55	14.00	42.00	22.8000	6.41295	.819	.322	.635	.634
	POST_DASS_DEPRESSION	39	14.00	36.00	21.3846	5.31441	.545	.378	-.168	.741
	FU_DASS_DEPRESSION	36	14.00	38.00	20.9444	5.98066	1.007	.393	1.100	.768
	BASELINE_FFMQ	55	15.00	55.00	37.8364	7.33274	.106	.322	1.236	.634
	POST_FFMQ	39	24.00	53.00	34.4615	6.15521	.861	.378	.842	.741
	FU_FFMQ	36	25.00	53.00	37.6944	6.57623	.575	.393	.149	.768
	BASELINE_Sleep	54	1.00	8.00	4.4444	2.05276	.008	.325	-1.011	.639
	POST_Sleep	39	1.00	10.00	5.1026	2.28029	.007	.378	-.908	.741
	FU_Sleep	36	1.00	10.00	5.2778	2.78374	.167	.393	-1.233	.768
	Valid N (listwise)	35								

Appendix S: Mindfulness submission guidelines

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

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Online Submission

Please follow the hyperlink "Submit manuscript" and upload all of your manuscript files following the instructions given on the screen.

Source Files

Please ensure you provide all relevant editable source files at every submission and revision. Failing to submit a complete set of editable source files will result in your article not being considered for review. For your manuscript text please always submit in common word processing formats such as .docx or LaTeX.

Suggested Reviewers

Authors of research and review papers, excluding editorial and book review submissions, are allowed to provide the names and contact information for, maximum, 4 to 6 possible reviewers of their paper. When uploading a paper to the Editorial Manager site, authors must provide complete contact information for each recommended reviewer, along with a specific reason for your suggestion in the comments box for each person. The journal will consider reviewers recommended by the authors only if the reviewers' institutional email is provided. A minimum of two suggested reviewers should be from a university or research institute in the United States. You may not suggest the Editor or Associate Editors of the journal as potential reviewers. Although there is no guarantee that the editorial office will use your suggested reviewers, your help is appreciated and may speed up the selection of appropriate reviewers.

Authors should note that it is inappropriate to list as preferred reviewers researchers from the same institution as any of the authors, collaborators and co-authors from the past five years as well as anyone whose relationship with one of the authors may present a conflict of interest. The journal will not tolerate this practice and reserves the right to reject submissions on this basis.

Title Page

The title page should include:

The name(s) of the author(s)

A concise and informative title

The affiliation(s) and address(es) of the author(s)

The e-mail address, and telephone number(s) of the corresponding author

If available, the 16-digit ORCID of the author(s)

Abstract

Please provide of structured abstract of up to 250 words

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

Structured Abstract

The structured abstract of up to 250 words with four labeled sections should containing the following, with sub-section headers in bold:

a. Objectives: Problem being addressed in the study

b. Methods: The participants, essential features of the study method

c. Results: The basic findings, including effect sizes and confidence intervals and/or statistical significance levels

d. Conclusions: What the authors conclude from study results

Text

Text Formatting

Manuscripts should be submitted in Word.

Use a normal, plain font (e.g., 12-point Times Roman) for text.

Use italics for emphasis.

Use the automatic page numbering function to number the pages.

Do not use field functions.

Use tab stops or other commands for indents, not the space bar.

Use the table function, not spreadsheets, to make tables.

Use the equation editor or MathType for equations.

Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

Footnotes

This journal does not allow the use of footnotes, except in reprinted papers.

Article length

Papers accepted for publication in this journal are 35 double-spaced pages, in 12-point font, inclusive of text, references, tables and figures. For manuscripts exceeding this length, authors should contact the Editor in Chief, Nirbhay N. Singh directly at nirbz52@gmail.com.

Terminology

• Please always use internationally accepted signs and symbols for units (SI units).

Scientific style

Generic names of drugs and pesticides are preferred; if trade names are used, the generic name should be given at first mention.

Please use the standard mathematical notation for formulae, symbols etc.:Italic for single letters that denote mathematical constants, variables, and unknown quantities Roman/upright for numerals, operators, and punctuation, and commonly defined functions or abbreviations, e.g., cos, det, e or exp, lim, log, max, min, sin, tan, d (for derivative) Bold for vectors, tensors, and matrices.

References

Citation

Cite references in the text by name and year in parentheses. Some examples:

Negotiation research spans many disciplines (Thompson, 1990).

This result was later contradicted by Becker and Seligman (1996).

This effect has been widely studied (Abbott, 1991; Barakat et al., 1995; Kelso & Smith, 1998; Medvec et al., 1999).

Authors are encouraged to follow official APA version 7 guidelines on the number of authors included in reference list entries (i.e., include all authors up to 20; for larger groups, give the first 19 names followed by an ellipsis and the final author's name). However, if authors shorten the author group by using et al., this will be retained.

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text.

Reference list entries should be alphabetized by the last names of the first author of each work.

Journal names and book titles should be *italicized*.

If available, please always include DOIs as full DOI links in your reference list (e.g. "https://doi.org/abc").

Journal article Grady, J. S., Her, M., Moreno, G., Perez, C., & Yelinek, J. (2019). Emotions in storybooks: A comparison of storybooks that represent ethnic and racial groups in the United States. *Psychology of Popular Media Culture, 8*(3), 207–217. https://doi.org/10.1037/ppm0000185

Article by DOI Hong, I., Knox, S., Pryor, L., Mroz, T. M., Graham, J., Shields, M. F., & Reistetter, T. A. (2020). Is referral to home health rehabilitation following inpatient rehabilitation facility associated with 90-day hospital readmission for adult patients with stroke? *American Journal of Physical Medicine & Rehabilitation*. Advance online publication. https://doi.org/10.1097/PHM.0000000000001435

Book Sapolsky, R. M. (2017). *Behave: The biology of humans at our best and worst*. Penguin Books.

Book chapter Dillard, J. P. (2020). Currents in the study of persuasion. In M. B. Oliver, A. A. Raney, & J. Bryant (Eds.), *Media effects: Advances in theory and research* (4th ed., pp. 115–129). Routledge.

Online document Fagan, J. (2019, March 25). *Nursing clinical brain*. OER Commons. Retrieved January 7, 2020, from https://www.oercommons.org/authoring/53029-nursing-clinical-brain/view

Please note:

If you are citing journal articles by their DOI please make sure to also include the volume and page numbers, if already available, e. g. as follows: “Slifka, M. K., & Whitton, J. L. (2000) Clinical implications of dysregulated cytokine production. Journal of Molecular Medicine, 78(2), 74-80. https://doi.org/10.1007/s001090000086”.

Tables

All tables are to be numbered using Arabic numerals.

Tables should always be cited in text in consecutive numerical order.

For each table, please supply a table caption (title) explaining the components of the table.

Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.

Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

Artwork and Illustrations Guidelines

Electronic Figure Submission

Supply all figures electronically.

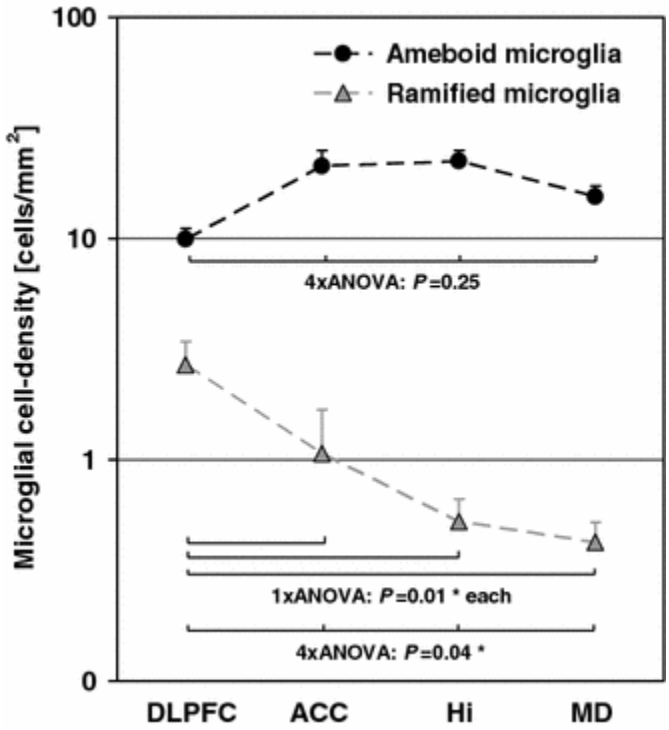
Indicate what graphics program was used to create the artwork.

For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.

Vector graphics containing fonts must have the fonts embedded in the files.

Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

Line Art



Definition: Black and white graphic with no shading.

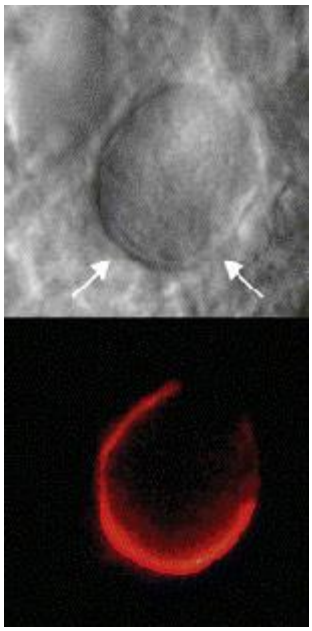
Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.

All lines should be at least 0.1 mm (0.3 pt) wide.

Scanned line drawings and line drawings in bitmap format should have a minimum resolution of 1200 dpi.

Vector graphics containing fonts must have the fonts embedded in the files.

Halftone Art

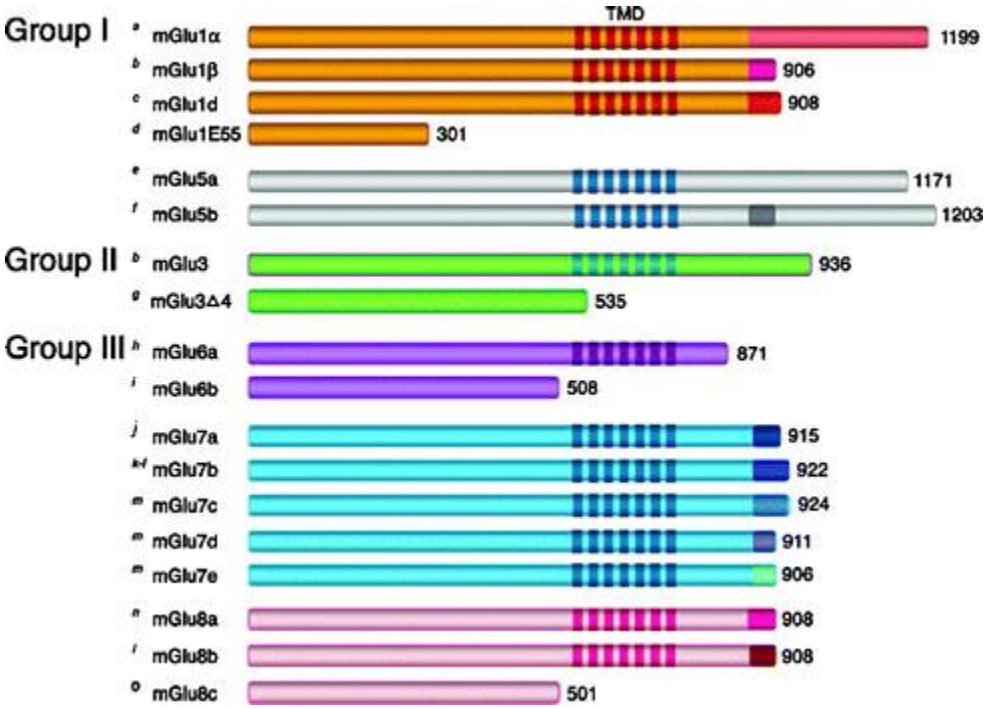


Definition: Photographs, drawings, or paintings with fine shading, etc.

If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.

Halftones should have a minimum resolution of 300 dpi.

Combination Art



Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc.

Combination artwork should have a minimum resolution of 600 dpi.

Color Art

Color art is free of charge for online publication.

If black and white will be shown in the print version, make sure that the main information will still be visible. Many colors are not distinguishable from one another when converted to black and white. A simple way to check this is to make a xerographic copy to see if the necessary distinctions between the different colors are still apparent.

If the figures will be printed in black and white, do not refer to color in the captions.

Color illustrations should be submitted as RGB (8 bits per channel).

Figure Lettering

To add lettering, it is best to use Helvetica or Arial (sans serif fonts).

Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).

Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.

Avoid effects such as shading, outline letters, etc.

Do not include titles or captions within your illustrations.

Figure Numbering

All figures are to be numbered using Arabic numerals.

Figures should always be cited in text in consecutive numerical order.

Figure parts should be denoted by lowercase letters (a, b, c, etc.).

If an appendix appears in your article and it contains one or more figures, continue the consecutive numbering of the main text. Do not number the appendix figures,"A1, A2, A3, etc." Figures in online appendices [Supplementary Information (SI)] should, however, be numbered separately.

Figure Captions

Each figure should have a concise caption describing accurately what the figure depicts. Include the captions in the text file of the manuscript, not in the figure file.

Figure captions begin with the term Fig. in bold type, followed by the figure number, also in bold type.

No punctuation is to be included after the number, nor is any punctuation to be placed at the end of the caption.

Identify all elements found in the figure in the figure caption; and use boxes, circles, etc., as coordinate points in graphs.

Identify previously published material by giving the original source in the form of a reference citation at the end of the figure caption.

Figure Placement and Size

Figures should be submitted separately from the text, if possible.

When preparing your figures, size figures to fit in the column width.

For large-sized journals the figures should be 84 mm (for double-column text areas), or 174 mm (for single-column text areas) wide and not higher than 234 mm.

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In order to give people of all abilities and disabilities access to the content of your figures, please make sure that

All figures have descriptive captions (blind users could then use a text-to-speech software or a text-to-Braille hardware)

Patterns are used instead of or in addition to colors for conveying information (colorblind users would then be able to distinguish the visual elements)

Any figure lettering has a contrast ratio of at least 4.5:1

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Submit your material in PDF format; .doc or .ppt files are not suitable for long-term viability.

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Name the files consecutively, e.g. "ESM_3.mpg", "ESM_4.pdf".

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2) drafted the work or revised it critically for important intellectual content;

3) approved the version to be published; and

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Transparency in authors' contributions and responsibilities to promote integrity in scientific publication, McNutt at all, PNAS February 27, 2018

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Summary of requirements

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The research leading to these results received funding from […] under Grant Agreement No[…].

This study was funded by […]

This work was supported by […] (Grant numbers […] and […]

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No funding was received to assist with the preparation of this manuscript.

No funding was received for conducting this study.

No funds, grants, or other support was received.

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Non-financial interests: none.

Financial interests: Author A and B declare they have no financial interests. Author C has received speaker and consultant honoraria from Company M and Company N. Dr. C has received speaker honorarium and research funding from Company M and Company O. Author D has received travel support from Company O.

Non-financial interests: Author D has served on advisory boards for Company M, Company N and Company O.

Examples of statements to be used when authors have nothing to declare:

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The authors have no competing interests to declare that are relevant to the content of this article.

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The authors have no financial or proprietary interests in any material discussed in this article.

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The trial registration number (TRN) and date of registration should be included as the last line of the manuscript abstract.

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Summary of requirements

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• This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University B (Date.../No. ...).

• Approval was obtained from the ethics committee of University C. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

• The questionnaire and methodology for this study was approved by the Human Research Ethics committee of the University of D (Ethics approval number: ...).

Examples of statements to be used for a retrospective study:

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• This research study was conducted retrospectively from data obtained for clinical purposes. We consulted extensively with the IRB of XYZ who determined that our study did not need ethical approval. An IRB official waiver of ethical approval was granted from the IRB of XYZ.

• This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Human Investigation Committee (IRB) of University B approved this study.

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• The data reproduced from Article X utilized human tissue that was procured via our Biobank AB, which provides de-identified samples. This study was reviewed and deemed exempt by our XYZ Institutional Review Board. The BioBank protocols are in accordance with the ethical standards of our institution and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Informed consent

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When biological material is donated for or data is generated as part of a research project authors should ensure, as part of the informed consent procedure, that the participants are made aware what kind of (personal) data will be processed, how it will be used and for what purpose. In case of data acquired via a biobank/biorepository, it is possible they apply a broad consent which allows research participants to consent to a broad range of uses of their data and samples which is regarded by research ethics committees as specific enough to be considered "informed". However, authors should always check the specific biobank/biorepository policies or any other type of data provider policies (in case of non-bio research) to be sure that this is the case.

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Summary of requirements

The above should be summarized in a statement and placed in a 'Declarations' section before the reference list under a heading of 'Consent to participate' and/or 'Consent to publish'. Other declarations include Funding, Competing interests, Ethics approval, Consent, Data and/or Code availability and Authors' contribution statements.

Please see the various examples of wording below and revise/customize the sample statements according to your own needs.

Sample statements for **"Consent to participate"**:

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

Informed consent was obtained from legal guardians.

Written informed consent was obtained from the parents.

Verbal informed consent was obtained prior to the interview.

Sample statements for **"Consent to publish"**:

The authors affirm that human research participants provided informed consent for publication of the images in Figure(s) 1a, 1b and 1c.

The participant has consented to the submission of the case report to the journal.

Patients signed informed consent regarding publishing their data and photographs.

Sample statements if identifying information about participants is available in the article:

Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

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DataCite

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Appendix T: Update to ethics committee

Margie Callanan

Chair of the Salomons Ethics Panel

Nikki Pitman

Salomons Centre for Applied Psychology CCCU

n.pitman263@canterbury.ac.uk

ETH1920-0332

12th April 2022

Dear Margie,

Re: MRP Project: Feasibility and acceptability of an online mindfulness-based intervention for mothers within the postpartum period.

I am writing to update you regarding my MRP for which you granted ethical approval in November 2020. I attach the abstract for part B for your information. The project has run as planned with only one minor unexpected event. The unexpected event occurred when a non-participant was added to one of the WhatsApp groups that were set up when the intervention began. This individual was removed as soon as this was identified and the participants within the group were informed of the error as well as explaining that this was someone who had signed up to the intervention outside of the study. Both supervisors were informed of this event, and no concerns were raised by any participant due to this.

Recruitment closed in January 2021 and the intervention ran until March 2021. The last participant completed their final questionnaire in May 2021. Two participants formally withdrew from the study (one in each condition), both contacting me by email to say they had become too busy to continue with the study after beginning work after maternity leave.

Abstract

Objectives: An 8-week brief mindfulness-based intervention (bMBI) for first-time mothers within the postpartum period (<12 months post birth) was examined for acceptability, feasibility, and preliminary efficacy in comparison to a control group.

Methods: One hundred and twelve postpartum mothers were recruited via social media and randomly assigned to either a bMBI (<20 minutes weekly sessions and <5 minutes daily home practice) or a control group (received course materials at study completion). Participants completed self-report measures at baseline, post-intervention and 4-weeks follow-up to assess perceived wellbeing, stress, anxiety, depression, maternal attachment, mindfulness, and sleep quality. A mixed methods approach was used to explore descriptive statistics, preliminary efficacy via analysis of covariance (ANCOVAs), reliable change indices (RCI) and thematic analysis.

Results: Findings suggest the bMBI was acceptable and feasible. On average participants engaged with meditations 2.92 times per week (48% of the recommended 6 times). ANCOVAs revealed a significant difference in stress between the two groups at post-intervention and follow-up with intervention group reporting reduced stress, supported further by RCIs.

Conclusion: The bMBI was acceptable and feasible, with preliminary evidence tentatively suggesting bMBIs may support stress reduction in first time, postpartum mothers. Importance of flexible delivery is highlighted with recommendations for future research.

Please do not hesitate to contact me if you require further information.

Yours Sincerely,

Nikki Pitman

CC Supervisors (By email)

Appendix U: Feedback to participants

An Online Mindfulness Course for New Mums

Dear participant,

In January 2021 to May 2021, you took part in my study, an online mindfulness course for new mums and asked to be updated with the study results.

The study looked at whether an online mindfulness course would be accessible (if it was easy to use) and supportive (increased wellbeing and decreased distress) for first time mums. Half of you were randomised to take part in the course and half were randomised to receive the course materials at the end of the study, which you can still access if you wish via this link:

https://cccusocialsciences.az1.qualtrics.com/jfe/form/SV_cSj8AtqWC3LlygS

Overall, it seemed that the course was seen as helpful, satisfactory and many of you who took part would recommend to another first-time mum. Several people commented on feeling calmer and more relaxed either during or just after a mindfulness session and felt that they were able to stay in the present moment more and notice thoughts and emotions without necessarily acting on them. The mini-meditations and ability to catch up on sessions seemed important and supportive for several people. New mums commented on the difficulty with daily meditations due to time restrictions and unpredictable schedules with a newborn.

They also fed back about the supportiveness of the group chats and feeling that others were in a similar place to them in having a new baby in the COVID-19 pandemic. New mums felt that the course was well suited to them within the pandemic too.

The study also found that the course had a positive impact on stress, with those who completed the course reporting less stress at the end of the course than those who had not. The results suggested that this course was accessible and supportive for first time mums. The

feedback given for alterations and changes for the course has been passed onto the 10 of zen facilitator, with this feedback being used to alter the course due to run this year.

Thank you very much for taking the time to take part in the study. I really appreciated your support with this research.

Best wishes,

Nikki Pitman

Trainee Clinical Psychologist

Canterbury Christ Church University