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Title: The effect of mindfulness-based interventions on stress, depression and anxiety during the perinatal period in women without pre-existing stress, depressive or anxiety disorders: a systematic review and meta-analysis of controlled trials.

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Abstract

Objectives

The objective of this systematic review and meta-analysis was to examine controlled trial evidence for the effectiveness of mindfulness-based interventions on stress, anxiety and depression in the perinatal period in women without pre-existing mental health issues.

Methods

Six databases were searched for studies exploring the effects of mindfulness-based interventions on mental health outcomes of women during the perinatal period. Quality of both controlled trials meeting inclusion criteria were assessed using a tool specifically designed for meta analyses of mindfulness-based interventions. Effect sizes were extracted for measures of mindfulness, depression, stress and anxiety outcomes. Effects from were pooled in separate meta analyses for all outcomes except anxiety which lacked sufficient studies.

Results

Twelve studies were analysed. Pooled effects suggest that mindfulness-based interventions cause small but clear increases in mindfulness and reductions in depression in women without pre-existing disorders. Effects of mindfulness-based interventions on other outcomes was unclear and confounded by heterogeneity.

Conclusions

Available controlled trial evidence suggests that mindfulness-based interventions improve mindfulness and decrease symptoms of depression during pregnancy in women without pre-existing mental health issues, and might be a useful approach to prevent or attenuate the development of depression in the perinatal period.

Keywords: Pregnancy; mental health; mindfulness; perinatal; childbirth; labour

51 Pregnancy, childbirth and the postnatal period are times of immense physical and emotional
52 change (Cowan, 1991). The transition to motherhood can be stressful, increasing
53 vulnerability to anxiety and depression (Grote and Bledsoe, 2007). Mental health issues are
54 prevalent at this time, with around 1 in 5 women experiencing depression during pregnancy
55 and in the postnatal period (Dhillon et al., 2017; Fairbrother et al., 2015; NICE, 2014). Stress
56 has been found to affect 58% of pregnant women (Stone et al., 2015). Stress and depression
57 during the perinatal period are predictive of short and long-term negative consequences for
58 mothers and infants (Staneva et al., 2015). Mental health issues during pregnancy have been
59 associated with an increase in the risk of premature and stillbirths (Dunkel Schetter, 2011;
60 Webb et al., 2005), and congenital malformations (Pereira et al., 2011). Maternal mental
61 health issues are also associated with greater risk of the baby going on to develop behavioural
62 and emotional problems in later life, with increased risk of a negative impact on IQ and
63 educational attainment (Stein et al., 2014). Prompt and effective treatment not only minimises
64 the risks for the mother, but also minimises the risks to her child's emotional, social and
65 cognitive development (National Collaborating Centre for Mental Health, 2018). Perinatal
66 stress is also known to increase the use of analgesia, and the risk of surgical/caesarean
67 deliveries and post-partum depression (Togher et al., 2017; Saeed et al., 2015; Saunders et
68 al., 2006). Moreover, suicide continues to be a leading cause of maternal death in the UK
69 (Knight et al., 2015). Given this context, preventing or attenuating stress, anxiety and
70 depression during pregnancy is a crucial public health goal (Cooper and Murray, 1998). The
71 need to establish pathways for effective prevention and treatment of maternal mental health
72 issues has driven substantial government funding into maternal mental health care in
73 England. There are plans to provide evidence-based mental health care in the perinatal period
74 for 30,000 women in England (Maruthappu et al., 2014). As the perinatal period (pregnancy
75 and a year postnatally) is considered a time of increased risk for mental health issues in

76 women (National Maternity Review, 2016), NHS resources are being directed to strategies
77 that are effective for detecting and preventing mental health issues during the perinatal
78 period. Given that prevention is a key public health agenda, the optimal target population for
79 interventions aimed at preventing the development of mental health issues is women without
80 pre-existing mental health disorders (Woolhouse et al, 2014). This is the scope of this review.
81
82 The management of mental health problems that develop during pregnancy and the postnatal
83 period presents unique challenges. There are risks associated with taking psychotropic
84 medication in pregnancy and during breastfeeding (NICE, 2016). Given the importance of
85 preventing and managing mental health issues in the perinatal period, and the difficulties
86 associated with medication, mindfulness-based interventions are a potential solution for
87 supporting women during this period. Attending a mindfulness-based intervention has also
88 been described as enabling flexibility in choice during childbirth, with this contributing to
89 positive experiences (Fisher et al., 2012). Kabat-Zinn (2013) described mindfulness as
90 "paying attention in a particular way: on purpose, in the present moment, and
91 nonjudgmentally". He outlined nine attitudes underlying mindfulness as beginner's mind,
92 non-judging, acceptance, letting go, trust, patience, non-striving, gratitude and generosity
93 (Kabat-Zinn, 2019). These attitudes are the foundation of mindfulness-based interventions.
94 Mindfulness teachers are trained to develop an awareness of these attitudes within their
95 mindfulness practice and in delivering mindfulness-based interventions (Crane et al., 2017).
96 Kabat-Zinn (2013) originally developed Mindfulness Based Stress Reduction (MBSR), with
97 Mindfulness Based Cognitive Therapy (MBCT) being developed as a relapse prevention
98 approach for depression (Segal et al., 2013). Mindfulness-based interventions have flourished
99 since their inception in the 1980s, with evidence for their effectiveness with anxiety,
100 depression, stress, managing chronic physical conditions and suicidality (Hofmann and

101 Gómez, 2017; Kuyken et al., 2016; Williams and Swales, 2017; Zhang et al., 2015).
102 Increasing capacity to be aware of and accept situations, thoughts, and feelings as they are
103 can lead to greater tolerance of stress and discomfort (Kashdan and Rottenberg, 2010;
104 Warriner et al., 2018). The perinatal period is a time when such skills and attitudes may
105 benefit women through reducing the effects of the stressors involved in this transition.
106
107 Previous systematic reviews of mindfulness-based interventions in the perinatal period have
108 included both pre-post and RCT studies, some of which sample from populations of women
109 with pre-existing mental health disorders and others that sample from populations of women
110 without pre-existing disorders. Previous systematic reviews have found some evidence from
111 pre-post studies of reductions in stress, anxiety and depression, but no significant benefit in
112 RCTs (Hall et al., 2016). In agreement with Hall et al. (2016), Lever Taylor et al. (2016)
113 found small to moderate benefits for depression, anxiety, stress and mindfulness from pre-
114 post studies. Larger effect sizes were found for studies on participants with pre-existing, or a
115 history of, depression, anxiety and stress, suggesting, in agreement with Woolhouse et al.
116 (2014), that such participants form a separate study population from participants without pre-
117 existing disorders. Between group comparisons from RCTs again showed no significant
118 benefits for depression, anxiety, stress and mindfulness. The most recent systematic review
119 and meta-analysis found no significant differences between the intervention and control
120 groups for anxiety, depression and perceived stress, with mindfulness being the only outcome
121 variable with a significant between-group difference (Dhillon et al., 2017). Similar to
122 preceding meta-analyses, Dhillon et al. (2017) found significant benefits in pre-post studies
123 for anxiety, depression, perceived stress and mindfulness.
124 Given contrasting evidence from pre-post versus controlled trials, and acknowledging the
125 inherent bias in, and inability to claim causal effects from, pre-post studies, previous meta-

126 analyses have concluded that additional large scale, adequately powered, randomised
127 controlled trials are needed to evaluate the effectiveness of mindfulness-based interventions
128 (Dhillon et al., 2017; Hall et al., 2016; Lever Taylor et al., 2016; Matvienko-Sikar et al.,
129 2016; Shi & MacBeth, 2017). This recommendation has also been motivated by high degrees
130 of heterogeneity reported in previous reviews. In response to these recommendations, there
131 have been several studies published since Dhillon et al. (2017).
132
133 A source of heterogeneity that does not seem to have been addressed in previous meta
134 analyses is the pooling together of studies that have sampled from populations with and
135 without pre-existing mental health disorders. Given the large difference in effects from
136 studies on women with and without pre-existing conditions reported by Lever Taylor et al.
137 (2016), it is surprising that subsequent meta analyses have not sought to examine these
138 populations separately. There is currently no pooled effect size estimate for the benefits of
139 mindfulness interventions in women without pre-existing mental health issues that is not
140 currently clouded by the effects on women that begin mindfulness interventions with pre-
141 existing mental health disorders. Given the inherent bias of pre-post studies, and the absence
142 of pooled evidence for the causal effects of mindfulness interventions on health in women
143 without pre-existing conditions, a systematic review and meta-analysis of controlled trials
144 conducted only on women without existing mental health issues is required. A review of RCT
145 evidence from women without pre-existing mental health disorders is the only way to
146 examine the possible preventative benefits of mindfulness interventions during pregnancy.
147
148 Existing meta analyses examining the efficacy of mindfulness interventions on mental health
149 outcomes in the perinatal period have combined studies sampling from populations with and
150 without pre-existing disorders. The pooling of sample populations prevents a clear summary

151 of the possible preventative benefits of mindfulness interventions for women without pre-
152 existing stress, anxiety or depression. Moreover, existing summaries of evidence and
153 recommendations are confounded by the inclusion of weak and conflicting evidence from
154 pre-post studies. Therefore, the aim of this systematic review and meta-analysis is to provide
155 an up-to-date evaluation of controlled trial evidence for the efficacy of mindfulness-based
156 interventions to attenuate anxiety, depression and stress in the perinatal period in women
157 without pre-existing depression, stress or anxiety disorders.
158
159 Methods
160 Search Strategy and Study Selection
161 We conducted the review according to the Preferred Reporting Items for Systematic Reviews
162 and Meta Analyses (PRISMA) guidelines (Hutton et al., 2015). The content of six databases
163 (Cochrane Library, Web of Science, PsycArticles, MEDLINE and PubMed, CINAHL and
164 Scopus) was searched from inception to April 4th 2020. The databases were chosen due to
165 comprehensive data coverage and their use in previous meta analyses (Dhillon et al., 2017;
166 Lever Taylor et al., 2016). The following search terms were applied and were based on
167 search strings used in previous systematic reviews in this area: Mindful* OR MBCT OR
168 MBSR AND prenatal OR antenatal OR postnatal OR postpartum OR puerperal OR
169 pregnancy OR pregnant OR trimester OR childbirth.
170
171 The search was restricted to peer-reviewed studies written in English and available in full
172 text. Only quantitative controlled trials exploring the effectiveness of a mindfulness-based
173 intervention during the perinatal period (i.e. during pregnancy or the first year following
174 childbirth) were included. A mindfulness-based intervention was defined as mental practice
175 to promote a structured mind set to being aware of the present-moment experience in an

176 accepting, non-judging, and non-avoiding way (Kabat-Zinn, 2013). Practices falling under
177 this definition include MBCT, MBSR, ACT, mindfulness-based yoga or other interventions
178 described by the authors. Included studies also needed to include a control group and
179 measures at baseline and after the intervention using validated measures of depression,
180 anxiety, stress and/or mindfulness. No other methodological requirements were set, but study
181 quality was rated.
182
183 We included studies if they were available at any time before the date of the search.
184 Articles from the search were tracked and a further search of potentially relevant articles and
185 review papers in the reference sections was conducted. Duplicates were removed and the
186 remaining studies were further screened by title, abstract and full text. Irrelevant articles were
187 excluded. Inclusion or exclusion decisions were based on the judgment of two independent
188 researchers. Any discrepancies were resolved through discussion.
189
190 Inclusion criteria.
191 In accordance with the PICOS approach [population (P), intervention (I), comparators (C),
192 main outcome (O), and study design (S)], the following inclusion criteria were used:
193 Participants were pregnant females (P); Studies had to include mindfulness-based
194 interventions (as defined above) delivered during the perinatal period (i.e. during pregnancy
195 of the first year after birth) (I); Passive-inactive, alternative-active or usual-care control
196 groups not receiving mindfulness interventions were acceptable controls (C); Validated
197 quantitative measures of mindfulness, state and/or trait anxiety, stress and depression
198 constituted the outcome measures (O); Only controlled trials (both randomised and non-
199 randomised) were included (S).
200

201 After removal of duplicates 870 papers were screened by abstract. Subsequently, 29 full-text
202 papers were reviewed and 12 met the criteria for inclusion (Figure 1).
203
204 Insert Figure 1. Prisma flow diagram of search results about here
205
206 Quality Assessment.
207 Studies were evaluated using a tool developed specifically for a large-scale meta-analysis of
208 mindfulness-based interventions (Khoury et al., 2013). This tool was chosen due to its ability
209 to assess both randomized and non-randomized designs, and the inclusion of items specific to
210 the validity of tools used to measure mindfulness, the mindfulness protocol, and the training
211 of the therapists to deliver mindfulness interventions (Khoury et al., 2013). The quality
212 scoring tool included items from the Jadad et al. (1996) scale and items not specific to
213 controlled studies. The items assessed by the tool included the following: (1) whether the
214 intervention followed a clearly described protocol based on, or adapted from, an established
215 programme (score of 0 or 1); (2) whether measures were administered at follow-up (score of
216 0 or 1); (3) whether a validated measure of mindfulness was used (score of 0 or 1); (4)
217 whether therapists were trained in delivering mindfulness-based interventions and (for studies
218 with clinical populations only) were clinically trained (based on good practice guidelines for
219 teaching mindfulness-based courses (UK Mindfulness-based teacher trainer network, 2015).
220 Mindfulness training was required for any study to obtain a score of 1, but clinical training
221 was only required for studies including clinical populations (score of 0 or 1); (5) whether the
222 study was randomised (score of 0 if not randomised, 1 if randomised with a no
223 intervention/waitlist control, 2 if randomised with a usual-care control, and 3 if randomised
224 with an active control); (6) whether investigators and/or participants were blinded to their
225 allocated condition (score of 0 if not blinded, 1 if single-blinded, 2 if double-blinded). The

226 maximum score from the scale was 9, with higher scores reflecting studies of higher quality.
227 Two independent researchers completed the quality assessments. As with study inclusion,
228 discrepancies were resolved through discussion.
229
230 Data Extraction and Analysis.
231 Participant characteristics, demographic data, type and characteristics of intervention, type of
232 control/comparison group, outcome measures, and effect sizes for post-intervention
233 difference between intervention and control groups were extracted.
234 Effect size was calculated as Cohen's d using the mean difference and pooled SD when
235 reported. Where SD was not reported, it was calculated either from the reported exact p
236 values or from t or F statistics using formulas provided in the Cochrane Handbook for
237 Systematic Reviews of Interventions (Higgins et al., 2021). Studies not reporting the statistics
238 required to calculate effect size as described were excluded from the analysis.
239 We extracted only composite scores from mindfulness questionnaires with subscales. Where
240 multiple scales were used to assess depression, the Edinburgh Postnatal Depression Scale
241 (EPDS) (Cox and Holden, 1987) was used in line with other meta analyses in this area (Lever
242 Taylor et al., 2016; Sockol, 2015;). The EPDS is the most frequently used self-report measure
243 of perinatal depressive symptom severity with strong psychometric properties amongst both
244 pregnant and postpartum samples (Cox and Holden, 1987; Murray and Carothers, 1990). For
245 other outcomes (i.e. anxiety and stress) and in cases where the EPDS was not used to assess
246 depression, but more than one scale was used to measure the construct, the scale with the
247 strongest psychometric properties was used to calculate effect size. Where more than one
248 scale was used to measure the construct, and there was no clear evidence for superiority of
249 one scale over another based on psychometric properties, a weighted mean effect size was

250 calculated to ensure only a single effect size estimate from each study sample (Lipsey and
251 Wilson, 2001, p 114).
252 For meta-analysis, Random effects models were run in JASP (version 0.14.1). Tables and
253 forest plots were produced for each outcome and heterogeneity was assessed using the Q
254 statistic and I^2 statistic. The I^2 statistic was interpreted against the following categories from
255 the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2021) : 0-
256 40% not important; 30-60% moderate; 50-90% substantial; >75-100% considerable
257 heterogeneity. An influential-cases analysis and funnel plots were used to identify outliers
258 and examine publication bias respectively. Influential cases were identified by a Cook's
259 distance value of >0.5 (Viechtbauer & Cheung, 2010). If outliers were identified, they were
260 removed and the analysis was repeated.
261
262 Results.
263 Study Characteristics.
264 A summary of studies included for analysis is shown in Table 1. There were 704 participants
265 across the 12 included studies with 635 involved in RCTs and the remaining 69 from non
266 RCTs. Demographic data from study participants are summarised in Table 2. Of these
267 studies, only Chan (2015) used an intervention not based on an established mindfulness
268 programme. Three RCTs did not measure mindfulness as an outcome of the intervention
269 (Chan, 2015; Muthukrishnan et al., 2016; Zhang et al., 2019). One study examined the impact
270 of a mindfulness-based intervention on outcomes after birth (Perez-Blasco et al., 2013). The
271 remaining RCTs focused on reducing general distress or anxiety or improving wellbeing
272 during the pregnancy period in samples not recruited for elevated baseline measures of
273 depression, stress and anxiety.
274

275 Insert Table 1 about here

276

277 Insert Table 2 about here

278

279 There were two non-randomised control trials in the included studies. Bowen et al. (2014) did
280 not explain how participants were allocated to the mindfulness-based intervention or the
281 alternative interpersonal therapy active control groups. Gambrel and Piercy (2015) used a
282 waiting-list control for comparison, with a primary aim of examining the effects of a
283 mindfulness-based intervention during the pregnancy period on relationship satisfaction.
284 Nevertheless, quantitative data were reported for outcomes of interest to this review for the
285 pregnant females separately. Bowen et al. (2014) sought to examine the effects of a
286 mindfulness-based intervention versus interpersonal therapy on depression and worry
287 symptoms in pregnant, anxious and depressed participants.

288

289 Across the 12 included studies, the duration of interventions ranged from four weeks to eight
290 weeks, with most delivering approximately eight 2-3hr weekly sessions albeit with some
291 variability between studies. No study explicitly followed the MBCT course structure.
292 Remaining studies mostly used variations or adaptations of MBCT, though two studies
293 delivered bespoke programmes that contained mindfulness elements including: Eastern-based
294 meditation (Chan, 2015) and mindful transition to parenthood (Gambrel and Piercy, 2015).
295 Where reported, the duration of instructor-led and home-practice sessions was generally less
296 than recommended in MBSR or MBCT (see Table 1).

297

298 Quality assessment of included studies.

299 Scores on the quality assessment ranged from 3 to 7 out of a possible 9, with a mean score of
300 4.9, a median of 5 and a modal score of 4. Quality scores were generally reduced by a lack of
301 trained mindfulness practitioners delivering interventions, failure/inability to blind
302 participants and researchers to the allocated conditions, failure to specify the random
303 allocation process and not including an assessment of mindfulness. Assessment scores for all
304 included studies are shown in Table 3.

305

306 Insert Table 3 about here.

307

308 Intervention effects.

309 Of the 12 studies included, 11 reported group comparison data for at least one measure of
310 depression (total n = 607), 7 for stress (total n = 403), and 8 for mindfulness (total n = 396).
311 Only 3 studies included measures of general anxiety (total n = 81).

312

313 General Anxiety.

314 The effect sizes for anxiety reduction differences between intervention and control groups at
315 post test ranged from d = -0.04, d = -0.25 and d = -1.23 from Woolhouse et al. (2014), Bowen
316 et al. (2014) and Perez-Blasco et al. (2013) respectively. Because of the small number of, and
317 large variation in reported effects on general anxiety, a meta-analysis was not performed on
318 this outcome. Perez-Blasco et al. (2013) delivered the mindfulness intervention in the post-
319 partum period with a sample of breastfeeding women. The difference in intervention period
320 could be a factor in the larger reduction observed in that study.

321

322 Depression.

323 There was a small and statistically significant reduction in depression after mindfulness
324 interventions compared with controls. The effect size estimate for the intervention-control
325 post-test difference was d = -0.20 (95% CI -0.40, -0.00, p = 0.04). Moreover, estimates of
326 heterogeneity were statistically nonsignificant and indicated unimportant between-study
327 variation in effect sizes (Q_{10} = 11.1, p = 0.35, I^2 = 23.1%). There were no influential cases
328 and no indication of publication bias. Figures 2 and 3 display a forest plot and funnel plot
329 respectively for the depression outcome.

330

331 Figures 2 and 3 about here

332

333 Mindfulness.

334 There was a small, statistically significant increase in mindfulness after mindfulness
335 interventions compared with controls. The effect size estimate for the intervention-control
336 post-test difference was d = 0.24 (95% CI 0.04, 0.43, p = 0.02). Heterogeneity estimates were
337 small and statistically nonsignificant (Q_7 = 6.52, p = 0.48, I^2 = 0.01%). There were no
338 influential cases and no indication of publication bias. Figures 4 and 5 display a forest plot
339 and funnel plot respectively for improvement in mindfulness.

340

341 Figures 4 and 5 about here

342

343 Stress.

344 Influence analysis suggested that the unusually large effect size for stress reduction reported
345 by Muthukrishnan et al. (2016) was a clear outlier. After removal of this effect from the
346 analysis, the evidence of the remaining 6 studies estimated a small but statistically

347 nonsignificant reduction in stress after mindfulness interventions compared with controls.
348 The effect size estimate for the intervention-control post-test difference was d = -0.21 (95%
349 CI -0.59, 0.16, p = 0.27). Heterogeneity statistics were statistically nonsignificant but
350 suggestive of moderate heterogeneity in the remaining 6 studies ($Q_5 = 10.5$, $p = 0.06$, $I^2 =$
351 54.2%). There was no indication of publication bias. Figures 6 and 7 display a forest plot and
352 funnel plot respectively for the stress outcome. Other than lack of evidence for the training of
353 the mindfulness instructors, there were no obvious aspects of the methods used by
354 Muthukrishnan et al. (2016) that could account for the large reduction in stress reported in
355 that study.

356

357 Figures 6 and 7 about here

358

359 Discussion.

360 This systematic review and meta-analysis has sought to provide an up-to-date summary of
361 controlled trials on the effectiveness of mindfulness-based interventions in the perinatal
362 period for reducing stress, anxiety and depression in women without pre-existing stress,
363 anxiety or depression disorders. The analysis included 12 studies comprising 10 randomised
364 and 2 non-randomised controlled trials on this population of women.

365

366 There was evidence to suggest that mindfulness interventions result in small, but clear and
367 statistically significant reductions in depression and increases in mindfulness in participants
368 without pre-existing disorders. The evidence for reductions in anxiety and stress was limited
369 and unclear. There were insufficient and highly variable effects for anxiety reduction, and
370 nonsignificant effects for stress reduction, with potentially problematic heterogeneity in the
371 findings.

372

373 Studies were evaluated using a tool developed specifically for a large-scale meta-analysis of
374 mindfulness-based interventions (Khoury et al., 2013). The maximum possible score of 9
375 would indicate studies of the highest quality in this field of research. The included studies
376 were, on average, of moderate quality despite all being controlled trials. The failure/inability
377 to blind participants to their allocated condition is understandable given the nature of
378 mindfulness interventions, however it is possible to blind researchers to the allocation,
379 though this was not generally reported. The lack of trained mindfulness practitioners in the
380 delivery of mindfulness interventions is possibly more problematic. Evidence of appropriate
381 training was lacking in 4 of the included studies. There was also considerable variation in the
382 mindfulness-based interventions used, with only one study explicitly following MBCT course
383 structure. The well-established approaches of mindfulness-based cognitive therapy and
384 mindfulness-based stress reduction are adapted in multiple ways, potentially providing
385 different mechanisms for change across studies and accounting for variability and magnitude
386 of effects.

387

388 Stress and anxiety effects were confounded by heterogeneity. Even after removal of an
389 outlier, the I^2 statistic suggested moderate to problematic heterogeneity in the remaining
390 studies. Though the Q statistic was not significant for the stress outcome, the small number of
391 remaining studies could result in insufficient power to reject the null hypothesis in this test.
392 Meta-analysis was not performed on the anxiety outcome as there were only three studies.
393 Nevertheless, the variation in effect sizes between these three studies was notable and ranged
394 from very small to very large. Even for depression and mindfulness outcomes, the pooled
395 analyses combine relatively small numbers of studies. As such, caution should possibly be
396 exercised in the interpretation of pooled effects, though the nonsignificant and very low

397 heterogeneity for mindfulness and nonsignificant and low heterogeneity for depression might
398 provide some reassurance. Potential sources of heterogeneity include length and number of
399 intervention sessions and different tools for measuring outcomes. Studies have also been
400 carried out in different countries with the potential for cultural influences on intervention
401 delivery and effectiveness, though these effects are speculative and beyond the scope of this
402 review to examine. There were also considerable study design limitations, such as small
403 sample sizes, lack of formal sample size estimation and specification of practical/clinically
404 meaningful effects sizes and subsequently, unspecified type two error rates. Studies also
405 often had many outcome measures/hypotheses being tested. Such issues inflate standard error
406 in individual studies and subsequently in the pooled effect size estimate and challenge meta-
407 analysis outcomes (Mayo-Wilson et al. 2017).
408
409 This review examined only controlled trials on women without pre-existing mental health
410 issues. The goal was to obtain estimates of the effects of mindfulness interventions in
411 mentally healthy women, free from the bias introduced by samples of women belonging to a
412 population with existing mental health issues. As such, comparisons with previous meta
413 analyses that pooled samples from populations both with and without mental health disorders
414 may be of limited value. However, our analysis of controlled trials provided no evidence of
415 benefit of mindfulness-based interventions on anxiety and stress, supporting the findings of
416 previous reviews (Dhillon et al., 2017; Lever Taylor et al., 2016). The heterogeneity of these
417 outcomes was also in agreement with the previous analyses, despite our studies being only
418 from the population of women without pre-existing disorders. In contrast to both previous
419 reviews, however, our estimated effect on depression suggested a clear albeit small reduction
420 in depression compared to controls after mindfulness interventions. The pooled effect on
421 depression was unclear/non-significant in the previous two meta analyses of this topic. In

422 agreement with Dhillon et al. (2017), we found clear evidence for increased mindfulness after
423 mindfulness-based interventions from controlled trials, though the size of effect was smaller
424 in our analysis than previously reported. Lever Taylor et al. (2016) reported similar effect
425 sizes to ours that were non-significant for controlled trials and with significant heterogeneity.
426 The contrast in finding between our review and previous reviews, and the difference in effect
427 size magnitude where findings agreed, could be explained by the single focus on studies from
428 the population of women without pre-existing mental health disorders in this review. It is
429 likely that removing studies on women with existing conditions reduced heterogeneity and
430 allowed for a clearer estimate of the effect size of interest in this review.
431
432 Limitations and Future Research.
433 The specific focus on controlled trials and studies of women without pre-existing conditions
434 meant that the pool of studies in this meta-analysis is smaller than previous meta-analyses.
435 However, this volume-quality trade off was required to address the research question.
436 We performed this review in accordance with PRISMA guidelines (Hutton et al., 2015). To
437 our knowledge, this is the first up-to-date systematic review and meta-analysis of controlled
438 trials on the effectiveness of mindfulness-based interventions on mental health outcomes
439 during pregnancy performed solely in women without pre-existing stress, anxiety or
440 depression. One aspect of the method that could have been strengthened was the approach to
441 quality assessment. Two independent researchers assessed study quality, but inter-rater
442 reliability of scores was not formally calculated. Such formal calculations are, however not
443 often reported in other reviews in this field. The limitations of this review are primarily due
444 to the volume and quality of the studies included. Some studies failed to report effect sizes or
445 statistics from which effect size could be calculated in the results. Several studies included
446 more than one psychometric measure of an outcome variable. Weighted average effect sizes

447 were calculated where psychometric properties of the multiple tools could not differentiate.
448 However, this does not address the issue of multiple and unnecessary hypothesis tests being
449 conducted in the original studies. Such practices are known to inflate type 1 error rate, a
450 problem that, in combination with underpowered studies, further confounds meta-analysis in
451 this field of study. Furthermore, and despite the homogeneity of the outcome for mindfulness
452 and depression, the relatively small number of studies analysed should be considered when
453 interpreting the findings.
454 Future research should define clinically-meaningful effects for intervention studies using
455 mindfulness. Future studies should limit the number of measurement tools and, where
456 possible, choose single tools with good psychometric properties to assess variables of
457 interest. Future studies should also simplify their designs to use the smallest number of
458 samples of sufficient size to detect a clinically-meaningful effect in mental-health variables
459 of interest. It would also be of value to explore if the benefits of a mindfulness-based
460 intervention are maintained in the postnatal period, building on the few studies available in
461 this area. In general, and in agreement with the recommendation of the previous meta
462 analyses on the topic, there is a need for more well-designed, controlled trials with trained
463 mindfulness practitioners and established interventions performed on women without pre-
464 existing stress, anxiety or depression. Moreover, a meta-analysis of controlled trials including
465 only studies on women with pre-existing depression, stress and anxiety disorders is warranted
466 given that different and clearer effects sizes appear when analyses separate studies on women
467 with and without pre-existing conditions.
468
469 This study suggests that mindfulness-based interventions cause small reductions in
470 depression and small increases in mindfulness in women without pre-existing disorders. If the
471 cost of offering mindfulness-based interventions is not prohibitive, such interventions could

472 be a useful addition to existing support for pregnant women without existing mental health
473 issues, and could serve to prevent or attenuate the development of depression symptoms
474 during the perinatal period. There remains a need for robust controlled trials with clear
475 hypotheses and parsimonious designs.
476

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481
482 LC had the idea for the review. LC and MW performed the literature search, screening and
483 risk of bias assessment. MW performed the data analysis. LC drafted the introduction and
484 discussion, MW drafted the methods and results. Both authors revised and agreed the final
485 version of the manuscript.
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498 References

499 Studies included in the meta-analysis are marked by an (*).

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Table 1. Summary of included studies.

Citation	Participant description, n, (mean, SD) age	Study type	Intervention description	Comparison	Outcome measures
Beattie et al. (2017)	n=48, n=24 exp (28.9, SD 5.7yrs), n=24 control (28.5, SD 6.4yrs)	RCT	Mindfulness in pregnancy programme (MIPP). 8 weeks, 2hr/week.	Active control-pregnancy support programme	PSS, EPDS, MAAS, birth outcomes
Bowen et al. (2014)	n =19 exp (30.67, SD 3.94yrs), n=18 control (28.94, SD 3.55yrs)	non RCT	Mindfulness based therapy. 5 weeks, unspecified frequency and duration of sessions.	Interpersonal therapy	EPDS, STAI, CWS, MSSS
Chan (2015)	n=64 exp (33.34, SD 4.11yrs), n=52 control (33.84, SD 3.74yrs)	RCT	Eastern based meditation intervention. 6 sessions, unspecified duration and frequency.	Usual care	PDQ, PCI, EPDS, BMSWBI, salivary cortisol
Duncan et al. (2017)	n=30, n=15 exp and control	RCT	PEARLS based on mindfulness-based childbirth and parenting education (MBCP). 8 weekly sessions, unspecified duration.	Active control	FFMQ, CES-D, CBSEI, PCS, W-DEQ
Gambrel and Piercey (2015)	n=32 (31.56yrs) n=15 exp , n=17 control	non RCT	Mindful transition to parenthood programme. 4 weeks, 2hr/wk.	Waiting list	CSI, FFMQ, IRI, DASS-21, PANAS
Lonnberg et al. (2020)	n=75 exp (32, SD 3.86yrs), n=89 control (32, SD 4.14yrs)	RCT	Child Birth and Parenting (MBCP). 8 weeks, 2hrs 15min/wk.	Active control	PSS, EPDS, PSOM, FFMQ
Muthukrishnan et al. (2016)	n=34 intervention (21, SD 2.56yrs), n=34 control (23, SD 2.4yrs)	RCT	Mindfulness meditation programme; 2 session p/wk for 5 weeks plus 30 min/day home practice. Modified MBCT.	Standard obstetric care	PSS, autonomic function tests a) HR response from sit to stand, b) HR response from stand to lying c) HRV d) BP response to hand cold water immersion.

Pan et al. (2019)	n=74 (32.8, SD 3.9yrs), n=39 exp, n=35 control	RCT	MBCP 8 weeks, 3hr session/wk plus 6 x 30-min home session/wk.	Standard treatment	PSS, EPDS, FFMQ
Perez-Blasco et al.(2013)	n=21 (34.33, SD 4.72yrs), n=13 exp, n=8 control	RCT	Based on MBCT/MBSR and Mindful self-compassion. 8 weeks, 1 x 2-hr session/wk.	No treatment	Parental Evaluation Scale, FFMQ, SCS, DASS-21, SWLS, SHS
Woolhouse et al. (2014)	n=23, n=13 exp (30.81, SD 0.75yrs), n=10 control (34.08, SD 0.09yrs)	RCT	Mind Baby Body, 6 weeks, 2hr/wk	Usual care	DASS-21, CES-D, STAI, PSS, FFMQ
Zhang and Emory (2015)	n=33 (25.3, SD 4.6yrs), n=16 exp, n=17 control	RCT	Mindful motherhood	Usual care	TMS, PSS, cortisol, PES, BDI-II
Zhang et al. (2019)	n=58, n=28 exp (25.7, SD 2.79yrs), n=30 control (25.58, SD 2.33yrs)	RCT	MBSR, 8 x 90min/wk	Usual care	STAI, PSRS, SDS

Key to abbreviations: STAI = State Trait Anxiety Inventory; PSS = Perceived Stress Scale; PSRS = Pregnancy Stress Rating Scale; SDS = Self-rating Depression Scale; BDI-II = Beck Depression Inventory-II; PES = Pregnancy Experience Scale; DASS-21 = Depression, Anxiety and Stress Scale-21; CES-D = Centre for Epidemiological Studies Depression Scale; TMS = Toronto Mindfulness Scale; FFMQ = Five-Factor Mindfulness Questionnaire; SCS = Self-compassion Scale; SWLS = Satisfaction With Life Scale; SHS = Subjective Happiness Scale; EPDS = Edinburgh Postnatal Depression Scale; PSOM = Positive States of Mind; HDS = Hamilton Depression Scale; ERDS = Emotion Regulation Difficulties Scale; CSI = Couple Satisfaction Index; IRI = Interpersonal Reactivity Index; PANAS = Positive and Negative Affect Schedule; CBSEI = Child Birth Self-Efficacy Inventory; PCS = Pain Catastrophising Scale; W-DEQ = Wijima Delivery Expectancy/Experience Questionnaire; PDQ = Prenatal Distress Questionnaire; PCI = Prenatal Coping Inventory; BMSWBI = Body-Mind-Spirit Well-Being Inventory; CWS = Cambridge Worry Scale; MSSS = Maternity Social Support Scale; MAAS = Mindfulness Attention Awareness Scale; MBCP = Mindfulness-based childbirth and parenting; MBSR = Mindfulness-based stress reduction; MBCT = Mindfulness-based cognitive therapy.

Table 2. Participant demographics from included studies.

Citation	Race/ethnicity	Education/ employment	Civil status	Sexual orientation	Other
Beattie et al. (2017)	Intervention: 62.5% Australian 37.5% other Control: 71.4% Australian 25% other	Intervention: 72.7% employed Control: 71.4% employed	I – 100% C – 100%	-	-
Bowen et al. (2014)	No data	Intervention: Grade 12/>than 10%; Post secondary 90% Control: Grade 12/>than 16.7% Post secondary 83.3%	I – 100% C – 85.7%	-	Gestation at intake. I – 21.35±5.59 wks C – 23.42±4.22 wks
Chan (2015)	All Chinese	Intervention: Middle school or < 7.9% High school 31.7% College or > 60.3% FT employment 87.5% Control: Middle school or < 14.5% High school 34.5% College or > 50.9% FT employment 80%	-	-	Present obstetric issues. I – 3.1% C – 0%
Duncan et al. (2017)	Hispanic 18% White 59% Asian 14% Multiracial 7% Black 3% American Indian 3%	-	-	-	>55% of sample below area median household income.

Gambrel and Piercey (2015)	White 82% Native American 4.5% Asian American 1.5% Multiracial 3% Other 9%	High school only 3% College 21.2 % Bachelor degree 36.4% Graduate school 39.4%	Married 75.8% Co-habiting 18.2% Engaged 6.1%	One lesbian couple	Religion. Christian 28.7% Catholic 12.1% Agnostic 6.1% Atheist 9.1% None 28.8%
Lonnberg et al. (2020)	Intervention: Swedish 89.6% Swedish + other 3.1% European 5.2% Non-European 2.1% Control: Swedish 83.6% Swedish + other 6.2% European 6.2% Non-European 2.1%	Intervention: Elementary 1% Secondary 12.5% College 86.5% Control: Elementary 0% Secondary 12.6% College 86.6%	Intervention: Single 3.1% Co-habiting 59.4% Married 37.5% Living apart 0% Control: Single 2.1% Co-habiting 61.7% Married 34% Living apart 2.1%	-	-
Muthukrishnan et al. (2016)	Indian	-	-	-	-
Pan et al. (2019)	Taiwanese	Junior college or< 12.2% University or > 87.8% Employed 81% Unemployed 19%	Married 98.6% Single 1.4%	-	No prior births 91.8% 1+ prior births 8.2%
Perez-Blasco et al.(2013)	Spanish	-	-	-	First child 57.1% 2 or > children 42.9%
Woolhouse et al. (2014)	Australian 50% Not born in Australia 50%	Higher Uni degree 43.8% Uni degree 40.6% Below Uni education 15.6%	Married 65.6% Co-habiting 31.3% Single 3.1%	-	Trimester at enrolment. First 25% Second 62.5% Third 12.5%

Zhang and Emory (2015)	African-American	Unemployed 84.6%	Single 29.4% Not living with partner 19.1% Co-habiting 38.2% Married 13.2%	-	Have children 84.6% Gestation 21.5 weeks Complications 32.3%
Zhang et al. (2019)	Chinese	Intervention: Middle school or> 28.1% High school 31.3% College or > 40.6% Control: Middle school or >22.6% High school 38.7% College or > 38.7% Intervention: Housewife 40.6% Employed 59.4% Control: Housewife 48.4% Employed 51.6%	-	-	Pregnancy period. Intervention: 1st trimester 43.8% 2nd trimester 56.2% Control: 1st trimester 48.4% 2nd trimester 51.6% Previous births. Intervention: One 84.4% ≥ two 15.5% Control: One 90.3% ≥ two 9.7%

I = intervention group; C = control group; - = no data

Table 3. Quality Assessment.

Citation	Protocol based on established mindfulness programme	Measures administered at follow up	Valid measure of mindfulness included	Therapists mindfulness trained	Randomised	Researchers and/or participants blinded	Total
Beattie et al. (2017)	1	1	1	1	3	0	7
Bowen et al. (2014)	1	1	0	1	0	0	3
Chan (2015)	0	1	0	0	2	0	3
Duncan et al. (2017)	1	1	1	1	3	0	7
Gambrel and Piercey (2015)	1	1	1	1	0	0	4
Lonnberg et al. (2020)	1	1	1	1	3	0	7
Muthukrishnan et al. (2016)	1	1	0	0	2	0	4
Pan et al. (2019)	1	1	1	1	2	0	6
Perez-Blasco et al. (2013)	1	1	1	0	1	0	4
Woolhouse et al. (2014)	1	1	1	1	1	0	5
Zhang and Emory (2015)	1	1	1	1	1	0	5
Zhang et al. (2019)	1	1	0	1	1	0	4

The quality score outcome can range from 0 = lowest quality to 9 = highest quality.

Figure 1. Flow diagram of study selection process.

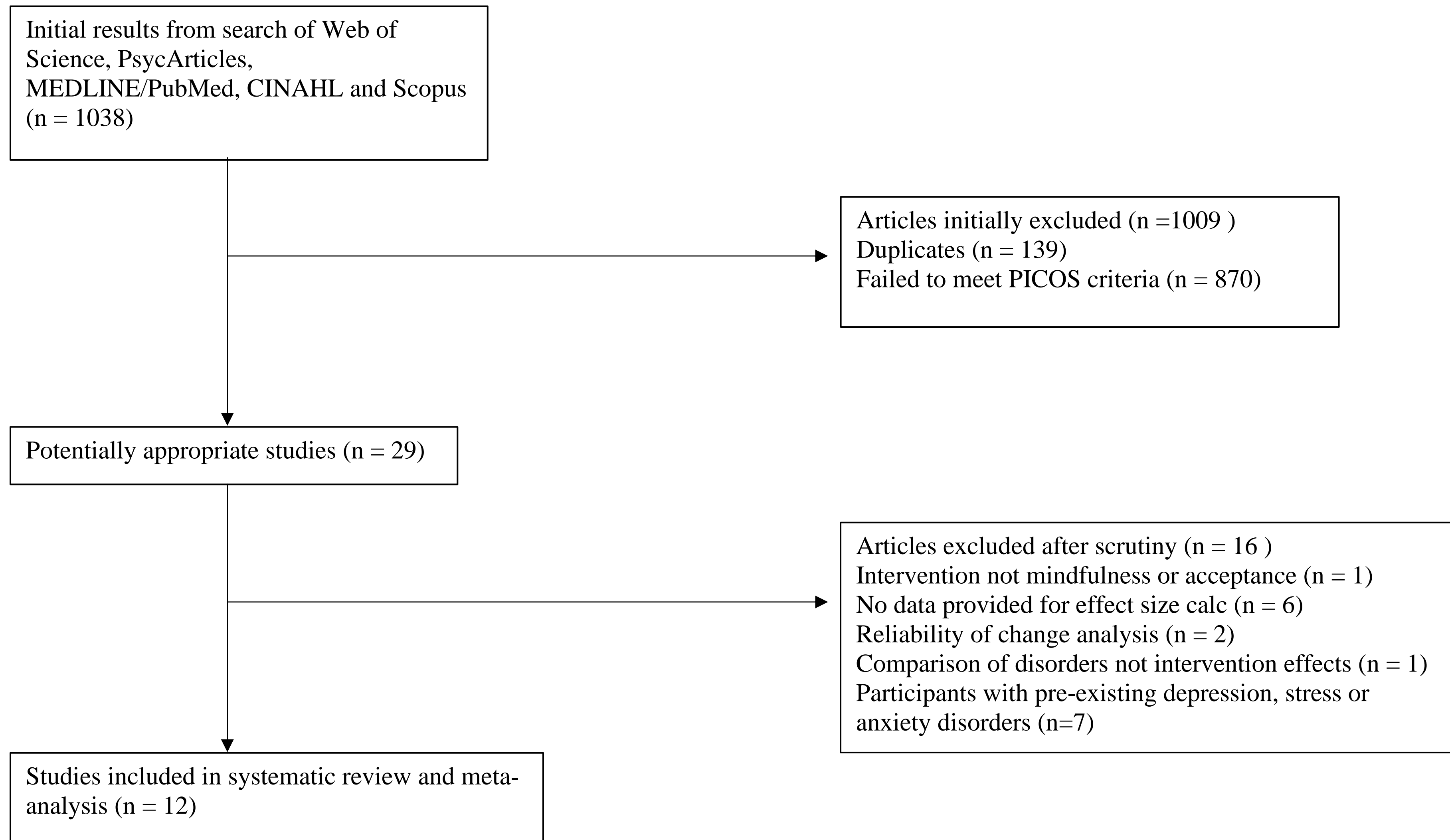

Figure 2. Forest plot of intervention-control post-test standardised mean differences in depression.

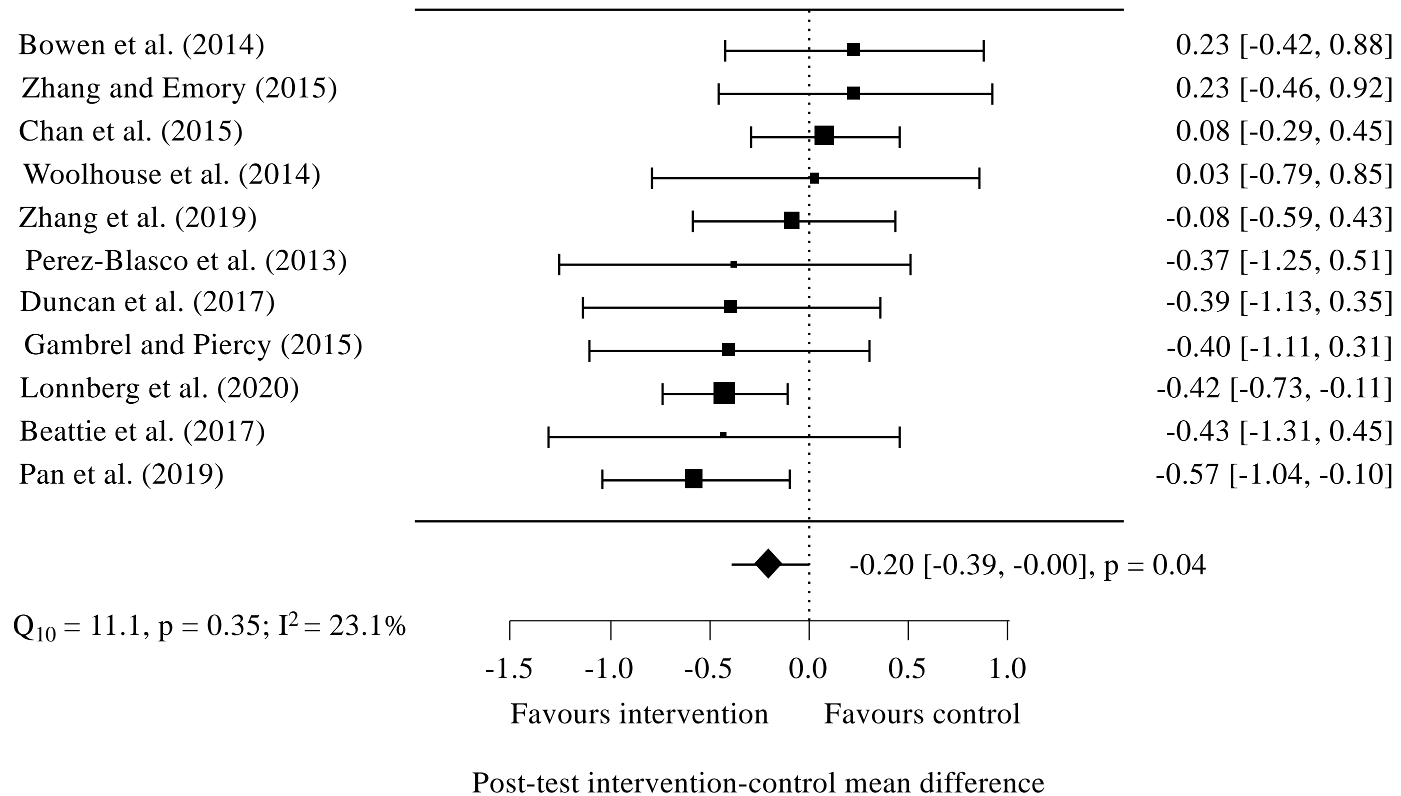

Figure 3. Funnel plot of effect sizes for intervention-control post-test standardised mean differences in depression.

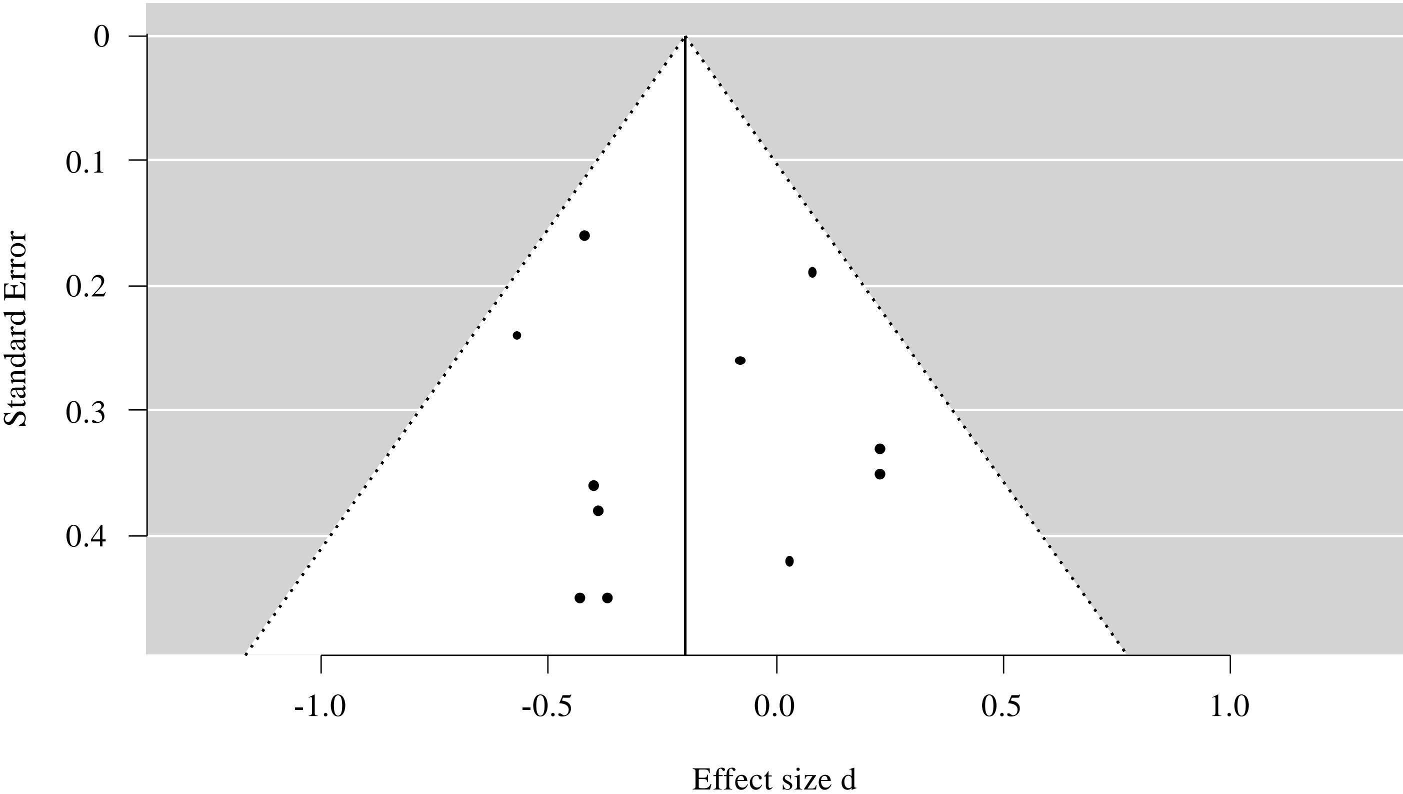

Figure 4. Forest plot of intervention-control post-test standardised mean differences in mindfulness.

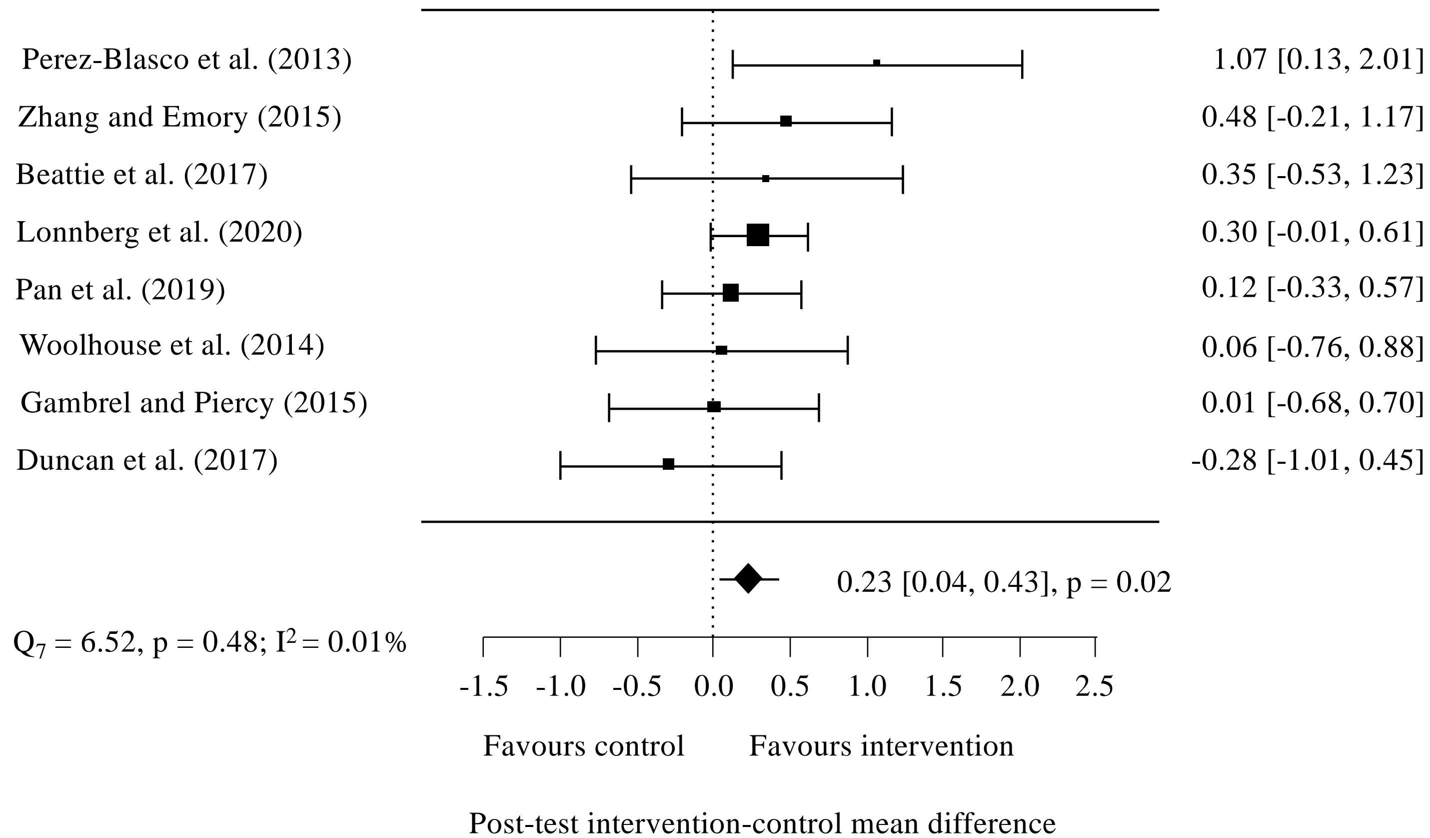

Figure 5. Funnel plot of effect sizes for intervention-control post-test standardised mean differences in mindfulness.

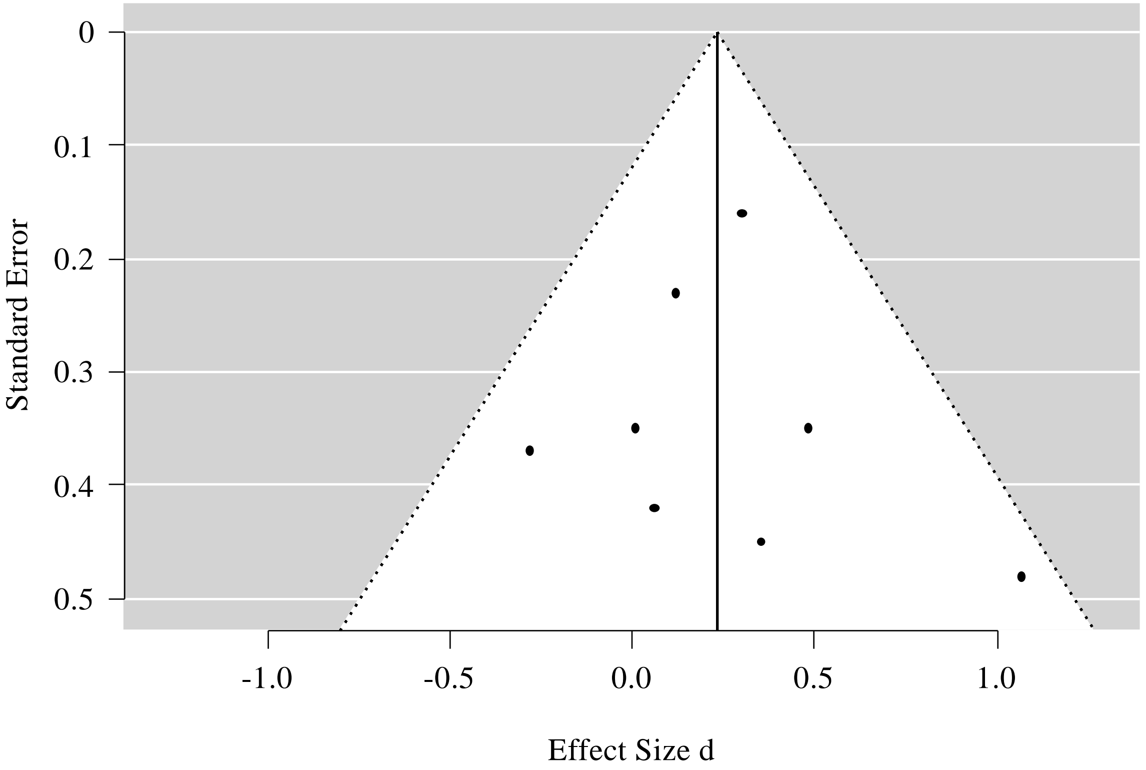

Figure 6. Forest plot of intervention-control post-test standardised mean differences in stress.

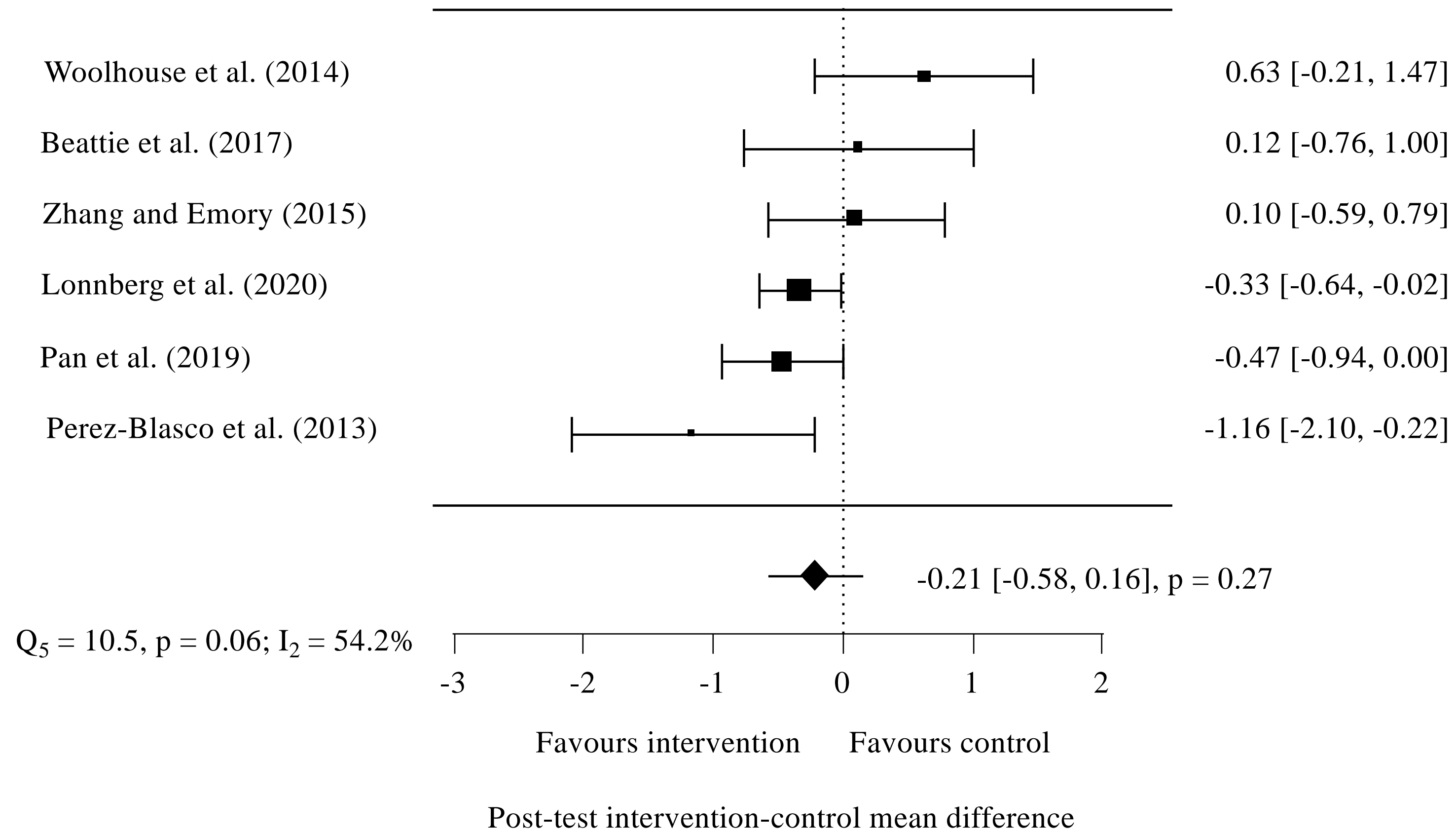

Figure 7. Funnel plot of effect sizes for intervention-control post-test standardised mean differences in stress.