

Fidelity of interventions to reduce or prevent stress and/or anxiety from pregnancy up to two years postpartum: A systematic review

Abstract

Purpose. Intervention fidelity refers to whether an intervention is delivered as intended and can enhance interpretation of trial outcomes. Fidelity of interventions to reduce or prevent stress and anxiety during pregnancy and postpartum has yet to be examined despite inconsistent findings for intervention effects. This study systematically reviews use and/or reporting of intervention fidelity strategies in trials of interventions, delivered to (expectant) parents during pregnancy and postpartum, to reduce or prevent stress and/or anxiety.

Methods. MEDLINE, Embase, CINAHL, PsychINFO, and Maternity and Infant Care were searched from inception to March 2019. Studies were included if they were randomised controlled trials including pregnant women, expectant fathers and/or partners during pregnancy, and/ or parents within the first two years postpartum. The National Institutes of Health Behavior Change Consortium checklist was used to assess fidelity across five domains (study design, provider training, delivery, receipt, enactment).

Results. Sixteen papers (14 interventions) were identified. Average reported use of fidelity strategies was 'low' (45%), ranging from 17.5% to 76%. Fidelity ratings ranged from 22% for provider training to 54% for study design.

Conclusions. Low levels of intervention fidelity may explain previous inconsistent effects of stress and anxiety reduction interventions. Important methodological areas for improvement include intervention provider training, fidelity of comparator conditions, and

consideration of non-specific treatment effects. Increased methodological rigour in fidelity enhancement and assessment will improve intervention implementation and enhance examination of stress and anxiety reduction and prevention interventions delivered during pregnancy and the postpartum.

Keywords: Fidelity, Stress, Anxiety, Pregnancy, Postpartum

The 'first 1000 days', a transitional period from pregnancy up to two years postpartum involves changing roles, responsibilities and identity for (expectant) parents (Condon, Boyce & Corkindale, 2004; Solmeyer & Feinberg, 2011). This can increase stress and anxiety levels (Chen et al., 2019). Up to 84% of women experience stress and/or anxiety during the perinatal period (Woods et al., 2010) and prevalence of paternal anxiety ranges from 25% to 50% (Philpott et al., 2019). Adverse outcomes associated with stress and anxiety in the first 1000 days include increased risk of depression (Vismara et al., 2016), impaired autoimmune functioning (Song et al., 2018), preeclampsia (Yu et al., 2013), low infant birth weight (Su et al., 2015), and impaired child motor development (Zijlmans et al., 2015), and emotional and behavioural difficulties (Lohaus et al., 2017; Neece, Green & Baker, 2012; Tharner et al., 2012).

Interventions to reduce and/or prevent stress and anxiety during the first 1000 days vary considerably by type, content, and delivery. For instance interventions examined to date include cognitive behavioural therapy (CBT), exercise, psychoeducation, mindfulness, and relaxation (Lavender et al., 2016; Matvienko-Sikar et al., 2020). Interventions can be delivered in antenatal and maternity care context, with a recent review indicating that the majority of such interventions were delivered in a medical context by healthcare professionals such as midwives (Matvienko-Sikar et al., 2020). This choice of intervention setting and delivery is logical and useful given women's increased contact with healthcare professionals during pregnancy and early parenthood. However there is also increasing evidence for usefulness and acceptability of remotely delivered interventions, included e-Health interventions for stress and anxiety (Loughnan et al. 2019). Delivery of interventions across the first 1000 days presents unique challenges however due to changing emotional

and developmental needs of women and infants across this time, in addition to changes in interactions with healthcare providers who often delivery interventions (for instance moving from antenatal care after birth). Such challenges may explain findings of inconsistent effects of interventions for stress and anxiety observed in previous reviews (Alderdice, McNeill & Lynn, 2013; Lavender et al., 2016; O'Brien et al., 2017).

Inconsistencies intervention effects may be attributable to poor intervention fidelity, which relates to interventions not being implemented as intended. Fidelity can be defined as 'methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions' (Bellg et al., 2004, p.443). *Enhancing* fidelity involves using strategies to enable interventions to be delivered and received as intended (Walton et al., 2017). *Assessing* fidelity involves assessing the degree to which interventions are delivered and received as intended (Toomey et al., 2016). Improving fidelity reporting can improve examination of intervention effects (Bellg et al., 2004; Borrelli, 2011) testing and refinement of hypotheses, and future intervention design (Walton et al., 2017). Despite the importance and benefits of enhancing and assessing fidelity, it is rarely adequately addressed in trials of interventions to reduce perinatal depression (Chowdary et al., 2014) and fidelity of interventions to reduce stress and anxiety interventions in the first 1000 days has yet to be examined. The aim of this review is therefore to examine the use of strategies to enhance and assess fidelity of stress and/or anxiety reduction interventions delivered to men and women during the period from pregnancy to two years postpartum (the first 1000 days).

Methods

This systematic review was conducted in conjunction with a corresponding systematic review of intervention effectiveness (removed for peer review). The review was registered in PROSPERO (removed for peer review) and is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009).

Searches, Selection and Eligibility Criteria

Full details of the systematic review search strategy are reported elsewhere (removed for peer review) and are presented briefly here. The electronic databases MEDLINE, Embase, CINAHL, PsychINFO, and Maternity and Infant Care were searched from inception to March 2019; reference lists of identified articles and reviews were also searched. See Supplementary file 1 for full search terms. Studies were eligible for inclusion if they reported on randomised controlled trials including pregnant women, expectant fathers and/or partners during pregnancy, and/or parents within the first two years postpartum from economically developed countries (based on membership of the Organisation for Economic Co-operation and Development (OECD)). Studies must have examined effects of non-pharmacological interventions developed to prevent or reduce stress and/or anxiety, and have examined intervention effects on stress and/or anxiety.

Data Extraction and Analysis

Intervention fidelity data was extracted independently by two reviewers (removed for peer review) using the updated National Institutes of Health Behaviour Change Consortium (NIHBCC) fidelity checklist with 40 components (Borrelli et al., 2005). The NIHBCC checklist

has previously been found to be valid and reliable (Borrelli et al., 2005; Toomey et al., 2018), and conceptualises five different fidelity domains 1) Study Design, relating to how adequately an intervention assesses its own hypotheses; 2) Provider Training, relating to how provider skills are trained and maintained throughout the intervention; 3) Treatment Delivery, relating to whether providers deliver the intended intervention throughout the intervention period for both control and intervention groups; 4) Treatment Receipt, relating to participant's intervention engagement by assessing and improving understanding and ability to perform intervention skills; 5) Treatment Enactment, relating to whether participants apply intervention skills and behaviour in daily life (Borrelli et al., 2005).

Data extraction was guided by a codebook adapted from Toomey et al. (2018) (See Supplementary File 2). Reviewers independently coded each study for all NIHBCB components, with components coded as either 'present' (numerical score: 1) or 'absent' (numerical score: 0); components not applicable to individual studies were coded as "not applicable" (Borrelli et al., 2005). Coding was agreed by consensus discussion between reviewers, with any discrepancies resolved with a third reviewer (removed for peer review). Total fidelity scores for each study were calculated by summing numeric scores for all fidelity components; percentage scores were calculated following by dividing the total number of 'present' scores from the total applicable components for the study (Borrelli et al. 2005). Average scores for 1) total fidelity, 2) NIHBCB domains and 3) individual fidelity components were calculated by adding all relevant 'present' scores and dividing them from total of applicable components for that category. In accordance with previously used cut-off

points, fidelity scores were considered 'low' if below 50%, 'moderate' at 50%-79% or 'high' at >80% (Borrelli et al., 2005; Toomey et al., 2018).

Quality assessment

Risk of bias was assessed for each study by two reviewers (removed for peer review) using the Cochrane risk of bias criteria (Higgins et al., 2011).

Results

Sixteen studies, representing 15 interventions were included in this review (Austin et al. 2008; Beattie et al., 2017; Bittner et al., 2014; Castel et al., 2016; Fotiou et al., 2016; Loughnan et al., 2018; Loughnan et al., 2019; Richter et al., 2012; Roman et al., 2009; Tragea et al., 2014; Urizar et al., 2011; Urizar et al., 2019; van der Zwan et al., 2019; Vieten & Astin, 2008; Weis et al., 2017; Zerkowitz et al., 2011). See Table 1 for full study details. Eligible studies predominantly included women during either the prenatal, postnatal, or both pre and postnatal phases. Full information on search results and intervention effects can be found in the corresponding effectiveness review (removed for peer review), however summary study characteristics, risk of bias, and intervention effects are presented in Table 1. Interventions were heterogeneous, demonstrating inconsistent outcomes across studies. Studies were mostly rated as being of 'high' or 'moderate' risk of bias.

[TABLE 1 HERE]

Reporting of Fidelity within Individual Studies

Most studies were rated as 'low' fidelity; the average reported use of fidelity strategies across all studies was 'low' at 45% (See Table 2). No study was rated as 'high' fidelity ($\geq 80\%$). Fidelity scores of individual studies ranged from 17.5% (Fotiou et al., 2016) to 76% (van der Zwan et al., 2019); see Table 2. Fidelity was not explicitly referred to in any of the reviewed studies, though one study discussed consideration of content, dose, methods and provider details in intervention development (Zerkowitz et al., 2011); another reported strategies to maintain treatment integrity (van der Zwan et al., 2019).

[TABLE 2]

Reported Use of Fidelity Strategies According to NIHBCD Domains and Components

Across the five NIHBCD domains, fidelity ratings ranged from 22% for Training of Providers to 54% for Study Design; see Table 3.

[TABLE 3]

Across individual NIHBCD components, reporting of components ranged from 0% (n=0 studies) to 100% (n=16 studies). See Table 4 and Supplementary file 3.

[TABLE 4]

Study Design. Reporting of the content and number of treatments in the intervention condition was good overall. The length of contact in intervention sessions and duration of contact over time demonstrated low to moderate fidelity respectively. Description of the content of comparison conditions was moderate but all other comparator components demonstrated low fidelity (see Table 4). Reporting of methods to ensure dose equivalence within conditions was good, though reporting of dose equivalence between conditions was poor overall. Only one study (Zelkowitz et al., 2011) sufficiently reported how equal doses were achieved between conditions, with a manual and equal facilitator contacts provided for both conditions. Specification of required provider credentials and reporting of potential confounders demonstrated moderate fidelity across trials. All other aspects of study design demonstrated low fidelity.

Training of Providers. Two interventions were delivered online (Loughnan et al., 2018; 2019) and so were not coded for this component. Eleven of the 14 eligible studies reported information on training of providers (See Table 4). Descriptions of how providers were trained, and standardisation of provider training, both demonstrated moderate fidelity. Reporting of assessment of provider skill acquisition and of skill maintenance over time was poor across trials, with the two studies that did report these aspects reporting use of regular supervision of facilitators by clinical psychologists. No studies reported assessment of provider good fit for the intervention at hiring stage or use of a training plan taking trainees' different learning styles, and educational and experiential backgrounds into account, which is a significant omission given its importance according to the NIHBC (Bellg et al., 2004; Borrelli et al., 2005).

Treatment Delivery. Overall fidelity for ensuring that intervention dose was delivered as intended was good. Specification of methods to ensure the content of the intervention was delivered as intended, and the use of a treatment manual for intervention delivery demonstrated moderate fidelity. In addition to treatment manuals, studies reported using facilitator self-reported adherence to intervention protocol (van der Zwan et al., 2019); training to ensure consistency of intervention delivery (Weis et al., 2017); online fixed-amount delivery of intervention sections (Loughnan et al., 2018; 2019) and audiotaped fidelity monitoring (Zelkowitz et al., 2011). All other aspects of treatment delivery were rated as low fidelity, except a priori specification of treatment fidelity, which was not reported in any study (see Table 4).

Treatment Receipt. Reporting of strategies to improve participant understanding of the intervention was good across trials and included education sessions (Austin et al., 2008; Beattie et al., 2017; Bittner et al., 2014; Fotiou et al., 2016; Richter et al., 2012; Urizar et al., 2011; van der Zwan et al., 2019; Vieten & Astin, 2008); home visits involving observation, clarity and feedback on child-parent interactions (Castel et al., 2016); additional online resources (Loughnan et al., 2018; 2019), weekly phone calls to answer queries (Tragea et al., 2014), and discussion (Urizar et al., 2019; Vieten & Astin 2008; Zerkowitz et al., 2011).

Reporting of strategies to improve participant performance of learned skills during the intervention period and in settings whether the intervention might be applied was moderate across studies. Reporting of assessment of participant understanding of the intervention, and assessment of participant ability to perform intervention skills in the intervention or settings in which skills might be applied, was poor. Of those studies that did assess participant performance of intervention skills, this was done using direct observation of participants (Castel et al., 2016), monitoring of group intervention sessions (van der Zwan et al., 2019), and video recording of participants engaging in intervention behaviours (Zerkowitz et al., 2011). Reporting of consideration of multicultural factors in the intervention was poor (Roman et al., 2009; Tragea et al., 2014; Urizar et al., 2011; uriaz et al., 2019) and those studies that did report this reported consideration of participant's native language (Urizar et al., 2011; 2019) and the use of experiential and cultural knowledge and skills in intervention development (Roman et al., 2009).

Treatment enactment. Reported of strategies to assess participant use of intervention skills in daily settings was poor. Those studies that did report this reported use of post-program phone interviews (Beattie et al., 2017), at home observations of intervention behaviours (Castel et al., 2016), diary use to record skill activity (Tragea et al., 2014; van der Zwan et al., 2019), and an at-home session involving evaluation (Zelkowitz et al., 2011). Reported of strategies to improve performance of intervention skills in daily settings was moderate and included: at-home intervention practice (Bittner et al., 2014; Richter et al., 2012; Urizar et al., 2011; van der Zwan et al., 2019), home visits (Castel et al., 2016; Roman et al., 2009; Zelkowitz et al., 2011), provision of at-home reading material (Vieten & Astin, 2008) and audio CDs (Fotiou et al., 2016; Tragea et al., 2014; Vieten & Astin, 2008), and action planning to implement skills (Loughnan et al., 2018; 2019).

Discussion

Main Findings

This review is the first systematic examination of reported intervention fidelity within trials of interventions to reduce or prevent anxiety and/or stress in the first 1000 days. Overall, average fidelity scores were 'low' to 'moderate' across reviewed studies, with considerable range in fidelity scores across studies. Ratings for fidelity domains were also 'moderate' to 'low', with variability across individual fidelity components.

All but one intervention (van der Zwan et al., 2019) included delivery within a medical setting, with many including delivery by healthcare professionals (HCPs). However, training of intervention providers was the lowest scoring fidelity component in the current review. Where facilitator training does occur, there is a lack of evaluation of provider intervention delivery skills. This is problematic because assessment of provider skills is associated with increased effectiveness of health interventions (Taylor et al., 2011; Wang et al., 2015). Insufficient reporting of provider characteristics (e.g. experience, knowledge) and skill assessment in the reviewed studies also makes it difficult to determine if outcome inconsistencies are due to true lack of effect, ineffective training and/or provider skill or suitability (Taylor et al., 2011; Toomey et al., 2017; Wang et al., 2017; Wang et al., 2015). As such, future consideration and reporting of provider training is essential in stress/anxiety interventions in the first 1000 days.

Although study design was the highest rated fidelity domain in the current review, many aspects were insufficiently reported. Poor reporting of control conditions has also been noted in previous fidelity reviews (McArthur et al., 2012; Preyde & Burnham, 2011) and leads to uncertainty regarding content and processes in these conditions, limiting interpretations of intervention effects (Hilvert-Bruce et al., 2012). In this review many control conditions are described as treatment-as-usual, without further elaboration (Bittner et al., 2014; Castel et al., 2016; Richter et al., 2012; Roman et al., 2009; Urizar et al., 2011; Weis et al., 2017). Standard prenatal and postpartum care differs across contexts, locations and individual circumstances, creating ambiguity about the content and processes of these conditions (Hanafin & O'Reilly, 2014). Similarly, limited reporting of dose equivalence between conditions in the current review, results in uncertainty about whether any observed differences relate to the amount of treatment received. Improving reporting of dose equivalency in future trials is essential to improve transparency and facilitate more robust and reliable estimates of intervention effects (Michie et al., 2016; Lorencatto et al., 2016).

Insufficient reporting of what intervention components were delivered impacts our ability to interpret outcomes of specific interventions and/or intervention components (Bellg et al., 2004). Useful methods to record intervention delivery identified in this review include facilitator self-report, videotaping and audio recording of intervention sessions. Increased utilisation of such approaches in future stress and anxiety interventions in the first 1000 days can maintain delivery integrity and overall fidelity, and facilitate more robust interpretations of intervention effects. Useful strategies to improve participant comprehension and ability to perform stress and/or anxiety reduction skills were also noted

in the current review. These included post-program phone call interviews, at-home observations, and diary use to record skill activity. Consideration and incorporation of such strategies are important as better understanding and ability to perform intervention skills and behaviours can improve participant engagement, adherence and intervention effectiveness (Lee et al., 2012). The reviewed studies insufficiently reported how or whether participant comprehension or ability to use intervention skills in daily life setting was assessed however. In the first 1000 days, (expectant) parents are experiencing a transitional period, involving adaptation to new roles, responsibilities and acquiring additional knowledge around aspects of pregnancy and infant care (Solmeyer & Feinberg, 2011; Condon, Boyce & Corkindale, 2004; Chen et al., 2019; Huizink et al., 2017). Determining if participants understand and engage directly with the intervention, especially during a time of potential upheaval, is therefore essential.

Similarly, reporting of nonspecific effects such as the warmth of the provider, participant satisfaction or the quality of the person-to-person relationship (Toomey et al., 2018) is important as they are associated with increased treatment adherence (Hilvert-Bruce et al., 2012) and efficacy (Elvins & Green, 2008), as well as stress and anxiety outcomes (Razurel et al., 2017). As such, these factors may be especially important during this period and should be better reported.

Strengths and Limitations

This review has a number of strengths, including the use of the NIHBCB checklist, which is a comprehensive, widely validated checklist that facilitates robust examination of intervention fidelity. The comprehensive codebook used to extract data enhances rigor and

transparency in this review. While this review makes a significant contribution to our understanding of the implementation of stress and/or anxiety interventions across the first 1000 days, it is not without its limitations. The current review is unable to examine associations between fidelity and intervention effectiveness, due to a lack of statistical power and intervention heterogeneity (removed for peer review). The review included interventions specifically developed to prevent and/or reduce stress and anxiety in the first 1000 days. The review did not include those interventions used in this context but that are not explicitly developed to target stress and anxiety because our aim was to examine those interventions developed to target specific stress and anxiety mechanisms during this time period. As a result, not all interventions that have been used to prevent and/or reduce stress and anxiety are included and further research is needed to determine fidelity to other interventions in this area. Weighting of fidelity components is not captured in the NIHBC (Toomey et al., 2016), which may influence fidelity outcomes.

Conclusion

This is the first systematic evaluation of the fidelity of interventions to reduce or prevent stress and/or anxiety during the first 1000 days. Interventions currently demonstrate insufficient fidelity across a range of domains. Key methodological areas for improvement in future examinations of pre and postnatal stress and anxiety interventions include fidelity of comparator conditions, consideration of non-specific treatment effects, and fidelity of participant understanding and performance of intervention behaviours. Increased focus on use and reporting of fidelity strategies in relation to intervention providers is especially

important given the findings of the current review and the role of relational and supportive interactions in prenatal and early parenting interventions. Improving use and reporting of fidelity strategies will facilitate more robust evaluations of the effects of stress and anxiety interventions delivered in the first 1000 days.

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Table 1. Study characteristics

Author (year)	Participants	Timing	Intervention	Control	Outcomes	Quality
Austin et al., 2008	Pregnant women at risk of developing perinatal depression or anxiety 97.3% partnered 88.1% English speaking background 90.3% combined family income >\$40k Mean age(years)= 31.4 (SD=3.5)	Prenatal Late 1st trimester/early second trimester at commencement	Brief CBT group intervention	Active control Information based	At 4 months postpartum No significant difference in anxiety $p>.05$	High
Beattie et al., 2017	Low risk pregnant women All married Majority Australian Mean age (years): MiPP= 28.9 (SD=5.7), PSP= 28.5 (SD= 6.4)	Prenatal 24-28 weeks gestation at intervention commencement	Mindfulness in pregnancy program (MiPP)	Pregnancy Support Program (PSP) Generalised midwifery approach to intervention topics, without mindfulness	At 6 weeks after intervention completion Non-significant reductions in stress for MiPP condition ($p=0.822$, $d=.15$)	Moderate
Bittner et al., 2014	Pregnant women with elevated anxiety or depression All married or in relationship	Prenatal Approx. 16 weeks gestation at commencement	Adapted cognitive behavioural group program	Usual care	At 3 months postpartum Anxiety from baseline to post-intervention ($p=.246$, $n2=.019$); from baseline to 3months follow-up ($p=.529$, $n2=.006$) Anxiety sensitivity from baseline to post-intervention	High

	Mean age= 29.5 years				(p=.406, n2=.010); from baseline to 3months follow-up (p=.139, n2=.031)	
Castel et al., 2016	<p>Mothers (n= 53) and fathers (n=42) of preterm infants</p> <p>Majority have bachelors degree or higher</p> <p>Mothers mean age: Intervention= 29.6 (SD=5.2); Control= 31.2 (SD=4.4)</p> <p>Fathers mean age: Intervention= 29.6 (SD=5.2); Control= 31.4 (SD=5.9)</p> <p>Children</p> <p>% female: intervention= 62.5%, control= 47.1%</p> <p>12 months corrected age</p>	<p>Post-partum</p> <p>Child was 12 months corrected age at intervention commencement</p>	<p>Triadic attachment intervention program</p>	<p>Usual care</p>	<p>At 3 months</p> <p>Overall stress</p> <p>Mothers= p>.05 Fathers= p>.05</p> <p>At 18 months</p> <p>Global stress: Mothers= p<.001, Fathers p=.019;</p> <p>Parent Stress: Mothers= p=.0026, Fathers p=.068;</p> <p>Parent child stress: Mothers= p<.001, Fathers p=.0024</p> <p>PTSD at 18 months: Mothers (p<.001), Fathers (p=.0023); (p=.37), Fathers (p=.16); PTSD at 18 months: Mothers (p<.001), Fathers (p=.0023);</p>	<p>High</p>
Fotiou et al., 2015	<p>Parents of hospitalised premature infants</p> <p>Median age 34.5 (IQR=32,5, 40.5)</p> <p>91.5% married</p> <p>Majority moderately to highly satisfied with income (73.5%)</p>	<p>Post-partum</p> <p>Child was 10-15 days old at intervention commencement</p>	<p>Interactive training courses including information and relaxation strategies</p>	<p>Active information control</p>	<p>At 3 months after discharge:</p> <p>Stress (p=.699)</p> <p>Higher baseline stress= higher stress after controlling for condition (p<.001)</p> <p>Higher education (p=.003) and lower income satisfaction (p=.003)= higher stress after controlling for condition</p>	<p>High</p>

	Child born at median gestational age 34.5 (IQR= 20,40); age at baseline= 10-15 days				Morning cortisol (p=.94), +30 minutes cortisol (p=.263), bedtime cortisol (p=.263) State anxiety (p=.515), Trait anxiety (p=.02)	
Loughnan et al., 2019	Pregnant women with anxiety and/or depression Mean age= 31.61 (SD=4.0) 77% married 79% University degree 82% Australian	Prenatal Mean gestational week 21.66 (M=5.93) at intervention commencement	MUMentum Pregnancy program Brief unguided prenatal iCBT intervention tailored to women with anxiety and depressive symptoms	Wait-list usual care from health services. Provided with MUMentum Pregnancy Program at intervention completion	Anxiety at 4 weeks after intervention F(2,54.67)=6.48, p<.01, g=.76	Moderate
Loughnan (2) et al, 2019	Postpartum women with anxiety and/or depression Mean age: Intervention = 32.56 (SD: 4.53) Control = 32.77 (SD: 4.21) TAU 32.31 (SD: 4.90) 88% Married 74% University degree 78% Australia	Post partum	'MUMentum postnatal': Internet-delivered cognitive behavioural therapy	Treatment as usual	Anxiety (GAD-7) (F2, 94.04 = 9.13, p < 0.001). Patient Health Questionnaire (PHQ-9) : (F2, 93.80 = 9.06, p < .001)	Moderate

Richter et al., 2012	<p>Pregnant women with elevated stress, anxiety, and depression</p> <p>Mean age: Intervention= 29.19 (SD: 4.54) Control= 29.95 (SD: 4.29)</p> <p>65.57%= €1000 to 3000 net income per household</p> <p>All married or cohabiting</p> <p>All Caucasian German</p>	<p>Prenatal and postnatal</p> <p>Intervention commenced when women approximately 11.9 weeks pregnant</p>	<p>Specified cognitive-behavioral group program for expectant mothers with subclinically elevated psychopathological symptoms</p>	<p>Treatment as usual</p>	<p>At 3 months postpartum</p> <p>Cortisol CAR: $F(8,51) = 2.300$ $p = 0.047$; AUC, $F(2,58) = 0.188$, $p = 0.829$.</p> <p>PDQ: $F(1, 59) = 0.022$, $p = .883$</p> <p>PSS: $F(2, 56) = 0.082$ $p = .922$</p>	High
Roman et al., 2009	<p>Low income pregnant women</p> <p>Age: 31%= <20years; 50%= 21-25years; 19% >25years, range= 16-42 years</p> <p>82.6% unmarried</p> <p>27% african american, 23% hispanic 41% white</p>	<p>Prenatal and postnatal</p> <p>Intervention commenced when women approximately 11.9 weeks pregnant</p>	<p>Nurse-community health worker intervention</p>	<p>State-sponsored, Medicaid provided by HCPS (primarily nurse).</p> <p>Up to 9 prenatal and 9 postnatal visits. Received an average of 8.5 face-to-face total contacts</p>	<p>At 15 months postpartum</p> <p>Stress ($p = .058$)</p> <p>No effect based on high baseline stress ($p = .336$), significant difference if low psychosocial resources ($p = .019$), no effect if both low resources and high stress ($p = .131$)</p>	Moderate
Tragea et al., 2014	<p>Pregnant women</p> <p>Median age= 32 years</p> <p>73% completed higher education</p> <p>85% married</p> <p>96.6% live in Greece</p>	<p>Prenatally</p> <p>2nd trimester</p> <p>Mean gestation= 17weeks at intervention commencement</p>	<p>Information and relaxation exercises</p>	<p>Wait-list control</p>	<p>At 6 weeks follow-up</p> <p>Stress: mean difference -3.23 (95% CI: -4.29 to -0.29)</p> <p>State anxiety: mean difference -1.5 (95% CI: -2.7 to 1.7)</p> <p>Trait anxiety:</p>	High

					mean difference -2.29 (95% CI: -4.9 to 0.3)	
Urizar et al. 2011	<p>Women during pregnancy and postpartum</p> <p>Approx. 25 years (18-35 years)</p> <p>87%= annual household income less than \$30,000</p> <p>77% married or living with partner</p> <p>80% Spanish speaking Latina</p>	<p>Prenatal and postpartum</p> <p>2-28 weeks gestation at intervention commencement</p>	Cognitive behavioural stress management intervention	Usual care	<p>At 6 months</p> <p>Stress ($p < .01$)</p> <p>Morning, evening and average cortisol ($p > .05$)</p> <p>Cortisol slope ($p > .05$)</p> <p>At 18 months</p> <p>Stress ($p > .05$)</p> <p>Morning and evening cortisol ($p > .05$)</p> <p>Average cortisol ($p < .05$)</p> <p>Cortisol slope ($p > .05$)</p>	High
Urizer et al, 2019	<p>Prenatal women less than 17 weeks pregnant.</p> <p>71% Latina Women, 18% African American, 4% Asian American, 4% non-Hispanic white, 3% mixed ethnicity</p> <p>51% single.</p> <p>70% unemployed</p> <p>76% Annual income $< \\$20,000$</p> <p>71% high school education or less</p>	Prenatal women, less than 17 weeks pregnant.	Cognitive behavioural stress management intervention	Foundation's "Becoming a Mom" handouts	<p>Women receiving CBSM had lower perceived stress levels throughout pregnancy and early post partum compared to women in the control group ($p = .020$)</p> <p>Women with high prenatal anxiety, those in CBSM showed a steeper decline in their diurnal cortisol at three months post partum compared to those in the</p>	Moderate

	63% had at least one child already.				control group (p = .015).	
Van der Zwan et al, 2019	<p>Pregnant and Non-Pregnant Women</p> <p>Mean age 31.6, SD = 5.9</p> <p>20% unemployed 31% working 18% college</p> <p>60% university level education</p> <p>65% Nulliparous</p>	Both pregnant and nonpregnant women	Heart rate variability (HRV)-biofeedback on stress and stress-related mental health problems	Waitlist condition	<p>Immediately after intervention</p> <p>Anxiety : p=0.001</p> <p>Stress: p=0.19</p>	Moderate
Vieten & Astin 2008	<p>Pregnant women with history of mood concerns</p> <p>Mean age 33.9 (SD 3.8) years</p> <p>Mean household income = USD 89,677 (SD, USD 17,792)</p> <p>All married</p> <p>Majority (74%) white</p>	<p>Prenatal</p> <p>18-31 weeks gestation, M=25 (SD=4) weeks at intervention commencement</p>	Mindful Motherhood	Wait list usual care	<p>At 3 month follow up</p> <p>Stress: p= .35, d= .39</p> <p>Anxiety : p= .04, d= .85</p>	High
Weis et al., 2017	<p>Active duty women and wives of military service members</p> <p>Mean age= 28.72 years</p> <p>42%= college education</p>	Prenatal	Mentors Offering Maternal Support (MOMS)	Usual care	<p>At approx. 30 weeks gestation</p> <p>Anxiety-wellbeing: p>.05; anxiety-acceptance p>.05; anxiety-identification with</p>	High

	98% married 60% white	1st and 2nd trimesters	Mentoring support program		motherhood role p=.049; Anxiety- preparation for labour p=.017; anxiety-helplessness p>.05	
Zelkowitz et al., 2011		Post-partum 5 in NICU, 1–2 sessions per week; 1 at home 2-4 weeks after discharge	Cues intervention to reduce anxiety and enhance maternal sensitivity	Attention control condition	At 6-8 weeks corrected age Stress- NICU infant behaviour/appearance: mean difference= -.02 (95%CI: -0.1, 0.5) p= .14 Stress- parent role restriction: mean difference= -.00 (95%CI: -0.3, 0.3) p= .76 PTSD symptoms: Stress- NICU infant behaviour/appearance: mean difference= -.3 (95%CI: -0.8, 1.5) p= .54 Anxiety: mean difference= .95 (95%CI: 0.88, 1.04) p= .28	Low

Table 2. Intervention and Control Characteristics

	Intervention							Control		
Author (year)	Description	Components	Facilitator	Mode of delivery	Timing of delivery*	Duration and frequency	Theoretical basis	Description	Components & theoretical basis	Mode of delivery
Austin et al., 2015	Brief CBT group intervention Skills based	Behavioural strategies Weekly home task practice Education (perinatal anxiety and depression, and infant needs and behaviour) Pleasant event scheduling Relaxation training	Clinical psychologist and trained midwife	Group sessions in primary care setting	Prenatal Late 1 st trimester/early second trimester at commencement	6 weekly 2-hour sessions 1 later follow-up session	None stated	Active control Information based	Information (risk factors for postnatal anxiety and depression, triggers for postnatal distress) strategies to prevent and/or manage anxiety or depression List of local postnatal support services and how to access services	Booklet Brief verbal delivery of booklet contents

		<p>Goal setting</p> <p>Problem solving</p> <p>Cognitive strategies to address unhelpful attitudes</p> <p>Assertion skills</p> <p>Developing a broad social support network, including local postnatal support services</p>						<p>Advice to contact GP if become symptomatic</p> <p>GP advised of above by letter</p> <p>No theoretical basis stated</p>		
Beattie et al., 2017	Mindfulness in pregnancy program (MiPP)	<p>Mindfulness (of breath, eating, walking, movement, and listening)</p> <p>Body scan meditation tailored to pregnancy</p>	Trained midwife researcher/ investigator	<p>Group sessions</p> <p>In maternity care setting</p>	<p>Prenatal</p> <p>24-28 weeks gestation at intervention commencement</p>	8 weekly 2-hour sessions	<p>Theoretical constructs of mindfulness and cognitive behavioural therapy adapted for a pregnant population.</p> <p>The co-emergence</p>	<p>Pregnancy Support Program (PSP)</p> <p>Generalised midwifery approach to intervention topics, without mindfulness</p>	<p>Information (communication, empathy, body image, pain relief, breastfeeding, newborn care, mental health and postnatal depression)</p>	<p>8 weekly 2-hour group sessions</p> <p>Delivered by midwife</p>

		<p>Ice meditation</p> <p>B.R.A.N.N. decision making model to work in partnership with HCPs during labour and birth</p> <p>Birthing suite visits</p> <p>Daily record of mindfulness practices</p>					<p>model of behaviour reinforcement , which is a mindfulness-based cognitive behavioural therapy model</p>		<p>Identification and discussion of stressors</p> <p>Listening</p> <p>Identifying own strengths, and wants versus needs</p> <p>Self-portrait highlighting physical changes, emotional response to birthing, and breastfeeding images;</p> <p>Envisaging support networks</p>	
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									Brainstorming resources and childcare options. Birthing suite visits	
Bittner et al., 2014 Richter et al., 2012	Adapted cognitive behavioural group program	Psycho-education (stress, anxiety and depression) Cognitive behavioural strategies Exercise performance/role playing Progressive muscle relaxation Homework exercises/role playing	Trained clinical psychologist	Group sessions of 4 or 6 women	Prenatal Approx. 16 weeks gestation at commencement	8 weekly 90 minute sessions	None stated	Usual care	n/a Monthly visits with an obstetrician (biweekly visits from 8th to 9th month of pregnancy) 3 ultrasound scans CTG during 3rd trimester Blood and urine tests	Individual in-person

		Progressive muscle relaxation between sessions								
Castel et al., 2016	Triadic attachment intervention program	<p>Discussion of perceptions, emotions and experiences</p> <p>Observation of parent-child interactions</p> <p>Identification of emotional states</p> <p>Promotion of parents-infant triadic relationships to foster infant's cognitive, motor, socio-emotional and behavioural development</p>	Clinical psychologist	<p>At-home individual visits</p> <p>Consultations in neonatology ward</p>	<p>Post-partum</p> <p>Child was 12 months corrected age at intervention commencement</p>	<p>First four months= twice monthly 1 hour at-home visits</p> <p>Followed by monthly consultations in neonatology ward up to 22 sessions total over 14 months.</p>	<p>Attachment theory</p> <p>Parental reflective functioning theory</p> <p>Emotion theory</p> <p>Parenting and co-parenting concepts</p>	Usual care	Monthly visits to a practitioner for the first 6 months, and then every 3 months	Individual in-person

		<p>Promotion of parenting skills and attachment</p> <p>Supporting parents to understand child's cues and to respond</p> <p>Develop realistic expectations of child behaviour</p>								
Fotiou et al., 2015	Interactive training courses including information and relaxation strategies	Information on prematurity, stress in NICU; breast-feeding; preparation for discharge; infant care at home; positive thinking; healthy lifestyle; and self-knowledge.	Postgraduate researcher for NICU sessions	<p>Group sessions in NICU</p> <p>Audio CD for at home</p>	<p>Post-partum</p> <p>Child was 10-15 days old at intervention commencement</p>	<p>Five 90 minute sessions during NICU stay,</p> <p>At-home practice for 3 months after discharge</p>	None stated	Active information control	Information on prematurity; stress in NICU; breast-feeding; preparation for discharge; infant care at home	Five 90 minute sessions in NICU delivered by researcher on PowerPoint in NICU.

		<p>Practice of breathing, progressive muscle relaxation, and guided imagery relaxation techniques in sessions (lasting 15-20 minutes)</p> <p>At-home twice-daily practice of relaxation techniques using audio cd encouraged</p> <p>Reminders sent by text messages, or respective weekly telephone calls, during 3-months post-discharge</p>								At-home informative audio CD for 3 months after discharge.
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Loughnan et al., 2019a	MUMentum Pregnancy program Brief unguided prenatal iCBT intervention tailored to women with anxiety and depressive symptoms	Stand-alone, psychoeducational courses Introduction to CBT skills for anxiety and depression symptoms Cognitive restructuring Problem-solving Behavioural activation Relapse prevention Provision of general resources	n/a (online)	Lessons accessed sequentially via online Virtual Clinic Lesson content presented as short illustrated story of two fictional characters experiencing anxiety and depression during their pregnancy	Prenatal Mean gestational week 21.66 (M=5.93) at intervention commencement	Three lessons over a 4 week period	None reported	Wait-list usual care from health services. Provided with MUMentum Pregnancy Program at intervention completion	Not stated	Not stated
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		<p>Participants were notified of new lessons and reminded to stay on schedule via email and SMS reminders.</p> <p>Technical assistance, but no coaching or counselling provided.</p>								
Loughnan et al., 2019b	MUMentum postnatal program	<p>Psychoeducation</p> <p>Problem solving</p> <p>Controlled breathing and muscle relaxation</p> <p>Activity planning</p> <p>Relapse prevention</p>	n/a (online)	<p>Lessons accessed sequentially via online Virtual Clinic system</p> <p>Lesson content presented as short illustrated</p>	<p>Postpartum</p> <p>Within 12 months postpartum</p> <p>M= 4.55 months (SD=3.05) postpartum</p>	<p>Three lessons, each completed every 2nd week, over 6 weeks in total</p>	None reported	<p>Wait-list treatment as usual, including any maternity or care services women wished to access</p>	Not stated	Not stated

		<p>Assertive communication</p> <p>Provision of general resources</p> <p>Technical assistance, but no coaching or counselling provided.</p>		<p>story of two fictional characters experiencing postpartum anxiety and depression</p>						
Roman et al., 2009	Nurse-community health worker intervention	<p>Relationship-based support</p> <p>Activities to increase self-esteem</p> <p>Promotion of positive health behaviours</p>	<p>Trained nurse and community health workers</p> <p>First assessment together followed by separate visits</p>	<p>Individual clinic and home visits</p>	<p>Prenatal and postnatal</p> <p>Intervention commenced when women approximately 11.9 weeks pregnant</p>	<p>Every other week during pregnancy</p> <p>Increased CHW visits for 1st month after birth if needed</p>	<p>Ecological stress theoretical framework</p>	<p>State-sponsored, Medicaid provided by HCPS (primarily nurse).</p> <p>Up to 9 prenatal and 9 postnatal visits.</p>	<p>Home visiting</p> <p>Multidisciplinary planning</p> <p>Transportation</p> <p>Psychosocial counselling</p>	In-person

		<p>Developing self awareness of stressors, causes of stressors</p> <p>Active problem solving</p> <p>Development of life goals</p> <p>Using community resources including specific focus on utilization of CHWs with nurses health.</p>				<p>Two visits per month until six months post birth.</p> <p>At six months, visits could be reduced to once a month if needed.</p> <p>Average no. of contacts was 24.4</p>		<p>Received an average of 8.5 face-to-face total contacts</p>	<p>Nutritional guidance</p> <p>Pregnancy and parenting education</p> <p>No theoretical basis</p>	
Tragea et al., 2014	Information and relaxation exercises	<p>Elements of standard maternity practice including:</p> <p>Lecture on stress and management techniques</p> <p>Education brochure about stress</p>	Trainer-consultant	<p>Individual</p> <p>Lecture</p> <p>Brochures</p> <p>Audio CD</p>	<p>Prenatally</p> <p>2nd trimester</p> <p>Mean gestation= 17weeks at intervention commencement</p>	<p>6 weeks</p> <p>Single lecture</p> <p>Relaxation techniques</p>	None stated	Wait-list control	<p>Elements of standard maternity practice including:</p> <p>Lecture on stress and management techniques</p> <p>Education brochure about stress</p>	<p>Lecture</p> <p>Brochures</p> <p>Telephone contact</p>

		<p>antecedents and consequences</p> <p>Brochures about diet and exercise</p> <p>Relaxation exercises:</p> <p>Diaphragmatic breathing</p> <p>Progressive muscle relaxation</p> <p>20 minute long audio cd</p> <p>Diary to record and control the frequency of relaxation techniques</p> <p>Brochure about importance of a healthy lifestyle through and routine to reduce stress and promote good health</p>		<p>Telephone/in-person contact</p>		<p>twice per day</p>			<p>antecedents and consequences</p> <p>Brochures about diet and exercise</p> <p>Weekly telephone communication</p> <p>Provided audio CD at end of 6 weeks</p>	
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		Weekly monitoring of relaxation techniques and effects via telephone or in-person meeting								
Urizar et al., 2011	Cognitive behavioural stress management intervention	<p>Prenatal sessions</p> <p>Cognitive behavioural strategies:</p> <p>Recognizing and modifying maladaptive thoughts</p> <p>Increasing positively reinforcing activities</p> <p>Identifying and increasing positive social networks</p> <p>Parenting strategies</p> <p>Stress management strategies:</p>	<p>Faculty, postdoctoral fellows, and advanced doctoral graduate students in clinical psychology</p> <p>Facilitators supervised by clinical psychologist</p>	<p>Group sessions (3-8 people) in hospital where receiving maternity services</p>	<p>Prenatal and postpartum</p> <p>2-28 weeks gestation at intervention commencement</p>	<p>Weekly sessions for 12 weeks prenatally</p> <p>Four booster sessions at 1, 3, 6, 12 months postpartum</p>	<p>Social learning theory</p> <p>Lewinsohn's behavioural approach to mood management</p>	<p>Usual care</p>	<p>Medical care from health care provider</p> <p>Information on locally available social services upon request, or if they developed clinical depression, throughout their participation in the study</p> <p>No theoretical basis</p>	<p>Individual in-person</p>

		<p>Information on physical symptoms and effects of stress</p> <p>Diaphragmatic breathing</p> <p>Guided imagery</p> <p>Mindfulness-based training</p> <p>Progressive muscle relaxation</p> <p>Postpartum booster sessions</p> <p>Reviewed prenatal concepts</p> <p>Discussed challenges with new-born care</p>								
Urizar et al., 2019	<p>SMART Moms</p> <p>Cognitive behavioural stress</p>	Interactive activities (e.g. role playing)	Clinically trained facilitators	Group sessions of 3 to 8 pregnant women in clinic	Prenatal 2-17 weeks pregnant at intervention	Weekly sessions for 8 weeks	Not stated	Active control group	<p>8 week program</p> <p>Received printed materials weekly</p>	None stated

	management intervention	<p>Cognitive behavioural strategies</p> <p>Psychoeducation</p> <p>Diaphragmatic breathing</p> <p>Muscle relaxation</p> <p>Mindful thought awareness</p> <p>Coping strategies</p> <p>Supportive imagery</p> <p>Communication skills</p> <p>Information on using skills in postpartum</p>		where women receive prenatal services	commencement (M=10, SD=4.25)	At home practice			on prenatal health information	
van der Zwan et al., 2019	HRV Biofeedback	<p>HRV biofeedback</p> <p>Abdominal breathing</p> <p>Psychoeducation</p> <p>Behavioural exercises (e.g.</p>	Trained clinical psychologist and trained research assistants	Group sessions of 2 to 6 women	<p>Prenatal</p> <p>Mean gestation 19.33 weeks (SD= 5.2) at</p>	Weekly sessions (60 to 90 mins) for 5 weeks	Not stated	Waitlist treatment as usual	Not stated	Not stated

		registering complaints, planning next weeks leisure and obligation activities).		At home practice	intervention commencement	At home breathing practice of 10min/day up to 2x 20 min/day				
Vieten & Astin (2008)	Mindful Motherhood	<p>Equal parts education, discussion, and experiential exercises</p> <p>Focus on thought sand feelings via breath awareness and contemplative practices</p> <p>Guided body awareness meditation</p> <p>Mindful hatha yoga</p> <p>Presentation of psychological concepts that incorporate</p>	<p>Clinical psychologist</p> <p>Certified yoga instructor</p>	<p>Group sessions of 12 to 20 women in large urban hospital and synagogue</p> <p>Audio CD</p> <p>Reading material</p>	<p>Prenatal</p> <p>18-31 weeks gestation, M=25 (SD= 4) weeks at intervention commencement</p>	<p>Weekly sessions (2hrs) for 8 weeks</p> <p>20 minutes daily at home practice</p>	<p>MBSR</p> <p>MBCT</p> <p>Acceptance and Commitment Therapy</p>	Wait list usual care	Not stated	Not stated

		<p>mindfulness, e.g. acceptance</p> <p>Weekly readings relevant to the material presented in class</p> <p>20-minute long audio CD disc of guided meditations for daily use</p>								
Weis et al., 2017	<p>Mentors Offering Maternal Support (MOMS)</p> <p>Mentoring support program</p>	<p>Educational sessions on:</p> <p>Pregnancy acceptance</p> <p>Identifying with motherhood</p> <p>Mother-daughter relationship</p> <p>Family-partner relationship</p> <p>Well-being of self and baby</p>	<p>Trained mentors who were women married to military members or were active duty personnel and were mothers</p>	<p>Group sessions in military prenatal clinics</p>	<p>Prenatal</p> <p>1st and 2nd trimesters</p> <p>Mean gestational age at baseline= 9 weeks (SD=2.47)</p>	<p>1 hour sessions bi-weekly for 16 weeks (8 sessions total)</p>	<p>None stated</p>	<p>Usual care</p>	<p>Note stated</p>	<p>Not stated</p>

		Fear of helplessness in labour Labour preparation								
Zelkowitz et al., 2011	Cues intervention to reduce anxiety and enhance maternal sensitivity	Reading and recognising own anxiety/distress Muscle relaxation Guided imagery Cognitive reframing Reading and recognising infant cues and distress Information about thoughts, feelings and behaviours Information about VLBW infant behaviour Telephone follow-up call, to review the techniques and maintain contact	Trained nurse, psychologist or graduate student in nursing or psychology	In-person individual sessions in private location in hospital Brochure	Postpartum	Six 60-90 minute individual sessions: 5 in NICU, 1-2 sessions per week; 1 at home 2-4 weeks after discharge Total dose= 9-10 hours	None stated	Attention control condition	6 contacts with a Care intervener at regular intervals Brochure Information on infant care, feeding and common health problems of preterm infants as well as general information about infant care and feeding readily available to all mothers of infants	Individual in-person contacts in private setting in NICU that parallel intervention group Brochure

		Videotaped mother-infant interaction								
		Videoed interaction reviewed with facilitator								
		Booklet of session contents								

Note: *= timing of intervention and control delivery the same unless otherwise stated

B.R.A.N.N: Benefits, Risks, Alternatives, Needed, Now; CBT: Cognitive Behavioural Therapy; CHW: Community Health Worker; CTG: Cardiotocography; GP: General Practitioner; HCPs: Healthcare Professionals; HRV: Heart rate variability; iCBT: Internet Cognitive Behavioural Therapy; MBCT: Mindfulness Based Cognitive Therapy; MBSR: Mindfulness Based Stress Reduction; MiPP: Mindfulness in Pregnancy Intervention; MOMS: Mentors Offering Maternal Support; NICU: Neonatal Intensive Care Unit; VLBW: Very Low Birth Weight

Table 3

Reported adherence within fidelity domains across studies

Category	Present	Applicable	Component percent (%)
Study Design	130	239	54%
Training of Providers	22	98	22%
Delivery of Intervention	60	142	42%
Receipt of intervention	35	80	44%
Enactment of Intervention	17	32	53%

Note. Each study was independently coded for all NIHBCB components, with components coded as either 'present' (1) or 'absent' (0). The 'present' scores above represent the total number of all NIHBCB components identified across all studies. The applicable scores represent the total number of all NIHBCB components that could have been across all studies; components not applicable to individual studies were coded as "not applicable".