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Depression Screening and Patient Outcomes in Pregnancy or Postpartum: a Systematic Review

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ABSTRACT

Objective: Clinical practice guidelines disagree on whether health care professionals should screen women for depression during pregnancy or postpartum. The objective of this systematic review was to determine whether depression screening improves depression outcomes among women during pregnancy or the postpartum period.

Methods: Searches included the CINAHL, EMBASE, ISI, MEDLINE, and PsycINFO databases through April 1, 2013; manual journal searches; reference list reviews; citation tracking of included articles; and trial registry reviews. RCTs in any language that compared depression outcomes between women during pregnancy or postpartum randomized to undergo depression screening versus women not screened were eligible.

Results: There were 9,242 unique titles/abstracts and 15 full-text articles reviewed. Only 1 RCT of screening postpartum was included, but none during pregnancy. The eligible postpartum study evaluated screening in mothers in Hong Kong with 2-month-old babies (N=462) and reported a standardized mean difference for symptoms of depression at 6 months postpartum of 0.34 (95% confidence interval=0.15 to 0.52, P<0.001). Standardized mean difference per 44 additional women treated in the intervention trial arm compared to the non-screening arm was approximately 1.8. Risk of bias was high, however, because the status of outcome measures was changed post-hoc and because the reported effect size per woman treated was 6-7 times the effect sizes reported in comparable depression care interventions.

Conclusion: There is currently no evidence from any well-designed and conducted RCT that screening for depression would benefit women in pregnancy or postpartum. Existing guidelines that recommend depression screening during pregnancy or postpartum should be re-considered.

INTRODUCTION

Depression is a leading cause of disability among women,¹ and pregnancy and postpartum are considered periods of high risk.^{2,3} The prevalence of major depressive disorder during pregnancy and postpartum is similar to rates among women during non-childbearing periods,⁴⁻⁸ but is associated with poor maternal and infant outcomes and, thus, has important consequences for depressed women, as well as for infants and families.^{3,9-13} Depression during pregnancy and postpartum is challenging to identify and manage, and healthcare professionals may prioritize health issues more directly related to pregnancy and the well-being of the foetus and infant. Improving depression care during pregnancy and postpartum is a priority, and one solution that has been proposed is routine depression screening.¹⁴⁻¹⁶

Screening for depression, however, is controversial.¹⁷⁻²¹ In the context of primary care, the United States Preventive Services Task Force (USPSTF), in 2009, recommended screening for depression only when staff-assisted depression care programs are in place to ensure accurate diagnosis and effective treatment and follow-up.²² In contrast, in their 2010 guideline, the United Kingdom (UK) National Institute for Health and Care Excellence (NICE), did not recommend routine screening, but rather that primary care physicians be alert to possible depression in their patients.²³ In 2013, the Canadian Task Force on Preventive Health Care's (CTFPHC) updated guideline recommended against screening for depression.²⁴

In 2010, the American College of Obstetricians and Gynecologists recommended that depression screening be "strongly considered" in both pregnancy and the postpartum period; the report noted that there was not sufficient evidence to support a "firm recommendation."¹⁴ Also in 2010, the American Academy of Pediatrics recommended that paediatricians screen new mothers for depression during well-child visits in the 6 months following birth.¹⁵ Neither of these recommendations, however, was based on a systematic review of the evidence. In the UK, the

National Screening Committee^{25,26} determined in 2001, and again in 2010, that there is no evidence that postnatal screening would improve health outcomes. A 2007 NICE guideline, on the other hand, recommended routine administration of 2 questions about depression at several points during pregnancy and postpartum.¹⁶ This recommendation was based on a review of screening tool accuracy, however, and not on evidence from any randomized controlled trials (RCTs) that depression screening would improve health outcomes.

Systematic reviews on depression screening in pregnancy and postpartum also differ in their findings. A 2009 UK Health Technology Assessment (HTA) systematic review included 5 studies, 3 of which were RCTs, and concluded that it was not possible to disentangle the effects of screening from the effects of enhanced depression care interventions that were linked to positive screens.^{27,28} In contrast, the authors of a 2013 United States Agency for Healthcare Research and Quality (AHRQ) systematic review,² consistent with the USPSTF recommendation for primary care, concluded that there was evidence for screening when staff-assisted depression care supports are in place, but not without these supports.²² This conclusion was based on 5 studies, 4 of which were RCTs. The different conclusions of the HTA and AHRQ reviews are not surprising when one considers that the sets of trials included in the reviews did not overlap. None of the RCTs in the HTA systematic review^{27,28} were included in the 2013² or 2005²⁹ versions of the AHRQ review and vice versa, though neither review addressed this discrepancy.

Criteria that should be met before a screening program is considered for clinical practice are well-established.^{25-26,33-34} It is reasonable to consider screening for important and prevalent conditions that can be effectively treated and that cannot be readily detected without screening. For screening to be considered, screening methods should be accurate and carry only a tolerably small risk of false positive results. Screening is an intervention, and, thus, for screening to be recommended for practice benefits in excess of potential harms should be demonstrated in wellconducted randomized controlled trials.

One reason why existing systematic reviews on depression screening have generated discordant results is that they have not defined the characteristics necessary for trials that test the effects of screening.^{20-21,30} A test of a screening program must include the use of a screening tool with a defined cut-off to select patients for further evaluation and, if appropriate, treatment.^{17,31} In addition, since screening is an intervention that is carried out to identify depressed patients who have not yet been diagnosed and treated, patient eligibility and randomization should occur before the screening intervention is conducted, and only patients without a current diagnosis and treatment should be included. In order to separate the effects of screening from the effects of providing additional or enhanced depression care, similar depression management options should be available to patients with depression in the screening arm of the trial and patients in the non-screening arm who are identified as depressed by patient report or unaided clinician diagnosis.

The USPSTF has described adverse effects that could occur with depression screening, including false-positive results with potentially expensive referrals and diagnostic workups in some women without depression, costs and adverse effects of treatment for women misdiagnosed as depressed, and the potentially adverse effects of labeling.²² Only one study has examined the cost-effectiveness of routine depression screening during pregnancy or postpartum, and the authors of the study concluded that the cost-effectiveness ratio would substantially exceed normal cost-effectiveness thresholds, even if screening would improve depression outcomes.³²

Before a screening program is initiated, there should be evidence from high-quality RCTs of improved health outcomes that would justify the cost and potentially adverse effects of screening.^{26,31,33,34} Thus, the objective of the present systematic review was to evaluate whether

there is evidence from well-conducted RCTs that depression screening programs designed to improve depression care in pregnancy or postpartum would reduce depression symptoms compared to usual care. An explicit set of criteria were used to determine whether RCTs evaluated depression screening, including (1) the determination of patient eligibility and randomization prior to screening; (2) the exclusion of patients with a current depression diagnosis or existing depression treatment; and (3) the provision, in both trial arms, of similar depression management options to patients determined to be depressed via screening or other mechanisms.

METHODS

Search strategy

The CINAHL, EMBASE, ISI, MEDLINE, and PsycINFO databases were initially searched on August 29, 2010. Searches were updated on July 26, 2012 and April 1, 2013. Searches included articles published January 2007 or later because we based our search strategy on the strategy used in the HTA systematic review,^{27,28} which included articles published through February 2007. See Appendix 1 for search terms. In addition to database searching, manual searching was performed on reference lists of included articles, relevant systematic reviews (Appendix 2), and 45 selected journals (January 2013 through May 2013; Appendix 3). We also tracked citations of included articles using Google Scholar³⁵ and searched clinical trial registries to attempt to identify unpublished depression screening RCTs. We searched the ClinicalTrials.gov trial registry ("depression AND screen*" in any field) and the World Health Organization's International Clinical Trials Registry Platform ("depression AND screen*" in title) from inception to April 30, 2013. The WHO registry platform is a central database that provides access to many different clinical trial registries from around the world. Search results were downloaded into the citation management database RefWorks (RefWorks-COS, Bethesda, MD, USA), and the software's duplication check was used to identify citations retrieved from multiple sources.

Identification of eligible studies

Eligible studies were RCTs reported in any language that compared depression outcomes between women in pregnancy or postpartum who underwent depression screening versus women who did not. Screening was defined per the UK National Screening Committee's definition.³¹ Thus, eligible RCTs had to include a case identification strategy based on a defined cut-off score on a depression screening tool to make decisions regarding further assessment or treatment of depression. Examples of screening tools used in pregnancy or postpartum include, but are not limited to, the Edinburgh Postnatal Depression Scale (EPDS) and the 9-item Patient Health Questionnaire (PHQ-9). Symptoms of postpartum depression may develop throughout the first year after the birth of the infant, and it is during this period that women have the most contact with health professionals.³⁶ Thus, studies that screened women at any time during pregnancy or up to 12 months postpartum were eligible for inclusion.

In addition to comparing depression outcomes between screened and non-screened patients, eligible RCTs were required to fulfil 3 criteria necessary to test the effects of depression screening. Included RCTs had to (1) determine patient eligibility and randomize patients prior to administering the screening test; (2) exclude patients who were known to have a current episode of depression and patients who were already being treated for depression close to the time of eligibility assessment; and (3) provide similar depression management and treatment resources to patients who were identified as depressed via screening in the screening arm of the trial and patients in either the screening or non-screening arms of the trial who were identified as depressed via other methods (e.g., unaided clinician diagnosis, patient report). We included RCTs that reported depression outcomes, but not RCTs that only reported rates of depression

recognition or treatment. This is because recommendations for screening should be based on evidence of improved health outcomes. Increased treatment without improved depression outcomes would expose patients to costs and potential harms, but would not provide health benefits.¹⁷

Two investigators independently reviewed articles for eligibility. If either deemed an article potentially eligible based on title/abstract review, then a full-text review was completed. Disagreements after full-text review were resolved by consensus. All titles/abstracts and full-text articles were available in English or Spanish and reviewed by two investigators fluent in those languages.

Evaluation of eligible studies

Two investigators independently extracted and entered data into a standardized spreadsheet (see Appendix 4). Discrepancies were resolved by consensus. Risk of bias was assessed with the Cochrane Risk of Bias tool³⁷ (see Appendix 5) by 2 investigators with discrepancies resolved by consensus. Continuous post-intervention effect sizes were reported using the Hedges' *g* statistic,³⁸ which represents a standardized difference between 2 means. Because only 1 eligible study was identified, there was no pooling of results.

RESULTS

Selection of Eligible RCTs and Outcomes

Of 9,242 unique titles/abstracts from the database search, 15 were selected for full-text review. There were no eligible RCTs of depression screening during pregnancy and only 1 eligible RCT during the postpartum period.³⁹ See Figure 1. No additional eligible trials were identified via manual searching of reference lists of included articles and relevant systematic reviews, citation tracking, or review of trial registries.

The RCT included in the systematic review³⁹ studied Chinese mothers with 2-month-old babies who visited maternal and child health centres in Hong Kong. This study was published after the 2009 HTA review,^{27,28} but was included in the 2013 AHRQ review.² Women in the intervention group were screened with the EPDS and provided with nurse counselling or a community psychiatry referral if they had EPDS scores ≥10, reported suicidal ideation, or were assessed as "probably" depressed based on a separate clinical assessment, described as "observing participants' expression and behaviour, enquiring about feelings, appetite, sleep pattern, childcare and suicidal ideas" (p. 294). Women in the control group were also provided counselling or a community psychiatry referral if they were evaluated as probably depressed based on the same clinical assessment protocol.

Of the 231 women in the screening arm of the trial, 73 were identified as possibly depressed (32%), and 55 received depression treatment (24%). In the non-screening trial arm, 14 of 231 patients were identified as possibly depressed (6%), and 11 received treatment (5%). As shown in Table 1, the authors of the study reported a standardized mean difference (SMD) for symptoms of depression per woman screened, based on EPDS scores at 6 months postpartum, of 0.34 (95% confidence interval [CI] = 0.15 to 0.52, P < 0.001). Based on General Health Questionnaire-12 (GHQ-12) scores, the SMD per woman screened was 0.16 (95% CI = -0.02 to 0.35, P = 0.084). However, most women in the screening group who are included in these calculations of effect did not receive a referral for intervention. If the achieved effect is allocated to the 44 additional women who received a referral for depression care in the intervention group (44 women), then the SMDs per additional woman who received depression care were approximately 1.78 based on the EPDS and 0.86 based on the GHQ-12.

Risk of Bias

Risk of bias ratings, assessed with the Cochrane Risk of Bias tool, for the eligible RCT are shown in Table 2. Risk of bias was rated "Low" for Random Sequence Generation and Allocation Concealment. Risk of bias was "Unclear" for Blinding of Participants and Personnel, since a physician with access to patient data at trial entry, including EPDS scores, made final treatment recommendations. Because the EPDS was only administered pre-treatment to women in the screening arm of the trial, this physician was likely not blind to whether women were in the screening or non-screening trial arms. Risk of bias was also "Unclear" for Blinding of Outcome Assessment since outcomes were based on self-report questionnaires, and women would have known whether they received depression management services and that depressive symptoms were being assessed. Risk of bias was "High" for Selective Outcome Reporting. This was because in their 2005 trial registration (NCT00251342,

http://clinicaltrials.gov/ct2/show/NCT00251342), the authors indicated that there would be 2 primary outcome measures, the EPDS and GHQ-12. In the published article³⁹ reporting trial results, however, they described only one primary outcome measure (EPDS scores), which was statistically significant. GHQ-12 scores, which were not statistically significant, were described as a secondary outcome. Remaining risk of bias domains were rated "Low" or "Unclear." Other Sources of Bias was rated "Unclear" because changing the status of outcome variables based on trial results raises general concerns about the fidelity of trial conduct and reporting, and the effect sizes reported appeared to be substantially larger than what could be reasonably expected from the low-intensity depression care intervention, which involved a psychiatric referral or nurse counselling (See Table 2 and Discussion).

Excluded Studies and Comparison with Previous Systematic Reviews

There were 5 studies⁴⁰⁻⁴⁴ included in the 2009 HTA systematic review,^{27,28} although only 3 were RCTs.⁴⁰⁻⁴² As shown in Table 3, 1 RCT⁴¹ used the EPDS to inform midwife home care,

but it was not used as a screening tool with a defined cut-off to determine whether women would be formally assessed or treated for depression. Another RCT,⁴² which was conducted with women at high risk for depression, included EPDS scores in a set of risk factors for postpartum depression, but the EPDS was not used for screening. General practitioners of all women in the intervention group received risk status letters that described a number of different risk factors, regardless of EPDS results. The only RCT⁴⁰ in the HTA review that included a depression screening component, which was published as an abstract only, provided major care enhancements that did not allow separation of the effects of screening and depression treatment.

The 2013 AHRQ review² also included 5 studies,^{39,45-48} 1 of which was included in the present review.³⁹ Of the other 4 studies, 3 were RCTs.⁴⁶⁻⁴⁸ As shown in Table 3, 1 RCT⁴⁶ used scores on a risk screening tool to determine study eligibility, but did not include screening as part of the study intervention. The other 2 RCTs^{47,48} incorporated screening with the EPDS. However, both tested enhanced depression care paradigms that were only provided to women identified as depressed in the intervention arms of the trials, but not to women identified as depressed in the control arm.

DISCUSSION

The main finding of this systematic review was that there was only 1 RCT³⁹ that fulfilled criteria for a test of a screening intervention since it compared depression outcomes between women in pregnancy or postpartum randomized to be screened or not screened for depression and (1) determined trial eligibility and randomized women prior to implementing a screening intervention; (2) excluded patients already being treated for depression who would not be screened in practice; and (3) provided similar depression care options to patients in the screening and non-screening arms of the trial who were determined to have depression. That RCT reported

that women in the screening arm of the trial had significantly lower depression symptom scores, based on the EPDS, than women in the control arm.

There appears to be substantial risk, however, that results from this trial may not be replicable in other patient samples. One reason is that the authors of the trial changed the status of outcome variables based on trial results.⁴⁹ Another reason is the unusually large size of the reported effect. The trial included 231 women in both the screening and non-screening arms of the trial, which is a fraction of the number that would likely be needed to test screening since most participants in a screening intervention do not receive treatment. The authors of the trial provided a minimally intensive depression care intervention to women with positive screens, which included either nurse counselling or a psychiatry referral, and reported an effect size on the EPDS of approximately 1.8 standard deviations per woman who received depression care. A meta-analysis of 30 collaborative depression care intervention trials, in contrast, reported an overall effect size of only 0.25 standard deviations.⁵⁰ Another meta-analysis, which reviewed evidence for psychological treatments of depression for adults in primary care, found an overall effect of 0.31 standard deviations in 15 included trials.⁵¹ None of the individual RCTs included in either meta-analysis approached the effect size reported in the trial included in our review. If the actual effect for minimally intensive depression interventions in non-psychiatric settings is between 0.25 and 0.31 standard deviations, the probability of finding an effect of SMD = 1.8standard deviations or greater in a sample the size of that reported by Leung et al.³⁹ would be less than 1 in 100,000. Positive results from substantially underpowered trials that report excessively large and statistically significant effects are often false positives,⁵² and there is concern that this may be the case with this study.

Of the 6 RCTs included in recent HTA and AHRQ systematic reviews^{40-42,46-48} that were excluded in the present systematic review, only 3^{40,47,48} used a defined cut-off on a screening tool

to identify patients for further assessment or treatment. All 3 of these RCTs determined trial eligibility and randomized patients prior to implementing the screening process, which is important because screening is intended to identify patients whose depression has not been previously recognized. All 3 trials, however, provided substantial depression care enhancements to patients who were identified as depressed via screening, but not to patients in the non-screening trial arms who were identified via other methods, such as patient report or clinician recognition, which did not allow the effects of screening and the effects of providing better depression care to be disentangled. In addition, none of the 3 trials excluded patients who were already being treated for depression. Existing depression treatment should be an exclusion criteria in depression screening trials, since screening is done to identify people who are not already known to have depression.

There are numerous examples of screening programs that have already been implemented in pregnancy or postpartum. In the US, at least 10 states have active legislation related to screening for postpartum depression.⁵³ The first of these programs, the New Jersey Postpartum Wellness Initiative, has required, since 2006, depression screening of women who have recently given birth.⁵³ A 2011 analysis of the effects of the program, however, did not find any increase in postpartum depression treatment or follow-up care among Medicaid recipients following implementation.⁵³ In the UK, beginning in 1999, the National Service Framework for mental health has required protocols for the management of postnatal depression, which has resulted in widespread implementation of screening strategies, although, similarly, without documented evidence of benefit.²⁶

The present systematic review did not find any well-designed and conducted RCTs that tested whether depression screening in pregnancy or postpartum is effective, with or without enhanced, staff-assisted depression care for women identified as depressed. Without evidence

from RCTs that depression screening would benefit patients, the possibility of adverse events due to depression screening should be considered.^{22,24,54} These may include a high rate of false positive findings and potentially costly referrals and diagnostic workups for some non-depressed women, the potentially adverse effects of labelling, and the costs and adverse effects of referral and treatment for some women who are not depressed. The one study³² that has examined the cost-effectiveness of routine depression screening in postpartum women concluded that the cost-effectiveness ratio would be unfavourable, even if outcomes were improved, largely due to the high cost of managing women incorrectly identified as depressed. This is an important consideration because screening would consume scarce healthcare resources that will not then be available for other activities, such as providing better care to women whose depression is recognizable without screening, but who often do not receive adequate care.

Treatment options for women identified as depressed via screening include psychological treatments and pharmacotherapy, although women may have concerns about taking antidepressants during pregnancy due to reports of possible negative effects on foetal development.⁵⁵ In a recent meta-analysis of 23 observational studies, for instance, the use of antidepressants during the gestational period was associated with an increased risk of preterm delivery, lower birth weights, and lower Apgar scores.⁵⁶ Furthermore, certain antidepressants, such as selective serotonin reuptake inhibitors, have been associated with an increased risk of congenital malformations (such as congenital heart defects),⁵⁷ and persistent pulmonary hypertension of the newborn.⁵⁸ The majority of studies that have investigated the potential harms of antidepressants during pregnancy and postpartum have been conducted among patients already diagnosed and treated with these agents before pregnancy. Women who are identified as depressed during pregnancy and postpartum via screening, but who would not have been recognized without screening, may have relatively lower severity depression, and the risk-benefit

ratio of using antidepressants needs to be considered in this context and included in discussions of treatment options.

In summary, we did not find evidence to support recommendations to screen women for depression during pregnancy or postpartum. Well-designed and executed trials that assess the effects of depression screening and that can determine whether there is benefit to women in excess of costs and potential harms are needed. Ideally, a trial will be conducted that randomizes women who are not known to have depression to be screened versus not screened, with women identified as depressed in both trial arms having access to staff-assisted, collaborative depression care. Without evidence from such a trial, current screening recommendations should be reevaluated. Instead of screening, health care professionals working with women during pregnancy and postpartum should be encouraged to provide women, as well as their partners and families, with information about depression. Health care professionals should also be alert to the possibility of depression among pregnant and postpartum women and should attend to symptoms that may suggest depression, such as low mood, anhedonia, insomnia, and suicidal thoughts, through assessment and, as appropriate, referral or management.²⁴ Health care providers should be particularly vigilant for depression among women with general risk factors for depression or risk factors that have been identified in women in pregnancy or postpartum, including a history of depression, the presence of a chronic medical condition, unexplained somatic symptoms, chronic pain, increased and unexplained use of medical services, a history of traumatic life events, domestic violence, drug or alcohol abuse, low income, a low education level, single status or poor social support, and unintended pregnancy.^{16,23,24,69-62}

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Table 1. Summary of Included Randomized Controlled Trial of Screening for Depression in Pregnancy or Postpartum: Leung et al.³⁹

Year, Country	Study Funding Source	Setting / Time of Recruitment	Comparison	Number of Patients Randomized	Number of Patients in Analyses ^b	Intervention Duration	n Depression Outcomes: Hedges's g (95% CI) ^c
2011 Hong Kong	Non-Industry ^a	Mothers of 2-month- old babies recruited at maternal and children health centres.	Intervention: Usual care with clinical assessment for depression + screening for depression (EPDS \geq 10 or suicide ideation based on item 10 of EPDS).	Total: 462 Intervention: 231 Control: 231	Total: 462 Intervention: 231 Control: 231	6 months	$\frac{\text{EPDS:}^{\text{d}}}{g=0.34 \text{ (0.15 to 0.52)}}$ $\frac{\text{GHQ-12:}^{\text{d}}}{g=0.16 \text{ (-0.02 to 0.35)}}$
_			Control: Usual care with clinical assessment for depression.				

Abbreviations: CI = confidence interval; EPDS = Edinburgh Postnatal Depression Scale; GHQ-12 = 12-item version of the General Health Questionnaire; Tx = treatment; UC = usual care.

^a Based on registration in ClinicalTrials.gov (NCT00251342). ^b There were 215 women in the intervention and control groups with outcome data. Depression scores for the 32 women without data were replaced by the overall mean of the 430 women with outcome data. ^c Positive values reflect better outcomes for women in the intervention arm of the trial. ^d Effect sizes are per patient screened. There were 44 more patients who received depression management services in the screening arm of the trial compared to the non-screening arm. Thus, effect per patient treated was approximately g = 1.78 for the EPDS and g = 0.86 for the GHQ-12.

 Table 2: Assessment of Risk of Bias in Included Randomized Controlled Trial of Screening for Depression in Pregnancy or Postpartum: Leung et al.³⁹

Cochrane Risk of Bias Tool Domains ^a	Review Authors' Judgment	Support for Review Authors' Judgment
Random Sequence Generation	Low	Computer random number generator.
Allocation Concealment	Low	Sequentially numbered, opaque, sealed envelopes.
Blinding of Participants and Personnel	Unclear	Initial recommendations for depression management were made by a nurse blind to group status. However, initial recommendations were reviewed and final recommendations were made by a physician described as not involved in the study, but with access to EPDS scores, clinical notes, and nurse recommendations. Since EPDS scores were only available for intervention group patients, this may have influenced the level of management recommended, even though the recommending physician was not involved in the study. Type and amount of depression management services recommended and received were not reported.
Blinding of Outcome Assessment	Unclear	Outcomes were based on self-report questionnaires, and women completing the questionnaires would have known whether or not they received depression management services and that depression was being assessed.
Incomplete Outcome Data	Unclear	Used overall mean scores on depression outcome measures to replace missing values, but only 15 of 231 in each trial arm were missing outcome data.
Selective Outcome Reporting	High	The authors registered two primary outcome measures, EPDS and GHQ-12, in ClinicalTrials.gov (NCT00251342). In the published article, however, the authors stated that there was only one primary outcome, which was statistically significant (EPDS scores). GHQ-12 scores (not statistically significant) were listed as a secondary outcome.
Pharmaceutical Industry Funding ^b	Low	Non-industry sponsorship. ^c
Author-Industry Financial Ties and/or Industry Employment ^b	Unclear	No conflict of interest statement provided.
Other Sources of Bias	Unclear	Changing the status of outcome variables from primary to secondary based on trial results raises concern, generally, about the fidelity of the trial conduct and reporting, particularly because the effect sizes reported appear to be implausible without substantial bias based on other published depression management trials. ^d

Abbreviations: EPDS = Edinburgh Postnatal Depression Scale; GHQ-12 = 12-item version of the General Health Questionnaire.

^a See Appendix 5 for domain descriptions. Domains are scored as 'high', 'low', or 'uncertain' risk of bias. Risk of bias ratings were based only on published information. ^b Additional domain added to standard Cochrane Risk of Bias tool.^{63,64 c} Not reported in published article, but listed in ClinicalTrials.gov (NCT00251342). ^d The standardized mean difference in a meta-analysis of 30 collaborative depression care intervention trials was 0.25 per patient randomized to treatment. The effects reported in the Leung et al. trial were approximately 7 times (EPDS) and 3-4 times (GHQ-12) as large.

First Author Year Country	Included in 2009 UK HTA ^{27, 28a} , 2013 AHRQ Review ^{2b}	Depression Assessment or Treatment Decisions Based on Defined Cut- off on Screening Tool? (No/Yes)	Use of Screening Tool	Determined Eligibility and Allocation of Patients Prior to Screening Intervention? (No/Yes)	Eligibility and Allocation Prior to Screening Intervention	Excluded Already Diagnosed and Already Treated Patients? (No/Yes)	Diagnostic /Treatment Status	Similar Depression Management Options for Screened and Unscreened Trial Arms? (No/Yes)	Depression Management
Kung 2002 China ⁴⁰	HTA	Yes	Patients in intervention arm with EPDS ≥ 10 referred for in-depth assessment and phone follow-up depression care.	Yes	Women who delivered at a single hospital were eligible and randomized prior to hospital discharge to screening with EPDS versus routine clinical care.	Unclear	No information on depression diagnosis or treatment at time of enrollment provided in published abstract.	No	Intervention Arm: Weekly telephone follow-up contacts with midwives, social workers, and volunteers trained in basic counseling and interviewing skills.
MacArthur 2002 United Kingdom ⁴¹	HTA	No	Midwives used a symptom checklist and the EPDS to inform care plans and visit scheduling. No defined cut- off was described for the EPDS, and EPDS scores did not directly determine evaluation, referral, or treatment decisions.	Yes	Study midwife practices were randomized to multifaceted care enhancement versus usual care. All women who received postnatal care in participating midwife practices were eligible.	No	Current depression diagnosis or treatment not an exclusion criteria. No information on depression diagnosis or treatment at time of enrollment provided.	No	Control Arm: Usual care. Intervention Arm: Multifaceted care enhancement, including training of midwives to implement new model of care and use of symptom checklist and EPDS for care planning.

Table 3: Summary of Randomized Controlled Trials Excluded from Systematic Review

Usual care.

Webster 2003 Australia ⁴²	HTA	No	A letter was sent to the general practitioner of women in the intervention arm of the trial describing postpartum depression risk status. The EPDS score was only 1 risk factor described, there was no cut-off described for the EPDS, and the letter was sent for all women in the intervention group, regardless of EPDS score. ^c	Yes	Women with at least one risk factor for postpartum depression (low partner or social support; past history of mental illness; family psychiatric history; history of postnatal depression; a mother with postnatal depression) were eligible and randomized.	No	Current depression diagnosis or treatment not an exclusion criteria. No information on depression diagnosis or treatment at time of enrollment provided.	No	Intervention Arm: Educational intervention provided and letter describing risk beyond EPDS scores sent to physicians of all women in intervention. Control Arm: Usual care.
Zlotnick 2006 United States ⁴⁶	ARHQ	No	The study intervention did not include the use of a depression screening tool.	No	Women who scored above a cut-off on a risk survey were eligible and randomized to receive depression treatment versus standard care.	Yes	Women currently receiving mental health treatment were excluded.	No	Intervention Arm: Four 60-minute group sessions plus a booster session designed to prevent postpartum depression. Control Arm: Usual care.
Morrell 2009 United Kingdom ⁴⁷	AHRQ	Yes	Women with EPDS \geq 12 at 6 and 8 weeks postpartum in the intervention arm of the trial, but not the usual care arm, were offered psychological treatment for depression by health visitors trained in depression assessment and intervention.	Yes	General practices were randomized to intervention or usual care arms of the trial.	No	Excluded women with severe mental health problems, but existing depression diagnosis or treatment not part of exclusion criteria.	No	Intervention Arm: Home visits from health visitors with training in psychological approaches, along with screening and psychological interventions. Control Arm: Usual care.
Yawn 2012 United States ⁴⁸	AHRQ	Yes	Physicians in the intervention arm only of the trial were instructed that a PHQ-9 score ≥ 10 or an EPDS score ≥ 10 were positive screens that should receive assessment and, as appropriate, treatment.	Yes ^d	Primary care practices were randomized to a complex depression care intervention, including screening with EPDS and PHQ-9, versus usual care. Women 5 to	No	Existing depression diagnosis or treatment not in exclusion criteria. No information on depression diagnosis or treatment at time	No	Intervention Arm: enhanced depression care. Control Arm: Usual care.

12 weeks postpartum were eligible. Only 408 patients with positive depression screen at baseline included in depression outcome	of enrollment provided.
analysis.	

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; EPDS = Edinburgh Postnatal Depression Scale; HTA = Health Technology Assessment; PHQ-9 = 9-item version of the Patient Health Questionnaire; UK = United Kingdom; US = United States.

^a One study⁴³ included in both published versions of the UK Health Technology Assessment^{27,28} is not described in the table because it was not a randomized controlled trial and assessed only depression detection rates, but no depression outcomes. Another study⁴⁴ that was included in only one version of the Health Technology Assessment review²⁷ is not described in the table because it was a naturalistic comparison and not a randomized controlled trial. ^b One study⁴⁵ included in the ARHQ review² is not described in the table because it was not a randomized controlled trial. ^c Based on published articles and clarification provided by corresponding author. ^d Eligibility was determined and randomization occurred pre-screening. However, of the 2,343 patients randomized, only the 408 (17%) with positive depression screens on the EPDS or PHQ were assessed for depression outcomes.



APPENDIX 1: Search Strategies (through April 1, 2013)

OVID Medline

- 1. pregnancy/
- 2. prenatal care/
- 3. postnatal care/
- 4. pregnancy.ti,ab.
- 5. pregnant.ti,ab.
- 6. prenatal.ti,ab.
- 7. pre-natal.ti,ab.
- 8. postnatal.ti,ab.
- 9. post-natal.ti,ab.
- 10. postpartum.ti,ab.
- 11. post-partum.ti,ab.
- 12. puerperal.ti,ab.
- 13. "new mother\$".ti,ab.
- 14. prepregnancy.ti,ab.
- 15. pre-pregnancy.ti,ab.
- 16. antenatal.ti,ab.
- 17. ante-natal.ti,ab.
- 18. antepartum.ti,ab.
- 19. ante-partum.ti,ab.
- 20. or/1-19
- 21. depression/
- 22. depression, postpartum/
- 23. pnd.ti,ab.
- 24. blues.ti,ab.
- 25. depres\$.ti,ab.
- 26. depressive disorder/
- 27. melancholia.ti,ab.
- 28. (anxiety or anxious).ti,ab.
- 29. anxiety/
- 30. ppd.ti,ab.
- 31. or/21-30
- 32. screen\$.ti,ab.
- 33. diagnos\$.ti,ab.
- 34. detect\$.ti,ab.
- 35. predict\$.ti,ab.
- 36. aware\$.ti,ab.
- 37. identif\$.ti,ab.
- 38. diagnosis/
- 39. (edinburgh adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 40. epds.ti,ab.
- 41. (postpartum adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 42. (post-partum adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 43. pdss.ti,ab.
- 44. (bromley adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.

- 45. bpds.ti,ab.
- 46. ("general health" adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 47. ghq.ti,ab.
- 48. (beck adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 49. bdi.ti,ab.
- 50. bai.ti,ab.
- 51. (state adj2 anxiety adj2 depression).ti,ab.
- 52. sad.ti,ab.
- 53. (hospital adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 54. hads.ti,ab.
- 55. (hamilton adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 56. hrsd.ti,ab.
- 57. (zung adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 58. sds.ti,ab.
- 59. "profile of mood states".ti,ab.
- 60. poms.ti,ab.
- 61. (centre adj2 "epidemiological studies" adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 62. (ces-d or cesd).ti,ab.
- 63. symptom checklist-90-revised.ti,ab.
- 64. scl-90-r.ti,ab.
- 65. (brief symptom adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab. 66. bsi.ti,ab.
- 67. ((inventory or questionnaire or scale or index or checklist or interview) adj5 depressive symptomology).ti,ab.
- 68. ida.ti,ab.
- 69. (montgomery-asberg adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 70. madrs.ti,ab.
- 71. (depressive adjective adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 72. dacl.ti,ab.
- 73. (schedule adj2 affective disorders adj2 schizophrenia).ti,ab.
- 74. sads.ti,ab.
- 75. (state-trait anxiety adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab. 76. stai.ti,ab.
- 77. (brisbane postnatal adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 78. (postpartum depression predictors adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 79. (post-partum depression predictors adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 80. ((depres\$ or anxiety) adj5 (inventory or questionnaire or scale or index or checklist or interview)).ti,ab.
- 81. questionnaires/
- 82. interviews/
- 83. antenatal psychosocial health assessment.ti,ab.
- 84. alpha.ti,ab.
- 85. or/32-84

86. 20 and 31 and 85

CINAHL (via EBSCOHost)

- S1 (MH "Pregnancy+") or (MH "Prenatal Care") or (MH "Postnatal Care+")
- S2 (TI pregnancy OR AB pregnancy) or (TI pregnant OR AB pregnant) or (TI prenatal OR AB prenatal)
- S3 (TI pre-natal OR AB pre-natal) or (TI postnatal OR AB postnatal) or (TI post-natal OR AB post-natal)
- S4 (TI postpartum OR AB postpartum) or (TI post-partum OR AB post-partum) or (TI puerperal OR AB puerperal)
- S5 (TI "new mother*" OR AB "new mother*") or (TI pre-pregnancy OR AB pre-pregnancy) or (TI prepregnancy OR AB prepregnancy)
- S6 (TI ante-natal OR AB ante-natal) or (TI antenatal OR AB antenatal) or (TI antepartum OR AB antepartum)
- S7 TI ante-partum OR AB ante-partum
- S8 S1 or S2 or S3 or S4 or S5 or S6 or S7
- S9 (MH "Depression+") or (MH "Depression, Postpartum") or (TI pnd OR AB pnd)
- S10 (TI blues OR AB blues) or (TI depress* OR AB depress*) or (TI melancholia OR AB melancholia)
- S11 (TI (anxiety or anxious) OR AB (anxiety or anxious)) or (MH "Anxiety+") or (TI ppd OR AB ppd)
- S12 S9 or S10 or S11
- S13 (TI screen* OR AB screen*) or (TI diagnos* OR AB diagnos*) or (TI detect* OR AB detect*)
- S14 (TI predict* OR AB predict*) or (TI aware* OR AB aware*) or (TI identif* OR AB identif*)
- S15 (MH "Diagnosis+")
- S16 (TI ((edinburgh W5 Inventory) or (edinburgh W5 Questionnaire) or (edinburgh W5 scale) or (edinburgh W5 index) or (edinburgh W5 checklist) or (edinburgh W5 interview)) or AB ((edinburgh W5 Inventory) or (edinburgh W5 Questionnaire) or (edinburgh W5 scale) or (edinburgh W5 index) or (edinburgh W5 checklist) or (edinburgh W5 interview))) or (TI EPDS OR AB EPDS) or (TI ((postpartum W5 Inventory) or (postpartum W5 Questionnaire) or (postpartum W5 scale) or (postpartum W5 index) or (postpartum W5 index) or (postpartum W5 checklist) or (postpartum W5 checklist) or (postpartum W5 interview)) or AB ((postpartum W5 Inventory) or (postpartum W5 checklist) or (postpartum W5 interview)) or AB ((postpartum W5 index) or (postpartum W5 checklist) or (postpartum W5 interview)) or AB (i postpartum W5 index) or (postpartum W5 checklist) or (postpartum W5 interview)))
- S17 (TI ((post-partum W5 Inventory) or (post-partum W5 Questionnaire) or (post-partum W5 scale) or (post-partum W5 index) or (post-partum W5 checklist) or (post-partum W5 interview)) or AB ((post-partum W5 Inventory) or (post-partum W5 Questionnaire) or (post-partum W5 scale) or (post-partum W5 index) or (post-partum W5 checklist) or (post-partum W5 interview))) or (TI PDSS OR AB PDSS) or (TI ((Bromley W5 Inventory) or (Bromley W5 Checklist) or (Bromley W5 checklist) or (Bromley W5 interview)) or AB ((Bromley W5 Inventory) or (Bromley W5 Questionnaire) or (Bromley W5 scale) or (Bromley W5 Inventory) or (Bromley W5 Questionnaire) or (Bromley W5 index) or (Bromley W5 i
- S18 (TI BPDS OR AB BPDS) or (TI (("general health" W5 Inventory) or ("general health" W5 Questionnaire) or ("general health" W5 scale) or ("general health" W5 index) or ("general health" W5 checklist) or ("general health" W5 interview)) or AB (("general health" W5

Inventory) or ("general health" W5 Questionnaire) or ("general health" W5 scale) or ("general health" W5 index) or ("general health" W5 checklist) or ("general health" W5 interview))) or (TI GHQ OR AB GHQ)

- S19 (TI ((Beck W5 Inventory) or (Beck W5 Questionnaire) or (Beck W5 scale) or (Beck W5 index) or (Beck W5 checklist) or (Beck W5 interview)) or AB ((Beck W5 Inventory) or (Beck W5 Questionnaire) or (Beck W5 scale) or (Beck W5 index) or (Beck W5 checklist) or (Beck W5 interview))) or (TI BDI OR AB BDI) or (TI BAI OR AB BAI)
- S20 (TI (State W2 anxiety W2 depression) OR AB (State W2 anxiety W2 depression)) or (TI SAD OR AB SAD) or (TI ((Hospital W5 Inventory) or (Hospital W5 Questionnaire) or (Hospital W5 scale) or (Hospital W5 index) or (Hospital W5 checklist) or (Hospital W5 interview)) or AB ((Hospital W5 Inventory) or (Hospital W5 Questionnaire) or (Hospital W5 scale) or (Hospital W5 index) or (Hospital W5 Questionnaire) or (Hospital W5 scale) or (Hospital W5 index) or (Hospital W5 Questionnaire) or (Hospital W5 interview)) or AB ((Hospital W5 Inventory) or (Hospital W5 Questionnaire) or (Hospital W5 scale) or (Hospital W5 Inventory) or (Hospital W5 Questionnaire) or (Hospital W5 scale) or (Hospital W5 Inventory) or (Hospital W5 Questionnaire) or (Hospital W5 scale) or (Hospital W5 Inventory) or (Hospital W5 Questionnaire) or (Hospital W5 scale) or (Hospital W5 Inventory) or (Hospital W5 Questionnaire) or (Hospital W5 scale) or (Hospital W5 Inventory) or
- S21 (TI HADS OR AB HADS) or (TI ((Hamilton W5 Inventory) or (Hamilton W5 Questionnaire) or (Hamilton W5 scale) or (Hamilton W5 index) or (Hamilton W5 checklist) or (Hamilton W5 interview)) or AB ((Hamilton W5 Inventory) or (Hamilton W5 Questionnaire) or (Hamilton W5 scale) or (Hamilton W5 index) or (Hamilton W5 checklist) or (Hamilton W5 interview))) or (TI HRSD OR AB HRSD)
- S22 (TI ((Zung W5 Inventory) or (Zung W5 Questionnaire) or (Zung W5 scale) or (Zung W5 index) or (Zung W5 checklist) or (Zung W5 interview)) or AB ((Zung W5 Inventory) or (Zung W5 Questionnaire) or (Zung W5 scale) or (Zung W5 index) or (Zung W5 checklist) or (Zung W5 interview))) or (TI SDS OR AB SDS) or (TI "Profile of mood states" OR AB "Profile of mood states")
- S23 (TI POMS OR AB POMS) or (TI ((Centre W2 "Epidemiological studies" W5 Inventory) or (Centre W2 "Epidemiological studies" W5 Questionnaire) or (Centre W2 "Epidemiological studies" W5 scale) or (Centre W2 "Epidemiological studies" W5 index) or (Centre W2 "Epidemiological studies" W5 checklist) or (Centre W2 "Epidemiological studies" W5 interview)) or AB ((Centre W2 "Epidemiological studies" W5 Inventory) or (Centre W2 "Epidemiological studies" W5 Questionnaire) or (Centre W2 "Epidemiological studies" W5 scale) or (Centre W2 "Epidemiological studies" W5 Questionnaire) or (Centre W2 "Epidemiological studies" W5 scale) or (Centre W2 "Epidemiological studies" W5 no (Centre W2 "Epidemiological studies" W5 scale) or (Centre W2 "Epidemiological studies" W5 index) or (Centre W2 "Epidemiological studies" W5 no (CESD) OR AB (CES-D or CESD))
- S24 (TI "Symptom Checklist-90-revised" OR AB "Symptom Checklist-90-revised") or (TI "SCL-90-R" OR AB "SCL-90-R") or (TI (("Brief symptom" W5 Inventory) or ("Brief symptom"W5 Questionnaire) or ("Brief symptom" W5 scale) or ("Brief symptom" W5 index) or ("Brief symptom" W5 interview)) or AB (("Brief symptom" W5 Inventory) or ("Brief symptom" W5 Questionnaire) or ("Brief symptom" W5 interview)) or ("Brief symptom" W5 interview)) or ("Brief symptom" W5 interview)))
- S25 (TI BSI OR AB BSI) or (TI ((Inventory W5 "depressive symptomatology") or (Questionnaire W5 "depressive symptomatology") or (scale W5 "depressive symptomatology") or (index W5 "depressive symptomatology") or (checklist W5 "depressive symptomatology") or (interview W5 "depressive symptomatology")) OR AB ((Inventory W5 "depressive symptomatology") or (Questionnaire W5 "depressive symptomatology") or (scale W5 "depressive symptomatology") or (index W5 "depressive symptomatology") or (index W5 "depressive symptomatology") or (scale W5 "depressive symptomatology") or (index W5 "depressive symptomatology") or (interview W5 "depressive symptomatology") or (II IDS OR AB IDS)
- S26 (TI (("Montgomery-Asberg" W5 Inventory) or ("Montgomery-Asberg" W5 Questionnaire) or ("Montgomery-Asberg" W5 scale) or ("Montgomery-Asberg" W5 index) or ("Montgomery-Asberg" W5 checklist) or ("Montgomery-Asberg" W5 interview)) or AB (("Montgomery-Asberg" W5 Inventory) or ("Montgomery-Asberg" W5 Questionnaire) or ("Montgomery-

Asberg" W5 scale) or ("Montgomery-Asberg" W5 index) or ("Montgomery-Asberg" W5 checklist) or ("Montgomery-Asberg" W5 interview))) or (TI MADRS OR AB MADRS) or (TI (("Depressive Adjective" W5 Inventory) or ("Depressive Adjective" W5 Questionnaire) or ("Depressive Adjective" W5 scale) or ("Depressive Adjective" W5 index) or ("Depressive Adjective" W5 checklist) or ("Depressive Adjective" W5 interview)) or AB (("Depressive Adjective" W5 Inventory) or ("Depressive Adjective" W5 Questionnaire) or ("Depressive Adjective" W5 Inventory) or ("Depressive Adjective" W5 Inventory) or ("Depressive Adjective" W5 Questionnaire) or ("Depressive Adjective" W5 Inventory) or ("

- S27 (TI DACL or AB DACL) or (TI (Schedule W2 "affective disorders" W2 schizophrenia) OR AB (Schedule W2 "affective disorders" W2 schizophrenia)) or (TI SADS OR AB SADS)
- S28 (TI (("Brisbane postnatal" W5 Inventory) or ("Brisbane postnatal" W5 Questionnaire) or ("Brisbane postnatal" W5 scale) or ("Brisbane postnatal" W5 index) or ("Brisbane postnatal" W5 checklist) or ("Brisbane postnatal" W5 interview)) or AB (("Brisbane postnatal" W5 Inventory) or ("Brisbane postnatal" W5 Questionnaire) or ("Brisbane postnatal" W5 scale) or ("Brisbane postnatal" W5 index) or ("Brisbane postnatal" W5 checklist) or ("Brisbane postnatal" W5 index) or ("Brisbane postnatal" W5 checklist) or ("Brisbane postnatal" W5 interview))) or (TI STAI OR AB STAI) or (TI (("State-Trait anxiety" W5 Inventory) or ("State-Trait anxiety" W5 Questionnaire) or ("State-Trait anxiety" W5 scale) or ("State-Trait anxiety" W5 index) or ("State-Trait anxiety" W5 checklist) or ("State-Trait anxiety" W5 interview)) or AB (("State-Trait anxiety" W5 Inventory) or ("State-Trait anxiety" W5 checklist) or ("State-Trait anxiety" W5 scale) or ("State-Trait anxiety" W5 checklist) or ("State-Trait anxiety" W5 interview)) or AB (("State-Trait anxiety" W5 inventory) or ("State-Trait anxiety" W5 Questionnaire) or ("State-Trait anxiety" W5 scale) or ("State-Trait anxiety" W5 index) or ("State-Trait anxiety" W5 scale) or ("State-Trait anxiety" W5 index) or ("State-Trait anxiety" W5 scale) or ("State-Trait anxiety" W5 index) or ("State-Trait anxiety" W5 scale) or ("State-Trait anxiety" W5 index) or ("State-Trait anxiety" W5 scale) or ("State-Trait anxiety" W5 index) or ("State-Trait anxiety" W5 interview)))
- S29 (TI (("Post-partum depression predictors" W5 Inventory) or ("Post-partum depression predictors" W5 Questionnaire) or ("Post-partum depression predictors" W5 scale) or ("Postpartum depression predictors" W5 index) or ("Post-partum depression predictors" W5 checklist) or ("Post-partum depression predictors" W5 interview)) or AB (("Post-partum depression predictors" W5 Inventory) or ("Post-partum depression predictors" W5 Questionnaire) or ("Postpartum depression predictors" W5 scale) or ("Post-partum depression predictors" W5 index) or ("Post-partum depression predictors" W5 checklist) or ("Post-partum depression predictors" W5 interview))) or (TI (("Postpartum depression predictors" W5 Inventory) or ("Postpartum depression predictors" W5 Questionnaire) or ("Postpartum depression predictors" W5 scale) or ("Postpartum depression predictors" W5 index) or ("Postpartum depression predictors" W5 checklist) or ("Postpartum depression predictors" W5 interview)) or AB (("Postpartum depression predictors" W5 Inventory) or ("Postpartum depression predictors" W5 Questionnaire) or ("Postpartum depression predictors" W5 scale) or ("Postpartum depression predictors" W5 index) or ("Postpartum depression predictors" W5 checklist) or ("Postpartum depression predictors" W5 interview))) or (TI ((depress* W5 Inventory) or (depress* W5 Questionnaire) or (depress* W5 scale) or (depress* W5 index) or (depress* W5 checklist) or (depress* W5 interview)) or AB ((depress* W5 Inventory) or (depress* W5 Questionnaire) or (depress* W5 scale) or (depress* W5 index) or (depress* W5 checklist) or (depress* W5 interview)) OR TI ((anxiety W5 Inventory) or (anxiety W5 Questionnaire) or (anxiety W5 scale) or (anxiety W5 index) or (anxiety W5 checklist) or (anxiety W5 interview)) or AB ((anxiety W5 Inventory) or (anxiety W5 Questionnaire) or (anxiety W5 scale) or (anxiety W5 index) or (anxiety W5 checklist) or (anxiety W5 interview)))
- S30 (MH "Questionnaires+") or (MH "Interviews+") or (MH "Scales")
- S31 (TI ("antenatal psychosocial health assessment") OR AB ("antenatal psychosocial health assessment")) or (TI alpha OR AB alpha) or (MH "Beck Depression Inventory, Revised Edition")

- S32 (MH "Beck Hopelessness Scale") or (MH "Center for Epidemiological Studies Depression Scale") or (MH "Edinburgh Postnatal Depression Scale")
- S33 (MH "Edinburgh Postnatal Depression Scale") or (MH "Hamilton Rating Scale for Depression") or (MH "Profile of Mood States, Revised")
- S34 (MH "Psychiatric Symptom Index") or (MH "Self-Rating Anxiety Scale") or (MH "Self-Rating Depression Scale")
- S35 (MH "State-Trait Anxiety Inventory") or (MH "Brief Symptom Inventory")
- S36 S30 or S31 or S32 or S33 or S34 or S35
- S37 S25 or S26 or S27 or S28 or S29
- S38 S21 or S22 or S23 or S24 or S25
- S39 S16 or S17 or S18 or S19 or S20
- S40 (S13 or S14 or S15)
- S41 S36 or S37 or S38 or S39 or S40
- S42 S8 and S12 and S41

EMBASE

'pregnancy'/exp OR 'prenatal care'/exp OR 'perinatal care'/exp OR 'postnatal care'/exp OR pregnancy:ab,ti OR pregnant:ab,ti OR prenatal:ab,ti OR 'pre natal':ab,ti OR postnatal:ab,ti OR 'post natal':ab,ti OR postpartum:ab,ti OR 'post partum':ab,ti OR puerperal:ab,ti OR 'new mother':ab,ti OR 'new mothers':ab,ti OR prepregnancy:ab,ti OR 'pre pregnancy':ab,ti OR antenatal:ab,ti OR 'ante natal':ab,ti OR antepartum:ab,ti OR 'ante partum':ab,ti AND ('depression'/exp OR pnd:ab,ti OR blues:ab,ti OR depress*:ab,ti OR melancholia:ab,ti OR anxiety:ab,ti OR anxious:ab,ti OR ppd:ab,ti OR 'mixed anxiety and depression'/exp OR 'depressive disorder':ab,ti) AND ('screening'/exp OR 'diagnosis'/exp OR screen*:ab,ti OR detect*:ab,ti OR predict*:ab,ti OR aware*:ab,ti OR identif*:ab,ti OR (edinburgh NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR epds:ab,ti OR (postpartum NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR ('post-partum' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR hrsd:ab,ti OR (zung NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR sds:ab,ti OR 'profile of mood states':ab,ti OR poms:ab,ti OR (('centre' NEXT/2 'epidemiological studies'):ab,ti AND ('epidemiological studies' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR inverview)):ab,ti) OR cesd:ab,ti OR 'ces d':ab,ti OR 'symptom checklist 90 revised':ab,ti OR 'scl 90 r':ab,ti OR ('brief symptom' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR bsi:ab,ti OR ((inventory OR questionnaire OR scale OR index OR checklist OR interview) NEXT/5 'depressive symptomology'):ab,ti OR ids:ab,ti OR ('montgomery asberg' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR madrs:ab,ti OR ('depressive adjective' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR dacl:ab,ti OR ((schedule NEXT/2 'affective disorders'):ab,ti AND ('affective disorders' NEXT/2 schizophrenia):ab,ti) OR sad:ab,ti OR ('state trait anxiety' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR stai:ab,ti OR ('brisbane postnatal' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR ('postpartum depression predictors' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR ('post-partum depression predictors' NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR (depress* NEXT/5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)):ab,ti OR (anxiety NEXT/5 (inventory OR questionnaire

OR scale OR index OR checklist OR interview)):ab,ti OR 'questionnaire'/exp OR 'interview'/exp OR 'antenatal psychosocial health assessment':ab,ti OR alpha:ab,ti) AND [embase]/lim

ISI – Web of Science

- 1. TS=(pregnancy OR pregnant OR prenatal OR pre-natal OR post-natal OR (postpartum OR post-partum OR "new mother" OR "new mothers" OR prepregnancy OR pre-pregnancy OR antenatal OR ante-natal OR ante-partum OR ante-partum OR puerperal))
- 2. TS=(pnd OR blues OR depress* OR melancholia OR anxiety OR anxious OR ppd)
- 3. TS=((screen* OR diagnos* OR detect* OR predict* OR aware* OR identif* OR epds OR pdss) OR (bpds OR ghq OR bdi OR bai OR sad OR hads OR hrsd OR sds OR poms) OR (ces-d OR cesd OR scl-90-r OR bsi OR ids OR madrs OR dacl OR sads OR stai OR alpha))
- 4. TS=((edinburgh SAME inventory) OR (edinburgh SAME questionnaire) OR (edinburgh SAME scale) OR (edinburgh SAME index) OR (edinburgh SAME checklist) OR (edinburgh SAME interview))
- TS=((postpartum SAME inventory) OR (postpartum SAME questionnaire) OR (postpartum SAME scale) OR (postpartum SAME index) OR (postpartum SAME checklist) OR (postpartum SAME interview))
- TS=((post-partum SAME inventory) OR (post-partum SAME questionnaire) OR (post-partum SAME scale) OR (post-partum SAME index) OR (post-partum SAME checklist) OR (post-partum SAME interview))
- TS=((bromley SAME inventory) OR (bromley SAME questionnaire) OR (bromley SAME scale) OR (bromley SAME index) OR (bromley SAME checklist) OR (bromley SAME interview))
- TS=(("general health" SAME inventory) OR ("general health" SAME questionnaire) OR ("general health" SAME scale) OR ("general health" SAME index) OR ("general health" SAME checklist) OR ("general health" SAME interview))
- 9. TS=((beck SAME inventory) OR (beck SAME questionnaire) OR (beck SAME scale) OR (beck SAME index) OR (beck SAME checklist) OR (beck SAME interview))
- 10. TS=((hospital SAME inventory) OR (hospital SAME questionnaire) OR (hospital SAME scale) OR (hospital SAME index) OR (hospital SAME checklist) OR (hospital SAME interview))
- 11. TS=((hamilton SAME inventory) OR (hamilton SAME questionnaire) OR (hamilton SAME scale) OR (hamilton SAME index) OR (hamilton SAME checklist) OR (hamilton SAME interview))
- 12. TS=((zung SAME inventory) OR (zung SAME questionnaire) OR (zung SAME scale) OR (zung SAME index) OR (zung SAME checklist) OR (zung SAME interview))
- 13. TS=((centre SAME "epidemiological studies" SAME inventory) OR (centre SAME "epidemiological studies" SAME questionnaire) OR (centre SAME "epidemiological studies" SAME scale) OR (centre SAME "epidemiological studies" SAME index) OR (centre SAME "epidemiological studies" SAME index) OR (centre SAME "epidemiological studies" SAME interview))
- 14. TS=(("brief symptom" SAME inventory) OR ("brief symptom" SAME questionnaire) OR ("brief symptom" SAME scale) OR ("brief symptom" SAME index) OR ("brief symptom" SAME checklist) OR ("brief symptom" SAME interview))

- 15. TS=(("depressive symptomatology" SAME inventory) OR ("depressive symptomatology" SAME questionnaire) OR ("depressive symptomatology" SAME scale) OR ("depressive symptomatology" SAME index) OR ("depressive symptomatology" SAME checklist) OR ("depressive symptomatology" SAME interview))
- 16. TS=((montgomery-asberg SAME inventory) OR (montgomery-asberg SAME questionnaire) OR (montgomery-asberg SAME scale) OR (montgomery-asberg SAME index) OR (montgomery-asberg SAME checklist) OR (montgomery-asberg SAME interview))
- 17. TS=(("depressive adjective" SAME inventory) OR ("depressive adjective" SAME questionnaire) OR ("depressive adjective" SAME scale) OR ("depressive adjective" SAME index) OR ("depressive adjective" SAME checklist) OR ("depressive adjective" SAME interview))
- 18. TS=(("state-trait anxiety" SAME inventory) OR ("state-trait anxiety" SAME questionnaire) OR ("state-trait anxiety" SAME scale) OR ("state-trait anxiety" SAME index) OR ("state-trait anxiety" SAME checklist) OR ("state-trait anxiety" SAME interview))
- 19. TS=(("brisbane postnatal" SAME inventory) OR ("brisbane postnatal" SAME questionnaire) OR ("brisbane postnatal" SAME scale) OR ("brisbane postnatal" SAME index) OR ("brisbane postnatal" SAME checklist) OR ("brisbane postnatal" SAME interview))
- 20. TS=(("postpartum depression predictors" SAME inventory) OR ("postpartum depression predictors" SAME questionnaire) OR ("postpartum depression predictors" SAME scale) OR ("postpartum depression predictors" SAME index) OR ("postpartum depression predictors" SAME checklist) OR ("postpartum depression predictors" SAME interview))
- 21. TS=(("post-partum depression predictors" SAME inventory) OR ("post-partum depression predictors" SAME questionnaire) OR ("post-partum depression predictors" SAME scale) OR ("postpartum depression predictors" SAME index) OR ("post-partum depression predictors" SAME checklist) OR ("post-partum depression predictors" SAME interview))
- 22. TS=(((depress* OR anxiety) SAME inventory) OR ((depress* OR anxiety) SAME questionnaire) OR ((depress* OR anxiety) SAME scale) OR ((depress* OR anxiety) SAME index) OR ((depress* OR anxiety) SAME checklist) OR ((depress* OR anxiety) SAME interview))
- 23. TS=(("antenatal psychosocial health assessment") OR (schedule SAME "affective disorders" SAME schizophrenia) OR ("symptom checklist-90-Revised") OR ("profile of mood states") OR (state SAME anxiety SAME depression))
- 24. #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23
- 25. #24 AND #2 AND #1

PsycINFO (via EBSCOHost)

S1 (DE "Prenatal Care" OR DE "Postnatal Period" OR DE "Perinatal Period" OR
 DE "Pregnancy" OR DE "Adolescent Pregnancy") OR TI (pregnancy OR pregnant OR prenatal OR pre-natal or postnatal OR post-natal OR postpartum OR post-partum OR puerperal OR "new mother" OR "new mothers" OR prepregnancy OR pre-pregnancy OR antenatal OR antenatal OR antenatal OR ante-partum) OR AB (pregnancy OR pregnant OR prenatal OR pre-natal or postnatal OR post-natal OR post-partum OR puerperal OR "new mother" OR antenatal OR antenatal OR post-partum OR pre-natal OR pre-natal or postnatal OR post-partum OR post-partum OR pre-natal OR post-natal OR post-partum OR pre-natal OR post-natal OR post-partum OR post-partum OR puerperal OR "new mother" OR

"new mothers" OR prepregnancy OR pre-pregnancy OR antenatal OR ante-natal OR antepartum OR ante-partum)

- S2 (DE "Major Depression" OR DE "Postpartum Depression" OR DE "Anxiety") OR TI (ppd OR blues OR depress* OR melancholia OR anxiety OR anxious OR ppd) OR AB (ppd OR blues OR depress* OR melancholia OR anxiety OR anxious OR ppd)
- S3 DE "Diagnosis" OR DE "Psychodiagnosis" OR DE "Psychodiagnostic Interview" OR DE "Questionnaires" OR DE "Interviews" OR DE"Scales"
- S4 TI (screen* OR diagnos* OR detect* OR predict* OR aware* OR identif*) OR AB (screen* OR diagnos* OR detect* OR predict* OR aware* OR identif*)
- S5 TI (hrsd OR sds OR poms OR ces-D OR cesd OR sci OR bsi OR ids OR madrs OR dacl OR sads OR stai OR alpha) OR AB (hrsd OR sds OR poms OR ces-D OR cesd OR sci OR bsi OR ids OR madrs OR dacl OR sads OR stai OR alpha)
- S6 TI (postpartum N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)
) OR AB (postpartum N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S7 TI (edinburgh N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
 OR AB (edinburgh N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S8 TI (post-partum N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB (post-partum N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S9 TI (Bromley N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
 OR AB (Bromley N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S10 TI ("general health" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB ("general health" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S11 TI (Beck N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR
 AB (Beck N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S12 TI (hospital N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
 OR AB (hospital N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S13 TI (hamilton N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
 OR AB (hamilton N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S14 TI (zung N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR
 AB (zung N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S15 TI ("brief symptom" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB ("brief symptom" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S16 TI ("depressive symptomatology" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB ("depressive symptomatology" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S17 TI (montgomery-asberg N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB (montgomery-asberg N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))

- S18 TI ("depressive adjective" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB ("depressive adjective" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S19 TI ("state-trait anxiety" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB ("state-trait anxiety" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S20 TI ("brisbane postnatal" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB ("brisbane postnatal" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S21 TI ("Postpartum depression predictors" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB ("Postpartum depression predictors" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S22 TI ("Post-partum depression predictors" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB ("Post-partum depression predictors" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S23 TI (depress* N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
 OR AB (depress* N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S24 TI (anxiety N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
 OR AB (anxiety N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S25 TI state N2 anxiety N2 depression OR AB state N2 anxiety N2 depression
- S26 TI (centre N2 "epidemiological studies" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview)) OR AB (centre N2 "epidemiological studies" N5 (inventory OR questionnaire OR scale OR index OR checklist OR interview))
- S27 TI schedule N2 "affective disorders" N2 schizophrenia OR AB schedule N2 "affective disorders" N2 schizophrenia
- S28 TI ("profile of mood states" OR "symptom checklest-90-revised" OR "antenatal psychosocial health assessment") OR AB ("profile of mood states" OR "symptom checklest-90-revised" OR "antenatal psychosocial health assessment")
- S29 (S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28)
- S30 S1 and S2 and S29

APPENDIX 2: Relevant Systematic Reviews and Meta-Analyses

- Austin MP, Priest SR, Sullivan EA. Antenatal psychosocial assessment for reducing perinatal mental health morbidity. *Cochrane Database of Systematic Reviews* 2008, Issue 4. Art. No.: CD005124. DOI: 10.1002/14651858.CD005124.pub2.
- Boyd RC, Le HN, Somberg R. Review of screening instruments for postpartum depression. *Arch Womens Ment Health*. 2005;8:141-153.
- 3. Downe SM, Butler E, Hinder S. Screening tools for depressed mood after childbirth in UK-based South Asian women: a systematic review. *J Adv Nurs*. 2007;57:565-583.
- 4. Eberhard-Gran M, Eskild A, Tambs K, Opjordsmoen S, Samuelsen SO. Review of validation studies of the Edinburgh Postnatal Depression Scale. *Acta Psychiatr Scand.* 2001;104:243-249.
- Gaynes BN, Gavin N, Meltzer-Brody S, Lohr KN, Swinson T, Gartlehner G, et al. Perinatal depression: prevalence, screening accuracy, and screening outcomes. Evidence Report/Technology Assessment No. 119. (Prepared by the RTI-University of North Carolina Evidence-based Practice Center, under Contract No. 290-02-0016). AHRQ Publication No. 05-E006-2. Rockville, MD. Agency for Healthcare Research and Quality. February 2005.
- Hewitt CE, Gilbody SM, Brealey S, Paulden M, Palmer S, Mann R, et al. Methods to identify postnatal depression in primary care: an integrated evidence synthesis and value of information analysis. *Health Technol Assess.* 2009;13:1-145.
- Hewitt CE, Gilbody SM. Is it clinically and cost-effective to screen for postnatal depression: a systematic review of controlled clinical trials and economic evidence. *BJOG*. 2009;116:1019-1027.

- 8. Liberto TL. Screening for depression and help-seeking in postpartum women during well-baby pediatric visits: An integrated review. *J Pediatr Health Care*. 2012;26:109-17.
- 9. Mann R, Gilbody S. Validity of two case finding questions to detect postnatal depression: a review of diagnostic test accuracy. *J Affect Disord*. 2011;133:388-97.
- 10. Mann R, Hewitt CE, Gilbody SM. Assessing the quality of diagnostic studies using psychometric instruments: applying QUADAS. *Soc Psychiatry Psychiatr Epidemiol*. 2009;44:300-307.
- Myers ER, Aubuchon-Endsley N, Bastian LA, Gierisch JM, Kemper AR, Swamy GK, et al. Efficacy and safety of screening for postpartum depression. Comparative Effectiveness Review 106. (Prepared by the Duke Evidence-based Practice Center, under Contract No. 290-2007-10066-I). AHRQ Publication No. 13-EHC064-DF. Rockville, MD. Agency for Healthcare Research and Quality, April 2013. www.effectivehealthcare.ahrq.gov/reports/final.cfm.
- Yawn BP, Olson AL, Bertram S, Pace W, Wollan P, Dietrich AJ. Postpartum depression: screening, diagnosis, and management programs 2000 through 2010. *Depress Res Treat*. 2012;2012:363964.

Appendix 3: Journals Included in Manual Searching

Acta Obstetricia et Gynecologica Scandinavica Acta Psychiatrica Scandinavica American Journal of Medicine American Journal of Obstetrics and Gynecology American Journal of Psychiatry American Journal of Public Health Annals of Family Medicine Annals of Internal Medicine Archives of General Psychiatry Archives of Internal Medicine Archives of Women's Mental Health Australian and New Zealand Journal of Psychiatry Australian and New Zealand Journal of Obstetrics and Gynaecology **Biological Psychiatry** Birth BJOG: an International Journal of Obstetrics and Gynaecology BMC Pregnancy and Childbirth **BMC** Psychiatry **BMC** Public Health British Journal of Psychiatry British Medical Journal Canadian Journal of Psychiatry Canadian Medical Association Journal General Hospital Psychiatry Health Psychology JAMA Journal of Affective Disorders Journal of Clinical Psychiatry Journal of General Internal Medicine Journal of Midwifery and Women's Health Journal of Obstetric, Gynecologic, and Neonatal Nursing Journal of Perinatology Journal of Psychosomatic Obstetrics and Gynecology Journal of Psychosomatic Research Journal of Reproductive Medicine Journal of Women's Health Lancet New England Journal of Medicine New Zealand Medical Journal **Obstetrics & Gynecology Psychiatry Research Psychological Medicine** Psychosomatic Medicine Psychosomatics Psychotherapy and Psychosomatics

Appendix 4

Variables Included in Data Extraction

Author Year Country Study funding source Timing of screening during pregnancy or postpartum Care setting where screening conducted Mean age Inclusion criteria Exclusion criteria N treatment N control Treatment / intervention procedure Control condition Screening instrument and cut-off Method to diagnose MDD Duration of intervention Follow-up time Primary outcome measure Effect size N drop out / lost to follow-up

Appendix 5

The Cochrane Tool for Assessing Risk of Bias

Sequence generation: Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

Allocation concealment: Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.

Blinding of participants, personnel and outcome assessors: *Assessments should be made for each main outcome (or class of outcomes).* Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.

Incomplete outcome data: Assessments should be made for each main outcome (or class of outcomes). Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.

Selective outcome reporting: State how the possibility of selective outcome reporting was examined by the review authors, and what was found.

***Pharmaceutical industry funding:** State the funding source(s) of the trial, or indicate if the trial funding source was not reported.

*Author-industry financial ties and/or employment: State whether any trial authors disclosed financial ties and/or employment by the pharmaceutical industry, or if author-industry financial ties or affiliation were not reported.

Other sources of bias: State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry. Was the study apparently free of other problems that could put it at a high risk of bias?

Reference: Higgins JPT, Altman DG, Sterne JAC, editors. Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. http://www.cochrane-handbook.org. Accessed June 1, 2012.

* Additional item added to Cochrane Risk of Bias tool based on (1) Roseman M, Turner EH, Lexchin J, Coyne JC, Bero LA, Thombs BD. Reporting of conflict of interest from drug trials in Cochrane reviews: A cross-sectional study. *BMJ*. 2012;345:e5155 and (2) Roseman M, Milette K, Bero LA, Lexchin J, Turner E, Coyne JC, Thombs BD. Reporting of conflicts of interest in meta-analyses of pharmacological treatments. *JAMA*. 2011;305(10):1008-1017.