Evidence Table 3. Data abstraction of trials

| **AuthorYearCountryTrial NameRisk of Bias** | **Population** | **Interventions** | **AgeEthnicity** | **Other Population Characteristics** | **Number Randomized** |
| --- | --- | --- | --- | --- | --- |
| Appleby 1997133UKMedium | Inclusion Criteria: Depressed 6-8 weeks after childbirth. Score ≥ 10 on Edinburgh postnatal depression scale; Score ≥ 12 on the revised clinical interview schedule; satisfied research diagnostic criteria for major or minor depressive disorder.Exclusion Criteria: Inadequate English and living outside district. Chronic (>2 years) or resistant depression, current drug or alcohol misuse, severe illness requiring close monitoring or hospital admission, and breast feeding.  | 1) Fluoxetine + 1 CBT session2) Fluoxetine + 6 CBT sessions3) Placebo + 1 CBT session4) Placebo + 6 CBT sessionsFluoxetine dose: NRTime Period: 12 wks | Mean age: 25Ethnicity NR | Unplanned Pregnancy: 13.75%Major Depressive Disorder: 12.75%History of Postnatal Depression: 7.5%Family History of postnatal depression: 4% | 87 |
| Bloch 2012134IsraelMedium | Age 18-45 years; criteria met during the screen and baseline visits for current major depressive disorder according to the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV), as assessed by the Structured Clinical Interview for DSM-IV Axis I disorders, and onset of the depressive episode starting within 2 months of parturition.  | Three Treatment Groups1) Sertraline+psychotherapy2) Placebo+PsychotherapySertraline mean (SD) dose at 4 weeks: 65.0 (23.5)mg, at 8 weeks: 67.5 (24.5)mgTime Period: 8 wks | Mean age: NREthnicity: NR | Anxiety Diagnosis: 22.5%Past Depression: 22.5%Depression in Family: 37.5%Pregnancies: 1.4% | 42 |
| Misri, 2004135CanadaMedium | Age 18-40 years; ≥18 on HAM-D, ≥ 20 on HAM-A and ≥ 12 on EPDS; delivered a healthy baby close to term (37-42 weeks) with a minimum birth weight of 2.5 kg; non smokers; willing to use adequate contraception during the study. | 1. Paroxetine2. Paroxetine+CBTParoxetine max. dose: 50 mgTime period: 12 wks | Mean age: 30White: 62.9%South Asian: 14.3%First Nations: 8.6%Mexican, Spanish, Indo-Canadian, Italian, South-American: 2.8% each | % of children previously born1: 57%2: 28.6%3: 11.4%4: 2.9%DSM diagnosisDepression only: 2.9%Depression+Anxiety: 34.3%Depression+Anxiety+Obsession: 31.4%Depression+Anxiety+OCD: 31.4% | 35 |
| Morrell 2009136UKMedium | Inclusion Criteria: At-risk women (who returned a 6-week EPDS score ≥ 12 on the postal questionnaire), had an 8-week EPDS score ≥ 12 when the EPDS was repeated face-to-face by the HV at 8 weeks postnatally. Women eligible for the intervention were therefore defined by two EPDS score ≥ 12. The HV was allowed to provide the intervention to those women whom the HV felt might benefit from the intervention, irrespective of their EPDS score. Women were recruited if they were registered with participating GP practices, became 36 weeks pregnant during the recruitment phase of the trial, had a live baby and were on a collaborating HV’s caseload for 4 months postnatally. | Primary comparison was between at-risk women randomized to Health Visitor training and women in practices randomized to provide Health Visitor usual care.Six Treatment Groups1) Cognitive behavioral approach face-to-face2) Cognitive behavioral approach postal3) Person-centered approach face-to-face4) Person-centered approach postal5) Control (Health Visitor usual care) | Mean age: 30.9 (SD 5.4) Ethnicity: 93.3% White British | 93.7% living with others, 6.3% living alone47.1% first baby | 101 clusters in 29 primary care trusts.595 |

| **AuthorYearCountryTrial NameRisk of Bias** | **Efficacy/Effectiveness Outcomes** | **Harms** | **Funding** |
| --- | --- | --- | --- |
| Appleby 1997133UKMedium | Revised Clinical Interview Schedule Score (Completer Analysis, N=61)% difference in geometric mean scores (95% CI): Fluoxetine vs placebo: 4 weeks=37.1% (5.7% to 58.0%), 12 weeks=40.7% (10.9% to 60.6%); 6 CBT sessions vs 1 CBT session: 4 weeks=53.9% (2.3% to 131.2%), 12 weeks=38.7% (-9.2% to 111.7%)Change in geometric mean scores from baseline to 4 weeks/12 weeks (ITT):Revised Clinical Interview ScheduleFluoxetine+1 CBT session= -16.3/-22.7Fluoxetine+6 CBT sessions= -16.9/-16.3Placebo+1 CBT session= -10.4/-10.2Placebo+6 CBT sessions= -13.7/-14.2Edinburgh postnatal depression scaleFluoxetine+1 CBT session= -7.1/-9.5Fluoxetine+6 CBT sessions= -9.7/-10.2Placebo+1 CBT session= -8.1/-7.2Placebo+6 CBT sessions= -6.6/6.9Hamilton scoreFluoxetine+1 CBT session= NR/-10Fluoxetine+6 CBT sessions= NR/-8.9Placebo+1 CBT session= NR/-5.9Placebo+6 CBT sessions= NR/-8.9 | NR |  |
| Bloch 2012134IsraelMedium | Sertraline+psychotherapy vs placebo+psychotherapyChange from baseline at 8 weeks, n=40 (p-values are NS presented as group by time interaction unless otherwise specified for MDRS, EPDS, CGI)Improvement in MADRS -13.86 vs -9.85, significant time effect p<0.0001Improvement in EPDS: -9.75 vs -3.55, significant time effect p<0.0001Improvement in CGI-S: -1.9 vs -1.5Improvement in CGI-I: -2.00 vs -0.25Response rates at 8 weeksMADRS or EPDS, n=40: 70% vs 55%, p=NSRemission rates at 8 weeksMADRS or EPDS, n=40, 65% vs 50%, p=NS  | Hypomaniac switch in 10% (n=2) of patients in sertraline + psychotherapy group vs 0 in placebo | Independent investigator award for National Alliance on Research on Schizophrenia and Depression |
| Misri, 2004135CanadaMedium | Paroxetine vs Paroxetine +CBTChange from baseline (reduction) at final visit (P<0.01 for all)HAM-D: 17.6 vs 15.2HAM-A: 14.3 vs 14.6EPDS: 8.4 vs 10.2YBOCS: 4.9 vs 9.1CGI-I: 2.75 vs 2.59% patients with reduction in symptom scores at final visit≥50% score (p=NS between groups)HAM-D: 87.5 vs 78.9HAM-A: 75.0 vs 84.2EPDS: 61.5 vs 58.3≥60% score reduction in symptom scores at final visit (p=NS between groups)YBOCS: 80.0 vs 78.6CGI (1=normal, not at all ill) (p=NS between groups) Depression (based on HAM\_D): 75 vs 63.2 Anxiety (based on HAM-A): 75 vs 57.9 Obsessions and/or OCD (based on YBOCS): 80 vs 71.4 | NR | Glaxo-Smithkline Canada |
| Morrell 2009136UKMedium | Intervention vs controlProportion of at-risk women with a 6-month Edinburgh Postnatal Depression Scale score >=12 (Primary Outcome)33.9% vs 45.6%OR, unadjusted: 0.62 (95% CI 0.40, 0.97); P=0.036OR, adjusted for 6-week EPDS score: 0.64 (95% CI 0.40, 1.01); P=0.058OR, adjusted for 6-week EPDS score, lives alone, history of postnatal depression, any life events: 0.60 (95% CI 0.38, 0.95); P=0.028OR, adjusted for lives alone, history of postnatal depression, any life events: 0.57 (95% CI 0.36, 0.90); P=0.0176-month outcomes: control vs intervention, adjusted mean difference in scores (95% CI)EPDS: -2.1 (-3.3, -0.9), P=0.001SF-12 PCS: -1.7 (-3.6, 0.1), P=0.069SF-12 MCS: 5.2 (2.5, 7.8), P=0.001SF-6D: 0.03 (0.00, 0.06), P=0.025CORE-OM well-being: -0.3 (-0.5, -0.2), P=0.001CORE-OM risk: -0.0 (-0.1, 0.0), P=0.149CORE-OM symptoms: -0.2 (-0.4, -0.1), P=0.005CORE-OM functioning: -0.3 (-0.4, -0.1), P=0.001CORE-OM total score: -0.2 (-0.4, -0.1), P=0.001State anxiety: -3.9 (-6.6, -1.3), P=0.003Trait anxiety: -3.7 (-6.1, -1.4), P=0.002PSI parenting distress: 3.5 (1.3, 5.8), P=0.002PSI PCDI: 2.1 (0.7, 3.5), P=0.003PSI difficult child: 2.9 (1.7, 4.2), P=0.001PSI total stress: 9.3 (137.3, 13.4), P=0.001 | NR | Government (UK NHS) |

CBT = cognitive behavioral therapy; CI = confidence interval; CGI-I = Clinical Global Impression scale - Improvement; CGI-S = Clinical Global Impression Scale - Severity; CORE-OM = Clinical Outcomes in Routine Evaluation ; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders; Fourth Edition; HAM-A = Hamilton Anxiety Rating Scale; HAM-D = Hamilton Depression Rating Scale; ITT = intention to treat; MADRS = Montgomery-Asberg Depression Rating Scale; NR = not reported; OCD = obsessive compulsive disorder; OR = odds ratio; PCDI = Parent Child Dysfunctional Interaction; PSI = Parenting Stress Index; SD = standard deviation; UK = United Kingdom; US = United States