**Table H15. Evidence table (Reference ID# 395)**

| Study Description | Intervention(s)/ Comparator(s) | Patient Population | Baseline Measure(s) | Outcome Measure(s) | Quality |
| --- | --- | --- | --- | --- | --- |
| **Author:**  Pollak et al., 2007  **Country:**  USA  **Enrollment period:**  May 2003 to  August 2005  **Setting:**  14 clinics  **Funding:**  Grant (Federal)  **Author industry relationship disclosures:**  0/11  **Study Design:**  RCT  **Blinding:**  None | **Intervention:**  Cognitive behavior therapy (CBT) plus nicotine replacement therapy (NRT)  **Intervention provider:**  Trained support specialists  **Intervention setting:**  Clinic  **Comparator:**  CBT only  **Followup:**  Telephone surveys at 7 weeks post randomization, 38 weeks gestation, and 3 months postpartum.  **Groups:**  **G1:** CBT+ NRT  **G2:** CBT | **Inclusion criteria:**   * Between 13 to 25 weeks pregnant * Smoked ≥100 cigarettes in their lifetime * Currently smoked ≥ 5 cigarettes per day * Planning to continue prenatal care in a participating clinic * ≥ 18 years old * Spoke English   **Exclusion criteria:**   * Evidence of cognitive or mental health problems, drug or alcohol addiction * History of placental abruption, poorly controlled hypertension, cardiac arrhythmia, MI within past 6 months, previous pregnancy with congenital anomaly, or family history congenital anomalies   **Enrollment, n:**  **G1:** 122  **G2:** 59  **Followup, n (%)**  38 weeks gestation  **G1:** 73 (59.8)  **G2:** 29 (50.9)  3 months postpartum  **G1:** 76 (62.3)  **G2:** 39 (66.1)  **Age, mean years ± SD:**  **G1:** 27 ± 6  **G2:** 26 ± 5  **Education**  Less than high school, %  **G1:** 27  **G2:** 31  High school/GED, %  **G1:** 31  **G2:** 33  Vocational school, %  **G1:** 6  **G2:** 10  Some college, %  **G1:** 33  **G2:** 17  College graduate or higher, %  **G1:** 3  **G2:** 9  **Gestation, mean weeks ± SD:**  **G1:** 17 ± 3  **G2:** 18 ± 4  **Insurance status:**  NR  **Parity:**  First pregnancy, %  **G1:** 18  **G2:** 12  Number of prior pregnancies, median (interquartile range):  **G1:** 2 (1, 4)  **G2:** 2 (1, 3)  **Partner status, %:**  Has partner  **G1:** 66  **G2:** 69  **Partner smoking status:**  NR  **Race/ethnicity, %:**  White  **G1:** 67  **G2:** 73  Black  **G1:** 26  **G2:** 19  Other  **G1:** 7  **G2:** 8  **Socioeconomic status, %:**  Employed full time  **G1:** 30  **G2:** 31  Employed part time  **G1:** 21  **G2:** 9  Not employed  **G1:** 49  **G2:** 60  **Smoking history:**  Cigarettes smoked daily 30 days before pregnancy, mean ± SD  **G1:** 19 ± 9  **G2:** 20 ± 8  24-hour quit attempt, %  **G1**: 57  **G2:** 61  24-hour quit attempts, mean number ± SD  **G1:** 3 ± 3  **G2:** 2 ± 2  Longest quit, mean days ± SD  **G1:** 100 ± 171  **G2:** 79 ± 133  24-hour quit attempt in previous pregnancy, %  **G1:** 50  **G2:** 62  Longest quit in previous pregnancy, mean days ± SD  **G1:** 102 ± 111  **G2:** 63 ± 90 | **Maternal smoking status**  Number of cigarettes per day, mean ± SD:  **G1:** 11 ± 5  **G2:** 12 ± 5 | **Maternal smoking status**  Abstinence at 7 weeks post randomization (unadjusted), %:  **G1:** 18.0  **G2:** 3.0  **G1 vs. G2:** p=0.006  Abstinence at 7 weeks post randomization (adjusted)[[1]](#footnote-1), %:  **G1:** 24.0  **G2:** 8.0  **G1 vs. G2:** p=0.02  Abstinence at 38 weeks pregnancy (unadjusted), %:  **G1:** 14.0  **G2:** 2.0  **G1 vs. G2:** p=0.01  Abstinence at 38 weeks pregnancy (adjusted)f, %:  **G1:** 18.0  **G2:** 7.0  **G1 vs. G2:** p=0.04  Relapse:  NR  **Child/infant outcomes**  Perinatal outcome data available, n  **G1:** 113  **G2:** 58  Gestational age, mean weeks ± SD:  **G1:** 37.9 ± 3.1  **G2:** 38.6 ± 2.7  **G1 vs. G2:** p=0.14  Birthweight, mean grams ± SD:  **G1:** 3061 ± 661  **G2:** 3132 ± 688  **G1** **vs.** **G2:** p=0.51  NICU admission, n:  **G1:** 13  **G2:** 4  Asthma exacerbation:  NR  Asthma hospitalization:  NR  Upper respiratory infection:  NR  **Adverse Events:**  At least one serious adverse event, n (%): **G1:** 34/113 (30)  **G2:** 10/58 (17)  **Risk difference:** 0.13 (95% CI: 0.00 to 0.26), p=0.07  At least one serious adverse event adjusted for previous history of preterm birth, %:  **G1:** 27.0  **G2:** 18**.**0  **Risk difference:** 0.09 (95% CI: 0.05 to 0.2), p=0.26 | **Overall quality:**  Poor  **Risk of bias**  Randomization:  Low  Allocation concealment:  Low  Selective reporting:  Low  Blinding patients/personnel:  High  Blinding outcome assessment:  Low  Incomplete outcome reporting:  Low  Other:  Low |

1. Adjusted analysis controlled for number of completed counseling sessions [↑](#footnote-ref-1)