**Table H2. Evidence table (Reference ID# 11)**

| Study Description | Intervention(s)/ Comparator(s) | Patient Population | Baseline Measure(s) | Outcome Measure(s) | Quality |
| --- | --- | --- | --- | --- | --- |
| **Author:**  Coleman et al., 2012  **Country:**  England  **Enrollment period:**  May 2007 to  February 2010  **Setting:**  7 Hospital prenatal clinics  **Funding:**  Grant  **Author industry relationship disclosures:**  0/7  **Study Design:**  RCT  **Blinding:**  Double blind (provider and patient) | **Intervention:**  Behavioral support and nicotine replacement therapy  **Intervention provider:**  Research midwives  **Intervention setting:**  Clinic  **Comparator:**  Placebo  **Groups:**  **G1:** Intervention  **G2:** Placebo  **Followup:**  1 month after quit date and end of pregnancy (at delivery) | **Inclusion criteria:**   * Pregnant 12 to 24 weeks gestation and agreed to set a quit date * Age 16 to 50 years * Smoked 10 or more cigarettes daily before pregnancy * Currently smoked 5 or more cigarettes per day * Exhaled carbon monoxide concentration of 8 ppm or greater   **Exclusion criteria:**   * Known major fetal abnormalities * Inability to provide informed consent * Chemical or alcohol dependence * Contraindications to nicotine replacement therapy (recent cerebral vascular accident or transient ischemic attack, chronic generalized skin disorders, sensitivity to nicotine patch)   **Enrollment, n:**  **G1:** 521  **G2:** 529  **Followup, n (%):**  **G1:** 485 (93.1)  **G2:** 496 (93.8)  **Age, mean years ± SD:**  **G1:** 26.4 ± 6.2  **G2:** 26.2 ± 6.1  **Education:**  Age leaving full-time education, mean ± SD  **G1:** 16.2 ± 1.4  **G2:** 16.3 ± 1.7  **Gestation, mean weeks ± SD:**  **G1:** 16.2 ± 3.6  **G2:** 16.3 ± 3.5  **Insurance status:**  NR  **Parity, n (%):**  0 to 1 previous births  **G1:** 356 (68.3)  **G2:** 356 (68.3)  2 to 3 previous births  **G1:** 129 (24.8)  **G2:** 129 (24.8)  4 or more previous births  **G1:** 36 (6.9)  **G2:** 36 (6.9)  **Partner status:**  NR  **Partner smoking status:**  Partner smokes, n (%)  **G1:** 356 (74.0)  **G2:** 360 (74.7)  **Race/Ethnicity, n (%):**  White  **G1:** 503 (96.5)  **G2:** 515 (97.4)  Other  **G1:** 18 (3.5)  **G2:** 14 (2.6)  **Socioeconomic status:**  NR  **Smoking history:**  Cigarettes per day before pregnancy, median number ( IQR):  **G1:** 20 (15 to 20)  **G2:** 20 (15 to 20) | **Maternal smoking status**  Number of cigarettes per day, median (IQR):  **G1:** 13 (10 to 20)  **G2:** 15 (10 to 20)  Cotinine level, median (IQR):  **G1:** 123.1 (80.1 to 179.8)  **G2:** 121.2 (77.2 to 175.9) | **Maternal smoking status**  Abstinence from quit date to delivery[[1]](#footnote-1), n (%):  **G1:** 49 (9.4)  **G2:** 40 (7.6)  **G1 vs. G2:** OR=1.26 (95% CI: 0.82 to 1.96)  Abstinent for 1 month after quit date[[2]](#footnote-2), n (%):  **G1:** 111 (21.3)  **G2:** 62 (11.7)  **G1 vs. G2:** OR=2.05 (95% CI: 1.46 to 2.88)  Abstinence from quit date to delivery[[3]](#footnote-3), n (%):  **G1:** 42 (8.1)  **G2:** 32 (6.0)  **G1 vs. G2:** OR=1.36 (95% CI: 0.84 to 2.19)  Abstinence at deliveryb, n (%)  **G1:** 63 (12.1)  **G2:** 53 (10.0)  **G1 vs. G2:** OR=1.23 (95% CI: 0.84 to1.82)  Relapse:  NR  **Child/infant outcomes**  Miscarriage, n (%):  **G1:** 3 (0.6)  **G2:** 2 (0.4)  Stillbirth, n (%):  **G1:** 5/512 (1.0)  **G2:** 2/519 (0.4)  Neonatal death, n:  **G1:** 0/507  **G2:** 2/517  Post-neonatal death, n:  **G1:** 1/507  **G2:** 0/517  Gestational age, mean weeks ± SD:  **G1:** 39.5 ± 2.1  **G2:** 39.5 ± 2.1  **G1 vs. G2:** p=NS  Birthweight, mean kg ± SD:  **G1:** 3.18 ± 0.61  **G2:** 3.20 ± 0.59  **G1 vs. G2:** p=NS  Low birthweight (less than 2.5 kg), n (%):  **G1:** 56/507 (11.0)  **G2:** 43/517 (8.3)  **G1** **vs.** **G2:** 1.38 (0.90 to 2.09)  NICU admission, n (%):  **G1:** 33/507 (6.5)  **G2:** 35/517 (6.8)  **G1 vs.** **G2:** OR=0.96 (95% CI: 0.58 to 1.57)  Asthma exacerbation :  NR  Asthma hospitalization :  NR  Upper respiratory infection:  NR  **Adverse Events:**  See manuscript table 4 on page 816. | **Overall quality:**  Good  **Risk of bias**  Randomization:  Low  Allocation concealment:  Low  Selective reporting:  Low  Blinding patients/personnel:  Low  Blinding outcome assessment:  Low  Incomplete outcome reporting:  Low  Other:  Low |

1. Biochemically verified by salivary cotinine [↑](#footnote-ref-1)
2. Biochemically verified by exhaled carbon monoxide [↑](#footnote-ref-2)
3. Biochemically verified at 1 month after quit date and at delivery [↑](#footnote-ref-3)