**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 toFebruary 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:** 2/517Post-neonatal death, n:**G1:** 1/507**G2:** 0/517Gestational age, mean weeks ± SD:**G1:** 39.5 ± 2.1**G2:** 39.5 ± 2.1**G1 vs. G2:** p=NSBirthweight, mean kg ± SD:**G1:** 3.18 ± 0.61**G2:** 3.20 ± 0.59**G1 vs. G2:** p=NSLow 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 :NRUpper respiratory infection:NR**Adverse Events:**See manuscript table 4 on page 816. | **Overall quality:**Good**Risk of bias**Randomization:LowAllocation concealment:LowSelective reporting:LowBlinding patients/personnel:LowBlinding outcome assessment:LowIncomplete outcome reporting:LowOther: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)