**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 toAugust 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:** 31High school/GED, %**G1:** 31**G2:** 33Vocational school, %**G1:** 6**G2:** 10Some college, %**G1:** 33**G2:** 17College 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:** 12Number 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:** 73Black**G1:** 26**G2:** 19Other**G1:** 7**G2:** 8**Socioeconomic status, %:**Employed full time**G1:** 30**G2:** 31Employed part time**G1:** 21**G2:** 9Not employed**G1:** 49**G2:** 60**Smoking history:**Cigarettes smoked daily 30 days before pregnancy, mean ± SD**G1:** 19 ± 9**G2:** 20 ± 824-hour quit attempt, %**G1**: 57**G2:** 6124-hour quit attempts, mean number ± SD**G1:** 3 ± 3**G2:** 2 ± 2Longest quit, mean days ± SD**G1:** 100 ± 171**G2:** 79 ± 13324-hour quit attempt in previous pregnancy, %**G1:** 50**G2:** 62Longest 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=0.006Abstinence at 7 weeks post randomization (adjusted)[[1]](#footnote-1), %:**G1:** 24.0**G2:** 8.0**G1 vs. G2:** p=0.02Abstinence at 38 weeks pregnancy (unadjusted), %:**G1:** 14.0 **G2:** 2.0**G1 vs. G2:** p=0.01Abstinence at 38 weeks pregnancy (adjusted)f, %:**G1:** 18.0**G2:** 7.0**G1 vs. G2:** p=0.04Relapse:NR**Child/infant outcomes**Perinatal outcome data available, n**G1:** 113**G2:** 58Gestational age, mean weeks ± SD:**G1:** 37.9 ± 3.1**G2:** 38.6 ± 2.7**G1 vs. G2:** p=0.14Birthweight, mean grams ± SD:**G1:** 3061 ± 661**G2:** 3132 ± 688**G1** **vs.** **G2:** p=0.51NICU admission, n:**G1:** 13**G2:** 4Asthma exacerbation:NRAsthma hospitalization:NRUpper 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=0.07At 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:LowAllocation concealment:LowSelective reporting:LowBlinding patients/personnel:HighBlinding outcome assessment:LowIncomplete outcome reporting:LowOther:Low |

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