**Table H12. Evidence table (Reference ID# 291)**

| Study Description | Intervention(s)/ Comparator(s) | Patient Population | Baseline Measure(s) | Outcome Measure(s) | Quality |
| --- | --- | --- | --- | --- | --- |
| **Author:**Oncken et al., 2008**Country:**USA**Enrollment period:** July 2003 toSeptember 2006**Setting:** 3 hospital prenatal clinics, private practice**Funding:**Grant (Federal)Nicotine gum provided by Glaxo-Smith Kline**Author industry relationship disclosures:**2/7**Study Design:** RCT**Blinding:** Double blind | **Intervention:**Nicotine gum (2 mg) plus individualized behavioral counseling**Intervention Provider:**Study nurse**Intervention setting:**Clinic**Comparator:**Placebo gum plus individualized behavioral counseling**Followup:**Visit 4 (6 weeks post-treatment), visit 5 (32 to 34 weeks gestation), and visit 6 (6 to 12 weeks postpartum)**Groups:****G1:** Intervention**G2:** Control | **Inclusion criteria:** * Currently smoking at least 1 cigarette/day
* ≤ 26 weeks gestation
* Age 16 or older
* Able to speak English or Spanish
* Intending to carry pregnancy to term
* Living in stable residence
* High risk pregnancies included if they were medically stable (e.g. HIV or diabetes)

**Exclusion criteria:** * Evidence of current illicit drug or alcohol disorder within preceding month (women taking methadone maintenance included if reported not currently using illicit drugs
* Twins or other multiple gestation
* Unstable psychiatric problem, unstable medical problem , or medical problem that would interfere with study participation

**Enrollment, n:** **G1:** 100 **G2:** 94**Followup, n (%):** Perinatal outcomes**G1:** 97 (97)**G2:** 89 (95)Visit 6 to 12 weeks postpartum, n (%)**G1:** 65 (65)**G2:** 47 (50)**Age, mean years ± SD:****G1:** 25.5 ± 6.8**G2:** 24.7 ± 5.4 **Education, n (%):**Less than high school**G1:** 53 (53)**G2:** 44 (47)High school**G1:** 28 (28)**G2:** 36 (39)More than high school**G1:** 19 (19)**G2:** 13 (14)**Gestation, mean weeks ± SD:****G1:** 17.1 ± 5.6**G2:** 17.1 ± 5.5**Insurance status, n (%):**Public **G1:** 81 (81)**G2:** 80 (85)Private**G1:** 19 (19)**G2:** 14 (15)**Parity:**Number of previous pregnancies, median (interquartile range)**G1:** 3 (2, 4)**G2:** 3 (2, 4)First pregnancy, n (%)**G1:** 16 (16)**G2:** 16 (17)History preterm delivery, n (%)**G1:** 13 (13)**G2:** 16 (17)**Partner status:**Married or partnered, n (%)**G1:** 30 (30)**G2:** 28 (30)**Partner smoking status:**NR**Race/ethnicity, n (%):**Hispanic**G1:** 53 (53)**G2:** 52 (55)Non-Hispanic white**G1:** 38 (38)**G2:** 30 (32)Non-Hispanic African-American**G1:** 8 (8)**G2:** 7 (7)Other**G1:** 1 (1)**G2:** 5 (5)**Socioeconomic status:**NR**Smoking history:**Cigarettes per day before pregnancy, mean ± SD**G1:** 17.5 ± 9.6**G2:** 17.8 ± 9.3Cigarettes per day previous 7 days, mean ± SD**G1:** 10.2 ± 6.6**G2:** 8.7 ± 5.7Previous quit attempts, mean ± SD**G1:** 3.03 ± 5.69**G2:** 2.55 ± 5.66Fagerstrom score, mean ± SD**G1:** 3.83 ± 1.91**G2:** 3.55 ± 1.95 | **Maternal smoking status**Number of cigarettes per day, mean ± SD:**G1:** 9.99 ± 6.1**G2:** 8.84 ± 5.7Expired carbon monoxide, mean ppm ± SD:**G1:** 9.43 ± 6.3 (n=100)**G2:** 8.69 ± 7.3 (n=94)Cotinine level, mean ng/ml ± SD:**G1:** 672 ± 438 (n=98)**G2:** 633 ± 559 (n=93)  | **Maternal smoking status**Abstinence[[1]](#footnote-1) at visit 4 (6 weeks post-treatment), mean %[[2]](#footnote-2):**G1:** 13.0**G2:** 9.6 **G1 vs. G2:** p=0.NSAbstinenced at visit 5 (32 to 34 weeks gestation), mean %e:**G1:** 18.0**G2:** 14.9 **G1 vs. G2:** p=0.56Abstinenced at 6 to 12 weeks postpartum, mean %e:**G1:** 11.0**G2:** 9.6 **G1 vs. G2:** p=NSRelapse:NR**Child/infant outcomes**Gestational age, mean weeks ± SD:**G1:** 38.9 ± 1.7**G2:** 38.0 ± 3.3**G1 vs. G2:** p=0.014Birthweight, mean grams ± SD:**G1:** 3287 ± 566**G2:** 2950 ± 653**G1** **vs.** **G2:** p<0.001NICU admission, n (%):**G1:** 7 (7)**G2:** 11 (13)**G1 vs.** **G2:** p=0.20Asthma exacerbation:NRAsthma hospitalization:NRUpper respiratory infection:NR**Adverse events:**Maternal hospitalization, n (%):**G1:** 9 (9)**G2:** 8 (9)**G1 vs. G2:** p=0.90Low birthweight (less than 2500 g), n (%):**G1:** 2 (2)**G2:** 16 (18)**G1 vs. G2:** p<0.001Very low birthweight (less than 1500 g), n (%):**G1:** 1 (1)**G2:** 4 (5)**G1 vs. G2:** p=0.19Preterm delivery (less than 37 weeks gestation), n (%):**G1:** 7 (7.2)**G2:** 16 (18.0)**G1 vs. G2:** p=0.027Spontaneous abortion, n (%):**G1:** 2 (2)**G2:** 0 (0)**G1 vs. G2:** p=0.50Intrauterine fetal death, n (%):**G1:** 2 (2)**G2:** 1 (1)**G1 vs. G2:** p=0.54Second trimester pregnancy loss, n (%):**G1:** 0 (0)**G2:** 1 (1)**G1 vs. G2:** p=0.47Newborn death, n (%):**G1:** 1 (1)**G2**: 2 (2)**G1 vs. G2:** p=0.60Any serious adverse event, n (%):**G1:** 24 (24.7)**G2:** 33 (37.9)**G1 vs. G2:** p=0.06 | **Overall quality:**Fair**Risk of bias**Randomization:LowAllocation concealment:LowSelective reporting:LowBlinding patients/personnel:LowBlinding outcome assessment:LowIncomplete outcome reporting:UnclearOther:Low |

Two outcome p-values for comparison between groups presented 1) with substitution of missing data with last available data or 2) analysis of change scores for participants with follow-up data (completer analysis)

1. Carbon monoxide exhalation value less than 8 ppm [↑](#footnote-ref-1)
2. Standard errors shown in figures only [↑](#footnote-ref-2)