**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 to  September 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 ± 9.3  Cigarettes per day previous 7 days, mean ± SD  **G1:** 10.2 ± 6.6  **G2:** 8.7 ± 5.7  Previous quit attempts, mean ± SD  **G1:** 3.03 ± 5.69  **G2:** 2.55 ± 5.66  Fagerstrom 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 ± 5.7  Expired 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.NS  Abstinenced at visit 5 (32 to 34 weeks gestation), mean %e:  **G1:** 18.0  **G2:** 14.9  **G1 vs. G2:** p=0.56  Abstinenced at 6 to 12 weeks postpartum, mean %e:  **G1:** 11.0  **G2:** 9.6  **G1 vs. G2:** p=NS  Relapse:  NR  **Child/infant outcomes**  Gestational age, mean weeks ± SD:  **G1:** 38.9 ± 1.7  **G2:** 38.0 ± 3.3  **G1 vs. G2:** p=0.014  Birthweight, mean grams ± SD:  **G1:** 3287 ± 566  **G2:** 2950 ± 653  **G1** **vs.** **G2:** p<0.001  NICU admission, n (%):  **G1:** 7 (7)  **G2:** 11 (13)  **G1 vs.** **G2:** p=0.20  Asthma exacerbation:  NR  Asthma hospitalization:  NR  Upper respiratory infection:  NR  **Adverse events:**  Maternal hospitalization, n (%):  **G1:** 9 (9)  **G2:** 8 (9)  **G1 vs. G2:** p=0.90  Low birthweight (less than 2500 g), n (%):  **G1:** 2 (2)  **G2:** 16 (18)  **G1 vs. G2:** p<0.001  Very low birthweight (less than 1500 g), n (%):  **G1:** 1 (1)  **G2:** 4 (5)  **G1 vs. G2:** p=0.19  Preterm delivery (less than 37 weeks gestation), n (%):  **G1:** 7 (7.2)  **G2:** 16 (18.0)  **G1 vs. G2:** p=0.027  Spontaneous abortion, n (%):  **G1:** 2 (2)  **G2:** 0 (0)  **G1 vs. G2:** p=0.50  Intrauterine fetal death, n (%):  **G1:** 2 (2)  **G2:** 1 (1)  **G1 vs. G2:** p=0.54  Second trimester pregnancy loss, n (%):  **G1:** 0 (0)  **G2:** 1 (1)  **G1 vs. G2:** p=0.47  Newborn death, n (%):  **G1:** 1 (1)  **G2**: 2 (2)  **G1 vs. G2:** p=0.60  Any 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:  Low  Allocation concealment:  Low  Selective reporting:  Low  Blinding patients/personnel:  Low  Blinding outcome assessment:  Low  Incomplete outcome reporting:  Unclear  Other:  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)