

Social Programs That Work Review

## Evidence Summary for a Pregnant Woman’s Self-Help Guide to Quit Smoking

### HIGHLIGHTS:

- **PROGRAM:** In this program, health counselors in public maternity clinics teach pregnant women how to use a 7-10 day self-directed smoking cessation guide. The program costs approximately \$16 per patient and is provided as a supplement to clinics’ usual care.
- **EVALUATION METHODS:** This program has been evaluated in six well-conducted randomized controlled trials (RCTs).
- **KEY FINDINGS:** A sizable increase in the quit rate: 13.9% of women assigned to the program quit smoking in the last 4-5 months of their pregnancy, compared with 8.3% of the women assigned to the control group.<sup>1</sup> In almost all of the RCTs, these effects were statistically significant.
- **OTHER:** One limitation in the evidence is that none of the studies reported on birth outcomes (e.g., miscarriage rates, birth weight, gestational age) or early childhood outcomes (e.g., cognitive development, health). Thus, the final impact on child well-being is unknown – and, specifically, whether smoking cessation during the second half of pregnancy (after mothers had smoked during the first half of pregnancy) improves child well-being in a meaningful way.

**I. Evidence rating:** **SUGGESTIVE TIER**

The standard for Suggestive Tier is:

*Programs that have been evaluated in one or more well-conducted RCTs (or studies that closely approximate random assignment) and found to produce sizable positive effects, but whose evidence is limited by only short-term follow-up, effects that fall short of statistical significance, or other factors. Such evidence suggests the program may be an especially strong candidate for further research, but does not yet provide confidence that the program would produce important effects if implemented in new settings.*

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<sup>1</sup> These are the average quit rates across the six trials, with each trial weighted by sample size.

## **II. Description of the Program:**

This educational program for pregnant smokers was provided by health counselors in public maternity clinics. It consisted of a 10-20 minute session during which counselors taught women how to use a 7-10 day self-directed smoking cessation guide (*A Pregnant Woman's Self-Help Guide to Quit Smoking*). The program cost approximately \$16 per patient (2017 dollars), and was provided in addition to clinics' usual care, which, in the study clinics described below, typically consisted of brief discussion of the risks of smoking during a nurse-led prenatal class, educational pamphlets, and information on local resources providing quitting assistance.

The *Guide* is currently out-of-print; the author and program developer is [Richard Windsor](#).

## **III. Evidence of Effectiveness:**

*A Pregnant Woman's Self-Help Guide to Quit Smoking* has been evaluated in six well-conducted randomized controlled trials. The following summarizes the program's effects on the main outcomes measured in these six studies, including any such outcomes for which no or adverse effects were found. All effects shown are statistically significant at the 0.05 level unless stated otherwise.

### **STUDY 1 (Three Public Health Clinics in Birmingham, Alabama)**

This was a randomized controlled trial of 206 smokers who were less than 32 weeks pregnant and who received services at three public health maternity clinics in Birmingham, Alabama from 1983 to 1984. The women were randomly assigned to a group that received the health education program or to a control group that received the clinics' usual care (e.g., brief discussion of smoking risks, educational pamphlets). This study also tested another smoking cessation program that used a different self-directed smoking cessation guide (*Freedom from Smoking*), but it was found to have substantially smaller effects than the above program and so is not summarized here.

On average, sample women were 24 years old and four months pregnant. 55% were African-American.

#### **Effects of the program near the end of women's pregnancies – i.e., 4-5 months after random assignment:**

Compared to the control group, program group women were much more likely to have:

- Quit smoking (13.7% of program group women reported quitting smoking vs. 1.9% of the control group).
- Quit and/or reduced smoking (31% of the program group had reduced their smoking by at least 30% based on biological tests vs. 14% of the control group).

**Discussion of Study Quality:**

- Prior to the study, the program and control groups were highly similar in their demographic characteristics and how much they smoked.
- The study had a short-term follow-up – 4-5 months after random assignment, on average –that varied depending on when during their pregnancy women entered the study. This follow-up was adequate to measure the program’s effects on smoking during pregnancy, but longer-term follow-up would be needed to determine whether it resulted in sustained reductions in tobacco use.
- The study had low sample attrition: Approximately 10-15 percent of women were lost to follow-up in each group. These women were counted as still smoking in the study’s analysis.
- The study sought to measure outcomes for all sample members assigned to the program group, regardless of whether or how long they participated in the program (i.e., the study used an “intention-to-treat” analysis).
- The study verified patients’ self-reported smoking behavior through a saliva test.
- The program was tested as it would be normally implemented in public health clinics, thus providing evidence of its effectiveness under real-world conditions.

**STUDY 2 (Four Public Health Clinics in Birmingham, Alabama)**

This was a randomized controlled trial of 994 smokers who were less than 32 weeks pregnant and who received services at four public health maternity clinics in Birmingham, Alabama from 1986 to 1991. The women were randomly assigned to either a group that received the health education program, or to a control group that received the clinics’ usual care (e.g., brief discussion of smoking risks, educational pamphlets). The program group in this study received a slightly enhanced version of the program, which included reminders from clinic staff about the importance of quitting smoking, encouragement to get social support for their quit attempt from a “buddy”, and a quarterly newsletter with testimonials from quitters and tips for quitting.

On average, sample women were 24 years old and four months pregnant. 52% were African-American.

**Effects of the program near the end of women’s pregnancies—i.e., approximately four months after random assignment:**

Compared to the control group, program group women were much more likely to have:

- Quit smoking (14.3% of the program group were tobacco-free at each of two follow-up clinic visits vs. 8.5% of the control group).
- Quit and/or substantially reduced smoking (31.1% of the program group had reduced their smoking by at least 50% based on biological tests vs. 20.8% of the control group). Although not explicitly reported, this effect appears to be significant at the 0.05 level.

**Discussion of Study Quality:**

- At the start of the study, the program and control groups were highly similar in their demographic characteristics and how much they smoked.
- The study had a short-term follow-up—four months after random assignment, on average—that varied in length depending on when during their pregnancy women entered the study. This follow-up was adequate to measure the program’s effects on smoking during pregnancy, but longer-term follow-up would be needed to determine whether it resulted in sustained reductions in tobacco use.
- The study had moderate sample attrition—outcome data were collected for 70% of the original sample at the 4-month follow-up. Approximately 18% of the sample became ineligible for the study after random assignment because they withdrew from public healthcare, or had a miscarriage or abortion (nearly identical percentages of program and control group members were lost for these reasons). An additional 12% of the original sample were eligible to participate but did not complete follow-up assessments and were counted as still smoking in the study’s analysis. The study does not report if the attrition rates among these women differed across the program and control groups.
- The study sought to measure outcomes for all sample members assigned to the program group, regardless of whether or how long they participated in the program (i.e., the study used an “intention-to-treat” analysis).
- The study verified patients’ self-reported smoking behavior through a saliva test.
- The program was tested as it would normally be implemented in public health clinics, providing evidence of its effectiveness under real-world conditions.

**STUDY 3 (One Hospital in North Carolina)**

This was a randomized controlled trial of 250 smokers who were less than 36 weeks pregnant and who received services at prenatal clinics at the University of North Carolina Women’s Hospital from 1991 to 1993. The women were randomly assigned to either a group that received the health education program, or to a control group that received the clinics’ usual care (e.g., brief discussion of smoking risks, educational pamphlets). The program group in this study received a slightly enhanced version of the program, which was provided by medical residents and included ongoing reminders at subsequent appointments about the importance of quitting smoking, a written “prescription” to stop smoking from a doctor, monthly postcards of encouragement, and telephone contact from a volunteer smoking cessation counselor.

On average, women were 25 years old and 3.5 months pregnant. 76% were white.

**Effects of the program at the end of women’s pregnancies—i.e., approximately 5-6 months after random assignment:**

Compared to the control group, program group women were much more likely to have:

- Quit smoking (19.6% of the program group were tobacco-free at follow-up vs. 10.0% of the control group). This effect was statistically significant at the 0.06 level, but not the 0.05 level.
- Quit and/or substantially reduced smoking (51.4% of the program group had reduced their smoking by at least 50% based on biological tests vs. 30.0% of the control group).

**Discussion of Study Quality:**

- At the start of the study, the program and control groups were highly similar in their demographic characteristics and smoking history.
- The study had a short-term follow-up – 5-6 months after random assignment, on average, which varied in length depending on when during their pregnancy women entered the study. This follow-up was adequate to measure the program’s effects on smoking during pregnancy, but longer-term follow-up would be needed to determine whether it resulted in sustained reductions in tobacco use.
- The study had low-to-moderate attrition – outcome data were collected for 83% of the original sample at the 4-month follow-up. Although not explicitly reported, follow-up rates for the program and control groups appear to be similar.
- The study sought to measure outcomes for all women assigned to the program group, regardless of whether or how long they participated in the program (i.e., the study used an “intention-to-treat” analysis).
- The study verified patients’ self-reported smoking behavior through a breath test that measured carbon monoxide levels.
- The program was tested as it would normally be implemented in a resident-staffed obstetric clinic, providing evidence of its effectiveness under real-world conditions.

**STUDY 4 (One Hospital in Ontario, Canada)**

This was a randomized controlled trial of 224 smokers who were less than 31 weeks pregnant and who received services in the early 1990’s at a teaching hospital in Ontario, Canada. The women were randomly assigned to either a group that received the health education program from a public health nurse, or to a control group that received the clinic’s usual care, consisting of a 3-5 minute discussion on the hazards of smoking and an invitation to a two-hour group cessation class covering *A Pregnant Woman’s Self-Help Guide to Quit Smoking* (no control group women participated in the class). The program group in this study received a slightly enhanced version of the program, which included a telephone follow-up from a nurse. The program was provided in both English and French.

On average, sample women were 27 years old and 3.5 months pregnant.

**Effects of the program six weeks after childbirth—i.e., approximately 8 months after random assignment:**

Compared to the control group, program group women:

- Were much more likely to have quit smoking (13.8% of the program group were tobacco-free at follow-up vs. 5.2% of the control group).
- Smoked 14% fewer cigarettes per day (the program group smoked an average of 12 cigarettes per day vs. 14 for the control group).

**Discussion of Study Quality:**

- At the start of the study, the program and control group were highly similar in their demographic characteristics, health status, and how much they smoked. However, program group women were considerably more likely to view their smoking as posing a risk to their pregnancy (69% vs. 58%)
- The study had a short-term follow-up – 8 months after random assignment, on average – that varied in length depending on when during their pregnancy women entered the study. This follow-up was adequate to measure the program’s effects on smoking during pregnancy, but longer-term follow-up would be needed to determine whether it resulted in sustained reductions in tobacco use.
- The study had low-to-moderate sample attrition – outcome data were collected for 76-85% of the original sample at the 8-month follow-up, depending on the outcome measure. Attrition rates did not differ across the two groups.
- The study sought to measure outcomes for all sample members assigned to the program group, regardless of whether or how long they participated in the program (i.e., the study used an “intention-to-treat” analysis).
- The study verified patients’ self-reported smoking behavior through a urine test.
- The program was tested as it would normally be implemented in a public hospital, providing evidence of its effectiveness under real-world conditions.

**STUDY 5 (One Hospital in Oslo, Norway)**

This was a randomized controlled trial of 112 smokers who were approximately 18 weeks pregnant and who received services at the National University Hospital in Oslo, Norway from June 1990 to October 1991. Women who visited the hospital’s maternity clinic for an ultrasound examination were randomly assigned to either a group that received the health education program as provided by either a midwife or obstetrician, or to a control group that received the clinic’s usual care (e.g., brief discussion of smoking risks, educational pamphlets). The program group in this study received a slightly enhanced version of

the program, which included two encouragement letters, and an extra ultrasound appointment around the 32<sup>nd</sup> week of pregnancy during which the program’s anti-smoking message was reinforced. The program used a translated version of the *A Pregnant Woman’s Self-Help Guide to Quit Smoking*.

On average, women were 28 years old and four months pregnant.

**Effects of the program in the week after childbirth—i.e., approximately five months after random assignment:**

Compared to the control group, program group women were much more likely to have:

- Quit smoking (20.4% of the program group were tobacco-free at follow-up vs. 4.0% of the control group).
- Reduced – but not quit – smoking (64.8% of the program group had reduced their smoking vs. 38.0% of the control group). Those who reduced their smoking did so by an average of eight cigarettes per day.

**Discussion of Study Quality:**

- At the start of the study, the program and control group were largely similar in their demographic characteristics and most measures of their prior smoking behavior, although the program group reported smoking significantly more cigarettes each day (14.8 cigarettes vs. 12.5).
- The study had a short-term follow-up – 5 months after random assignment, on average – that varied in length depending on when during their pregnancy women entered the study. This follow-up was adequate to measure the program’s effects on smoking during pregnancy, but longer-term follow-up would be needed to determine whether it resulted in sustained reductions in tobacco use.
- The study had low sample attrition – outcome data were collected for 93% of the original sample at the 5-month follow-up. Follow-up rates differed somewhat for the two groups (outcome data were collected for 96% of the program group women and 89% of control group women).
- The study sought to measure outcomes for all women assigned to the program group, regardless of whether or how long they participated in the program (i.e., the study used an “intention-to-treat” analysis).
- The program was tested as it would normally be implemented in a public hospital, providing evidence of its effectiveness under real-world conditions.
- One limitation is that the study results are based on women’s self-reported smoking behavior and not more conclusive biological tests as in the above studies.

### **STUDY 6 (Prenatal Clinics in Alabama)**

This was a randomized controlled trial of 1,340 Medicaid beneficiaries who received services at prenatal clinics in 17 counties in Alabama from 1997 to 2001. The women were randomly assigned to either a group that received the health education program or to a control group that received the clinics' usual care (described above). The program group in this study received a slightly enhanced version of the program, which included a viewing of a 14-minute video presenting motivational themes from ex-smokers.

On average, sample women were 23 years old and 10 weeks pregnant. 13% were African-American.

#### **Effects of the program at follow-ups ranging from 60 days after the initial visit to 90 days postpartum—i.e., approximately 2 to 10 months after random assignment:**

Compared to the control group, program group women were:

- Only slightly more likely to have quit smoking, and this difference did not reach statistical significance (12% of program women reported quitting smoking, versus 10% of the control group;  $p = 0.31$ ).
- 27% more likely to have made a substantial reduction in smoking (18.2% of program women reduced their smoking by at least 50% based on biological tests, versus 13.2% of the control group).

#### **Discussion of Study Quality:**

- At the start of the study, program and control groups were highly similar in their observable characteristics (e.g., demographics, smoking history).
- The study had a short-term follow-up — 2-10 months after random assignment, on average— that varied depending on when during their pregnancy women entered the study. This follow-up was adequate to measure the program's effects on smoking during pregnancy (and, in some cases, shortly thereafter), but longer-term follow-up would be needed to determine whether it resulted in sustained reductions in tobacco use.
- The study had moderate-to-high sample attrition. Outcome data were obtained from 67% of the original randomized sample. (18% of the sample became ineligible and was dropped from the analysis because two counties' Medicaid contracts were rebid partway through the study, meaning that Medicaid patients in these counties were seen at different clinics. Another 14% were lost to follow-up and treated as smokers in the study's analysis of program effects.) Follow-up rates were similar for the two groups.
- The study sought to measure outcomes for all sample members assigned to the program group, regardless of whether or how long they participated in the program (i.e., the study used an "intention-to-treat" analysis).

- The study evaluated the program as it would normally be implemented with a Medicaid-recipient population attending prenatal clinics in Alabama, providing evidence of its effectiveness under real-world conditions.
- The study verified patients' self-reported claims of abstinence through a saliva test (if not confirmed, the patient was classified as a smoker in the analysis).
- A study limitation is that 15% to 20% of control group participants received the smoking cessation program, likely causing the study to under-estimate the effect of the program. This may help account for the smaller effects found in this trial compared to the five other trials.

### **OTHER STUDIES**

Two other randomized controlled trials of *A Pregnant Woman's Self-Help Guide to Quit Smoking* have been conducted, but are not summarized here for the following reasons. The first trial evaluated a considerably different version of the *Guide* from the one used in the above trials (e.g., the *Guide* was substantially revised, with new sections included). The other trial suffered from an important study limitation that may undermine its validity – namely, high sample attrition, with smoking data only collected for about half of its original sample. (The first of these trials found that the program increased quit rates, whereas the second did not.)

### **THOUGHTS ON WHAT MORE IS NEEDED TO BUILD STRONG EVIDENCE**

Longer-term study follow-up measuring birth outcomes (e.g., miscarriage rates, birth weight, gestational age) and/or early childhood outcomes (e.g., cognitive development, health) would be desirable to determine whether the program's demonstrated impact on smoking cessation leads to improvement in these outcomes.

## **IV. References:**

### **Study 1:**

Windsor, Richard A., Gary Cutter, Joyce Morris, Yoland Reese, Brynda Manzella, Edward E. Bartlett, Carole Samuelson, and Debra Spanos. "The Effectiveness of Smoking Cessation Methods for Smokers in Public Health Maternity Clinics: A Randomized Trial." *The American Journal of Public Health*, 1985, vol. 75, pp. 1389-1392.

### **Study 2:**

Windsor, Richard A., John B. Lowe, Laura L. Perkins, Dianne Smith-Yoder, Lynn Artz, Myra Crawford, Kim Amburgy, and Neal Richard Boyd. "Health Education for Pregnant Smokers: Its Behavioral Impact and Cost Benefit." *The American Journal of Public Health*, February 1993, vol. 83, no. 2, pp. 201-206.

**Study 3:**

Hartmann, Katherine E., John M. Thorpe, Laurie Pabel-Short, and Matthew A. Koch. "A Randomized Controlled Trial of Smoking Cessation Intervention in Pregnancy in an Academic Clinic." *Obstetrics and Gynecology*, 1996, vol. 87, pp. 621-626.

**Study 4:**

O'Connor, Annette M., Barbara L. Davies, Corinne S. Dulberg, P. Lynn Buhler, Claudette Nadon, Beverly H. McBride, and Ronald J. Benzie. "Effectiveness of a Pregnancy Smoking Cessation Program." *Journal of Obstetrics, Gynaecology, and Neonatal Nursing*, 1992, vol. 21, pp. 385-392.

**Study 5:**

Valbo, Annelill and Gro Nylander. "Smoking Cessation in Pregnancy: Intervention Among Heavy Smokers." *Acta Obstetrica et Gynecologica Scandinavia*, 1994, vol. 73, pp. 215 - 219.

**Study 6:**

Windsor, Richard A., Lesa Woodby, Thomas Miller, and Michael Hardin. "Effectiveness of Smoking Cessation and Reduction in Pregnancy Treatment (SCRIPT) Methods in Medicaid-Supported Prenatal Care: Trial III." *Health Education & Behavior*, 2011, vol. 38, no. 4, pp. 412-422.

**Other Studies:**

Gielen, Andrea C., Richard A. Windsor, Ruth R. Faden, Patricia O'Campo, John Repke, and Mary V. Davis. "Evaluation of a Smoking Cessation Intervention for Pregnant Women in an Urban Prenatal Clinic." *Health Education Research*, 1997, vol. 12, pp. 247-254.

Hjalmarson, A. I. M., L. Hahn, and B. Svanberg. "Stopping Smoking in Pregnancy: Effect of a Self-Help Manual in a Controlled Trial." *British Journal of Obstetrics and Gynaecology*, 1991, vol. 98, pp. 260-264.