

Clinical trials and tribulations: Lessons learned from recruiting pregnant ex-smokers for relapse prevention

Elena N. Lopez, Vani Nath Simmons, Gwendolyn P. Quinn, Cathy D. Meade, Thomas N. Chirikos, Thomas H. Brandon

Received 19 September 2006; accepted 14 February 2007

The development of smoking cessation and relapse prevention interventions for pregnant and postpartum women is a public health priority. However, researchers have consistently reported substantial difficulty in recruiting this population into clinical trials. The problem is particularly acute for relapse prevention studies, which must recruit women who have already quit smoking because of their pregnancy. Although these individuals are an important target for tobacco control efforts, they represent an extremely small subgroup of the general population. This paper describes multiple recruitment strategies used for a clinical trial of a self-help relapse prevention program for pregnant women. The effectiveness of the strategies and the direct expense per participant recruited are provided. A proactive recruitment strategy (telephoning women whose phone numbers were purchased from a marketing firm) was ultimately much more successful than a variety of reactive strategies (advertisements, press releases, direct mail, Web placement, health care provider outreach). We found few differences between proactively and reactively recruited participants on baseline variables. The primary difference was that the former had smoked fewer cigarettes per day and reported lower nicotine dependence prior to quitting. Strengths and limitations of the recruitment strategies are discussed.

Introduction

The risks associated with smoking during pregnancy are well established and highly publicized (Britton, 1998; Centers for Disease Control and Prevention, 1995; U.S. Department of Health and Human Services [USDHHS], 1990, 2001). Consequently, an increasing proportion of women (estimates range from 15% to 60%) spontaneously quit smoking

immediately prior to or during their pregnancies (Ershoff, Solomon, & Dolan-Mullen, 2000; Morasco, Dornelas, Fischer, Oncken, & Lando, 2006). However, maintenance of tobacco abstinence among pregnant and postpartum women remains a challenge. Smoking relapse rates among pregnant and postpartum women range from 70% to 80%, with approximately half of these women resuming smoking within the first 12 weeks postdelivery (Fingerhut, Kleinman, & Kendrick, 1990; Ockene, 1993; Polanska, Hanke, & Sobala, 2005; USDHHS, 2001). Postpartum smoking exposes the infant to environmental tobacco smoke, which is associated with a range of health problems in children including middle ear infections, asthma, sudden infant death syndrome, behavioral problems, and developmental delays (Charlton, 1994; USDHHS, 2006). Of course, by resuming smoking, the mother also re-exposes herself to the myriad health risks associated with tobacco use. Given the high rate of self-quitting among pregnant smokers, as well as the success of

Elena N. Lopez, M.A., Department of Psychology, University of South Florida, and the H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL; Vani Nath Simmons, Ph.D., Gwendolyn P. Quinn, Ph.D., Cathy D. Meade, R.N., Ph.D., F.A.A.N., Thomas N. Chirikos, Ph.D., Department of Interdisciplinary Oncology, University of South Florida, and the H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL; Thomas H. Brandon, Ph.D., Departments of Psychology and Interdisciplinary Oncology, University of South Florida, and the H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL.

Correspondence: Thomas H. Brandon, Ph.D., Tobacco Research and Intervention Program, H. Lee Moffitt Cancer Center & Research Institute, 4115 E. Fowler Avenue, Tampa, FL 33617, USA. Tel: +1 (813) 745-1750; Fax: +1 (813) 745-1755; E-mail: thomas.brandon@moffitt.org