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Short Communication

Characteristics of Romanian women who enrolled in a postpartum tobacco smoking relapse prevention trial

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Introduction

Women in Romania and other low- and middle-income countries (LMIC) have high smoking rates during and around pregnancy[1] due to the fewer available cessation and relapse prevention services and fewer tobacco control policies in place. In Romania, 27% of the overall adult population smokes and 16.7% of women are using tobacco products.[2] Recent data show that 28% of pregnant women report smoking six months before becoming pregnant, and 15% continue to smoke during pregnancy.[3] The prepregnancy and pregnancy quit rates are higher than in the general population, and there are high rates of postpartum smoking relapse among women who spontaneously quit before or during pregnancy.

Smoking persistence during pregnancy, as well as relapse once pregnant women quit is significantly associated with the partner's smoking. At the same time, the presence of the life partner during and around pregnancy may present an opportunity for couple-oriented tobacco cessation and prevention interventions. Yet, few couple-focused smoking cessation and relapse prevention trials exist, most were implemented in high-income countries, and were in general unsuccessful in reducing pregnancy smoking and relapse.[4] In high-income countries, factors associated with participation in tobacco trials participation include older age, employment, higher levels of education, heavier smoking, and greater nicotine dependence.[5,6] There is little evidence to guide culturally adapted interventions to LMIC as most tobacco cessation and

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relapse prevention interventions were conducted in high-income countries.

This study investigated correlates of participation in a couples-focused postpartum tobacco smoking relapse prevention randomized clinical trial (RCT) in Cluj-Napoca, Romania described elsewhere.[7] A better understanding of the factors associated with enrollment in this trial may be used to increase enrollment of spontaneous quitters and their life partners in postpartum relapse couples-oriented trials in LMICs.

Among the 4195 postpartum women approached by the trained data collectors in the largest two state-owned obstetrics and gynecology clinics in Cluj-Napoca between November 2013 and May 2016, 51 refused participation, 4144 went through the screening process, and 389 met the eligibility criteria and agreed to fill out the study's paper-based, self-administered survey. Out of these 389 women, 199 agreed to participate in the RCT. The outcome variable of interest dichotomized the study sample in women who met the eligibility criteria and accepted ($n = 199$) or declined ($n = 190$) participation in the RCT.

We tested a variety of RCT enrollment correlates that have either been demonstrated[8,11,12] or hypothesized to influence smoking relapse after birth, including sociodemographics (age, education, ethnicity, residence, income, and employment status), reproductive history (gravidity, pregnancy intent, and the availability of support in taking care of the baby), and smoking and alcohol-related items: heaviness of smoking before quitting;[8] number of previous quit attempts; importance of staying quit; intention to resume smoking in the next six months; life partner's smoking status; teamwork standards, assessing the extent to women consider that problems related to smoking cessation should be managed alone or together with their partner;[9] dyadic efficacy for smoking cessation;[10] positive and negative smoking-specific partner support;[11] smoking abstinence self-efficacy;[12] ban of smoking in the house; attitude toward the harmfulness of light cigarettes; and alcohol use during pregnancy. Emotional health measures included perceived stress using Cohen's Perceived Stress Scale (PSS-4);[13] depressive symptoms using the Romanian version of the Edinburg Postnatal Depression Scale (EPDS-R);[14] and anxiety symptoms using Spitzer's Generalized Anxiety Disorder scale (GAD-7).[15] Data analysis was performed using SPSS Statistical Software version 13.0 (SPSS Inc., Chicago, IL, USA). We present multivariate logistic regression results to identify characteristics associated with RCT enrollment.

Characteristics of women who enrolled in the postpartum tobacco smoking relapse prevention trial

Among the 389 eligible women who were invited to enroll in a couple-focused postnatal relapse prevention trial, 51% (199) enrolled in the trial and 49% (190) declined, for a higher participation rate compared with similar RCTs.[16] Women included in the sample had a mean age of 30.2 years (range 20–44, SD = 4.59), 89% were of Romanian ethnicity, 35.2% had less than high school education, 85.2% were married, and 28.8% were living in a rural area. Women who enrolled in a couples-focused intervention to prevent postnatal smoking relapse were similar with women who declined on most of the characteristics of interest, including many abstinence-relevant characteristics (e.g. quit attempts, abstinence importance and intent, mental health, self-efficacy, smoking partner). Unreported results indicate that women who were part- or full-time employed (80% vs 67.8%, $P = 0.01$), wanted the pregnancy (88.9% vs 80.7%, $P = 0.03$), and had higher teamwork standards scores (7.79 vs 7.20, $P = 0.03$) were significantly more likely to enroll in the trial.

The multivariate logistic model (Table 1) indicated that trial enrollment was positively associated with rural residence, Romanian ethnicity, employment, and having had a wanted pregnancy. After adjusting for all the included covariates, women living in urban dwellings had significantly lower odds of enrolling in the RCT compared with women living in rural areas (odds ratio [OR] = .60; 95% confidence interval [95% CI] = .37, .97), women of Romanian ethnicity had more than twice the odds of enrolling in the RCT compared with women of other ethnicities (OR = 2.29; 95% CI = 1.08, 4.87), women who were employed part- or full-time had almost twice the odds of enrolling in the RCT compared with women who were not employed (OR = 1.95; 95% CI = 1.10, 3.45), and women who wanted the pregnancy then or sooner had almost twice the odds of enrolling in the RCT compared with women who wanted the pregnancy later or not at all (OR = 1.90; 95% CI = 1.06, 3.39).

Our results show that women living in urban dwellings had almost half the odds of enrolling in the RCT compared with rural women although the trial was set in two large public urban obstetrics and gynecology clinics. This finding suggests that greater efforts and possibly other recruitment strategies and locations may be needed to tailor such interventions to urban women who may have a higher socio-economic status. One strategy may be to expand recruitment in private clinics where the population tends to be more urban and of higher socio-economic status.

The study also found that minority women have approximately half the odds of enrollment compared with women of Romanian ethnicity. This is a concern, given that some minority women, Roma in particular, have significantly higher pregnancy and postpartum smoking rates. Enrollment that takes place in minority communities, rural areas, and is attempted by community health workers of similar ethnicity may be needed. Materials and recruitment procedures in the specific minority language may also increase the likelihood of enrollment of minority populations.

Women with an unintended pregnancy had half the odds of enrolling in the relapse prevention RCT compared with women with an intended pregnancy. They may be less motivated to stay smoke-free after birth as they may perceive the pregnancy and the birth as unwelcome events and may be therefore less interested to enroll in a relapse prevention trial. Motivation-enhancing efforts may be needed to both increase trial representativeness but also the potential positive effects of prevention trials as women carrying unintended