Fourth Contact Attempts and Screening Pregnant/Postpartum Women in a Smoking Cessation Clinical Trial

Courtney Kimmell, Madeline Scherven, Katherine Harrison, Devin Dolquist, Sharon Allen

Introduction

BurPPP Study

- The BurPPP study (Bupropion for Prevention of Postpartum Smoking Relapse) is a clinical research study being conducted at the University of Minnesota with the Tobacco Research Program
- Although many women quit smoking during pregnancy, 50-60% of women relapse in the first year of the postpartum period. [1]
- Depression can be a risk factor for smoking relapse in postpartum women.[2]
- Bupropion, commonly used as an anti-depressant agent, has been shown to be effective in smoking cessation.[3]
- The BurPPP study investigates if taking bupropion can help postpartum women quit or stay quit smoking tobacco cigarettes after having a child.

Contacting Participants for Eligibility Phone Screening

- Pregnant and postpartum women can be hesitant to engage with clinical research trials due to time constraints, health concerns, and social influences.[4]
- We completed a smaller analysis (n=97) last year that showed that extending the timeframe to recruit participants did not lead to an increase in study interest or eligibility phone screens.[5]

Goals

Objectives

- Analyze if adding an additional contact attempt to the recruitment protocol will yield an increase in completed eligibility screenings and study enrollments.

Hypothesis

- Given a smaller analysis done last year showing that an additional contact attempt yielded a 3% screening rate (n=97), we predict completing an additional contact attempt on a larger sample size will yield a similarly low eligibility screening rate of less than 5%.[5]

Methods

BurPPP Study

- Participants for the BurPPP study are recruited primarily through two avenues:

  1. Build Clinical : This software advertises the study online (eg Facebook) and interested pregnant or postpartum women with a history of smoking can submit their contact information to be sent to our study staff.
  2. Clinic Contacts: Participants can elect to have their contact information shared with our staff from their healthcare offices.

- Participants are contacted three times via phone, email, and/or text within four weeks of providing their contact information to learn more about the study and complete an eligibility screening over the phone.

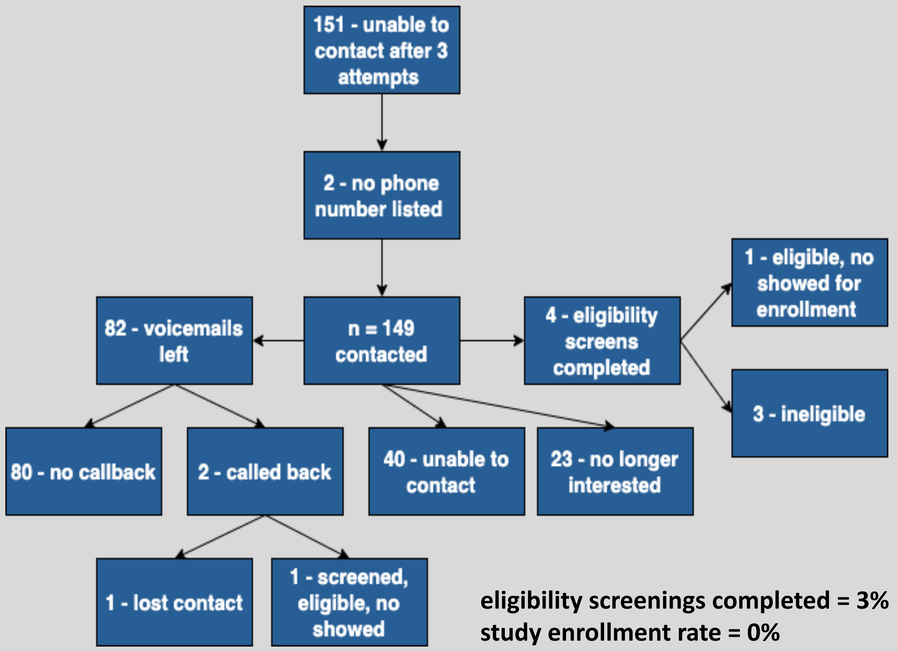
Contacting Participants for Eligibility Phone Screening

- Participants that we were unable to contact after three contact attempts between December 1, 2022 and May 31, 2023 were contacted for a fourth time in July 2023 via a phone call.
- Individuals were categorized as:
  - Unable To Contact if we were unable to leave a voicemail or if the call could not be completed due service issues
  - Uninterested if participants verbally stated uninterested or hung up after introducing the study

Acknowledgements

Funding for this work was supported part by Minnesota Academy of Family Physicians. Thank you to the donors of the MAFP foundation for supporting this project through the David Mersy, MD Summer Externship.

Results



eligibility screenings completed = 3%
study enrollment rate = 0%

Discussion

- Contacting participants an additional fourth time did not increase the number of enrolled participants in the study
- BurPPP and other clinical studies can use this data when designing, executing, and adjusting enrollment and recruitment processes
- Further studies should be conducted to assess novel recruitment strategies that address common hesitations of pregnant or postpartum women

References

1. Valent, A. and Choby, B. (2020). Tobacco and Nicotine Cessation During Pregnancy. *135,* 5.
2. Yang I, Hall L. (2014). Smoking cessation and relapse challenges reported by postpartum women. *39,* 375-380.
3. Allen, S. Thomas, J. Harris, K., Emery, R. L., Petersen, A., Winickoff, J. P., Japuntich, S. (2021). Bupropion for postpartum smoking relapse: a remote protocol for a two-arm, double-blind, placebo-controlled randomized clinical trial. *105,* 106352.
4. van der Zande, I.S.E., van der Graaf, R., Hooft, L., van Delden, J.J. M. (2018). Facilitators and barriers to pregnant women's participation in research: A systematic review. *31,* 350-361.
5. Harrison, K., Mengesha, D., Thomas, J., Allen, S. (2022). Timing for Recruiting Pregnant and Postpartum Women for a Smoking Cessation/Relapse Prevention Trial. [Manuscript in Preparation].