

Title: Integrated Smoking Cessation and Mood Management Following Acute Coronary Syndrome: Protocol for the Post-Acute Cardiac Event Smoking (PACES) Trial

Authors: Atefeh Alavi Fili, Melissa Adkins-Hempel, Pearl Fang, Nathalia Gutierrez Sacasa, Carina Lundtvedt, Oscar Oranday Perez, Sandra J. Japuntich, Woubeshet Ayenew, Andrew M. Busch

Significance: Approximately 400,000 people who smoke cigarettes survive Acute Coronary Syndrome (ACS; unstable angina, ST and non-ST elevation myocardial infarction) each year in the US. Continued smoking following ACS is an independent predictor of mortality. Depressed mood post-ACS is also predictive of mortality, and smokers with depressed mood are less likely to abstain from smoking following an ACS. A single, integrated treatment targeting depressed mood and smoking could be effective in reducing post-ACS mortality.

Methods: The overall aim of the current study is to conduct a fully powered efficacy trial enrolling 324 smokers with ACS and randomizing them to 12 weeks of an integrated smoking cessation and mood management treatment (Behavioral Activation Treatment for Cardiac Smokers [BAT-CS]) or control (smoking cessation and general health education topics such as sleep, communication with your provider, and eating fruits/vegetables). Both groups are offered 8 weeks of the nicotine patch if medically cleared. Counseling in both arms is provided by tobacco treatment specialists. Follow-up assessments are conducted at end-of-treatment (12 weeks) and 6, 9, and 12 months after hospital discharge. We track major adverse cardiac events and all-cause mortality for 36 months post-discharge. Primary outcomes are depressed mood and biochemically validated 7-day point prevalence abstinence from smoking over 12 months.

Discussion: Results of this study will inform smoking cessation treatments post-ACS and provide unique data on the impact of depressed mood on the success of post-ACS health behavior change attempts.

Keywords: *Smoking; depression; behavioral activation; secondary prevention; acute coronary syndrome; cardiovascular disease*

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