



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Award ID:
RP150228

Project Title:
Varenicline and Combined NRT for Initial Smoking Cessation and Rescue
Treatment in Smokers: A Randomized Pilot Trial

Award Mechanism:
Individual Investigator Research Awards for Prevention and Early
Detection

Principal Investigator:
Cinciripini, Paul M

Entity:
The University of Texas M.D. Anderson Cancer Center

Lay Summary:

Smoking accounts for at least 30% of all cancer deaths and plays a role in causing 18 different cancers. Over 40% of smokers make a serious cessation attempt each year, but each year less than 3% of all smokers successfully quit. There are several medications to help people quit including varenicline (Chantix), bupropion (Wellbutrin) and nicotine replacement products such as the patch and lozenge. But not all people respond the same to these medications. The major challenge of tobacco dependence disorders is that effective treatment may require repeated quit attempts and changes in treatment strategy when quitting is not achieved. Currently, there is very little information available to guide health care providers in knowing what to do if an initial treatment approach fails. Should they continue the course, extending treatment a bit longer; should they increase the medication dose; or should they change to another medication? We will use a new experimental design known as a "SMART" design (Sequential Multiple Assignment Randomization Trials) to help answer this question. We will also examine a number of patient characteristics to see if we can determine who will respond best to a particular treatment. In phase 1 of this study, 250 smokers will receive smoking cessation counseling, plus either varenicline or the nicotine patch + lozenge, to help them quit. In phase 2, people who quit by week 6 will remain on the medication they have been assigned. People who have not quit will receive one of three treatment assignments: 1) continue with the current medication; 2) augment treatment by increasing medication dose; or 3) switch to the medication they did not receive initially. All participants will receive counseling. This study will help researchers better understand how to provide the most effective medication for the first quit attempt and help people quit with a second medication treatment if they are unsuccessful.