

Appendix

Characteristics of Randomized Clinical Trials at Stanford University

Stanford Trial 1: Nicotine patch and paroxetine (Killen et al., 2000)	
Recruitment dates	1998
Method	Recruitment: newspaper announcements Design: RCT, double-blind, placebo-controlled
Participants	N = 224
Intervention	Pharmacotherapy: Nicotine patch (NP) + placebo OR NP + paroxetine (20 mg) OR NP + paroxetine (40 mg); NP (8 weeks) and paroxetine (9 weeks); Behavioral therapy: all received 2, 15 minute brief advice counseling sessions
Inclusion criteria	Adults \geq 18; cigarettes per day minimum = 10
Exclusion criteria	Pregnancy, lactation, history of severe liver or kidney disease, epilepsy, bipolar disorder, schizophrenia, current depression, substance abuse, medications that could negatively interact with paroxetine. Those who reported a history of heart disease, diabetes, thyroid disease, recent chest pain, very high blood pressure, skin conditions, or peptic ulcers were required to obtain written permission from their health care provider prior to study entry.
Stanford Trial 2: Extended treatment with bupropion SR (Killen et al., 2006)	
Recruitment dates	2001 – 2004
Method	Recruitment: announcements via newspaper, radio, community website, local organizations Design: RCT - open label followed by extended treatment
Participants	N = 362
Intervention	Pharmacotherapy: bupropion SR and NP followed by 14 weeks of extended treatment with bupropion or matching placebo: Behavioral therapy: 11 weeks of open label relapse prevention training and 14 weeks of relapse prevention training.
Inclusion criteria	Adults 18-65; cigarettes per day minimum = 10
Exclusion criteria	Pregnancy, lactation, epilepsy, bipolar disorder, schizophrenia, or current depression or substance abuse. Current use of bupropion or Nicotine Replacement Therapy (NRT) or medications that could negatively interact with bupropion or NRT.
Stanford Trial 3: Extended cognitive behavioral therapy for cigarette smoking cessation (Killen et al., 2008)	

Recruitment dates	2004 – 2006
Method	Recruitment: announcements via newspaper, radio, community website, local organizations Design: RCT with open label followed by extended treatment
Participants	N = 304
Intervention	8 weeks of open label NP, 9 weeks of bupropion SR, NP, and cognitive behavioral therapy (CBT) followed by 12 weeks of extended CBT + voicemail monitoring and phone counseling OR 4, brief telephone-based general support
Inclusion criteria	Adults 18-65; cigarettes per day minimum = 10
Exclusion criteria	Pregnancy, lactation, epilepsy, bipolar disorder, schizophrenia, or current depression or substance abuse. History of heart problems in the past six months, head trauma resulting in unconsciousness in the past year, severe head injury resulting in brain surgery or certain neurological problems. Current use of bupropion or NRT or medications that could negatively interact with bupropion or NRT.
Stanford Trial 4: Transdermal selegiline and cognitive behavioral therapy (Killen et al., 2010)	
Recruitment dates	2006 – 2008
Method	Recruitment: announcements via newspaper, radio, community website, local organizations Design: RCT, double-blind, placebo-controlled
Participants	N = 243
Intervention	8 weeks of selegiline transdermal therapy or placebo; all participants received CBT
Inclusion criteria	Adults 18-65; cigarettes per day minimum = 10
Exclusion criteria	Pregnancy, lactation, bipolar disorder, schizophrenia, and current depression or substance abuse. Current liver or kidney disease, uncontrolled diabetes, Parkinson's disease, Alzheimer's disease, unstable thyroid disorder. History of heart problems in the previous 6 months, uncontrolled hypertension, orthostatic hypotension, and current use of medications intended to assist in smoking cessation or medications contraindicated with use of selegiline.
Stanford Trail 5: Extended treatment for smoking cessation (Davis, 2015)	
Recruitment dates	2010 – 2013
Method	Recruitment: announcements via radio, newspaper, television, targeted mailings, bus shelters, social media, internet websites, and local companies/businesses Design: RCT with open label followed by double-blind extended treatment
Participants	N = 223

Intervention	10 weeks of NP and bupropion SR followed by 16 weeks of adaptive medication treatment (no meds, NP and bupropion SR, or varenicline). All participants received CBT. Next 26 weeks consisted of CBT OR monthly phone check.
Inclusion criteria	Adults 18-65; cigarettes per day minimum = 10
Exclusion criteria	Pregnancy, lactation, current or past seizure disorder, severe liver or kidney disease, uncontrolled diabetes or hypertension, current anorexia nervosa or bulimia. History of brain tumor, severe head injury resulting in brain surgery or blood clot in the brain, permanent loss of nerve function, or loss of consciousness. Recent history of stomach ulcer, recent heart problems, history of or current heart valve problem, recent stroke or TIA. Current major depressive disorder, history of schizophrenia or bipolar disorder, current alcohol or drug abuse, and any other severe mental illness. History of severe skin reaction to nicotine patches, current use of medications intended to assist in smoking cessation or medications contraindicated with use of bupropion SR or varenicline.

Characteristics of Randomized Clinical Trials at UCSF

UCSF Trial 1: Standard Intervention and Mood-Management (Hall et al., 1994)	
Recruitment dates	1990 – 1992
Method	Recruitment: advertising, public service announcements, and flyers Design: 2x3, double-blind, placebo-controlled, RCT
Participants	N = 149
Intervention	Standard treatment (ST) including 5 2-hour sessions of Standard Smoking Cessation + NRT gum over 8 weeks vs ST + 5 additional 2-hour sessions of depression prevention intervention with mood management
Inclusion criteria	Adults \geq 18-65; cigarettes per day minimum = 10
Exclusion criteria	Serious heart disease, angina, vasopastic disease, current or past peptic ulcer, temporomandibular joint disease or hypertension; life-threatening illnesses; alcohol or drug problems within the past 6 months; current treatment for a psychiatric illness; pregnant or nursing.
UCSF Trial 2: Nortriptyline and Cognitive-Behavioral Therapy (Hall et al., 1998)	
Recruitment dates	1992 – 1994
Method	Recruitment: advertising, public service announcements, and flyers Design: 2 (nortriptyline vs placebo) x 2 (cognitive-behavioral therapy vs control) x 2 (history of MDD vs no history), double-blind, placebo-controlled RCT
Participants	N = 199
Intervention	Pharmacotherapy: Nortriptyline hydrochloride, 25 mg/d for 3 days, 50 mg/d for 4 days, increased to 75 mg/d and 100 mg/d at weeks 2 and 4, respectively, if therapeutic level not yet reached. At week 6, titrated downward vs. Placebo Cognitive-Behavioral therapy: 10 2-hour group sessions for 8 weeks. Focused on mood management skills and maintenance of non-smoking; Health Education Intervention: 5 90-minute sessions for 8 weeks. Health-related informational handouts, brief didactic presentations, homework assignments, and smoking monitoring. History of MDD vs. No History
Inclusion criteria	Adults 18-65; cigarettes per day minimum = 10
Exclusion criteria	Electrocariographic abnormalities, current or past 3-month diagnosis of MDD, psychotropic medication, evidence of alcohol or other non-nicotine use, past 2 week MAOI use.
UCSF Trial 3: Medical Management, Psychotherapy, Bupropion, and Nortriptyline (Hall et al., 2002)	

Recruitment dates	1996 – 1998
Method	Recruitment: advertising, public service announcements, and flyers Design: 2x3, double-blind, placebo-controlled, RCT
Participants	N = 219
Intervention	Management for smoking cessation by Nortriptyline titrated to therapeutic serum level (50-150 ng/mL) as detailed in Study 2 vs 150 mg/d Bupropion hydrochloride for 3 days, 300 mg/d until week 12, then titrated down to 150 mg/d 3 days, and discontinued vs Placebo
Inclusion criteria Exclusion criteria	Adults 18-65; cigarettes per day minimum = 10 Cardiovascular disease, hyperthyroidism, seizure or bulimia, use of MAOIs within 2 weeks, severe allergies including allergies to either experimental drug, life-threatening disease, bipolar disease, current major depressive disorder (MDD), pregnancy or lactation, use of levodopa, migraines, previous treatment for cigarette smoking with nortriptyline or bupropion, treatment for alcohol or other drugs within 6 months, psychiatric hospitalization or other drug use within 6 months, psychiatric hospitalization within 1 year, use of psychiatric medication, suicidal or psychotic symptoms, or current NRT use.
UCSF Trial 4: Extended Nortriptyline and Psychological Treatment (Hall et al., 2004)	
Recruitment dates	1998 – 2000
Method	Recruitment: announcements via newspaper, radio, community website, local organizations Design: 2x2, double-blind, placebo-controlled, RCT
Participants	N = 160
Intervention	Nortriptyline vs Placebo Brief vs Extended: 5 brief group sessions over 12 weeks with NRT patch from weeks 4-12 weeks vs brief treatment + extension including weekly monthly counseling *Participants randomized to brief received no additional therapeutic contact
Inclusion criteria Exclusion criteria	Adults 18-65; cigarettes per day minimum = 10 Cardiovascular disease, history of seizure, severe allergies, life-threatening disease, bipolar disorder, current major depressive disorder, use of levodopa, migraine headaches, current use of any psychiatric medication including bupropion, suicidal or psychotic symptoms, current use of NRT, previous treatment for cigarette smoking with nortriptyline treatment for drugs of alcohol within 6 months, psychiatric hospitalization within 1 year, and pregnancy or lactation.