

Power To Quit II: A Randomized Clinical Trial To Enhance Smoking and Alcohol Cessation Among Homeless Adults



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BACKGROUND

- Cigarette smoking is the leading preventable cause of cancer and heart disease in the United States.
- Despite the declining rates of smoking in the general population (~15%), smoking prevalence among homeless is 70% or greater
- The prevalence of cigarette smoking among alcohol-dependent persons is nearly 80%, more than five times the smoking rate of the general population.
- Cigarette smokers drink alcohol more often and more heavily than nonsmokers
- Power To Quit I (PTQ I) (n=430), a two-arm randomized clinical trial targeting homeless smokers, (regardless of alcohol use) found cotinine-verified 7-day quit rates of 9.3% for motivational interviewing (MI) vs. 5.6% for stand care at 26 weeks (p= 0.15)

POWER TO QUIT II

- Building on the results of PTQ I, we were funded to conduct a second community-based study targeting cigarette smoking among persons who are homeless and drink alcohol
- PTQ-II is a two arm smoking cessation randomized controlled trial (RCT) in a community of homeless persons who smoke and drink alcohol.
- The two study conditions are:
 - integrated intensive smoking intervention using cognitive behavioral therapy (CBT) and motivational interviewing (MI) plus alcohol intervention + NRT
 - Usual care (UC); brief smoking cessation and brief alcohol counseling + NRT
- All participants offered a 12-week treatment with a combination of nicotine replacement patch + gum or lozenge.
- Collaboration with homeless shelters and advice from a 10 member Community Advisory Board

AIM

- The primary aim of the research study is to evaluate the effects of an intensive smoking intervention that integrates alcohol abuse treatment and smoking cessation in a homeless population
- Primary smoking outcome is cotinine-verified 7-day smoking abstinence at week 26
- Secondary outcome is prolonged smoking abstinence at weeks 12 and 26 with CO verification at week 26.
- Secondary alcohol outcome will be self-reported continuous alcohol abstinence for 90 days at week 26

METHODS

PARTICIPANTS

- 400 participants experiencing homelessness will be enrolled from emergency shelters and transitional housing units in Minneapolis/St. Paul, MN.
- Homelessness is defined as anyone lacking a “fixed, regular, and adequate nighttime residence” or a publicly or privately operated shelter

INCLUSION CRITERIA:

- Currently homeless (Stewart B. McKinney Act, Congress 1987)
- Smokes > 5 cigarettes per day in past 7 days
- Smoked at least 100 cigarettes in lifetime
- AUDIT score ≥8 and <27
- Aged 18 years or older
- Willing to attend study sessions and follow study protocol

EXCLUSION CRITERIA:

- Suicidal ideation with plan (Columbia Suicide Severity Rating Scale)
- Unstable medical illness that requires immediate medical care
- Previous severe alcohol withdrawal-related symptoms/events
- Alcohol Use Disorders Identification Test (AUDIT) score ≤7 or >27
- Pregnancy or other NRT contraindications
- Current or past 6 months of psychotic disorder or major depressive disorders that is not stable for past 3 months.
- Cognitive impairment (Short Blessed test)

PROCEDURE

- Data will be derived from a two-arm RCT that compares:
 - Standard Care (one-time brief advice) to
 - Cognitive Behavioral Therapy (CBT) and Motivational Interviewing (MI) (10 sessions)
- All participants receive 12 weeks of treatment with 14 mg (<10 cigarettes/day) or 21mg of nicotine patch (>10 cigarettes/day)
- Participants are instructed in usage of the nicotine gum or lozenge (minimum of 6 pieces and maximum of 20 pieces a day)

INTERVENTION

- 45 minute protocol-driven counseling intervention conducted in-person, audio recorded and reviewed for fidelity
- Counselors receive 80 hours of in-person protocol driven training in CBT and MI + weekly group-based supervision and feedback

RECRUITMENT

- Community mobilizers (individuals with experience working with homeless adults) are liaisons to bolster recruitment.
- Flyers and collaboration with local shelters help facilitate recruitment

RETENTION

- Multiple contacts, large appointment windows, raffles, and financial compensation are used to incentivize participation and retention

MEASURES

DEMOGRAPHICS VARIABLES

- Age, gender, gender, gender orientation, education, marital status, income, employment status, race/ethnicity

ALCOHOL-RELATED VARIABLES

- Alcohol drinking history- frequency, quantity and binge
- Alcohol craving – intensity, frequency, duration and ability to resist alcohol

PSYCHOSOCIAL VARIABLES

- Depression (PHQ, in past 2 weeks)
- Stress (PSS-4, past 30 days)
- MINI Nueropsychiatric-9 scale
- MINI Anxiety

TOBACCO-RELATED VARIABLES

- Serum Cotinine in ng/ml, Mean (SD)
- Exhaled carbon Monoxide in ppm, mean (SD)
- Cigarettes per day, mean (SD)
- Time to first cigarettes, < 30 minutes, n (%)
- No of 24 hour quit attempts in past year, mean (SD)
- Motivation to quit, mean (SD)
- Confidence to quit, mean (SD)

METHODS

DATA ANALYSIS PLAN

- Randomization success will be determined using analysis of variance (ANOVA) method for continuous data and Chi-square tests for categorical data
- Descriptive statistics completed use mean (±SD) or frequency (%)
- The primary analysis will be based on an intention to treat (ITT) analysis at week 26
 - Any participants lost to follow-up will be classified as treatment failures (i.e. smoker or drinker).
- The intervention effects for the primary outcomes be tested using Chi-square test for biochemically verified 7-day abstinence from cigarette smoking) and 90-day abstinence from alcohol consumption

Figure 1: Power To Quit II Study

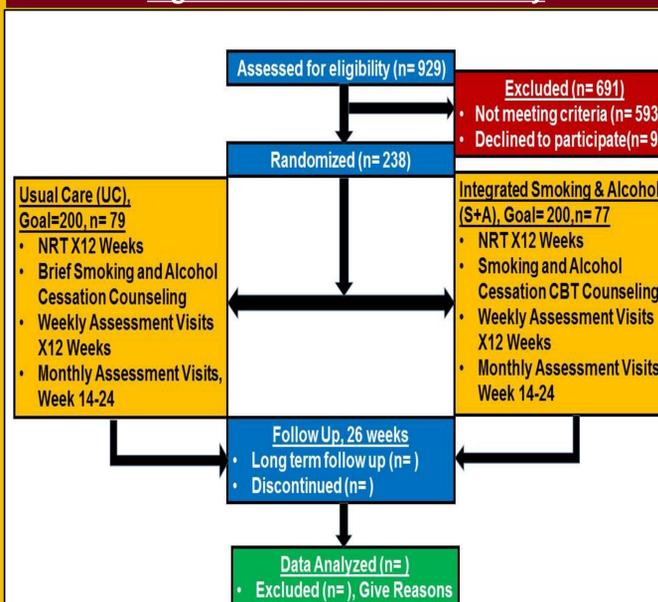


Table 1: Enrollment Data As of November 30,2016

Enrollment characteristics	Total	
	Count	%
Screening Completed (not unique)	1005	
Screening Completed (unique)	929	
Eligible (unique)	336	33.4%
Eligible Declined (unique)	98	29.2%
Enrolled (% of eligible)	238	70.8%
Ineligible (unique)	593	
AUDIT Score < 7	325	54.8%
AUDIT Score > 27	186	31.4%
Severe Alcohol Withdrawal	116	19.6%
Other Alcohol	32	5.4%
Housing Criteria Not Met	103	17.4%
Smoking Criteria Not Met	48	8.1%
Cognitive Impairment	35	5.9%
Unwilling to use NRT	30	5.1%
Medically Ineligible	50	8.4%
All Other	58	9.8%

RECRUITMENT

Table 2: Participants Characteristics

	N	%
Total N = 238		
Gender		
• Male	184	77
• Female	53	22
• Transgender/gender nonconforming	1	<1
• Unknown	0	0
Ethnicity		
• Hispanic or Latino	12	5
• Non-Hispanic	221	93
• Not reported/Unknown	5	2
Race		
• African American/Black	171	72
• American Indian/Alaskan Native	3	1
• Asian	0	0
• Native Hawaiian or other pacific islander	0	0
• White	45	19
• More than one race	15	6
• Not reported/Unknown	4	2
Age, mean (SD), range	46 (11)	19-69
¹ Cigarettes per day, mean (SD), range	16 (11)	0.5-60
² AUDIT score, mean (SD), range	13 (4)	3-24
Site		
• Dorothy Day	158	66
• Harbor Lights	75	32
• Our Saviors	1	<1
• Peace House	1	<1
• People Inc.	3	1

DISCUSSION

- This study is designed to address the comorbidity of smoking and alcohol abuse among persons who are homeless by providing both smoking and alcohol cessation counseling
- At present we have recruited 238/400 targeted participants.
- We are demonstrating the feasibility of identifying and enrolling a diverse sample of homeless smokers who also abuse alcohol into a smoking cessation clinical trial with 6 months follow-up
- Specific initiatives have been implemented to effectively recruit and retain this hard to reach population
- Smoking cessation programs conducted in this population should be tailored to address the unique challenges of homelessness to enhance cessation and ultimately reduce smoking-related comorbidities

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