**INTENSIVE HYPNOTHERAPY WITH ACUPUNCTURE FOR SMOKING CESSATION**

**IN AN UNDERSERVED POPULATION - RESEARCH STRATEGY**

**SIGNIFICANCE**

**The CDC continues to identify smoking as the top cause of preventable death.** However, pharmacotherapy (including varenicicline and bupropion), e-cigarettes, motivational counseling, and cognitive behavioral therapy – more often fails than not. Success rates are less than 25% for long-term cessation, and dramatically less outside of trials.1-5 **Likely, the single and greatest limitation common to the aforementioned interventions is their insensitivity to the role cigarettes play in a smoker’s mental health, mood, and coping with daily stresses.** Individuals with psychiatric illness, including depression, anxiety, and substance abuse disorders are 50% more likely to smoke.6, 7

Tobacco addiction, in particular, is extremely intertwined with mental and physical health, **and two recent studies at major U.S. academic institutions on anxiety-targeted hypnotherapy illustrate its promise for smoking cessation- both with biochemical validation of quitting at approximately 40%.8** To some smokers, cigarettes are not just something they do but are part of their identity. The clinical hypnotherapy practice of co-PI S.G. is specifically targeted to this subgroup of smokers. S.G. utilizes an intensive five-day hypnotherapy session for smoking cessation aimed at identifying and relieving emotional distress, followed by teaching self-hypnosis techniques. **Success rates approach 90% in the clinical hypnotherapy practice of S.G..**

**The overall hypothesis of this proposal is that a more intensive hypnotherapy regimen will be even more effective than usual care best practice (including pharmacotherapy, nicotine replacement, and motivational counseling) at smoking cessation**. Additionally, we will test the additive effectiveness of acupuncture at the onset of withdrawal symptoms at the 72-hour post-abstinence timepoint. Acupuncture has been shown to have similar effect size to nicotine replacement therapy.9

**TARGET POPULATION**

Underserved community, specifically smokers in norther Louisiana who present to a safety net hospital.

**EXPECTED OUTCOME**

We hypothesize that intensive hypnotherapy plus acupuncture will be superior to usual best practices smoking cessation in smokers who have failed prior therapies, as measured by long-term urine cotinine testing.

**POTENTIAL IMPACT**

If successful, our work would be the first-ever study demonstrating that intensive hypnotherapy addressing emotional relief, with acupuncture for strong somatic withdrawal symptoms, is more impactful than pharmacotherapies and/or behavior change alone for smoking cessation.

**APPROACH AND METHODS**

**Specific Aim 1: Administer intensive hypnotherapy course to current smokers.**

**Inclusion criteria:** smoking ≥ 12 cigarettes daily, all genders, consenting adults > 18 yrs. of age, prior cessation attempts including pharmacotherapy, nicotine replacement, e-cigarettes, and counseling

***Primary Outcome Variable*** *– Biochemically validated smoking cessation rate at 1, 6, 12, and 26 week timepoints.*

***Secondary Outcome Variables*** *-* Edmonton Symptom Assessment System (ESAS) and Minnesota Tobacco Withdrawal Scale (MTWS)

***Methods***

Subjects will be recruited from the LSU Health Shreveport Smoking Cessation clinic and randomized to a control group (i.e. compared to best practice smoking cessation care alone including pharmacotherapy, nicotine replacement, and motivational counseling) or one of two intervention groups (intensive hypnotherapy group with or without acupuncture; see below). All patients will have access to best practice smoking cessation. Intensive hypnotherapy will be conducted for five consecutive days, followed by self-hypnosis instruction and audio recordings thereafter. Urine cotinine testing will be performed at the beginning of the study and at 1, 6, 12, and 26 week timepoints. Subjects will complete the ESAS and the MTWS before and after each hypnotherapy session and at aforementioned timepoints.

**Specific Aim 2: Administer intensive hypnotherapy course plus acupuncture for withdrawal symptoms to current smokers.** Similar methods will be employed, except that this second intervention arm will undergo acupuncture at the 72-hour timepoint at the onset of withdrawal symptoms. Acupuncture sessions will be a one-hour comprehensive assessment and treatment by Geoff Mcleod, DO at the LSU Health Shreveport multispecialty clinic, aimed at treating withdrawal symptoms and/or smoking cessation at his discretion.

**Power analysis:** Based on several permutations of power analysis with alpha level 0.05, beta 0f 0.2, and power of 80%:

If 5% of control subjects are abstinent vs. 40% of intervention, 21 per group are needed.

If 5% of control subjects are abstinent vs. 30% of intervention, 35 per group are needed.

If 5% of control subjects are abstinent vs. 60% of intervention, 10 per group are needed.

**We will aim to recruit 30 subjects per group, anticipating a loss-to-follow up rate of 30% and resulting in 20 subjects per group, in keeping with prior literature.** We will use an institutional RedCap database to store study data and use STATA BE (StataCorp, College Station, TX) software to perform descriptive statistics, then chi-square test to compare abstinent rate between groups. T-test and multiple analysis of variance (MANOVA) testing will be used to test continuous variables amongst the three groups.

**Feasibility and Resources**

LSU Health Shreveport sees sufficient subjects for recruitment in Smoking Cessation clinic. Clinical space for hypnotherapy will be provided via a telehealth platform (Thera platform). Acupuncture administered (labor and supplies) by G.H. will be funded by Medicaid insurance or study funds. Co-P.I. J.P. is an academic head and neck oncologic and reconstructive surgeon. He has experience with treating patients with head and neck cancer, motivational counseling for smoking cessation, and biostatistics for analysis of study data. Co-P.I. S.G. worked previously as a family medicine physician, subsequently specialized in hypnotherapy and has treated over 2,000 patients using hypnotherapy worldwide. LSU Health Shreveport Institutional Review Board approval is being acquired for the completion of this study

**Budget**

We have submitted a grant application for $56,000 from the Louisiana Cancer Research Center to cover the cost of a clinical research associate, hypnotherapy, urine cotinine tests, acupuncture, bus/taxi fare for subjects, and indirect cost of institute. **The additional $1,000 from the AHNS Community Service Award would likely go directly to assisting study subjects, who are often low-income, for travel stipend or to cover childcare to be able to participate.**

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