# A Pilot Trial Comparing NicoBloc to Nicotine Lozenges: Initial Acceptability and Feasibility Trial

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**Purpose**

This pilot study will examine the feasibility, acceptability, and preliminary impact of using NicoBloc compared to nicotine lozenges. Forty (n=40) participants will be randomized to one of two interventions 1) NicoBloc or 2) nicotine lozenge. All participants will complete approximately 60 minutes of baseline assessment to determine smoking history and characteristics prior to randomization, including previous experience with NRT.

**Analysis strategy**

Feasibility and acceptability will be measured through high study retention (70%) and recruitment (recruitment of all participants within 24 months) in our groups. Additional items of acceptability include high scores on treatment satisfaction and credibility/expectancies that are equal or higher to the NicoBloc group. Medication adherence is a third primary outcome with expected differences between our groups. Adherence is notoriously difficult to determine. Self-reported adherence is not always reliable, particularly during treatment studies where there is a demand characteristic to report the desired targeted behavior (e.g., adherence to medication). The behavioral methods described under the assessment section represent the best available self-report tools for determining NRT adherence (e.g., Timeline Follow Back (TLFB) report, returning used products and packaging). Adherence will be defined by self-report using the TLFB and verified through returned patches and packaging. Good adherence is defined by taking greater than 80% of doses of medication at each time point.

**Background**

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the design of this protocol. Include any relevant past or current research by the PI. For drug and device studies, summarize the previous results (i.e., Phase I/II or III studies).

Smoking remains the leading cause of preventable death in the U.S. with approximately 18% of the population continuing to smoke. However, smoking is concentrated in disadvantaged populations where the prevalence of smoking may be as high as 70-80 %. Participants will receive a sampling experience (use of nicotine lozenges or NicoBloc during sessions) with counseling focused around their experience of using these interventions, including side effects and smoking cessation expectancies.

NicoBloc is a pink occlusion fluid supplied in 15 ml bottles. Three drops applied to a cigarette filter will trap up to 99% of tar and nicotine in the filter (depending upon cigarette brand). The ingredients of NicoBloc are: Corn Syrup (86.83%), Water (12.76%), Citric Acid (E330) – acidity regulator (0.30%), Sodium Benzoate (E211) – food preservative (0.05%), Potassium Sorbate (E202) – food preservative (0.05%), Allura Red 40 (E129) – red food colouring (0.01%). These ingredients are classified as FDA approved food grade ingredients.

**Procedure**

A urine drug screen and pregnancy test for females will be obtained during the screen visit. If positive, participants will be screen failures and will not be enrolled in the study. Specimens will not be

distributed or stored. They will be labeled with a unique study identifier. There will be no clinical data associated with the specimens. They are used only to establish eligibility for the study.

After eligibility determination and consent to participate, the baseline assessments will be administered. This assessment is expected to take about 60 minutes and will provide basic smoking history, smoking behavior, and proposed mediators and moderators such as treatment interest, expectancies for NRT and NicoBloc, previous use of NRT, craving, withdrawal, and side effects associated with NRT use (see Table 1 description) and will be repeated during the study period (see Table 2 for assessment schedule). At each visit the participant will have a carbon monoxide test (CO) which will determine how much CO is in the lungs. At the baseline visit, participants will be asked to prolong smoking as long as they can on the days of the study sessions. Female participants will be screened monthly for pregnancy.

Participants will be randomized to either NicoBloc or Nicotine Lozenge and will undergo the following interventions. Interventionists will be undergraduate level research assistants (RAs) with degrees in psychology or a related field. They will be trained to follow the manual and deliver both behavioral interventions by the PI, although they will not have extensive tobacco training. All sessions will be audio-taped and 20% will be coded for treatment fidelity to ensure no contamination between behavioral interventions.

NicoBloc: NicoBloc participants will be provided with NicoBloc to use in each 30-minute session and will test smoking their conventional cigarette with NicoBloc. In session, they will discuss their experience of smoking their cigarette with NicoBloc at each of the sessions. For Session 1, participants will use one drop of NicoBloc (which will block 33% of tar and nicotine) on their conventional cigarette and then will smoke this cigarette in session. Following smoking, they will discuss the effects of the NicoBloc on their withdrawal, cravings, and overall enjoyment of their cigarette. To bolster their in vivo NicoBloc experience, participants will be provided with NicoBloc to use between sessions to acclimate to the NicoBloc and to make practice quit attempts (PQAs). Sessions 2 and 3 are similar to Session 1 except they will use more NicoBloc product during the session and will be instructed to use the product between sessions. For example, in Session 2, they will use 2 drops on their cigarettes (which blocks about 66% of tar and nicotine) and then smoke. Similarly, in Session 3 they will use 3 drops of NicoBloc which is equivalent to blocking 99% of the tar and nicotine exposure from a cigarette and then smoke. At Session 4 they will discuss their experiences using NicoBloc and will set a quit date prior to their 8 week visit. Participants will return at 8 and 12 weeks (EOT) with a final one month follow-up at Week 16.

Nicotine Lozenge: Participants who receive nicotine lozenge (mini lozenge) will be given either a 2 or 4 mg lozenge to use in session, depending on how soon they smoke after waking. If a participant smokes within 30 minutes of waking, they start with the 4 mg lozenge; more than 30 minutes, they start with the 2 mg lozenge. Similar to NicoBloc, they will use the lozenge in session and will discuss the effects of using the lozenge in session. They will do this for all four Sessions and will be given lozenges between sessions to make PQAs. They will be asked to set a quit date during Session 4 similar to the NicoBloc participants.

After the four week intervention, participants will be given an additional 8 weeks of medication (NicoBloc or Lozenge) in four week allotments to use for a sustained quit attempt. Thus, both groups will receive the medication for 12 weeks total to make a quit attempt. All participants will continue to receive medication and monitoring for side effects, regardless of their medication adherence. Study visits occur at baseline (Week 0), intervention Weeks 1-4, Week 8, Week 12 (EOT), and then a 1 month follow-up after medication use has ended.

Phone numbers will be collected to send study appointment reminders, missed appointment notifications only or if the participant needs to be reached concerning the study.