



Computerized Scheduling of Nicotine Inhaler Use

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Abbreviated Abstract

The overall goal of this Phase II project is to assess the efficacy of a computer-assisted program to schedule nicotine inhaler dosing for smoking cessation. The product, LifeSign for Nicotine Inhalers (LS-NI), will be refined based on information obtained during the Phase I trial. Efficacy will be evaluated by comparing two computer-assisted nicotine inhaler dosing and reduction schedules—fast-paced and slow-paced—to ad libitum nicotine inhaler use (AL-NI). Subjects (N = 480) will be evaluated on various smoking-related measures at pre-treatment and at 9- and 21-week follow-ups. Subjects also will complete weekly smoking and inhaler logs, and data from the computer units will be uploaded for analysis of inhaler use. A 1-year follow-up also will be performed. The results of the study will provide useful information on the effects of computer-assisted scheduling and duration of use of nicotine inhalers as well as patterns of ad libitum inhaler use.

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Total Budget

\$924,530

Research Objectives

AIMS

1. Revise the product software and program materials based on results from the Phase I trial.
2. Develop fast- and slow-paced versions of the scheduled gradual reduction program to evaluate the effect of program length on inhaler use compliance, latency to smoking relapse, and gradual cessation of inhaler use.
3. Compare the effects of fast- and slow-paced versions of computer-assisted scheduled nicotine inhaler dosing with an ad libitum nicotine inhaler dosing condition on smoking cessation rates in a study of 480 smokers.
4. Compare adherence, initial dosing levels, and successful tapering effects of each of these study conditions.



5. Assess self-report and computer-obtained program use variables to determine further design modifications for commercial product development.

Theory/Hypothesis

Although inhalers have shown considerable promise as an effective treatment for nicotine dependence, problems with treatment compliance, inadequate dosing, and concerns about long-term nicotine dependence may limit effectiveness and overall product appeal. The key hypothesis of this project was that an adequate initial dosing of nicotine inhalers would enhance compliance with use and reduce abuse liability as well as provide a formal tapering procedure. The LS-NI program may be able to resolve these issues by providing a structured nicotine inhaler schedule that ensures adequate initial dosing while also extinguishing stimulus cues for nicotine use and gradually tapering inhaler use until cessation is achieved.

Experimental Design

Randomized cessation trial comparing three treatment conditions: (1) LS-NI-Fast (LS-NI-F), (2) LS-NI-Slow (LS-NI-S), or (3) ad libitum nicotine inhaler use (AL-NI).

The study trial lasted for 18 weeks. All subjects visited the clinic on three occasions: (1) for the pre-treatment assessment, (2) for a 9-week post-assessment evaluation (corresponding with the LS-NI-F end of treatment), and (3) for an 18-week post-assessment evaluation. Subjects were also briefly contacted via telephone 1 year following study entry to determine present smoking and inhaler status. Subjects reporting no smoking or nicotine replacement use were asked to provide a saliva cotinine and carbon monoxide (CO) sample for validation of their self-report.

Final Sample Size & Study Demographics

Four hundred and sixty-two subjects between ages 18 and 67 were recruited. Over half of the subjects were female ($n = 256$, 55.4%), and about three-quarters were White, not of Hispanic origin ($n = 343$, 74.4%). About one-third of the subjects ($n = 153$) had graduated from college, an additional 63.1% ($n = 291$) had graduated from high school, and 3.7% ($n = 17$) had not finished high school.

LS-NI-F. Subjects in the LS-NI-F condition were given nicotine inhalers and the fast-paced version of the LS-NI program. The handheld computer first provided a 7-day baseline period (stage I) during which subjects recorded each cigarette smoked. Subjects then attempted to quit smoking on the last day of baseline and then began following the computer-administered inhaler schedule (stage II). The computer prompted users when to start and stop each inhaler session. Subjects recorded use by pressing the data input button on the handheld computer. Subjects were instructed to puff at a comfortable rate (approximately 4 puffs per minute) throughout the inhaler session. Subjects maintained their initial inhaler dose for 3 weeks, with dynamic adjustment for increased or decreased usage as appropriate. The computer then prompted inhaler use on a gradual scheduled reduction over the next 3 to 5 weeks, depending on the subject's initial inhaler dose.

LS-NI-S. Subjects in the LS-NI-S condition were given nicotine inhalers and the slow-paced version of the LS-NI program. All features of this condition were the same as the LS-NI-F except for the duration of the program. Subjects maintained their initial inhaler dose for 12 weeks, with dynamic adjustment for increased or decreased usage as appropriate. The computer then prompted inhaler use on a gradual scheduled reduction over the next 3 to 5 weeks, depending on the subject's initial inhaler dose.

AL-NI. Subjects in the nicotine inhaler use only condition were given nicotine inhalers and instructed to follow product instructions and to do their best to quit smoking. They were encouraged to make a quit attempt within 1 week of receiving their program and, after up to 12 weeks of stable use, to try to cut back on their use as quickly or slowly as desired in order to achieve the goal of no smoking and no nicotine inhaler use by the end of 18 weeks. Subjects



were given the handheld computer monitoring units and asked to record each cigarette smoked and each inhaler use during the study period.

Data Collection Methods

Self-reported nicotine patch and tobacco use diaries; expired CO; questionnaires.

Outcome Measures

Percentage abstinent from smoking at the end of treatment and 6 months; nicotine patch and tobacco use (measured with expired CO); nicotine dependence; nicotine withdrawal; motivation and confidence in quitting; and program convenience and satisfaction.

Evaluation Methods

Changes in smoking status from baseline were compared for the three groups using t-tests, chi-square analyses, and survival curve functions.

Research Results

Participants using the computerized scheduled inhaler dosing system (LS-NS-F and LS-NS-S) had longer periods of not smoking than did participants using the inhaler as needed (AL-NI). The differences between the two LifeSign groups were not significant. The LS-NS-F group, with a faster tapering time of reducing inhaler use, reported having less severe withdrawal symptoms than did participants in the LS-NS-S group. Perhaps the faster system of reducing inhaler use, as used by the LS-NS-F group, would be most beneficial since the efficacy is the same as that of the slower tapering system (LS-NS-S) without additional withdrawal symptoms.

Barriers & Solutions

The key barrier is the reluctance of the pharmaceutical companies to partner on the delivery of a product that combines their nicotine inhaler and the PICS product.

Product(s) Developed from This Research

LifeSign for Nicotine Inhalers: is a specific-purpose handheld computer device designed to obtain a prospective baseline of smoking rate and utilize this information to provide for stable and adequate dosing of nicotine inhalers (frequency and duration) during a quit attempt. Following a period of stable dosing, the program gradually tapers the user from nicotine to reduce abuse liability. The program is intended to serve as a behavioral adjunct to nicotine inhaler treatment, assuring adequate initial dosing as well as appropriate and sustained dosing until cessation is achieved.