



Combining Scheduled Reduction with Nicotine Replacement

Grant Number: R44CA71305-03

Abbreviated Abstract

The overall goal of this Phase II project was to develop an easily administered behavioral program to serve as a companion to the use of the nicotine patch for smoking cessation. The program, LifeSign for the Nicotine Patch (LS NP), consists of a credit card size computer and a program guide. The computer works by altering smoking habits prior to use of the nicotine patch. The computer assesses baseline smoking patterns, prompts users to smoke at fixed intervals, and then gradually increase intervals between cigarettes, thereby reducing smoking. The goal of the computerized smoking schedule was twofold: decrease nicotine intake and disrupt conditioned smoking patterns prior to using the nicotine patch. The product is suitable as either a self help program or for use in clinical treatment settings. During Phase I, a prototype system was developed and tested in a clinical study with 94 subjects. Promising results were obtained, demonstrating the feasibility of the product concept. During Phase II, a second generation system was developed, and a randomized clinical outcome study with 6 month follow up conducted to evaluate the product. Smokers were randomly assigned to one of two conditions: patch plus LS NP or patch alone. Data on smoking, patch use, withdrawal symptoms, compliance with the computerized program, and ratings of satisfaction and usability were collected. Following completion of the trial, plans will be formulated for a version of the product appropriate for commercial release.

Primary Investigator

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Dr. William Riley was the Director of Research at Personal Improvement Computer Systems, a research and development company that develops, evaluates, and markets computer applications for health behavior problems. Dr. Riley received his Ph.D. from Florida State University in 1984, and served as assistant professor at the Medical College of Georgia and associate professor at the Medical College of Virginia before joining PICS in 1999. His research areas include depression, anxiety, cardiovascular risk factors, and tobacco use. PICS has been involved in a number of NCI and NIDA supported studies involving combining various nicotine replacement treatments with their scheduled gradual reduction technology.

Research Team & Affiliations

William Riley, Ph.D (PI); Clayton Raymond, BS (developer); Albert Behar, M.S., (engineer); Herb Severson, Ph.D., (consultant, site PI)

Total Budget

\$752,454.00

Research Objectives

Aim 1: Develop a prototype of the LS-NP software based on Phase I results

Aim 2: Develop a program guide to accompany the LS-NP computer

Aim 3: Evaluate the efficacy of the LS-NP program by comparing it with standard patch use in a randomized trial.

Aim 4: Develop a set of proposed modifications for a commercial version of the product

Theory/Hypothesis

The effectiveness of nicotine patches have been firmly established through numerous clinical trials involving thousands of patients. A meta-analysis summarizing data from 17 studies (5098 patients) reported overall end of treatment abstinence rates of 27% (vs. 13% for placebo) and 6 month abstinence rates of 22% (vs. 9% for placebo) (Fiore et al., 1994). Results of the meta-analysis also supported the following conclusions: 1.) active patches were superior to placebo patches regardless of patch type (16 vs. 24 hour), treatment duration, weaning schedule, and type of counseling; 2.) 16- and 24-hour patches were equally effective; 3.) continuing treatment beyond 8 weeks did not increase effectiveness; 4.) intensive behavioral counseling improved quit rates to a modest degree; and 5.) the patch appeared to be effective when coupled with minimal adjuvant therapy.

The LS-NP program was designed to provide an additional behavioral support for nicotine patch use in minimal contact conditions. The product is based on our earlier work with computerized scheduled reduction of smoking. The program is designed to provide a scheduled gradual reduction of smoking based on a one week baseline smoking rate. This reduction program was designed to serve two purposes: a) gradual reduce estimated nicotine levels from smoking to the nicotine replacement level from a 15 mg. Patch, and b) provide a scheduled smoking period prior to smoking cessation to disrupt conditioned cues to smoking. Based on the results of Phase I, a third purpose was added: to insure appropriate daily patch use after smoking cessation. The product has been designed to serve as an adjuvant treatment with nicotine patches that can be utilized in self-help or minimal contact conditions.



It was hypothesized that the LS-NP program would be superior to a Nicotine Patch alone (NPa) group in a randomized trial.

Experimental Design

Randomized cessation trial comparing the LS-NP program to NPa in tobacco users attempting to quit smoking

Final Sample Size & Study Demographics

337 adult smokers were recruited into the study. The sample was 56% male, 62% white, and on average 41 years of age. Subjects smoked a mean 24.4 cigarettes per day at base line for a mean of 22.4 years.

Data Collection Methods

Self-reported nicotine patch and tobacco use diaries; expired carbon monoxide, self-reported nicotine dependence (FTQ), nicotine withdrawal (WSQ), motivation and confidence in quitting, and convenience and satisfaction measures.

Outcome Measures

Percent abstinent from smoking at end of treatment and 6 months.

Evaluation Methods

T-Tests, chi-square analyses, and survival curve functions

Research Results

End of Treatment: 18.4% of subjects in the LS-NP condition were abstinent at end of treatment, compared to 11.4% of subjects in the NPa condition ($P < .05$, one-tailed), on a point-prevalent assessment technique. Subjects in the LS-NP group were also more likely to report continuous abstinence (biochemically verified by expired carbon monoxide) at end of treatment (12.3% vs. 5.7%, $P < .05$).

Survival Analyses revealed that subjects in the LS-NP condition had a significantly longer days to relapse throughout most of the study period ($P < .01$), and mean time to first slip after cessation was higher in the LS-NP group than the NPa group (27.5 days vs. 18.7 days).

Barriers & Solutions

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

Product(s) Developed from This Research

LifeSign for Nicotine Patch