



Computerized SGR for Smoking Reduction

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Abbreviated Abstract

The overall goal of this project is to continue development and evaluation of a self-help behavioral smoking reduction program for chronic smokers. The program, LifeSign for Smoking Reduction (LS-SR), is targeted to chronic smokers who are unwilling to quit smoking and for whom a reduction in smoking is a reasonable short-term goal. In Phase I, we developed a prototype of the LS-SR program that used scheduled gradual reduction principles to reduce smoking by 50% and maintain these reductions, successfully recruited 99 smokers appropriate for a smoking reduction intervention, and assessed the feasibility of this prototype in a randomized controlled trial comparing LS-SR to a manually guided research trial. The LS-SR condition produced greater reductions in various measures of smoking behavior, dependence, and nicotine exposure. For Phase II, we propose to modify the LS-SR program based on Phase I results and compare this program to a manually based smoking reduction condition in 375 smokers who are not amenable to quitting smoking. Subjects will be randomly assigned to one of these self-help interventions and will be assessed at pre-intervention, at post-intervention 7 weeks later, and at 14 and 28 weeks post-intervention. The primary outcome measure for the study will be 7-day reconstruction of daily smoking corroborated by carbon monoxide (CO) and saliva cotinine assessment. CO and measures of short-term changes in health status (e.g., blood pressure, cardio reactivity, health status questionnaire), as well as physical fitness, will be obtained at all assessment points. To determine the effects of smoking reduction on subsequent quit attempts, we will assess reported quit attempts, methods of quitting, and periods of abstinence (biochemically validated), as well as self-efficacy to quit and stages of change, at all visits. Additionally, measures of smoking topography will be obtained to measure directly the degree of compensatory smoking resulting from reduced smoking.

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Research Team & Affiliations

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Total Budget

\$943,497

Research Objectives

AIMS

1. Refine the functions of the LS-SR-1 software, hardware, and program guide based on Phase I results.



2. Perform a randomized controlled trial of the LS-SR programs compared to a manual treatment for smoking reduction in a sample of 375 smokers who are unwilling or unable to quit smoking.
3. Follow study participants and evaluate their ability to maintain their smoking reduction, as well as the relationship of their smoking reduction success to subsequent quit attempts and success, to changes in smoking typography, and to short-term health improvements such as cardiovascular and respiratory function.
4. Develop a set of proposed modifications for a Phase III commercial product.

Theory/Hypothesis

The logic of reduced smoking is predicated on two assumptions: (1) smokers are able to reduce their smoking and (2) there are commensurate health benefits that accompany reduced smoking.

Experimental Design

A randomized controlled trial of the LS-SR computer software compared to a control treatment (comparable information presented using a manual). Subjects in the LS-SR condition received an LS-SR computer and corresponding program guide. The computer operated in three stages: baseline, scheduled gradual reduction (SGR), and maintenance. Subjects were instructed to record each cigarette smoked during the 7-day baseline and then to smoke as prompted during the SGR and maintenance phases. During the SGR phase, the intervals between cigarettes were increased gradually, so that progressively fewer cigarettes were smoked. The program reduced smoking by 50% every 2 weeks. When the user could reduce no further or was satisfied with the level of reduction, he or she could toggle to the maintenance mode, in which the intervals between cigarettes were held constant. If the user subsequently decided that he or she could reduce further, the program could be toggled back into SGR or reduction mode. During each program phase, the number of days in that phase was displayed continuously and decremented as each day was completed. Subjects in the manual condition received a treatment guide that provided instructions on gradual reduction of smoking rate. The manual included instructions for how to reduce smoking (including a table for determining daily smoking rate) and equivalent information on ancillary topics contained in the LS-SR program guide: (1) information on harm reduction; (2) self-management strategies to facilitate smoking reduction (e.g., understanding smoking cues, minimizing smoking cues in the environment, learning stress management procedures, acquiring behaviors incompatible with smoking, practicing coping strategies); and (3) relapse prevention techniques that focus on maintaining a reduced smoking rate (e.g., anticipating and coping with high-risk situations, finding new ways to manage affect).

The study trial lasted for 9 weeks. All subjects visited the clinic on three occasions: (1) pretreatment assessment, (2) 9-week post-assessment evaluation (corresponding to the LS-SR end of treatment), and (3) 26-week post-assessment evaluation. Subjects were also briefly contacted at 18 weeks post-assessment to determine present smoking status.

Final Sample Size & Study Demographics

Two hundred sixty-eight participants between ages 18 and 67 were eligible and enrolled in the current study. Recruitment occurred through television and newspaper advertisements in the greater Washington, D.C., area. Inclusion criteria consisted of (1) self-reported daily smoking rate of at least 15 cigarettes per day for the previous 12 months; (2) a history of an unsuccessful quit attempt in the previous 12 months; (3) a desire to reduce smoking at the current time, but not to quit smoking; (4) no current use of nicotine replacement products; (5) no use of Zyban for the past 2 weeks; and (6) not pregnant or planning to become pregnant.

The average age of the sample was 45.5 years (sd = 13 years). The racial/ethnic composition of the sample was as follows: 65% White (non-Hispanic), 28.7% Black, 2.6% Asian, 2.6% White (Hispanic), and 1.4% other. Slightly fewer than half of the subjects were female (n = 126, 47%



female). Mean educational attainment of the sample was 14.3 years (sd = 2.5 years). Mean number of cigarettes smoked per day at baseline was 26.4 (sd = 10.8 cigarettes).

Data Collection Methods

Questionnaires, daily smoking logs, physiologic measures (expired air CO levels, saliva cotinine, pulse rate, blood pressure, weight, and cardiovascular functioning)

Outcome Measures

Primary outcomes: Differences in average decreases in smoking rates; changes in expired air CO levels

Secondary outcomes: Symptoms of nicotine dependence (measured with the Nicotine Dependence Symptoms Scale), withdrawal symptoms (measured with the Withdrawal Symptoms Questionnaire), self-efficacy to stay off of cigarettes in a variety of settings (measured with the Smoking Self-Efficacy Questionnaire), motivation and self confidence, program satisfaction.

Evaluation Methods

Change scores were compared for those in the experimental and control groups using multivariate analysis of covariance (MANCOVA).

Research Results

The data indicated that participants in the LS-SR condition achieved a greater reduction in smoking from baseline levels to 9 weeks than did participants in the manual condition. Participants in the LS-SR condition were more than twice as likely to report at least a 50% decrease in smoking levels from baseline to 9 weeks. These changes were not sustained at 6 months, however, as manual participants and LS-SR participants demonstrated approximately equal amounts of smoking. There were no group differences in either salivary cotinine or expired CO after controlling for initial exposure levels. Similarly, no group differences in cardiovascular functioning emerged for either pulse or blood pressure after a sub-maximal aerobic activity.

Barriers & Solutions

The key barrier to wider dissemination of the resulting product *LifeSign for Smoking Reduction* is the market unfamiliarity with the concept of "Harm Reduction." The typical smoker is barraged by both commercial messages from the pharmaceutical companies and public health organizations pitching cessation as the only desirable strategy. PICS is pursuing several solutions: (1) Education through presentations at scientific and public health events and (2) the development of a 30-minute infomercial that allows for the more complex message to be delivered effectively.

Product(s) Developed from This Research

LifeSign for Smoking Reduction is a specific-purpose handheld computer program designed to obtain a prospective baseline smoking rate, which is then utilized to assist smokers currently unwilling or unable to quit to reduce their smoking using a scheduled gradual reduction approach. Users can toggle between reduction and maintenance stages to reduce their smoking as much as they are capable of, even to cessation if possible.