Self-help Smokeless Tobacco Cessation for Young Users
Grant Number: R44CA084936-03

Abbreviated Abstract
The research plan for this Phase II grant extends our work on a computerized self-help program for the cessation of smokeless tobacco use in young and adult users. This program utilizes a 7-day baseline period in which users record the initiation, termination, and frequency of dips, to produce a tailored, gradual reduction program, thereafter. For Phase II, we plan to fully develop an effective program that targets both young and adult users, that provides an effective algorithm to assist users in quitting smokeless tobacco use, and that is easy to carry. The resulting program will be compared to a low-tech self-help manual, “Enough Snuff”, in a 26 week randomized controlled trial.

Primary Investigator
Jami Obermayer, Ph.D.
PICS, Inc.
12007 Sunrise Valley Drive, Suite 480
Reston, VA 20191
(703) 758-1790
Fax: (703) 758-0068
Jobermayer@lifesign.com; www.healthtrials.org; www.certas.com

Research Team & Affiliations
Mr. Clayton Raymond is a Senior Programmer at PICS and was the lead developer for this project.

Total Budget
$799,987

Research Objectives
AIMS
1) Develop the QuitKey ST program, including modifications based on Phase feedback, porting the software to a new device, and developing the device so that it could be carried as a keychain.
2) Manufacture production quality QuitKey ST devices and program guides for the evaluation trial.
3) Recruit 250 smokeless tobacco users across the country to compare QuitKey ST to a low-tech self-help manual in a 26 week randomized controlled trial.
4) Prepare a final report.

Theory/Hypothesis
We hypothesized that our evaluation would determine that our product results in a) superior quit rates relative to a self-help manual in this sample due to higher adoptability among users (e.g. high tech and more novel than a manual) and due to the greater “treatment intrusiveness” which QuitKey ST provided, and b) even in those who
failed to quit, QuitKey ST would produce greater reductions in ST use and tobacco dependence than the control condition (n= 250).

**Experimental Design**
250 subjects randomly assigned to receive either a self-help manual or the QuitKey ST to help them quit smokeless tobacco use.

**Final Sample Size & Study Demographics**
Regular smokeless tobacco users (n=250): 98% Male, 2% Female; Mean Age - 36 years (sd – 9 years); 95% White, 3% Black, 2% American Indian or Alaskan Native; 99% Non-Hispanic; 22% of participants had some high school education or high school degree, 70% had completed some college or obtained a bachelors degree, and 7% had post-graduate education; Mean age reported at which participants started using smokeless tobacco - 16 years (sd - 4 years).

**Data Collection Methods**
Subjects completed the assessments through the study associated web site www.QuitNow.org at 8 weeks and 26 weeks after treatment initiation. Subject usability was assessed at the 8-week point.

**Outcome Measures**
Point prevalence and continuous abstinence rates and usability rates.

**Evaluation Methods**
Descriptive analyses, Repeated Measures, ANOVA, Chi Square Analyses.

**Research Results**
The current trial did not succeed in meeting the expectations of the primary hypothesis, which predicted the QuitKey ST to produce superior quit rates relative to the “Enough Snuff” condition. Overall, the results of the current study suggest that the use of the QuitKey ST device and the “Enough Snuff” manual contribute to reductions in the use of smokeless tobacco, as well as abstinence rates. The QuitKey ST did not produce greater reductions in dependence or in dip frequencies and amounts in comparison to the “Enough Snuff” manual as it was predicted by the secondary hypothesis, however, it provided help to participants in diminishing dependence and reducing the use of ST. Although the significance analyses showed that the QuitKey ST did not yield higher quit rates or greater reductions in dependence than the “Enough Snuff” manual, the trial provided useful information to suggest that the QuitKey ST device compares to other available sources to quit smokeless tobacco such as the widely used “Enough Snuff” program.

**Barriers & Solutions**
N/A

**Product(s) Developed from This Research**
QuitKey ST