



**The effect of the Freedom Quit Smoking System
on long term habitual cigarette smokers.**

Freedom Quit Smoking Study

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Abstract

A quit smoking program consisting of information, aversion tools, supplements and a relaxation headset (manufactured by Freedom Inc.) was studied to determine the effects on long term habitual smokers with a stated desire to quit smoking. This open label trial documented the success or failure of the test subjects in quitting smoking by using the Freedom Quit Smoking System also known to test subjects as the Freedom Quit Smoking Program as well as the Freedom Quit Smoking Kit. 15 subjects were accepted to participate in an open label market acceptance research study. Out of the 15 subjects initially accepted, 7 female and 6 male subjects (13) completed the minimum 10 day portion of the study. These volunteer subjects were initially examined to assess the effects of utilizing a quit smoking therapy known as the Freedom Quit Smoking system, program and or kit. Subjects were screened to meet criteria. Subjects completed baseline entry questionnaires for qualification.

Questionnaires used were designed to track usage, number of consecutive smoke free days, and subjects overall satisfaction with the product use in an attempt to evidence efficacy of the product during the term. Subjects were then given the program and told to refrain from using any other quit smoking aid during the term of the study.

The subjects followed the program for a total of 30 days.

The majority of subjects smoked 20 or more cigarettes per day. The 10 day questionnaire revealed 54% of the subjects noted they had been smoke free for the 10 days due to the program they were testing.

INTRODUCTION:

Tobacco use remains the single largest preventable cause of disease and premature death in the U.S., yet more than 45 million Americans still smoke cigarettes. As of 2010, there were also 13.2 million cigar smokers in the U.S., and 2.2 million who smoke tobacco in pipes. Cigarette smoking is the #1 preventable cause of death in the United States.

We live in a society that is becoming more and more aware of the health concerns cigarette smoke can cause and more intolerant towards those that smoke or smell like cigarette smoke. In fact many cities have begun to ban smoking in public areas and law suits are popping up for second hand smoke cases. Many of those concerned for their health and or public scrutiny are especially interested in becoming a non-smoker.

Many of the current quit smoking aides in the market place are nicotine replacement therapies including the gums, patches, lozenges and nasal sprays which in turn may actually keep the user addicted to nicotine by simply allowing for another transporter of the toxins. The market place is devoid of effective products used to combat nicotine addiction without using nicotine. Hence, there is a need for a product that will promote a tobacco free life without prescriptive side effects or replacement nicotine.

Detuag Testing, Inc. conducted an open label market acceptance research study for Freedom Inc. designed to document a user's rate of result and to solicit user feedback on the use of a quit smoking program. The results of this study will help Freedom Inc. document user reaction to product effectiveness and provides user feedback information including a user's level of satisfaction, and success.

Product Components:

The Freedom Quit Smoking System works by its unique blend of psychological tools to modify behavior patterns associated with smoking; a homeopathic spray with ingredients traditionally used to temporarily relieve cravings, proprietary antioxidants to support the body's natural fight against toxins, education on understanding nicotine addiction, and relaxation techniques and tools including a headset.

Freedom Relaxation Headset:

The headset is equipped with light emitting diodes that transmit soothing heat to specific acupressure points in your ears providing a relaxing effect. The relaxation headset plays calming and tranquil music intended to soothe your mind and body.

The Freedom Relaxation Headset is designed to provide the user with a 12-minute natural relaxation technique to combat symptoms of stress.

Nicotine Reduction Craving Control Spray:

Temporarily relieves the symptoms of cravings for cigarettes & tobacco.

Quit Smoking Therapy CD:

Helps the smokers break the psychological aspects of nicotine addiction, gives education about nicotine addiction and teaches new behavioral habits to remain nicotine free for life.

Freedom Aversion Therapy Wristband

Assists the smoker in creating a negative association whenever thoughts of smoking occur and inspires the newly former smoker to stay quit.

Freedom Stress Ball

This enjoyably squeezable ball provides the newly former smoker an amazing tool to occupy their idle time and can create a feeling of comfort for them in social situations. The stress ball helps break the hand to mouth fixation that a former smoker can experience of appearing fidgety or even awkward not knowing what to do with their hands

Freedom Commitment card

Motivates the smoker to establish a specific quit date and then helps them track their success over a 10-day period, which is considered the crucial detoxification period of ridding the body of tobacco and nicotine. The commitment calendar card also provides the smoker 24 immediate actions to commit to right now to quit smoking for good.

The Science:

The Mayo clinic staff states, “Using a quit-smoking product can greatly increase your chance of success. Only about 5 percent of people who try to quit tobacco succeed without a quit-smoking product. But more than 30 percent can succeed when using a quit-smoking product. You have the best chance at quitting smoking when you combine behavior therapy with use of one or more quit-smoking products.”¹

¹ **Quit-smoking products: Boost your chance of quitting for good**, Mayo Clinic staff,
Original Article: <http://www.mayoclinic.com/health/quit-smoking-products/MY00781>

MATERIALS AND METHODS:

Recruiting volunteers for this 30 day study was achieved by placing advertisements in local newspapers following the generally accepted guidelines of study recruitment with no guarantee of results or material connection. Desired subjects were men and women who smoked an absolute minimum of one half pack of cigarettes (10) per day for a minimum of 2 years. The selection criterion was determined by Detuag Testing Inc., a 3rd party research and recruitment service.

Thirteen subjects attended the ten day compliance check in mark of the study. The initial characteristics/measurements for the subjects were the following:

Smoker Characteristics				
Subject #	Gender	Age	Cigarettes per day	Years as a smoker
1	M	54	9 to 14	30
2	M	39	20	20
3	F	58	15 to 20	25
4	F	43	10 to 20	30
5	F	52	12	35
6	F	39	10+	22
7	M	59	15 to 20	40
8	F	33	10 to 15	15
9	F	50	12 to 15	32
10	F	47	10 to 20	27
11	M	45	10 to 20	25
12	M	45	20+	30
13	M	40	20+	20

As can be noted above, those that completed the initial 10 day portion of the study represented a spectrum of ages ranging from 33 years to 59 years. The average length as a smoker was 27 years currently smoking no less than 10 cigarettes each day. The above characteristics indicate the group represented long term habitual smokers when beginning the program.

Objectives:

The key objectives of this study were to:

- 1) Track results of using the Freedom Quit Smoking System after 10 days, 20 days, and at 30 days of daily use (according to package instructions).
- 2) Obtain verbal testimonials of study participants' personal opinions about the product and their experience with using the product.

- 3) Solicit user feedback on the system use.
- 4) Solicit user feedback on any side effect.
- 5) Solicit user feedback on key benefits and key challenges of the product use.
- 6) Solicit user feedback on individual experience of product effectiveness.

The study was monitored by director of research Eddie Gaut. Participants completed a registration questionnaire prior to enrolling in the trial. Participants were expected to complete questionnaires and participate in one on one videotaped interviews. Participants were volunteers and were not compensated.

After selection, 15 subjects were initially examined and questioned. Questionnaires used were designed to track usage and subjects overall satisfaction of the product use while notes were taken to evaluate efficacy of the product during the 30 day term. Subjects were then given the components of the product to be used daily and told to continue to refrain from using any other quit smoking product until the completion of the study.

Recruitment Summary

Print Ads were placed in various daily newspapers designed to attract smokers that want to quit.

15 participants met the criteria and were invited to participate in the study. 13 actually participated.

Study Methodology

Once a potential participant passed the telephone screen, a screening visit was scheduled and if the subject fulfilled all inclusion criteria, the subject was enrolled as a participant. This visit served as the baseline visit.

Data Collection Methods

The protocol was administered by Eddie Gaut, Director of Research at the DETUAG Testing Center and holds a JAEB Center for Health Research Certificate.

Procedures

Prior to beginning the program all subjects were screened according to the methods previously described. The subjects were instructed to initiate the Freedom Quit Smoking plan of action on the next day. After 10, 20 and 30 days on the plan, the subjects were questioned regarding their use of the system and their efforts to quit smoking.

RESULTS:

In the first 10 days 54% had quit for 10 consecutive days. At 20 days, 8 had quit for a minimum of 10 days (61.53%) and 7 had quit for 20 days.

At 30 days nearly 70% (69.23%) quit smoking for 15 or more consecutive days and 61.53% were smoke free for 20 or more days.

During the study participants completed a number of questionnaires - the 10 day answers to which are summarized below in Tables 1, 2, 3, and Table 4.

Table 1: Number of consecutive smoke free days			
Name	Day 10	Day 20	Day 30
Chris	10 days	20 days	30 days
Edward	10 days	20 days	30 days
Candie	1 day	11 days	21 days
Michelle	3 days	0	0
Donnell	10 days	Drop	Drop
Jessica	10 days	20 days	30 days
Jack	7 days	6 days	16 days
Laura	1 day	11 days	21 days
Jana	1 day	0	0
Nancy	10 days	20 days	30 days
Ken	1 day	0	0
John	10 days	20 days	30 days
Jeff	10 days	20 days	30 days
Robert	DROP before 10 days		
Frank	DROP before 10 days		

Table 2: 10 Day Questionnaire Summary of 13 participants					
Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Easy to incorporate into daily routine.	2	7	3	1	0
Would Recommend to Others	4	8	1	0	0
Question	Highly Satisfied	Satisfied	Neutral	Dissatisfied	Strongly Dissatisfied
How Satisfied are you with this method to quit smoking?	5	7	1	0	0

As seen in Table 2 as per the 10 days:

A combined total of 8 subjects either ‘Agreed’ or ‘Strongly Agreed’ they would recommend the Freedom Quit Smoking System to others while 1 answered ‘Neutral’.

A combined total of 92% stated they were either ‘Satisfied’ or ‘Highly Satisfied’ with the Freedom Quit smoking method.

Table 3: 20 Day Questionnaire Summary of 13 participants					
Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Easy to incorporate into daily routine.	5	2	5	0	1
Would Recommend to Others	6	4	2	1	0
Question	Highly Satisfied	Satisfied	Neutral	Dissatisfied	Strongly Dissatisfied
How Satisfied are you with this method to quit smoking?	6	3	3	1	0

As per 20 days, a combined total of 10 subjects either ‘Agreed’ or ‘Strongly Agreed’ they would recommend the Freedom Quit Smoking System to others.

Subject compliance rate decreased for the full 30 day portion of the test, in that 11 of the 13 answered the 30 day questionnaire. Subjects dropped out of the program or were disqualified due to lack of motivation in continuing compliance regardless of smoke free days.

Consistent with the initial 10 and 20 days the majority of subjects responded with continued satisfaction towards the product.

Table 4: 30 Day Questionnaire Summary of 11 participants					
Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Easy to incorporate into daily routine.	2	7	2	0	0
Would Recommend to Others	5	6	0	0	0
Question	Highly Satisfied	Satisfied	Neutral	Dissatisfied	Strongly Dissatisfied
How Satisfied are you with this method to quit smoking?	6	5	0	0	0

As seen in Table 3 and Table 4:

At 30 days a combined total of 11 subjects either ‘Agreed’ or ‘Strongly Agreed’ they would recommend the Freedom Quit Smoking System to others. This represents 100% of those that completed the full 30 days.

CONCLUSIONS

The combination of some or all of the components of the tested quit smoking program, led to a measurable period of time (30 days) where nearly 70% of the test subject had been smoke free for 15 or more consecutive days. These test subjects also stated, at the end of the study, that they expect to remain smoke free permanently and attributed their success to the Freedom Quit Smoking System. Of the 13 test subjects 6 had quit for the full 30 day term of the study. 46% had quit for the full 30 days with the average expected quit rate of most other quit smoking programs including nicotine replacement therapies being 30% or better.

This study provides evidence as to the tested product’s efficacy and safety. There were no reported serious adverse events during the 30 day trial.

This research found that not many of the users understood exactly why different components worked for them with many simply appreciating the distraction from smoking each of the components allowed them when used.

The Freedom Quit Smoking System proved to have a little something for everybody and works by its unique blend of psychological tools to modify behavior patterns associated with smoking including a relaxation headset. Also included is a homeopathic spray with ingredients traditionally used to temporarily relieve cravings and proprietary antioxidants to support the body’s natural fight against toxins along with education on understanding nicotine addiction.

The results of the study indicate this product to be an effective stop smoking product for those having a desire to quit.

The subjective satisfaction is also notable. The data tells us that of the participants who completed the full 30 day trial - 100% are satisfied with the tested quit smoking method at 30

days. In addition, 100% also stated at 30 days that they either 'Strongly Agreed' or 'Agreed' they would recommend it to others.

The Freedom Quit Smoking system proved to be an effective tool for those with the desire to quit smoking. It would be expected that a longer term study would prove a high percentage of smokers to quit permanently because of the psychological and behavior modification methods incorporated without the use of nicotine.