Study Protocol with Statistical Analysis Plan

Official Study Title:
Evaluation of a Smoking Cessation Program for Long-Term Abstinence

ClinicalTrials.gov Identifier:
NCT06746025

Protocol ID:
052024CESS

Document Date:
June 3, 2026
---

1. Background and Rationale

Tobacco use and nicotine dependence remain significant public health concerns. While the health benefits of smoking cessation are well established, sustained abstinence remains challenging for many individuals. Behavioral and group-based approaches to smoking cessation may provide an alternative or complementary pathway to traditional pharmacologic interventions.

This study evaluates a structured, group-based smoking cessation program designed to support cessation through behavioral change strategies, peer interaction, and self-directed techniques. The program is delivered remotely, increasing accessibility to participants across geographic regions.

---

2. Objectives

Primary Objective:
To assess the proportion of participants who achieve self-reported smoking abstinence at the end of the 8-week program.

Secondary Objectives:
- To assess the proportion of participants who maintain self-reported smoking abstinence at 6 months following program completion.
- To assess the proportion of participants who maintain self-reported smoking abstinence at 12 months following program completion.
- To describe demographic characteristics of participants enrolled in the program.

---

3. Study Design

This is an observational, prospective cohort study.

Participants are enrolled in a structured smoking cessation program and followed over time. There is no randomization, no comparator group, and no pharmacologic intervention.

All participants receive the same program intervention.

---

4. Study Population

Inclusion Criteria:
- Adults residing in the United States
- Current users of combustible cigarettes and/or electronic nicotine delivery systems (vaping products)
- Willingness to participate in a smoking cessation program

Exclusion Criteria:
- Individuals who are not current smokers or vapers
- Individuals unable or unwilling to participate in remote sessions
- Individuals currently enrolled in other health/wellness programs

---

5. Intervention

Participants enroll in the Quit Center Smoking Cessation Program, a structured, group-based program delivered remotely via weekly videoconference sessions.

Program characteristics:
- Duration: 8 weeks
- Session frequency: Weekly
- Session length: Approximately 1 hour
- Group size: Approximately 15–20 participants per session

The program is behavioral and educational in nature and does not include pharmacologic interventions or nicotine replacement therapies. It focuses on behavioral change strategies, peer support, and self-directed techniques intended to support smoking cessation.

---

6. Data Collection

Data are collected at three timepoints:

1. Baseline:
  - Demographic information
  - Smoking/vaping status

2. End of Program (8 weeks):
  - Self-reported smoking/vaping status

3. Follow-up:
  - 6 months post-program completion
  - 12 months post-program completion
  - Self-reported smoking/vaping status

All data are collected remotely through questionnaires.

---

7. Outcome Measures

Primary Outcome:
- Smoking Abstinence at End of Program (8 weeks)
  - Percentage of participants who self-report abstinence from smoking and/or vaping at the end of the 8-week program.

Secondary Outcomes:
- Smoking Abstinence at 6 Months
  - Percentage of participants who self-report continued abstinence from smoking and/or vaping at 6 months following completion of the program.

- Smoking Abstinence at 12 Months
  - Percentage of participants who self-report continued abstinence from smoking and/or vaping at 12 months following completion of the program.

---

8. Statistical Analysis Plan

Analysis Population:
All participants who enroll in the program and provide outcome data at the relevant timepoints.

Primary Analysis:
- The proportion of participants reporting abstinence at 8 weeks will be calculated as a percentage of respondents.

Secondary Analyses:
- The proportion of participants reporting abstinence at 6 months and 12 months will be calculated as percentages of respondents at each timepoint.

Handling of Missing Data:
- Analyses will be based on available data at each timepoint.
- Participants lost to follow-up will not be included in the denominator for that specific timepoint analysis.

Descriptive Analyses:
- Demographic characteristics will be summarized using descriptive statistics (e.g., counts, percentages).

No formal hypothesis testing is planned. This study is descriptive in nature.

---

9. Ethics and Oversight

This study involves a behavioral, non-pharmacologic program delivered remotely. Participation is voluntary. No medical treatments are administered as part of the study.

---

10. Study Timeline

- Program duration: 8 weeks
- Follow-up assessments:
 - 6 months post-program
 - 12 months post-program

End of Document