Statistical Analysis Plan

A Large-Scale Randomized Control Trial to Determine the Effects of Dress by Adolescents on Electronic Cigarette Retailer Behaviors in Regulation Compliance in China

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APPROVAL

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ABBREVIATION

Abbreviation or Term	Definition/Explanation
E-cigarette	Electronic cigarette
RCT	Randomized controlled trial
ID	Identification card

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1. Introduction

The Statistical Analysis Plan (SAP) aims to provide a comprehensive and detailed description of the methods and strategies to be adopted for analyzing data collected from e-cigarette stores in China. The SAP is finalized prior to database lock to ensure the credibility of the study's findings.

1.1. Overview

1.1.1. Study Design

This study is a two-armed, national-level, open-label cluster RCT conducted among e-cigarette stores located in 36 metropolitan areas across mainland China (including 4 municipalities directly under the Central Government, 27 provincial capitals, and 5 cities specially designated in the national plan). This RCT will adopt the mystery shopping approach to measure the effect of adolescent buyers' type of attire (school uniforms vs. casual attire) on the likelihood of sellers' compliance with the minimum age restriction for e-cigarette sales, defined by both age verification and sales. The e-cigarette stores will be randomly assigned to the intervention group or control group at a ratio of 1:1. Each store in the intervention group will receive a simulated buyer dressed in a school uniform, while each store in the control group will receive a simulated buyer dressed in casual attire. The simulated buyers in this study are adolescents aged 18-19 years old. The simulated buyers will attempt to purchase e-cigarette products and record the behaviors and marketing claims of the sellers, as well as store internal and external characteristics.

Eligible stores as study subjects will be identified from the AutoNavi Map through keyword searches. Stores are eligible for enrollment if they have reachable contact information and claim to be open for business on a regular basis when contacted. The expected number of e-cigarette stores sampled in each metropolitan area is approximately 32, with an additional 8 e-cigarette stores serving as backups, if the

number allows, for a minimum expected total enrollment of approximately 1,080 retailers. In addition, we plan to conduct the same trial for cigarette stores and perform a 1:1 match of e-cigarette stores and cigarette stores, allowing us to compare the business practices of e-cigarette stores and cigarette stores between the two attire groups.

1.1.2. Randomization

Generating clusters to which the stores belong: Considering traveling time and the efficiency of data collection, this trial will use a cluster randomization approach rather than simple randomization. Investigators will first map all the 40 selected stores within each metropolitan area and then divide them into clusters containing the same number of e-cigarette stores (approximately 5 stores per cluster), taking into account their locations and public transportation. Each cluster will then be digitally labeled, from area 1 to area 8. The labeling of the clusters will follow the principle of from top to bottom, and from left to right on the map.

Assigning clusters to treatment and control groups: Each cluster will be randomly assigned to one simulated buyer, and the type of attire (school uniforms or casual attire) they wear on a specific day will also be randomized. In this way, the e-cigarette stores will ultimately be allocated at a 1:1 ratio to either the intervention or control group.

- Specifically, the simulated buyers (data collectors) to be recruited are 18 to 19 years old, with a 1:1 ratio of males to females. To reduce bias associated with the personal characteristics of the simulated buyers, they will be randomly assigned a new digital number for each metropolitan area, which will be used for matching the clusters.

- The type of attire worn by each adolescent on a specific day will be pre-determined using Excel's random number generator within each sex, ensuring that each

adolescent has an equal probability of wearing school uniforms and casual attire during the entire study.

1.1.3. Blinding

It will be impossible to blind study subjects (e-cigarette stores) regarding the assignment to the intervention or control group, as letting sellers in the e-cigarette stores see the buyers' attire is part of the treatment. However, sellers will not be aware of their participation in this trial due to the mystery shopping approach adopted.

The trial team, consisting of both simulated buyers and coordinators, will also not be blinded to the e-cigarette stores in the intervention and control groups, as there is no way to prevent them from knowing which e-cigarette stores have simulated buyers wearing school uniforms or casual attire on each day.

The statistician conducting the analyses will have no direct contact with the e-cigarette stores but will not be blinded to the treatment allocation.

1.2. Study Objectives

1.2.1. Primary Objective

To measure the effect of dressing in school uniforms (compared to casual attire) by adolescents on regulation compliance-related behaviors of e-cigarette sellers defined by both age verification and underage-cigarette sales.

1.2.2. Secondary Objectives

- To determine the impact of type of attire by adolescents on in-store communication between sellers and customers, specifically dissuading use.
- To discern the differences in regulation compliance-related behaviors between e-cigarette and cigarette retailers.

1.2.3. Exploratory Objectives

- To describe the regulatory compliance of e-cigarette and cigarette retailers across mainland China.
- To document the marketing and communication strategies adopted by e-cigarette and cigarette retailers, e.g. store location, advertisements, decorations and online delivery service, across mainland China.

1.3. Study Hypotheses

We hypothesize that dressing in school uniforms by adolescents will significantly increase the likelihood of e-cigarette sellers verifying the age of buyers in stores and reduce the probability of their illegal sales to minors.

The corresponding null hypothesis that will be tested is that dressing by school uniforms by adolescents will have no effect upon e-cigarette selling behaviors in regulation compliance.

1.4. Sample Size

Successful purchase rates of e-cigarette products for the school uniform group and casual attire group will be derived from the pilot study. Other parameters required for cluster-RCT sample size calculation are as follows:

- Randomization in a 1:1 ratio for the school uniform (intervention) group and casual attire (control) group
- $\alpha = 0.05$ (two-sided)
- power = 0.85
- cluster size = 4 (both for intervention group and control group)

- inter-cluster correlation coefficient = 0.5 (default)

However, considering the primary goal of this study is to characterize e-cigarette seller behaviors at a national level, we decide to set the final sample size to be approximately 1,080. This may be far more than the minimum sample required (about three times) for testing the effect of buyer attire on e-cigarette sales to adolescents in China.

2. Statistical and Analytical Procedure

2.1. Study Subjects

This study will be conducted across 36 major metropolitan areas in mainland China (including 4 municipalities directly under the Central Government, 27 provincial capitals, and 5 cities specially designated in the national plan). The expected number of study subjects sampled from each metropolitan area is approximately 32 e-cigarette stores, if the number allows, for a minimum expected total enrollment of approximately 1,080. This study will include cigarette stores for comparisons with e-cigarette stores. For each e-cigarette store, one nearby cigarette shop will be conveniently selected for matching, as cigarettes are widely available in convenience stores, supermarkets, and tobacco and liquor shops, making it impossible to systematically pre-identify these stores.

2.2. Study Variables

2.2.1. Outcomes

Primary Outcome Measure

The primary outcome is the sales of e-cigarettes to adolescent buyers, measured by the successful purchase of e-cigarette products from the stores without showing any age proof.

Secondary Outcome Measures

- The seller verbally inquiring about the simulated buyer's age
- The seller requesting ID cards from the simulated buyer for age verification
- The seller dissuading the simulated buyers from using e-cigarettes

Other Outcome Measures

- Illegal flavored products being sold: The simulated buyer will report if the seller mentions that flavored (non-national-standard) e-cigarette products are available in the stores.
- Online contact: The simulated buyer will report if WeChat account information is publicly displayed for adding contacts.
- Delivery service offered: The simulated buyer will report if the seller mentions that products ordered online can be delivered.
- Marketing claims: The simulated buyer will record the marketing claims made by the seller to promote the products

2.2.2. Covariates

The assessment tool should be designed primarily based on the Vape Shops Standardized Tobacco Assessment for Retail Setting (V-STARS)[1] and the Tobacco Advertising, Promotion and Sponsorship (TAPS) bans compliance guide[2], as well as published articles[3]. It will be further adapted by investigators who are familiar with Chinese e-cigarette retailers and laws and have observed store characteristics, to the Chinese context to collect information mainly on store internal/external environmental features (e.g., location, advertising, warning signs, and licensing), product availability, and seller behaviors. Detailed information on covariates is listed as below:

- Buyer characteristics: Sex, Age
- Seller characteristics: Sex, Age perceived by the simulated buyers (18-29, 30-40, >40 years old)
- Store characteristics: Store location (In mall, on street), region, age-of-sale warning sign presented, license to sell e-cigarettes presented, health warning presented, and advertising.

2.3. Statistical Methods

2.3.1. General Considerations

Summary statistics will be presented for both the treatment and control groups. Continuous variables will be summarized by the number of observations, mean, standard deviation, median, minimum, and maximum. Categorical variables will be summarized using frequency counts and percentages. Descriptive analyses of the distributions of the e-cigarette seller behavior outcomes between two types of attire (treatment and control groups), including successful purchases, inquiring about buyer age, requesting ID cards for age verification, and dissuading buyers from use, as well as store environment features, and sellers' demographic characteristics, will be conducted with t-tests and chi-square tests detecting statistically significant differences.

The significance level for comparisons between the two groups is set at α=0.05 (two-sided). Differences between the study groups will be considered statistically significant if the p-value is less than 0.05. All analyses will be performed using Stata MP 17.

2.3.2. Analysis of Primary Outcome

For the primary outcome, successful purchase rates will be analyzed using Chi-square tests to determine if the differences between the treatment group and the control group are statistically significant. Multivariate logistic regression models will be further employed to analyze the treatment effect, adjusting for covariates.

A national map depicting the geographic variations in the outcomes of successful purchase rates will be created using the R package DrawChinaMap.

2.3.3. Analysis of Secondary Outcome

Secondary outcomes, including inquiring about the buyer's age, requesting ID

cards for age verification, and dissuading buyers from use, will be analyzed in a similar manner to the primary outcome. Chi-square tests will be used to detect the statistical significance of differences between the two study groups, and logistic regression models, adjusted for covariates and appropriate for the distribution of the outcomes, will be employed. Additionally, similar national maps describing geographic variations will be generated.

2.3.4. Analysis of Other Outcomes

Other outcomes, including illegal flavored products, online contact, and delivery service offered, will be analyzed in a similar way as the primary outcome. Chi-square tests will be used to detect statistical significance in differences between the two groups, and logistic regression models appropriate for the distribution of the binary outcomes with covariate adjustments will be employed. Similar national maps describing geographic variations will be generated as well. For marketing claims and strategies, we will further employ thematic framework analysis to qualitatively analyze and describe the marketing methods and tactics of e-cigarette stores.

2.3.5. Subgroup Analysis

For matched e-cigarette and cigarette stores, we will employ McNemar's tests to assess the distinctions in the outcomes between e-cigarette stores and cigarette stores. Rates of successful e-cigarette purchases stratified by age checking behaviors and buyer attire will also be reported. Planned subgroup analyses are intended to explore potential effect modifications of gender, age, metropolitan area and store types.

3. Software Documentation

All the statistical analyses will be conducted using Stata MP 17 (StataCorp, College Station, TX, US). The maps depicting geographic variations will be generated using DrawChinaMap (https://rdrr.io/github/psychbruce/drawMap/src/R/drawChinaMap.R).

4. Reference

1. Kong AY, Eaddy JL, Morrison SL, Asbury D, Lindell KM, Ribisl KM. Using the Vape Shop Standardized Tobacco Assessment for Retail Settings (V-STARS) to Assess Product Availability, Price Promotions, and Messaging in New Hampshire Vape Shop Retailers. Tob Regul Sci 2017;3(2):174-182. (In eng)
2. Polanska K, Kaleta D. Tobacco and E-Cigarettes Point of Sale Advertising-Assessing Compliance with Tobacco Advertising, Promotion and Sponsorship Bans in Poland. Int J Environ Res Public Health 2021;18(4) (In eng)
3. Nian Q, Cohen JE, Cui Y, Zhang S. Tobacco retailers around schools in 10 cities across China. Tob Control 2022 (In eng)