A Study of Hookah Café Customers in the Atlanta Area

Approval Date: 11/05/2024
NCT Number: 05916170
IRB Number: 00095123

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Funding Source:	National Cancer Institute (NCI) R01CA241420

Background, Rationale, and Context

Young adults have the highest prevalence of waterpipe tobacco smoking (WTS) of any age group in the U.S.[1] Extensive evidence shows that they consistently misperceive WTS as less harmful and less addictive than cigarette smoking, and these misperceptions are positively associated with WTS.[2-7] Despite these widely held misperceptions, WTS is associated with serious acute and chronic harms, even among infrequent users.[8] In addition, WTS is prospectively associated with cigarette smoking initiation putting young adults at greater risk for cancer.[9] Considerable evidence shows that *cigarette warnings* effectively convey health information to consumers,[10,11] resulting in increased motivation to quit and quit attempts. Waterpipe warnings have the potential to convey accurate information about health harms to consumers, but the currently mandated text warning, focused solely on nicotine addiction, is likely to have limited impact.

The goal of the overall grant is to develop warnings to promote greater understanding of harms and to reduce WTS behavior among young adults. We have used a systematic, evidence-driven, rigorous approach to develop waterpipe warnings and test these newly developed warnings in two contexts: (1) on waterpipe tobacco packaging; and (2) in an ecologically valid waterpipe café setting. In Aim 1, we developed text and pictorial waterpipe tobacco warnings to effectively communicate a broad range of health harms. We first developed 30 text warnings based on three themes: acute health harms, chronic health harms, and correcting misperceptions. We tested these warnings in a national survey to determine the five most effective text warnings (IRB00062703). We then selected three illustrative images of the health effects presented by the warnings for each of these warnings, plus the federally mandated nicotine warning. We conducted an experiment to determine the most effective image for each of the six warning messages (IRB00080199). In Aim 2 (IRB00091946), we compared the effects of pictorial warnings versus the text-only warnings and a no-warning control placed on fictional packaging on WTS intentions.

Warning placement on packaging and at the point-of-sale is typically the result of legal mandates. In order to approximate the impact of a legal mandate to require health warnings at the point-of-sale, we will partner with places that sell waterpipe tobacco for use onsite. These places may be cafés, restaurants, lounges, bar, etc. (herein referred to as “hookah cafés”). Conducting an experiment where hookah café customers are exposed to waterpipe warnings will allow us to test the impact of the warnings on actual behavior, in the absence of legal mandates. In this experiment (Aim 3), we will conduct a cluster randomized crossover trial with up to 32 hookah cafés in Atlanta, GA (1 pilot and 31 trial cafés). We plan to overenroll cafés to account for dropout/early termination. The goal is at least 20 cafés with 15 participants per arm. Each café will serve as its own comparison as it cycles through the two trial arms: intervention (text warning) and control (no warning). The pictorial warning condition was removed in July 2024 after consultation with E&W and NCI regarding unwillingness of cafés to allow placement of pictorial warning signs. We will randomly select one of four health warning messages from Aim 2 to be displayed in each of

the partner café. However, each café will only have one warning displayed on its premises for the duration of its participation in the intervention arm.

Objective(s)

1. To determine the effect of warnings on hookah smoking behavior, measured with an objective biomarker of consumption (expired carbon monoxide), and behavioral antecedents.

Roles

Wake Forest Baptist Health
Wake Forest's role in this study will be to develop the protocol and data collection instruments, create the study stimuli, program all online data collection tools, train data collectors hired by Ewald & Wasserman, monitor data collection, conduct all analyses, and lead dissemination of results.

University of North Carolina at Chapel Hill
Dr. Noar will assist in developing data collection instruments and interpreting the results of analyses on final data.

Boston University
Dr. Ross will assist in developing data collection instruments and interpreting the results of analyses on final data.

Ewald & Wasserman Research Consultants, L32
Ewald & Wasserman (E&W) will conduct the Aim 3 cluster randomized crossover trial at up to 32 hookah cafés (1 pilot and 31 trial cafés) in Atlanta, GA. This trial will be conducted entirely in the field at the participating cafés. Hookah cafés will be recruited to partner with the research team, which involves allowing participants to be recruited and data collection to occur outside the café prior to café entry and after café exit on at least two data collection periods (across the two trial arms). Cafés must also agree to allow the research team to post health warnings about hookah smoking in the cafés on some of the days of data collection. E&W will be responsible for the recruitment of hookah cafés, hiring of field staff, training of field staff on data collection procedures (in conjunction with the Wake Forest study team), and implementing all data collection procedures. Data collection will involve field research at the hookah cafés. Field staff will approach potential participants before they enter the café to assess interest in the study and eligibility. For those eligible, field staff will complete the consenting process, administer a brief survey on tablet computers, collect expired carbon monoxide breath measurements, and distribute incentives at two time points: before participants enter the café and after they exit. Additionally, field staff will debrief participants at the end of the study. E&W will also be responsible for all participant payments. Finally, E&W will be responsible for printing, implementing, and removing the warning signs at waterpipe cafés.

Methods and Measures

Design
The design of the study is a cluster randomized crossover trial, where the hookah café is the cluster and randomization is at the cluster level. Each hookah café will serve as its own control and will be used for data collection for both study arms: (1) intervention, and (2) control. Each café will start in the no warning control arm to avoid the potential for contamination, since customers may visit the same café on multiple days. In the intervention arm, cafés will display one of four text warnings. In the intervention arm, warning messages will be displayed at various agreed-upon locations in the café, such as on hookah pipes, tables, countertops, walls, and menus. The goal is to maximize the potential for customers to be exposed to warnings.

Setting

Data collection will occur outside hookah cafés in the Atlanta, GA metro area. Atlanta was chosen as the study site because Georgia's weak smoke-free air law allows smoking in bars and restaurants, including hookah cafés. There are over 100 hookah cafés in the Atlanta metropolitan area and Atlanta is home to 57 colleges and universities. The number of cafés and young adults, and the weak smoke-free air laws make Atlanta the ideal location for this study. We will partner with one pilot café and up to 31 additional cafés to allow study activities, including collecting data with customers before café entry and after café exit, and display of study-produced health warnings about hookah smoking during the times when data collection is occurring. Participants will complete data collection outside of the café at two time points, before entry into the café and after exit from the café.

Subject Selection Criteria

Participants will be those planning to enter a hookah café where the study is being conducted. We aim to have 15 participants complete Time 1 (before café entry) and Time 2 (after café exit) data collection at each café for each arm. In order to account for attrition between time points, we will enroll up to 30 participants at each café during each data collection period. We will schedule data collection periods for when the café is most busy, based on information provided by the café manager or owner.

Inclusion Criteria

- Planning to enter the hookah café where study is being conducted
- Age 18 or older
- English speakers
- Planning to smoke hookah inside
- Planning not to smoke cigarettes, cigars, cigarillos, or marijuana while at the hookah café
- Had not previously entered the café earlier in the day on the same day/night as data collection
- Has not been approached to participate in the study at another café or another day/night at the current café
- Are not employees of the business
- Have capacity to participate as determined by the staff member conducting eligibility screening

Exclusion Criteria

- Not planning to enter the hookah café where the study is being conducted
- Age 17 or under
- Non-English speakers
- Not planning to smoking hookah in the café
- Planning to smoke cigarettes, cigars, or marijuana while at the hookah café
- Are employees of the business
- Has not been approached to participate in the study previously
- Had previously entered the café on the same day/night as data collection
- Does not have capacity to participate as determined by the staff member conducting eligibility screening

Sample Size

- We will enroll up to 1,560 participants in total, across the 32 cafes (this includes up to 30 participants per night, per café. The goal is 15 **completions** per night, per café).

Interventions and Interactions

Intervention Arm

Study staff will place signs containing a text-only warning (selected from a pool of four warnings on lung damage, heart damage, carbon monoxide poisoning, and stunting fetal growth tested in WT Warnings Aim 2 – IRB00091946) in various locations around the café, as agreed upon with the café owner or designated representative. Locations may include the hookah pipes, tables, interior wall signs, countertop signs, menus,

and bathroom signs (see Figure 1. Table Sign). Sign placement and quantity may differ between cafés. Signs will be removed by study staff at the end of each data collection period.

Control – No Warnings
In the Control arm, there will be no signs placed by the study team at any location within the café.

Data Collection
The timing of data collection periods will be agreed upon in advance between the study team and the café owner, manager, or their designee. When the data collectors first arrive at the café, they will introduce themselves to the café point person and place signs in the agreed-upon locations and will document the locations in the café record (on intervention nights). Additionally, photographs of sign placement will be taken.

The study team will set up tables outside the café, where data collection will be completed. In 2017, we completed a pilot study to test these methods (IRB00044196), which worked well. Data collection will be conducted during café hours, when young adults are most likely to visit waterpipe cafés, based on the advice from café employees. Data collectors will approach individuals before they enter the café to determine interest in the study. Interested individuals may also approach the data collectors. Data collectors will conduct eligibility screening with interested individuals (described above).

Figure 1. Table Sign

Data collectors will also make a determination, based on their interaction with the participant, of the participant's capacity to participate in the study. If they determine that the person does not have capacity, they will mark this on the Eligibility Form and the participant will be Not Eligible. If they determine that the person does have capacity, they will mark the participant such on the Eligibility Form and will continue with the Consent process. Determination of capacity to participate will be based on whether people can adequately answer the eligibility screening questions. Eligible participants will be read the consent information by a data collector prior to enrollment and provide verbal consent. A printed consent document will be available for participants if they ask to see it.

After completing the consent process, participants will be given a wristband with their participant ID. Then, they will complete a brief survey about their hookah use behaviors, demographics, and recent use of other combustible products. The will enter their email into a Qualtrics link managed by Ewald & Wasserman to receive their first ($25) electronic gift card; this is not stored with study data, although it is linked to PID. Next, participants will provide up to two samples of expired carbon monoxide (eCO) by blowing into a carbon monoxide (CO) monitor. This non-invasive process involves taking a deep breath, holding it for 15 seconds, and then exhaling into a sterile tube until the lungs are completely empty. Expired CO is a well-established measure of tobacco smoke exposure. Participants will then be able to enter the café as planned. All participants will be asked to return to the data collectors after exiting the café to complete the follow-up measures. If the data collection period is scheduled to end before the café closes, data collectors will instruct the participants to come outside for Time 2 measures before the data collection period will end. Upon exiting the café, participants will complete a similar brief survey, provide their email again for their second ($50) compensation, and provide up to two new samples of eCO, using the same procedure as described above. Participants will be debriefed on the purpose of the study and the CO measure. The debrief form will also have resources for more information about CO and health harms of hookah smoking, and contact information for the study PI, the Wake Forest IRB, and E&W for assistance with compensation.

The participant incentives are not intended to be an enticement to smoke hookah within the café, but rather as compensation for time needed to complete the surveys and eCO monitoring, which we anticipate will take up to 20 minutes at each time point. Participants will only be eligible if they indicate they are planning to smoke hookah in the café. We will not recruit people to come to the café, but rather recruit café customers to participants in the study. Participants will be instructed to behave as they normally would in the café. The incentive will not be able to be used in the café.

Pilot/Soft Launch

We will conduct a pilot/soft launch with a single hookah café to assess feasibility of the protocol and to make changes, if required, before conducting the full trial. Any changes to protocol and/or measures will be submitted as amendments before conducting the remainder of the trial. If no changes are made as a result of the soft launch, this café will be included in the final study sample. If significant changes are made as a result of the soft launch, we will conduct the study with up to 25 additional cafés and the data from the soft launch café will not be included in the final dataset. We will implement both text-only and pictorial warnings on different nights at the pilot café to fully test the two versions of the intervention signs, in addition to the control arm.

Outcome Measure(s)

Primary Outcome

Change in Expired Carbon Monoxide from baseline to follow-up. We will use eCO, an objective, biological marker of waterpipe tobacco consumption. There is a linear relationship between waterpipe tobacco smoking intensity and carboxyhemoglobin concentration, and eCO is strongly correlated with several topography measures of waterpipe smoking. Carbon monoxide has a half-life of 3-4 hours and is influenced by other forms of combustible tobacco; therefore, the primary outcome will be the change in eCO from before entry to after café exit, known as eCO boost. We will also record the percentage of carboxyhemoglobin concentration measured by the CO monitor.

Secondary Outcome(s)

None

Other Outcomes

Behavioral intentions. Participants will be asked at Time 2 three items assessing their expected hookah smoking within the next month. Items will be averaged to create a composite score of intent to continue the behavior within the next month.

1. How interested are you in smoking tobacco in a hookah in the next month?
2. How likely are you to smoke tobacco in a hookah in the next month?
3. How much do you plan to smoke tobacco in a hookah in the next month?

Response Options: (1) Not at all, (2) A little, (3) Somewhat, (4) Very, (5) Extremely

Quit motivation. One item to measure participants' motivation to quit smoking hookah, rated on a 1-10 scale of Not at all motivated – Extremely motivated. This item is asked only of those who did not smoke for the first time tonight (by self-report).

Hookah use behaviors. Participants will be asked a variety of items to assess their hookah smoking behaviors within the café. Items will be scored individually.

1. Did you smoke hookah in this café/lounge/bar today? (1) Yes, (2) No
2. (If no) Why didn't you smoke hookah in this café/lounge/bar today? Free text response
3. (If yes) Compared to a typical night, how much did you smoke? (1) Less hookah than usual, (2) About the same amount of hookah as usual, (3) More hookah than usual, (4) This was my first time smoking hookah
4. (If less) Why did you smoke less than usual? Free text response
5. (If more) Why did you smoke more than usual? Free text response

Subjective experiences of smoking hookah. Eight items of the Satisfaction subscale of the Product Evaluation Scale[12] will be used to assess participants' subjective experiences of smoking hookah. Items scores will be averaged across the subscale.

1. Was it satisfying?
2. Did it taste good?
3. Did you enjoy the sensations in your mouth?
4. Did you enjoy it?

5. Did it make you dizzy?
6. Did it make you nauseous?
7. Was it too much nicotine?
8. Were there bothersome side effects?

Response options: (1) Not at all – (7) Extremely

Knowledge. Four items to measure the participants' knowledge of the health harms presented by the four selected warnings used in the study, although participants will be exposed to none (Control) or only one (Intervention) during their participation.

Beliefs. Four items to assess the participants' belief that the health effects named by the four selected warnings will affect them personally.

Warning recall. One Y/N item and one free-text follow-up to assess participants' recall of warning messages shown (if any) during participation.

Warning recognition (Intervention Arms Only). Participants will be asked to select the warning(s) that they saw at the café from a selection of the four possible warnings for their study arm. For each warning message that they report having seen, they will be asked to select where they saw the warning from a list of possible locations.

Social interactions. For each warning selected in the Warning Recognition section, participants will be asked if they discussed the warning with others. If they answer positively, they will be given a list of topics to choose from to describe what they talked about, including a free-text option.

Perceived influence of warning on smoking behavior. Participants will be asked whether they changed their smoking behavior as a result of the warning(s) they saw (as reported in the Warning Recognition section). They will be asked to report whether they smoked more, less, or the same amount as they usually do. These items will be asked for each warning the participant reports seeing.

Time spent in the café. Duration of time in café will be calculated from the time of completion of eCO measurement at Time 1 to start of survey at Time 2. Additionally, we will utilize a subjective measure of time spent in the café: Compared to what you planned, how long did you stay at the café/lounge/bar? (Longer, shorter, about the same).

Analytical Plan

The sample size will allow us to detect meaningful differences in the eCO boost between study arms. We estimate the minimum difference in eCO boost detectable between the two arms (intervention vs control) with 80% power between two periods I) using a cluster randomized crossover trial design with a minimum of 20 cafés, each with completed data for 30 café patrons (15 per arm). Sample size is based on formulae from Giraudeau et al. (2018) that takes into account both the intraclass correlation coefficient r (correlation within a café) and the inter-period correlation h induced by the crossover design.[13] We consider both small and moderate ICCs or r=0.10 and r=0.30 and a smaller h specified to be half of r as recommended by Donner et al. (2004).[14] A review of the literature[15-18] suggests a standard deviation of s=30 parts per million (ppm) for the change in eCO. Based on these assumptions, we will have 80% power to detect differences in eCO boost between two periods of 8.81ppm for a low r and 11.78ppmfor a moderate r. In one of the few studies in waterpipe cafés, the mean absolute change in CO was 51.7pmm with a relative boost of 795%.[15] we are more than sufficiently powered to detect differences this large as well as much smaller changes in the range of 8.81ppm to 11.78ppm. We can convert this to number of fewer puffs based on data that a single puff results in a 0.4ppm eCO boost.[19] We will be able to detect a reduction of between 22.0 and 29.4 puffs.[20] This is consistent with the reduction in mean puffs (26.0) found in the lab-based pilot study of WTS warnings.[21]

A hierarchical linear modeling (HLM) approach (model C1 in Turner et al. 2007) will be used for the analysis.[138] In contrast to cluster-level methods, which aggregate data, hierarchical modeling offers more flexibility and allows us to incorporate both café-level and individual-level covariates, as well as the correlation

of individuals within study arm within cafés. We let eCO_{ijk} represent the outcome measurement for individual k within study arm j within cluster (café) I, assumed continuous and normally distributed. The model will include a fixed effect for study arm (intervention or control) and random cluster and cluster-arm effects. Models will adjust for individual-level sociodemographics and tobacco use at baseline. In secondary analyses, we will examine the impact of sociability of waterpipe behavior by adjusting models for the number of people with whom the individual is smoking in the café. Secondary analyses will examine the impact of text versus pictorial warnings. These hierarchical models will be fit using PROC MIXED in SAS. Because the intervention effect is estimated within clusters, it is also adequate to model fixed cluster effects but retain random cluster-arm effects. Turner (2007) demonstrated through simulation that these two models perform similarly with 18 clusters with slight differences depending on the degree of correlation. We will examine both approaches as a sensitivity analys.[22] Using the same HLM modeling approach, we will perform analyses on secondary outcomes shown in Table 5.

Human Subjects Protection

Overview

The study will recruit participants at partnering hookah cafés. Potential participants will be screened for age, intention to smoke hookah, intention to smoke other tobacco products, previous entry into the café before or during the data collection period, current employment with the café, previous encounters with the study team, and capacity to participate. The risks to participants are minimal; the principal risk to participants is the risk of breach of confidentiality. All study data will be entered into databases created on the PHS Surveys website, which is behind the Wake Forest firewall; no data will be stored locally on the tablets. The only personally identifiable information collected is the participant's email, which is to be used for compensation purposes only, which will be linked to their participant ID, but will not be saved or stored with study data. This identifier record will be destroyed upon completion of study activities. Since there is a risk that the tablets may be stolen during data collection, steps will be taken to minimize any potential access to study data. These steps include separating survey data from other data collected during the study, so that the surveys can be opened on a webpage that is not linked to the larger database; enabling remote log-out features on all tables; not storing any data locally on tablets, and not collecting identifiers with study data. There is a possibility that internet access may be lost during data collection. In this instance, the study team will utilize paper forms of all data collection materials. These materials will be locked in a box closely monitored by the study team and will be removed and stored securely after the data collection period has completed. The principal investigator will be responsible for overseeing data and safety risks, although the onsite team will be responsible for day-to-day risk assessment and monitoring. The study team will also submit periodic reports to the Wake Forest Data and Safety Monitoring Board (I-DSMB), per the grant application.

Potential Risks

The risks of this study are not expected to be more than in daily life or from routine physical or psychological examinations or tests. There is a slight risk of breach of confidentiality. The personally identifiable information we are collecting is email for the purposes of compensation. It will not be stored with study data or accessible by the Wake Forest team and will be removed after completion of study activities. No identifying information will be linked to study data.

Expected Benefits

There is no expected benefit to participants for participating in this study, but we hope that the information learned will help others in the future. Participants in the intervention arm may increase their knowledge of health harms of waterpipe smoking.

Subject Recruitment Methods

Café owners/managers will be asked to post study-provided advertisement cards for current patrons inviting them to return to the café on the date of data collection if they are interested in participating in a research study. Additionally, on the day/night of data collection, the study team will have a sign advertising the study and will have a brief FAQ sheet to give to participants to help them decide whether or not to agree to eligibility screening.

A trained member of the study staff will approach customers entering the café where data is being collected to introduce the study, briefly. If customers are interested in being screened for participation, the study staff will ask them eligibility questions and record their responses. No identifying information from the patron will be obtained at screening. Once eligibility and consent have been confirmed, the participant will be enrolled into the study and assigned a participant ID.

Consent
A waiver of the signature requirement for informed consent is requested for this study. Study staff will make a determination of capacity to participate during eligibility screening, based on their impression of the participant's ability to comprehend the questions, answer the questions, and general behavior. Anyone who the study staff do not feel have capacity to participate will be marked Not Eligible. For those who are Eligible, we will utilize a verbal consent process where study staff will explain all required elements of consent to the participant. A printed consent document will be available for participants if they ask to see it. The participant will be given time to ask any questions they might have and will verbally confirm their agreement to participate, if desired. The study staff will mark the appropriate response (Yes, No) on the Verbal Consent Form in the database.

Confidentiality and Privacy
Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and by maintaining all study information in a secure manner. Identifying information (email, described below) will not be stored with study data. In order to track participants from the baseline visit to the follow-up visit, we will provide them with a bracelet containing a unique identification number (participant ID), which will be linked to their study data. Participants will complete surveys on a tablet (or paper if internet access is unavailable) at a table set up for data collection. Access to study data will be limited to study staff and will be password-protected. No reference to any individual participant with identifiable information will appear in reports, presentations, or publications that may arise from the study.

All study data will be collected on tablets opened to the PHS Surveys website databases created for this study. The tablets will be password-locked, as will the PHS Survey site. Study staff will log in to the secure PHS site to enter data (other than the surveys which are self-administered). Participants will not have the ability to enter into the PHS study databases, even when they are using tablets to complete the self-administered surveys. Participant surveys will be accessed through an external survey link, where access is protected by requiring the entry of the participant's ID number and the interviewer's ID number. No participant data will be stored locally on the tablet, including in cached website data entry systems (i.e. if a previous participant has entered their data into a form, the form will not show previous entries to another user). No identifiable information is collected.

In the (unlikely) case of internet access failure during the data collection period, paper forms will be used to collect data. Paper forms will be labeled with the participant's study ID only, not any identifiable information. Once forms are completed and collected from the participant, they will be locked in a box monitored by a member of the study team. At the end of the data collection period, the study data will be returned to the E&W office in Atlanta and stored securely. Study coordinators will double-enter participant data as soon as possible and will securely destroy paper forms once data is entered and verified.

E&W will be responsible for paying participant incentives. Participants will provide their email address, linked to their participant ID, in a Qualtrics form to be maintained by E&W. This form will trigger a link to be sent to participants to select their compensation from a list of e-gift cards. This process is standard protocol for survey research companies. The email will not be saved locally on the tablet or be connected to study data in any way. Storage of the email with participant ID is to facilitate addressing any participant concerns regarding study compensation, which will be managed by E&W staff. This identifier will be destroyed upon completion of study activities.

Data and Safety Monitoring

The Principal Investigator, Dr. Sutfin, will be responsible for the overall monitoring of the data and safety of study participants (and staff). Since the study will be conducted in Atlanta, GA, E&W staff will be responsible for onsite safety. Staff will be instructed to be mindful of their surroundings and to cease activities and leave immediately if they feel unsafe. Any issues with data, participant, or staff safety will be reported immediately to Dr. Sutfin. The Wake Forest I-DSMB will also review the study, and any data or safety concerns will be reported to this board and to the IRB by the PI, when applicable, in addition to periodic monitoring reports

Reporting of Unanticipated Problems, Adverse Events, or Deviations
As with any concerns of data and safety, any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes that occur onsite will be reported by a member of E&W staff to the Principal Investigator, who will report to the IRB and appropriate government agency, as applicable. There are no anticipated adverse events for this study.

Adverse Event Definitions

Adverse Event (AE)
An adverse event (AE) is defined as any unexpected, unfavorable or unintended condition that occurs immediately during sample or data collection.

Serious Adverse Event (SAE)
A serious adverse event (SAE) is any untoward medical occurrence that occurs during sample or data collection that satisfies any of these criteria: results in death; is life-threatening; requires inpatient hospitalization or prolongs existing hospitalization; results in persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions; or if the event results in a congenital anomaly or birth defect.

Recording Adverse Events.
When an AE occurs, it is the responsibility of the Investigator to review all documentation (e.g., medical progress notes, laboratory, and diagnostics reports) relative to the event. The study staff will then record all relevant information regarding an AE on the AE Form.

'Expectedness': AEs can be 'Unexpected' or 'Expected' for expedited reporting purposes only.

Attribution of the AE:

Definite–The AE is clearly related to the study participation.
Probable–The AE is likely related to the study participation.
Possible–The AE may be related to the study participation.
Unlikely–The AE is doubtfully related to the study participation.
Unrelated–The AE is clearly NOT related to the study participation.

STRC SAE Reporting Requirements.
The Safety and Toxicity Reporting Committee (STRC) is responsible for reviewing SAEs for WFBCCC Institutional studies. STRC currently requires that all unexpected 4 and all grade 5 SAEs on these trials be reported to them for review. All WFBCCC Clinical Protocol and Data Management (CPDM) staff members assisting a Principal Investigator in investigating, documenting and reporting an SAE qualifying for STRC reporting are responsible for informing a clinical member of the STRC as well as the entire committee via the email notification procedure of the occurrence of an SAE

WFUHS IRB AE Reporting Requirements.
Any unanticipated problems involving risks to subjects or others and adverse events shall be promptly reported to the IRB, according to institutional policy. Reporting to the IRB is required regardless of the funding source, study sponsor, or whether the event involves an investigational or marketed drug, biologic or device. Reportable events are not limited to physical injury, but include psychological, economic and social harm. Reportable events may arise as a result of drugs, biological agents, devices, procedures or other interventions, or as a result of questionnaires, surveys, observations or *other* interactions with research subjects.

All members of the research team are responsible for the appropriate reporting to the IRB and other applicable parties of unanticipated problems involving risk to subjects or others. The Principal Investigator, however, is ultimately responsible for ensuring the prompt reporting of unanticipated problems involving risk to subjects or others to the IRB. The Principal Investigator is also responsible for ensuring that all reported unanticipated risks to subjects and others which they receive are reviewed to determine whether the report represents a change in the risks and/or benefits to study participants, and whether any changes in the informed consent, protocol or other study-related documents are required.

Any unanticipated problems involving risks to subjects or others occurring at a site where the study has been approved by the WFUHS IRB (internal events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.
Any unanticipated problems involving risks to subjects or others occurring at another site conducting the same study that has been approved by the WFUHS IRB (external events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.
Any event, incident, experience, or outcome that alters the risk versus potential benefit of the research and as a result warrants a substantive change in the research protocol or informed consent process/document in order to ensure the safety, rights or welfare of research subjects.

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Appendix

1. Eligibility Form
2. Consent Form Handout
3. Verbal Consent Form
4. Time 1 Survey
5. Time 2 Survey
6. eCO Form
7. Debrief Form
8. Study Debrief Handout
9. Adverse Event Form – Café
10. Adverse Event Form – Participant
11. Protocol Deviation Form – Café
12. Protocol Deviation Form – Participant
13. Café ad
14. Café sign
15. Participant FAQs
16. Hookah Café Interviewer Scripts