Official Title: Optimizing risk messages for waterpipe tobacco cessation in young adults

NCT Number: NCT03595280

Statistical Analysis Plan

Initial Approval: November 28, 2017

MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board

Date:	12/1/2017
To:	Darren Mays
From:	Cindi Charles Institutional Review Board
IRB #:	2017-1378
Title:	Optimizing Risk Messages for Promoting Waterpipe Tobacco Cessation in Young Adults
Approval Date:	11/28/2017
Expiration Date:	11/27/2018
Action:	Initial Review - Expedited

Attachments being reviewed:

Document	Version
Mays Hookah R01 CRC Exemption.doc	0.01
ICF for Vanguard Pilot.doc	0.04
ResearchMatch Contact Message.docx	0.01
CDC - Fact Sheet - Hookahs - Smoking & Tobacco Use.pdf	0.01
Recruitment Flyer.pdf	0.01
Scientific Review Correspondence.pdf	0.01
References.docx	0.01
Sample Image Directory.docx	0.01
Follow-Up Surveys 10102017.doc	0.01
Mays CV.pdf	0.01
ICF for Randomized Trial.doc	0.04
Baseline Survey 10102017.doc	0.01
Facebook Ad.docx	0.01
Mays Hookah R01 CRC Exemption.doc	0.01
Craigslist Advertisemen Message.docx	0.01
Hookah Messaging Matrix	0.01
Vanguard Pilot Interview Outline.docx	0.01
Waterpipe R01 Final.docx	0.01

Stamped Documents:

Document	Version
ICF for Vanguard Pilot.doc.pdf	0.01
ICF for Randomized Trial.doc.pdf	0.01
2017-1378_Recruitment Flyer.pdf_IRB Stamped.pdf	0.01
2017-1378_Craigslist Advertisement Message.docx_IRB Stamped.pdf	0.01
2017-1378_Facebook Ad.docx_IRB Stamped.pdf	0.01
2017-1378_ResearchMatch Contact Message.docx_IRB Stamped.pdf	0.01

The above-referenced study and supporting documents were approved through expedited review by the IRB Chair or a designee on 11/28/2017. The IRB has determined that the research involves no greater than minimal risk and falls under the following expedited review category:

7. Research on:
(a) individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), **OR**
(b) research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

This is to inform you that you may commence your project. Please note that this approval is granted through 11/27/2018.

This study will automatically become inactive when its approval expires on 11/27/2018 *unless* a continuing review submission is approved by the IRB before that date. The IRB requires that you submit an application for continuing review at the end of each approval period and/or at study completion. ***It is the PI's responsibility to submit the application for continuing review and the appropriate IRB forms with adequate time for review and approval prior to the expiration date.***

Any investigator whose project is externally funded must submit the applicable sponsor grant or contract for review and approval by the appropriate sponsored research office of the recipient institution (GU or MHRI). The project cannot proceed without the approval of the sponsored research office.

The International Committee of Medical Journal Editors (ICMJE) has established a requirement for registration of clinical trials in a public registry prior to enrollment as a condition of consideration for publication. Georgetown University has established a central registration process through the National Library of Medicine's Clinical Trials Protocol Registration System (PRS) known as ClinicalTrials.gov. Please contact the GU PRS administrator, Patricia Mazar, by e-mail at mazarp@georgetown.edu to set up a PRS user account to register clinical trials. The e-mail should contain the principal investigator's full name, department, phone number, and e-mail address.
Additional information may be found at http://ora.georgetown.edu, http://clinicaltrials.gov/, and at http://www.icmje.org/clin_trialup.htm.

For all Department of Defense (DoD) sponsored research, please note that you must obtain approval from the DoD human subjects committee as well as the local IRB before commencing this project.

** If promotional advertisements will be used for patient recruitment, they must be submitted for IRB review and approval prior to their use.

** Any incentives for participation in research are subject to IRB review and approval as well.

Please remember to:

1. Seek and obtain prior approval for any modifications to the approved protocol.

2. Promptly report any unexpected or otherwise significant adverse effects encountered in the course of this study to the IRB within seven (7) calendar days. This includes information obtained from sources outside GU or MHRI that reveals previously unknown risks from the procedures, drugs, or devices used in this study.

Georgetown University IRB
Medical-Dental Building, SW104
3900 Reservoir Road NW
Washington, DC 20057
(202)687-1506 *telephone*
(202)687-4847 *facsimile*

2017-1378_ResearchMatch Contact Message.docx_IRB Stamped.pdf

We used descriptive statistics to characterize the sample overall and by trial arm. For primary outcome measures of risk appraisals and motivation to quit, we tested mean differences by trial arm at each time point using general linear models. Levene's test confirmed homogeneity of variance assumptions for each model (i.e., all p's >0.05). We interpreted the F statistic for trial arm and pair-wise differences in least squares means using Tukey's adjustment for multiple comparisons.

For frequency of use, we summarized data by arm descriptively (mean, standard deviation) and we used the Wilcoxon Rank Sums test for differences by trial arm. We interpreted the Kruskal-Wallis χ^2 statistic for trial arm and the Wilcoxon Z test for pair-wise comparisons between arms.

We used logistic regression to test if cessation differed by arm at each time point. We interpreted the χ^2 statistic for trial arm and the odds ratios (ORs) and 95% confidence intervals for differences in cessation between arms.