Research Subject
Full Study Informed Consent Form

Title of Study: Using Multiphase Optimization Strategy (MOST) to Optimize a Cost-effective, Sustainable and Scalable Smoking Cessation Package for Smokers in HIV Clinical Care, "MOST Quits"

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Study Medical Doctor: Dr. Donna Shelley
917-494-4210

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study. If you decide to participate, you can change your mind at any time.

People who agree to take part in research studies are called "subjects" or "research subjects". These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

This is a research study of people living with HIV who also smoke cigarettes. The purpose of this study is to compare different ways of helping smokers living with HIV to quit smoking. You are being asked to take part in this study because we still have a lot to learn about how we can best help people living with HIV quit smoking.

The study examines different supports to quit smoking and research subjects are randomly assigned to receive one or more supports, or no additional support besides what is routinely offered at the clinic where they receive routine care. Some activities in this study are text messaging, peer mentoring, phone counseling, and combination NRT (Nicotine Replacement Therapy). You may participate in one, several or none of these activities. Below we describe more about these study activities.

3. How long will I be in the study? How many other people will be in the study?

Your part of the study will last about 6-9 months. Approximately 500 other people will participate in this study.

4. What will I be asked to do in the study?

This study has a number of parts. If you agree to participate, you will be asked to: (1) participate in smoking cessation activities designed to help you stop smoking; (2) attend study visits to complete surveys and for monitoring; (3) and a smaller group of study subjects will be asked to participate in interviews. Below are details on all of these activities.

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A. Smoking Cessation Activities

All participants will be asked to participate in an initial health education session with staff to discuss the importance of smoking cessation. At this session, we will discuss the benefits of smoking cessation and provide you with quitting-related resources.

After that initial session, you will be randomly assigned to join up to four different smoking cessation activities. Being "randomly assigned" means that you and every person in the study have an equal chance of being placed in some, all or none of these 4 activities. There are 16 different possible combinations of activities. Your assignment to these activities will be done randomly (like the flip of a coin). Some participants will be randomly assigned to receive none of the activities; but most will be randomly assigned to participate in 2 or 3 of the activities. All the activities are scheduled at times that are convenient for you. The activities are stretched out over time.

The activities are:

1) 6 **telephone counseling sessions** (lasting about 30-40 minutes each) with a study counselor to discuss smoking and other related issues. These sessions will be spread out over about 10-11 weeks and some sessions may be recorded. You can choose not to be recorded and still participate in the sessions.

2) 8 one-on-one sessions with a supportive and knowledgeable **peer mentor** in-person or by phone over a six-month period. Peers will be persons living with HIV who have successfully quit smoking and some of these sessions may also be recorded. You can choose not to be recorded and still participate in the sessions.

3) **Quitting-related text messages** with tips and information for quitting smoking that you sign up for and can automatically receive on your cell phone over an 8-week period; we will also capture some information on how long you are receiving text messages, responses to some of the text messaging questions you will receive and keywords you use to get more information on quitting, which will be provided by the National Cancer Institute's smokefreetxt program.

4) **Combination NRT (Nicotine Replacement Therapy)** will include a 6-week treatment of combination NRT, which includes a nicotine patch and nicotine lozenges. These medications are available over the counter but we will provide them to you directly for free as part of this study and instruct you on how best to use them. If you are randomized to receive this medication, the NYU study team will follow up with you to see if you have taken the medication and if you have any concerns or side effects, and to provide tips for reducing side effects if you have any. You can also call the study PI, Dr. Cantrell, the study medical doctor, Dr. Shelley, or the study project manager with any questions or concerns regarding the medication.

Depending on which activities you get selected for, these activities could last 2 to 6 months, or you may be assigned to receive no activities. If you are assigned to receive no activities, this means you will be in a 'control group' and you will only be asked to attend study visits to complete the surveys and complete a carbon monoxide breath test and a cotinine test (discussed further below).

B. Study Visits - Surveys & Monitoring

At the beginning of the study, we will ask you to complete a survey about your health, history and current use of cigarettes and other tobacco products, social support, mental health, and other questions. Some of the questions will be asked by a study staff member, while other questions you will answer by yourself into a computer. Surveys generally take approximately one hour to complete.

We will ask you to return 3 more times for study visits related to surveys. The second visit will be 6-10 weeks after this first visit, then you will come 3 to 4 months after this first visit, and the last visit will be 6 to 9 months after this first visit. At these visits, you will complete more surveys asking similar questions so we can see how things are going with you while you're in the study. In later surveys, we may also ask about some of your experiences and thoughts regarding your participation in this study (i.e., what you liked, what you didn't like). There are no right answers to any of the survey questions.

At each of the four visits we may conduct a carbon monoxide (CO) test and cotinine test. The CO test involves

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breathing into a monitor that measures how much CO is in your lungs. The cotinine test involves spitting into a collection tube to gather a saliva sample. This sample is then analyzed for cotinine, a substance produced when the body breaks down nicotine. Both tests are used to see if you have smoked cigarettes recently.

We will also ask for some of your contact information to follow up with you when it is time for you to do your follow-up surveys. For each of the four visits, you will be asked to come to the New York University School of Global Public Health located at 708 Broadway, New York, NY, 10003.

C. In-depth Interview Sub-Group

At the end of the study, a sample of 30 participants will be asked whether they are willing to share their experiences and opinions about the study. If you are selected, a member of Dr. Cantrell's research team will contact you and ask if you would like to participate in this part of the research. If you agree, a telephone or online (i.e., Zoom) interview will be arranged with you at a day and time that works best with your schedule. These interviews will be audio-recorded and are designed to learn more about your experiences in the study – what worked well for you, what didn't work well for you, etc. For audio-recorded interviews, we will ask subjects not to verbalize their name or any other identifying information to minimize the chance of a breach of confidentiality.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

D. Recruit people you know for the study

We will give you "recruitment coupons" to give up to other people and help you get ready to recruit other people living with HIV who smoke for the MOST Quits study. We won't tell the people you recruit anything about your participation in the study, and we won't tell you anything about their participation in the study (other than which coupons were used). You will be compensated $15 for each person you send to us to do an initial screen for the study, and you may receive additional coupons to recruit more people.

5. What are the possible risks or discomforts?

Study Activities: Participating in peer mentoring and/or counseling as well as answering some of the questions in the survey may make you feel uncomfortable and it is possible that you may experience distress when discussing smoking and quitting with your counselor, if randomized to peer mentoring and/or counseling. All answers you give will be kept private. You do not have to answer any questions at any time for any reason. The study may involve other risks that are unknown at this time.

Carbon Monoxide and Cotinine tests: There are no risks associated with the carbon monoxide and cotinine tests.

Combination Nicotine Replacement Therapy (NRT):
Combination NRT is very well-tolerated and very safe. It is even over-the-counter and does not have to be prescribed. However we will provide this medication free to you directly as part of this study if you are randomized to the medication intervention. There is the potential for some side effects from the medication. The more common side effects for the patch include a rash at the site of application and vivid dreams, and for the lozenge, upset stomach, increased saliva, mouth sores and hiccups. Extremely rare side effects include an allergic reaction to the patch, such as rash, hives, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips or tongue, or pounding in the chest. Additional rare side effects include nausea, vomiting, dizziness, weakness, and irregular heartbeat or palpitations. Please note that these side effects are rare and we will assess them through the medication treatment period. Most side effects can be addressed with additional explanation to you regarding proper use of the medication. We will provide information on how to limit medication side effects. We will assess side effects by phone assessments approximately 1 week after the medication is provided using a standard protocol and 2 more times during the treatment.

Quitting-related Text messages: If you are in one of the groups receiving text messages, you should know that the texts you receive are not secure and could be intercepted. However the texts sent contain no personal

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information, there are only messages about smoking cessation. At any time during the study if you would like to stop getting the quitting-related text messages, please reach out to the study coordinator or study Principal Investigator so that we can assist you with stopping the quitting text messages.

Confidentiality: There is also the risk that the information you give us could be seen by other people (loss of confidentiality). However, this is unlikely as we take keeping your information private very seriously. We will create a code number for you that will help us keep track of your participation in the different parts of the study.

6. Who can be in the study? Can I be in the study if I am pregnant or breastfeeding?

The main criteria for being included in the study are being age 18 or older, living with HIV and smoking cigarettes and being in HIV clinical care. We also have some other criteria such as living in the NYC metropolitan area. Pregnant or breastfeeding women are not eligible for this study. If you become pregnant during the study, you must tell the Principal Investigator, Dr. Cantrell, as soon as possible. If you become pregnant or start breastfeeding, you will need to stop taking part in the study. The reason is that smoking cessation medication is used in the study. Some exclusion criteria include not suffering from any medical condition that may preclude use of nicotine replacement therapy (NRT), such as having a heart attack in the last 2 weeks, having a serious heart condition in the past year, such as serious cardiac arrhythmia, stroke or cardiac arrest, or being diagnosed in the past year with unstable angina, which means serious pain and discomfort in your chest. Other exclusion criteria include having a psychiatric hospitalization or psychiatric emergency room visit in the past 6 months, having been diagnosed with schizophrenia or schizo-affective disorder. We also have some other exclusion criteria.

7. What are the possible benefits of the study?

You may benefit from the smoking cessation activities or medications you receive in this study but it is not known if the treatment you will receive will be of benefit to you. Although there may be no direct benefit to you from agreeing to take part in this study, what we learn may benefit others in the future. This study may help develop better services to help people living with HIV quit smoking.

8. What other choices do I have if I do not participate?

You do not have to take part in this study if you do not want to. You can discuss ways to quit smoking with your HIV health care provider or other health care providers without taking part in this study. You can also go somewhere else for help in quitting smoking. You can call the New York State Quitline at (1-888-NYQUITS) to speak with cessation counselors or to receive cessation materials and to be referred to local places that have a smoking cessation program if you do not participate.

9. Will I be paid for being in this study?

For taking part in the study, you will receive $65 after you complete the first survey, $70 for the second survey, $75 for the third survey and $80 for your fourth survey. The total we will reimburse you if you attend all 4 visits is $290. We will also reimburse you for your travel to and from the office at NYU School of Global Public Health during each followup assessment visit (1st visit, 6-10 weeks, 3-4 months, and 6-9 months) with reimbursement of an additional $6.00 to cover round-trip subway or bus fare.

If you are assigned to the quitting-related text messaging intervention, you will not be charged for text messages if you have a phone plan with unlimited text messages. However if you do not have an unlimited text message plan, you may be billed for text messages by your cell phone carrier. If you do not have an unlimited text message plan, we will reimburse you up to $30 for the quitting-related text messaging. In very limited cases if participants are not able to receive the text messages due to service or technical issues, we will provide a temporary cellphone and service plan for 3 months during the study to receive the smokefreeTXT text messaging program. The phone and service plan will be through Tracphone and will involve a basic smartphone compatible with text messaging, minimal internet access and 90 days of service for talk, text and limited data. This phone will only be provided in limited cases if the text messaging service cannot be received on your regular phone due to technical barriers, as assessed by a study team member. The purpose of the phone is to receive the text messaging intervention and not for personal use.

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If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for the study visits you have completed.

If you complete all 4 of the study visits, you will receive $290 for being in this study. This does not include the telephone interview at the end of the study (for $40) as not all participants will be involved in that interview.

You will be asked to complete a W-9 form, which includes your social security number, full name, and mailing address, so that NYU can track the total amount of money that you receive from it across all sources (not just this research study). If you receive more than $600 in one calendar year from NYU, then it will notify the IRS and issue you a form for your taxes (Form 1099), in which case you may have to pay taxes on it.

10. When is the study over? Can I leave the study before it ends?

This study is completely VOLUNTARY. You are not giving up any legal claims or rights for being a part of this study. If you agree to participate, you are free to quit at any time. You may refuse to answer any question.

We may decide to withdraw or pull you out of the study for certain reasons, for example, if the Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision. Some other reasons may be that you have already participated in this study or the study has been stopped. If we learn that you have been incarcerated after you have agreed to take part in this study and as a result you will not be able to take part in study activities, we may need to stop your participation in the study.

11. How will you protect my confidentiality?

Confidentiality of your research records will be strictly maintained by the study PI, Dr. Cantrell and the study research team. Information not containing identifiers may be used in future research, shared with other researchers, or placed in a data repository without your additional consent. The study team and NYU School of Global Public Health is committed to protecting the privacy and confidentiality of your personal information.

A. Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the NIH, which adds extra protection for your identifying information. Researchers cannot disclose this information without your consent, even in legal proceeding, unless required by law (e.g., reporting child or elder abuse).

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse).

B. What information may be used or shared with others in connection with this study?

The following information may be used or shared in connection with this study among research study staff: Information in your research record. For example, Dr. Cantrell and her study team will ask you to participate in several activities that are part of your research record. These may include: completing a locator form, participating in interviews, participation in NYU study activities and sessions, your carbon monoxide and cotinine measures. This may also include any information solely for your medical care, if needed, during this study.

C. Why is information being used?

Your information will be used by the research team and others involved in the study to conduct and oversee the

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study.

D. Who may use and share information in connection with this study?

The following individuals may use, share, or receive your information for this research study:

- The NYU research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Cancer Institute (NCI)
- Governmental agencies responsible for research oversight
- Any health care providers who may provide services to you in connection with this study, if needed.

E. What if I do not want to give permission to use and share my information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

F. Can I change my mind and withdraw permission to use or share my information?

Yes, you may withdraw or take back your permission to use and share your information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the Principal Investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

G. Can I have access to my information in relation to this study?

Yes you may have access to your information upon request by sending a written notice to the PI at the top of page 1 of this form.

H. How long may my information be used or shared?

Your permission to use or share your personal research and health information solely in relation to this study will not expire unless you withdraw it.

12. Optional Permission to Contact about Future Research

The principal investigator, Dr. Jennifer Cantrell and her Co-Investigators would like to contact you about future research on smoking cessation within the New York University School of Global Public Health provided that this future research is approved by the IRB of record and that the Principal Investigator and Co-Investigator(s) are affiliated with the research protocol.

If you agree, then someone from Dr. Cantrell's research staff might contact you in the future and he or she will tell you about a research study. At that time, you can decide whether or not you are interested in participating in that particular study. You will then have the opportunity to contact the researcher and be fully informed about the research project if you are interested.

The study PI, Dr. Cantrell and the NYU School of Global Public Health will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

Do you provide permission to store, use, and share your health information from this study in research databases or registries for future research conducted by the PI, Dr. Cantrell and her research partners?
You do not need to provide permission for this to participate in this study.

_____YES
_____ NO

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Please provide your initials here confirming your response to whether you will provide this optional permission.

_____

Initials of participant

13. Communicating with the Research Team

Researchers may need to communicate with you about information relevant to the research study. The research team will usually contact you for these purposes by phone, but if you have given the Researchers your and mobile/cell phone number and permission to send a text message, the research team may contact you that way.

Below are some important points about texting in this research study. This only applies to texts from the research team with followups and reminders regarding your study visits. These texts are separate from the Quitting-related Text Messages described earlier that you may be assigned to receive as part of your smoking cessation activities in this study.

- Text messages are not encrypted (protected), and therefore are unsecure and may result in a breach of your confidentiality.
- You will be responsible for fees charged by your carrier's service plan for text messaging.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. If you no longer wish to receive appointment reminders for MOST Quit, reply STOP.
- You may change your mind later if you decide to revoke your permission to receive text messages.

Please make sure to keep the research team updated if your mobile/cell phone number changes during the study.

Do you agree to receive texts from this research group regarding your study appointments?
(Please note that these texts are separate from the quitting-related text messages that you may receive as part of participating in this study.)

__ Yes
__ No

If yes,
What is your cell phone number? _____

Please provide your initials here confirming your response to whether you will receive texts for study appointments or not.

_____

Initials of participant

14. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If there is anything about the study or your participation that is unclear or that you do not understand, if you have questions or wish to report a research-related problem, you may contact the study PI, Dr. Jennifer Cantrell at 917-568-1359 or 212 998 5797; Jennifer.cantrell@nyu.edu.

For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects (UCAIHS), New York University, 665 Broadway, Suite 804, New York, New York, 10012, at ask.humansubjects@nyu.edu or (212) 998-4808. Please reference the study #IRB-FY2024-9065 when contacting the IRB (UCAIHS).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This

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website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to participate.

Do you agree to take part in this study?
___ I agree to take part in this study
___ I do not agree to take part in this study

Study Participant to sign below if consenting to participate in the study

Study Participant Name, Signature

First Name of Study Participant

Last Name of Study Participant

Full Signature of Study Participant

Date of signature

Has the study participant signed and dated above?
___Yes
___ No

Staff Person signature required below if participant signs and consents above.

First Name of Staff Person Obtaining Consent

Last Name of Staff Person Obtaining Consent

Full Signature of Staff Person Obtaining Consent

Date

Has the staff person signed above?
___Yes
___No

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