Title: Using Open Contest and Neuro-influence Experiment to Develop and Evaluate PrEP Promotion Messages for High Risk Men

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Using Open Contest and Neuro-Influence Experiment to Develop and Evaluate PrEP Promotion Messages for High Risk Men.

Principal Investigator: Cui Yang, PhD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to explore how people's brains react to messages that promote pre-exposure prophylaxis (PrEP), a medication that can effectively prevent HIV infection if taken as prescribed.

If you join the study, you will be asked to first complete a survey, which will take up to 15 minutes. Then you will be invited for a study visit, roughly a week after you complete the first survey. During the study visit, a machine will monitor your brain activity as you read messages on a computer screen. This machine is called functional near infrared spectroscopy (fNIRS). fNIRS is not FDA approved for clinical or diagnostic use, and only for research. It creates images of brain activity using LED lights, the same kind of lights used in high efficiency lamps or LED lamps. You will be asked to complete a few questions after you complete all the messages. Your study visit will take about 60 minutes. We will contact you again about 30 days after your study visit with a couple more questions, which will take up to 10 minutes. Depending on your preference, we can either call you or ask you to complete those questions online.

Possible harms or burdens of taking part in the study may be that some of questions may make you feel embarassed or uneasy. If there are questions that you do not want to answer, you do not have to answer them. Also, you can stop participating at any time and leave the study. There is also a potential risk of loss of confidentiality.

There are no known risks associated with the use of this technology, but you may feel uncomfortable wearing the headband connected to fNIRS. You may also experience fatigue from looking at a computer screen while wearing the headband.

Possible benefits of taking part may be that people who read PrEP promotion messages find them to be helpful and may start considering PrEP as one of the options for HIV prevention. This study will help us understand which messages might be most effective to promote PrEP.

An alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you

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completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Cui Yang, PhD is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Cui Yang, PhD may be reached at cui.yang@rutgers.edu.

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: National Institute of Mental Health.

Why is this study being done?
PrEP is a medication that can effectively prevent HIV infection if taken as prescribed. There has been increased effort to identify persuasive messages for increasing awareness, acceptability, and uptake of PrEP as a HIV primary prevention tool, especially among people at a greater risk of HIV, such as men who have sex with men (MSM). Neuroscience research has demonstrated that how people's brains react to messages can tell how persuasive these messages are. We conduct this study to find out whether neuroscience technique can help us better which PrEP promotion messages are more effective in promoting PrEP use among MSM at risk of HIV in the United States.

Who may take part in this study and who may not?
Key inclusion criteria in this study are 1) 18 years and older; 2) biological male sex at birth; 3) sexually active with men in the past 6 months; 4) never taken PrEP; 5) HIV negative; 6) reside in Baltimore City or surrounding counties; and 7) meet one of the criteria for being an appropriate PrEP candidate: a) in a relationship with a partner not known to be HIV-negative, b) were in a nonmonogamous relationship, c) had any condomless anal sex with a casual male partner regardless of status in the prior 6 months, or d) had a positive STI diagnosis within the prior 6 months. Individuals who don't meet the inclusion criteria may not take part in this study.

Why have I been asked to take part in this study?
You are being invited to participate in this study because you may be eligible for this study.

How long will the study take and how many subjects will take part?
The whole study will take about 2 months to complete. We aim to recruit 60 participants.

What will I be asked to do if I take part in this study?
You will be asked to complete the following study activities:

- In your **first survey**:
  - You will answer a series of questions, which takes about 15 minutes.
  - Then you will be scheduled for a study visit, roughly a week after you complete the first survey. We will ask you to provide your phone number in order for us to contact you for the following visit.
- During the **study visit**:
  - A research assistant will take you to a private interview room. The research assistant will measure your head size for a headband. This headband is connected to a machine, and this machine will monitor your brain activity as you read messages on a computer screen. We will use a machine called functional near infrared spectroscopy (fNIRS). It creates

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images of brain activity using LED lights, the same kind of lights used in high efficiency lamps or LED lamps.
    - Participants will see two different groups of messages related to PrEP.
    - After completing all messages, you will answer more questions on the computer.
    - Your study visit will take about 60 minutes.
- For your **follow up survey**:
    - We will contact you again about 30 days after your study visit with a few more questions, which will take up to 10 minutes.
    - Depending on your preference, we can either call you or ask you to complete those questions online.

What are the risks of harm or discomforts I might experience if I take part in this study?

You may find some of questions in the surveys embarassed or uneasy. If there are questions that you do not want to answer, you do not have to answer them. Also, you can stop participating at any time and leave the study. There is also a small potential risk of loss of confidentiality.

There are no known risks associated with the use of fNIRS, which employs harmless light sources, fNIRS is safe for studies with infants and adults as well. However, you may feel uncomfortable wearing the headband connected to fNIRS. fNIRS is not FDA approved for clinical or diagnostic use, and only for research. You may also experience fatigue from looking at a computer screen while wearing the headband.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be that people who read PrEP promotion messages find them to be helpful and may start considering PrEP as one of the options for HIV prevention. This study will help us understand which messages might be most effective to promote PrEP. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take Part in this study?
Costs to your participation may include transportation to the study site to complete consent, the baseline survey and neuroimaging experiment. In return for your time and effort, you will be paid compensations.

Will I be paid to take part in this study?
You will receive $ 85.00 gift cards for taking part in this study according to the following schedule:

- $ 15.00 to complete the first survey
- $ 60.00 at your study visit
- $ 10.00 to complete the follow-up survey.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. The data will be kept on a secure server with limited access granted to study researchers and the Data Manager.

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The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Rutgers Human Subjects Protection Program
- The National Institutes of Health

A description of this study will be available on ClinicalTrials.gov, as required by U.S. law. This 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What will happen to my information—data, recordings and/or images—and biospecimens collected for this research after the study is over?

After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you.

Who can I contact if I have questions?

If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Cui Yang, PhD, Department of Health Behavior, Society and Policy, Rutgers School of Public Health.

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If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

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