Informed Consent

IGHID 12118 - Pay-it-forward Gonorrhea and Chlamydia Testing Among Men in China: The PIONEER Pragmatic Randomized Controlled Trial

NCT number NCT05723263

Document Date 02/23/2023

PIONEER RCT
RCT Phase Eligibility Screener

Pay-it-forward gonorrhea and chlamydia testing among men in China: The PIONEER pragmatic randomized controlled trial

About this Study:
You are being asked to take part in a research study that will help us better understand sexually transmitted disease (STD) testing among men in China. Your participation in this project will allow us to develop better interventions to promote integrated STD testing among men in China.

What's Involved?

If you participate in this study, you will be asked to complete a questionnaire and then offered STD testing. The questionnaire will ask you to provide sociodemographic information and information about your sexual behaviors. In order to ensure that your privacy is protected, all of your responses will be encrypted and securely transferred to our data servers. If you have any questions about the research or your participation in the study, feel free to contact us.
The following questions will determine if you are eligible to participate in the study.

A. Basic Information (Eligibility Survey)

A1. How would you describe your assigned sex at birth?

- Male
- Female (Not eligible to take this survey – Skip to End of Survey)
- Intersex (Not eligible to take this survey – Skip to End of Survey)
- Other (Not eligible to take this survey – Skip to End of Survey)

A2. Please enter your date of birth
mm.yyyy (*Calendar input*) (Not eligible to take this survey if the year is greater than Launch day + 2003 or < 18 y/o – Skip to End of Survey)

A3. Have you had gonorrhea testing in the past year?

- No
- Yes (Not eligible to take this survey – Skip to End of Survey)

A4. Have you resided in the city in the past three months?

- Yes
- No (Not eligible to take this survey – Skip to End of Survey)

A5. Can you speak Mandarin Chinese or Cantonese?

- Yes
- No (Not eligible to take this survey – Skip to End of Survey)

A6. Are you mentally capable to provide informed consent to test for gonorrhea?

- Yes
- No (Not eligible to take this survey – Skip to End of Survey)

A7. Do you own a mobile phone?

- Yes
- No (Not eligible to take this survey – Skip to End of Survey)

A8. Please provide us with your cell phone number. This will be kept confidential and will be used for results notification.

RCT Phase Electronic Consent Form
Title of Study: IGHID 12118 - Pay-it-forward gonorrhea and chlamydia testing among men in China: The PIONEER pragmatic randomized controlled trial

Consent Form version 2023-02-23

UNC IRB study number: 21-1667

Project leader: Joseph D. Tucker

Moderator Department: Infectious Diseases Global Health

Contact for project work: Qiwen Tang

Phone: +1-919-966-3113, +86-137-6330-4075

Email: qiwen.tang@seshglobal.org

Project funding source: NIH National Institute of Allergy and Infectious Diseases (NIAID)

Concise Summary

The purpose of this study is to find ways to improve gonorrhea and chlamydia testing among men in China. Your participation would last for approximately 30 minutes and would involve taking a brief survey and being tested for sexually transmitted infections. The greatest risks of this study include the possibility of embarrassment, emotional distress, and loss of confidentiality. Men who participate and receive testing will benefit from knowing their gonorrhea and chlamydia status. If you are interested in learning more about this study please continue to read below.

What are some general things you should know about research studies? You are being asked to participate in a research study. To join this research study is voluntary. You may for whatever reason refuse to join or withdraw your consent to be in the study at any time, without penalty. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about joining this research study.

What is the purpose of this study? New approaches are needed to improve gonorrhea and chlamydia testing among men. There are two main objectives:

1) To compare point-of-care gonorrhea test uptake in a standard pay-it-forward implementation strategy arm, a community-engaged pay-it-forward implementation strategy arm, and a control arm using a three-arm cluster randomized controlled trial.
2) To determine mechanisms by which pay-it-forward motivates testing and donations across the two intervention arms, and how these are moderated by individual and organizational characteristics.

How many people will take part in this study? If you decide to participate in this research study, you will be one of 1200 individuals recruited in Guangdong Province.

What will happen if you take part in the study? Your part in this research study will last approximately 30 minutes. During this study, you will be asked to first complete a questionnaire. Upon completion of this initial questionnaire, you will be asked to input your mobile phone number as a means for the research team to prevent duplicate responses and to send results notification. The study questionnaire will ask you to provide sociodemographic information as well as details about your sexual health and sexual activity.

You will be offered a test for gonorrhea and chlamydia; the samples will be taken from your throat, rectum and urethra.

You will then receive testing through the clinic. The study staff will contact you with the results, and refer you for treatment if the test positive is positive. This is not part of the study and will not be paid for. Samples are for clinical testing only and will not be used for research purposes. Please note the clinic staff are required to report positive test results to the local CDC.

You do not have to participate in the study in order to receive testing and care.

You may also be asked to participate in a sub-study related to this study. You will be asked to sign a separate consent form if you agree to participate in the sub-study.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. The proposed study will make important contributions to the sexual health literature. Many men do not receive appropriate gonorrhea and chlamydia testing. The results from this study will help the research team to better understand how best to increase STD testing among men in China.

What are the possible risks or discomforts involved from being in this study? We will ask participants to provide sensitive information about their sexual partners and practices. Participants may feel embarrassed, anxious, or otherwise distressed by providing information of such a personal nature. Some men who have high-risk sexual behaviors may fear that these behaviors would be disclosed to others. While the risk is minimal, there is still the possibility for breaches of confidentiality.

How will your privacy be protected? All data are directly entered into computers and will be transmitted securely using SSL (TLS) 128 bit encryption across the Internet (HTTP). Data will be located in a secured server at UNC Chapel Hill.

Access to the data will be password protected within the server's firewall. Survey responses will be kept separately from participants' email addresses; the two files will be linked with a non-descript, unique, randomly generally identifier. Only the PI and a designated senior staff member will have the password to access to the "key" that links the nondescript identifier to personally identifiable information. Cookies will not be used in any way to track participant activity.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

In addition to the efforts of the study staff to help keep your personal information private, we have a Certificate of Confidentiality. This certificate means that researchers cannot be forced to tell people who are not connected with this study about your participation. The Certificate of Confidentiality will not be used to prevent disclosure if required by law, such as mandatory reporting requirements for communicable diseases. It will also not be used if disclosure is for other scientific research, if allowed by US and China regulations protecting research participants or for any purpose you have consented to in this informed consent document.

What if you want to stop before your part in the study is complete? If at any point in the study you do not want to answer a question or no longer want to participate, you can stop and withdraw from this study without penalty. The investigators also have the right to stop your participation if they feel it is in your best interest. If you leave the study early, data already collected will be kept.

You will be given any new information that might affect your willingness to continue to participate.

Will you receive anything for being in this study? Will it cost anything? You will receive 50 yuan in return. It will not cost anything to be a part of this research study. The cost of testing will be dependent upon the group you are randomized into, but you will have to pay no more than you usually would for the testing. If you decide to get tested and your results are positive, the treatment is not paid for by the study.

What if you have questions about this study? If you have any questions, complaints, or concerns about the research or your participation in the study, feel free to contact the study staff listed at the beginning of this form.

Who is sponsoring this study?
This research is supported by UNC-Chapel Hill. In addition, Dr. Joseph Tucker, the principal investigator on this study, participates in unpaid activities which are not part of this study for SESH Global, a company involved with this study. These activities may include consulting, service on advisory boards, giving speeches, or writing reports.

If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about your rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns, or if you would like to obtain information or offer input, please contact the UNC Institutional Review Board at 1-919-966-3113 or by email to IRB_subjects@unc.edu. You may also contact the Guangdong Provincial Skin Diseases & STI

Control Center IRB at 020 − 83027652 or by email to sesh@seshglobal.org.

If you understand and agree to participate in this research study, please select “Agree” from the options below. We thank you for your participation!

- o Agree
- o Decline

Enter Name
Date