Study protocol: HIV self-testing with online supervision (STOS) for Vietnamese MSM

Authors: Thomas E Guadamuz, Worawalan Waratworawan, Yamol Kongjareon, Giang Minh Le, Lan Anh Thi Do

IDENTIFIERS	
MAHIDOL Ethic Project ID	2021/119.2010
Full (Scientific) title	HIV self-testing with online supervision (STOS) for Vietnamese MSM
Study Type	Interventional
Target sample size	100
STUDY TIMELINES	
Study Duration	01/07/2021-30/06/2025
Expected Start Date for Cohort Recruitment	05/01/2023
End of Study Date	05/21/2025
KEY STUDY CONTACTS	1. Assoc. Prof. Thomas E Guadamuz, Mahidol Center for Health, Behavior and Society Faculty of Tropical Medicine, Mahidol University 2. Worawalan Waratworawan, Mahidol Center for Health, Behavior and Society Faculty of Tropical Medicine, Mahidol University 3. Yamol Kongjareon, Mahidol Center for Health, Behavior and Society Faculty of Tropical Medicine, Mahidol University 4. Prof. Giang Minh Le, Center for Training and Research on Substance Abuse and HIV and School of Preventive Medicine and Public Health, Hanoi Medical University 5. Dr. Lan Anh Thi Do, Department of Epidemiology, Faculty of Public Health, Pham Ngoc Thach University of Medicine Ho Chi Minh City
STUDY SPONSOR	National Institute of Mental Health (NIMH)
KEY WORDS	YMSM, HIV/AIDS, STOS, Vietnam, HIV self-testing, online supervision

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1. Introduction

1.1 Overview of the Problem

HIV infection among men who have sex with men (MSM) in Vietnam continues to rise, with prevalence in Ho Chi Minh City (HCMC) estimated at 17% and incidence among young MSM (YMSM) in Hanoi at 5.8%.[1] Behavioral risks such as unprotected sex, multiple partners, and untreated STIs sustain high levels of circulating virus within MSM networks.[22-25] Low HIV testing rates and poor engagement in care further exacerbate transmission.[7] Meanwhile, widespread smartphone and internet use among Vietnamese MSM offers an opportunity for online testing innovations.[8,9,10]

1.2 Supporting Evidence

National surveillance shows that HIV prevalence among MSM increased from 6.2% in 2006 to 14% in 2009 in HCMC, reaching 19% nationwide by 2011.[1] Epidemiological studies identify consistent risk factors including low HIV knowledge,[11] sexual risk and STIs,[22-25] identity- and stigma-related challenges,[12,13] and limited access to appropriate health services.[7] A Vietnam-based survey found that 76.5% of MSM had never been voluntarily tested for HIV.[14] Evidence from Thailand demonstrates that an online HIV testing (OHT) model achieved 90% retention and 100% linkage to care.[15,16] Additionally, 97% of Vietnamese MSM report HIV self-testing as acceptable.[10]

1.3 Rationale for This Study

Persistent barriers such as stigma, low perceived risk, and fear of disclosing same-sex behaviour continue to limit HIV testing among Vietnamese YMSM.[12,13,8,9] Increasing HIV testing is essential for achieving the UNAIDS 90-90-90 goals, which require individuals at high risk to test at least annually.[17] Online HIV self-testing with real-time supervision can overcome institutional and psychological barriers while ensuring linkage to treatment or prevention.[8,9,10] Building on successful online HIV self-testing with online supervision (STOS) implementation in Thailand,[15,16] adapting this model for Vietnam could substantially increase testing uptake and reduce HIV incidence.[18,19]

1.4 Objective

Aim 1: To conduct focus group discussions to identify potential barriers and facilitators to the uptake of online HIV testing among YMSM in Ho Chi Minh City

Aim 2: To adapt the existing Thai online HIV self-testing with online supervision intervention for use among YMSM in Vietnam, willingness to engage in online HIV self-testing with online supervision as well as factors related to sustained testing will be collected through an online survey

Aim 3: To demonstrate the feasibility and acceptability of the adapted online HIV self-testing with online supervision (STOS) intervention, including use of an HIV rapid diagnostic antibody/antigen-based self-testing with an HIV counselor through video conferencing

2. Study design and methods of data collection

This study aims to evaluate the effectiveness of the HIV self-testing with online supervision (STOS) intervention, which includes the introduction of a HIV rapid diagnostic antibody/antigen-based self-testing conducted with the support of a trained counsellor via video conferencing, among young men who have sex with men (YMSM) aged 16–29 years.

The study employs a pilot randomized controlled trial (RCT) design with two groups: an intervention group (STOS) and a control group. The total sample size is 100 participants (50 per group). The follow-up period spans 12 months, with data collected at three time points: baseline, 6 months, and 12 months.

Data collection includes self-administered online questionnaires completed through the Qualtrics platform.[20] For participants in the intervention group, the study involves the implementation of real-time online supervised HIV self-testing conducted by a trained counsellor through video conferencing.

2.1 Procedures

2.1.1 Recruitment and Enrollment

Participant recruitment will be conducted over a one-year period, using a combination of online and offline outreach strategies to reach the target population of young men who have sex with men (YMSM) in Ho Chi Minh City.

For the online cross-sectional survey, recruitment will primarily be conducted through online platforms, including Google advertisements, Facebook, the CARMAH fan page, CARMAH networks, other MSM community networks, and youth networks in Ho Chi Minh City (such as university and high school students). To encourage participation, each respondent will receive a mobile top-up e-voucher valued at 50,000 VND (approximately 2 USD), delivered via SMS.

Individuals interested in participating will complete an online eligibility screening form. [20] Those who meet the inclusion criteria will receive detailed study information and proceed with the initial electronic consent (e-consent). After completing the survey, if an individual is found to be HIV-positive, they will not be invited to participate in the pilot study.

For the pilot study, a total of 100 Vietnamese YMSM will be recruited and followed for 12 months. Participants will be randomly assigned into two groups of 50 each:

- The intervention group, which will receive the HIV self-testing with online supervision (STOS) intervention; and
- The control group, which will refer to the standard of care, consisting of a voucher for venue-based HIV testing.

The STOS program begins when a counsellor contacts eligible participants via the Zalo communication platform. After confirming eligibility, the counsellor obtains verbal informed consent and schedules an appointment for the HIV self-testing with online supervision (STOS) session.

Once the appointment is confirmed, HIV self-testing kits are delivered to participants through Be Delivery service. Before the testing session, participants receive a link to an instructional YouTube video developed by CARMAH and Mahidol University, which demonstrates the correct procedure for performing the HIV self-test.

During the scheduled session, the counsellor provides pre-test counselling and real-time supervision via video conferencing as participants perform the self-test. This process ensures proper use of the test kit, supports accurate interpretation of results, and maintains participant confidentiality throughout the HIV self-testing process.

2.1.2 Data Collection

Data collection will occur at three time points: at baseline and again at 6 and 12 months of follow-up. During each assessment, participants will complete self-administered questionnaires on tablets or smartphones via the Qualtrics platform. For individuals assigned to the STOS group, HIV self-testing outcomes will be documented by a trained counselor and stored in an encrypted file with restricted access. Only the Principal Investigator (PI) and the Study Statistician will be authorized to view these data to maintain strict confidentiality.

All study data will be housed on secure institutional servers in encrypted, password-protected formats to ensure robust data security.

2.1.3 Retention and Engagement Strategies

To ensure sustained participation throughout the follow-up period, the research team will implement continuous engagement measures using multiple digital communication channels, including the Zalo application, SMS, telephone calls, and support from community peer leaders. Participants will be contacted regularly to receive project updates, appointment reminders, and encouragement to take part in each data-collection round. Ongoing assistance will also be provided to help maintain participants' motivation and consistency in completing questionnaires. For the STOS group, follow-up communication will additionally ensure that participants receive their self-testing kits. These combined strategies are expected to achieve follow-up retention rates exceeding 80% at each assessment point.

2.2 Eligibility criteria

Inclusion Criteria:

- Aged between 16 and 29 years
- Have been residing in Ho Chi Minh City for more than 6 months
- Assigned male at birth or intersex
- Self-identify as men who have sex with men (MSM), Homosexual, bisexual, or male (straight)
- Have engaged in anal sex (insertive or receptive) with a male partner within the past 6 months
- Willing and able to provide informed consent to participate in the study

Exclusion Criteria:

- Aged ≤15 years or ≥30 years
- Have been residing in Ho Chi Minh City for less than 6 months or do not currently live in Ho Chi Minh City.
- Assigned female at birth
- Self-identify as a woman, transgender woman, or transfeminine individual
- Unwilling to participate in follow-up activities associated with the study

2.3 Consent

2.3.1 Consent Procedures

All participants will provide informed consent by clicking "accept button" at the time they begin the online survey. For participants under 18 years of age, a waiver of parental consent will be obtained from the ethics committee to protect them from the potential risk of unintentional

disclosure of their sexual orientation or HIV status. Before joining the study, participants will receive a study information sheet explaining the research objectives and procedures. This document will appear immediately before the consent question in the online survey, allowing participants to review the study details before providing consent. After completing the survey, participants who are interested in joining the STOS intervention will be introduced to additional information, as follows: Participants will be informed that the study involves an online HIV self-testing intervention and that they may be randomly assigned to one of two testing approaches.

The first approach involves receiving an HIV home self-testing kit, with real-time guidance and support from trained staff via video calls and instructional videos. The second approach involves receiving information about free HIV testing services available at public hospitals, where participants can go for testing independently. If selected for participation, study staff will contact participants using the contact information provided to explain further details and confirm their willingness to take part. For those who are randomly assigned to the STOS group, multiple formats will be used to ensure a full understanding of study procedures. These include printed materials, instructional videos (e.g., how to perform HIV self-testing), and verbal explanations provided by trained counsellor. Participants will be encouraged to ask questions about any aspect of the study, including the survey process, HIV self-testing procedures, and their right to withdraw from the study at any time without penalty or loss of benefits. Informed consent will be obtained only after participants demonstrate clear understanding and express their willingness to participate voluntarily. At each follow-up round, field staff will reassess participants' understanding and verbally reconfirm consent before administering questionnaires or conducting STOS sessions, to ensure that participants remain fully informed and voluntarily engaged throughout the longitudinal study

2.3.2 Withdrawal/discontinuation criteria

Participants could withdraw from the study at any time and for any reason. Withdrawal did not affect the compensation they had already received or their access to HIV-related services. Common reasons for discontinuation included being unreachable, or unwillingness to continue participation.

2.4 Data analysis

Both descriptive and inferential statistical methods will be employed to evaluate the effectiveness of the STOS intervention throughout the study period. Analyses will compare the STOS intervention group and the control group across demographic variables, behavioral measures, and health-related outcomes associated with HIV infection.

2.4.1 Descriptive Analyses

Baseline characteristics of participants, including demographic, behavioral, and health-related information, will be summarized using descriptive statistics, stratified by study group (intervention vs. control) to assess baseline differences between the two groups and changes over time. Categorical variables will be presented as frequencies and percentages, while continuous variables will be summarized using means and standard deviations (mean ± SD) or medians with interquartile ranges (IQR: 25th–75th percentile), depending on the data distribution.

2.4.2 Primary and Secondary Outcome Analyses

To evaluate the effects of the STOS intervention, two groups will be compared: the STOS group, who receive an HIV self-testing kit and complete the online questionnaires, and the control group, who complete the questionnaires only. The primary outcomes are the rate of HIV testing uptake and the rate of new HIV infections during the study period. The secondary outcomes include changes in sexual behaviors, mental health, and other psychosocial indicators over time. To assess the effects of the intervention across time points, Generalized Estimating Equations (GEE) models will be applied, using a log link function for rate outcomes and an identity link function for continuous outcomes. The models will include variables for study arm (STOS vs. control), time (follow-up round), and their interaction term (arm × time) to estimate longitudinal intervention effects. Robust standard errors will be used to account for within-subject correlation due to repeated measures. The results will be presented as Rate Ratios (RRs or Incidence Rate Ratios, IRRs) with 95% confidence intervals (CIs) and p-values to indicate the magnitude and statistical significance of the observed effects.

2.4.3 Multiple Comparisons and p-value Adjustment

When multiple comparisons are made, such as in subgroup analyses or secondary outcomes, adjustments to p-values will be considered to control for the risk of type I error. Methods such as Bonferroni correction or false discovery rate (FDR) adjustment will be applied as appropriate.

2.4.4 Statistical Software

All data analyses will be conducted using STATA version 18.0,[21] which is the primary statistical software used by the research team for data management, descriptive analyses, regression modeling, and longitudinal data analysis.

2.5 Assessment and management of risk

This study will be conducted as a low-risk observational cohort study. However, certain items in the questionnaire, such as those related to sexual behavior or HIV status, may be considered sensitive. To minimize potential risks, several protective measures will be implemented. All data will be collected anonymously and stored securely using an encrypted system with restricted access, ensuring that no personally identifiable information is recorded.

Participants will be informed of their right to skip any question they find uncomfortable and their right to withdraw from the study at any time without any negative consequences. Additionally, counsellor will provide continuous support by explaining study procedures and addressing participants' questions throughout the study period. If necessary, participants will be referred to mental health or HIV-related services for appropriate care.

In cases where participants are found to be HIV positive, they will receive preliminary counseling and be referred to appropriate healthcare facilities for further testing and treatment in accordance with the Ministry of Public Health guidelines.

A Data and Safety Monitoring Board (DSMB) will also be established to oversee the project's risk management strategies, monitor participant safety and well-being, and ensure continuous ethical compliance. The DSMB will operate independently to review study procedures and provide recommendations to the research team regarding any necessary protocol adjustments to maintain ethical and safety standards throughout the study.

2.6. Data management

Data collection will be carried out through the Qualtrics platform, where key items will be configured with mandatory responses and skip logic will be applied to ensure that participants are directed only to questions relevant to their previous answers. Once data collection is completed, the dataset will be exported, cleaned, and analyzed using STATA software.

Participant records across follow-up periods will be matched using the nicknames and phone numbers provided to the research team. All identifying information will be safeguarded through a dual-encryption system and stored on secure, password-protected servers maintained by Mahidol University. Access to these data will be limited to authorized study personnel, including the Principal Investigator (PI) and designated data managers responsible for overseeing data handling procedures.

2.7 Recording and reporting of risk events and incidents

If an adverse or risk-related event occurs during the study, the research team will systematically document and review the incident. Key information, including the type of event, the time it occurred, the individuals involved, and any immediate actions taken, will be recorded.

The research team will evaluate the seriousness of the incident and determine the appropriate follow-up steps. Any event deemed serious or potentially compromising participant safety will be promptly reported to the Data and Safety Monitoring Board (DSMB) for independent assessment and recommendations. These incidents will also be submitted to the Institutional Review Board (IRB) within the required reporting window in accordance with ethical guidelines.

Clear procedures are in place to ensure that all incidents are handled in a timely, transparent, and appropriate manner. All incident documentation will be securely stored and treated as confidential. Participants may also communicate any concerns or discomfort to the research team through the confidential communication channels routinely used in the study, including Zalo and telephone contact.

3. Funding

This study is funded by the National Institute of Mental Health (NIMH), under Grant R34MH123337.

4. Monitoring and auditing

The Principal Investigator (PI) will oversee the full implementation of the study and ensure that all procedures align with the approved protocol and applicable ethical standards. Local field activities and data collection will be carried out with support from the Center for Applied Research on Men and Community Health (CARRMAH), a trusted community-based partner located in Ho Chi Minh City.

A Community Advisory Board (CAB) will contribute guidance on participant recruitment approaches and study operations to ensure meaningful community engagement and cultural appropriateness. Four CAB consultations were conducted and included representatives from NGOs such as HAIVN, community-based organizations including TestSGN, CARMAH, G3VN, and Galant clinics, as well as HIV testing and counseling staff and young men who have sex with men (YMSM).

Regular internal monitoring will be performed by the core coordination team to check data accuracy, review informed consent processes, and verify adherence to study procedures, including pre- and post-test counseling, data handling practices, and confidentiality safeguards. The Data and Safety Monitoring Board (DSMB) will independently review study progress, safety reports, and any risk events at scheduled intervals. The DSMB may also conduct audits to evaluate compliance with the protocol, ethical standards, and data quality. Three DSMB meetings were conducted with participation from the following experts: Dr. Kanokwan Chair, PhD in Anthropology, Institute for Population and Social Research at Mahidol University; Dr. Giang Truong Le, PhD in Public Health and former Deputy Director of the Ho Chi Minh City Department of Health, now serving as President of the Vietnam Public Health Association and Consultant at Pham Ngoc Thach University of Medicine; and Dr. Truc Thai Thanh, PhD in Health Sciences and Vice Head of the Biostatistics and Informatics Department, Faculty of Public Health, University of Pharmacy and Medicine in Ho Chi Minh City.

All monitoring and auditing outcomes will be documented, and any deviations from the protocol will be addressed through appropriate corrective measures. Required reports will be submitted to the IRB and the DSMB, and all follow-up actions will be tracked to maintain ongoing quality assurance throughout the study.

5. Publication and dissemination

Study findings will be disseminated through peer-reviewed publications and presentations at national and international conferences, following all ethical and reporting standards to ensure participant confidentiality. Summary results will also be shared with key stakeholders, including local health authorities, NGOs, service providers, and community-based organizations. Plain-language summaries and aggregated participant updates will be prepared to improve accessibility for non-academic audiences.

Given the intervention-focused nature of the study, the research team will engage multisectoral partners—such as government agencies, public health institutions, and community networks—to support the translation of findings into practice and explore opportunities for scale-up. Policy briefs may be developed to inform decision-making at local and national levels. Digital platforms may also be used to distribute summaries or infographics where appropriate.

The Community Advisory Board (CAB) will provide input to ensure culturally appropriate dissemination strategies. Authorship will follow international guidelines (e.g., ICMJE), and all dissemination materials will be reviewed and approved by the Principal Investigator before release.

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7. Annexes

7.1 Participant Information Sheet

Participant Information Sheet

In this document, there may be some statements that you do not understand. Please ask the principal investigator or her representative to give you explanations until they are well understood. To help your decision making in participating the research, you may bring this document home to read and consult your relatives and intimates.

Title of Research Project: "HIV self-testing with online supervision for Vietnamese MSM"

Name of Researcher: Associate Professor Dr. Thomas E. Guadamuz
Work place address: Department of Society and Health and Center of Excellence in Research on Gender, Sexuality, and Health, Faculty of Social Science and Humanities, Mahidol University
Tel: +6686-084-4154
E-mail: tguadamu@hotmail.com

Source of funding: National Institutes of Health (NIH)

Research objective

This research project aims to (1) to qualitatively explore potential barriers and facilitators to the uptake of OHT among YMSM in HCMC; (2) to adapt the existing Thai OHT intervention for use among YMSM in Vietnam, including translation and socio-cultural refinement of testing kits, clip video content, online pre- and post-test counseling, and broader socio-cultural contexts and identify factors associated with willingness to access OHT and willingness to participate in a pilot study; (3) to demonstrate the feasibility and acceptability of the adapted OHT intervention, including use of an HIV rapid diagnostic antibody/antigen-based self-testing with an HIV counselor through video conferencing.

Why you are asked to participate

You are invited to participate in this research project since you are interested in our project, who are 16-29 years old, being male sex at birth, had anal intercourse with a man in the past 6 months, self-reported HIV negative or unknown status, HCMC resident for at least 6 months, and who can speak/write Vietnamese fluently. There will be about 330 participants who will participate in this online survey, and the research will last for 3 years September 2021 to August 2024.

How you would participate
(For the online survey)

If you decide to participate in the research project, you would like to click online "agree to participate" in this online survey. The survey will be last in 45 minutes.

Benefits of participation

The hope is that the findings of this study will contribute to assess the potential for OHT intervention to overcome profound and longstanding barriers to HIV testing among YMSM in Vietnam, an outcome that if brought to scale could significantly improve enrolment in ART and reduce HIV incidence in Ho Chi Minh City specifically and in Vietnam generally.

Risks of participation

Participating in the study means that you may share sensitive information and we may talk about topics that can be experienced emotionally and some questions may create uneasiness or

discomfort. You always have the right to choose not to answer any question, and you can choose to cancel the interview at any time or take a break.

If relevant information arises about benefits and risks of the research project, the researcher will inform the participant immediately and without concealment.

Handling of private information

Any private information that would make it possible to identify you will be kept confidential and will never be included in any sort of report. Only the researcher and his research team will analyze the information, and information about you will be treated so that unauthorized persons cannot access them.

Compensation for participation

When participating in this research project you will be compensated with top-up telephone card 70 THB (~50.000 VND).
No expenses by you as a participant are required.

You are free to decide whether to participate or not. As a participant, you have the right to withdraw from the project at any time without prior notice, and the refusal to participate or the withdrawal from the research project will not at all affect any service or treatment. However, if you experience uneasiness or discomfort due to participating in the research project, the researcher is happy to answer all of your questions or concerns. If you have comments, complaints, or questions about this research, please feel free to contact Assoc. Prof. Dr. Thomas Guadamuz (Principal Investigator), Tel. +66 86 084 4154, Email: tguadamu@hotmail.com or Dr. Lan Anh Do (Project director), Tel. +84 94 521 7146, E-mail: lananhytcc08@mail.com.

On the condition that you are not treated as indicated in this information sheet, you can contact the Chair of The Committee for Research Ethics (Social Sciences(at the office of MUSSIRB, Office of Faculty of Social Sciences and Humanities, Mahidol University, Tel: 02 441 9180, Fax: 02 441 9181, E-mail: musssirb310@gmail.com

Sincerely,
Thomas Guadamuz

Ho Chi Minh City, 30 Mar 2023

Participant Information Sheet

In this document, there may be some statements that you do not understand. Please ask the principal investigator or her representative to give you explanations until they are well understood. To help your decision making in participating the research, you may bring this document home to read and consult your relatives and intimates.

Title of Research Project: "HIV self-testing with online supervision for Vietnamese MSM"

Name of Researcher: Associate Professor Dr. Thomas E. Guadamuz
Work place address: Department of Society and Health and Center of Excellence in Research on Gender, Sexuality, and Health, Faculty of Social Science and Humanities, Mahidol University
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You are invited to participate in this research project since you are interested in our project, who are 16-29 years old, being male sex at birth, had anal intercourse with a man in the past 6 months, self-reported HIV negative or unknown status, HCMC resident for at least 6 months, and who can speak/write Vietnamese fluently. There will be about 100 participants who will participate in this randomized control trial (RCT), and the RCT will last for 12 months.

How you would participate
(For the RCT)

If you decide to participate in the research project, you will be received our phone calls, emails and/or SMS/text messages to have guideline and providing information via Skype, Zalo Video call, Zoom, Facebook video call or Line Video sessions. You may be randomly divided into one group between getting HIV self-testing with our online support and getting information care about HIV testing clinic in Ho Chi Minh City, and we may follow up for 12 months (both groups will get an online survey in 6 months and 12 months). If you were random to the getting HIV group, you will also receive HIV testing kits online by post-office at home from our research for three times to test and follow-up (at the beginning, 6 months and 12 months).

Benefits of participation

The hope is that the findings of this study will contribute to assess the potential for OHT intervention to overcome profound and longstanding barriers to HIV testing among YMSM in Vietnam, an

outcome that if brought to scale could significantly improve enrolment in ART and reduce HIV incidence in Ho Chi Minh City specifically and in Vietnam generally.

Risks of participation

Participating in the study means that you may get HIV testing and we may follow up for 12 months that can be experienced emotionally and create uneasiness or discomfort. You always have the right to choose not continue in our RCT at any time.

If relevant information arises about benefits and risks of the research project, the researcher will inform the participant immediately and without concealment.

Handling of private information

Any private information that would make it possible to identify you will be kept confidential and will never be included in any sort of report. Only the researcher and his research team will analyze the information, and information about you will be treated so that unauthorized persons cannot access them.

Compensation for participation

Participating in this research project will compensate you with 100 THB each time (6 months and 12 months follow-up) (~68.058 VND) as well as getting free online HIV testing kits for the intervention group and getting an information card about HIV testing places in Ho Chi Minh City for the control group.

No expenses by you as a participant are required.

You are free to decide whether to participate or not. As a participant, you have the right to withdraw from the project at any time without prior notice, and the refusal to participate or the withdrawal from the research project will not at all affect any service or treatment. However, if you experience uneasiness or discomfort due to participating in the research project, the researcher is happy to answer all of your questions or concerns. If you have comments, complaints, or questions about this research, please feel free to contact Assoc. Prof. Dr. Thomas Guadamuz (Principal Investigator), Tel. +66 86 084 4154, Email: tguadamu@hotmail.com or Dr. Lan Anh Do (Project director), Tel. +84 94 521 7146, E-mail: lananhytcc08@mail.com.

On the condition that you are not treated as indicated in this information sheet, you can contact the Chair of The Committee for Research Ethics) Social Sciences(at the office of MUSSIRB, Office of Faculty of Social Sciences and Humanities, Mahidol University, Tel: 02 441 9180, Fax: 02 441 9181, E-mail: musssirb310@gmail.com

Sincerely,
Thomas Guadamuz

Ho Chi Minh City, 15 Sept 2021

7.2 Informed Consent Script

Verbal Informed Consent Script

This research project was developed and designed for 3 aims (1) to understand the potential barriers and facilitators to the uptake of online HIV self-testing among young MSM in Ho Chi Minh City; (2) to adapt the existing Thai online HIV self-testing intervention for use among Yong MSM in Vietnam, including translation and socio-cultural refinement of testing kits, clip video content, online pre- and post-test counseling, and broader socio-cultural contexts and identify factors associated with willingness to access online HIV self-testing and willingness to participate in a pilot study; (3) to demonstrate the feasibility and acceptability of the adapted online HIV self-testing intervention, including use of an HIV rapid diagnostic antibody/antigen-based self-testing with an HIV counselor through video conferencing. In this pilot study, you will be invited to participate in the HIV self-testing pilot study.

- You will be contacted by the project staff to explain the details of the project. You can ask for more details about the project until you totally understand. After you understand this research, project staff will ask for your verbal consent to participate in the research project. You may or may not agree to participate in the research. The decision of participating or not participating in this project will not have any effects on you.
- If you agree to participate in this research. The project staff will randomize you into 2 groups: control group and intervention group. In the control group, you will get the information card about HIV testing clinics in Ho Chi Minh City. In intervention group, you will get HIV self-testing with online supervision by our HIV counselor on Zalo video call, Skype or Facebook video without video recording. You will be followed up for 12 months with our staff (both groups will get an online survey in 6 months and 12 months). You are not required to disclose your real name in this study or sign any documents. Therefore, you will be the most comfortable and confidential to join in our pilot study.

This research project is anonymous that the participants in this research will not be asked for full name on ID card number and other information that can recognize the participants. Participants voluntarily agree to participate in this project and are able to withdraw from the project whenever you want. This research was conducted by Assoc. Prof. Dr. Thomas Guadamuz from Mahidol University, Thailand. If you would like to get more information, please contact Assoc. Prof. Dr. Thomas Guadamuz (Principal Investigator), Tel. +6686-084-4154, Email: tguadamu@hotmail.com or Dr. Lan Anh Thi Do (Project director), Tel. +8494-521-7146, E-mail: lananhytcc08@mail.com

I certify that the details of this research have been clarified to the participants.

Signature.....

( )

Researcher

7.3 Statistical Analysis Plan (SAP)

Study Title: HIV self-testing with online supervision (STOS) for Vietnamese MSM

ClinicalTrials.gov Identifier (NCT Number): NCT05797961

Document Date: 01/01/2022

1. Introduction

1.1 Objectives of the Statistical Analysis Plan

The primary objective of this Statistical Analysis Plan (SAP) is to prospectively define the analytical framework, statistical methods, and procedures that will be used to analyze data from the clinical study titled “HIV self-testing with online supervision (STOS) for Vietnamese MSM”. This SAP is designed to ensure that the analysis is transparent, reproducible, and aligned with the registered study protocol under ClinicalTrials.gov Identifier NCT05797961.

This SAP is intended to:

- Describe the planned analyses for the primary and secondary study objectives
- Specify the statistical techniques and data handling procedures to be used
- Define the analysis populations
- Outline approaches to address missing data, conduct sensitivity analyses, and implement subgroup analyses

1.2 Background and Significance of the Study

This study aims to evaluate the effectiveness of the STOS intervention in:

- Increasing the frequency of HIV testing (at least once every six months)
- Reducing sexual risk behaviors

The study is conducted as a pilot randomized controlled trial (pilot RCT) using a longitudinal cohort design among young men who have sex with men (YMSM Cohort, N = 100) residing in Ho Chi Minh City, Vietnam, with participants randomized into two groups: the STOS intervention group and the control group.

Given that YMSM in Ho Chi Minh City, Vietnam continue to have low rates of HIV testing, a high burden of HIV, and face structural and behavioral barriers to accessing healthcare services, this study is of significant public health importance and holds meaningful implications for national HIV policy development and prevention programming.

2. Study Design Overview

This study is a pilot randomized controlled trial (pilot RCT) using a longitudinal cohort design among young men who have sex with men (YMSM) aged 15–29 years, with a total of 100 participants equally allocated into two groups:

- STOS intervention group (n = 50)
- Control group (n = 50)

Participants will be followed for a period of 12 months, with data collection conducted at three times: baseline, 6 months, and 12 months of follow-up.

2.1 Data Collection and Sources

Data will be obtained through an online, self-completed survey administered via the Qualtrics platform, which participants can access on mobile phones or tablets. To protect confidentiality, the survey will not gather any personal identifiers. Participants will instead log in using the same chosen nickname or pseudonym and their approved contact method, enabling the research team to reliably match their responses across multiple survey waves without compromising anonymity.

2.2 Retention and Follow-up

To maintain strong participant retention throughout the study, the research team will employ ongoing engagement activities delivered through digital communication channels and peer-supported community networks.

3. Study Objectives and Endpoints

3.1 Primary Objective

To evaluate the effectiveness of the STOS intervention in increasing access to and uptake of HIV testing among young men who have sex with men (YMSM).

3.2 Secondary Objectives

- To evaluate the effect of the intervention on reducing the incidence of HIV infection.
- To evaluate the effect of the intervention on reducing sexual risk behaviors (e.g., condomless anal intercourse with male partners).
- To evaluate the effect of the intervention on reducing health-related risk behaviors, including mental health problems (depression and suicidal risk) and substance use.

3.3 Primary Outcome

- **HIV testing uptake:**
  Proportion of participants who report having tested for HIV at least once within a 6-month period, based on STOS testing records and self-reported survey data.

3.4 Secondary Outcomes

- **HIV incidence:**
  Number of new HIV infections per 100 person-years, based on STOS testing results and self-reported data during follow-up.
- **Sexual risk behavior:**
  Proportion of participants reporting condomless anal intercourse with male partners during the past 6 months, measured through self-reported survey data.
- **Health-related risk behaviors (mental health and substance use):**
  Proportion of participants reporting mental health problems (e.g., depressive symptoms, suicidal risk) and frequency of substance use during the past 6 months, based on self-reported survey data.

4. Analysis Populations

4.1 Intention-to-Treat (ITT) Population

The ITT population will consist of all individuals who completed the baseline assessment and were allocated to either the intervention or control condition, independent of their subsequent engagement with any intervention components. This group will be used as the primary sample for assessing intervention effectiveness, aligning with a real-world evaluation approach that accounts for variations in actual participation.

5. Data Management and Quality Assurance

5.1 Handling of Missing Data

Data will be collected through an online Qualtrics survey[20] with required-response items and programmed skip logic to minimize missing data at baseline. Despite these measures, some missingness is expected across follow-up rounds due to participant drop-out or missed assessments. All missing values will be clearly coded in the dataset.

For analysis, we will examine differences between participants with complete and incomplete data. When missingness is substantial, multiple imputation (MI) or maximum likelihood (ML) methods will be applied under the missing-at-random (MAR) assumption.[26] Sensitivity analyses using pattern-mixture models will be conducted to assess the robustness of this assumption.[27] Complete-case analysis may be used when missing data are minimal.

5.2 Data Cleaning and Preparation

After exporting the data from Qualtrics, the research team will conduct structured cleaning procedures using STATA[21] command scripts to ensure accuracy and consistency. Key tasks will include identifying outliers, detecting logically inconsistent answers, checking the correctness of skip patterns, and verifying that numerical variables fall within acceptable ranges. Variables that depend on previous responses will also be reviewed to confirm internal coherence.

For the preparation of the analytic dataset, information from two sources will be combined: (1) the self-administered online questionnaires collected through Qualtrics, and (2) HIV self-testing outcomes obtained from participants in the STOS intervention group. These datasets will be harmonized before merging. To ensure accurate linkage across time points, participants will be asked to provide the same nickname or pseudonym during every round of data collection.

5.3 Variable Coding and Labeling

All variables will be coded and labeled according to a standardized data dictionary to ensure consistency across all study rounds. Dichotomous variables will use fixed coding (e.g., 1 = Yes, 0 = No), and Likert-scale items will follow predefined response categories. Maintaining uniform coding conventions will facilitate accurate interpretation, allow meaningful comparisons over time, and improve the reproducibility of the analyses.

6. Statistical Methods

6.1 Descriptive Analysis

Descriptive statistics will be used to summarize baseline characteristics and study variables, separated by study arm: the STOS intervention group and the control group. Statistical comparisons will be performed between these two groups to evaluate the effects of the STOS intervention over time. Categorical variables will be presented as frequencies and percentages, while continuous variables will be summarized as means with standard deviations (mean ± SD) or medians with interquartile ranges (IQRs), depending on the data distribution.

6.2 Primary and Secondary Outcome Analyses

Generalized Estimating Equations (GEE) with appropriate link functions (e.g., logit for binary outcomes, identity for continuous variables) will be applied to assess intervention effects

over time. Each model will include study arm, follow-up time, and an interaction term to estimate differential changes between groups. Robust standard errors will be used to account for correlations within individuals. Person-time will also be calculated, and rate ratios with 95% confidence intervals will be reported.

6.3 Multiple Comparisons and p-value Adjustment

For secondary outcomes and subgroup analyses involving several statistical tests, adjustments for multiple comparisons will be applied as appropriate. Methods such as Bonferroni correction or false discovery rate (FDR) procedures will be considered to control the risk of type I error.

6.4 Statistical Software

All statistical analyses will be performed in STATA version 18.0, which will be used for data management, descriptive analysis, regression modeling, and longitudinal analyses.

7. Sensitivity Analyses

Sensitivity analyses will be conducted to evaluate the robustness of the results under alternative assumptions. These may involve varying model specifications, use alternative link functions, or compare findings from GEE models with those from mixed-effects models.