Study protocol: Addressing the Continuum of Care Among High-risk Thai Men

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IDENTIFIERS	
MAHIDOL Ethic Project ID	2020/121.2605
Full (Scientific) title	Addressing the Continuum of Care Among High-risk Thai Men
Study Type	Interventional
Target sample size	600
STUDY TIMELINES	
Study Duration	01/07/2019-31/05/2024
Expected Start Date for Cohort Recruitment	01/06/2020
End of Study Date	31/12/2023
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STUDY SPONSOR	National Institute of Mental Health (NIMH)
KEY WORDS	YMSM, HIV/AIDS, HUG-M, Mpowerment

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1. Introduction

1.1 Overview of the Problem

Thailand is currently experiencing an alarming HIV epidemic among young men who have sex with men (YMSM), particularly those aged 15–29. In Bangkok, HIV prevalence among YMSM aged 18–24 is as high as 31%. The HIV incidence rate in this group is approximately 12%, which is the highest level documented in Asia.[1,2] These rates far exceed those in high-risk populations in the United States, where even the most at-risk group, Black MSM, has an incidence rate of around 4%.[3] Contributing risk factors among Thai YMSM include being paid for sex, having sex at saunas, and living away from family. The HIV prevalence in northeastern provinces like Ubon Ratchathani and Mahasarakham ranges between 10%–25%, which is over ten times higher than the national average. If no effective prevention strategies are implemented, other regions in Thailand may follow the same trajectory as Bangkok.

1.2 Supporting Evidence

Despite the high risk, very few YMSM are accessing HIV testing or care. According to a joint study conducted by the US CDC and the Thai Ministry of Public Health, only 50.3% of MSM in Thailand had ever been tested for HIV. Of those, merely 24.9% returned for their test results. [4] As a result, only 12.5% actually knew their HIV status. [5] Our previous research found that 73.3% of YMSM aged 15–19 and 45% of those aged 20–24 had never tested for HIV. [6] This indicates that current HIV prevention efforts are failing to reach adolescents and young adults, especially in terms of HIV testing and linkage to care. Furthermore, many healthcare providers, including HIV test counselors, lack adequate knowledge of the Continuum of Prevention and Care (CPC), especially regarding the importance of achieving viral suppression, and often perpetuate stigma and discrimination against YMSM. These systemic issues further hinder engagement in HIV prevention and treatment services.

1.3 Rationale for This Study

To address these urgent gaps, the BAAN HUG-M intervention was developed as a community-based, multi-level approach designed to mobilize YMSM, reduce sexual risk behaviors, and improve access to HIV testing and care. Building on the foundation of the original HUG-M model, BAAN HUG-M integrates individual-level behavior change strategies with community mobilization and health system strengthening, with a particular focus on the full Continuum of Prevention and Care (CPC). The intervention seeks to address structural, social, and individual barriers to HIV testing, engagement in care, and achievement of viral suppression among Thai YMSM. Thailand offers a unique and timely opportunity to evaluate this intervention, owing to its existing public health infrastructure, strong community partnerships, and a policy environment conducive to rapid implementation of evidence-based practices. Findings from this study could help shape national HIV strategies and inform similar efforts throughout Asia and beyond.

1.4 Objective

To evaluate the efficacy of Baan HUG-M in decreasing sexual risk behavior; increasing HIV testing to at least biannually; and increasing prompt, sustained engagement in care among YMSM living with HIV by using a longitudinal cohort of YMSM in Ubon Ratchathani and Mahasarakham

2. Study design and methods of data collection

This study aims to evaluate the effectiveness of the Baan HUG-M intervention, a community-based strategy designed to promote HIV prevention and facilitate access to care among young men who have sex with men (YMSM) aged 15 to 29 years. A longitudinal cohort design is employed across two geographic locations: Ubon Ratchathani (intervention site) and Mahasarakham (control site), with a total sample size of 600 participants (300 per site). The follow-up period spans 24 months, with data collection occurring at five time points: baseline and months 6, 12, 18, and 24.

Data collection comprises self-administered surveys completed via the Qualtrics platform[7] and self-collected biological specimens, including urine samples and rectal swabs, for chlamydia and gonorrhea testing. All specimens will be transported to and analyzed at the Office of Disease Prevention and Control 10 (ODPC 10), located in Ubon Ratchathani Province. Additionally, study data will be linked to the national HIV database maintained by the Ministry of Public Health. To protect participant confidentiality, no personally identifiable information is collected within the survey. Instead, a Unique Identification Code (UIC) is assigned to each participant to enable secure and systematic linkage of data across multiple sources.

2.1 Procedures

2.1.1 Recruitment and Enrollment

Participant recruitment will be conducted over a one-year period using a comprehensive outreach strategy encompassing both online and offline channels to reach young men who have sex with men (YMSM) in two study locations: Ubon Ratchathani and Mahasarakham. The initial target sample size will be 600 participants (300 per province).

Offline recruitment will involve the distribution of QR codes linking to an online screening form. These will be disseminated at public venues and community gathering points frequented by the target population, including local markets, university canteens, schools (through educational sessions on military conscription), shopping centers, and entertainment venues. The research team will also organize community engagement events such as volleyball tournaments, photography contests, and cultural festivals (e.g., Mor Lum folk music events), as well as outreach activities at bars and clubs popular among YMSM. Collaboration with university lecturers, local public health agencies, and public hospitals will support recruitment efforts.

Online recruitment will be conducted through targeted communication campaigns on social media platforms, supplemented by peer-driven outreach activities to increase engagement and visibility among potential participants.

Interested individuals will be required to complete an online eligibility screening form. Those who meet the eligibility criteria will receive detailed study information and complete an initial electronic consent process. A study team member will then follow up to schedule an appointment, during which a comprehensive informed consent discussion will be conducted. Written informed consent and a photocopy of the participant's national identification card will be obtained. Participants will then view a demonstration video on how to self-collect rectal swab specimens, complete the baseline questionnaire, and provide their first set of biological specimens.

2.1.2 Data Collection

Data will be collected at five time points: baseline, and months 6, 12, 18, and 24 of follow-up. At each round, participants will complete self-administered surveys using tablets or smartphones via the Qualtrics platform. A Unique Identification Code (UIC) will be used to longitudinally link participant data across time points. The UIC will consist of the first letter of the province name, followed by an underscore, the first two letters of the participant's last name, and the date of birth in the DDMMYYYY format (e.g., P_AB01012025). To minimize entry errors, local research staff will select the UIC from a predefined list using a forced-choice format.

At each follow-up round, participants will self-collect biological specimens, including urine samples and rectal swabs, for chlamydia and gonorrhea testing. All specimens will be transported under temperature-controlled conditions to the Office of Disease Prevention and Control 10 (ODPC 10) in Ubon Ratchathani for laboratory analysis. Prior to specimen collection, participants will watch a standardized instructional video to ensure correct self-collection procedures.

HIV-related clinical data including the date of the most recent HIV test, HIV status, initiation of antiretroviral therapy (ART), treatment continuity, and viral load results will be extracted from the national HIV database maintained by the Ministry of Public Health using the participant's national identification number. Access to this database will be restricted to the principal investigator and the study statistician to ensure data confidentiality. All data will be stored in encrypted and password-protected formats on secure institutional servers.

2.1.3 Retention and Engagement Strategies

To promote high retention throughout the study period, the research team will implement continuous engagement strategies through digital communication channels, including the LINE application, SMS, and phone calls, as well as peer-led community outreach. The team will maintain regular contact with participants to provide project updates, appointment reminders, and encouragement to take part in each round of data collection. Participants will receive ongoing support throughout their involvement in the study to foster motivation and consistency in completing questionnaires and providing biological specimens. These combined efforts are expected to result in follow-up retention rates of greater than 60% at each follow-up time point.

2.2 Eligibility criteria

Inclusion Criteria:

- Aged between 15 and 29 years
- Currently residing, studying, or working in either Warin Chamrap District or Mueang District of Ubon Ratchathani Province (intervention site), or in Kantharawichai District or Mueang District of Mahasarakham Province (control site)
- Intend to remain in the study area for at least the next three years
- Assigned male at birth
- Self-identify as gay, men who have sex with men (MSM), bisexual, or *toot* (a locally understood term)
- Have engaged in anal sex (insertive or receptive) with a male partner within the past 12 months
- Willing and able to provide informed consent to participate in the study

Exclusion Criteria:

- Aged ≤14 years or ≥30 years
- Not currently residing, studying, or working in one of the designated study areas
- Planning to move out of the study area within the next three years
- 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 written informed consent at the time of enrollment. For participants under the age of 18, a waiver of parental consent will be obtained from the ethics committee to protect them from the risk of involuntary disclosure of their sexual orientation or HIV status. Prior to enrollment, participants will receive a study information sheet in advance. On the scheduled enrollment day, the document will be provided again, and participants will have the opportunity to review it with the support of field staff.

To ensure full comprehension of study procedures, multiple formats will be used, including printed materials, instructional videos (e.g., on self-collection of biological specimens), and verbal explanations by trained personnel. Participants will be encouraged to ask questions about any aspect of the study, including the survey process, biospecimen collection, and their right to withdraw at any time. Informed consent will only be obtained after participants demonstrate understanding and express willingness to participate.

Additionally, at each follow-up visit, field researchers will reassess participants' understanding of the study and reconfirm their voluntary participation. This will include obtaining verbal reconfirmation before completing questionnaires and providing biological specimens, to ensure that participants remain informed and continue to consent 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 relocation, 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 Baan HUG-M intervention over the study period. Analyses will compare the intervention group (Ubon Ratchathani) and the control group (Mahasarakham) across demographic variables, behavioral measures, and health-related outcomes associated with HIV and sexually transmitted infections (STIs).

2.4.1 Descriptive Analyses

Baseline demographic, behavioral, and health characteristics of participants will be summarized using descriptive statistics, stratified by study arm (intervention vs. control). Comparisons will be made between the two study sites (Ubon Ratchathani as the intervention site, and Mahasarakham as the control site) to assess initial differences and changes over time. Categorical variables will be presented as frequencies and percentages. Continuous variables will be summarized using means and standard deviations, or medians with interquartile ranges (25th to 75th percentile), depending on data distribution.

2.4.2 Primary and Secondary Outcome Analyses

To evaluate the effects of the intervention over time, Generalized Estimating Equations (GEE) with appropriate link functions will be applied (e.g., logit for binary outcomes and identity for continuous outcomes). The models will include study arm, time (follow-up round), and their interaction to estimate the effect of the intervention across time points. Robust standard errors will be used to account for within-subject correlation due to repeated measurements. For incidence outcomes (e.g., HIV, chlamydia, and gonorrhea infections), person-time will be calculated, and incidence rate ratios (IRRs) with 95% confidence intervals will be reported.

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 [8], 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 survey items such as those related to sexual behavior and HIV status may be considered sensitive. To minimize potential risks, several protective measures will be implemented. All surveys will be administered anonymously, and data will be stored securely using encrypted systems with restricted access, ensuring that no personally identifiable information is collected.

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. Field researchers will be available throughout the study to provide support, clarify procedures, and address any concerns. Participants will also be referred to mental health or HIV-related services as appropriate.

In addition, participants who are diagnosed with a sexually transmitted infection such as chlamydia or gonorrhea will receive preliminary counseling and will be referred to appropriate healthcare facilities for further examination and treatment, in accordance with Ministry of Public Health guidelines.

Furthermore, a Data and Safety Monitoring Board (DSMB) will be established to oversee the study's risk mitigation strategies and ensure the ongoing protection of participant safety and well-being. The DSMB will also be responsible for monitoring ethical compliance, providing independent review of study procedures, and advising the research team on any necessary protocol modifications to uphold ethical and safety standards throughout the study.

2.6. Data management

Data will be collected using the Qualtrics platform, with force-response enabled for critical items and programmed skip logic applied where appropriate. After data collection, datasets will be exported, cleaned, and processed using STATA.

Participant data across follow-up rounds will be linked using a Unique Identification Code (UIC) and, for data retrieved from the Ministry of Public Health, the national identification number. All personally identifiable information will be protected through double encryption and securely stored on password-protected servers hosted at Mahidol University. Access to these data will be restricted to authorized personnel only, including the Principal Investigator (PI) and designated data managers.

2.7 Recording and reporting of risk events and incidents

In the event that an adverse or risk-related incident occurs during the study, the research team will document and review the incident systematically. Key information such as the nature of the incident, time of occurrence, individuals involved, and any immediate actions taken will be recorded.

The research team will assess the severity of the incident and determine appropriate follow-up measures. Incidents considered serious or potentially affecting the safety and well-being of participants will be promptly reported to the Data and Safety Monitoring Board (DSMB) for independent review and recommendations. Such incidents will also be reported to the Institutional Review Board (IRB) within the required timeframe in accordance with ethical guidelines.

The research team has clear procedures in place to respond to such incidents in a timely, transparent, and appropriate manner. All incident records will be stored securely and treated as confidential. Participants will also be able to report any concerns or discomfort through confidential communication channels available throughout the duration of their participation in the study.

3. Funding

This study is funded by the National Institute of Mental Health (NIMH), under Grants R01MH119015.

4. Monitoring and auditing

The Principal Investigator (PI) will be responsible for overseeing the overall implementation of the study and ensuring adherence to the approved protocol and ethical standards. In addition, two Project Managers will be assigned to supervise and coordinate different study components, with one responsible for the intervention arm and the other for the control group, to ensure fidelity to procedures and consistency across study sites.

Local implementation and data collection activities will be supported by provincial-level advisors, including representatives from provincial hospitals and Provincial Public Health Offices who will assist in monitoring field operations and ensuring data quality in their respective provinces.

A Community Advisory Board (CAB) will be engaged to provide guidance on participant recruitment strategies and the implementation process, ensuring community involvement and cultural appropriateness throughout the study.

Internal monitoring will be conducted regularly by the core study coordination team to verify data accuracy, review informed consent procedures, and ensure compliance with study protocols, including biospecimen handling and confidentiality safeguards.

The Data and Safety Monitoring Board (DSMB) will conduct independent reviews of study progress, risk events, and participant safety data on a scheduled basis. Additionally, representatives from the Institutional Review Board (IRB) or study sponsors may perform audits to assess protocol compliance, ethical conduct, and data integrity.

All findings from monitoring and auditing activities will be recorded, and any deviations from the protocol will be addressed through corrective actions. Reports will be submitted to the IRB and DSMB as required, and follow-up actions will be tracked to ensure continuous quality assurance throughout the study.

5. Publication and dissemination

The findings from this study will be disseminated through a range of channels to ensure impact at both academic and programmatic levels. Results will be published in peer-reviewed journals and presented at national and international conferences to contribute to the scientific knowledge base. All publications will adhere to ethical guidelines, ensuring the confidentiality of participants and transparent reporting of both positive and negative outcomes.

In addition to academic dissemination, the study team will share summary findings with key stakeholders, including local health authorities, service providers, NGOs, and community-based organizations. Plain-language summaries will be prepared where appropriate to enhance accessibility among non-academic audiences, including community members and local decision-makers.

Given the intervention-focused nature of the study, particular attention will be given to engaging multi-sectoral partners in the study areas to support the refinement and potential scale-up of effective components. Collaboration will include government agencies, the public health system, local NGOs, and community networks. These partnerships are intended not only to support the implementation of the intervention but also to foster sustainability and integration into existing systems beyond the research period.

A Community Advisory Board (CAB) will be consulted in the development of community dissemination strategies to ensure that findings are returned in a culturally appropriate and meaningful manner. Authorship on all publications will be determined based on substantial contributions, following international authorship guidelines (e.g., ICMJE). All dissemination activities will be reviewed and approved by the Principal Investigator.

6. References

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7. Annexes

7.1 Participant Information Sheet

Participant Information Sheet and Informed Consent Form for Survey Participation

Note: This document may contain information that you do not fully understand. Please ask the principal investigator or their representative to explain it to you until you are completely clear.

Study Title	Addressing the continuum of care among high-risk Thai
Principal Investigator	Associate Professor Dr. Thomas Guadamuz
Affiliation:	Faculty of Social Sciences and Humanities, Mahidol University
Contact Numbers	During office hours: 02 441 9184, After hours: 086 084 4154
Study Sites:	Maha Sarakham Province and Ubon Ratchathani Province, Thailand
Funding Agency	National Institutes of Health (NIH), United States

Project Summary: This research project aims to: 1. Explore the sociocultural contexts related to risk behaviors and access to health services among young men who have sex with men (YMSM), in order to develop culturally appropriate health promotion and HIV prevention interventions that align with the lived experiences of youth. 2. Implement intervention activities designed to increase the rate of HIV testing and regular retesting among YMSM, as well as improve access to antiretroviral therapy (ART) and continuous HIV care among HIV-positive youth. The project will include both intervention and control provinces. 3.Compare knowledge, prevention practices, HIV testing behaviors, and access to HIV treatment among YMSM across the two study sites (intervention vs. control), in order to evaluate the effectiveness of the intervention activities conducted in the intervention site.

You are invited to participate in this study because you identify as a man who has sex with men (MSM), are between the ages of 18 and 29, and reside in one of the study sites selected by the researchers.

Total number of study participants 300 participants per province (600 participants in total)

The total duration of the study is 3 years (June 2020 – May 2023)

If you agree to participate in this research study, the researchers will ask you to:

1. You will be asked to complete a questionnaire on your electronic device via a link sent to you through the contact method you provide. The questionnaire consists of nine sections: (1) demographic information, (2) sexual behaviors, (3) HIV status, (4) sexually transmitted infections, (5) substance use, (6) PEP and PrEP, (7) mental health, (8) social stigma, and (9) social support. The questionnaire contains approximately 94 items and will take about 15 minutes to complete. You will be asked to complete this questionnaire five times over a three-year period, once every six months.
2. You will be asked to undergo testing for sexually transmitted infections once per year for three years. This includes testing for gonorrhea and chlamydia, using self-collected specimens from the rectum and urine. The study team will send you the testing kits and provide your results. If you are diagnosed with a sexually transmitted infection, field staff will assist you in accessing appropriate treatment in accordance with your healthcare coverage.
3. If you are a person living with HIV, the research team will request your permission to access your treatment records, including your viral load and CD4 results, as well as records of screening and treatment for sexually transmitted infections.

- The information you provide through the questionnaire will be recorded using a code in place of your name and personal details. All personal data and any other information related to you will be destroyed after the completion of the study.
- While participating in this research, you may feel uncomfortable or distressed by some of the questions. You have the right to skip any question that you do not wish to answer. You also have the right to withdraw from the study at any time without prior notice. Choosing not to participate or deciding to withdraw from the study will have no negative consequences for you in any way.
- Your personal information will be kept confidential and will not be disclosed to the public in any individually identifiable form. Research findings will be reported in aggregate form only. Access to your information will be limited to members of the research team and the Human Research Ethics Committee.
- You will receive a compensation of 300 Baht for each participation in this study.
- If you have any questions regarding this research study, you may contact the Principal Investigator, Associate Professor Dr. Thomas Guadamuz, at 02 441 9184 during office hours or 086 084 4154 outside office hours.
- This research study has been approved by the Committee for Research Ethics (Social Sciences), Mahidol University. The committee office is located at the Faculty of Social Sciences

and Humanities, Mahidol University, Phutthamonthon Sai 4 Road, Salaya Subdistrict, Phutthamonthon District, Nakhon Pathom 73170. Telephone: 0 2441 9180, Fax: 0 2441 9181. If you feel that you have not been treated in accordance with what has been described in this document, you may contact the Chair of the Ethics Committee or their representative at the address and telephone number provided above.

Thank you for taking the time to complete the questionnaire.

Sincerely,

Associate Professor Dr. Thomas Guadamuz

7.2 Consent Form

Form of Informed and Voluntary Consent to Participate in Research

Participant Information			
Date ..... /..... /.....			
Full Name		Age	years
House Number		Street	
Subdistrict		District	
Province		Postal Code	
Phone Number			

I hereby express my consent to participate as a subject in the research project entitled	Addressing the continuum of care among high-risk Thai

I have been fully informed of the research project's background and objectives, the details of procedures I will undertake and receive, the expected benefits of the research, and any potential risks that may arise from participating in the study, as well as the measures in place to prevent and manage such risks. I have thoroughly read the information sheet provided to research participants, received sufficient explanations, and had my questions answered by the principal investigator.

Therefore, I voluntarily agree to participate in this research project.

I understand that I have the right to request further information regarding the benefits and potential risks of participating in this study, and that I may withdraw or decline to participate at any time without any consequences to my access to current or future healthcare or services.

I consent to the research team's use of my personal data, including access to my HIV treatment records (if I am a person living with HIV) or records related to sexually transmitted infection (STI) treatment (if I am diagnosed with an STI). I understand that my confidentiality will be strictly protected, and my identity will not be disclosed. Research findings will be reported only in aggregate form and not at the individual level.

If I have any questions regarding the study, I may contact Associate Professor Dr. Thomas Guadamuz at 086 084 4154 or 086 690 0850 at any time.

If I believe that I have been treated in a manner inconsistent with what is described in the information sheet, I may contact the Chair or representative of the Committee for Research Ethics (Social Science) at the Office of the Ethics Committee for Human Research, Faculty of Social Sciences and Humanities, Mahidol University, Phutthamonthon Sai 4 Road, Salaya Subdistrict, Phutthamonthon District, Nakhon Pathom 73170, Tel: 02 441 9180, Fax: 02 441 9181 during official working hours.

I thoroughly understand the statements in the information sheet for the research subjects and in this consent form. I thereby give my signature.

Signature..... Participant
(.....)
Date.....

Signature..... Research staff obtaining consent
(.....)
Date.....

7.3 Statistical Analysis Plan (SAP)

Study Title: Addressing the Continuum of Care Among High-risk Thai Men

ClinicalTrials.gov Identifier (NCT Number): NCT05161689

Document Date: 01/01/2020

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 “Addressing the Continuum of Care Among High-risk Thai Men”. This SAP is designed to ensure that the analysis is transparent, reproducible, and aligned with the registered study protocol under ClinicalTrials.gov Identifier NCT05161689.

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 efficacy of the BAAN HUG-M intervention in:

- Reducing sexual risk behaviors
- Increasing the frequency of HIV testing (at least biannually)
- Promoting prompt and sustained engagement in HIV care

The study is conducted through a longitudinal cohort of young men who have sex with men (YMSM) (“YMSM Cohort”, *N* = 600) residing in Ubon Ratchathani (intervention site) and Mahasarakham (control site). Given the disproportionate burden of HIV among YMSM in Thailand, and the structural and behavioral barriers to care, this study addresses a critical public health challenge with implications for national HIV policy and intervention programming.[1-3]

2. Study Design Overview

This will be a prospective, longitudinal cohort study involving 600 young men who have sex with men (YMSM) aged 15–29 years, with equal allocation to two study sites:

- Intervention city: Ubon Ratchathani (n = 300)
- Control city: Mahasarakham (n = 300)

Participants will be followed for 24 months, with data collection scheduled at five time points: baseline, 6 months, 12 months, 18 months, and 24 months.

Data Collection and Sources

Data will be collected through online self-administered questionnaires hosted on the Qualtrics platform and completed using tablets or smartphones. To ensure anonymity while enabling longitudinal data linkage, no personal identifiers will be recorded. Instead, participants will enter a Unique Identification Code (UIC) at each round of data collection.

Retention and Follow-up

To promote high retention throughout the study period, the research team will implement continuous engagement strategies via digital platforms and peer-led community outreach. These efforts are expected to result in follow-up retention rates of greater than 60% at each follow-up time point.

3. Study Objectives and Endpoints

3.1 Primary Objective

To evaluate the effectiveness of the BAAN HUG-M intervention in increasing access to and engagement with the intervention activities, and in promoting HIV testing uptake among young men who have sex with men (YMSM) who have never previously been tested for HIV.

3.2 Secondary Objectives

- To evaluate the effect of the intervention on reducing HIV incidence.
- To evaluate the effect of the intervention on reducing the incidence of chlamydia trachomatis and gonorrhea infections.
- To evaluate the effect of the intervention on reducing sexual risk behaviors (e.g., condomless anal intercourse).
- To evaluate linkage to and retention in HIV care among HIV-positive participants, including the proportion with undetectable viral load.
- To evaluate the uptake of pre-exposure prophylaxis (PrEP) among HIV-negative participants.

3.3 Primary Outcome

- **HIV testing uptake:**
  Proportion of participants who report having ever tested for HIV during the 24-month follow-up period. Data will be collected from HIV testing records provided by the Ministry of Public Health national database.

3.4 Secondary Outcomes

- **HIV incidence:**
  Number of new HIV infections per 100 person-years, based on seroconversion during follow-up, using data from the Ministry of Public Health national HIV database.
- **Incidence of Chlamydia and Gonorrhea infections:**
  Number of new chlamydia and gonorrhea infections identified at each follow-up round, based on self-collected urine and anal specimens.
- **Sexual risk behavior:**
  Proportion of participants reporting condomless anal intercourse with male partners in the past 6 months, measured via self-reported survey data.
- **Retention in HIV care:**
  Proportion of HIV-positive participants who remain engaged in HIV care at months 6, 12, 18, and 24, based on data from the Ministry of Public Health national database.
- **Undetectable viral load:**
  Proportion of HIV-positive participants with a viral load of <200 copies/mL at each follow-up round, as reported in the Ministry of Public Health national database.
- **Current PrEP use:**
  Proportion of HIV-negative participants who report currently using PrEP at each follow-up round, based on self-reported data.

4. Analysis Populations

4.1 Intention-to-Treat (ITT) Population

The ITT population will include all participants who completed the baseline assessment and were assigned to either the intervention or control site, regardless of their level of

participation in the intervention activities thereafter. This population will serve as the primary analytic population for evaluating the effectiveness of the intervention, reflecting real-world implementation outcomes.

4.2 High Exposure Subgroup

This subgroup will include participants from the intervention site who reported a high level of engagement with the BAAN HUG-M intervention activities at each follow-up round. This subgroup will be analyzed separately to evaluate the impact of sustained and intensive participation on health behaviors and outcomes.

5. Data Management and Quality Assurance

5.1 Handling of Missing Data

Data collection will be conducted using an online survey platform (Qualtrics)[4] with enforced “force response” and appropriately programmed skip logic to minimize item non-response and ensure completeness of key variables. These design features significantly reduced the risk of missing data, especially at baseline.

However, due to the longitudinal nature of the study and the possibility of participant drop-out or missed follow-up visits, some missing data may still occur, particularly in follow-up rounds. In such cases, missing values will be clearly identified and coded within the dataset.

For statistical analysis, appropriate methods will be employed to handle missing data. When the proportion of missing data is non-trivial, we will compare the characteristics of participants with complete versus incomplete data. Depending on the nature and extent of missingness, we will use multiple imputation (MI) or maximum likelihood (ML) methods under the assumption that the data are missing at random (MAR).[5] Sensitivity analyses using pattern-mixture models will also be conducted to assess the robustness of the MAR assumption.[6] Complete case analysis may be applied in cases where missingness is minimal and ignorable.

5.2 Data Cleaning and Preparation

Following data export from the Qualtrics platform, the research team will perform systematic data cleaning procedures to ensure data quality, consistency, and readiness for analysis. This process will be conducted using STATA[7] syntax and command scripts to automate checks and corrections.

Key steps in data cleaning will include the detection of outliers and logically inconsistent responses, verification of skip logic compliance, and range checks for numeric variables. Variables that are expected to align conditionally (e.g., responses to dependent questions) will be cross validated for logical coherence.

In preparation for analysis, data from three key sources will be merged and harmonized:

- Self-administered questionnaires (Qualtrics)
- Laboratory-based test results (chlamydia and gonorrhea from self-collected urine and anal specimens)

• HIV-related clinical data (e.g., HIV status, ART access, viral load) from the Ministry of Public Health national HIV database.

To enable accurate data linkage across timepoints and data sources, participants will be assigned a Unique Identification Code (UIC), which comprises parts of the participant's last name and date of birth. Additionally, linkage to the Ministry of Public Health national HIV database will use the participant's 13-digit national ID number alongside the UIC to ensure robust data matching. The UIC will play a central role in aligning participant records across survey rounds, lab results, and national HIV data systems while preserving confidentiality.

5.3 Variable Coding and Labeling

All variables will be coded and labeled systematically following a standardized data dictionary. Coding will be consistent across all follow-up rounds. For example, dichotomous variables will be labeled as "1 = Yes" and "0 = No," and Likert-scale items will include clearly defined scales. This consistency supports accurate interpretation, longitudinal comparison, and reproducibility of analyses in the future.

6. Statistical Methods

6.1 Descriptive Analysis

Descriptive statistics will be used to summarize baseline characteristics and study variables, stratified by study arm (intervention vs. control). All statistical comparisons will be made between the two study sites — Ubon Ratchathani (intervention site) and Mahasarakham (control site) to assess the impact of the BAAN HUG-M intervention over time. Frequencies and percentages will be used for categorical variables and means with standard deviations or medians with interquartile ranges will be used for continuous variables, depending on their distribution.

6.2 Primary and Secondary Outcome Analyses

To evaluate the effects of the intervention over time, Generalized Estimating Equations (GEE) with appropriate link functions (e.g., logit for binary outcomes, identity for continuous outcomes) will be used.[8] The models will include study arm (intervention vs. control), time (follow-up visits), and their interaction term to estimate intervention effects over time. Robust standard errors will be used to account for within-subject correlation. Person-time will be calculated and compared using rate ratios and 95% confidence intervals.

6.3 Multiple Comparisons and p-value Adjustment

If multiple statistical comparisons are conducted for secondary outcomes or subgroup analyses, adjustments for multiple testing will be considered using methods such as Bonferroni or false discovery rate (FDR) correction to control for type I error.

6.4 Statistical Software

All analyses will be conducted using STATA (version 18.0), which is the primary software tool used by the research team for data management, descriptive statistics, regression modeling, and longitudinal analyses.

7. Subgroup and Sensitivity Analyses

7.1 Subgroup Analysis

Subgroup analysis will be conducted to explore whether the effects of the intervention vary across specific participant characteristics. Pre-specified subgroups will include:

- Age groups (15–19, 20–24, 25–29 years)
- Level of exposure to the BAAN HUG-M intervention (high vs. low/moderate — intervention site only)
- Province (Ubon Ratchathani vs. Mahasarakham)

Interaction terms will be incorporated into the GEE models to evaluate whether intervention effects differ significantly across these subgroups.

7.2 Sensitivity Analysis

Sensitivity analyses will be performed to examine the robustness of the study findings under alternative assumptions. These may include:

- Varying the model assumptions (e.g., using alternative link functions or comparing GEE models with mixed-effects models)

8. References

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