PROTOCOL TITLE:
Adapting an Intervention to Reduce Stigma among MSM and Healthcare Providers in Vietnam

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1.0 Study Summary

Study Title	Adapting an Intervention to Reduce Stigma among MSM and Healthcare Providers in Vietnam
Study Design	Randomized wait-list controlled trial (pilot)
Primary Objective	Assess the feasibility, acceptability, and fidelity of the adapted intervention among men who have sex with men (MSM) and healthcare providers (HCP) in Hanoi, Vietnam.
Secondary Objective(s)	Test whether, relative to wait-list control, intervention participants: (1) experience reductions in immediate and sustained HIV-related, PrEP-related, and intersectional stigma and discrimination; (2) experience improvements in HIV continuum-of-care outcomes (HIV testing, PrEP uptake and adherence, ART uptake and adherence); and (3) experience improvements in self-efficacy, empowerment, and mental health.
Research Intervention(s)	DONGHANH, a culturally adapted version of FRESH: a ten-module, one-and-a-half-day, in-person workshop that brings MSM and HCP together, supplemented by an e-module (website) co-designed with participants.
IND/IDE #	N/A
Study Population	MSM and HCP recruited from HIV outpatient clinics (OPCs) and community-based organization (CBO) clinics in Hanoi, Vietnam
Sample Size	**Aim 1:** IDIs with 20 MSM and 20 HCP; 2 focus groups (7 MSM; 7 HCP); theater testing (7 MSM; 7 HCP); e-module concept focus groups (7 MSM; 7 HCP); 2–3 topical experts. **Aim 2:** 180 participants (120 MSM, 60 HCP). **Aim 3:** focus groups with 10 MSM, 10 HCP, and 10 DONGHANH staff.
Study Duration for Individual Participants	Aim 2: 3 and 6 months post-intervention
Study Specific Abbreviations / Definitions	CAB – Community Advisory Board; CBO – community-based organization; FGD – focus group discussion; HCP – healthcare providers; MSM – men who have sex with men; OPC – HIV outpatient clinic; PrEP – pre-exposure prophylaxis; WLC – wait-list control.

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives.

We propose to culturally adapt and pilot test a patient–provider stigma-reduction intervention, FRESH, to address intersectional stigma and enhance HIV prevention among MSM and HCP in Vietnam. The adapted intervention is called DONGHANH. The study has three aims:

- **Aim 1.** Adapt the patient–provider FRESH intervention into DONGHANH to address the intersectional stigmas experienced by MSM in Vietnam.
- **Aim 2.** Pilot DONGHANH in a randomized wait-list controlled trial to assess feasibility, acceptability, and fidelity, and to obtain preliminary efficacy estimates for HIV-related intersectional stigma and HIV continuum-of-care outcomes.
- **Aim 3.** Assess barriers and facilitators to implementation to inform future adoption and scale-up.

2.2 State the hypotheses to be tested.

We will test four hypotheses, one primary and three secondary:

- **H1 (primary).** DONGHANH intervention will be feasible, acceptable, and deliverable with fidelity among MSM and HCP.
- **H2 (secondary).** DONGHANH intervention participants will show greater reductions at 3 months, relative to wait-list control, in HIV-related stigma, PrEP stigma, and intersectional stigma and discrimination.
- **H3 (secondary).** DONGHANH participants will show greater improvement, relative to wait-list control, in HIV testing, PrEP uptake and adherence, and ART uptake and adherence.
- **H4 (secondary).** DONGHANH participants will show greater improvement, relative to wait-list control, in self-efficacy, empowerment, and mental health.

3.0 Background

3.1 Describe the relevant prior experience and gaps in current knowledge.

Men who have sex with men (MSM) bear a disproportionate and growing burden of HIV worldwide, particularly where stigma and discrimination are high. In Vietnam, an estimated 250,000 people were living with HIV in 2023, and the epidemic is concentrated among MSM, people who inject drugs, and female sex workers. HIV prevalence among MSM rose from 6.6% in 2015 to 12.5% in 2023, even as prevalence declined in the other two groups (UNAIDS, 2023). Only about 30.5% of MSM in Vietnam are covered by HIV prevention programs (UNAIDS, 2023).

Uptake of prevention services remains low. A recent study found that 82% of young MSM in Vietnam had heard of PrEP but only 36% had ever used it, and only 58% had ever been tested for HIV (Nguyen et al., 2024). PrEP persistence declines from 89% at three months to 47% at 18 months (Green et al., 2021). Intersectional stigma, an overlapping stigma related to sexual orientation and HIV, is a major barrier to HIV testing, PrEP uptake, and adherence (Philbin et al., 2018). In Vietnam, MSM were historically labeled “social evils” (tệ nạn xã hội), and the early association of HIV with MSM, together with collectivist norms that emphasize family reputation and lineage continuity, has reinforced concealment of sexual identity and avoidance of care.

Healthcare settings are a critical site of stigma. In a 2019 study in Hanoi and Ho Chi Minh City, 12.7% of healthcare workers said they would refuse to provide services to MSM if given a choice (Nguyen et al., 2019). A 2022 study found that 81% of HCP feared HIV infection and 54% held negative attitudes toward people living with HIV (Pollack et al., 2022). Yet few stigma-reduction interventions in Vietnam involve both patients and providers.

eHealth offers a promising venue. About 97.5% of internet users in Vietnam owned a mobile phone in 2023, nearly 92% of MSM use online technologies, and 75% of them use smartphones to locate HIV testing services. To our knowledge, FRESH has not been digitalized.

3.2 Describe any relevant preliminary data.

- **FRESH.** FRESH is a participatory, workshop-based intervention that brings clients and healthcare providers together to reduce stigma in health facilities. It was developed in five African countries (Uys et al., 2009), adapted and piloted in the United States (Batey et al., 2016), and adapted for the Dominican Republic (Budhwani et al., 2022). A similar adaptation is being

piloted in Guatemala (R01TW012904; MPI Orellana). FRESH has not been tested in Asia or in a collectivist society such as Vietnam.

- **Stigma-reduction principles.** FRESH meets the key principles for effective facility-based stigma reduction: addressing actionable drivers of stigma, centering affected groups, and building partnerships between affected groups and opinion leaders (Nyblade et al., 2021).
- **Team experience.** The investigators have led HIV and stigma research in Vietnam, India, China, Malaysia, and the U.S., including an R21 on HIV risk among young women migrant workers in Vietnam (R21MH118986), and mHealth development and testing (R21TW011665, R21AI157857, R34MH130233) in Malaysia. The Vietnam partner (ISMS) has conducted more than 40 studies with MSM, people with HIV, and other key populations, and has an established network of OPCs and CBO clinics in Hanoi.

3.3 Provide the scientific background, rationale, and significance of the research.

DONGHANH is grounded in three theories and a set of stigma-reduction principles. **Intergroup Contact Theory** (Allport, 1954) holds that structured contact between groups can reduce prejudice; here, interaction between MSM and HCP is intended to build empathy and improve communication. **Social Cognitive Theory** (Bandura, 1991) identifies outcome expectations, behavioral capability, observational learning, self-efficacy, and environmental factors as determinants of behavior change. **Empowerment Theory** (Perkins & Zimmerman, 1995) emphasizes participation and control; participants co-create stigma-reduction tools and strategies to take back to their communities. By addressing actionable drivers of stigma (fear and misconceptions about HIV, shame and blame), DONGHANH is hypothesized to reduce intersecting stigmas and thereby improve psychological resources, mental health, and interpersonal factors that influence engagement with HIV prevention and care.

The study has several innovative features: (1) adaptation of FRESH to a collectivist Asian setting; (2) a co-design approach in which MSM and HCP help shape materials and the e-module; (3) a novel e-module that extends reach and scalability; (4) integration with a status-neutral continuum of care; and (5) simultaneous work at the patient and provider levels. Findings will inform a larger hybrid effectiveness–implementation trial.

4.0 Study Endpoints

4.1 Describe the primary and secondary study endpoints.

The primary endpoints are the feasibility, acceptability, and fidelity of DONGHANH among MSM and HCP, assessed at 3 months post-intervention in Aim 2 (participation and retention, modules attended, acceptability, appropriateness, feasibility, satisfaction, fidelity, and e-module usability). Secondary endpoints are preliminary changes at 3 and 6 months post-intervention in HIV-related, PrEP, and intersectional stigma and discrimination; HIV testing; PrEP and ART uptake and adherence; self-efficacy; empowerment; and mental health (6 months for the intervention arm only).

4.2 Describe any primary or secondary safety endpoints.

If participants experience undue stress, emotional distress, or discomfort during their sessions, they will be given the option to unenroll from the study and leave the session.

5.0 Study Intervention / Test Articles

5.1 List and describe any article or product that may be evaluated in the research.

Training manual. The final content and format will depend on the Aim 1 adaptation results, but the core elements of FRESH will be retained: sharing information and knowledge about HIV and stigma; increasing contact between HCP and people with or affected by HIV; empowerment strategies to improve coping with stigma; and development of stigma-reduction tools to disseminate at the community level. The adapted intervention is a one-and-a-half-day, in-person workshop of ten modules. The focus group guide covers four main module groups: (1) foundational knowledge about stigma, including anticipated, internalized, experienced, and community-perceived stigma, with a "tree" activity identifying causes (roots) and consequences (leaves); (2) intersecting identities, using a "genderbread person" diagram and paired sharing; (3) coping and systemic or institutional barriers; and (4) action planning and practical solutions, including communication, intake procedures, welcoming posters, and digital tools. Each workshop includes 12 MSM and 6 HCP and is led by three facilitators: one MSM, one HCP, and one co-facilitator experienced in HIV prevention and group work.

Wait-list control. Control participants receive no intervention for 3 months and are then offered the workshop.

5.2 Handling of articles or products.

The facilitator manual, participant materials, and fidelity checklists are controlled by the study team at ISMS and distributed only to trained facilitators and workshop participants.

5.3–5.4 FDA-regulated products; IND/IDE.

N/A. DONGHANH manual is a behavioral and educational intervention.

6.0 Procedures Involved

6.1 Describe and explain the study design.

The study follows the ADAPT-ITT model (Wingood & DiClemente, 2008). Steps 1–7 (Aim 1) produce the adapted intervention; Step 8 (Testing) is the Aim 2 pilot trial; Aim 3 is the implementation evaluation.

Aim 1. Adapt FRESH into DONGHANH (ADAPT-ITT Steps 1–7)

Step	Activities	Participants
1. Assessment	Individual in-depth interviews (IDIs) and one focus group discussion (FGD) per group to explore sources and characteristics of intersectional stigma in healthcare settings, impact on HIV testing, PrEP uptake, and ART adherence, coping, and (for HCP) attitudes, barriers, and facilitators to delivering HIV services. Audio-recorded; analyzed with rapid qualitative analysis (RQA).	20 MSM and 20 HCP (IDIs); 7 MSM and 7 HCP (FGDs)
2. Decision	The research team, local partners, and CAB review all FRESH components and decide which need cultural and linguistic adaptation, informed by Step 1 findings.	Study team, CAB (no new participant data)
3. Administration (theater testing)	A preliminary Vietnamese curriculum and facilitator guides are developed. Modules of the adapted intervention are delivered to target-population members; feedback is collected through an FGD and a written post-intervention process survey. Dr. Nguyen and 3–5 local HIV prevention	Theater test: 7 MSM and 7 HCP. E-module FGDs: 7 MSM and 7 HCP

Step	Activities	Participants
	stakeholders observe and give feedback. Separately, FGDs gather reactions to the e-module concept design and sitemap (visual appeal, content, interactivity, usability, cultural relevance).	
4. Production	First formal draft of DONGHANH using a six-stage adaptation plan (aim, original intervention, new population, components requiring modification, aim of each adaptation, new materials); quality-assurance and process-evaluation procedures for recruitment, retention, survey administration, and consent.	Study team
5. Topical experts	Two to three Hanoi-based experts in stigma, Vietnamese collectivist culture, and HIV research, plus the FRESH expert (Dr. Orellana) and CAB, review the draft in person and by video conference.	2–3 experts; CAB
6. Integration	Expert feedback is integrated; Vietnamese-language training manual and adapted measures are finalized; readability test of all materials with study team and CAB.	Study team, CAB
7. Training	Five-day training for 4 ISMS research staff and 4 MSM community representatives who will serve as facilitators, led by Drs. Ha, Nguyen, and Orellana (role-plays, problem-solving, group facilitation). Training content is standardized into a manual.	8 facilitators/staff

Procedures for interviews and focus groups. Trained research assistants conduct sessions in a private room at the ISMS research office or at a place selected by the participant. Participants arrive 15 minutes early to review the IRB-approved consent form and interview guide and to sign the consent form. Names appear only on signed consent forms, which are stored separately; interview data carry study codes only. Each session begins with an introduction and ground rules (no interruptions, respect for others' comments, confidentiality). IDIs last about 45–60 minutes (per the IDI consent forms) and FGDs about 1–1.5 hours; sessions are digitally audio-recorded with consent (participants may decline recording).

Data analysis (Aim 1). Interviews and focus groups are audio-recorded, transcribed verbatim in Vietnamese, translated, and analyzed using Rapid Qualitative Analysis (RQA) (Kowalski et al., 2024). Team members summarize transcripts into templates organized by interview domains, review each other's summaries, and meet to reach consensus; results guide the next adaptation step.

Aim 2. Pilot randomized wait-list controlled trial (ADAPT-ITT Step 8)

Design. A total of 180 participants (120 MSM, 60 HCP) will be randomized 1:1 to the DONGHANH intervention (60 MSM, 30 HCP) or a 3-month wait-list control (60 MSM, 30 HCP). Intervention participants attend five workshops of 12 MSM and 6 HCP each (n=90). To limit contamination, each workshop will be delivered in a geographically distant district of Hanoi. Wait-list participants receive the workshop after their 3-month assessment.

Screening, consent, and randomization. Screening, eligibility, and enrollment follow Aim 1 procedures (Section 10.0). Trained ISMS staff obtain written informed consent, administer the baseline assessment, and then randomize the participant.

Intervention delivery. Workshops are led by three trained facilitators (one MSM, one HCP, one co-facilitator). Drs. Ha, Nguyen, and Orellana provide coaching, especially during training and in debriefs on group dynamics after each workshop. A fidelity checklist is used to rate each workshop; trained observers complete the ratings.

Assessment schedule. Assessments are completed at baseline, 3 months, and 6 months post-intervention. Wait-list control participants complete assessments at baseline and at 3 months post-randomization. Because this is a pilot feasibility trial, wait-list participants complete only baseline and 3-month assessments and do not complete a 6-month follow-up. Intervention participants complete assessments at baseline, 3 months post-intervention, and 6 months post-intervention.

Measures. See Table 6-1. Implementation outcomes (acceptability, appropriateness, feasibility, satisfaction, fidelity) are analyzed at the 3-month post-intervention time point.

Table 6-1. Outcome measures and assessment schedule

Construct	Measure / Source	Group	Time	Notes
Feasibility	Participation rate, modules attended; 4-item feasibility questionnaire (Proctor et al., 2011)	MSM, HCP	3m	Target retention ≥85%
Acceptability / Appropriateness / Satisfaction	4-item acceptability and 4-item appropriateness questionnaires; satisfaction items	MSM, HCP	3m	Target score ≥4/5
Fidelity	Session fidelity checklist (% activities delivered; quality score)	Workshops	Each workshop	Observer rated
E-module Usability	System Usability Scale (SUS)	MSM, HCP	3m	Target SUS ≥70
HIV-related Stigma	HIV Stigma Scale; brief facility-staff HIV stigma questionnaire for HCP	MSM, HCP	BL, 3m, 6m	Primary outcome domain
Sexual Orientation Stigma	Homosexuality-related stigma scale, Vietnamese-adapted version	MSM, HCP	BL, 3m, 6m	—
Intersectional Stigma / Discrimination	Intersectional Discrimination Index; Experiences of Discrimination	MSM, HCP	BL, 3m, 6m	—
PrEP Stigma	PrEP Anticipated Stigma Scale	MSM, HCP	BL, 3m, 6m	—
HIV Testing & Care	Self-report; 3-item adherence measure	MSM	BL, 3m, 6m	PrEP/ART uptake & adherence
Knowledge	HCP: Brief HIV Knowledge Questionnaire. MSM: PrEP knowledge, motivation, self-efficacy; ART knowledge	MSM, HCP	BL, 3m, 6m	—
Self-efficacy	MSM: general self-efficacy. HCP: self-efficacy for behavior change	MSM, HCP	BL, 3m, 6m	—
Empowerment	Health Care Empowerment Inventory	MSM	BL, 3m, 6m	—
Mental Health	PHQ-8; GAD-7; Rosenberg Self-Esteem Scale	MSM	BL, 3m, 6m	—
Perceived HIV Risk & Contact	Perceived Risk of HIV Scale	HCP	BL, 3m, 6m	—
Demographics	Age, education, occupation/role, sexual identity, HIV status, clinic type	All	BL	Baseline covariate

BL = baseline; 3m = 3-month follow-up; 6m = 6-month follow-up; MSM = men who have sex with men; HCP = healthcare providers; SUS = System Usability Scale.

Data management and analysis (Aim 2). See Section 17.1 for the statistical analysis plan and power.

Aim 3. Evaluate barriers and facilitators to implementation

Guided by CFIR (Damschroder et al., 2009) and ERIC (Powell et al., 2015), we will conduct focus groups with DONGHANH participants including MSM (n=10) and HCP (n=10), and DONGHANH project staff (facilitators and interviewers; n=10). Discussions will cover intervention characteristics (e.g., scalability and sustainability; whether the adaptation captured the lived experience of MSM), outer setting (e.g., barriers MSM face in accessing the intervention), inner setting (e.g., team cultural values; best workshop venues), and characteristics of individuals (e.g., the influence of HCP on peers' stigmatizing attitudes). Participants will also give feedback on 15–20 prioritized ERIC implementation strategies.

Acceptability and appropriateness are assessed with a brief 4-item questionnaire each, administered at the end of each session; e-module usability is assessed with the SUS and paradata (navigation paths, time spent, feature use), and participants give qualitative feedback on functionality and errors. Sessions are audio-recorded, transcribed, translated, and back-translated, and coded in Dedoose using a codebook of CFIR constructs, with CFIR rating guidelines used to identify positive/negative and weak/strong influences.

6.2 Describe all research procedures and when they are performed.

Table 6-2. Aim 2 schedule of procedures

Procedure	Intervention arm	Wait-list arm
Screening and written informed consent	Before baseline	Before baseline
Baseline assessment and randomization	Day 0	Day 0
DONGHANH workshop (1.5 days; 10 modules)	Shortly after baseline	After 3-month assessment
Retention contacts	Every 3 weeks post-intervention	Every 2 weeks (first 3 months); then every 3 weeks
3-month assessment	3 months post-intervention (includes implementation outcomes)	3 months after baseline, before workshop
6-month assessment	6 months post-intervention	Not collected
Safety monitoring	Throughout	Throughout

6.3 Procedures to lessen risk; articles used; source records.

Risk-minimization procedures are described in Section 15.0. No drugs, devices, biologics, or other regulated articles are used (Section 5.0). All instruments, scripts, and guides will be attached to the IRB submission in English and Vietnamese.

6.4 Describe what data will be collected and how.

Data include qualitative data (audio recordings and transcripts of IDIs and FGDs; observation notes from theater testing), quantitative survey data (Table 6-1), fidelity ratings, and e-module paradata. Surveys are administered by trained interviewers or self-administered using Qualtrics (Section 17.3).

6.5 Long-term follow-up.

N/A. The last study assessment is the 6-month post-intervention assessment.

6.6 Humanitarian Use Devices.

N/A.

7.0 Data and Specimen Banking

7.1–7.3: N/A. No specimens are collected. De-identified study data will not be banked beyond what is described in the NIH Data Management and Sharing (DMS) Plan.

7.4: This study is funded by NIH and is subject to the NIH Data Management and Sharing Policy; the DMS Plan is submitted with the application and will be uploaded to the IRB submission. In summary: (1) **Data types:** survey data from 120 MSM and 60 HCP (including recoded variables and redacted open-text responses) and digitally recorded interviews and focus groups. (2) **Sharing:** de-identified individual-level and aggregate survey data, de-identified and redacted interview transcripts, and coding summaries will be shared through the Mendeley Data repository (NIH GREI member) with a study DOI, along with codebooks, questionnaires, interview guides, consent forms, de-identification steps, and analysis code. Voice recordings are deleted after transcripts are generated and checked; raw transcripts are retained but not shared. (3) **Timing:** data from published manuscripts are shared at publication; all other data by the end of the award; data remain in the repository at least 7 years. (4) **Participant choice:** participants may decline data sharing during consent; once de-identified, data cannot be removed, and the consent process will explain this limit. (5) **Oversight:** Dr. Ha oversees the DMS Plan, with annual evaluations, monthly meetings with key personnel, and reporting in the Research Performance Progress Report.

8.0 Sharing of Results with Subjects

8.1 Describe whether results will be shared with subjects or others.

No individual clinical results are generated and individual survey responses will not be shared with anyone outside the study team, including clinic staff, employers, or other participants.

Dissemination plan. Dissemination will first focus on reporting aggregate results to the MSM community and HCP. A public event in an easily accessible location will allow research volunteers and members of the larger MSM community to learn about the results. The event will also serve as a platform to share results with LGBTQ-led organizations, academic researchers, NGOs, hospitals, clinics, and government agencies, including the Ministry of Health and the Vietnam Administration for HIV/AIDS Control. It will highlight the initial impact of DONGHANH on intersectional stigma and HIV prevention and care among MSM and advocate for national scale-up to increase HIV testing, PrEP uptake, and adherence to PrEP and ART among MSM and other high-risk groups. Additional efforts include presentations at national, regional, and international conferences (e.g., the International Conference on HIV/AIDS) and peer-reviewed publications of the protocol and findings. The CAB will help develop dissemination strategies.

9.0 Study Timelines

9.1 Describe the duration of individual participation, anticipated enrollment duration, and estimated completion date.

Table 9-1. Proposed study timeline

Activity	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Start-up and hiring												
CAB meetings (monthly Y1; quarterly after)												
Aim 1: Steps 1 (IDIs, FGDs) and RQA												
Aim 1: Steps 2–4 (Decision, theater test, Production)												
Aim 1: Steps 5–6 (Experts, Integration)												
E-module development												
Aim 1: Step 7 (Facilitator training)												
Aim 2: Recruitment, baseline, workshops												
Aim 2: Follow-up assessments (3, 6 months)												
Fidelity monitoring												
Aim 3: Implementation focus groups												
Data analysis												
Dissemination and wrap-up												
Safety team meetings (at least quarterly)												

Aim 1. One-time in-depth interview.

Aim 2. 1.5-day workshop for MSM and HCP, with follow-up assessments at 3 and 6 months post-intervention (6 months for the intervention arm only).

Aim 3. One-time focus group.

Enrollment and completion. Aim 1 begins in Year 1 (Steps 1–6) and finishes in Year 2 with facilitator training (Step 7). Aim 2 enrolls participants in Year 2 (Q2–Q4), with follow-up assessments continuing through Year 3, Q2. Aim 3 focus groups are conducted in Year 3 (Q1–Q2). The study period is 2026–2029. Primary analyses are expected to be completed by Year 3, Q3.

10.0 Inclusion and Exclusion Criteria

10.1 Describe how individuals will be screened for eligibility.

Individuals who respond to recruitment materials (in person, by phone, or through social media inboxes) undergo a brief screening by a trained research assistant to determine initial eligibility, based on self-report. Those who are not eligible are thanked and asked whether they want to be contacted about future studies. Those who appear eligible are told about the study and invited to take part in the informed consent procedures (Section 22.0). HCP employment at a participating clinic is verified by self-report.

Consistent with the status-neutral design, screening does not exclude anyone based on HIV status. MSM of any HIV status (positive, negative, or unknown) are eligible, and HIV status is self-reported.

Stigma Reduction Intervention

10.2 Describe the criteria that define who will be included or excluded.

Group	Criteria
MSM (Aims 1–3)	(1) HIV-positive, HIV-negative, or unknown HIV status (status-neutral); (2) age ≥18 years; (3) cisgender male; (4) self-reported history of condomless sex; (5) able to provide informed consent.
HCP (Aims 1–3)	(1) Age ≥18 years; (2) able to provide informed consent; (3) currently working at a participating OPC or CBO clinic.
DONGHANH staff (Aim 3)	Facilitators and interviewers who delivered or supported DONGHANH workshops and are willing to provide informed consent.
Aim 3 MSM and HCP	Must have participated in DONGHANH (Aim 2) and be willing to provide informed consent.
Exclusion	Unable to provide informed consent; unable to read and understand Vietnamese; currently enrolled in another HIV intervention study.

10.3 Special populations.

We will not include adults unable to consent, individuals under 18 years, or prisoners.

11.0 Vulnerable Populations

11.1 Additional safeguards for individuals vulnerable to coercion or undue influence.

N/A

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally.

Activity	Total	MSM	HCP	Project intervention staff	Notes
IDIs and focus groups (Aim 1)	54	27	27	—	20 IDIs (MSM and HCP each) + 7 FGD participants per group (MSM and HCP each)
Theater testing (Aim 1)	14	7	7	—	—
E-module concept focus groups (Aim 1)	14	7	7	—	—
Intervention: pilot trial (Aim 2)	180	120	60	—	Unique trial cohort

Stigma Reduction Intervention

Activity	Total	MSM	HCP	Project intervention staff	Notes
Contextual process: implementation focus groups (Aim 3)	30	10	10	10	MSM and HCP sub-sampled from Aim 2 (already counted in Aim 2); staff are separate individuals
Total accrual events	**292**	**171**	**111**	**10**	Count of all activity enrollments (sum of rows above)
Total unique community participants	**262**	**161**	**101**	—	Excludes the 20 Aim 3 MSM and HCP already counted in Aim 2 (292 − 20 − 10 staff = 262)

12.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

N/A

13.0 Recruitment Methods

13.1–13.3 Describe when, where, and how potential subjects will be recruited and identified.

All recruitment will be conducted in Hanoi by the Vietnam study team (ISMS). **MSM** will be recruited using in-person and online methods: peer referral (peer educators and CBO collaborators contacting individuals in their networks); flyers distributed and posted at local outreach and partner organizations, including OPCs, CBO clinics, and LGBT-led organizations' clinics; and posts on general and MSM-specific social media platforms, such as focused Facebook pages (e.g., Rainbow Village), the MSM Blue app, and Zalo, with contact details for research assistants so that interested people can reach out through social media inboxes or by phone. Drs. Nguyen and Bui will also use their CBO networks from prior ISMS studies.

HCP will be recruited directly from OPCs and CBO clinics (physicians, nurses, counselors, pharmacists, laboratory technicians, public health officers, and community health workers/peer educators at CBO clinics).

13.4 Describe materials used to recruit subjects.

Flyers, social media posts, and recruitment scripts will be developed with the CAB and written in plain Vietnamese. They will describe the study in general terms, state that compensation is provided, and include contact and IRB information. To protect privacy, materials will not require individuals to identify as MSM or as living with HIV in public settings. Materials will be submitted to the ISMS IRB before use.

13.5 Payment, reimbursement, or other incentives.

As reimbursement for time and travel, participants will receive $10 USD (or equivalent in VND) for each session, including IDIs, FGDs, and quantitative assessments at baseline, 3 months, and 6 months. Payment is not contingent on completing the entire study; participants who skip questions or withdraw still receive payment for completed activities.

14.0 Withdrawal of Subjects

14.1 Circumstances for withdrawal without consent.

An adverse event (AE) is any untoward event occurring during the study. AEs are classified as serious or non-serious, related or not related to study activities, and expected or unexpected. Serious AEs (SAEs) include death, life-threatening events, events requiring hospitalization, or events causing persistent or substantial disability. Investigators may withdraw a participant if continued participation poses a risk to the participant or others (e.g., disruptive behavior that threatens the safety of workshop participants) or if the participant can no longer provide consent. All AEs will be reported to the Lead PI, who will report to the ISMS IRB (the IRB of record) and, where required, to NIH (Section 18.0). SAEs related to study participation will trigger an immediate meeting of the PIs (Drs. Ha and Nguyen), and additional meetings will be arranged as needed following any emergent AE issues. Whether an affected participant continues is decided case by case by the PIs, depending on health conditions and any risks of continuing (Section 18.0). When a participant is discontinued, the PIs will complete the End of Study form, the AE/SAE form, and any problem report required by the ISMS IRB. Each ongoing AE or SAE will be followed until resolved or stabilized.

14.2 Orderly termination.

If a participant is withdrawn or the study is stopped, participants will be informed, offered referral to appropriate services if needed, and given the opportunity to ask questions. Workshop participants who withdraw mid-workshop may remain in the room only if they agree to the confidentiality ground rules.

14.3 Procedures when subjects withdraw.

Participants may withdraw at any time by verbal or written request. Data collected before withdrawal will be retained and analyzed unless the participant explicitly asks for removal. For focus groups and workshops, participants' contributions to group discussion cannot be fully removed from recordings or notes once the session has occurred; participants will be told this during consent.

15.0 Risks to Subjects

15.1 Reasonably foreseeable risks, discomforts, hazards, or inconveniences, and how risks are minimized.

We expect study procedures to pose no more than minimal risk. Risks are primarily psychological and social: emotional distress from sensitive questions, and unwanted disclosure of sexual orientation or HIV status, including by other participants in group sessions. These risks are low in probability, and we reduce them as described below (confidentiality safeguards, ground rules for groups, trained staff, and referral to counseling). The IRB will make the final risk determination.

Risk	Likelihood / magnitude	Minimization
Breach of confidentiality; unwanted disclosure of	Low probability; potentially serious and not easily reversible	Identifiers separated from data and stored on encrypted, access-controlled systems; study

Risk	Likelihood / magnitude	Minimization
sexual orientation or HIV status (social, legal, employment, family consequences)		IDs only; no names on transcripts; consent form and recruitment materials avoid revealing sexual orientation or HIV status; private interview rooms; participants not required to disclose HIV status or orientation in workshops; Certificate of Confidentiality (automatic for NIH-funded research).
Disclosure by other participants in group settings (FGDs, workshops)	Low–moderate; cannot be fully controlled	Ground rules and a confidentiality pledge at the start of every group; participants told that confidentiality cannot be guaranteed; first names/pseudonyms only; avoid grouping MSM with their own treating HCP where feasible; facilitators trained to redirect disclosures.
Emotional distress from sensitive questions or discussion of stigma, sexual behavior, HIV, or mental health	Moderate probability; usually mild and transient	Voluntary participation; may skip questions or take breaks; trained interviewers and facilitators; distress protocol with referral to counseling/mental health services through the CBO and clinic network (Section 25.0).
Suicidal ideation, abuse, or intent to harm others disclosed during the study	Low	Consent discloses limits of confidentiality; staff trained in risk assessment, escalation to qualified mental health professionals, and handling suicidality when a participant declines referral (active listening, respect for autonomy, local resources, safety planning); referral to HIV clinics, CBO clinics, or emergency services, or notification of authorities where required.
Group dynamics during MSM–HCP contact (conflict, feeling judged)	Low–moderate	Trained facilitators (one MSM, one HCP, one group-work expert); structured activities; debriefs after each workshop with coaching from senior investigators.
Online recruitment and e-module data privacy	Low	No identifying information on public posts; e-module accounts and paradata linked only to study IDs; secure hosting; vendor data-protection requirements.
HIV testing and seroconversion during the study (psychological and social impact of a positive result)	Low; potentially serious	MSM who report a positive HIV self-test are accompanied by the research team to Hanoi CDC clinics for confirmatory testing; those with a confirmed reactive test are offered referral to a clinic of their choice in Hanoi for treatment and care. All participants receive a Study and Medical Information Packet (study description, participant rights, contacts for the Pitt and ISMS human subjects offices, and study staff).
Inconvenience and time burden	Certain; minor	Flexible scheduling; compensation for time and transportation.

15.2 Deception or incomplete disclosure.

N/A. Participants will be told the study's purpose. Wait-list participants will be told they will receive the workshop after 3 months.

15.3 Procedures with currently unforeseeable risks.

N/A.

15.4 Risks to an embryo or fetus.

N/A.

15.5 Risks to others who are not subjects.

Participants may mention partners, colleagues, or patients. They will be asked not to use names or identifying details, and transcripts will be de-identified.

15.6 Children.

N/A. Individuals under 18 are excluded.

16.0 Potential Benefits to Subjects

16.1–16.2 Describe potential benefits.

Aim 1 and Aim 3 participants are not expected to benefit directly, except by having an opportunity to reflect on and discuss experiences with stigma and HIV services. Aim 2 intervention-arm participants may benefit through greater knowledge about HIV and stigma, improved coping, self-efficacy, and empowerment (MSM) and improved attitudes and skills (HCP); wait-list participants will be offered the workshop. The knowledge gained is expected to benefit MSM and HCP in Vietnam and similar settings.

17.0 Data Management and Confidentiality

17.1 Data analysis plan, including statistical procedures and power.

Qualitative analysis (Aims 1 and 3)

Aim 1 data are analyzed with RQA (Section 6.1). Aim 3 data are coded in Dedoose using a codebook of CFIR constructs and definitions, with CFIR rating guidelines and coding of the 15–20 prioritized ERIC strategies. Quantitative implementation measures are summarized descriptively. Fidelity is summarized as the percentage of session activities delivered as intended and the mean quality-of-delivery score.

Quantitative analysis (Aim 2)

- **Data preparation.** Analysis is conducted in SPSS and includes exploratory data analysis of all variables.
- **Missing data.** Amount, patterns, and correlates of missingness will be evaluated. If attrition is differential or high, multiple imputation with ten imputed datasets and pooling by Rubin's rules (Rubin, 1987) will be used.
- **Implementation outcomes.** Analyzed at the 3-month post-intervention time point among intervention-arm participants (MSM n=60; HCP n=30), the only participants who have completed

the workshop by that time. MSM and HCP are analyzed as separate samples using means and standard deviations for continuous outcomes and proportions for categorical outcomes.

- **Preliminary efficacy.** Intent-to-treat analysis including all randomized participants. Each outcome is modeled using a generalized linear mixed model (GLMM) or generalized estimating equations (GEE), as appropriate. The primary contrast is the intervention-by-time interaction (baseline to 3 months, intervention vs. wait-list). Planned contrasts within the intervention arm compare baseline with 3 months and baseline with 6 months.
- **Workshop cohort effects.** Models include dummy variables for workshop cohort and their interaction with the intervention effect; a likelihood ratio test compares models with and without workshop-specific effects. If effects differ by workshop, effects are estimated by cohort and combined as a weighted average.

Sample size and power

This pilot is not powered to detect statistically significant efficacy and will provide preliminary effect size estimates only. For MSM, assuming 80% power, Type I error of 5%, and moderate temporal stability of measures (r=0.40), post-baseline data from 50 participants per group (60 per group enrolled, allowing 15% attrition) can detect an effect size as small as d=0.57 for the intervention-by-time interaction. For HCP, 27 participants per group (30 per group enrolled, allowing 10% attrition) can detect d=0.78. Estimates are conservative because longitudinal models use all available data, including partial data (UCSF CTSI sample size calculators, sample-size.net).

17.2 Quality control of collected data.

Interviewers and facilitators complete standardized training. Surveys use Qualtrics with range and logic checks. Transcripts are checked against recordings, and translations are back-translated. The study biostatistician reviews data for completeness and consistency at each assessment wave. Fidelity checklists and facilitator coaching ensure intervention quality. The contact PI meets monthly with key study personnel to monitor data-entry timeliness and quality, and the team reviews safety data at least quarterly (Section 18.0).

17.3 Steps to secure the data.

- **Surveys.** All survey data will be collected in Qualtrics through a secure link accessible via QR code on a computer, mobile device, or tablet. QR codes will be updated for each new round of data collection. Qualtrics data will be downloaded after each data collection time point. Encrypted and protected data files containing survey data will be stored on ISMS secure servers and on the University of Pittsburgh Secure Box.
- **Qualitative data and paper records.** Staff notes, audio recordings, and transcripts are kept in a locked cabinet at ISMS until uploaded to the University of Pittsburgh Secure Box (HIPAA-compliant, CAS and Duo authentication, firewalled, audited). Recordings are permanently deleted once transcripts are generated and checked.
- **Physical and administrative controls.** Databases are double password-protected; computers are kept in double-locked offices when not in use; data are backed up daily; project files are accessible only with PI authorization; all staff with access sign confidentiality agreements; computers have locks and virus protection.
- **Identifiers.** Interview and focus group data carry study codes only; names appear only on signed consent forms. Contact information needed for trial retention is stored separately from study data

and linked by study ID; paper contact information and signed consent forms are in locked files at ISMS, separate from study data.

- **Transmission.** Data transferred between ISMS and Pitt are de-identified or encrypted; identifiable data are not sent by email.
- **Training.** Staff complete the Pitt Basic Human Subjects Research course and HIPAA Security and Privacy courses, with certificates on file.
- **Certificate of Confidentiality.** Automatically applies to this NIH-funded research.

17.4 How data will be handled study-wide.

ISMS staff collect data in Vietnam. Only selected study staff have access to the linking key. Data are stored as described in 17.3 for at least seven years after study completion, after which physical materials are destroyed and electronic data are securely purged. Participants' information is not released without their written permission except as needed for monitoring by representatives of the study team and the ISMS IRB. Datasets shared with other researchers or repositories are de-identified and linked only to study IDs (Section 7.4).

17.5 NIH Data Management and Sharing Policy.

The DMS Plan submitted with the application describes how scientific data will be managed, protected, and shared; see Section 7.4. De-identification follows HIPAA standards (removal of direct identifiers, review of transcripts for indirect identifiers) before shared files are finalized.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

18.1 Data and safety monitoring plan.

- **Oversight.** Dr. Ha (leading MPI) and Dr. Nguyen (local MPI) monitor individual events and determine whether the protocol needs modification to minimize risk.
- **Team review.** The study team meets at least quarterly with investigators and staff to review individual cases and ensure close monitoring of participants.
- **Withdrawal.** Withdrawal of enrolled participants is assessed case by case, depending on health conditions and any risks of following the protocol.
- **Reporting.** All potential AEs are reported to the ISMS IRB (the IRB of record) and to the University of Pittsburgh Data and Safety Monitoring Board/Committee (DSMB/C) in accordance with required timelines. If an IRB determines that an AE was attributable to the intervention, the Lead Principal Investigator (Dr. Ha) notifies the NIH grant administrator within 72 hours of receiving the IRB decision.
- **Safety and referral.** MSM identified with depression, trauma, or suicidal risk, and those who seroconvert, receive immediate referral to HIV treatment, care, and counseling. Staff are trained in risk assessment and in handling suicidality when a participant declines referral. A referral network with local OPCs, CBO clinics, and Hanoi CDC, with written procedures for medical and psychological care, is being established.
- **Confidentiality breaches.** Participants who experience a breach are told to contact the research team. Serious breaches are reported to the leading PI (Dr. Ha), who convene in person or by video/phone to address the breach and plan prevention. Incident reports are filed and kept by the

PIs, appropriate action is taken against violators, and all events are reported to the ISMS IRB. Staff are trained to report policy violations immediately.

- **Data safeguards.** See Section 17.3.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Steps to protect privacy.

Privacy risks and mitigations are described in Section 15.0. Interviews take place in a private room at the ISMS research office or at a place chosen by the participant, and surveys in private spaces away from clinic staff and other patients. Participants choose where and how to be contacted (e.g., phone, messaging app) and are asked whether it is safe to leave messages. Study materials sent to participants will not reference HIV, sexual orientation, or MSM on the outside or in the subject line.

19.2 Steps to make subjects feel at ease.

Recruitment and consent materials describe the nature of the questions in advance. Interviewers and facilitators are trained in nonjudgmental, culturally sensitive communication, and the MSM community is represented among facilitators, staff, and the CAB. Participants may skip any question, take breaks, or stop at any time.

19.3 How the research team is permitted to access sources of information.

Research data are collected directly from participants. Team members who analyze data receive de-identified datasets. All personnel must keep human subjects training current.

19.4 Health information (HIPAA).

The study is conducted in Vietnam and does not obtain protected health information from U.S. covered entities. Pitt-hosted systems (Secure Box) are HIPAA-compliant, and shared data are de-identified using HIPAA standards.

19.5 GDPR.

N/A. No participants are located in the EU/EEA.

20.0 Compensation for Research-Related Injury

20.1 Arrangements and referrals for research-related injury.

Participants experiencing distress or harm related to the study will be referred to appropriate medical, counseling, or mental health services through the clinic and CBO network in Hanoi (Section 25.0).

20.2–20.3 Available compensation; contract language.

The study does not provide compensation for research-related injury beyond the referral measures described in Section 15.0. This will be stated in the consent form.

21.0 Economic Burden to Subjects

Participants will not be charged for any study procedure. Transportation costs are covered through study compensation (Section 13.5). Time away from work or clinic duties is an indirect cost; workshop dates will be scheduled to minimize disruption.

22.0 Consent Process

22.1 Indicate whether you will obtain consent, and describe the process.

Written informed consent will be obtained from all participants (Aims 1–3) by trained ISMS research assistants, in Vietnamese, using consent forms approved by the ISMS IRB. Pitt personnel will not obtain consent. Participants arrive 15 minutes early to read the form. The research assistant explains the purpose, procedures, expectations, risks, benefits, compensation, audio recording (participants may decline recording), confidentiality protections and their limits (e.g., suicidal intent, harm to others, abuse), data sharing (including the option to decline sharing and the limits on removing de-identified data), and withdrawal rights, and answers questions. Participants sign the form, the person obtaining consent signs, and the participant receives a signed copy. Participants are reminded that refusing or withdrawing will not affect their relationship with any participating agency or clinic, treatment, or access to medical services. Consent is re-confirmed verbally at each assessment and before each workshop; there is no required waiting period. Consent forms for the IDIs (MSM and healthcare providers) are attached.

For HCP, staff emphasize that supervisors and employers will not learn who participates and that declining has no effect on employment.

Non-English-speaking subjects

All participants are expected to speak Vietnamese. All consent forms, scripts, surveys, and interview guides will be translated into Vietnamese and back-translated, and reviewed by the local team and CAB for cultural and linguistic appropriateness. English versions are kept in the study file and available to the ISMS IRB and NIH on request.

23.0 Process to Document Consent in Writing

23.1: Consent is documented with a signed written consent form (participant and person obtaining consent), with a signed copy given to the participant. Signed forms are stored in locked files at ISMS, separate from study data and the linking key.

24.0 Setting

24.1 Describe the sites where the research will be conducted.

Study site. Hanoi, Vietnam. Participants are recruited through OPCs and CBO clinics with Dr. Nguyen leading the process at ISMS. Workshops are held in geographically distant districts of Hanoi.

Community Advisory Board (CAB). The CAB consists of two MSM, one physician, one nurse, a leader of an MSM-serving CBO, and a representative of the Hanoi Center for Disease Control and Prevention. In Year 1 the CAB meets monthly to give iterative feedback on study materials, the protocol, recruitment strategies, and the DONGHANH curriculum and e-module; thereafter it meets quarterly to promote outreach, foster collaboration, ensure cultural competence, and help develop dissemination strategies.

Data and safety monitoring. See Section 18.0 (quarterly team review; DSMB/C at the University of Pittsburgh).

Site-specific regulations and local review. We will comply with all governing policies of Vietnam and those required by the National Institutes of Health, as a USA federal funding agency.

25.0 Resources Available

25.1 Describe the resources available to conduct the research.

Feasibility of recruitment. The study requires 120 MSM and 60 HCP for Aim 2 (plus Aim 1 participants). Each Hanoi OPC and CBO clinic serves hundreds of MSM, and each is staffed by physicians, nurses, counselors, pharmacists, laboratory technicians, and public health officers (CBO clinics also have community health workers and peer educators). ISMS has longstanding relationships with these sites and with MSM-led CBOs, and has conducted similar studies with people with HIV in Hanoi OPCs (R01CA240481).

Time. The proposed study is part of the Principal Investigator's portfolio of scientific research; he will commit 20% annual effort to this work and will travel to Vietnam as needed to provide appropriate oversight, training, and coaching.

Medical and psychological resources. Medical and psychological resources. CBO and clinic partners offer counseling, mental health, and HIV services. Before enrollment begins, the study team will finalize a referral list and written referral procedures with these partners and designate a clinician available for risk assessment.

Personnel qualifications and training. All research staff complete the Pitt Basic Human Subjects Research course and the HIPAA Security and Privacy courses (certificates kept on file and renewed before expiry), and study-specific training on respectful engagement and confidentiality, data management and secure transport, the Protocol and Procedures Manual, sensitivity training for work with MSM and people living with HIV, data collection instruments and online surveys, interviewing, and responding to participants who become upset or report abuse, violence, depression, or suicidality. Facilitators and staff also complete the 5-day DONGHANH training and coaching (Section 6.1, Step 7). Duties are documented in a delegation log; CVs and training certificates are filed with the IRB.

25.2 Funding application and award notice.

The complete NIH application and Notice of Award (R01TW013193) will be uploaded to the IRB submission.

26.0 Multi-Site Research

26.1 Study-wide number of subjects.

All participants are recruited in Hanoi, Vietnam, through ISMS and partner OPCs and CBO clinics (Section 12.0). Please see the Recruitment and Retention plan for these details.

26.2 Study-wide recruitment methods

Recruitment methods are described in Section 13.0.

26.3 Communication among sites and multiple-PI governance

The MPIs, local research team, and CAB members will meet by video conference at least every two weeks with written agendas and minutes, with additional emails or calls as needed; Dr. Ha chairs project team meetings, and Dr. Ha and the US MPIs will visit Vietnam each year.

Multiple-PI governance. The MPIs will share leadership responsibilities, with scientific decisions guided by the expertise of the relevant MPI in consultation with the broader team. Disagreements are first discussed by the project team and, if unresolved, referred to an arbitration committee of one impartial

senior executive from each PI's institution plus a third mutually agreed executive. An Intellectual Property Committee will copyright the curriculum and keep it freely available for research and clinical use; a publication policy will reflect scientific contributions. If a PI changes institutions, the relevant grant portion will be transferred where possible; otherwise the other MPI becomes overall PI.

26.4 Communicating problems, interim results, and study closure.

Sites have already agreed to participate. The point of contact in Vietnam, Dr. Nguyen, will communicate with sites regarding problems, results, and closure of study.

26.5 Local confidentiality procedures (participating site).

ISMS stores consent forms and identifiable data in locked storage and on encrypted, password-protected servers. Only designated staff have access. Data sent to Pitt are de-identified or encrypted. There are no specimens in this study.

Research team members using the study-related data will not link the participant to identifying information or learn of his or her identity. All study personnel are required to renew Human Subjects trainings annually, or in accordance with their site regulatory mandates. No data will be accepted from or distributed to investigators or study staff if regulatory training is not current or if site regulatory approval has lapsed. Requests for study-related datasets will be submitted to the investigative team. Copies of study documents will be kept on file with the PI.

Survey data will be collected in Qualtrics via secure link accessible by QR code on a mobile device. QR codes will be updated for each round of data collection. Data will be downloaded to Excel after each data collection. Excel files will be encrypted and password protected. Protected files containing survey data, which will be imported into statistical software, will be stored on ISMS secure servers and on the University of Pittsburgh Secure Box (Section 17.3).

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