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# Investigating an intervention to improve screening, diagnosis and treatment of persons with very early HIV infection at Indonesian sexual health clinics

**Submission date**
07/03/2025

**Recruitment status**
No longer recruiting

**Registration date**
12/03/2025

**Overall study status**
Ongoing

**Last Edited**
11/03/2025

**Condition category**
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
HIV remains a significant public health issue in Indonesia, particularly among key populations such as men who have sex with men (MSM), transgender people, and sex workers. Early detection and treatment of acute HIV infection (AHI) can reduce transmission and improve long-term health outcomes. This study aims to evaluate a new approach to HIV screening, diagnosis, and treatment, integrating advanced diagnostic tools and digital behavioral interventions to improve HIV care in Indonesia.

Who can participate?
The study targets individuals at high risk of HIV who are seeking HIV testing services at participating sexual health clinics. This includes MSM, transgender people, sex workers, and other key populations at increased risk of HIV exposure.

What does the study involve?
Participants will undergo an enhanced HIV screening process, including a risk assessment and HIV-PCR testing. Those diagnosed with HIV will be offered assisted partner notification services and immediate treatment start. A digital behavioral intervention at CekUpYuk.id will be provided to promote HIV prevention, risk assessment and testing.

What are the possible benefits and risks of participating?
Benefits:
1. Early detection of HIV, enabling prompt treatment and rapid viral suppression.
2. Improved access to care and support services.
3. Contribution to public health efforts to reduce HIV transmission.
Risks:
1. Confidentiality risks, although strict data protection measures are in place.

Where Is the study run from?
The study is being conducted at high-volume sexual health clinics in Jakarta and Bali, Indonesia, in collaboration with local and international research institutions.

When is the study starting and how long is it expected to run for?
September 2022 to August 2025

Who is funding the study?
The study is funded by the Medical Research Council, UK Research and Innovation, and is sponsored by the University of Oxford (UK).

Who is the main contact?
1. Prof. Irwanto Irwanto, irwanto@atmajaya.ac.id
2. Prof. Raph Hamers, rhamers@oucru.org

### Study website
https://www.oucru.org/project/interact/

# Contact information

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Scientific, Principal Investigator

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Internal reference number 37-IND

## Study information

### Scientific Title
Indonesia intervention study to test & treat people with acute HIV infection (INTERACT)

### Acronym
INTERACT

### Study objectives

The principal overarching research question of the INTERACT project is to evaluate whether implementing a patient-centered care pathway to test and treat acute HIV infection (AHI), coupled with a tailored digital behavioural intervention, can curb the rapidly growing HIV epidemic among key populations in Jakarta and Bali.

The INTERACT project aims to answer the following key scientific questions:
1. What is the effectiveness/yield of implementing an AHI clinical pathway?
1.1. Is a risk/symptom screening score an effective method for detecting AHI among men who have sex with men (MSM) and other key populations in Jakarta and Bali? Can the score be locally optimized?
1.2. Do same-visit delivery of diagnosis and immediate initiation of antiretroviral therapy (ART) shorten the time to reaching undetectable viral load?
1.3. What are the factors associated with AHI diagnosis and immediate ART failure/success?

2. What is the uptake/adoption, acceptability and feasibility of an AHI clinical pathway?
2.1. Does the clinical pathway lead to an increased number of individuals and their sexual partners tested for and diagnosed with AHI, and starting immediate ART during AHI, compared to the usual care? What is the uptake, feasibility, and acceptability of the clinical pathway?
2.2. Are AHI patients willing to start ART on the day of diagnosis and adhere to immediate ART? And what are the barriers and facilitators to immediate ART start?
2.3. Can we identify HIV-negative, high-risk populations for enhanced sexual health counselling, and preparation for future PrEP introduction?

3. What is the potential impact of implementing an AHI clinical pathway on curbing the HIV epidemic in Indonesia?
3.1. How many infections and deaths would be averted and quality-adjusted life-years (QALYs) gained in various intervention scale-up scenarios?
3.2. What are the incremental costs or cost savings of those possible scenarios?

## Ethics approval required
Ethics approval required

## Ethics approval(s)
1. Approved 02/12/2022, Oxford Tropical Research Ethics Committee (University of Oxford; Research Services, Research Governance, Ethics & Assurance; Wellington Square, Oxford, OX1 4BH, United Kingdom; +44 (0)1865 (2)82106; oxtrec@admin.ox.ac.uk), ref: 565-22

2. Approved 17/11/2022, Atma Jaya Catholic University of Indonesia; Institute of Research and Community Service Ethics Committee (Jendral Sudirman Street, number 51, Jakarta, 12930, Indonesia; +61 (0)21 570-3306; lppm@atmajaya.ac.id), ref: 0009R/III/PPPE.PM.10.05/10/2022

## Study design
Longitudinal multi-center non-randomized non-blinded implementation and intervention research study

## Primary study design
Interventional

## Secondary study design
Cohort study

## Study setting(s)
Other

## Study type(s)
Diagnostic, Screening

## Participant information sheet
See study outputs table

## Health condition(s) or problem(s) studied
Screening of individuals attending a sexual health clinic at risk of HIV acquisition for acute HIV infection (AHI)

## Interventions
1. Implementing an optimally sensitive AHI screening approach through a client self-completed risk assessment ("AHI Risk Assessment"), coupled with HIV-PCR diagnostic testing (sequential to and additional to current local standard-of-care HIV Ag/Ab based testing).
2. Strengthening HIV care cascades by same-day delivery of HIV-PCR test results, immediate offer of ART in newly HIV-diagnosed persons, and monitoring HIV-RNA at 3 and 6 months after ART initiation to ensure response and adherence to treatment.
3. Implementing an evidence-based digital behavioural intervention tool, tailored to the wider target population at high risk of HIV, through media platforms, to promote uptake/adoption of HIV prevention, testing and the AHI clinical pathway.

## Intervention Type
Other

## Primary outcome measure
1. Evaluation of the effectiveness/yield of an AHI clinical pathway:

1.1. AHI screening outcomes*:
1.1.1. Performance of the Amsterdam screening risk score in diagnosing AHI (sensitivity, specificity and Area Under the Curve [AUC], overall and stratified per risk group, including the complete longitudinal dataset)
1.1.2. Yield of HIV-PCR in diagnosing AHI compared with standard-of-care 4th generation HIV Ag /Ab testing and 3rd generation HIV Ab RDT testing (number and percentage of additional HIV case-detection, overall and stratified per risk group, including the complete longitudinal dataset)
1.1.3. Prevalence of reported symptoms and risk behaviour, and their association with AHI (number and percentage, overall and stratified per risk group, including the complete longitudinal dataset)
1.1.4. Number and proportion of participants who are newly diagnosed with AHI (compared to historical records for all HIV diagnoses) (number and percentage, overall and stratified per risk group, including the complete longitudinal dataset)
Analysed with a time-to-event analysis with right censoring, hence the time HIV diagnosis may be between 0 days and 23 months (determined by study recruitment duration)

1.2. HIV care cascade outcomes**:
1.2.1. Proportion of those HIV diagnosed who start ART (compared to historical records) (number and percentage, overall and stratified per risk group, including the complete longitudinal dataset)
1.2.2. Time (days) from confirmed HIV diagnosis to ART initiation (compared to historical

records) (median days and number and percentages started on ART at <24 hours, <7 days, <30 days, including the complete longitudinal dataset)
1.2.3. HIV-RNA load levels at the time of HIV diagnosis and after 12 and 24 weeks of ART (compared to historical records for all HIV diagnoses) (mean/median and proportion <50 cps/mL including the complete longitudinal dataset)
1.2.4. CD4 T-cell counts at the time of HIV diagnosis and after 12 and 24 weeks of ART (mean /median cells/mm3, including the complete longitudinal dataset)

2. Evaluation of uptake/adoption, acceptance and feasibility of AHI testing and partner screening and notification, as part of the AHI clinical pathway:
2.1. Number of AHI risk screens conducted (overall and stratified per risk group, including the complete longitudinal dataset)
2.2. Number of individuals who are tested for HIV/STI for the first time ever and at the study clinic; who repeat the HIV/STI test at the study clinic; and the time interval since previous HIV/STI test (median days and number, overall and stratified per risk group, including the complete longitudinal dataset)
2.3. HIV and STI incidence among individuals in follow-up (overall and stratified per risk group, including the complete longitudinal dataset)
2.4. Number of HIV-negative individuals who are eligible for PrEP (according to MOH guidelines) (overall and stratified per risk group, including the complete longitudinal dataset)
2.5. Number of sexual partners of individuals who are newly HIV diagnosed (index clients), who are contacted, tested for HIV, and newly HIV diagnosed (overall and stratified per risk group, including the complete longitudinal dataset)
2.6. Barriers and enablers of implementing the AHI clinical pathway from the participant's and provider's perspective (qualitative analysis, including complete study period)
Analysed with a time-to-event analysis with right censoring, hence the time HIV diagnosis may be between 0 days and 23 months (determined by study recruitment duration)

3. Estimation of the potential population impact and cost-effectiveness of an AHI clinical pathway on curbing the HIV epidemic in Indonesia:
3.1. Projections of HIV infections, hospitalizations, and deaths averted and QALYs gained under different intervention scale-up scenarios, including maintenance of the status quo (overall and stratified per risk group, mathematical modelling)
3.2. Cost-effectiveness of different intervention scale-up scenarios, expressed as ICER measured as cost-per QALY gained (overall and stratified per risk group, mathematical modelling)
Analysed with a time-to-event analysis with right censoring, hence the time HIV diagnosis may be between 0 days and 23 months (determined by study recruitment duration)

## Secondary outcome measures

1. To improve the implementation of the AHI clinical pathway through a tailored digital behavioural/risk assessment intervention and community outreach:
1.1. Uptake of a tailored digital risk reduction intervention amongst MSM at risk in the local area in all clinical sites (number, including complete study period)
1.2. Usability of the tool via user-centred interaction design methods including focused user questionnaires and remote usability testing (subjective feedback on the interface by users) (qualitative analysis, including complete study period)
1.3. Number of digital engagements and length of digital interaction time spent on the tool, and number of returning digital users (number, including complete study period)
1.4. Number of those engaged enrolling in the INTERACT study (number, including complete longitudinal dataset)
Analysed with a time-to-event analysis with right censoring, hence the time HIV diagnosis may be between 0 days and 23 months (determined by study recruitment duration)

### Overall study start date
01/09/2022

### Completion date
31/08/2025

# Eligibility

### Key inclusion criteria
Individuals are eligible to participate in the INTERACT study if they meet all the following criteria:
1. Aged 18 years or older (or 16-17 years old if deemed mature enough by a clinic doctor /counsellor)
2. Answered "YES" or "I PREFER NOT TO SAY" to at least one of the following:
2.1. Are a man who has sex with men (MSM)
2.2. Are a transgender person
2.3. Have ever injected drugs
2.4. Sell sex or work as a sex worker
2.5. Have sex with a sex worker
2.6. Have sex with a person living with HIV; and/or
2.7. Believe they are at risk of having HIV
3. Provided informed consent by answering "YES" to both:
3.1. Agreement to take part in the study; and
3.2. Agreement to the anonymized use of their medical record and blood sample for the study

For adolescents aged 16-17 years, additional criteria include:
A clinic doctor or nurse confirms that:
1. It is in their best interest to access HIV prevention and testing services;
2. They cannot be persuaded to inform their parents/carers; and
3. They understand the study, its risks and benefits, and can make an informed decision

### Participant type(s)
Healthy volunteer, Patient, Population, Other

### Age group
Adult

### Lower age limit
16 Years

### Sex
Both

### Target number of participants
7500

### Total final enrolment
6604

### Key exclusion criteria

Individuals are not eligible to participate if they:
1. Are younger than 16 years old
2. Are 16-17 years old but are not deemed mature enough to consent to study participation
3. Have previously tested HIV positive and are already registered in care and/or receiving treatment for HIV

### Date of first enrolment
12/05/2023

### Date of final enrolment
28/02/2025

## Locations

### Countries of recruitment
Indonesia

### Study participating centre
**Globalindo Clinic**
Jl. Guntur No.44 8, RT.8/RW.1
Guntur
Kecamatan Setiabudi
South Jakarta
Indonesia
12980

### Study participating centre
**Yayasan Bali Peduli Denpasar**
Pertokoan Imam Bonjol Square
Jl. Imam Bonjol Ruko No. A-17
Pemecutan Klod
Kec. Denpasar Baru
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Indonesia
80119

### Study participating centre
**Yayasan Bali Peduli Ubud - Klinik Anggrek**
Jalan Raya Kutuh
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80571

# Sponsor information

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**Sponsor type**
University/education

**Website**
https://www.ox.ac.uk

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Research council

**Funder Name**
Medical Research Council

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

## Publication and dissemination plan

Several summary manuscripts, reporting the results of the implementation study, will be prepared by the core investigator team, and be submitted for publication in peer-reviewed scientific journals. Any manuscript derived from this study will be published under the Open Access policy. Stakeholder meetings and policy briefs will be used to share results with local and national policymakers. Results will be shared with the target community through the project's community advisory board and the project community website at CekUpYuk.id.

## Intention to publish date

01/08/2025

## Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be available upon request from Raph Hamers (rhamers@oucru.org), with approval from the investigator team.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 1.0 | 10/10/2022 | 10/03/2025 | No | Yes |
| Protocol file | version 1.0 | 10/10/2022 | 10/03/2025 | No | No |