ISRCTN95309635 https://doi.org/10.1186/ISRCTN95309635

# Reducing stigma and promoting HIV wellness /mental health of sexual and gender minorities: a novel group-based cognitive behavioural therapy program in Nigeria

**Submission date**
19/02/2024

**Recruitment status**
No longer recruiting

**Registration date**
23/02/2024

**Overall study status**
Completed

**Last Edited**
26/05/2026

**Condition category**
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

**Plain English summary of protocol**
Background and study aims
High levels of stigma due to identifying as a sexual or gender minority (SGM) and living with HIV are increasingly documented in the African setting, and often manifest as internalized stigma (self-stigma). Such stigmas, especially when they are multiple and compounding, impede psychosocial wellbeing as well as HIV prevention and care. Yet there are few, if any, interventions specifically focused on reducing intersecting internalized stigmas tested in Africa. In this study, the researchers will develop and evaluate a novel, group-based cognitive behavioural therapy (CBT) intervention for the MSM and TGW populations.

Who can participate?
Men who have sex with men (MSM) and transgender women (TGW) 18 years of age or older and at risk for or living with HIV in Lagos, Nigeria.

What does the study involve?
Participants are randomly allocated to either the immediate intervention or the delayed intervention group. The intervention comprises four weekly in-person group sessions facilitated by community health workers. The comparison group (i.e., the delayed intervention group) were made aware of the HIV and other services available through partner implementing organizations (e.g., HIV and STI prevention and treatment services). Surveys are carried out before and after the intervention and at a 3-month follow-up (immediate group only).

What are the possible benefits and risks of participating?
Participants benefit from the group sessions, specifically the opportunity to learn and talk about stigma, HIV services, being a sexual and gender minority in Nigeria, and having support from peers and community health workers.
The main risks posed to participants from the study and intervention procedures are psychological distress and breach of confidentiality. Psychological distress could arise from participating in the group sessions and surveys since they touch upon enacted and internalized

stigma, depression and anxiety, HIV risk, living in the HIV, and experiences of violence. Psychological distress could also arise from breaches of confidentiality, particularly given the stigmatized and even criminalized nature of identities and behaviours in question in the country context. While breach of confidentiality is unlikely given protections in place, any potential breach is concerning particularly given same-sex behaviour is criminalized in Nigeria, as well as the stigmatized nature of both same-sex behaviour and HIV.

Where is the study run from?
Population Council (USA). The study is conducted in Lagos, Nigeria.

When is the study starting and how long is it expected to run for?
October 2021 to October 2023

Who is funding the study?
Elton John AIDS Foundation (USA)

Who is the main contact?
1. Dr Waimar Tun, wtun@popcouncil.org
2. Dr Julie Pulerwitz, jpulerwitz@popcouncil.org

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Waimar Tun

### Contact details
1015 15th St NW Fl 5
Washington
United States of America
20005-2644
+1 (0)2409450638
wtun@popcouncil.org

# Additional identifiers

### Protocol serial number
988

# Study information

### Scientific Title
Evaluation of an internalized stigma reduction intervention for men who have sex with men, and transgender women, in Lagos, Nigeria via a prospective delayed group randomized controlled trial

### Study objectives

The intervention will result in greater decreased internalized stigma related to being a sexual /gender minority, and related to living with HIV, among individuals randomized to the immediate vs delayed arm.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 15/02/2022, Population Council Institutional Review Board (1230 York Avenue, New York, 10065, United States of America; +1 (0)917 685 7660; ngontarz@popcouncil.org), ref: 988

## Primary study design
Interventional

## Study design
Prospective delayed randomized controlled trial

## Study type(s)
Prevention, Treatment

## Health condition(s) or problem(s) studied
Prevention of mental health disorders (depression, anxiety) and increased uptake of HIV prevention and treatment services

## Interventions
After recruitment, from separate listings of MSM and transgender women (TGW) enrolled participants, an investigator used a random numbers table and assigned individuals from each list to an intervention group (either the immediate intervention or the delayed intervention group); there were separate groups for MSM or TGW (given different experiences and social networks). Within 10 days of completion of the baseline survey, research assistants called participants to inform them of their randomization assignment.

Group-based affirmative cognitive behavioral therapy: The intervention comprises four weekly in-person group sessions facilitated by community health workers. The evaluation design is a delayed intervention group randomized controlled trial, with pre-post surveys plus 3-month follow-up (immediate group only), as well as qualitative research with participants and program staff.

The comparison group (i.e., the delayed intervention group) were made aware of the HIV and other services available through partner implementing organizations (e.g., HIV and STI prevention and treatment services).

## Intervention Type
Behavioural

## Primary outcome(s)
Internalized stigma related to being a sexual/gender minority and living with HIV (among those individuals living with HIV), measured using an adaptation of the Internalized AIDS-Related Stigma Scale (IA-RSS) at baseline and three additional points (approximately 1 month after baseline, 2 months after baseline, and 3 months after baseline)

### Key secondary outcome(s)
Measured at baseline and three additional points (approximately 1 month after baseline, 2 months after baseline, and 3 months after baseline):
1. Depression measured using the Patient Health Questionnaire-8 (PHQ-8)
2. Anxiety measured using the General Anxiety Disorder-7 (GAD-7), such as 'trouble relaxing' and 'not being able to control or stop worrying' in the last 2 weeks
3. Coping was measured using the 4-item Brief Coping Scale
4. Uptake of pre-exposure prophylaxis and antiretroviral therapy (among participants living with HIV). Among those with HIV, adherence was defined as reporting "No days" to the question "During the past 3 days, on how many days have you missed all your pills?". Antiretroviral treatment self-efficacy was assessed based on seven items from a validated scale (HIV-Adherence Self-Efficacy Scale with last month as the reference period.

### Completion date
31/10/2023

## Eligibility

### Key inclusion criteria
1. 18 years or older
2. Assigned male at birth
3. [Among MSM subgroup] Had sex with a biological man in the last year; [Among Transgender women subgroup] Identify as a woman
4. Willing to participate in all four sessions of the intervention
5. Willing to participate in the study
6. Residing in Lagos State for the next 1 year

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
99 Years

### Sex
Male

### Total final enrolment
240

### Key exclusion criteria

1. Do not agree to participate in either the group sessions or study surveys
2. Planning to move out of Lagos State within the next one year
3. Currently participating in any other stigma reduction intervention
4. Not providing consent to participate in the intervention and study
5. Not providing contact information for follow-up

### Date of first enrolment
26/04/2022

### Date of final enrolment
29/09/2022

## Locations

### Countries of recruitment
Nigeria

### Study participating centre
**Centre for Population and Health Initiatives (CPHI)**
6C Ireti St, opposite Lebanese international school, Sabo yaba
Lagos
Nigeria
100001

## Sponsor information

### Organisation
Population Council

### ROR
https://ror.org/03zjj0p70

## Funder(s)

### Funder type
Charity

### Funder Name
Elton John AIDS Foundation

### Alternative Name(s)

Elton John AIDS Foundation, Inc., Elton John AIDS Foundation Inc, THE ELTON JOHN AIDS FOUNDATION, EJAF

### Funding Body Type
Government organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
United States of America

## Results and Publications

### Individual participant data (IPD) sharing plan
The dataset generated during the study will be stored in a publicly available repository (https://dataverse.harvard.edu/dataverse/popcouncil).
The type of data stored – quantitative de-identified data from the multiple rounds of survey.
The process for requesting access (if non-publicly available): Although it will be made available on DataVerse, the researchers require anyone interested in the data to contact one of the two contact investigators (Julie Pulerwitz or Waimar Tun) for permission to use the data. Interested persons must state their affiliation, qualifications, intended purpose, and how they will use the data. Given the sensitive nature of the topic in this environment, the researchers use stringent measures before making the data available.
Dates of availability: 23 February 2024
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: Data has been stripped of any identifiers.

Added 19/03/2024:
Link to dataset: https://doi.org/10.7910/DVN/SG5XLP

### IPD sharing plan summary
Stored in publicly available repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 05/06/2024 | 26/05/2026 | Yes | No |
| Dataset | | 18/03/2024 | 19/03/2024 | No | No |