ISRCTN14264476 https://doi.org/10.1186/ISRCTN14264476

Evaluation of the Journeys of Shared Resilience group program among Black sexual minority men in Washington, DC

Submission date	**Recruitment status**	[X] Prospectively registered
08/10/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/10/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/10/2024	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Stigmas due to identifying as a sexual minority, being at risk for/living with HIV, and due to race, are common and often manifest as internalized stigmas (self-stigmas). 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 and promoting shared resilience. In this study, the researchers will evaluate Journeys of Shared Resilience - a novel, group-based program that positively affirms identities and builds cognitive behavioral therapy (CBT) skills among Black sexual minority men living in the Washington, DC area.

Who can participate?
Black sexual minority men ages 18 years or older, who are living or working in the Washington, DC area.

What does the study involve?
Participants will attend four weekly in-person group Journeys of Shared Resilience sessions facilitated by community health workers. Surveys will be carried out before and 3 months after the program to assess its acceptability, appropriateness, feasibility, and effectiveness. Additional qualitative in-depth / group interviews will be completed with a subset of participants, as well as other stakeholders.

What are the possible benefits and risks of participating?
Participants may benefit from the group sessions, specifically the opportunity to learn and talk about stigma, information about available health services, and 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 with HIV, and experiences of violence. Psychological distress could also arise from breaches of confidentiality, particularly given the

often stigmatized nature of the identities in question. While a breach of confidentiality is unlikely given protections in place, any potential breach would be concerning.

Where is the study run from?
Us Helping Us, Washington, DC (USA)

When is the study starting and how long is it expected to run for?
June 2023 to May 2025

Who is funding the study?
National Institutes of Health via the Washington DC CFAR (Center for AIDS Research) (USA)

Who is the main contact?
1. Dr Julie Pulerwitz, jpulerwitz@popcouncil.org
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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
Nil known

Study information

Scientific Title
Evaluation of Journeys of Shared Resilience: a group program to address intersectional stigmas, and support shared resiliency and HIV wellness, among Black sexual minority men in Washington, DC

Acronym
JSR Eval

Study objectives
The program will result in significant declines in internalized stigma and depression, and improvements in community connectedness.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/07/2023, Population Council Institutional Review Board (1230 York Avenue, New York, 10065, United States of America; +1 (0)917 685 7660; ngontarz@popcouncil.org), ref: 1023

Study design
Pre-post comparison, complemented by qualitative research

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, Other

Study type(s)
Other, Prevention

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Prevention of internalized stigma and depression and promotion of community connectedness among Black sexual minority men

Interventions
Group program based on affirmative cognitive behavioral therapy, with four curriculum-based sessions, each ~2.5 hours long, facilitated by trained community health workers. The program will be evaluated by pre- and 3-month post-surveys, complemented by qualitative research.

Intervention Type
Behavioural

Primary outcome measure
Intersectional internalized stigma, as measured by several scales (including a nine-item scale adapted from scale developed by Dr Lisa Bowleg and colleagues), at baseline and 3-month post assessments

Secondary outcome measures
1. Acceptability of program, measured using survey responses to a set of 11 satisfaction questions at the end of the final program session, plus themes elucidated from post-assessment in-depth/group interviews
2. Depression measured by the Patient Health Questionnaire-8 at baseline and 3-month post assessments
3. Community connectedness measured by a nine-item Community Connectedness scale, at baseline and 3-month post assessments
4. Exploratory outcome: self-reported current PrEP use at baseline and 3-month post assessments

Overall study start date
01/06/2023

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Lives or works in the city of DC or neighboring Prince George's County, Maryland
2. Age 18 years or older
3. Self-reported sexual orientation is gay/sexual minority man/MSM
4. Self-reported sex assigned at birth is male
5. Self-reported race is Black/African American
6. Has ready access to a personal computer, tablet, or smartphone with a connection to the internet
7. Speaks English well enough to read English study-related documents and participate in the intervention, conducted in English
8. Willing and able to participate in the intervention/study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Male

Target number of participants
60

Key exclusion criteria
1. Participated in previous formative research related to the program
2. Do not agree to participate in either the group sessions or study surveys

Date of first enrolment
15/10/2024

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
United States of America

Study participating centre

Us Helping Us
3636 Georgia Ave NW
Washington
United States of America
20010

Sponsor information

Organisation
Population Council

Sponsor details
One Dag Hammarskjold Plaza
2nd Floor
New York, NY
United States of America
10017
+1 (0)212 339 0500
pubinfo@popcouncil.org

Sponsor type
Research organisation

Website
http://www.popcouncil.org/

ROR
https://ror.org/03zjj0p70

Organisation
Us Helping Us People Into Living

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Sponsor type
Charity

Website
http://www.ushelpingus.org

ROR
https://ror.org/05w0kdr76

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIAID) via Washington DC Center for AIDS Research

Results and Publications

Publication and dissemination plan
Planned presentations at conferences and publication in a high-impact peer-reviewed journal.

Intention to publish date
01/03/2026

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 each survey round.

The process for requesting access (if non-publicly available): Although it will be made available on DataVerse, given the sensitive nature of the topic, the researchers will require anyone interested in the data to contact the investigators for permission to use the data.

IPD sharing plan summary
Stored in publicly available repository