ISRCTN63954463 https://doi.org/10.1186/ISRCTN63954463

Understanding and sharing strategies for linking community members to HIV and mental health/substance use services

Submission date
22/10/2025

Recruitment status
Recruiting

Registration date
28/10/2025

Overall study status
Ongoing

Last Edited
27/10/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
HIV organizations use different approaches to help community members get HIV-prevention and mental health/substance use treatment services. This study is trying to learn from community organizations about how they help community members get these services, then develop a website that showcases those approaches. These are our study aims:
Aim 1: Learn from HIV organizations about their approaches for helping community members get HIV-prevention and mental health/substance use treatment services.
Aim 2: Create a website that explains all of the different approaches we learned about in Aim 1.
Aim 3: Share the website with HIV organizations across the United States to see if it helps them get community members in their area linked to HIV-prevention and mental health/substance use treatment services.

Who can participate?
Aim 1: HIV organizations that serve Latino men who have sex with men and are in the Miami FL area, Orlando FL area, or San Juan PR area can participate.
Aim 2: HIV implementers from the organizations in Aim 1 can participate. HIV implementers from other organizations across the US can also participate.
Aim 3: HIV organizations that are not already part of Aim 1 that are in “Ending the HIV Epidemic” priority jurisdictions in the United States can participate.

What does the study involve?
Aim 1: The study team will visit HIV organizations that are part of our network (Miami, Orlando, San Juan) and learn about their approaches for helping community members get linked to HIV-prevention and mental health/substance use treatment services. The team will create protocols and evaluate the approaches against the published literature (e.g., does the approach address things that we know from past research affects engagement in services; does the approach use methods that we know from past research can improve engagement in services).
Aim 2: The study team will create an initial version of a website that explains all the approaches /protocols from Aim 1. Implementers from HIV within and outside our existing network will give feedback on the website to make sure it’s helpful to HIV organizations. We will revise the

website based on their feedback.
Aim 3: The study team will invite HIV organizations across the United States to join the project. Those HIV organizations will get access to the website we developed in Aim 2. We'll invite those organizations to do surveys and interviews to learn about their experiences using the website to see if it is helpful in getting their communities linked to HIV-prevention and mental health /substance use treatment services.

What are the possible benefits and risks of participating?
The benefits of participating in Aim 1 include having the public learn about the organizations' approaches for getting their communities linked to HIV-prevention and mental health services. It gives a potentially national platform for their expertise. Benefits of participating in Aim 2 include contributing to a public online tool that could be helpful to other HIV organizations. Benefits of participating in Aim 3 include getting access to an online resource that could help HIV organizations achieve their goals with respect to linking communities to HIV-prevention and mental health/substance use treatment services. Risks of participating in any of the aims are minimal; of note, this project was considered not human subjects research but the IRB because we aren't collecting personal information about the organizations but moreso learning about and developing processes to help them get HIV-prevention and mental health/substance use treatment services to reach their communities more effectively.

Where is the study run from?
The study is run from University of Miami, with collaborators throughout the Miami FL area, Orlando FL area, and San Juan PR area.

When is the study starting and how long is it expected to run for?
January 2025 to May 2029

Who is funding the study?
1. National Institute of Mental Health (NIMH) (USA)
2. National Institute of Allergy and Infectious Diseases (NIAID) (USA)

Who is the main contact?
1. Dr Audrey Harkness, aharkness@miami.edu
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Leveraging a strategic alliance to characterize, protocolize, and scale up local implementation strategies for improving pre-exposure prophylaxis and mental health/substance use treatment reach

Acronym
SOMOS Alianza

Study objectives
This study is guided by the following research aims:

Aim 1: To characterize, assess, and protocolize implementation strategies that are currently used in SOMOS Alianza organizations to improve pre-exposure prophylaxis (PrEP) and mental health/substance use treatment reach.

Aim 2: Through user-centered design, to build a Dashboard of locally used implementation strategies identified in Aim 1 that improve the reach of PrEP and mental health/substance use treatment.

Aim 3: To assess Dashboard usability and associated organizational outcomes.

Ethics approval required
Ethics approval not required

Ethics approval(s)

Study design
Multicenter sequential exploratory mixed method project grounded in implementation science

Primary study design
Observational

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
The reach of pre-exposure prophylaxis (PrEP), mental health, and substance use treatment services to Latino men who have sex with men

Interventions
This study uses reverse implementation mapping to assess unique implementation strategies and adjunctive interventions local organizations are using to improve the reach of PrEP and mental health/substance use treatment services to Latino MSM (Aim 1). Then, through user-centered design, we will build a Dashboard of the locally used implementation strategies and adjunctive interventions identified (Aim 2). We will assess the usability, acceptability, appropriateness of the Dashboard and associated organizational outcomes (e.g., adoption /implementation of Dashboard strategies/interventions, reach of Latino men who have sex with men in PrEP and mental health/substance use treatment services) (Aim 3).

Intervention Type
Behavioural

Primary outcome(s)
1. Implementation strategies and adjunctive interventions identified using reverse implementation mapping during Aim 1
2. Usability of the Dashboard measured using the Systems Usability Scale and User Data during Aim 3 (years 4 and 5)
3. Adoption of the Dashboard measured using Implementation Science Coordination Initiative (ISCI) implementation measure during Aim 3 (years 4 and 5)
4. Adoption of implementation strategies and adjunctive intervention measured using ISCI implementation measures during Aim 3 (years 4 and 5)

Key secondary outcome(s))
1. Acceptability of implementation strategies and adjunctive interventions measured using Acceptability of Intervention Measure during Aim 3 (years 4 and 5)

2. Acceptability of the Dashboard measured using Acceptability of Intervention Measure during Aim 3 (years 4 and 5)
3. Appropriateness of implementation strategies and adjunctive interventions measured using Intervention Appropriateness Measure during Aim 3 (years 4 and 5)
4. Appropriateness of the Dashboard measured using Intervention Appropriateness Measure during Aim 3 (years 4 and 5)
5. Feasibility of implementation strategies and adjunctive interventions measured using Feasibility of Intervention Measure during Aim 3 (years 4 and 5)
6. Implementation of implementation strategies and adjunctive interventions measured using Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS) and Resource Utilization Measure during Aim 3 (years 4 and 5)
7. Reach of clinical interventions (PrEP, mental health/substance use treatments) to Latino MSM measured using ISCI measures during Aim 3 (years 4 and 5)

Completion date
31/05/2029

Eligibility

Key inclusion criteria
HIV organizations providing PrEP and mental health/substance use treatment services to Latino MSM in Ending of the HIV Epidemic jurisdictions

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Organizations that do not have any strategies or adjunctive interventions to improve the reach of PrEP or mental health/substance use treatment services to Latino MSM
HIV organizations that are not in an Ending of the HIV Epidemic jurisdiction

Date of first enrolment
30/09/2025

Date of final enrolment
31/05/2029

Locations

Countries of recruitment
United States of America

Study participating centre
University of Miami
5030 Brunson Drive
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Sponsor information

Organisation
National Institute of Mental Health

ROR
https://ror.org/04xeg9z08

Funder(s)

Funder type
Government

Funder Name
National Institute of Mental Health

Alternative Name(s)
Mental Health NIMH, NIH National Institute of Mental Health, Instituto Nacional de la Salud Mental, NIMH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
National Institute of Allergy and Infectious Diseases

Results and Publications

Individual participant data (IPD) sharing plan

Aim 1 data will be publicly available as it will be featured in the Aim 1 Implementation Strategy Dashboard which we plan to launch for public use as part of this study. Aim 2 data will be largely qualitative, therefore we will retain it but will not deposit in a public repository which are typically used for quantitative data. We plan to deposit de-identified Aim 3 data into the Inter-University Consortium for Political and Social Research (ICPSR) repository to facilitate replicability and secondary analysis.

IPD sharing plan summary

Stored in non-publicly available repository