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A community approach to protecting Hispanic youth at risk from HIV, substance use, and mental health challenges

Submission date
28/10/2025

Recruitment status
Recruiting

Registration date
04/11/2025

Overall study status
Ongoing

Last Edited
04/02/2026

Condition category
Other

[X] 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
This study is working with local organizations in Miami-Dade County to get ready for a new program called Familias con Orgullo ("Families with Pride"). The program is designed to support Hispanic youth who may be at risk for HIV, substance use, and mental health challenges. The goal is to help families and communities prevent these issues before they start. Researchers are teaming up with community groups from the beginning to make sure the program is practical and easy to use in real life. They're also creating a toolkit to help organizations adopt the program and testing how well it works. This effort supports national goals to end the HIV epidemic and reduce health problems in Hispanic communities.

Who can participate?
Community-based organizations in Miami-Dade County that work with Hispanic youth and families are invited to take part in the study.

What does the study involve?
Participating organizations will work with the research team to share their experiences, help design the toolkit, and test how useful and realistic it is. This may include meetings, interviews, and trying out parts of the program.

What are the possible benefits and risks of participating?
Benefits include helping shape a program that could make a real difference in the community and gaining tools to support youth and families. Risks are expected to be minimal, but may include time commitment and sharing organizational challenges.

Where is the study run from?
The study is based in Miami-Dade County, Florida, and is led by researchers at the University of Miami (USA)

When is the study starting and how long is it expected to run for?
January 2025 to August 2030

Who is funding the study?
National Institute of Mental Health (USA)

Who is the main contact?
Dr Alyssa Lozano, adl122@med.miami.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Planning for implementation of a family-based intervention for prevention of HIV, substance use, and mental health problems among Hispanic youth at risk: a community-engaged approach

Study objectives
This study is guided by the following research aims:
AIM 1: Identify determinants affecting adoption and implementation of behavioral HIV prevention interventions, such as Familias con Orgullo, in community agencies.
AIM 2: Iteratively co-design an implementation strategy package to support community agencies in adopting and implementing Familias con Orgullo.
AIM 3: Evaluate the relative priority, acceptability, appropriateness, and feasibility of the implementation strategy package for promoting adoption and implementation of Familias con Orgullo.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 06/02/2025, University of Miami Institutional Review Board (1531 Brescia Avenue, Coral Gables, 33146, United States of America; +1 3052433195; vcarrasco@miami.edu), ref: 20250083

Primary study design
Observational

Study design
Multicenter mixed method project grounded in implementation science

Study type(s)
Prevention

Health condition(s) or problem(s) studied
A community approach to protecting Hispanic youth at risk from HIV, substance use, and mental health challenges

Interventions
This study will iteratively develop an implementation strategy package in collaboration with community agencies across Miami-Dade County using a systematic implementer-driven method to inform the future adoption and implementation of a family-based intervention for Hispanic youth at risk, Familias con Orgullo ("Families with Pride"). We will first identify determinants affecting adoption and implementation of behavioral HIV prevention interventions, such as Familias con Orgullo, in SMY-serving community agencies (Aim 1). Then, we will iteratively co-design an implementation strategy package to support community agencies in adopting and implementing Familias con Orgullo (Aim 2), and evaluate the relative priority, acceptability, appropriateness, and feasibility of the implementation strategy package for promoting adoption and implementation of Familias con Orgullo (Aim 3).

Participants enrolled in this study may participate in the following activities. First, participants may complete a one-time one-on-one interview (approximately 60 minutes) to describe barriers and facilitators that have impacted the adoption and implementation of behavioural HIV preventive interventions in their respective community agencies and the anticipated barriers and facilitators to adopting and implementing Familias con Orgullo in their setting. Second, participants may take part in a workgroup that meets for two-hours three times over the course of two years to collaboratively develop implementation strategies. As part of the workgroup, participants will also complete a one-time survey to assess the relative priority, acceptability, appropriateness, and feasibility of the developed implementation strategy package. Participants who participated in the interviews have the option to also participate in the workgroup. There is no follow-up.

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability of implementation strategies is measured using the Acceptability of Intervention Measure via electronic survey prior to Aim 3, following the second workgroup meeting
2. Appropriateness of implementation strategies is measured using the Appropriateness of Intervention Measure via electronic survey prior to Aim 3, following the second workgroup

meeting
3. The Relative Priority of implementation strategies is measured using participant reported ratings via electronic survey during Aim 3.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/08/2030

Eligibility

Key inclusion criteria
Community agency staff ≥18 years working at community agencies that deliver standard community outreach which consists of distributing informational pamphlets about HIV testing, PrEP, and behavioral health (i.e., substance use and mental health).

Participant type(s)
Employee

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable to provide consent
2. Deemed that participating would be potentially harmful to the participant
3. Have a medical or psychiatric condition that would interfere with ability to participate in study procedures

Date of first enrolment
03/02/2026

Date of final enrolment
01/12/2029

Locations

Countries of recruitment
United States of America

Study participating centre
University of Miami
5030 Brunson Drive
Coral Gables
United States of America
33146

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available