Title: Promoting Viral Suppression Among Transgender Women Living With HIV in Santo Domingo
NCT #: NCT06316102
Date: April 21, 2023

**University of North Carolina at Chapel Hill**
**Consent to Participate in a Research Study**
**Adult Participants (study enrollment)**

**Consent Form Version Date:** 21 April 2023
**IRB Study #** 22-3282
**Title of Study**: Piloting a multilevel intervention to promote viral suppression among transgender women living with HIV in Santo Domingo
**Principal Investigator**: Clare Barrington
**Principal Investigator Department**: Health Behavior
**Principal Investigator Phone number**: (919) 966-9009
**Principal Investigator Email Address**: cbarring@email.unc.edu
**Funding Source and/or Sponsor:** NIH National Institute of Mental Health (NIMH)

**Local Principal Investigator:** Yeycy Donastorg
**Local Principal Investigator Department:** Unidad de Vacunas e Investigación del Instituto Dermatológico y Cirugía de Piel (IDCP)
**Local Principal Investigator Phone number:** (809) 684-3257 ext. 342 y (809) 570-3439
**Local Principal Investigator Email Address:** yeycy@hotmail.com

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**Concise Summary**

The purpose of this study is to test an intervention to support transgender women living with HIV to improve and sustain HIV outcomes and overall wellbeing. We will recruit approximately 120 transgender women living with HIV who are at least 18 years old. Participants will be randomly assigned to receive the intervention (n=60) or to be in the control group (n=60).

The study will last for approximately 12 months.

There are no significant risks associated with participation in this study.

If you are interested in learning more about this study, please continue to read below.

**What are some general things you should know about research studies?**
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher team or the University of North Carolina-Chapel Hill. You do not have to be in the research study to receive health care. Your participation in this study will not affect the care that you receive.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You can ask the researchers named above or any study team members any questions you have about this study at any time.

**What is the purpose of this study?**

The purpose of this research study is to test an intervention called GAP (Gender Affirming *Abriendo Puertas*). The first aim of the study is to test if participating in GAP helps to achieve and sustain viral suppression. The second aim is to assess how GAP helps people and how it can be improved.

You are being asked to be in this study because you are a transgender woman who is living with HIV and you are at least 18 years of age.

**How many people will take part in this study?**

Approximately 168 people will take part in this study at the Unidad de Vacunas e Investigacion Instituto Dermatológico y Cirugía de Piel (IDCP). This includes 120 transgender women living with HIV. We will also conduct interviews and discussions with intervention staff (n=24) and HIV care providers (n=24).

**How long will your part in this study last?**

The study will last approximately 12 months. All participants will complete three assessments including baseline, midline (at 6 months), and endline (at 12 months). Each assessment will include a survey and blood draw. It will last 1-2 hours.

Individuals in the intervention study group will participate in four individual counseling sessions and approximately six community building sessions, each one lasting 1-2 hours. Individuals in the intervention group will also have continuous interaction with a peer navigator. Participation in all study activities is voluntary.

**What will happen if you take part in the study?**

- **Design**

This study is an evaluation of the GAP intervention (Gender Affirming *Abriendo Puertas*). The GAP intervention includes four components: 1) individual counseling; 2) peer navigation; 3) provider training and 4) community building. Participation in all intervention activities is voluntary.

- **Randomization**

Upon enrolling in the study, half of the study participants will be randomly assigned to the intervention and half to the control group. Random assignment means that participants will be assigned by chance, like flipping a coin, to a study group.

- **Assessments**

Both intervention and control study group participants will complete a baseline socio-behavioral survey and blood draw for viral load testing. These assessments are required of all study participants and will be repeated at midline (6 months) and endline (12 months). Participants will always have the option to skip any questions in the survey that they do not want to answer. There are no plans to re-contact you or other participants with information about research results. You are welcome to contact us in the future if you would like to learn about the study results.

- **Intervention Components**

Participants who are randomly assigned to the intervention study group will be invited to participate in the GAP intervention. Participation in all intervention activities is voluntary. The GAP intervention includes 4 components:

1) *Individual counseling:*
   The intervention includes 4 individual counseling sessions. Intervention study group participants will be scheduled for their first individual counseling session within two weeks following enrollment. They will be invited to complete a total of four individual counseling sessions during the first half of the intervention period. These sessions will be completed during the first 6 months of the intervention.
2) *Peer navigation:*
   Intervention study group participants will be assigned a navigator. Navigators will maintain monthly communication (at a minimum) with intervention participants. This communication will be via telephone and in-person, depending on the participants' preferences.
3) *Community building:*
   During the second half of the intervention period (months 6-12), intervention participants will be invited to participate in community building activities hosted at two local trans community organizations. There will be approximately 6 community activities, one per month.
4) *Provider training:*
   During the 12-month intervention period, the study team will facilitate training with providers and staff at the HIV clinics where study participants receive care.

Control study group participants will be contacted monthly by a member of the study team to facilitate retention and maintain contact information. They will not receive any other intervention.

**What are the possible benefits from being in this study?**

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study if you are randomly assigned to the intervention may be improved emotional wellbeing and HIV treatment outcomes.

**What are the possible risks or discomforts involved from being in this study?**

All research can involve some risk. Some of the questions we ask you during the interviews or

intervention sessions about personal and sensitive topics may cause you to feel embarrassment or emotional distress. You can take a break during the interview. You can choose not to answer any of the questions we ask you or to stop the interview at any time. If you feel that you would like to speak to someone after the interview, we can refer you to someone.

Another possible risk is breach of confidentiality where your participation in the research could be known outside of the study team. This could also lead to embarrassment or affect your reputation in the community. To minimize these risks, all intervention and research staff will be trained to maintain confidentiality and will only use participant identification instead of your name on any data forms. All study activities will be conducted in safe and private offices. Communication will only be made directly with study participants.

You may experience discomfort during blood draws or bruising where the needle enters the body. There is a small risk of infection. This is expected to be rare. Our study team staff are experienced and will use best practices for blood draws.

**How will information about you be protected?**

If you decide to participate, you will be assigned an identification number that is not connected to your name in any way. This number will be used on all study instruments. The information that you share in the surveys and your biological data will be stored using your study identification number in a secure database that will only be accessible to the study team.

Your name and other information that could identify you will not be used on any study documents. Your name and contact information will only be used to facilitate communication with you during the study period. We will have one file that links names and contact information that will be stored on a password protected computer.

We will not share your answers to the questions that we ask you with anyone. In the reports and other publications we make from this study, we will not identify who you are. We may use de-identified data and/or specimens from this study in future research without additional consent.

If you do not agree to take part in the study, it will not change any services related to HIV or benefits that you receive now or may receive in the future. You can choose not to participate in the interview; if you participate, you can stop at any time without penalty. We can also decide to stop the interview if we do not feel that we can maintain a private environment or we have concerns about your wellbeing.

A description of the design and main results of this study will be available on the website: http://www.ClinicalTrials.gov. This website will not include information that can identify you. You can search this website at any time.

**What if you want to stop before your part in the study is complete?**

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected.

**Will you receive anything for being in this study?**
You will receive $US 15 for each study visit. Individuals in the intervention group will have a total of 7 study visits at the Instituto Dermatológico y Cirugía de Piel (IDCP), including three assessments and four individual counseling sessions. Individuals in the control group will have a total of 3 study visits, one for each assessment. You will receive the payment upon completion of the study visit. If you decide to terminate a study visit before completion, you will still receive the payment.

**Will it cost you anything to be in this study?**
There is no cost associated with participation in this study.

**Who is sponsoring this study?**.
This research is funded by the National Institute of Mental Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. This study will be posted on ClinicalTrials.gov

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, or concerns, you can contact the researchers listed below.

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by committees that work to protect your rights and welfare.

If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at the University of North Carolina at +1 919-966-3113 or by email to IRB_subjects@unc.edu.

You may also contact Coordinator of the Institutional Review Board at the Instituto Dermatalogico y Cirugia de Piel (IDCP), Dr. Juan Periche, at 809-684-3257 ext 1789.

If you have questions about this study, you may contact Dr. Clare Barrington at the University of North Carolina (+1 919 966 9009) or Dr Yeycy Donastorg at the in Santo Domingo at 809 684 3257 ext 3257 and y (809) 570-3439.

**Participant's Agreement**:

**Title of Study:** A pilot intervention study with transgender women in the Dominican Republic

**Principal Investigator: Clare Barrington and Yeycy Donastorg**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

***Interviewer:*** *Please sign and provide each participant with a consent script signed by the person obtaining consent and keep one signed copy.*