

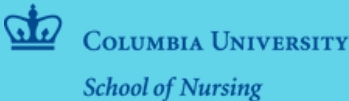


**PARTNER CONSORTIUM**

Romanian Association Against AIDS (ARAS)  
National Institute of Infectious Diseases in Bucharest ([NIID)  
Infectious Diseases Clinic (IDC), Cluj-Napoca

**IMPLEMENTED BY**

Columbia University School of Nursing in collaboration with the  
Yale School of Public Health, Florida State University, and One Cow  
Standing (OCS)





## THE SHORT OF IT

Development of a hybrid in-person + mHealth PrEP uptake and adherence program that aims to address the increasing rates of HIV among gay and bisexual men in Central-Eastern Europe and introduce pre-exposure prophylaxis (PrEP) and adherence support into Romania's healthcare system.

**10**

**Ten participants enrolled in field testing**

**20**

**Twenty participants enrolled in pilot testing**



**RCT will enroll 120 gay and bisexual men in Bucharest and Cluj-Napoca**



**The final aim will identify institutional and individual barriers regarding the access and adherence of PrEP consumption**

# BACKGROUND

Despite the globally proven effectiveness of PrEP in preventing the transmission of HIV, **PrEP is not currently medically prescribed in Romania.** However, the demand for PrEP is increasing, as is evidence-based knowledge on effective rollout strategies. **Romania has the second highest increasing HIV incidence amongst the 15 countries that make up the Central-Eastern European region.** Gay and bisexual men (GBM) overwhelmingly account for this epidemic-driven group; however, despite such findings there is no targeted national programming for the GBM population. According to a large GBM report **in 2019, Romania was the 8th of 44 European countries with the largest gap between PrEP use (1%) and PrEP demand (70%).**

Additionally, Romania exhibits some of the highest homophobic attitudes amongst Central-Eastern European countries. As a result of this stigma, GBM remain hidden and proper healthcare services are underutilized.

Therefore, Romanian GBM obtain PrEP on their own without

proper medical guidance, resulting in increased HIV incidence.



To address the unmet HIV-prevention needs of GBM in Romania, **the established US-Romanian team has introduced a culturally competent PrEP program in Romania integrating two tools that have been developed and tested in the US.** First, SPARK is an in-person motivational intervention for PrEP adherence utilizing an empowering sexual health approach. PrEP Romania, a mobile app, serves as the adherence support tool used within the program. Adapted and customized from HMP in the study's two formative phases, **the Prepare Romania app utilizes engaging social networking, game-based elements and an in-app portal for tailored live adherence counseling to support PrEP uptake and adherence.**

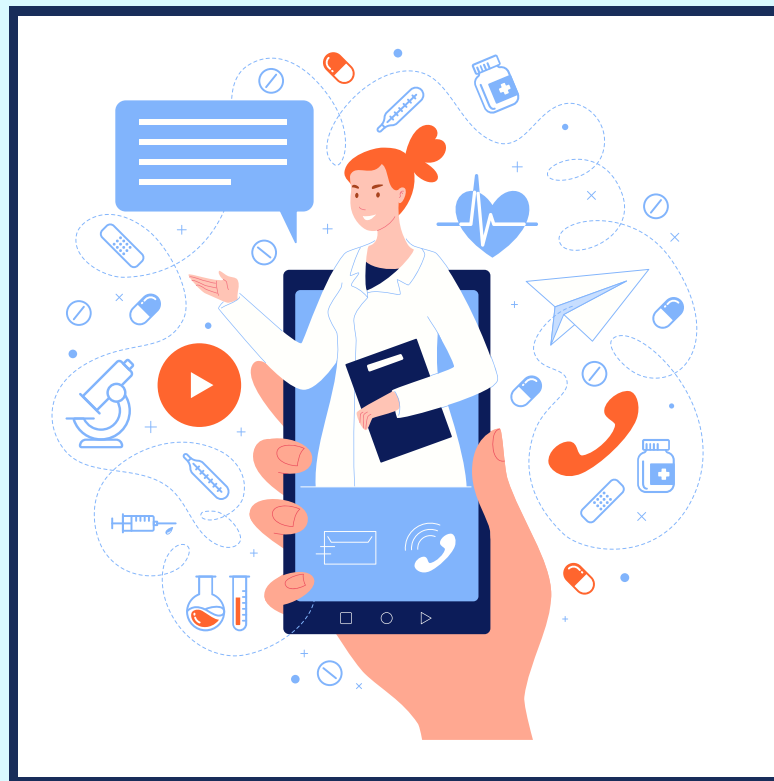


# PREP ROMANIA STUDY DESCRIPTION

To culturally adapt and test Prepare Romania for long-term healthcare practice implementation, this study has four aims. The first two were accomplished between September 2020 and April 2022.

**Aim 1 consisted of the creation of Prepare Romania by integrating and tailoring to the local context the in-person intervention (SPARK) and the mHealth app for Romanian GBM.** In months 2-7 the US team worked alongside a Romanian Partner Consortium and GBM community experts to culturally adapt and combine both SPARK and HMP. Qualitative data from working groups and survey data (groups included HIV counselors, infectious disease physicians, psychologists, US-based investigators, directors of LGBTQ Romanian resource centers and members of the Romanian GBM community) were analyzed and integrated into PrEP Romania to meet local needs. During months 8-9 the full **Prepare Romania protocol was field-tested amongst 10 GBM for one month, in Bucharest and Cluj-Napoca.** Components tested included PrEP counseling, prescription fills, app use and adherence support. During this time piloting of Dried Blood Spot (DBS) samples were collected by the study physicians at the baseline and follow-up visits, and stored within the clinic at -20 degrees Celsius.

**Aim 2 included pilot testing app usability, feasibility, and acceptability of PrEP Romania with 20 GBM in the same two cities.** During months 12-20, 20 GBM were recruited, screened and consented to be a part of the research study. Eligible participants completed the baseline survey, attended their first clinic visit and were prescribed PrEP for three months. The PrEP counselor checked in with participants via the app at the two and six week mark post PrEP initiation. Participants engaged in non-controlled pilot-testing for three months, followed by a second clinic visit



for a prescription refill and a follow-up survey. **As in Aim 1, DBS samples were collected at baseline and follow-up**, and shipped to the UNC School of Pharmacy Clinical Pharmacology and Analytical Chemistry Lab for analyses, together with the samples collected in Aim 1.

Aim 3 of Prepare Romania (July 2022–June 2025) will implement a **randomized controlled trial (RCT) to test the early efficacy of PrEP Romania** and identify necessary adjustments to be made to **improve the PrEP counseling and adherence protocol**, as well as **app usability**. During this time, 120 GBM from Bucharest and Cluj-Napoca will be randomized to receive either PrEP Romania (counseling, self-directed app use and in-app text support for six months) or a PrEP education condition. Evaluation of differences within PrEP uptake, adherence, and persistence from both groups will be measured.

Aim 4 of Prepare Romania is to **identify institutional and individual barriers regarding the access and adherence of PrEP consumption to help inform a future multi-city effectiveness-implementation hybrid trial**.

## APP HIGHLIGHTS

### Forum

Space used to create community while allowing peer-to-peer interaction.



### Ask the Expert

Ask health and wellness questions. Study-affiliated experts provide answers to both study and general health-related questions.



### Activities

Participants can complete activities (quizzes, fill-it-in, break-it-down, etc.) on a variety of topics. Upon completing a certain number of activities, participants can earn in-app badges.



### Resources

Participants can read up on a variety of topics determined to be relevant to them during the study's formative phases.



## PRELIMINARY FINDINGS FROM FIELD TESTING

Ten participants were enrolled in the PrEP Romania program between July 29 and August 26, 2021 for field testing. Participants found their experience starting PrEP to be positive, and reported a decrease in anxiety upon starting the PrEP regimen. Their **interactions with the PrEP counselors and physicians were informative and clear**. No changes to the counseling protocol were suggested. Overall, **participants found the app to be intuitive and easy to use, with appealing user interface (UI) and helpful features, especially the PrEP tracker and adherence reminders**. Participants suggested several feasible points of improvement for this app, which were noted and incorporated into the app by developers in October and November 2021.

# PRELIMINARY FINDINGS FROM PILOT TESTING

**20 participants were enrolled in the pilot version of Prepare Romania** between December 2021 and January 2022. Of the 20 participants, 19 (95%) of participants completed their 3-month follow-up survey. One participant voluntarily discontinued PrEP due to lack of perceived sexual risk. Eighteen (90%) DBS samples were collected, stored, and transported to the University of North Carolina (UNC) School of Pharmacy Clinical Pharmacology and Analytical Chemistry Laboratory for analyses.

**Seventeen participants provided feedback on their experience with the intervention and app.** Overall, participants reported taking PrEP an easy and hassle-free integration into their daily lives. **The majority of participants reported that taking PrEP alleviated their anxiety associated with contracting HIV** and recommended that others who could benefit should take PrEP as well. The app was found easy to use, interesting, and engaging. The best features were deemed to be those geared to help participants monitor their PrEP use and emotional states. Participants also liked seeing the graphs generated by the daily tracking they performed (e.g., PrEP use, alcohol use, sexual behavior). Some participants mentioned the usefulness of the articles posted within the app (e.g., about relationships, STIs, mental health). The frequency of post-PrEP initiation check-ins by counselors was found to be “exactly right” and useful. Thirteen of 17 participants (76%) indicated that they would continue using the app beyond the study and 11 (65%) would recommend it to others.

## WHAT'S NEXT

The RCT is planned to begin Fall 2022. Results from the completion of Prepare Romania will serve as evidence to create a scaled-up effectiveness-implementation hybrid trial across several Romanian cities.