

Building Mobile HIV Prevention and Mental Health Support  
in Low-Resource Settings

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## BACKGROUND

### *Study Purpose and Rationale*

This research is designed to remedy unaddressed and interlocking HIV-prevention and mental health needs among gay, bisexual, and other men who have sex with men (GBMSM) in the Central Eastern European country of Romania, and their underpinning stigma-related mechanisms. Rampant stigma contributes to the increasing prevalence of HIV among Romanian GBMSM (from under 10% in 2009 to close to 20% in 2014, by best available estimates) and keeps GBMSM out-of-reach of HIV prevention services. The team's mHealth pilot intervention (titled "Comunica: Despre Mine. Despre Noi." [COMUNICA] translated as "About Me. About Us."), which reduced US and Romanian GBMSM's risk for HIV infection while also reducing depression and alcohol abuse in initial pre-post trials, is now ready for testing in a randomized controlled trial with a large national sample in the current study. The Comunica intervention entails eight 60-minute live chat sessions delivered by trained counselors on our mobile study platform using motivational interviewing (MI) and cognitive-behavioral skills training (CBST).

First, during pre-trial (months 1-5), in collaboration with a community advisory board consisting of GBMSM community members, GBMSM-affirmative physical and mental health providers, and a technical developer, the team fine-tuned the Comunica intervention based on pilot findings and evaluation interviews, and expand the original Comunica education materials for an education attention condition that will serve as a control arm.

Second, during the intervention phase (months 6-45), the team will recruit, screen, assess, and randomize GBMSM at risk for HIV infection and alcohol abuse to either the Comunica intervention (n=163) or education attention condition (n=163). The conditions are content matched, and both are hosted on the study platform. While Comunica will consist of eight weekly mHealth live chat sessions, the education attention control condition will consist of eight self-administered educational modules.

Third, during the follow-up phase (months 8-55), the team will assess at 4, 8, and 12 months post-baseline, in a mobile fashion identical to the baseline, the primary outcome of condomless anal sex (CAS) with male partners, secondary outcomes of alcohol abuse, depression, and anxiety, and psychosocial mechanisms rooted in the Information-Motivation-Behavioral Skills (IMB)

model (e.g., HIV/STI knowledge, condom use self-efficacy) and minority stress theory (e.g., identity concealment, internalized homophobia).

### *Research Aims & Abstracts*

Aim 1. Test the relative efficacy of the Comunica mHealth intervention compared to a content-matched education attention control condition in changing (a) the primary outcome: CAS with HIV-positive or unknown-status partners and (b) secondary outcomes: depression, anxiety, and alcohol abuse. Outcomes are measured at preintervention (baseline), and at 4-, 8-, and 12-month follow-ups.

Primary and Secondary Outcomes (Aim 1). Comunica GBMSM, compared to education attention control condition GBMSM, will report significantly greater changes on primary (decreased CAS) and secondary (decreased alcohol use, depressive symptoms, and anxiety symptoms) outcomes across 12 months.

Aim 2. Test motivational and stigma-related mechanisms of intervention efficacy. Hypothesized motivational mechanisms include HIV/STI and alcohol-related knowledge and behavioral skills as well as condom-use and refraining-from-alcohol-use self-efficacy, grounded in the IMB model. Hypothesized minority stress mechanisms include collective self-esteem, internalized homophobia, identity concealment, and stigma consciousness, which are grounded in minority stress theory and are particularly relevant for GBMSM in high-stigma countries.

IMB and Minority Stress Mediation Hypothesis (Aim 2). Comunica GBMSM, compared to education attention condition GBMSM, will report greater improvement in 1) knowledge of sexual health and deleterious effects of alcohol use, 2) motivation to change risk behavior and 3) behavioral self-efficacy to execute changes across 12 months. Comunica GBMSM, compared to education attention condition GBMSM, will also report significantly greater shifts in minority stress (e.g., attenuated internalized homophobia, identity concealment) across 12 months. Improvements in IMB and minority stress mechanisms will precede and statistically mediate intervention effects, based on our conceptual model.

## STUDY DESIGN

First, in a pre-trial phase (months 1-5), in collaboration with a community advisory board (CAB) consisting of collaborators, gay and bisexual men, gay and bisexual men-affirmative physical and mental health providers, and technical developer, we will first fine-tune and pre-test the Comunica intervention based on pilot findings and exit interviews, and expand the preliminary education materials for the education attention control condition.

Second, during the intervention phase (months 6-45), the team will recruit, screen, assess, and randomize gay and bisexual men at risk for HIV infection, alcohol abuse, and depression to either the Comunica intervention (n=163) or education attention condition (n=163). The conditions are content matched, and both are hosted on the study platform. Comunica consists of eight weekly mHealth live chat sessions; education attention condition will consist of eight self-administered educational modules.

### *Eligibility*

Potential participants will be eligible if they report:

- 1) Male sex at birth and current male identity
- 2) Age 16 years and above
- 3) At least 1 CAS act with an HIV-positive or status-unknown male partner in the prior month
- 4) At least 1 heavy drinking day in the prior month
- 5) Own a mobile device (e.g., smartphone, tablet, laptop)
- 6) Planned residence in Romania for the duration of study participation (12 months)
- 7) Not currently using HIV pre-exposure prophylaxis (PrEP)
- 8) Confirmed to be HIV-negative upon testing at baseline

### *Baseline (BL), 4-, 8-, and 12-month Assessments*

The project coordinator will send a link to the BL survey to all HIV-negative participants, and tell them that they will be contacted by their counselor after submitting the survey. The quarterly self-administered mobile assessments are identical, take 45 minutes to complete, have been validated by the Romanian pilot gay and bisexual men participants, and assess: 1) sexual

behavior (e.g., number of CAS acts; number and types of partners; sex under the influence) and 2) past-3-month alcohol use; 3) depressive symptoms; 4) HIV/STI testing and other healthcare access (e.g., annual exams; mental health) patterns; 5) hypothesized mediators of intervention efficacy, including IMB model components (e.g., HIV-risk-related information, motivation, behavioral skills) and minority stress (e.g., outness, internalized homonegativity, collective self-worth); and 6) demographics and psychosocial risk contexts, including intimate partner violence. Third, during the follow-up phase (mos 8-55), we will assess at 4, 8, and 12-mos post-baseline, in the same web-based fashion as at baseline, the primary outcome of CAS with male partners, and secondary outcomes of alcohol abuse, depression, anxiety, and psychosocial mechanisms rooted in the Information-Motivation-Behavioral Skills (IMB) model (e.g., HIV/STI knowledge, condom use self-efficacy) and minority stress theory (e.g., identity concealment, stigma consciousness).

We hypothesize that 1) compared to gay and bisexual men in the education attention control arm, those randomized to the Comunica arm will report significant reductions in CAS acts, depression symptoms, and anxiety symptoms across the 12-month follow-up, 2) IMB and minority stress mechanisms will statistically mediate intervention efficacy, and 3) compared to the control condition, the Comunica intervention will prove cost-effective in terms of reducing depression, anxiety, and alcohol abuse.

#### *Intervention Content*

Comunica Content. The intervention aims to support gay and bisexual men in reducing their CAS act and alcohol use and improving their mental health. Comunica is delivered over eight 60-min live chat sessions on our mHealth study platform compatible with any mobile device (e.g., laptops, smartphones).

Theoretical Grounding. Comunica is based on the IMB model of health behavior change, which postulates that individuals must possess the requisite information on sexual health and alcohol, motivation to change their HIV risk and alcohol use, and behavioral skills self-efficacy to reduce their risk. Therefore, Comunica includes MI to provide accurate information about HIV transmission, alcohol abuse, and local GBMSM-affirmative health resources (e.g., HIV-testing sites) and build motivation to improve behavioral skills (via CBST). MI is an evidence-based form of person-centered therapeutic communication that privileges client values and preferences for change to help individuals resolve ambivalence and move toward their valued goals. Skills-

building is often a natural outcome of MI, especially for individuals who attain a high degree of motivation for change. CBST is a therapeutic approach used in the treatment of various behavioral problems, such as alcohol abuse, depression, and more recently high HIV risk. CBST can help modify cognitions driving unhealthy behaviors, promote awareness of contextual triggers and unhealthy behavioral patterns, and teach coping skills to improve health. Comunica also draws upon minority stress theory recognizing that stigmatizing societal contexts compromise health behavior. GBMSM in highly stigmatizing contexts such as Romania experience a lack of structural protections (e.g., national policies), institutional support (e.g., GBMSM-affirmative healthcare), and coping resources (e.g., social support). Thus, the CBST skills in Comunica are presented in a manner that acknowledges the barriers that social stigma poses to GBMSM's health, while empowering them to circumvent these barriers by building self-efficacy, effective communication, and planful problem-solving. Safety protocols include instructions for protecting participants' identities, data, and safety.

Education Attention Control Condition. The control condition consists of eight modularized topics content-matched with the Comunica sessions, which we have generated based on the team's HIV-prevention education with GBMSM in the US and Romania. Topics include 1) GBMSM identity, 2) "HIV 101," 3) HIV/STI testing, 4) alcohol and the body, 5) the role of alcohol in HIV risk, 6) HIV-status disclosure and sexual health communication, 7) finding social supports, and 8) a summary. To maintain uniformity of information exposure across participants and maximize learning, each screen will be timed at a comfortable speed and participants will be unable to advance to the next screen prior to the set time limit. Control participants will receive five quiz questions after each module, with correct answers on a subsequent screen.