



## Addressing intersectional stigma as a care barrier for HIV-positive people who inject drugs: Design of an RCT in St. Petersburg, Russia

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### ABSTRACT

**Background:** HIV-positive people who inject drugs (PWID) experience stigma related to their substance use and HIV, with adverse consequences to their health care utilization and mental health. To help affected individuals cope with their intersectional stigma and reduce its negative impact on health and health care, we adapted a behavioral stigma coping intervention for this HIV key population.

**Objective:** To conduct a randomized controlled trial (RCT) testing the 'Stigma Coping to Reduce HIV risks and Improve substance use Prevention and Treatment' (SCRIPT) intervention, a community-based, adapted form of Acceptance and Commitment Therapy (ACT), for PWID living with HIV in St. Petersburg, Russia.

**Methods:** We recruited 100 PWID living with HIV from civil society organizations (CSO) delivering harm reduction and HIV prevention services in St. Petersburg, Russia. We randomized participants 2:1 to receive either the intervention (three adapted ACT sessions in a group format over one month and usual CSO care) or usual CSO care alone. ACT aims to help affected individuals cope with stigma by increasing their psychological flexibility to handle stigma-related negative expectations, emotions and experiences. The primary outcomes were satisfaction with the intervention, and changes in HIV and substance use stigma scores.

**Conclusions:** Stigma coping interventions targeting HIV-positive PWID outside of formal health care settings may help them confront negativities in their lives originating from intersectional stigma and reduce stigma's impact as a health care barrier.

### 1. Introduction

The HIV epidemic continues to grow in the Russian Federation (Russia), with an increase in incident infections by 10–15% each year [1–3]. Almost half of all new HIV diagnoses in Russia are among people who inject drugs (PWID) [4]. PWID with HIV experience multiple layers

of stigma related with their substance use, HIV status, and other identities, such as gender and involvement in criminal activities. The stigma that PWID with HIV experience can be understood as a label, marking and identifying these individuals to be devalued based on socially defined characteristics [5]. Sociologists have historically defined stigma as the social exclusion and dehumanization of marginalized individuals resulting in social status loss [6,7]. As a consequence of the process of

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## Nomenclature

- <sup>1</sup> SCRIPT Stigma Coping to Reduce HIV risks and Improve substance use Prevention and Treatment  
<sup>2</sup> ACT Acceptance and Commitment Therapy  
<sup>3</sup> CSO Civil Society Organization  
<sup>4</sup> ARC Addiction Rehabilitation Center  
<sup>5</sup> UIPHP Ukrainian Institute on Public Health Policy

stigmatization, social interactions are characterized by devaluation, exclusion, blame, and rejection, derived from actual or anticipated adverse social judgements of an individual or group with a specific health problem [8,9]. Stigma can be mainly classified into 1) external stigma: attitudes from other people and groups such as providers, family, communities, or law enforcement, 2) structural stigma: translation of external stigma and discriminatory attitudes into norms, laws, and policies, and 3) stigma manifestations among affected people: endorsement of the perceived public attitudes by individuals with the identity that is stigmatized, and anticipated or actual experiences of shame and devaluation [10,11]. External stigma, such as beliefs about someone living with HIV, can lead to discrimination towards the marginalized individual, which can then prompt the affected person to endorse others' attitudes and consequently experience negative feelings about themselves (internalized stigma) [12].

Internalized, stigma-related thoughts and feelings, through fear and shame, can adversely impact all components of the HIV care cascade, including testing, diagnosis, treatment, and adherence [13–15]. Individuals in HIV key populations, such as PWID, almost always experience intersectional stigma, or multiple layers of stigma, by virtue of their substance use and other marginalized identities [8,16–18]. Understanding the interaction between HIV and substance use stigma is vital to understanding the experience of PWID living with HIV, and to recognizing the impact on physical and mental health outcomes [19,20]. Fueled by criminalization of substance use and the legal ban on opioid agonist treatment (i.e., methadone and buprenorphine), structural stigma is pervasive in Russia and has led PWID with HIV to experience increased discrimination, delaying progress towards the UNAIDS 95-95-95 targets [21–25].

While external stigma persists in most settings globally, stigma interventions should also focus on internalized stigma, helping PWID who are living with HIV to cope with intersectional substance use and HIV stigma experiences [26]. Previous quantitative analyses of an existing cohort of PWID living with HIV in addiction care in St. Petersburg, Russia, showed intersectional stigma's adverse association with health care access and utilization [27]. People with less access to a formal health care setting might experience even worse stigma [27]. Due to social resistance and policy within Russia, external stigma interventions on a public scale are not currently implemented. Consequently, within or outside of the formal health care setting in Russia, there are no internalized stigma interventions to support PWID with HIV cope with intersectional internalized stigma.

Thus, we sought to evaluate a stigma intervention targeting internalized substance use and HIV stigma among PWID who are living with HIV, who are not currently on ART [28].

To target internalized substance use and HIV stigma, we adapted an *Acceptance and Commitment Therapy* (ACT) intervention to the context in St. Petersburg, Russia [29]. We chose ACT because a literature review of interventions for internalized stigma toward HIV and substance use revealed its preliminary effectiveness for people with addictions [29, 30]. ACT is a behavioral intervention that guides people to cope with stigma by detaching from judgmental and self-critical thinking; confronting shame, fear, and other emotions; and focusing on taking effective action connected to their values, for example through seeking

HIV treatment or engaging in addiction recovery or harm reduction services [31]. The SCRIPT study was a randomized controlled trial (RCT) comparing usual civil society organization (CSO) care and ACT to usual CSO care alone. The trial examined 1) intervention feasibility and 2) the intervention's effect on substance use and HIV internalized stigma scores, furthering an understanding of possible coping techniques for PWID living with HIV who experience internalized stigma.

## 2. Materials and methods

Stigma Coping to Reduce HIV risks and Improve substance use Prevention and Treatment (SCRIPT) was an RCT enrolling 100 HIV-positive PWID to implement and evaluate the feasibility of the adapted ACT intervention. We also tested the effects of the ACT intervention plus usual CSO care compared to solely usual CSO care on the reduction of internalized HIV and substance use stigma scores, and on HIV care entry, substance use care engagement, and substance use frequency. Eligible participants were randomly assigned at a ratio of 2:1 to either the ACT intervention or the control group (civil society organization's standard of care as described). The intervention comprised of an adapted form of ACT in three group sessions.

### 2.1. Study setting

We conducted this study at two sites: *Humanitarian Action*, a CSO, and the outpatient *Addiction Rehabilitation Center* (ARC) of City Addiction Hospital, both located in St. Petersburg, Russia. Usual care provided by *Humanitarian Action* includes free harm reduction and HIV prevention services in mobile units (outreach busses) through medical, social, and psychological resources to individuals who use substances. From October 2019 to September 2020, the *Humanitarian Action* staff recruited participants at their service sites [32].

Following pre-screening at *Humanitarian Action*, we referred eligible participants to the outpatient ARC of City Addiction Hospital to conduct the intervention and all study procedures in this facility. This government-funded medical facility in St. Petersburg delivers outpatient addiction rehabilitation services to residents [33]. Participants did not receive any intervention or treatment services at the ARC beyond the study procedures and ACT sessions as described below.

### 2.2. Participants and recruitment

Table 1 lists study eligibility criteria [Table 1]. Screening occurred in two steps: 1) a phone screening initiated on the bus by interaction with *Humanitarian Action* staff; and 2) an in-person screening for those participants who were eligible after the phone screening at the ARC. Research Assessors (RAs) who were ARC staff (psychologists and social workers), conducted phone screening and in-person screening. When a client entered a *Humanitarian Action* bus for standard services, the outreach worker provided information about the SCRIPT study through the study pamphlet and flyer. If the client expressed interest in participating and being screened, the outreach worker immediately connected the client with the ARC study team through the study phone number, which was answered by an RA at the ARC. During the phone call, the RA provided a detailed description of the study and conducted the phone screening to evaluate whether the client met study inclusion criteria. After confirming study eligibility, the ARC RA scheduled the client for an in-person screening at the rehabilitation center and provided navigation directions. After the phone call, the *Humanitarian Action* staff additionally provided written directions to the ARC from the bus location. The client was scheduled for the visit at the ARC, where the RA met with the client in a private location to explain the study in more detail and conducted in-person screening to confirm the client's eligibility for the study. Once the participant was confirmed as eligible, the RA administered informed consent procedures and enrolled the client into the study. The participant then provided contact information for themselves

**Table 1**  
SCRIPT eligibility criteria.

Inclusion Criteria	Exclusion Criteria
Age 18 years or older HIV-positive (self-report)	Not fluent in Russian Cognitive impairment precluding informed consent
Current injection drug use (past 30 days)	Participants in the main study did not participate in the practice portion of the study.
Not currently on ART Provision of two contacts to assist with follow-up Address within St. Petersburg or districts within 100 km of St. Petersburg Not enrolled in any other research studies	Acute severe psychiatric illness (i.e., answered yes to any of the following: past three month active hallucinations; mental health symptoms prompting a visit to the emergency room or hospital; mental health medication changes due to worsening symptoms; presence of suicidal plans) and research clinical observation (i.e. clinical observation or prior knowledge of severe personality disorder; past three months active mania; past three months active psychosis)
Possession of a home or mobile phone Ability and willingness to comply with all study protocols and procedures over 6 months Available at the specific days of the week and times that the group sessions will be occurring for the subsequent 3–4 weeks (to ensure that participants randomized into the intervention arm will be able to receive the intervention)	

Inclusion and exclusion criteria for the Stigma Coping to Reduce HIV risks and Improve substance use Prevention and Treatment (SCRIPT) study.

and at least two alternative contacts. The baseline assessment took place the same day.

### 2.3. Randomization

The randomization sequence, with an allocation ratio of 2:1, was created using random block size in R, version 3.5.2 and uploaded to the REDCap platform, an electronic data collection tool, and used to reduce selection bias and make the sequence less predictable [34,35]. The unequal randomization ratio allowed to gather more data on the ACT intervention, given that this innovative intervention was developed for and implemented in this population for the first time.

### 2.4. Intervention

The SCRIPT study utilized two interventions: ACT and usual CSO care (intervention arm) compared to usual CSO care alone (control arm).

#### 2.4.1. Intervention group

The ACT intervention developed for the SCRIPT study was a culturally adapted version of Acceptance and Commitment Therapy (ACT), designed to help people cope with stigma and related thoughts and emotions; as well as take action to counter stigma's adverse consequences on health behaviors [31].

**2.4.1.1. Acceptance and Commitment Therapy content.** Sessions occurred in groups of approximately five participants and followed a manual based on prior work by Luoma et al. (2008, 2012), that was culturally adapted to the Russian context by the study team, with the assistance of a Russian ACT trainer [29,30]. The goal of the group sessions was to help participants overcome negative thoughts and emotions related to stigma-related shame and negative judgements of self and others. We modified standard ACT exercises to focus on how participants respond to shame and stigma so as to encourage substance use disorder recovery, harm reduction, and health care utilization. Interventionists trained participants to utilize techniques focused on mindfully observing and accepting indications of internalized, anticipated, or experienced stigma manifestations (e.g., shame or fear), in order to diminish their conditioned association with potentially ineffective or harmful behavior (i.e.

health care avoidance, or drug use and sex risk behaviors). The intervention helped participants identify and commit to meaningful values and life goals that could guide more effective and healthier behavior.

We audio recorded all sessions for supervision purposes and to monitor intervention fidelity.

**2.4.1.2. Intervention logistics.** We scheduled the three ACT intervention group sessions with five planned participants in each group, for 2 h each, in weekly succession. The sessions occurred at the ARC and were led by two interventionists (clinical psychologists) trained in ACT by peer-reviewed ACT trainers. If a participant missed the first session, the RA scheduled the participant for the subsequent group. If a participant missed the second session, the RA invited the participant for an individual make-up session, prior to the scheduled third session. If a participant missed the third session, this was a missed session, but the RA invited the participant to complete subsequent 1-month and 6-month assessments.

#### 2.4.2. Control group

Both intervention and control groups received the usual care from the CSO, which included counseling and referral to addiction treatment clinics (for detoxification and rehabilitation care, as opioid agonist treatment is not available in Russia) [36] and to HIV treatment clinics (for ART and HIV care) in St. Petersburg. Both groups also were given printed flyers with drug harm reduction, HIV care, and safer sex information.

### 2.5. Compensation

RAs compensated participants for their travel and time in Russian rubles equivalent to approximately 30 USD at the time of the study (2019–2020) for each of the three intervention sessions and all in-person assessment visits. For assessments that took place over the phone instead of in-person, participants received partial compensation in equivalent of approximately 8 USD. This procedure was modified during the pandemic, with participants receiving full compensation for their follow-up visits even if they were completed over the phone. In order to dis-incentivize coming late to group, participants who arrived 1 h or later to a session received partial compensation in equivalent of approximately 15 USD. If a participant arrived to a session with less than 30 min remaining, they received no compensation for that session.

### 2.6. Outcomes

We evaluated implementation of the intervention with the following outcomes: 1) proportion of participants satisfied with the intervention at 1 month from an overall satisfaction score (primary implementation outcome, assessed among intervention arm participants); 2) rate of participation in three intervention sessions; and 3) fidelity to the intervention. We evaluated the effectiveness of the intervention on the following outcomes: 1) change in substance use and HIV internalized stigma at 1 month (primary effectiveness outcomes); 2) initiation of HIV care (ART) at 6 months; 3) engagement in substance use care at 6 months; 4) change in total number of injections in the past 30 days at 6 months.

The proportion of participants satisfied post-intervention at 1-month was defined as the proportion of participants with a mean score of 3 or greater on a Likert scale (1 = low, 5 = high) of three items that signified overall satisfaction ("1. How much did you enjoy attending the ACT trainings?", "2. Did the ACT trainings meet or exceed your expectations?", and "3. Do you think the ACT trainings would be useful in helping others with HIV and substance use?"). Data for other domains of satisfaction were collected for exploratory analyses.

This study was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT03695393).

2.7. Assessments

RAs assessed all participants at baseline, one, and six months post-enrollment [Fig. 1]. All follow-up study visits took place at the ARC. Table 2 lists baseline and follow-up study assessments [Table 2]. Trained RAs administered all sections of the assessments using REDCap, an electronic database.

2.8. Serious adverse events/safety monitoring

RAs and interventionists determined a participant’s ability to continue to participate in the study from clinical observation. They appropriately documented and reported any event meeting the criteria for an adverse event, serious adverse event, or unanticipated problem. As this was a behavioral intervention, this was a minimal-risk study, however in the event that a study staff member believed a participant was at risk of hurting themselves and/or others, appropriate action was taken with a defined suicide and homicide safety protocol.

2.9. Data management

Specialists from the Ukrainian Institute on Public Health Policy (UIPHP) designed, developed, and maintained the electronic data collection and database systems which compiled participant data, intervention adherence information, scheduling, and participant tracking. UIPHP implemented procedures for external data quality control, including pre-programmed skip patterns, real-time range checks, and internal logic to minimize missing data. For data collection questionnaires, where data were directly entered into the study record, the RA, local study coordinator, and the overall study coordinator reviewed records on a regular schedule to ensure data quality.

2.10. Analytic methods

The main purpose of this study was to assess implementation and effects of the intervention on stigma scores and health outcomes to

**Table 2**

Assessment table of participants in SCRIPT study (n = 100).

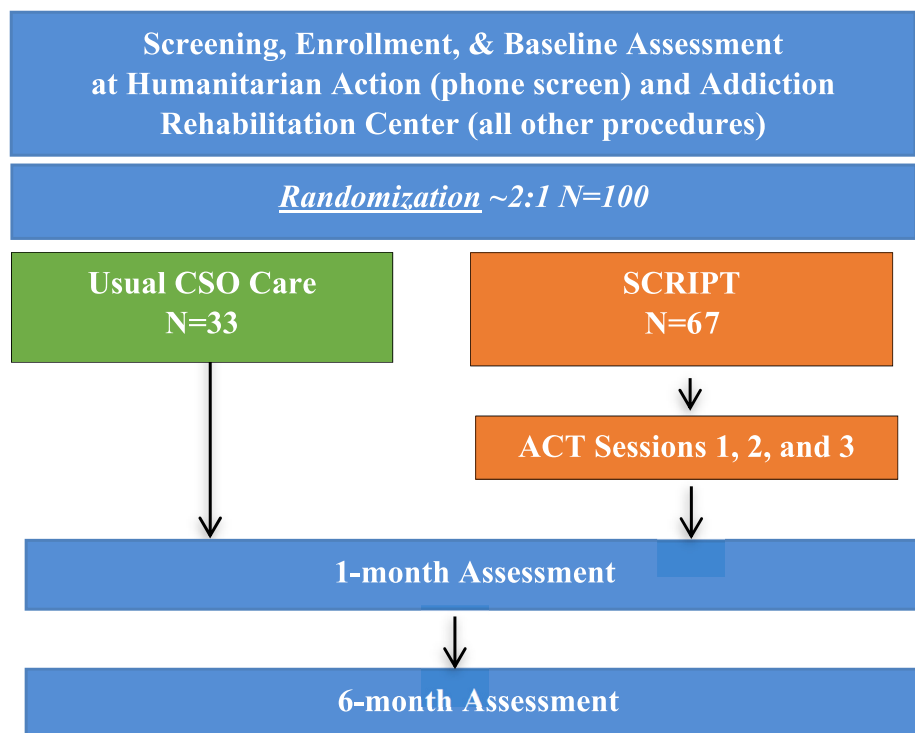
Administered Assessment	Baseline	1-Month	6-Month
Demographics [40–42]	X		
ART Use and Adherence [43]	X	X	X
HIV Sex Risk Behaviors [44,45]	X	X	X
HIV Risk Categories [46,47]	X		
HIV Disclosure [48,49]	X		X
HIV Stigma [50,51]	X	X	X
Substance Use Stigma (SASSS) [52]	X	X	X
Stigma-Related Rejection Scale (SRS) [53]	X		
Acceptance and Action (AAQ-II – SA) [54]	X	X	X
Patient Health Questionnaire (PHQ-9) [55]	X	X	X
Anxiety (GAD-7) [56]	X	X	X
Partner Violence and Sexual Assault [57]	X		
Alcohol Use: AUDIT-C [58]	X		
Perceived Alcohol Stigma [59]	X		
Drug Use [60,61]	X	X	X
Overdose	X		X
Social Support Scale [62]	X		X
VR-12 Health Survey [63,64]	X		X
Health Care Utilization [65]	X		X
Abbreviated PTSD Checklist [66]	X		
Involvement with Police	X		X
<sup>‡</sup> Satisfaction with the Intervention		X	
<sup>*</sup> HIV Testing History [67]	X		

<sup>‡</sup>Intervention group participants only.

<sup>\*</sup>If this information is not collected at baseline, RAs will collect this information at a later study visit.

Administered assessment measures at the baseline, 1-month, and 6-month study visits for participants in the Stigma Coping to Reduce HIV risks and Improve substance use Prevention and Treatment (SCRIPT) study.

inform future, larger effectiveness trials. In this pilot project, the sample size was justified by an 80% power to detect an absolute difference of 40% (i.e., 60% vs. 20% in the intervention and control arms, respectively) in the proportions of care initiation, with an estimated 90 evaluable subjects, assuming 10% loss to follow-up of the initial sample of n = 100. We expected 14 participants to be enrolled each month. Given the lengths of follow-up of 6 months, this allowed for enrollment



**Fig. 1.** Study design and procedures for the Stigma Coping to Reduce HIV risks and Improve substance use Prevention and Treatment (SCRIPT) study.



of 100 participants.

This study will use an intent-to-treat analysis that includes all participants according to their randomized assignment. To assess whether there appears to be any differences across treatment arms, all variables at baseline and follow-up visit will undergo descriptive analyses. We will use Chi-square test to compare differences in proportions and T-test or Mood's median to explore differences in means and medians, respectively.

Primary outcomes will be proportion of participants satisfied with the intervention from an overall satisfaction score and change in total substance use and in HIV stigma scores between baseline and 1 month after randomization. Initiation of ART at 6 months, engagement in substance use care at 6 months, change in the number of injections in the past 30 days at 6 months, as well as participation in all three intervention sessions and fidelity to the intervention will be assessed as secondary outcomes.

Because the ACT intervention is delivered in the form of group sessions, individuals within the same group will be correlated. We will use linear probability model for binary outcomes and linear regression for continuous outcomes with robust standard errors to account for within cluster/correlation due to the group sessions in the ACT intervention. For continuous outcomes, we will use quartile regression models with robust standard errors in case of major departures from normality. Models for primary outcomes (changes in stigma scores) will be adjusted for baseline stigma score, injecting frequency, history of ART, and depressive symptoms to account for residual confounding. This set of covariates was defined by the study team based on the literature and considering the sample size. Models for secondary outcomes will be unadjusted except for continuous outcomes calculated as change; they will be adjusted for the baseline scores. We will calculate effect sizes using Cohen's *d* for numerical outcomes and Cohen's *h* for categorical outcomes to understand the clinical significance of observed differences. We will conduct analyses in R, version 4.0.5 (Copyright (C) 2021 The R Foundation for Statistical Computing).

### 2.11. Protection of study participants and their data

The Institutional Review Boards of Boston University Medical Campus and First St. Petersburg Pavlov State Medical University approved the SCRIPT study. All study participants completed written informed consent.

All data collection occurred on a secure, web-based system, located on a secure server within the UIPHP domain [37]. The system used various methods to protect against malicious users who may attempt to identify and exploit any security vulnerabilities in the system, such as secure logins, user privilege settings, automatic log outs after inactivity, and audit trail logs of all user activity and pages viewed by every user. Participant contact information was kept in separate programs from research data.

## 3. Discussion

The SCRIPT study assessed an intervention designed to help PWID living with HIV in Russia to cope with internalized substance use and HIV stigma and provides effect sizes on stigma scores, health care utilization, and other outcomes. This community-based study aimed to engage those who are already connected to harm reduction CSOs, to the formal HIV and addiction health care systems. The SCRIPT study provided effect size data to appropriately power subsequent effectiveness and implementation trials for this stigma intervention.

Beyond assessing health care utilization and ART initiation, future studies should also measure retention in HIV care, adherence to ART, and viral load suppression. Other intervention design enhancements could include bundling the ACT intervention with other support, including mental health counseling, social support networks, or case management. Studying intervention delivery by peers or patient

navigators could improve the reach of this approach, and potentially allow for scale-up in resource-constrained settings. Future studies should investigate intervention adoption and variations of exposure (number and time length of sessions) and timing (temporal spacing of sessions). Other variants could include individual versus group delivery of the intervention, as well as utilizing telemedicine and embodied conversational agents, a computer-generated interface that utilizes human verbal and non-verbal characteristics [38]. We implemented this study with CSOs, as they are in close proximity to people who are out of care, who are the most vulnerable and most stigmatized. Most importantly, other researchers should investigate how to utilize the ACT intervention in different settings.

A particular strength of this study is that it examines a stigma coping intervention for PWID living with HIV *outside* of the formal health care system in Russia. Engaging PWID living with HIV in medical care is a high priority in Russia, as only 10% of this population in St. Petersburg are accessing HIV treatment [39]. This trial was conducted in Russia, where public stigma towards PWID and people living with HIV remains high, and for that reason, the results from this study may be applied to other settings with pervasive intersectional public stigma. As both public and internalized stigma remain a high barrier to health care utilization, this research is integral towards reaching Russia's and global HIV targets and reaching the goal of zero discrimination.

### Clinical trial registration details

This study was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) through the National Institutes of Health - Stigma, Risk Behaviors and Health Care Among HIV-infected Russian People Who Inject Drugs (SCRIPT): NCT03695393.

### Ethics approval and consent to participate

The SCRIPT study was approved by the Institutional Review Boards of Boston University Medical Campus and Pavlov University.

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### Author contributions

Sarah L. Rossi: Writing – original draft; Visualization; Project administration. Yuliia Sereda: Data curation; Formal analysis; Methodology; Software; Writing – review & editing. Jason B. Luoma: Conceptualization; Methodology; Resources; Supervision; Writing – review & editing. Nikolai Pavlov: Conceptualization; Resources; Supervision. Olga Tousseva: Investigation; Writing – review & editing. Janna Vasileva: Investigation. Kristina Abramova: Investigation. Sally Bendiks: Project administration; Writing – review & editing. Tetiana Kiriazova: Writing – review & editing. Marina Vetrova: Writing – review & editing. Elena Blokhina – Conceptualization; Project administration; Supervision; Writing – review & editing. Evgeny Krupitsky – Conceptualization. Dmitry Lioznov – Conceptualization; Resources; Supervision. Sara Lodi – Conceptualization; Formal analysis; Methodology. Karsten Lunze – Conceptualization; Funding acquisition; Methodology; Supervision; Writing – original draft.

### Data availability

No data was used for the research described in the article.

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