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Home-based hepatitis C self-testing in people who inject drugs and men who have sex with men in Georgia: a protocol for a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-056243
Article Type:	Protocol
Date Submitted by the Author:	09-Aug-2021
Complete List of Authors:	Shilton, Sonjelle; Foundation for Innovative New Diagnostics Stvilia, Ketevan; National Centre for Disease Control and Public Health of Georgia Japaridze, Maia; Foundation for Innovative New Diagnostics Tsereteli, N.; 4. Center for Information and Counselling on Reproductive Health-Tanadgoma Usharidze, Dali; New Way Phevadze, Shota; Equality Movement Jghenti, Miranda; Batumi Imedi Mozalevskis, Antons; WHO Regional Office for Europe Markby, Jessica; Foundation for Innovative New Diagnostics Luhmann, Niklas; WHO Global HIV Hepatitis and STI Programmes Johnson, Cheryl; World Health Organization, Department of HIV/AIDS Nabeta, Pamela; Foundation for Innovative New Diagnostics Ongarello, Stefano; Foundation for Innovative New Diagnostics Reipold, Elena; Foundation for Innovative New Diagnostics Gamkrelidze, Amiran; National Centre for Disease Control and Public Health of Georgia
Keywords:	Public health < INFECTIOUS DISEASES, World Wide Web technology < BIOTECHNOLOGY & BIOINFORMATICS, Hepatology < INTERNAL MEDICINE

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Manuscripts

Home-based hepatitis C self-testing in people who inject drugs and men who have sex with men in Georgia: a protocol for a randomized controlled trial

Sonjelle Shilton[1], Ketevan Stvilia[2,3], Maia Japaridze[1], Nino Tsereteli[4], Dali Usharidze[5], Shota Phevadze[6], Miranda Jghenti[7], Antons Mozalevskis[8], Jessica Markby[1], Niklas Luhmann[9], Cheryl Johnson[9], Pamela Nabeta[1], Stefano Ongarello[1], Elena Ivanova Reipold[1], Amiran Gamkrelidze[2]

1. Foundation for Innovative New Diagnostics, Geneva, Switzerland
2. National Center for Disease Control, Tbilisi, Georgia,
3. Tbilisi State Medical University, Tbilisi, Georgia
4. Center for Information and Counselling on Reproductive Health-Tanadgoma, Tbilisi, Georgia
5. New Way, Tbilisi, Georgia
6. Equality Movement, Tbilisi, Georgia
7. Batumi Imedi, Batumi, Georgia
8. WHO Regional Office for Europe, Copenhagen, Denmark
9. WHO Global HIV Hepatitis and STI Programmes, Geneva, Switzerland

Corresponding author: Sonjelle Shilton Campus Biotech, Chemin des Mines 9, 1202 Geneva, Switzerland, Sonjelle.Shilton@finddx.org

Word count: 3390 (max. 4000)

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ABSTRACT

Introduction: Globally, it is estimated that more than three-quarters of people with chronic hepatitis C virus (HCV) are unaware of their HCV status. HCV self-testing (HCVST) may improve access and uptake of HCV testing particularly amongst key populations such as PWID and MSM where HCV prevalence and incidence is high and barriers to accessing health services due to stigma and discrimination are common.

Methods and analysis: This randomized controlled trial compares an online programme offering oral fluid based HCVST delivered to the home with referral to standard-of-care HCV testing at HCV testing sites. Eligible participants are adults self-identifying as either men who have sex with men (MSM) or people who inject drugs (PWID) who live in Tbilisi or Batumi, Georgia, and whose current HCV status is unknown. Participants will be recruited through an online platform and randomized to one of three arms for MSM (courier delivery, peer delivery, and standard-of-care HCV testing (control)) and two for PWID (peer delivery and standard of care-HCV-testing (control)). Participants in the postal delivery group will receive a HCVST kit delivered by anonymized courier. Participants in the peer delivery groups will schedule delivery of the HCVST by a peer. Control groups will receive information on how to access standard of care testing at a testing site. The primary outcome is the number and proportion of participants who report completion of testing. Secondary outcomes include the number and proportion of participants who a) receive a positive result and are made aware of their status, b) are referred to and complete HCV RNA confirmatory testing, and c) start treatment. Acceptability, feasibility, attitudes around HCV testing and cost will also be evaluated. The target sample size is 1,250 participants (250 per arm).

Ethics and dissemination: Ethical approval has been obtained from the National Centers for Disease Control and Public Health Georgia Institutional Review Board (IRB# 2021-049). Study results will be disseminated by presentations at conferences and via peer-review journals. Protocol version 1.1; 14 July 2021.

Trial registration number: clinicaltrials.gov registry number NCT04961723 registered 14 July 2021

Keywords: Hepatitis C virus, self-testing, people who inject drugs, men who have sex with men

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ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This will be one of the first clinical trials to assess the impact of, and evidence on optimal service delivery options for, hepatitis C self-testing.
- The randomized design allows for comparison of two different hepatitis C self-testing service delivery models compared with the standard of care.
- The intervention group employing peer delivery of testing may generate some negative bias if participants wish to remain anonymous.
- The control arm uptake rates may be more heavily affected by ongoing COVID-19 movement restrictions than the delivery arms.
- The study will reach only people who have access to the internet, therefore the results may not be generalisable to harder to reach populations/settings.

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INTRODUCTION

The World Health Organization (WHO) estimates that 58 million people globally have chronic hepatitis C virus (HCV) infection.[1] Of these, only 21% are diagnosed, with lack of awareness, poor access to testing services and stigma and discrimination surrounding HCV infection contributing to low uptake of HCV testing services.[1] As evidenced by self testing for HIV, the option to self-test at home can increase access to testing. As such, WHO recently published the first recommendations and guidance for HCV self-testing (HCVST), which highlights HCVST as an additional approach to HCV testing to reduce the gap in diagnosis.[1] The recommendations are based on broad evidence with self-testing for HIV, as well as specific studies on HCVST performance, usability, acceptability and user values and preferences.[2-6] A number of evidence gaps relating to HCVST remain however, including a need for data on the impact of HCVST on uptake of HCV testing and linkage to care, the need for better understanding of optimal service delivery options for HCVST, and on the use of HCVST in key populations such as people who inject drugs (PWID) and men who have sex with men (MSM).

Georgia is a middle-income country with a high prevalence of chronic HCV infection (5.4%) in the adult population from a population based serosurvey conducted in 2015 ,[7] with the burden of infection largely within the PWID population (numbering over 52,250 in 2017).[8 9] Prior to the implementation of a national elimination programme in 2015,[7 8] the seroprevalence in PWIDs in Georgia ranged from 50–92%, depending on region.[10-13] The programme has been successful in identifying and linking people with HCV to care,[8] but gaps still remain in hard to reach key populations, and so a pilot HCVST programme has been initiated, based on an existing self-testing programme for HIV.[14] Here we describe the protocol of an randomized controlled trial (Georgian IRB Ethics Approval Number: IRB# 2021-049, clinicaltrials.gov: NCT04961723) that aims to assess the impact and acceptability of an online programme offering home delivery of HCVST to PWID and MSM in Georgia.

METHODS AND ANALYSIS

Study settings and participants

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This is a factorial randomized controlled trial comparing home-delivery of HCV self-tests to referral to standard of care community-based HCV testing sites in PWID and MSM in Tbilisi or Batumi, Georgia. Six study HCV sites in Tbilisi and five in Batumi will participate as outlined in **Table 1**.

Table 1. Study sites

	Tbilisi	**Batumi**
MSM peer delivery site and community testing site	Tbilisi Tanadgoma center	Batumi Tanadgoma center
MSM courier delivery site and community testing site	Tbilisi Equality Movement center	Batumi Identoba center
PWID peer delivery site and community testing site	"Tbilisi New Way" Harm Reduction Site	"Batumi Imedi" Harm Reduction Site
Hepatitis testing and treatment site	Tbilisi Infectious Diseases Hospital	Batumi Infectious Diseases Hospital
Hepatitis testing and treatment site	"Neo-Lab" clinic	
Hepatitis testing and treatment site	"Hepa" clinic	

Eligible participants are adults aged ≥18 years living in Tbilisi or Batumi who can access services on the online platform and who self-identify as a PWID or MSM. Participants must be able to read and understand Georgian and have unknown HCV status (defined as never tested for anti-HCV or most recent test for anti-HCV antibodies negative and performed ≥6 months prior to enrolment). People who have a self-reported previously confirmed anti-HCV positive status or who are ineligible for the Georgian National Hepatitis Elimination programme (i.e do not have a Georgian ID card) will be excluded from the study.

Study participants will be prospectively recruited through an existing HIV self-testing programme using an online platform (http://selftest.ge), with community organizations and peers promoting the study. Interested participants will sign up to be contacted for study eligibility screening and to complete online informed consent. All study participants will complete a baseline survey collecting demographics and knowledge and attitudes towards HCV testing. Recruitment is expected to start in October 2021.

Study design

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Eligible participants who primarily identify as MSM will be randomized separately from those who primarily identify as PWID (**Figure 1**). Those who primarily identify as MSM will be randomized to one of the following study arms in a 1:1 ratio: a) courier l delivery; b) peer delivery and c) control. Participants in the courier delivery group will receive a home-delivered HCVST kit, this test kit package includes the self-test, instructions for use and supporting materials such as details on how to access to live chat and call centre for questions about testing. Participants in the peer delivery group will schedule delivery of the self-test to the location of their choice and instructions for use by a peer worker from the study site. The peer worker is a member of the community who has been trained to engage in HIV prevention services, this peer worker will provide basic information on the test, how to proceed after a positive result, and how to access live chat and call centre. Participants in the control arm will receive information about standard of care HCV testing at one of the study sites. These participants will also have access to the live chat and call centre facilities. Participants who primarily identify as PWID will be randomized to either peer delivery or control in a 1:1 ratio.

Approximately 2–4 weeks after enrollment, each participant will complete a follow-up survey, which will include the opportunity to upload any test result (**supplementary annex 2**). A second follow-up survey will be sent after the closure of the first survey (approximately 6–8 weeks after enrolment) (**supplementary annex 3**). Up to 3 telephone reminders may be sent for each survey if a survey has not been completed. Participants will receive telephone credit (10 GEL, equivalent to ~$3 USD) for completion of each survey.

Any individual reporting a positive HCV self-test will be referred to further HCV testing. Those confirmed to have active HCV infection will be linked to HCV treatment and care.

Participants may withdraw from the study at any time or be withdrawn at the discretion of the Primary Investigator. Participants will be considered lost to follow-up to the study if they fail to complete one of the online surveys after receiving three reminders.

FIGURE 1 HERE

Strategies to improve adherence to interventions

Participants will be provided several supporting tools to minimize the rate of errors in the self-testing process and any possible confusion in interpretation of the test results. Printed instructions for use (IFU) in Georgian will be delivered with the test kit and contain pictorial guides on how to use the test. In addition, participants will be provided a link to a video guide and have access to live chat and a call center.

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Randomization and blinding

Prior to study enrolment, a list of study IDs in ascending numerical order for each key population (PWID or MSM) will be generated by an employee of the sponsor who will not be involved in the execution of the study. Study IDs will be randomized by use of an algorithm to a study arm. Enrolment and assignment of study IDs will take place via the online platform. Participants will be assigned via the online platform study IDs in a consecutive fashion, thereby completing assignment to a study group. Due to the nature of the study there is no blinding as the study sites will know which participant received courier delivery, peer delivery or standard of care.

Interventions

The HCVST used in this study will be the OraQuick® HCV Rapid Antibody Test (OraSure Technologies Inc., Bethlehem, PA, USA). This test is CE marked and has received WHO prequalification for professional use by healthcare workers. The test has been validated by the manufacturer for self-testing, but use as a self-test is currently for Research Use Only (RUO), thus test results are not used for patient management. Instructions for use in Georgian were developed for previous studies and have been optimized based on feedback received.

Outcomes

The primary outcome of the study is the number and proportion of participants who report completion of testing in the postal or peer delivery arms. We hypothesize the intervention arms will show 20% more participants reporting completion of the testing result compared with the control arms (**Table 2**).

Secondary outcomes include the number and proportion of HCV antibody positive participants who are made aware of their HCV status, who are referred to and complete HCV RNA confirmatory testing, and who receive a positive HCV RNA result and start treatment, in each study arm (**Table 2**). Acceptability and feasibility of HCVST, along with knowledge, attitudes, and practices around HCV testing and care, will be assessed by analysis of survey responses at baseline and post-testing. The cost of HCVST will be evaluated by comparing costs in the intervention arms versus the control arm.

Table 2. Trial objectives and endpoints

Objectives	**Endpoints**

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Primary	
To assess the impact of HCV self-testing home delivery on HCV antibody testing rates in PWID and MSM	Number and point estimate of the proportion of participants who report completing the HCV antibody testing in the intervention groups. Superiority of the proportion of participants who report completing the HCV antibody testing in the intervention groups compared with the control groups (margin 20%).
Secondary	
To assess the impact of HCV self-testing on the number of HCV antibody positive individuals who are aware of their status	Number and estimate of the proportion of HCV antibody positive participants made aware of their status in the intervention vs control groups
To assess the impact of HCV self-testing on linkage and completion of HCV RNA confirmatory testing in HCV antibody positive individuals	Number and estimate of the proportion of HCV antibody positive participants who are referred to and complete HCV RNA confirmatory testing in the intervention vs control groups
To assess the impact of HCV self-testing on treatment initiation in HCV RNA positive individuals eligible to start treatment	Number and estimate of the proportion of HCV RNA positive participants who start treatment in the intervention vs control groups
To assess the acceptability and feasibility of HCV self-testing at baseline and after study participation. Information about knowledge, attitudes, and practices related to HCV and risk taking behaviours may also be collected	Analysis of survey responses using proportions and means
To assess the cost of HCV self-testing	Cost per test completed, cost per person diagnosed (serology, RNA) in the intervention vs control groups

Safety analyses will not be performed, as the HCVST used in this study is a low-risk test already approved for professional use by a stringent regulatory authority. Social harms relating to self-testing will be evaluated by a community stakeholder group (**Figure 2**).

FIGURE 2 HERE

Sample size and statistical analyses

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The target sample size is a minimum of 1,250 participants (250 per study arm). The sample size was calculated using G*Power 3.1 software (University of Dusseldorf, Germany) using a one-tailed test, 80% power and a 5% significance level in order to detect a significant change in the primary outcome between the control and intervention groups. With up to a 20% loss to follow up rate, we conservatively estimate that 250 participants in each group will be sufficient to detect differences between the control and each intervention group.

As the estimated proportion of anti-HCV positive results among study participants is estimated to be ≤10%, the study is not powered to detect statistical differences between study arms in the secondary endpoints.

Statistical analyses will be performed in the per protocol population (all participants who fully comply with the protocol). A 20% difference between intervention and control arms for the primary endpoint will be considered as demonstrating superiority of HCVST compared with referral to standard of care. Secondary outcomes will be analysed using descriptive statistics including proportions and means, with the exception of cost of HCVST, for which a cost-effectiveness analysis will be performed.

Building off the lessons learned from the HIVST pilot study, the sample size will be reached using social media to promote the study to the target population. The promotional strategies will be tailored to the clientele of each site. For Tanadgoma and Equality Movement posts and social media advertisements will be generated using Facebook and online dating sites and mobile applications Hornet, PlanetRomeo and Tinder, advertisements will also be placed in the gay video section of pornography sites. For Imedi Batumi and Tbilisi New Way promotions will be done through posts and advertisements on Facebook as well as flyers distributed at the harm reduction sites. Promotional materials will include digital fliers and posters (approved by the National Ethics Board), as well as online talk shows and videos which will provide basic information on hepatitis C and why testing is important and explain about the HCVST study providing information on where to enroll.

Data collection and management

Participants will complete the baseline, the first and second follow up surveys on the online platform (supplementary annex 1). The baseline survey will assess participants' current knowledge of hepatitis C including risk factors for contracting hepatitis C, as well as gathering information on their current risk-related behaviours.

The first follow up survey will be given 2 to 4 weeks post enrolment will ask participants to report if they

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conducted the HCV test and if so, the results of the test. If the participant reports having taken the test, they will be asked to answer questions relating to their perception of the testing experience and the actions they took following the test. If the participant reports that they did not take the test they will be asked questions as to why they have not yet taken the test. This survey will also gather information for all participants on their current behaviours that may be related to risk factors for HCV.

The second follow up survey will be given 4 to 8 weeks post enrolment (at least 2 weeks after completion of first survey), will ask the participant to report, if they have not already reported taking the test in the first follow up survey, if they conducted the HCV test and if so, the results of the test. If the participant reports having taken the test, they will be asked to answer questions relating to their perception of the testing experience and the actions they took following the after test. If the participant reports that they did not take the test they will be asked questions as to why they have not yet taken the test. For those that reported taking the HCV test in the first follow up survey, this survey will start by gathering information on what actions the person has since taken regarding seeking further HCV care (if their HCV test was positive). This survey will also gather information from all participants on their current behaviours that may be related to risk factors for HCV.

Data recorded in the online platform will be protected with multilayer security and each study personnel will have individualized access rights appropriate to their role in the study. Any participant records that are transferred from the online platform for analysis will contain the study ID only; no information that would allow identification of participants will be transferred. FIND is responsible for data management, including quality control checks and assessment of protocol compliance. FIND or a designee may conduct audits of investigational sites as part of routine quality assurance.

Study Oversight and monitoring

The support for this study is provided by:

Principle investigator who has overall responsibility for the supervision of the study and medical responsibility of the participants.

Batumi Imedi, Equality Movement, Tanadgoma, and Tbilisi New Way which each have a study coordinator which ensures the online platform is functioning correctly and that study procedures are followed as needed in terms of the arm of the study they are responsible for.

Study team members send out reminders to participants to complete surveys, organizes payment of incentives to participants that have completed the surveys.

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Study peer support team provide support to participants if they have questions or concerns regarding the testing process, assist those participants who have an HCV positive antibody result, and are interested, with linkage to further care (both intervention and control group).

FIND is the study sponsor and has written the protocol, maintains the data collection tools, will oversee the data analysis, and have final decision to submit the study report for publication.

The study team meets weekly. While there is no study steering committee there is a social harm monitoring structure (**Figure 2**). This structure is comprised of the individual, community, and instructional partners and is designed to capture any potential harms that may arise related to the use of HCVST.

There is no data monitoring committee for this study due in large part to the lack of SAEs in the previous feasibility and acceptability studies on HCVST completed in Georgia as well as 6 other countries as well the fact that many large scale HIVST studies and pilots have been conducted without such committees.

Patient and public involvement

Several of the organizations involved in this trial are community-based organizations which include people with experience of living with HCV, living with HIV, and injection drug use. They have contributed their input into the trial from the conceptualization phase and are included as authors in the this paper. Members of the public will be engaged in the social harms monitoring structure throughout the trial. The trial partners have several dissemination events planned which will be open to the public.

Ethics and dissemination

Ethical approval of the study protocol has been obtained from the National Centers for Disease Control and Public Health Georgia Institutional Review Board (IRB# 2021-049) and any protocol amendment that may arise will be submitted to the same. The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, Good Clinical Practice guidelines (ICH GCP E6 [R2]) and applicable laws and regulations. All participants will be informed that their participation is voluntary and will be required to sign and date a statement of informed consent meeting Georgian regulations. The consent form will be available on the online platform and will include information on the nature of the trial in Georgian, and details on access to a hotline for questions about the trial.

A variety of methods and forums will be used to disseminate the results of the study including presentation at scientific conferences, peer reviewed publications, and advocacy-based literature.

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Special efforts will be put into sharing the results with organizations representing PWID and MSM at the national, regional and global level. Dependent on the outcomes of the trial, dissemination work may entail working with stakeholders to facilitate the national programming for scale up of HCVST.

DISCUSSION

To our knowledge, this will be the first study to assess the acceptability and impact of using an online platform, which was developed initially for HIV self-testing (HIVST), for providing home-delivery of hepatitis C virus self-tests (HCVST).

Limitations of this study design include the use of an online platform for enrolment, limiting the study population to people who have access to the internet and have internet literacy. This may exclude people who could also benefit from HCVST but are not able to access the internet. There could be operator errors while participants conduct the test and false reporting of results. Uptake of testing in the control arm may be affected by the geographical location of the participant and the distance to a nearest testing centre. Moreover, the ongoing COVID-19 pandemic may affect participants' willingness to visit a healthcare facility and therefore, may negatively impact the uptake of testing in the control arm and the uptake of treatment in both intervention and control arms. The survey questionnaires have a multiple-choice design and may not capture some important context-specific aspects. Finally, the context of Georgia, which has an advanced elimination program, can be both and advantage and limitation. An advantage in thatpeople are more aware of HCV and could be more motivated to seek testing. However, ss most of Georgia's population has been tested at least once already, this may result in challenges in recruiting the needed sample size (mitigated by including those previously tested anti-HCV negative).

Understanding how integration of HCVST into self-testing platforms for HIV can leverage existing mechanisms to maximize investments that global funders have made in other areas is critical for HCV, as there is very limited funding available, of which most is domestic.[15] The findings of this study will inform the Georgian National Center for Disease Control and Public Health on scale up of HCVST to reach last mile service delivery for HCV. Additionally, these findings will have global importance as this will provide some of the first ever evidence about implementation of HCV ST in key populations that could be relevant to other settings and countries which are advancing in their hepatitis response.

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CONFLICT OF INTEREST

S.S, M.J, P.N and E.R declare that they are employees of the Foundation for Innovative New Diagnostics (FIND). The other authors have no conflicting or competing interests to declare. The opinions expressed herein are the author's own and do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated. Where the authors are identified as personnel of the World Health Organization, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the World Health Organization.

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FUNDING

This work is funded by the Government of the Netherlands.

AVAILABILITY OF DATA AND MATERIALS

The final dataset will be housed with FIND and will be made available upon reasonable request to the corresponding author.

CONTRIBUTIONS

S.S, K.S, and E.R conceptualized the study. S.S designed and wrote the protocol. S.S, K.S, E.R, M.J, N.T, D.U, S.P, M.J finalized the protocol. A.M, N.L, C.J, P.N provided technical input on the trial design. C.J provided guidance on the social harm monitoring structure. S.S wrote the first draft of the manuscript. S.O developed the statistical component of the protocol. K.S, E.R, M.J, N.T, D.U, J.M, S.P, M.J, A.M, N.L, P.N, A.G reviewed the manuscript. All authors have read and approved the manuscript.

ACKNOWLEDGEMENTS

The information described herein is based on version 1 of the study protocol, dated 31 May 2021. Medical writing services, funded by FIND, were provided by Rachel Wright, PhD, in accordance with Good Publication Practice (GPP3).

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FIGURE LEGENDS

Figure 1. Study design

Figure 2. Social harms monitoring structure

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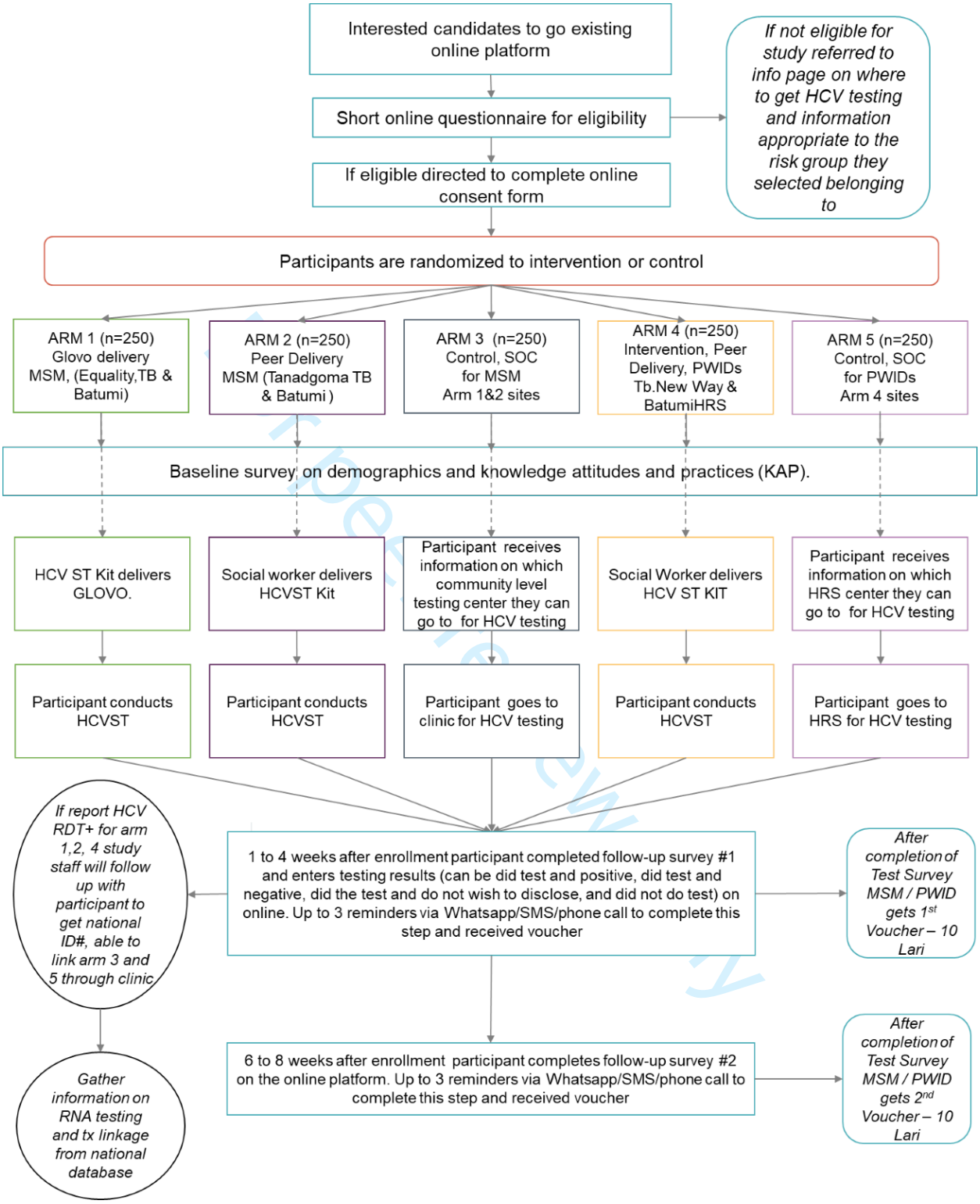
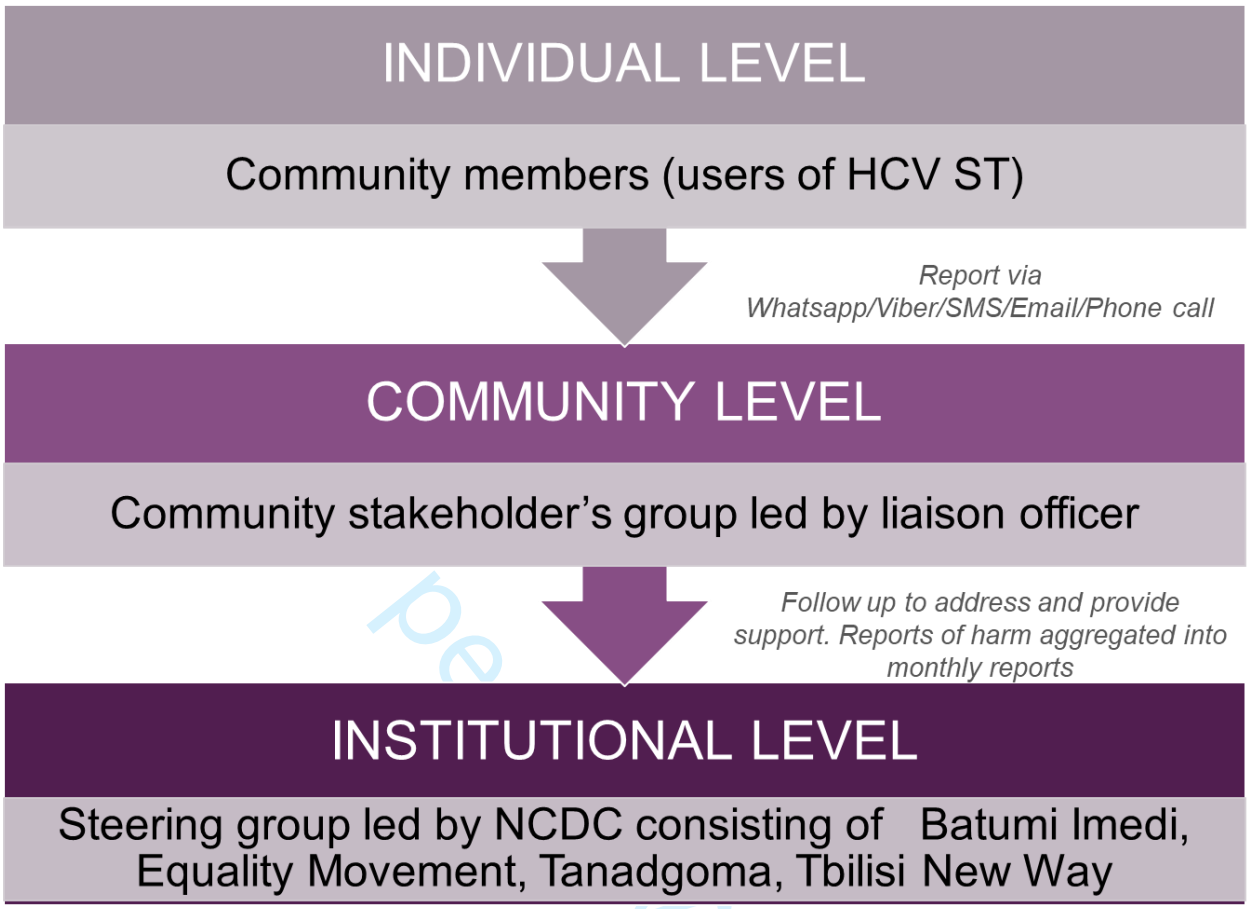


HCV= hepatitis C virus, MSM= men who have sex with men, TB= Tbilisi, SOC= standard of care, PWID= people who inject drugs, HCVST= hepatitis C virus self test, HRS= harm reduction site, RDT+= rapid diagnostics test positive, tx= treatment



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Supplementary Annex 1
Study information form and informed consent form

Hepatitis C Study Information Sheet

Title of Study

Randomized controlled trial of home-based hepatitis C self-testing in key populations in Georgia

Participating Organizations

NCDC, Equality Movement, Tanadgoma, Tbilisi New Way HRS, Batumi Imedi HRS, Foundation for Innovative New Diagnostics

Introduction

Hepatitis C is a liver infection caused by a virus that can lead to serious liver damage, cancer, and even death. You are being invited to take part in this study to help understand different ways people can be tested for hepatitis C.

Purpose

The purpose of this study is to evaluate different models of hepatitis C testing

Study Procedures

If you take part in the study, you will only have to sign the consent form, take two surveys, and consider getting tested for hepatitis C. You will be randomly selected for testing models: a) to either receive a hepatitis C testing kit delivered to your home or b) receive information about how to get tested for hepatitis C at a local clinic or community center.

If you are selected for the hepatitis c self-test it is a simple procedure using oral fluids. If you are selected for the hepatitis C self-test group you will either be placed in the group that gets the hepatitis C self test delivered by Glovo delivery or be placed in the group that will have the test delivered to your house by a peer outreach worker or a social worker

Your information will be reviewed by the study personnel and grouped with all other persons in the study.

Benefits

As a participant in this study, you may learn if you have been exposed to hepatitis C or not and be offered care and treatment if you have hepatitis C.

Risks

There is minimal discomfort with hepatitis C testing. There is a minimal risk that you could encounter social harms from this study.

Framed in the study the observational team is set up to identify any social harm associated with participation in the study and testing. They will give you recommendations and to get the appropriate services as needed.

You can contact the study coordinator for the information how to contact this group *(The phone numbers will be provided by Arms)*

Compensation and Costs

There are no costs to you for participation in this study. All participants will receive a phone credit voucher of 10 GEL for completion of the first follow up questionnaire to enter test result and another phone credit voucher of 10 GEL when the finish the second study survey. You will receive the phone credits to the phone number that you provide on the online platform approximately 7 days after you complete each survey. You will be offered hepatitis C testing but are not required to be tested for hepatitis C to receive compensation.

Confidentiality

All information collected about you during the course of this study will be stored without any personal identifiers. No one will be able to match you to your information. No one will be able to determine your identity in the frame of the study. Only study personnel will have access to the information.

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Voluntary Participation/Study Withdrawal

Taking part in this study is completely voluntary. You are free to withdraw at any time. Whether or not you are part of this study does not in any way affect your medical or preventive care.

Questions

If you have any questions about the study, you may ask the study staff at any time.

The name and phone number of the study personnel of the relevant center will be indicated.

Online informed consent form

Project title: Randomized controlled trial of home-based hepatitis C self-testing in key populations in Georgia

I confirm that I have read and understood the information as provided in the information sheet for the above project and have had the opportunity to ask questions.

I understand that the project team may look at my health records for the current study. I agree to this access. I understand that my identity will not be revealed in any information released to third parties or published. I understand that I may freely withdraw from this project at any time.

I agree to be a part of the above project.

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Supplementary Annex 2

PARTICIPANT FOLLOW-UP SURVEY #1

These forms will be provided to the participants in Georgian language
STUDY ID: ***automatically inputted and date and timestamped by the platform***
SURVEY DATE: ***automatically generated/timestamped by the platform***

INFORMATION TO PARTICIPANTS
This questionnaire will be anonymized before being analyzed and your name will never appear in the database. Your answers will be used to better understand hepatitis C testing in Georgia.

SECTION A – STUDY TESTING AND FOLLOW-UP

A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
1. Yes
2. No

A1ai. *(if answered Yes to question A1, version of question for arm 3 and 5)* What was the result?
1. Positive
2. Negative
3. Don't know, have forgotten
4. Do not want to disclose

A1aii. *(if answered Yes to question A1, version of question for arm 1,2 and 4)* What was the result?
1. Positive
2. Negative
3. Test did not work
4. Don't know, could not read the test
5. Do not want to disclose

A1b. (*If answered No to question A1)* If no, why not?
1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Others, specify: _____

A1c. *(If answered Yes for question A1, for arm 3 and 5 only)* Where did you go to get the hepatitis C test done?
_____ (select from drop down list the name of the facility)
(For participants who live in Tbilisi)
1. Tbilisi Tanadgoma center
2. Tbilisi Equality movement center
3. Tbilisi New Way HRS
4. Tbilisi ID Hospital
5. Neo Lab clinic

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6. Hepa clinic
7. Other: _____

(For participants who live in Batumi)

1. Batumi Tanadgoma center
2. Batumi Equality movement
3. Batumi Imedi HRS
4. Batumi ID hospital
5. Batumi Mary time hospital
6. Other: _____

A1f. *(If answered Negative in question A1aii, for arm 1,2, and 4 only)* If you had tested positive for hepatitis C, what do you think your next steps would have been?

1. To go to a community-based organization for more information and advice
2. To go to a healthcare clinic for a confirmation test
3. To go to a hospital for a confirmation test
4. I would not do next step
5. Don't know
6. Others, specify: _____

A1g. *(If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only)* Have you taken any further step to get a second test done?

1. Yes, have gone to a community-based organization for more information and advice
2. Yes, have gone to a clinic and asked for another test
3. No, I have not made next step
4. Others, specify: _____

A1h. *(If answered No in question A1g)* If you do not made any next step, why not?

1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Transportation was too expensive
6. Others, specify: _____

A2a. (*version of question for arm 3 and 5 group)* Did you ask anyone any question about process of hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, person who performed the test
4. Yes, friend or family member

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5. Yes; others, specify: _____
6. No, I have not asked the question

A2b. (*version of question for arm 1)* Did you ask anyone any question about process of hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, friend or family member
4. Yes; others, specify: _____
5. No, I have not asked the question

A2c. (*version of question for arm 2 and 4)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, by asking the peer deliver who dropped of my test
3. Yes, online through searching the internet
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No, I have not asked the question

A3. *(If answered Yes in question A1)* How would you rate the hepatitis C testing you were offered in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)

	Not very easy		Average		Very easy
How easy was the testing process?	1	2	3	4	5

	Not very convenient		Average		Very convenient
How convenient was the testing process?	1	2	3	4	5

	Not very private		Average		Very private
How private did you think the testing process was?	1	2	3	4	5

	Not very trustworthy		Average		Very trustworthy
How much do you feel you can trust the test results?	1	2	3	4	5

	Not very secure		Average		Very secure
How secure did you feel during the testing process?	1	2	3	4	5

	Not very stressful		Average		Very stressful
How stressful was the testing process?	1	2	3	4	5

	Not very easy		Average		Very easy	
If you needed further care, how easy was it to access it?	1	2	3	4	5	Did not need it

A4. *(If answered Yes in question A1)* Did you feel you could understand the result of your test?

1. Yes
2. No

A4ai. *(If answered Yes in question A4, version of question for arm 1,2 and 4)* What do you think have helped you to understand the result of your test (select all that apply)?

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1. The printed instructions for use that came with the HCV self-test
2. Video instructions on how to perform a self-test
3. Being able to communicate with the selftest.ge team
4. Other; specify: _____

A4aii. *(If answered No in question A4, version of question for arm 1,2 and 4)* Why do you think you were unable to understand the result of your test? Select all that apply

1. The printed instructions for use that came with the HCV self-test were not easy to understand
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand
4. Others; specify: _____

A5. *(If answered Positive, test did not work or Don't know in question A1aii)* Did you feel you knew what steps you needed to take to be further linked to hepatitis C care after you got the result of your test?

1. Yes
2. No

A6. *(If answered No in question A5)* What do you think would have helped you to know what steps you need to take to be further linked to care?

1. A list of clinics near me that provide HCV care with their contact information
2. More information on how community-based organizations near me could help me navigate how to be linked to care
3. A video explaining how I could get linked to care
4. Others; specify:_____

A7. In the future, where would you prefer to be tested for hepatitis C?

1. By myself at home
2. At home with someone I trust
3. By myself at a healthcare clinic
4. In a community centre by community-based organization staff
5. In a healthcare clinic by a healthcare worker
6. In a pharmacy by a healthcare worker
7. No preference
8. Prefer not to get tested for hepatitis C
9. Other, specify:_____

A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and instructions on how to do it?

1. Yes
2. No
3. Don't know

A8a. *(If answered Yes in question A8)* If yes, how often do you think you would test yourself?

1. More than once every 6 months
2. Once every 6 months
3. Once a year

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4. Once every 2 years
5. Don't know
6. Others, specify:_____

A1d. *(If answered Positive in question A1ai or A1aii)* Have you taken further steps for hepatitis C care after your positive test? Please select all that applies

1. Yes, have gone for confirmation test
2. Yes, have had doctor consultation and completed additional testing
3. Yes, have started treatment
4. others, specify: _____
5. No, I do not plan to take further steps

A1e. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* What was the result of your confirmation test?

1. I was confirmed active chronic Hepatitis C (viremia)
2. I do not have active chronic hepatitis C (viremia)
3. Have not been told the results yet
4. Do not want to disclose
5. Others, specify:_____

A1i. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* Where did you go for this further hepatitis C care?

(select from drop down list the name of the facility

(For participants who live in Tbilisi)

1. Tbilisi ID Hospital
2. Neo Lab clinic
3. Hepa clinic
4. Other: _____

(For participants who live in Batumi)

1. Batumi Imedi HRS
2. Batumi ID hospital
3. Batumi Mary time hospital
4. Other: _____

SECTION B – RISK BEHAVIORS

B1. How many times have you or your partner(s) used a condom during sexual contact in the last month?

1. I have not had sexual contact in the last month
2. Always
3. Often
4. Sometimes
5. Never used

B2. In the last month, have you taken any substance by snorting it?

1. Yes

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2. No

B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?

1. Yes
2. No

B4. In the last month, have you injected unprescribed drugs?

1. Once
2. More than once
3. Never

B4a. (*If answered Once or More than once to question B4)* Within the last month, how often did you inject illicit drugs?

1. Once a month
2. Several times a month
3. Once a week
4. 2-3 times a week
5. 4-5 times a week
6. Once a day
7. Several times a day
8. Don't know

B4b. (*If answered Once or More than once to question B4)* In the past month, have you ever used a needle/syringe that was used by somebody else before?

1. Yes
2. No
3. Don't know

B4c. (*If answered Yes to question B4b)* If you have used a needle/syringe that was used by somebody else before in the past month, how many people share it with you?

1. __ (fill in the number of people you shared with)
2. Don't know

SECTION C – Help us to make HCV testing accessible to everyone who needs it, your opinion counts!

Please let us know how we can improve HCV testing and care services - your feedback will help to guide how these services can best serve to Georgia population.

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Supplementary annex 3:

PARTICIPANT FOLLOW-UP SURVEY #2

STUDY ID: ***automatically linked and date and timestamped by the platform***
SURVEY DATE: ***automatically generated/timestamped by the platform***

INFORMATION TO PARTICIPANTS
This questionnaire will be anonymized before being analyzed and your name will never appear in the database. Your answers will be used to better understand hepatitis C testing in Georgia.

SECTION A – STUDY TESTING AND FOLLOW-UP

A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
1. Yes
2. No

A1ai. *(if answered Yes to question A1, version of question for arm 3 and 5)* What was the result?
1. Positive
2. Negative
3. Don't know, have forgotten
4. Do not want to disclose

A1aii. *(if answered Yes to question A1, version of question for arm 1,2 and 4)* What was the result?
1. Positive
2. Negative
3. Test did not work
4. Don't know
5. Do not want to disclose

A1b. (*If answered No to question A1)* If no, why not?
1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Others, specify: _____

A1c. *(If answered Yes for question A1 for arm 3 and 5 only)* Where did you go to get the hepatitis C test done?

_____ (select from drop down list the name of the facility)

(For participants who live in Tbilisi)
1. Tbilisi Tanadgoma center
2. Tbilisi Equality movement center
3. Tbilisi New Way HRS
4. Tbilisi ID Hospital
5. Neo Lab clinic
6. Hepa clinic

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7. Other: _____

(For participants who live in Batumi)

1. Batumi Tanadgoma center
2. Batumi Equality movement
3. Batumi Imedi HRS
4. Batumi ID hospital
5. Batumi Mary time hospital
6. Other: _____

A1f. *(If answered Negative in question A1aii, for arm 1,2, and 4 only)* If you had tested positive for hepatitis C, what do you think your next steps would have been?

1. To go to a community-based organization for more information and advice
2. To go to a policlinic for a confirmation test
3. To go to a healthcare clinic for a confirmation test
4. I would not do next step
5. Don't know
6. Others, specify: _____

A1g. *(If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only)* Have you taken any further step to get a second test done?

1. Yes, have gone to a community-based organization for more information and advice
2. Yes, have gone to a clinic and asked for another test
3. No, I have not made next step
4. Others, specify: _____

A1h. *(If answered No in question A1g)* If no, why not?

1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Test was too expensive
6. Others, specify: _____

A2a. (*version of question for arm 3 and 5 group)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, person who performed the test
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No

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A2b. (*version of question for arm 1)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, friend or family member
4. Yes; others, specify: _____
5. No

A2c. (*version of question for arm 2 and 4)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, by asking the peer deliver who dropped of my test
3. Yes, online through searching the internet
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No

A3. *(If answered Yes in question A1)* How would you rate the hepatitis C testing you were offered in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)

	Not very easy		Average		Very easy
How easy was the testing process?	1	2	3	4	5

	Not very convenient		Average		Very convenient
How convenient was the testing process?	1	2	3	4	5

	Not very private		Average		Very private
How private did you think the testing process was?	1	2	3	4	5

	Not very trustworthy		Average		Very trustworthy
How much do you feel you can trust the test results?	1	2	3	4	5

	Not very secure		Average		Very secure
How secure did you feel during the testing process?	1	2	3	4	5

	Not very stressful		Average		Very stressful
How stressful was the testing process?	1	2	3	4	5

	Not very easy		Average		Very easy	
If you needed further care, how easy was it to access it?	1	2	3	4	5	Did not need it

A4. *(If answered Yes in question A1)* Did you feel you could understand the result of your test?

1. Yes
2. No
3. I do not know

A4ai. *(If answered Yes in question A4, version of question for arm 1,2 and 4)* What do you think have helped you to understand the result of your test (select all that apply)?

1. The printed instructions for use that came with the HCV self-test
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand

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4. Being able to communicate with the selftest.ge team
5. Other; specify: _____

A4aii. *(If answered No in question A4, version of question for arm 1,2 and 4)* Why do you think you were unable to understand the result of your test? Select all that apply

1. The printed instructions for use that came with the HCV self-test were not easy to understand
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand
4. Others; specify: _____

A5. *(If answered Positive, Invalid or Don't know in question A1aii)* Did you feel you knew what steps you needed to take to be further linked to hepatitis C care after you got the result of your test?

1. Yes
2. No

A6. *(If answered No in question A5)* What do you think would have helped you to know what steps you need to take to be further linked to care?

1. A list of clinics near me that provide HCV care with their contact information
2. More information on how community-based organizations near me could help me navigate how to be linked to care
3. A video explaining how I could get linked to care
4. Others; specify:_____

A7. In the future, where would you prefer to be tested for hepatitis C?

1. By myself at home
2. At home with someone I trust
3. By myself at a healthcare clinic
4. In a community centre by community-based organization staff
5. In a healthcare clinic by a healthcare worker
6. In a pharmacy by a healthcare worker
7. No preference
8. Prefer not to get tested for hepatitis C
9. Other; specify: _____

A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and instructions on how to do it?

4. Yes
5. No
6. Don't know

A8a. *(If answered Yes in question A8)* If yes, how often do you think you would test yourself?

1. More than once every 6 months
2. Once every 6 months
3. Once a year
4. Once every 2 years
5. Don't know

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6. Others, specify:_____

A1d. *(If answered Yes to question A1, Positive in question A1a and No in question A1d in Follow-up survey #1, this will be the first question for them in this Follow-up survey #2. After questions A1d and A1e have been answered by this group in Follow-up survey #2, they will proceed to section B. This question is also for those who answered Positive in question A1a in Follow-up survey #2; for this group, they will proceed through the rest of section A following skip patterns based on their answers)* Have you taken further steps for hepatitis C care after your positive test?

Please select all that applies

1. Yes, have gone for confirmation test
2. Yes, have had doctor consultation and completed additional testing
3. Yes, have started treatment
4. Others, specify: _____
5. No, I do not plan to take further steps

A1e. *(If answered Yes, have gone for confirmation test or Yes,* , have had doctor consultation and completed additional testing *and have started treatment in question A1d)* What was the result of your confirmation test?

1. I have hepatitis C viremia
2. I do not have hepatitis C viremia
3. Have not been told the results yet
4. Others, specify: _____

A1i. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* Where did you go for this further hepatitis C care?

(select from drop down list the name of the facility

(For participants who live in Tbilisi)

1. Tbilisi ID Hospital
2. Neo Lab clinic
3. Hepa clinic
4. Other: _____

(For participants who live in Batumi)

1. Batumi Imedi HRS
2. Batumi ID hospital
3. Batumi Mary time hospital
4. Other: _____

SECTION B – RISK BEHAVIORS

B1. How many times have you or your partner(s) used a condom during sexual contact in the last month?

1. I have not had sexual contact in the last month
2. Always
3. Often
4. Sometimes
5. Never used

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B2. In the last month, have you taken any substance by snorting it?

1. Yes
2. No

B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?

1. Yes
2. No

B4. In the last month, have you injected unprescribed drugs?

1. Once
2. More than once
3. Never

B4a. (*If answered Once or More than once to question B4)* Within the last month, how often did you inject drugs?

1. Once a month
2. Several times a month
3. Once a week
4. 2-3 times a week
5. 4-5 times a week
6. Once a day
7. Several times a day
8. Don't know

B4b. (*If answered Once or More than once to question B4)* In the past month, have you ever used a needle/syringe that was used by somebody else before?

1. Yes
2. No
3. Don't know

B4c. (*If answered Yes to question B4b)* If you have used a needle/syringe that was used by somebody else before in the past month, how many people share it with you?

1. __ (fill in the number of people you shared with)
2. Don't know

SECTION C – Help us to make HCV testing accessible to everyone who needs it, your opinion counts!

Please let us know how we can improve HCV testing and care services - your feedback will help to guide how these services can best serve the people in Malaysia:

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

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Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	13
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	10
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team,	10 and 11

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		and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	7 and 8
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4 and 7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data	4 and 5

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		will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a there are no modificaitons
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	6
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical	7 and 8

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		relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8 and 9
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6 and 7

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Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6 and 7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and	9 and 10

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		validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	6
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9 and 10
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	7 and 8
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			

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Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	11
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	8
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2 and 11

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Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	11
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	6

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Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	13
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	13
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	16 and 17
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Notes:

- 11b: n/a there are no modificaitons The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was

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Home-based hepatitis C self-testing in people who inject drugs and men who have sex with men in Georgia: a protocol for a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-056243.R1
Article Type:	Protocol
Date Submitted by the Author:	06-Feb-2022
Complete List of Authors:	Shilton, Sonjelle; Foundation for Innovative New Diagnostics Stvilia, Ketevan; National Centre for Disease Control and Public Health of Georgia Japaridze, Maia; Foundation for Innovative New Diagnostics Tsereteli, N.; 4. Center for Information and Counselling on Reproductive Health-Tanadgoma Usharidze, Dali; New Way Phevadze, Shota; Equality Movement Jghenti, Miranda; Batumi Imedi Mozalevskis, Antons; WHO Regional Office for Europe Markby, Jessica; Foundation for Innovative New Diagnostics Luhmann, Niklas; WHO Global HIV Hepatitis and STI Programmes Johnson, Cheryl; World Health Organization, Department of HIV/AIDS Nabeta, Pamela; Foundation for Innovative New Diagnostics Ongarello, Stefano; Foundation for Innovative New Diagnostics Reipold, Elena; Foundation for Innovative New Diagnostics Gamkrelidze, Amiran; National Centre for Disease Control and Public Health of Georgia
Primary Subject Heading:	Public health
Secondary Subject Heading:	Diagnostics, Gastroenterology and hepatology
Keywords:	Public health < INFECTIOUS DISEASES, World Wide Web technology < BIOTECHNOLOGY & BIOINFORMATICS, Hepatology < INTERNAL MEDICINE

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Manuscripts

Home-based hepatitis C self-testing in people who inject drugs and men who have sex with men in Georgia: a protocol for a randomized controlled trial

Sonjelle Shilton[1], Ketevan Stvilia[2,3], Maia Japaridze[1], Nino Tsereteli[4], Dali Usharidze[5], Shota Phevadze[6], Miranda Jghenti[7], Antons Mozalevskis[8], Jessica Markby[1], Niklas Luhmann[9], Cheryl Johnson[9], Pamela Nabeta[1], Stefano Ongarello[1], Elena Ivanova Reipold[1], Amiran Gamkrelidze[2]

1. Foundation for Innovative New Diagnostics, Geneva, Switzerland
2. National Center for Disease Control, Tbilisi, Georgia,
3. Tbilisi State Medical University, Tbilisi, Georgia
4. Center for Information and Counselling on Reproductive Health-Tanadgoma, Tbilisi, Georgia
5. New Way, Tbilisi, Georgia
6. Equality Movement, Tbilisi, Georgia
7. Batumi Imedi, Batumi, Georgia
8. WHO Regional Office for Europe, Copenhagen, Denmark
9. WHO Global HIV Hepatitis and STI Programmes, Geneva, Switzerland

Corresponding author: Sonjelle Shilton Campus Biotech, Chemin des Mines 9, 1202 Geneva, Switzerland, Sonjelle.Shilton@finddx.org

Word count: 3390 (max. 4000)

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ABSTRACT

Introduction: Globally, it is estimated that more than three-quarters of people with chronic hepatitis C virus (HCV) are unaware of their HCV status. HCV self-testing (HCVST) may improve access and uptake of HCV testing particularly amongst key populations such as PWID and MSM where HCV prevalence and incidence is high and barriers to accessing health services due to stigma and discrimination are common.

Methods and analysis: This randomized controlled trial compares an online programme offering oral fluid based HCVST delivered to the home with referral to standard-of-care HCV testing at HCV testing sites. Eligible participants are adults self-identifying as either men who have sex with men (MSM) or people who inject drugs (PWID) who live in Tbilisi or Batumi, Georgia, and whose current HCV status is unknown. Participants will be recruited through an online platform and randomized to one of three arms for MSM (courier delivery, peer delivery, and standard-of-care HCV testing (control)) and two for PWID (peer delivery and standard of care-HCV-testing (control)). Participants in the postal delivery group will receive a HCVST kit delivered by anonymized courier. Participants in the peer delivery groups will schedule delivery of the HCVST by a peer. Control groups will receive information on how to access standard of care testing at a testing site. The primary outcome is the number and proportion of participants who report completion of testing. Secondary outcomes include the number and proportion of participants who a) receive a positive result and are made aware of their status, b) are referred to and complete HCV RNA confirmatory testing, and c) start treatment. Acceptability, feasibility, attitudes around HCV testing and cost will also be evaluated. The target sample size is 1,250 participants (250 per arm).

Ethics and dissemination: Ethical approval has been obtained from the National Centers for Disease Control and Public Health Georgia Institutional Review Board (IRB# 2021-049). Study results will be disseminated by presentations at conferences and via peer-review journals. Protocol version 1.1; 14 July 2021.

Trial registration number: clinicaltrials.gov registry number NCT04961723 registered 14 July 2021

Keywords: Hepatitis C virus, self-testing, people who inject drugs, men who have sex with men

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ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This will be one of the first clinical trials to assess the impact of, and evidence on optimal service delivery options for, hepatitis C self-testing.
- The randomized design allows for comparison of two different hepatitis C self-testing service delivery models compared with the standard of care.
- The intervention group employing peer delivery of testing may generate some negative bias if participants wish to remain anonymous.
- The control arm uptake rates may be more heavily affected by ongoing COVID-19 movement restrictions than the delivery arms.
- The study will reach only people who have access to the internet, therefore the results may not be generalisable to harder to reach populations/settings.

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INTRODUCTION

The World Health Organization (WHO) estimates that 58 million people globally have chronic hepatitis C virus (HCV) infection.[1] Of these, only 21% are diagnosed, with lack of awareness, poor access to testing services and stigma and discrimination surrounding HCV infection contributing to low uptake of HCV testing services.[1] As evidenced by self testing for HIV, the option to self-test at home can increase access to testing. As such, WHO recently published the first recommendations and guidance for HCV self-testing (HCVST), which highlights HCVST as an additional approach to HCV testing to reduce the gap in diagnosis.[1] The recommendations are based on broad evidence with self-testing for HIV, as well as specific studies on HCVST performance, usability, acceptability and user values and preferences.[2-6] A number of evidence gaps relating to HCVST remain however, including a need for data on the impact of HCVST on uptake of HCV testing and linkage to care, the need for better understanding of optimal service delivery options for HCVST, and on the use of HCVST in key populations such as people who inject drugs (PWID) and men who have sex with men (MSM).

Georgia is a middle-income country with a high prevalence of chronic HCV infection (5.4%) in the adult population from a population based serosurvey conducted in 2015 ,[7] with the burden of infection largely within the PWID population (numbering over 52,250 in 2017).[8 9] Prior to the implementation of a national elimination programme in 2015,[7 8] the seroprevalence in PWIDs in Georgia ranged from 50–92%, depending on region.[10-13] The programme has been successful in identifying and linking people with HCV to care,[8] but gaps still remain in hard to reach key populations, and so a pilot HCVST programme has been initiated, based on an existing self-testing programme for HIV.[14] Here we describe the protocol of an randomized controlled trial (Georgian IRB Ethics Approval Number: IRB# 2021-049, clinicaltrials.gov: NCT04961723) that aims to assess the impact and acceptability of an online programme offering home delivery of HCVST to PWID and MSM in Georgia.

METHODS AND ANALYSIS

Study settings and participants

This is a randomized controlled trial comparing home-delivery of HCV self-tests to referral to standard of care community-based HCV testing sites in PWID and MSM in Tbilisi or Batumi, Georgia. Six study HCV sites in Tbilisi and five in Batumi will participate as outlined in **Table 1**.

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Table 1. Study sites

	Tbilisi	Batumi
MSM peer delivery site and community testing site	Tbilisi Tanadgoma center	Batumi Tanadgoma center
MSM courier delivery site and community testing site	Tbilisi Equality Movement center	Batumi Identoba center
PWID peer delivery site and community testing site	"Tbilisi New Way" Harm Reduction Site	"Batumi Imedi" Harm Reduction Site
Hepatitis testing and treatment site	Tbilisi Infectious Diseases Hospital	Batumi Infectious Diseases Hospital
Hepatitis testing and treatment site	"Neo-Lab" clinic	
Hepatitis testing and treatment site	"Hepa" clinic	

Eligible participants are adults aged ≥18 years living in Tbilisi or Batumi who can access services on the online platform and who self-identify as a PWID or MSM. Participants must be able to read and understand Georgian and have unknown HCV status (defined as never tested for anti-HCV or most recent test for anti-HCV antibodies negative and performed ≥6 months prior to enrolment). People who have a self-reported previously confirmed anti-HCV positive status or who are ineligible for the Georgian National Hepatitis Elimination programme (i.e do not have a Georgian ID card) will be excluded from the study.

Study participants will be prospectively recruited through an existing HIV self-testing online platform (http://selftest.ge), with community organizations and peers promoting the study. Interested participants will sign up to be contacted for study eligibility screening and to complete online informed consent. All study participants will complete a baseline survey collecting demographics and knowledge and attitudes towards HCV testing. Recruitment is expected to start in October 2021.

Study design

Eligible participants who primarily identify as MSM will be randomized separately from those who primarily identify as PWID (**Figure 1**). Those who primarily identify as MSM will be randomized to one of the following study arms in a 1:1 ratio: a) courier l delivery; b) peer delivery and c) control. Participants in the courier delivery group will receive a home-delivered HCVST kit, this test kit package includes the

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self-test, instructions for use and supporting materials such as details on how to access to live chat and call centre for questions about testing. Participants in the peer delivery group will schedule delivery of the self-test to the location of their choice and instructions for use by a peer worker from the study site. The peer worker is a member of the community who has been trained to engage in HIV prevention services, this peer worker will provide basic information on the test, how to proceed after a positive result, and how to access live chat and call centre. Participants in the control arm will receive information about standard of care professionally administered HCV testing at one of the study sites. These participants will also have access to the live chat and call centre facilities. Participants who primarily identify as PWID will be randomized to either peer delivery or control in a 1:1 ratio.

Approximately 2–4 weeks after enrollment, each participant will complete a follow-up survey, which will include the opportunity to upload any test result (**supplementary annex 1**). A second follow-up survey will be sent after the closure of the first survey (approximately 6–8 weeks after enrolment) (**supplementary annex 2**). Up to 3 telephone reminders may be sent for each survey if a survey has not been completed. Participants will receive telephone credit (10 GEL, equivalent to ~$3 USD) for completion of each survey.

Any individual reporting a positive HCV self-test will be referred to further HCV testing. Those confirmed to have active HCV infection will be linked to HCV treatment and care which is provided for free through the Georgian National Elimination program.

Participants may withdraw from the study at any time or be withdrawn at the discretion of the Primary Investigator. Participants will be considered lost to follow-up to the study if they fail to complete one of the online surveys after receiving three reminders.

FIGURE 1 HERE

Data collection

Participants will complete the baseline, the first and second follow up surveys on the online platform (supplementary annex 3). The baseline survey will assess participants' current knowledge of hepatitis C including risk factors for contracting hepatitis C, as well as gathering information on their current risk-related behaviours.

The purpose of the follow up surveys is to collect from the participant if they have completed the test, and if completed what the result of the test was, to collect information on risk behaviours to assess if any change in risk behaviours may have taken place during the study, and the gather feedback on how the

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participants felt about the testing process.

The first follow up survey will be given 2 to 4 weeks post enrolment will ask participants to report if they conducted the HCV test and if so, the results of the test. If the participant reports having taken the test, they will be asked to answer questions relating to their perception of the testing experience and the actions they took following the test. If the participant reports that they did not take the test they will be asked questions as to why they have not yet taken the test. This survey will also gather information for all participants on their current behaviours that may be related to risk factors for HCV.

The second follow up survey will be given 4 to 8 weeks post enrolment (at least 2 weeks after completion of first survey), will ask the participant to report, if they have not already reported taking the test in the first follow up survey, if they conducted the HCV test and if so, the results of the test. If the participant reports having taken the test, they will be asked to answer questions relating to their perception of the testing experience and the actions they took following the after test. If the participant reports that they did not take the test they will be asked questions as to why they have not yet taken the test. For those that reported taking the HCV test in the first follow up survey, this survey will start by gathering information on what actions the person has since taken regarding seeking further HCV care (if their HCV test was positive). This survey will also gather information from all participants on their current behaviours that may be related to risk factors for HCV.

Strategies to improve adherence to interventions

Participants will be provided several supporting tools to minimize the rate of errors in the self-testing process and any possible confusion in interpretation of the test results. Printed instructions for use (IFU) in Georgian will be delivered with the test kit and contain pictorial guides on how to use the test. In addition, participants will be provided a link to a video guide and have access to live chat and a call center.

Randomization and blinding

Prior to study enrolment, a list of study IDs in ascending numerical order for each key population (PWID or MSM) will be generated by an employee of the sponsor who will not be involved in the execution of the study. Study IDs will be randomized by use of an algorithm to a study arm. Enrolment and assignment of study IDs will take place via the online platform. Participants will be assigned via the online platform study IDs in a consecutive fashion, thereby completing assignment to a study group. Due

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to the nature of the study there is no blinding as the study sites will know which participant received courier delivery, peer delivery or standard of care.

Interventions

The HCVST used in this study will be the OraQuick® HCV Rapid Antibody Test (OraSure Technologies Inc., Bethlehem, PA, USA). This test is CE marked and has received WHO prequalification for professional use by healthcare workers. The test has been validated by the manufacturer for self-testing, but use as a self-test is currently for Research Use Only (RUO), thus test results are not used for patient management. Instructions for use in Georgian were developed for previous studies and have been optimized based on feedback received.

Outcomes

The primary outcome of the study is the number and proportion of participants who report completion of testing in the postal or peer delivery arms. We hypothesize the intervention arms will show 20% more participants reporting completion of the testing result compared with the control arms (**Table 2**).

Secondary outcomes include the number and proportion of HCV antibody positive participants who are made aware of their HCV status, who are referred to and complete HCV RNA confirmatory testing, and who receive a positive HCV RNA result and start treatment, in each study arm (**Table 2**). Acceptability and feasibility of HCVST, along with knowledge, attitudes, and practices around HCV testing and care, will be assessed by analysis of survey responses at baseline and post-testing. The cost of HCVST will be evaluated by comparing costs in the intervention arms versus the control arm.

Table 2. Trial objectives, endpoints, and statistical analysis methods

Objectives	**Endpoints**	**Statistical Analysis Methods**
Primary		
To assess the impact of HCV self-testing home delivery on HCV antibody testing rates in PWID and MSM	Number and point estimate of the proportion of participants who report completing the HCV antibody testing in the intervention groups. Superiority of the proportion of participants who report completing the HCV antibody testing in the	The primary outcome 1.2 will be evaluated in the MITT population (primary analysis) and will be repeated for the PP population. The difference $p_{fo,I}$ - $p_{fo,C}$ will be assessed in a one-sided test with a margin of 20% by applying the following hypothesis: % Intervention types (Arm 1, 2, 4) as well as the control groups (Arm 3, 5) will be considered. The proportion of individuals reporting HCV completing the test in the following intervention

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	intervention groups compared with the control groups (margin 20%).	and control groups will be compared (three comparisons): ▪ Arm 1 (intervention) vs. Arm 3 (control) for MSM, ▪ Arm 2 (intervention) vs. Arm 3 (control) for MSM ▪ Arm 4 (intervention) vs. Arm 5 (control) for PWID.
Secondary		
To assess the impact of HCV self-testing on the number of HCV antibody positive individuals who are aware of their status	Number and estimate of the proportion of HCV antibody positive participants made aware of their status in the intervention vs control groups	The outcome (patient has a positive test result y/n) is defined overall (as primary analysis) and for visit 1 (as additional analysis). The proportion of test positives p_{pos} will be calculated among all patients with test results (=favourable outcome) as well as among all MITT and PP patients. These proportions will be investigated in the comparison via hypothesis testing.
To assess the impact of HCV self-testing on linkage and completion of HCV RNA confirmatory testing in HCV antibody positive individuals	Number and estimate of the proportion of HCV antibody positive participants who are referred to and complete HCV RNA confirmatory testing in the intervention vs control groups	The outcome (patient is referred to and complete HCV RNA confirmatory testing: y/n) is defined overall (as primary analysis) and for visit 1 (as additional analysis). The proportion of patients referred p_{ref} will be calculated among all patients with positive test results as well as among all MITT and PP patients. These proportions will be investigated in the comparison via hypothesis testing.
To assess the impact of HCV self-testing on treatment initiation in HCV RNA positive individuals eligible to start treatment	Number and estimate of the proportion of HCV RNA positive participants who start treatment in the intervention vs control groups	Hereby the outcome (patient has started treatment y/n) is defined overall (as primary analysis) and for visit 1 (as additional analysis). The proportion of patients treated p_{trt} will be calculated among all patients with positive test results as well as among all MITT and PP patients. The comparisons will refer to proportion with number with patients with a positive test result in the denominator (a+b, f+g).
To assess the acceptability and feasibility of HCV self-testing at baseline and after study participation. Information about knowledge, attitudes, and practices related to	Analysis of survey responses using proportions and means	The secondary outcome 2.4 will be evaluated for the PP and MITT population. Intervention types (Arm 1, 2, 4) as well as the control groups (Arm 3, 5) will be considered separately. Descriptive statistics for survey responses [variables see chapter **Error! Reference source not found.**, if not stated otherwise] will be reported either in absolute numbers and

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HCV and risk taking behaviours may also be collected		proportions or summarized by mean, median, standard deviation, minimum, maximum and quartiles by arm and visit.
To assess the cost of HCV self-testing	Cost per test completed, cost per person diagnosed (serology, RNA) in the intervention vs control groups	

Acronyms: MITT (Modified-Intention-To-Test): *all participants* in ITT who were *randomized to HCV self-testing* (Arm 1 to Arm 5). PP (Per-Protocol): *all participants* in ITT *who fully complied with the protocol* (i.e.: primary endpoint variable is available)

Safety analyses will not be performed, as the HCVST used in this study is a low-risk test already approved for professional use by a stringent regulatory authority. Social harms relating to self-testing will be evaluated by a community stakeholder group (**Figure 2**).

FIGURE 2 HERE

Sample size and statistical analyses

The target sample size is a minimum of 1,250 participants (250 per study arm). The sample size was calculated using G*Power 3.1 software (University of Dusseldorf, Germany) using a one-tailed test, 80% power and a 5% significance level in order to detect a significant change in the primary outcome between the control and intervention groups. With up to a 20% loss to follow up rate, we conservatively estimate that 250 participants in each group will be sufficient to detect differences between the control and each intervention group.

As the estimated proportion of anti-HCV positive results among study participants is estimated to be ≤10%, the study is not powered to detect statistical differences between study arms in the secondary endpoints.

Statistical analyses will be performed in the per protocol population (all participants who fully comply with the protocol). A 20% difference between intervention and control arms for the primary endpoint will be considered as demonstrating superiority of HCVST compared with referral to standard of care. Secondary outcomes will be analysed using descriptive statistics including proportions and means, with the exception of cost of HCVST, for which a cost-effectiveness analysis will be performed.

Building off the lessons learned from the HIVST pilot study, the sample size will be reached using social media to promote the study to the target population. The promotional strategies will be tailored to the

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clientele of each site. For Tanadgoma and Equality Movement posts and social media advertisements will be generated using Facebook and online dating sites and mobile applications Hornet, PlanetRomeo and Tinder, advertisements will also be placed in the gay video section of pornography sites. For Imedi Batumi and Tbilisi New Way promotions will be done through posts and advertisements on Facebook as well as flyers distributed at the harm reduction sites. Promotional materials will include digital fliers and posters (approved by the National Ethics Board), as well as online talk shows and videos which will provide basic information on hepatitis C and why testing is important and explain about the HCVST study providing information on where to enroll.

Data management

Data recorded in the online platform will be protected with multilayer security and each study personnel will have individualized access rights appropriate to their role in the study. Any participant records that are transferred from the online platform for analysis will contain the study ID only; no information that would allow identification of participants will be transferred. FIND is responsible for data management, including quality control checks and assessment of protocol compliance. FIND or a designee may conduct audits of investigational sites as part of routine quality assurance.

There is only one study database with no direct links with any other databases. In terms of following participants along the continuation of care offered by the National Elimination Program, the NCDC study team will, with consent from participants, attain the ID numbers of individuals who test positive in the control group, as well as those in the intervention groups who attend to a clinic for a professional use RDT after completion of a self-test. This ID number will allow NCDC study staff to follow their progress in the national HCV database which captures all diagnostic and treatment data of the National Elimination Program

Study Oversight and monitoring

The support for this study is provided by:

Principle investigator who has overall responsibility for the supervision of the study and medical responsibility of the participants.

Batumi Imedi, Equality Movement, Tanadgoma, and Tbilisi New Way which each have a study coordinator which ensures the online platform is functioning correctly and that study procedures are followed as needed in terms of the arm of the study they are responsible for.

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Study team members send out reminders to participants to complete surveys, organizes payment of incentives to participants that have completed the surveys.

Study peer support team provide support to participants if they have questions or concerns regarding the testing process, assist those participants who have an HCV positive antibody result, and are interested, with linkage to further care (both intervention and control group).

FIND is the study sponsor and has written the protocol, maintains the data collection tools, will oversee the data analysis, and have final decision to submit the study report for publication.

The study team meets weekly. While there is no study steering committee there is a social harm monitoring structure (**Figure 2**). This structure is comprised of the individual, community, and instructional partners and is designed to capture any potential harms that may arise related to the use of HCVST.

There is no data monitoring committee for this study due in large part to the lack of SAEs in the previous feasibility and acceptability studies on HCVST completed in Georgia as well as 6 other countries as well the fact that many large scale HIVST studies and pilots have been conducted without such committees.

Patient and public involvement

Several of the organizations involved in this trial are community-based organizations which include people with experience of living with HCV, living with HIV, and injection drug use. They have contributed their input into the trial from the conceptualization phase and are included as authors in this paper.

Representatives and target end users from the MSM and PWID organizations have reviewed and commented on an information overview sheet that is provided with the self-tests. Prior to finalization of the data collection forms and website interface we piloted the forms and interface with 41 potential end users from MSM community and 19 potential end users from PWID community. We incorporated the feedback into the final design of the data collection tools and website interface.

Members of the public will be engaged in the social harms monitoring structure throughout the trial. The trial partners have several dissemination events planned which will be open to the public.

Ethics and dissemination

Ethical approval of the study protocol has been obtained from the National Centers for Disease Control and Public Health Georgia Institutional Review Board (IRB# 2021-049) and any protocol amendment that may arise will be submitted to the same. The trial will be conducted in accordance with the ethical

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principles that have their origin in the Declaration of Helsinki, Good Clinical Practice guidelines (ICH GCP E6 [R2]) and applicable laws and regulations. All participants will be informed that their participation is voluntary and will be required to sign and date a statement of informed consent meeting Georgian regulations. The consent form will be available on the online platform and will include information on the nature of the trial in Georgian, and details on access to a hotline for questions about the trial.

A variety of methods and forums will be used to disseminate the results of the study including presentation at scientific conferences, peer reviewed publications, and advocacy-based literature. Special efforts will be put into sharing the results with organizations representing PWID and MSM at the national, regional and global level. Dependent on the outcomes of the trial, dissemination work may entail working with stakeholders to facilitate the national programming for scale up of HCVST.

DISCUSSION

To our knowledge, this will be the first study to assess the acceptability and impact of using an online platform, which was developed initially for HIV self-testing (HIVST), for providing home-delivery of hepatitis C virus self-tests (HCVST).

Limitations of this study design include the use of an online platform for enrolment, limiting the study population to people who have access to the internet and have internet literacy. This may exclude people who could also benefit from HCVST but are not able to access the internet. There could be operator errors while participants conduct the test and false reporting of results. Uptake of testing in the control arm may be affected by the geographical location of the participant and the distance to a nearest testing centre. Moreover, the ongoing COVID-19 pandemic may affect participants' willingness to visit a healthcare facility and therefore, may negatively impact the uptake of testing in the control arm and the uptake of treatment in both intervention and control arms. The survey questionnaires have a multiple-choice design and may not capture some important context-specific aspects. Finally, the context of Georgia, which has an advanced elimination program, can be both and advantage and limitation. An advantage in thatpeople are more aware of HCV and could be more motivated to seek testing. However, ss most of Georgia's population has been tested at least once already, this may result in challenges in recruiting the needed sample size (mitigated by including those previously tested anti-HCV negative).

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Understanding how integration of HCVST into self-testing platforms for HIV can leverage existing mechanisms to maximize investments that global funders have made in other areas is critical for HCV, as there is very limited funding available, of which most is domestic.[15] The findings of this study will inform the Georgian National Center for Disease Control and Public Health on scale up of HCVST to reach last mile service delivery for HCV. Additionally, these findings will have global importance as this will provide some of the first ever evidence about implementation of HCV ST in key populations that could be relevant to other settings and countries which are advancing in their hepatitis response.

CONFLICT OF INTEREST

S.S, M.J, P.N and E.R declare that they are employees of the Foundation for Innovative New Diagnostics (FIND). The other authors have no conflicting or competing interests to declare. The opinions expressed herein are the author's own and do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated. Where the authors are identified as personnel of the World Health Organization, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the World Health Organization.

FUNDING

This work is funded by the Government of the Netherlands.

AVAILABILITY OF DATA AND MATERIALS

The final dataset will be housed with FIND and will be made available upon reasonable request to the corresponding author.

CONTRIBUTIONS

S.S, K.S, and E.R conceptualized the study. S.S designed and wrote the protocol. S.S, K.S, E.R, M.J, N.T, D.U, S.P, M.J finalized the protocol. A.M, N.L, C.J, P.N provided technical input on the trial design. C.J provided guidance on the social harm monitoring structure. S.S wrote the first draft of the manuscript.

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S.O developed the statistical component of the protocol. K.S, E.R, M.J, N.T, D.U, J.M, S.P, M.J, A.M, N.L, P.N, A.G reviewed the manuscript. All authors have read and approved the manuscript.

ACKNOWLEDGEMENTS

The information described herein is based on version 1 of the study protocol, dated 31 May 2021. Medical writing services, funded by FIND, were provided by Rachel Wright, PhD, in accordance with Good Publication Practice (GPP3).

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FIGURE LEGENDS

Figure 1. Study design

Figure 2. Social harms monitoring structure

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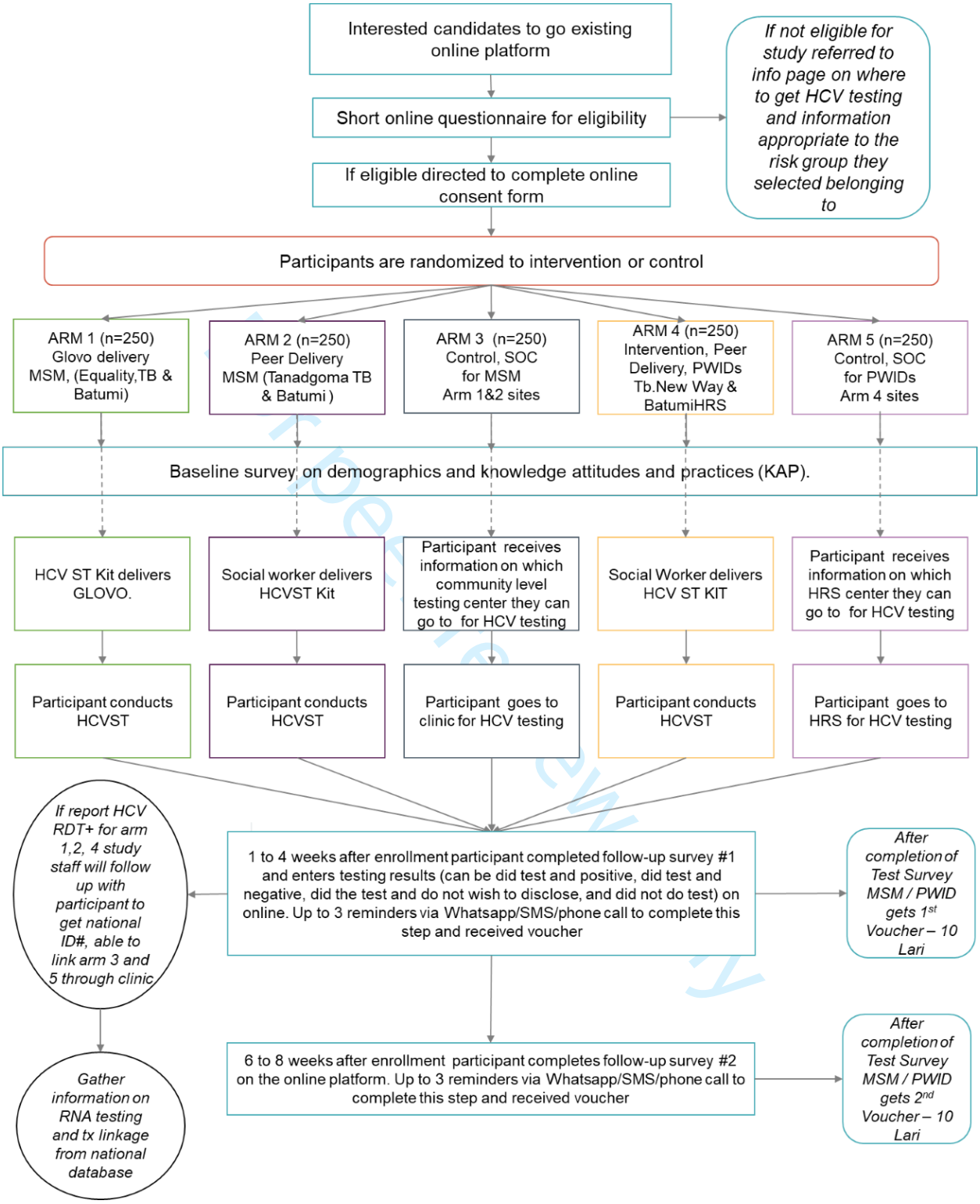
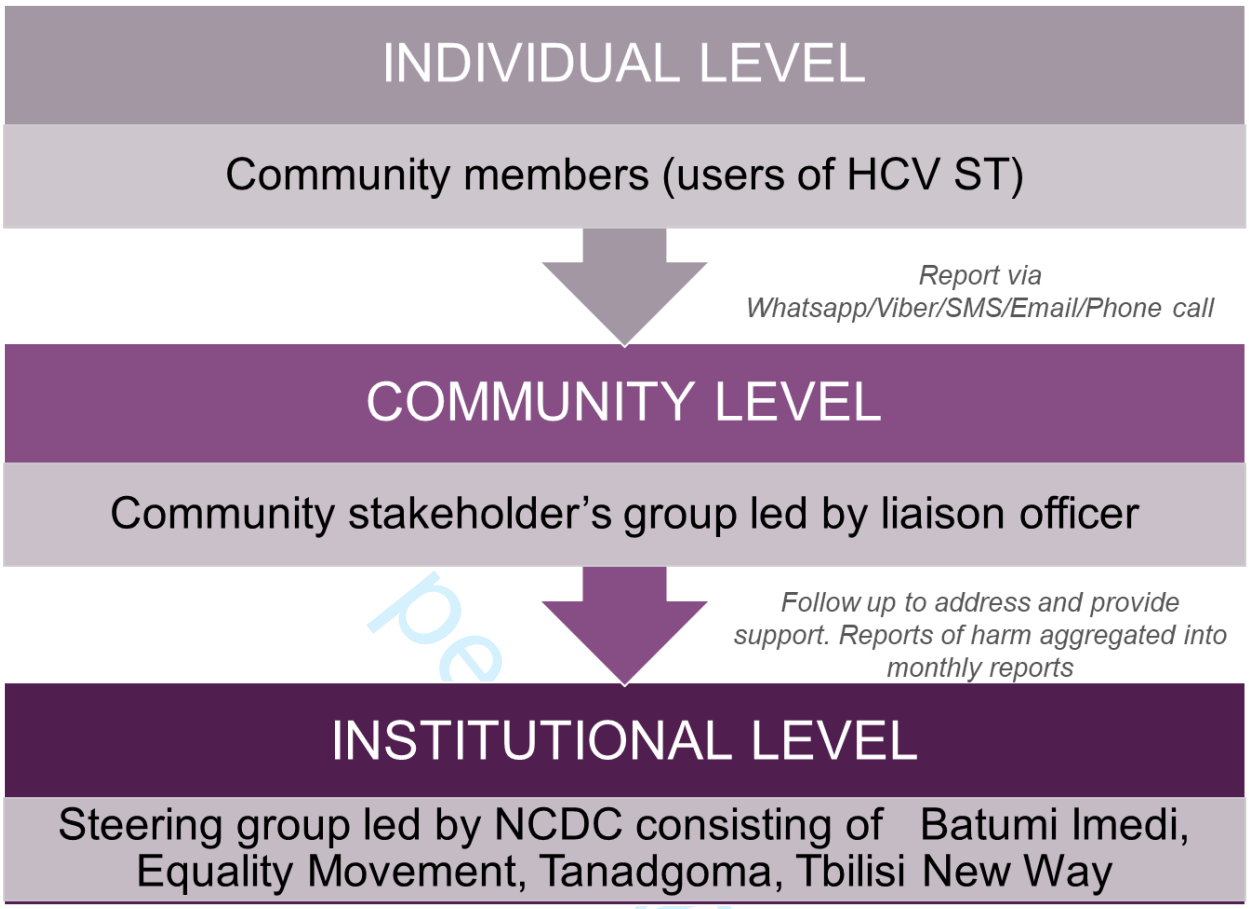


HCV= hepatitis C virus, MSM= men who have sex with men, TB= Tbilisi, SOC= standard of care, PWID= people who inject drugs, HCVST= hepatitis C virus self test, HRS= harm reduction site, RDT+= rapid diagnostics test positive, tx= treatment



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Supplementary Annex 1
Study information form and informed consent form

Hepatitis C Study Information Sheet

Title of Study

Randomized controlled trial of home-based hepatitis C self-testing in key populations in Georgia

Participating Organizations

NCDC, Equality Movement, Tanadgoma, Tbilisi New Way HRS, Batumi Imedi HRS, Foundation for Innovative New Diagnostics

Introduction

Hepatitis C is a liver infection caused by a virus that can lead to serious liver damage, cancer, and even death. You are being invited to take part in this study to help understand different ways people can be tested for hepatitis C.

Purpose

The purpose of this study is to evaluate different models of hepatitis C testing

Study Procedures

If you take part in the study, you will only have to sign the consent form, take two surveys, and consider getting tested for hepatitis C. You will be randomly selected for testing models: a) to either receive a hepatitis C testing kit delivered to your home or b) receive information about how to get tested for hepatitis C at a local clinic or community center.

If you are selected for the hepatitis c self-test it is a simple procedure using oral fluids. If you are selected for the hepatitis C self-test group you will either be placed in the group that gets the hepatitis C self test delivered by Glovo delivery or be placed in the group that will have the test delivered to your house by a peer outreach worker or a social worker

Your information will be reviewed by the study personnel and grouped with all other persons in the study.

Benefits

As a participant in this study, you may learn if you have been exposed to hepatitis C or not and be offered care and treatment if you have hepatitis C.

Risks

There is minimal discomfort with hepatitis C testing. There is a minimal risk that you could encounter social harms from this study.

Framed in the study the observational team is set up to identify any social harm associated with participation in the study and testing. They will give you recommendations and to get the appropriate services as needed.

You can contact the study coordinator for the information how to contact this group *(The phone numbers will be provided by Arms)*

Compensation and Costs

There are no costs to you for participation in this study. All participants will receive a phone credit voucher of 10 GEL for completion of the first follow up questionnaire to enter test result and another phone credit voucher of 10 GEL when the finish the second study survey. You will receive the phone credits to the phone number that you provide on the online platform approximately 7 days after you complete each survey. You will be offered hepatitis C testing but are not required to be tested for hepatitis C to receive compensation.

Confidentiality

All information collected about you during the course of this study will be stored without any personal identifiers. No one will be able to match you to your information. No one will be able to determine your identity in the frame of the study. Only study personnel will have access to the information.

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Voluntary Participation/Study Withdrawal
Taking part in this study is completely voluntary. You are free to withdraw at any time. Whether or not you are part of this study does not in any way affect your medical or preventive care.
Questions
If you have any questions about the study, you may ask the study staff at any time.
The name and phone number of the study personnel of the relevant center will be indicated.

Online informed consent form
Project title: Randomized controlled trial of home-based hepatitis C self-testing in key populations in Georgia
I confirm that I have read and understood the information as provided in the information sheet for the above project and have had the opportunity to ask questions.
I understand that the project team may look at my health records for the current study. I agree to this access. I understand that my identity will not be revealed in any information released to third parties or published. I understand that I may freely withdraw from this project at any time.
I agree to be a part of the above project.

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Supplementary Annex 2

PARTICIPANT FOLLOW-UP SURVEY #1

These forms will be provided to the participants in Georgian language
STUDY ID: ***automatically inputted and date and timestamped by the platform***
SURVEY DATE: ***automatically generated/timestamped by the platform***

INFORMATION TO PARTICIPANTS
This questionnaire will be anonymized before being analyzed and your name will never appear in the database. Your answers will be used to better understand hepatitis C testing in Georgia.

SECTION A – STUDY TESTING AND FOLLOW-UP

A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
1. Yes
2. No

A1ai. *(if answered Yes to question A1, version of question for arm 3 and 5)* What was the result?
1. Positive
2. Negative
3. Don't know, have forgotten
4. Do not want to disclose

A1aii. *(if answered Yes to question A1, version of question for arm 1,2 and 4)* What was the result?
1. Positive
2. Negative
3. Test did not work
4. Don't know, could not read the test
5. Do not want to disclose

A1b. (*If answered No to question A1)* If no, why not?
1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Others, specify: _____

A1c. *(If answered Yes for question A1, for arm 3 and 5 only)* Where did you go to get the hepatitis C test done?
_____ (select from drop down list the name of the facility)
(For participants who live in Tbilisi)
1. Tbilisi Tanadgoma center
2. Tbilisi Equality movement center
3. Tbilisi New Way HRS
4. Tbilisi ID Hospital
5. Neo Lab clinic

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6. Hepa clinic
7. Other: _____

(For participants who live in Batumi)

1. Batumi Tanadgoma center
2. Batumi Equality movement
3. Batumi Imedi HRS
4. Batumi ID hospital
5. Batumi Mary time hospital
6. Other: _____

A1f. *(If answered Negative in question A1aii, for arm 1,2, and 4 only)* If you had tested positive for hepatitis C, what do you think your next steps would have been?

1. To go to a community-based organization for more information and advice
2. To go to a healthcare clinic for a confirmation test
3. To go to a hospital for a confirmation test
4. I would not do next step
5. Don't know
6. Others, specify: _____

A1g. *(If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only)* Have you taken any further step to get a second test done?

1. Yes, have gone to a community-based organization for more information and advice
2. Yes, have gone to a clinic and asked for another test
3. No, I have not made next step
4. Others, specify: _____

A1h. *(If answered No in question A1g)* If you do not made any next step, why not?

1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Transportation was too expensive
6. Others, specify: _____

A2a. (*version of question for arm 3 and 5 group)* Did you ask anyone any question about process of hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, person who performed the test
4. Yes, friend or family member

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5. Yes; others, specify: _____
6. No, I have not asked the question

A2b. (*version of question for arm 1)* Did you ask anyone any question about process of hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, friend or family member
4. Yes; others, specify: _____
5. No, I have not asked the question

A2c. (*version of question for arm 2 and 4)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, by asking the peer deliver who dropped of my test
3. Yes, online through searching the internet
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No, I have not asked the question

A3. *(If answered Yes in question A1)* How would you rate the hepatitis C testing you were offered in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)

	Not very easy		Average		Very easy
How easy was the testing process?	1	2	3	4	5

	Not very convenient		Average		Very convenient
How convenient was the testing process?	1	2	3	4	5

	Not very private		Average		Very private
How private did you think the testing process was?	1	2	3	4	5

	Not very trustworthy		Average		Very trustworthy
How much do you feel you can trust the test results?	1	2	3	4	5

	Not very secure		Average		Very secure
How secure did you feel during the testing process?	1	2	3	4	5

	Not very stressful		Average		Very stressful
How stressful was the testing process?	1	2	3	4	5

	Not very easy		Average		Very easy	
If you needed further care, how easy was it to access it?	1	2	3	4	5	Did not need it

A4. *(If answered Yes in question A1)* Did you feel you could understand the result of your test?

1. Yes
2. No

A4ai. *(If answered Yes in question A4, version of question for arm 1,2 and 4)* What do you think have helped you to understand the result of your test (select all that apply)?

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1. The printed instructions for use that came with the HCV self-test
2. Video instructions on how to perform a self-test
3. Being able to communicate with the selftest.ge team
4. Other; specify: _____

A4aii. *(If answered No in question A4, version of question for arm 1,2 and 4)* Why do you think you were unable to understand the result of your test? Select all that apply

1. The printed instructions for use that came with the HCV self-test were not easy to understand
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand
4. Others; specify: _____

A5. *(If answered Positive, test did not work or Don't know in question A1aii)* Did you feel you knew what steps you needed to take to be further linked to hepatitis C care after you got the result of your test?

1. Yes
2. No

A6. *(If answered No in question A5)* What do you think would have helped you to know what steps you need to take to be further linked to care?

1. A list of clinics near me that provide HCV care with their contact information
2. More information on how community-based organizations near me could help me navigate how to be linked to care
3. A video explaining how I could get linked to care
4. Others; specify:_____

A7. In the future, where would you prefer to be tested for hepatitis C?

1. By myself at home
2. At home with someone I trust
3. By myself at a healthcare clinic
4. In a community centre by community-based organization staff
5. In a healthcare clinic by a healthcare worker
6. In a pharmacy by a healthcare worker
7. No preference
8. Prefer not to get tested for hepatitis C
9. Other, specify:_____

A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and instructions on how to do it?

1. Yes
2. No
3. Don't know

A8a. *(If answered Yes in question A8)* If yes, how often do you think you would test yourself?

1. More than once every 6 months
2. Once every 6 months
3. Once a year

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4. Once every 2 years
5. Don't know
6. Others, specify:_____

A1d. *(If answered Positive in question A1ai or A1aii)* Have you taken further steps for hepatitis C care after your positive test? Please select all that applies

1. Yes, have gone for confirmation test
2. Yes, have had doctor consultation and completed additional testing
3. Yes, have started treatment
4. others, specify: _____
5. No, I do not plan to take further steps

A1e. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* What was the result of your confirmation test?

1. I was confirmed active chronic Hepatitis C (viremia)
2. I do not have active chronic hepatitis C (viremia)
3. Have not been told the results yet
4. Do not want to disclose
5. Others, specify:_____

A1i. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* Where did you go for this further hepatitis C care?

(select from drop down list the name of the facility

(For participants who live in Tbilisi)

1. Tbilisi ID Hospital
2. Neo Lab clinic
3. Hepa clinic
4. Other: _____

(For participants who live in Batumi)

1. Batumi Imedi HRS
2. Batumi ID hospital
3. Batumi Mary time hospital
4. Other: _____

SECTION B – RISK BEHAVIORS

B1. How many times have you or your partner(s) used a condom during sexual contact in the last month?

1. I have not had sexual contact in the last month
2. Always
3. Often
4. Sometimes
5. Never used

B2. In the last month, have you taken any substance by snorting it?

1. Yes

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2. No

B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?

1. Yes
2. No

B4. In the last month, have you injected unprescribed drugs?

1. Once
2. More than once
3. Never

B4a. (*If answered Once or More than once to question B4)* Within the last month, how often did you inject illicit drugs?

1. Once a month
2. Several times a month
3. Once a week
4. 2-3 times a week
5. 4-5 times a week
6. Once a day
7. Several times a day
8. Don't know

B4b. (*If answered Once or More than once to question B4)* In the past month, have you ever used a needle/syringe that was used by somebody else before?

1. Yes
2. No
3. Don't know

B4c. (*If answered Yes to question B4b)* If you have used a needle/syringe that was used by somebody else before in the past month, how many people share it with you?

1. __ (fill in the number of people you shared with)
2. Don't know

SECTION C – Help us to make HCV testing accessible to everyone who needs it, your opinion counts!

Please let us know how we can improve HCV testing and care services - your feedback will help to guide how these services can best serve to Georgia population.

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Supplementary annex 3:

PARTICIPANT FOLLOW-UP SURVEY #2

STUDY ID: ***automatically linked and date and timestamped by the platform***
SURVEY DATE: ***automatically generated/timestamped by the platform***

INFORMATION TO PARTICIPANTS
This questionnaire will be anonymized before being analyzed and your name will never appear in the database. Your answers will be used to better understand hepatitis C testing in Georgia.

SECTION A – STUDY TESTING AND FOLLOW-UP

A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
1. Yes
2. No

A1ai. *(if answered Yes to question A1, version of question for arm 3 and 5)* What was the result?
1. Positive
2. Negative
3. Don't know, have forgotten
4. Do not want to disclose

A1aii. *(if answered Yes to question A1, version of question for arm 1,2 and 4)* What was the result?
1. Positive
2. Negative
3. Test did not work
4. Don't know
5. Do not want to disclose

A1b. (*If answered No to question A1)* If no, why not?
1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Others, specify: _____

A1c. *(If answered Yes for question A1 for arm 3 and 5 only)* Where did you go to get the hepatitis C test done?

_____ (select from drop down list the name of the facility)

(For participants who live in Tbilisi)
1. Tbilisi Tanadgoma center
2. Tbilisi Equality movement center
3. Tbilisi New Way HRS
4. Tbilisi ID Hospital
5. Neo Lab clinic
6. Hepa clinic

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7. Other: _____

(For participants who live in Batumi)

1. Batumi Tanadgoma center
2. Batumi Equality movement
3. Batumi Imedi HRS
4. Batumi ID hospital
5. Batumi Mary time hospital
6. Other: _____

A1f. *(If answered Negative in question A1aii, for arm 1,2, and 4 only)* If you had tested positive for hepatitis C, what do you think your next steps would have been?

1. To go to a community-based organization for more information and advice
2. To go to a policlinic for a confirmation test
3. To go to a healthcare clinic for a confirmation test
4. I would not do next step
5. Don't know
6. Others, specify: _____

A1g. *(If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only)* Have you taken any further step to get a second test done?

1. Yes, have gone to a community-based organization for more information and advice
2. Yes, have gone to a clinic and asked for another test
3. No, I have not made next step
4. Others, specify: _____

A1h. *(If answered No in question A1g)* If no, why not?

1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Test was too expensive
6. Others, specify: _____

A2a. (*version of question for arm 3 and 5 group)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, person who performed the test
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No

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A2b. (*version of question for arm 1)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, friend or family member
4. Yes; others, specify: _____
5. No

A2c. (*version of question for arm 2 and 4)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, by asking the peer deliver who dropped of my test
3. Yes, online through searching the internet
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No

A3. *(If answered Yes in question A1)* How would you rate the hepatitis C testing you were offered in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)

	Not very easy		Average		Very easy
How easy was the testing process?	1	2	3	4	5

	Not very convenient		Average		Very convenient
How convenient was the testing process?	1	2	3	4	5

	Not very private		Average		Very private
How private did you think the testing process was?	1	2	3	4	5

	Not very trustworthy		Average		Very trustworthy
How much do you feel you can trust the test results?	1	2	3	4	5

	Not very secure		Average		Very secure
How secure did you feel during the testing process?	1	2	3	4	5

	Not very stressful		Average		Very stressful
How stressful was the testing process?	1	2	3	4	5

	Not very easy		Average		Very easy	
If you needed further care, how easy was it to access it?	1	2	3	4	5	Did not need it

A4. *(If answered Yes in question A1)* Did you feel you could understand the result of your test?

1. Yes
2. No
3. I do not know

A4ai. *(If answered Yes in question A4, version of question for arm 1,2 and 4)* What do you think have helped you to understand the result of your test (select all that apply)?

1. The printed instructions for use that came with the HCV self-test
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand

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4. Being able to communicate with the selftest.ge team
5. Other; specify: _____

A4aii. *(If answered No in question A4, version of question for arm 1,2 and 4)* Why do you think you were unable to understand the result of your test? Select all that apply

1. The printed instructions for use that came with the HCV self-test were not easy to understand
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand
4. Others; specify: _____

A5. *(If answered Positive, Invalid or Don't know in question A1aii)* Did you feel you knew what steps you needed to take to be further linked to hepatitis C care after you got the result of your test?

1. Yes
2. No

A6. *(If answered No in question A5)* What do you think would have helped you to know what steps you need to take to be further linked to care?

1. A list of clinics near me that provide HCV care with their contact information
2. More information on how community-based organizations near me could help me navigate how to be linked to care
3. A video explaining how I could get linked to care
4. Others; specify:_____

A7. In the future, where would you prefer to be tested for hepatitis C?

1. By myself at home
2. At home with someone I trust
3. By myself at a healthcare clinic
4. In a community centre by community-based organization staff
5. In a healthcare clinic by a healthcare worker
6. In a pharmacy by a healthcare worker
7. No preference
8. Prefer not to get tested for hepatitis C
9. Other; specify: _____

A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and instructions on how to do it?

4. Yes
5. No
6. Don't know

A8a. *(If answered Yes in question A8)* If yes, how often do you think you would test yourself?

1. More than once every 6 months
2. Once every 6 months
3. Once a year
4. Once every 2 years
5. Don't know

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6. Others, specify:_____

A1d. *(If answered Yes to question A1, Positive in question A1a and No in question A1d in Follow-up survey #1, this will be the first question for them in this Follow-up survey #2. After questions A1d and A1e have been answered by this group in Follow-up survey #2, they will proceed to section B. This question is also for those who answered Positive in question A1a in Follow-up survey #2; for this group, they will proceed through the rest of section A following skip patterns based on their answers)* Have you taken further steps for hepatitis C care after your positive test?

Please select all that applies

1. Yes, have gone for confirmation test
2. Yes, have had doctor consultation and completed additional testing
3. Yes, have started treatment
4. Others, specify: _____
5. No, I do not plan to take further steps

A1e. *(If answered Yes, have gone for confirmation test or Yes,* , have had doctor consultation and completed additional testing *and have started treatment in question A1d)* What was the result of your confirmation test?

1. I have hepatitis C viremia
2. I do not have hepatitis C viremia
3. Have not been told the results yet
4. Others, specify: _____

A1i. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* Where did you go for this further hepatitis C care?

(select from drop down list the name of the facility

(For participants who live in Tbilisi)

1. Tbilisi ID Hospital
2. Neo Lab clinic
3. Hepa clinic
4. Other: _____

(For participants who live in Batumi)

1. Batumi Imedi HRS
2. Batumi ID hospital
3. Batumi Mary time hospital
4. Other: _____

SECTION B – RISK BEHAVIORS

B1. How many times have you or your partner(s) used a condom during sexual contact in the last month?

1. I have not had sexual contact in the last month
2. Always
3. Often
4. Sometimes
5. Never used

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B2. In the last month, have you taken any substance by snorting it?

1. Yes
2. No

B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?

1. Yes
2. No

B4. In the last month, have you injected unprescribed drugs?

1. Once
2. More than once
3. Never

B4a. (*If answered Once or More than once to question B4)* Within the last month, how often did you inject drugs?

1. Once a month
2. Several times a month
3. Once a week
4. 2-3 times a week
5. 4-5 times a week
6. Once a day
7. Several times a day
8. Don't know

B4b. (*If answered Once or More than once to question B4)* In the past month, have you ever used a needle/syringe that was used by somebody else before?

1. Yes
2. No
3. Don't know

B4c. (*If answered Yes to question B4b)* If you have used a needle/syringe that was used by somebody else before in the past month, how many people share it with you?

1. __ (fill in the number of people you shared with)
2. Don't know

SECTION C – Help us to make HCV testing accessible to everyone who needs it, your opinion counts!

Please let us know how we can improve HCV testing and care services - your feedback will help to guide how these services can best serve the people in Malaysia:

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

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Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	13
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	10
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team,	10 and 11

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		and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	7 and 8
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4 and 7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data	4 and 5

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		will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a there are no modificaitons
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	6
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical	7 and 8

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		relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8 and 9
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6 and 7

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Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6 and 7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and	9 and 10

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		validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	6
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9 and 10
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	7 and 8
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			

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Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	11
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	8
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2 and 11

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Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	11
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	6

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Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	13
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	13
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	16 and 17
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Notes:

- 11b: n/a there are no modificaitons The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was

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completed on 07. August 2021 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

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BMJ Open

Home-based hepatitis C self-testing in people who inject drugs and men who have sex with men in Georgia: a protocol for a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-056243.R2
Article Type:	Protocol
Date Submitted by the Author:	05-Aug-2022
Complete List of Authors:	Shilton, Sonjelle; Foundation for Innovative New Diagnostics Stvilia, Ketevan; National Centre for Disease Control and Public Health of Georgia Japaridze, Maia; Foundation for Innovative New Diagnostics Tsereteli, N.; 4. Center for Information and Counselling on Reproductive Health-Tanadgoma Usharidze, Dali; New Way Phevadze, Shota; Equality Movement Jghenti, Miranda; Batumi Imedi Mozalevskis, Antons; WHO Regional Office for Europe Markby, Jessica; Foundation for Innovative New Diagnostics Luhmann, Niklas; WHO Global HIV Hepatitis and STI Programmes Johnson, Cheryl; World Health Organization, Department of HIV/AIDS Nabeta, Pamela; Foundation for Innovative New Diagnostics Ongarello, Stefano; Foundation for Innovative New Diagnostics Reipold, Elena; Foundation for Innovative New Diagnostics Gamkrelidze, Amiran; National Centre for Disease Control and Public Health of Georgia
Primary Subject Heading:	Public health
Secondary Subject Heading:	Diagnostics, Gastroenterology and hepatology
Keywords:	Public health < INFECTIOUS DISEASES, World Wide Web technology < BIOTECHNOLOGY & BIOINFORMATICS, Hepatology < INTERNAL MEDICINE

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Manuscripts

Home-based hepatitis C self-testing in people who inject drugs and men who have sex with men in Georgia: a protocol for a randomized controlled trial

Sonjelle Shilton[1], Ketevan Stvilia[2,3], Maia Japaridze[1], Nino Tsereteli[4], Dali Usharidze[5], Shota Phevadze[6], Miranda Jghenti[7], Antons Mozalevskis[8], Jessica Markby[1], Niklas Luhmann[9], Cheryl Johnson[9], Pamela Nabeta[1], Stefano Ongarello[1], Elena Ivanova Reipold[1], Amiran Gamkrelidze[2]

1. Foundation for Innovative New Diagnostics, Geneva, Switzerland
2. National Center for Disease Control, Tbilisi, Georgia,
3. Tbilisi State Medical University, Tbilisi, Georgia
4. Center for Information and Counselling on Reproductive Health-Tanadgoma, Tbilisi, Georgia
5. New Way, Tbilisi, Georgia
6. Equality Movement, Tbilisi, Georgia
7. Batumi Imedi, Batumi, Georgia
8. WHO Regional Office for Europe, Copenhagen, Denmark
9. WHO Global HIV Hepatitis and STI Programmes, Geneva, Switzerland

Corresponding author: Sonjelle Shilton Campus Biotech, Chemin des Mines 9, 1202 Geneva, Switzerland, Sonjelle.Shilton@finddx.org

Word count: 3529 (max. 4000)

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ABSTRACT

Introduction: Globally, it is estimated that more than three-quarters of people with chronic hepatitis C virus (HCV) are unaware of their HCV status. HCV self-testing (HCVST) may improve access and uptake of HCV testing particularly amongst key populations such as PWID and MSM where HCV prevalence and incidence is high and barriers to accessing health services due to stigma and discrimination are common.

Methods and analysis: This randomized controlled trial compares an online programme offering oral fluid based HCVST delivered to the home with referral to standard-of-care HCV testing at HCV testing sites. Eligible participants are adults self-identifying as either men who have sex with men (MSM) or people who inject drugs (PWID) who live in Tbilisi or Batumi, Georgia, and whose current HCV status is unknown. Participants will be recruited through an online platform and randomized to one of three arms for MSM (courier delivery, peer delivery, and standard-of-care HCV testing (control)) and two for PWID (peer delivery and standard of care-HCV-testing (control)). Participants in the postal delivery group will receive a HCVST kit delivered by anonymized courier. Participants in the peer delivery groups will schedule delivery of the HCVST by a peer. Control groups will receive information on how to access standard of care testing at a testing site. The primary outcome is the number and proportion of participants who report completion of testing. Secondary outcomes include the number and proportion of participants who a) receive a positive result and are made aware of their status, b) are referred to and complete HCV RNA confirmatory testing, and c) start treatment. Acceptability, feasibility, attitudes around HCV testing and cost will also be evaluated. The target sample size is 1,250 participants (250 per arm).

Ethics and dissemination: Ethical approval has been obtained from the National Centers for Disease Control and Public Health Georgia Institutional Review Board (IRB# 2021-049). Study results will be disseminated by presentations at conferences and via peer-review journals. Protocol version 1.1; 14 July 2021.

Trial registration number: clinicaltrials.gov registry number NCT04961723 registered 14 July 2021

Keywords: Hepatitis C virus, self-testing, people who inject drugs, men who have sex with men

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ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This will be one of the first clinical trials to assess the impact of, and evidence on optimal service delivery options for, hepatitis C self-testing.
- The randomized design allows for comparison of two different hepatitis C self-testing service delivery models compared with the standard of care.
- The intervention group employing peer delivery of testing may generate some negative bias if participants wish to remain anonymous.
- The control arm uptake rates may be more heavily affected by ongoing COVID-19 movement restrictions than the delivery arms.
- The study will reach only people who have access to the internet, therefore the results may not be generalisable to harder to reach populations/settings.

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INTRODUCTION

The World Health Organization (WHO) estimates that 58 million people globally have chronic hepatitis C virus (HCV) infection.[1] Of these, only 21% are diagnosed, with lack of awareness, poor access to testing services and stigma and discrimination surrounding HCV infection contributing to low uptake of HCV testing services.[1] As evidenced by self testing for HIV, the option to self-test at home can increase access to testing. As such, WHO recently published the first recommendations and guidance for HCV self-testing (HCVST), which highlights HCVST as an additional approach to HCV testing to reduce the gap in diagnosis.[1] The recommendations are based on broad evidence with self-testing for HIV, as well as specific studies on HCVST performance, usability, acceptability and user values and preferences.[2-6] A number of evidence gaps relating to HCVST remain however, including a need for data on the impact of HCVST on uptake of HCV testing and linkage to care, the need for better understanding of optimal service delivery options for HCVST, and on the use of HCVST in key populations such as people who inject drugs (PWID) and men who have sex with men (MSM).

Georgia is a middle-income country with a high prevalence of chronic HCV infection (5.4%) in the adult population from a population based serosurvey conducted in 2015 ,[7] with the burden of infection largely within the PWID population (numbering over 52,250 in 2017).[8 9] Prior to the implementation of a national elimination programme in 2015,[7 8] the seroprevalence in PWIDs in Georgia ranged from 50–92%, depending on region.[10-13] The programme has been successful in identifying and linking people with HCV to care,[8] but gaps still remain in hard to reach key populations, and so a pilot HCVST programme has been initiated, based on an existing self-testing programme for HIV.[14] Here we describe the protocol of an randomized controlled trial (Georgian IRB Ethics Approval Number: IRB# 2021-049, clinicaltrials.gov: NCT04961723) that aims to assess the impact and acceptability of an online programme offering home delivery of HCVST to PWID and MSM in Georgia.

METHODS AND ANALYSIS

Study settings and participants

This is a randomized controlled trial comparing home-delivery of HCV self-tests to referral to standard of care community-based HCV testing sites in PWID and MSM in Tbilisi or Batumi, Georgia. Six study HCV sites in Tbilisi and five in Batumi will participate as outlined in **Table 1**.

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Table 1. Study sites

	Tbilisi	Batumi
MSM peer delivery site and community testing site	Tbilisi Tanadgoma center	Batumi Tanadgoma center
MSM courier delivery site and community testing site	Tbilisi Equality Movement center	Batumi Identoba center
PWID peer delivery site and community testing site	"Tbilisi New Way" Harm Reduction Site	"Batumi Imedi" Harm Reduction Site
Hepatitis testing and treatment site	Tbilisi Infectious Diseases Hospital	Batumi Infectious Diseases Hospital
Hepatitis testing and treatment site	"Neo-Lab" clinic	
Hepatitis testing and treatment site	"Hepa" clinic	

Eligible participants are adults aged ≥18 years living in Tbilisi or Batumi who can access services on the online platform and who self-identify as a PWID or MSM. Participants must be able to read and understand Georgian and have unknown HCV status (defined as never tested for anti-HCV or most recent test for anti-HCV antibodies negative and performed ≥6 months prior to enrolment). People who have a self-reported previously confirmed anti-HCV positive status or who are ineligible for the Georgian National Hepatitis Elimination programme (i.e do not have a Georgian ID card) will be excluded from the study.

Study participants will be prospectively recruited through an existing HIV self-testing online platform (http://selftest.ge), with community organizations and peers promoting the study. Interested participants will sign up to be contacted for study eligibility screening and to complete online informed consent. All study participants will complete a baseline survey collecting demographics and knowledge and attitudes towards HCV testing. Recruitment is expected to start in October 2021.

Study design

Eligible participants who primarily identify as MSM will be randomized separately from those who primarily identify as PWID (**Figure 1**). Those who primarily identify as MSM will be randomized to one of the following study arms in a 1:1 ratio: a) courier l delivery; b) peer delivery and c) control. Participants in the courier delivery group will receive a home-delivered HCVST kit, this test kit package includes the

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self-test, instructions for use and supporting materials such as details on how to access to live chat and call centre for questions about testing. Participants in the peer delivery group will schedule delivery of the self-test to the location of their choice and instructions for use by a peer worker from the study site. The peer worker is a member of the community who has been trained to engage in HIV prevention services, this peer worker will provide basic information on the test, how to proceed after a positive result, and how to access live chat and call centre. Participants in the control arm will receive information about standard of care professionally administered HCV testing at one of the study sites. These participants will also have access to the live chat and call centre facilities. Participants who primarily identify as PWID will be randomized to either peer delivery or control in a 1:1 ratio.

Approximately 2–4 weeks after enrollment, each participant will complete a follow-up survey, which will include the opportunity to upload any test result (**supplementary annex 1**). A second follow-up survey will be sent after the closure of the first survey (approximately 6–8 weeks after enrolment) (**supplementary annex 2**). Up to 3 telephone reminders may be sent for each survey if a survey has not been completed. Participants will receive telephone credit (10 GEL, equivalent to ~$3 USD) for completion of each survey.

Any individual reporting a positive HCV self-test will be referred to further HCV testing. Those confirmed to have active HCV infection will be linked to HCV treatment and care which is provided for free through the Georgian National Elimination program.

Participants may withdraw from the study at any time or be withdrawn at the discretion of the Primary Investigator. Participants will be considered lost to follow-up to the study if they fail to complete one of the online surveys after receiving three reminders.

FIGURE 1 HERE

Data collection

Participants will complete the baseline, the first and second follow up surveys on the online platform (supplementary annex 3). The baseline survey will assess participants' current knowledge of hepatitis C including risk factors for contracting hepatitis C, as well as gathering information on their current risk-related behaviours.

The purpose of the follow up surveys is to collect from the participant if they have completed the test, and if completed what the result of the test was, to collect information on risk behaviours to assess if any change in risk behaviours may have taken place during the study, and the gather feedback on how the

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participants felt about the testing process.

The first follow up survey will be given 2 to 4 weeks post enrolment will ask participants to report if they conducted the HCV test and if so, the results of the test. If the participant reports having taken the test, they will be asked to answer questions relating to their perception of the testing experience and the actions they took following the test. If the participant reports that they did not take the test they will be asked questions as to why they have not yet taken the test. This survey will also gather information for all participants on their current behaviours that may be related to risk factors for HCV.

The second follow up survey will be given 4 to 8 weeks post enrolment (at least 2 weeks after completion of first survey), will ask the participant to report, if they have not already reported taking the test in the first follow up survey, if they conducted the HCV test and if so, the results of the test. If the participant reports having taken the test, they will be asked to answer questions relating to their perception of the testing experience and the actions they took following the after test. If the participant reports that they did not take the test they will be asked questions as to why they have not yet taken the test. For those that reported taking the HCV test in the first follow up survey, this survey will start by gathering information on what actions the person has since taken regarding seeking further HCV care (if their HCV test was positive). This survey will also gather information from all participants on their current behaviours that may be related to risk factors for HCV.

Strategies to improve adherence to interventions

Participants will be provided several supporting tools to minimize the rate of errors in the self-testing process and any possible confusion in interpretation of the test results. Printed instructions for use (IFU) in Georgian will be delivered with the test kit and contain pictorial guides on how to use the test. In addition, participants will be provided a link to a video guide and have access to live chat and a call center.

Randomization and blinding

Prior to study enrolment, a list of study IDs in ascending numerical order for each key population (PWID or MSM) will be generated by an employee of the sponsor who will not be involved in the execution of the study. Study IDs will be randomized by use of an algorithm to a study arm. Enrolment and assignment of study IDs will take place via the online platform. Participants will be assigned via the online platform study IDs in a consecutive fashion, thereby completing assignment to a study group. Due

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to the nature of the study there is no blinding as the study sites will know which participant received courier delivery, peer delivery or standard of care.

Interventions

The HCVST used in this study will be the OraQuick® HCV Rapid Antibody Test (OraSure Technologies Inc., Bethlehem, PA, USA). This test is CE marked and has received WHO prequalification for professional use by healthcare workers. The test has been validated by the manufacturer for self-testing, but use as a self-test is currently for Research Use Only (RUO), thus test results are not used for patient management. Instructions for use in Georgian were developed for previous studies and have been optimized based on feedback received.

Outcomes

The primary outcome of the study is the number and proportion of participants who report completion of testing in the postal or peer delivery arms. We hypothesize the intervention arms will show 20% more participants reporting completion of the testing result compared with the control arms (**Table 2**).

Secondary outcomes include the number and proportion of HCV antibody positive participants who are made aware of their HCV status, who are referred to and complete HCV RNA confirmatory testing, and who receive a positive HCV RNA result and start treatment, in each study arm (**Table 2**). Acceptability and feasibility of HCVST, along with knowledge, attitudes, and practices around HCV testing and care, will be assessed by analysis of survey responses at baseline and post-testing. The cost of HCVST will be evaluated by comparing costs in the intervention arms versus the control arm.

Table 2. Trial objectives, endpoints, and statistical analysis methods

Objectives	**Endpoints**	**Statistical Analysis Methods**
Primary		
To assess the impact of HCV self-testing home delivery on HCV antibody testing rates in PWID and MSM	Number and point estimate of the proportion of participants who report completing the HCV antibody testing in the intervention groups. Superiority of the proportion of participants who report completing the HCV antibody testing in the	The primary outcome 1.2 will be evaluated in the MITT population (primary analysis) and will be repeated for the PP population. The difference $p_{fo,I}$ - $p_{fo,C}$ will be assessed in a one-sided test with a margin of 20% by applying the following hypothesis: % Intervention types (Arm 1, 2, 4) as well as the control groups (Arm 3, 5) will be considered. The proportion of individuals reporting HCV completing the test in the following intervention

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	intervention groups compared with the control groups (margin 20%).	and control groups will be compared (three comparisons): ▪ Arm 1 (intervention) vs. Arm 3 (control) for MSM, ▪ Arm 2 (intervention) vs. Arm 3 (control) for MSM ▪ Arm 4 (intervention) vs. Arm 5 (control) for PWID.
Secondary		
To assess the impact of HCV self-testing on the number of HCV antibody positive individuals who are aware of their status	Number and estimate of the proportion of HCV antibody positive participants made aware of their status in the intervention vs control groups	The outcome (patient has a positive test result y/n) is defined overall (as primary analysis) and for visit 1 (as additional analysis). The proportion of test positives p_{pos} will be calculated among all patients with test results (=favourable outcome) as well as among all MITT and PP patients. These proportions will be investigated in the comparison via hypothesis testing.
To assess the impact of HCV self-testing on linkage and completion of HCV RNA confirmatory testing in HCV antibody positive individuals	Number and estimate of the proportion of HCV antibody positive participants who are referred to and complete HCV RNA confirmatory testing in the intervention vs control groups	The outcome (patient is referred to and complete HCV RNA confirmatory testing: y/n) is defined overall (as primary analysis) and for visit 1 (as additional analysis). The proportion of patients referred p_{ref} will be calculated among all patients with positive test results as well as among all MITT and PP patients. These proportions will be investigated in the comparison via hypothesis testing.
To assess the impact of HCV self-testing on treatment initiation in HCV RNA positive individuals eligible to start treatment	Number and estimate of the proportion of HCV RNA positive participants who start treatment in the intervention vs control groups	Hereby the outcome (patient has started treatment y/n) is defined overall (as primary analysis) and for visit 1 (as additional analysis). The proportion of patients treated p_{trt} will be calculated among all patients with positive test results as well as among all MITT and PP patients. The comparisons will refer to proportion with number with patients with a positive test result in the denominator (a+b, f+g).
To assess the acceptability and feasibility of HCV self-testing at baseline and after study participation. Information about knowledge, attitudes, and practices related to	Analysis of survey responses using proportions and means	The secondary outcome 2.4 will be evaluated for the PP and MITT population. Intervention types (Arm 1, 2, 4) as well as the control groups (Arm 3, 5) will be considered separately. Descriptive statistics for survey responses [variables see chapter **Error! Reference source not found.**, if not stated otherwise] will be reported either in absolute numbers and

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HCV and risk taking behaviours may also be collected		proportions or summarized by mean, median, standard deviation, minimum, maximum and quartiles by arm and visit.
To assess the cost of HCV self-testing	Cost per test completed, cost per person diagnosed (serology, RNA) in the intervention vs control groups	

Acronyms: MITT (Modified-Intention-To-Test): *all participants* in ITT who were *randomized to HCV self-testing* (Arm 1 to Arm 5). PP (Per-Protocol): *all participants* in ITT *who fully complied with the protocol* (i.e.: primary endpoint variable is available)

Safety analyses will not be performed, as the HCVST used in this study is a low-risk test already approved for professional use by a stringent regulatory authority. Social harms relating to self-testing will be evaluated by a community stakeholder group (**Figure 2**).

FIGURE 2 HERE

Sample size and statistical analyses

The target sample size is a minimum of 1,250 participants (250 per study arm). The sample size was calculated using G*Power 3.1 software (University of Dusseldorf, Germany) using a one-tailed test, 80% power and a 5% significance level in order to detect a significant change in the primary outcome between the control and intervention groups. With up to a 20% loss to follow up rate, we conservatively estimate that 250 participants in each group will be sufficient to detect differences between the control and each intervention group.

As the estimated proportion of anti-HCV positive results among study participants is estimated to be ≤10%, the study is not powered to detect statistical differences between study arms in the secondary endpoints.

Statistical analyses will be performed in the per protocol population (all participants who fully comply with the protocol). A 20% difference between intervention and control arms for the primary endpoint will be considered as demonstrating superiority of HCVST compared with referral to standard of care. In our settings, the superiority test is a (one-sided) hypothesis test where the null hypothesis is that the outcome in the intervention arm is not better than in the control arm, so rejecting the null hypothesis will support the evidence of the anticipated superiority of the intervention arm.

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Secondary outcomes will be analysed using descriptive statistics including proportions and means, with the exception of cost of HCVST, for which a cost-effectiveness analysis will be performed.

Building off the lessons learned from the HIVST pilot study, the sample size will be reached using social media to promote the study to the target population. The promotional strategies will be tailored to the clientele of each site. For Tanadgoma and Equality Movement posts and social media advertisements will be generated using Facebook and online dating sites and mobile applications Hornet, PlanetRomeo and Tinder, advertisements will also be placed in the gay video section of pornography sites. For Imedi Batumi and Tbilisi New Way promotions will be done through posts and advertisements on Facebook as well as flyers distributed at the harm reduction sites. Promotional materials will include digital fliers and posters (approved by the National Ethics Board), as well as online talk shows and videos which will provide basic information on hepatitis C and why testing is important and explain about the HCVST study providing information on where to enroll.

Data management

Data recorded in the online platform will be protected with multilayer security and each study personnel will have individualized access rights appropriate to their role in the study. Any participant records that are transferred from the online platform for analysis will contain the study ID only; no information that would allow identification of participants will be transferred. FIND is responsible for data management, including quality control checks and assessment of protocol compliance. FIND or a designee may conduct audits of investigational sites as part of routine quality assurance.

There is only one study database with no direct links with any other databases. In terms of following participants along the continuation of care offered by the National Elimination Program, the NCDC study team will, with consent from participants, attain the ID numbers of individuals who test positive in the control group, as well as those in the intervention groups who attend to a clinic for a professional use RDT after completion of a self-test. This ID number will allow NCDC study staff to follow their progress in the national HCV database which captures all diagnostic and treatment data of the National Elimination Program

Study Oversight and monitoring

The support for this study is provided by:
Principle investigator who has overall responsibility for the supervision of the study and medical responsibility of the participants.

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Batumi Imedi, Equality Movement, Tanadgoma, and Tbilisi New Way which each have a study coordinator which ensures the online platform is functioning correctly and that study procedures are followed as needed in terms of the arm of the study they are responsible for.

Study team members send out reminders to participants to complete surveys, organizes payment of incentives to participants that have completed the surveys.

Study peer support team provide support to participants if they have questions or concerns regarding the testing process, assist those participants who have an HCV positive antibody result, and are interested, with linkage to further care (both intervention and control group).

FIND is the study sponsor and has written the protocol, maintains the data collection tools, will oversee the data analysis, and have final decision to submit the study report for publication.

The study team meets weekly. While there is no study steering committee there is a social harm monitoring structure (**Figure 2**). This structure is comprised of the individual, community, and instructional partners and is designed to capture any potential harms that may arise related to the use of HCVST.

There is no data monitoring committee for this study due in large part to the lack of SAEs in the previous feasibility and acceptability studies on HCVST completed in Georgia as well as 6 other countries as well the fact that many large scale HIVST studies and pilots have been conducted without such committees.

Patient and public involvement

Several of the organizations involved in this trial are community-based organizations which include people with experience of living with HCV, living with HIV, and injection drug use. They have contributed their input into the trial from the conceptualization phase and are included as authors in this paper.

Representatives and target end users from the MSM and PWID organizations have reviewed and commented on an information overview sheet that is provided with the self-tests. Prior to finalization of the data collection forms and website interface we piloted the forms and interface with 41 potential end users from MSM community and 19 potential end users from PWID community. We incorporated the feedback into the final design of the data collection tools and website interface.

Members of the public will be engaged in the social harms monitoring structure throughout the trial. The trial partners have several dissemination events planned which will be open to the public.

Ethics and dissemination

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Ethical approval of the study protocol has been obtained from the National Centers for Disease Control and Public Health Georgia Institutional Review Board (IRB# 2021-049) and any protocol amendment that may arise will be submitted to the same. The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, Good Clinical Practice guidelines (ICH GCP E6 [R2]) and applicable laws and regulations. All participants will be informed that their participation is voluntary and will be required to sign and date a statement of informed consent meeting Georgian regulations. The consent form will be available on the online platform and will include information on the nature of the trial in Georgian, and details on access to a hotline for questions about the trial.

A variety of methods and forums will be used to disseminate the results of the study including presentation at scientific conferences, peer reviewed publications, and advocacy-based literature. Special efforts will be put into sharing the results with organizations representing PWID and MSM at the national, regional and global level. Dependent on the outcomes of the trial, dissemination work may entail working with stakeholders to facilitate the national programming for scale up of HCVST.

DISCUSSION

To our knowledge, this will be the first study to assess the acceptability and impact of using an online platform, which was developed initially for HIV self-testing (HIVST), for providing home-delivery of hepatitis C virus self-tests (HCVST).

Limitations of this study design include the use of an online platform for enrolment, limiting the study population to people who have access to the internet and have internet literacy. This may exclude people who could also benefit from HCVST but are not able to access the internet. There could be operator errors while participants conduct the test and false reporting of results. Uptake of testing in the control arm may be affected by the geographical location of the participant and the distance to a nearest testing centre. Moreover, the ongoing COVID-19 pandemic may affect participants' willingness to visit a healthcare facility and therefore, may negatively impact the uptake of testing in the control arm and the uptake of treatment in both intervention and control arms. The survey questionnaires have a multiple-choice design and may not capture some important context-specific aspects. Finally, the context of Georgia, which has an advanced elimination program, can be both and advantage and limitation. An advantage in thatpeople are more aware of HCV and could be more motivated to seek testing. However, ss most of Georgia's population has been tested at least once

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already, this may result in challenges in recruiting the needed sample size (mitigated by including those previously tested anti-HCV negative).

Understanding how integration of HCVST into self-testing platforms for HIV can leverage existing mechanisms to maximize investments that global funders have made in other areas is critical for HCV, as there is very limited funding available, of which most is domestic.[15] The findings of this study will inform the Georgian National Center for Disease Control and Public Health on scale up of HCVST to reach last mile service delivery for HCV. Additionally, these findings will have global importance as this will provide some of the first ever evidence about implementation of HCV ST in key populations that could be relevant to other settings and countries which are advancing in their hepatitis response.

CONFLICT OF INTEREST

S.S, M.J, P.N and E.R declare that they are employees of the Foundation for Innovative New Diagnostics (FIND). The other authors have no conflicting or competing interests to declare. The opinions expressed herein are the author's own and do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated. Where the authors are identified as personnel of the World Health Organization, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the World Health Organization.

FUNDING

This work is funded by the Government of the Netherlands.

AVAILABILITY OF DATA AND MATERIALS

The final dataset will be housed with FIND and will be made available upon reasonable request to the corresponding author.

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CONTRIBUTIONS

S.S, K.S, and E.R conceptualized the study. S.S designed and wrote the protocol. S.S, K.S, E.R, M.Jg, N.T, D.U, S.P, M.J finalized the protocol. A.M, N.L, C.J, P.N provided technical input on the trial design. C.J provided guidance on the social harm monitoring structure. S.S wrote the first draft of the manuscript. S.O developed the statistical component of the protocol. K.S, E.R, M.Jg, N.T, D.U, J.M, S.P, M.J, A.M, N.L, P.N, A.G reviewed the manuscript. All authors have read and approved the manuscript.

ACKNOWLEDGEMENTS

The information described herein is based on version 1 of the study protocol, dated 31 May 2021. Medical writing services, funded by FIND, were provided by Rachel Wright, PhD, in accordance with Good Publication Practice (GPP3).

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FIGURE LEGENDS

Figure 1. Study design

Figure 2. Social harms monitoring structure

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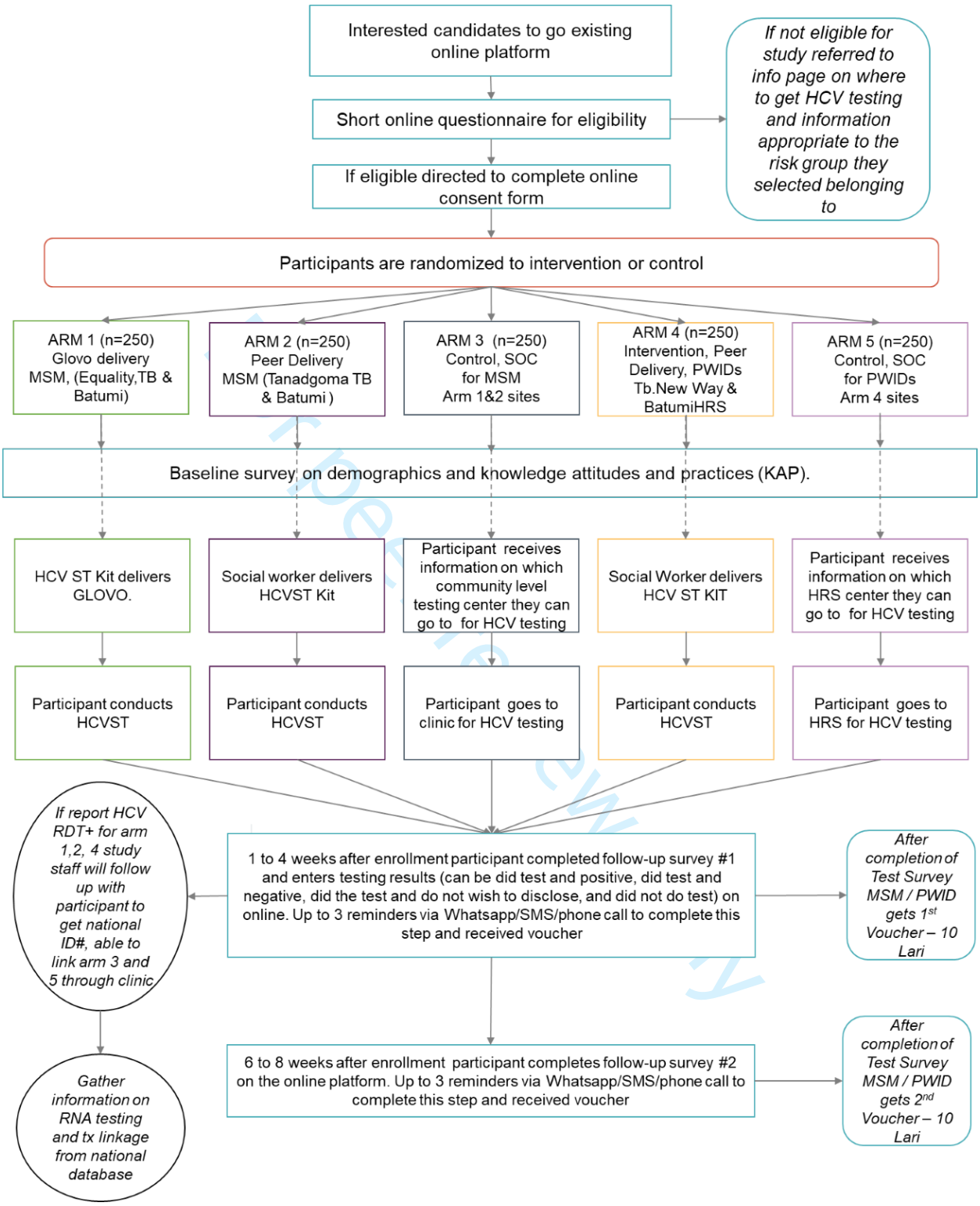
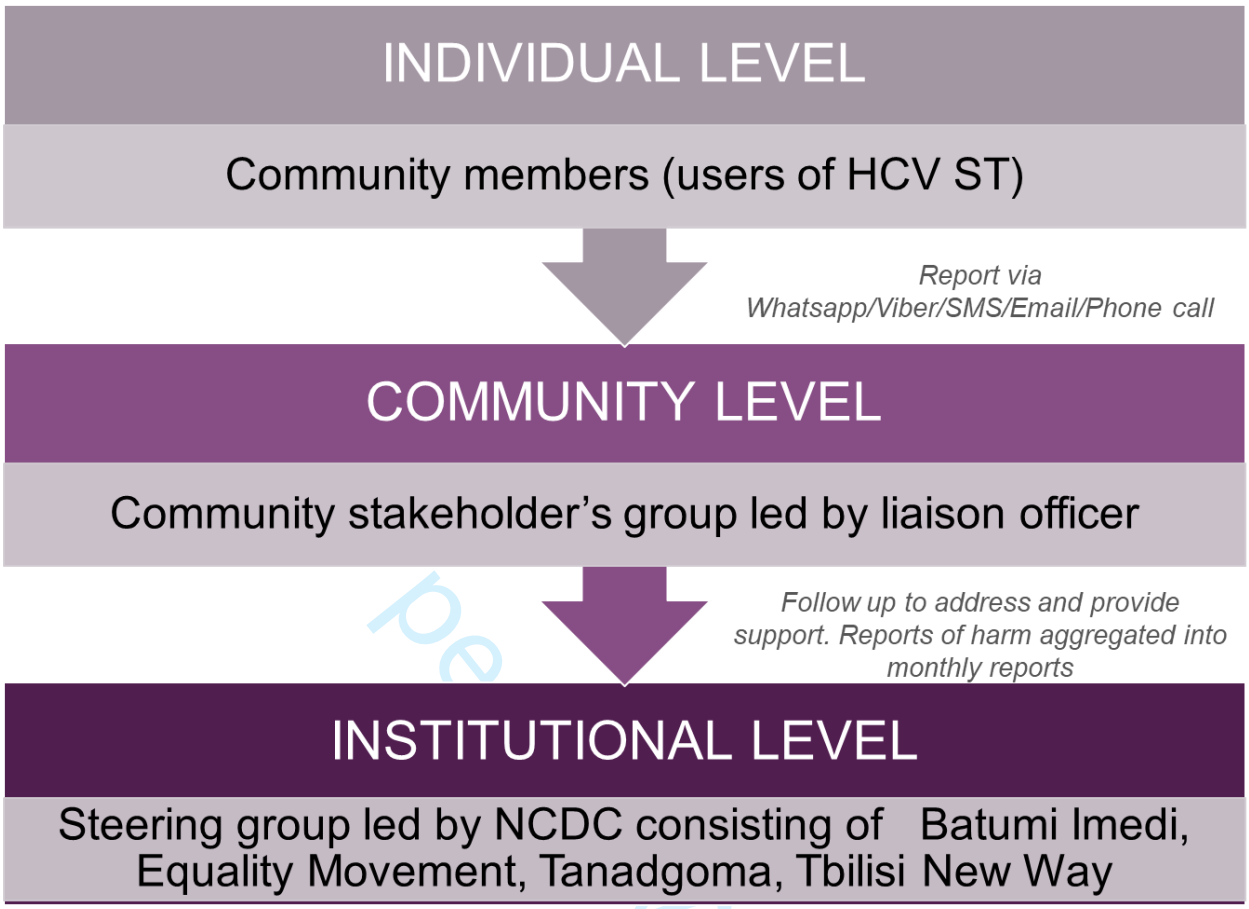


HCV= hepatitis C virus, MSM= men who have sex with men, TB= Tbilisi, SOC= standard of care, PWID= people who inject drugs, HCVST= hepatitis C virus self test, HRS= harm reduction site, RDT+= rapid diagnostics test positive, tx= treatment



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Supplementary Annex 1
Study information form and informed consent form

Hepatitis C Study Information Sheet

Title of Study

Randomized controlled trial of home-based hepatitis C self-testing in key populations in Georgia

Participating Organizations

NCDC, Equality Movement, Tanadgoma, Tbilisi New Way HRS, Batumi Imedi HRS, Foundation for Innovative New Diagnostics

Introduction

Hepatitis C is a liver infection caused by a virus that can lead to serious liver damage, cancer, and even death. You are being invited to take part in this study to help understand different ways people can be tested for hepatitis C.

Purpose

The purpose of this study is to evaluate different models of hepatitis C testing

Study Procedures

If you take part in the study, you will only have to sign the consent form, take two surveys, and consider getting tested for hepatitis C. You will be randomly selected for testing models: a) to either receive a hepatitis C testing kit delivered to your home or b) receive information about how to get tested for hepatitis C at a local clinic or community center.

If you are selected for the hepatitis c self-test it is a simple procedure using oral fluids. If you are selected for the hepatitis C self-test group you will either be placed in the group that gets the hepatitis C self test delivered by Glovo delivery or be placed in the group that will have the test delivered to your house by a peer outreach worker or a social worker

Your information will be reviewed by the study personnel and grouped with all other persons in the study.

Benefits

As a participant in this study, you may learn if you have been exposed to hepatitis C or not and be offered care and treatment if you have hepatitis C.

Risks

There is minimal discomfort with hepatitis C testing. There is a minimal risk that you could encounter social harms from this study.

Framed in the study the observational team is set up to identify any social harm associated with participation in the study and testing. They will give you recommendations and to get the appropriate services as needed.

You can contact the study coordinator for the information how to contact this group *(The phone numbers will be provided by Arms)*

Compensation and Costs

There are no costs to you for participation in this study. All participants will receive a phone credit voucher of 10 GEL for completion of the first follow up questionnaire to enter test result and another phone credit voucher of 10 GEL when the finish the second study survey. You will receive the phone credits to the phone number that you provide on the online platform approximately 7 days after you complete each survey. You will be offered hepatitis C testing but are not required to be tested for hepatitis C to receive compensation.

Confidentiality

All information collected about you during the course of this study will be stored without any personal identifiers. No one will be able to match you to your information. No one will be able to determine your identity in the frame of the study. Only study personnel will have access to the information.

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Voluntary Participation/Study Withdrawal
Taking part in this study is completely voluntary. You are free to withdraw at any time. Whether or not you are part of this study does not in any way affect your medical or preventive care.
Questions
If you have any questions about the study, you may ask the study staff at any time.
The name and phone number of the study personnel of the relevant center will be indicated.

Online informed consent form
Project title: Randomized controlled trial of home-based hepatitis C self-testing in key populations in Georgia
I confirm that I have read and understood the information as provided in the information sheet for the above project and have had the opportunity to ask questions.
I understand that the project team may look at my health records for the current study. I agree to this access. I understand that my identity will not be revealed in any information released to third parties or published. I understand that I may freely withdraw from this project at any time.
I agree to be a part of the above project.

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Supplementary Annex 2

PARTICIPANT FOLLOW-UP SURVEY #1

These forms will be provided to the participants in Georgian language
STUDY ID: ***automatically inputted and date and timestamped by the platform***
SURVEY DATE: ***automatically generated/timestamped by the platform***

INFORMATION TO PARTICIPANTS
This questionnaire will be anonymized before being analyzed and your name will never appear in the database. Your answers will be used to better understand hepatitis C testing in Georgia.

SECTION A – STUDY TESTING AND FOLLOW-UP

A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
1. Yes
2. No

A1ai. *(if answered Yes to question A1, version of question for arm 3 and 5)* What was the result?
1. Positive
2. Negative
3. Don't know, have forgotten
4. Do not want to disclose

A1aii. *(if answered Yes to question A1, version of question for arm 1,2 and 4)* What was the result?
1. Positive
2. Negative
3. Test did not work
4. Don't know, could not read the test
5. Do not want to disclose

A1b. (*If answered No to question A1)* If no, why not?
1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Others, specify: _____

A1c. *(If answered Yes for question A1, for arm 3 and 5 only)* Where did you go to get the hepatitis C test done?
_____ (select from drop down list the name of the facility)
(For participants who live in Tbilisi)
1. Tbilisi Tanadgoma center
2. Tbilisi Equality movement center
3. Tbilisi New Way HRS
4. Tbilisi ID Hospital
5. Neo Lab clinic

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6. Hepa clinic
7. Other: _____

(For participants who live in Batumi)

1. Batumi Tanadgoma center
2. Batumi Equality movement
3. Batumi Imedi HRS
4. Batumi ID hospital
5. Batumi Mary time hospital
6. Other: _____

A1f. *(If answered Negative in question A1aii, for arm 1,2, and 4 only)* If you had tested positive for hepatitis C, what do you think your next steps would have been?

1. To go to a community-based organization for more information and advice
2. To go to a healthcare clinic for a confirmation test
3. To go to a hospital for a confirmation test
4. I would not do next step
5. Don't know
6. Others, specify: _____

A1g. *(If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only)* Have you taken any further step to get a second test done?

1. Yes, have gone to a community-based organization for more information and advice
2. Yes, have gone to a clinic and asked for another test
3. No, I have not made next step
4. Others, specify: _____

A1h. *(If answered No in question A1g)* If you do not made any next step, why not?

1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Transportation was too expensive
6. Others, specify: _____

A2a. (*version of question for arm 3 and 5 group)* Did you ask anyone any question about process of hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, person who performed the test
4. Yes, friend or family member

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5. Yes; others, specify: _____
6. No, I have not asked the question

A2b. (*version of question for arm 1)* Did you ask anyone any question about process of hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, friend or family member
4. Yes; others, specify: _____
5. No, I have not asked the question

A2c. (*version of question for arm 2 and 4)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, by asking the peer deliver who dropped of my test
3. Yes, online through searching the internet
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No, I have not asked the question

A3. *(If answered Yes in question A1)* How would you rate the hepatitis C testing you were offered in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)

	Not very easy		Average		Very easy
How easy was the testing process?	1	2	3	4	5

	Not very convenient		Average		Very convenient
How convenient was the testing process?	1	2	3	4	5

	Not very private		Average		Very private
How private did you think the testing process was?	1	2	3	4	5

	Not very trustworthy		Average		Very trustworthy
How much do you feel you can trust the test results?	1	2	3	4	5

	Not very secure		Average		Very secure
How secure did you feel during the testing process?	1	2	3	4	5

	Not very stressful		Average		Very stressful
How stressful was the testing process?	1	2	3	4	5

	Not very easy		Average		Very easy	
If you needed further care, how easy was it to access it?	1	2	3	4	5	Did not need it

A4. *(If answered Yes in question A1)* Did you feel you could understand the result of your test?

1. Yes
2. No

A4ai. *(If answered Yes in question A4, version of question for arm 1,2 and 4)* What do you think have helped you to understand the result of your test (select all that apply)?

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1. The printed instructions for use that came with the HCV self-test
2. Video instructions on how to perform a self-test
3. Being able to communicate with the selftest.ge team
4. Other; specify: _____

A4aii. *(If answered No in question A4, version of question for arm 1,2 and 4)* Why do you think you were unable to understand the result of your test? Select all that apply

1. The printed instructions for use that came with the HCV self-test were not easy to understand
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand
4. Others; specify: _____

A5. *(If answered Positive, test did not work or Don't know in question A1aii)* Did you feel you knew what steps you needed to take to be further linked to hepatitis C care after you got the result of your test?

1. Yes
2. No

A6. *(If answered No in question A5)* What do you think would have helped you to know what steps you need to take to be further linked to care?

1. A list of clinics near me that provide HCV care with their contact information
2. More information on how community-based organizations near me could help me navigate how to be linked to care
3. A video explaining how I could get linked to care
4. Others; specify:_____

A7. In the future, where would you prefer to be tested for hepatitis C?

1. By myself at home
2. At home with someone I trust
3. By myself at a healthcare clinic
4. In a community centre by community-based organization staff
5. In a healthcare clinic by a healthcare worker
6. In a pharmacy by a healthcare worker
7. No preference
8. Prefer not to get tested for hepatitis C
9. Other, specify:_____

A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and instructions on how to do it?

1. Yes
2. No
3. Don't know

A8a. *(If answered Yes in question A8)* If yes, how often do you think you would test yourself?

1. More than once every 6 months
2. Once every 6 months
3. Once a year

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4. Once every 2 years
5. Don't know
6. Others, specify:_____

A1d. *(If answered Positive in question A1ai or A1aii)* Have you taken further steps for hepatitis C care after your positive test? Please select all that applies

1. Yes, have gone for confirmation test
2. Yes, have had doctor consultation and completed additional testing
3. Yes, have started treatment
4. others, specify: _____
5. No, I do not plan to take further steps

A1e. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* What was the result of your confirmation test?

1. I was confirmed active chronic Hepatitis C (viremia)
2. I do not have active chronic hepatitis C (viremia)
3. Have not been told the results yet
4. Do not want to disclose
5. Others, specify:_____

A1i. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* Where did you go for this further hepatitis C care?

(select from drop down list the name of the facility

(For participants who live in Tbilisi)

1. Tbilisi ID Hospital
2. Neo Lab clinic
3. Hepa clinic
4. Other: _____

(For participants who live in Batumi)

1. Batumi Imedi HRS
2. Batumi ID hospital
3. Batumi Mary time hospital
4. Other: _____

SECTION B – RISK BEHAVIORS

B1. How many times have you or your partner(s) used a condom during sexual contact in the last month?

1. I have not had sexual contact in the last month
2. Always
3. Often
4. Sometimes
5. Never used

B2. In the last month, have you taken any substance by snorting it?

1. Yes

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2. No

B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?

1. Yes
2. No

B4. In the last month, have you injected unprescribed drugs?

1. Once
2. More than once
3. Never

B4a. (*If answered Once or More than once to question B4)* Within the last month, how often did you inject illicit drugs?

1. Once a month
2. Several times a month
3. Once a week
4. 2-3 times a week
5. 4-5 times a week
6. Once a day
7. Several times a day
8. Don't know

B4b. (*If answered Once or More than once to question B4)* In the past month, have you ever used a needle/syringe that was used by somebody else before?

1. Yes
2. No
3. Don't know

B4c. (*If answered Yes to question B4b)* If you have used a needle/syringe that was used by somebody else before in the past month, how many people share it with you?

1. __ (fill in the number of people you shared with)
2. Don't know

SECTION C – Help us to make HCV testing accessible to everyone who needs it, your opinion counts!

Please let us know how we can improve HCV testing and care services - your feedback will help to guide how these services can best serve to Georgia population.

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Supplementary annex 3:

PARTICIPANT FOLLOW-UP SURVEY #2

STUDY ID: ***automatically linked and date and timestamped by the platform***
SURVEY DATE: ***automatically generated/timestamped by the platform***

INFORMATION TO PARTICIPANTS
This questionnaire will be anonymized before being analyzed and your name will never appear in the database. Your answers will be used to better understand hepatitis C testing in Georgia.

SECTION A – STUDY TESTING AND FOLLOW-UP

A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
1. Yes
2. No

A1ai. *(if answered Yes to question A1, version of question for arm 3 and 5)* What was the result?
1. Positive
2. Negative
3. Don't know, have forgotten
4. Do not want to disclose

A1aii. *(if answered Yes to question A1, version of question for arm 1,2 and 4)* What was the result?
1. Positive
2. Negative
3. Test did not work
4. Don't know
5. Do not want to disclose

A1b. (*If answered No to question A1)* If no, why not?
1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Others, specify: _____

A1c. *(If answered Yes for question A1 for arm 3 and 5 only)* Where did you go to get the hepatitis C test done?

_____ (select from drop down list the name of the facility)

(For participants who live in Tbilisi)
1. Tbilisi Tanadgoma center
2. Tbilisi Equality movement center
3. Tbilisi New Way HRS
4. Tbilisi ID Hospital
5. Neo Lab clinic
6. Hepa clinic

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7. Other: _____

(For participants who live in Batumi)

1. Batumi Tanadgoma center
2. Batumi Equality movement
3. Batumi Imedi HRS
4. Batumi ID hospital
5. Batumi Mary time hospital
6. Other: _____

A1f. *(If answered Negative in question A1aii, for arm 1,2, and 4 only)* If you had tested positive for hepatitis C, what do you think your next steps would have been?

1. To go to a community-based organization for more information and advice
2. To go to a policlinic for a confirmation test
3. To go to a healthcare clinic for a confirmation test
4. I would not do next step
5. Don't know
6. Others, specify: _____

A1g. *(If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only)* Have you taken any further step to get a second test done?

1. Yes, have gone to a community-based organization for more information and advice
2. Yes, have gone to a clinic and asked for another test
3. No, I have not made next step
4. Others, specify: _____

A1h. *(If answered No in question A1g)* If no, why not?

1. Did not want to test/was not interested
2. Forgot to get tested
3. Afraid of testing
4. Did not have time
5. Test was too expensive
6. Others, specify: _____

A2a. (*version of question for arm 3 and 5 group)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, person who performed the test
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No

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A2b. (*version of question for arm 1)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, online through searching the internet
3. Yes, friend or family member
4. Yes; others, specify: _____
5. No

A2c. (*version of question for arm 2 and 4)* Did you ask anyone any question about hepatitis C testing?

1. Yes, online through the support offered on selftest.ge platform
2. Yes, by asking the peer deliver who dropped of my test
3. Yes, online through searching the internet
4. Yes, friend or family member
5. Yes; others, specify: _____
6. No

A3. *(If answered Yes in question A1)* How would you rate the hepatitis C testing you were offered in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)

	Not very easy		Average		Very easy
How easy was the testing process?	1	2	3	4	5

	Not very convenient		Average		Very convenient
How convenient was the testing process?	1	2	3	4	5

	Not very private		Average		Very private
How private did you think the testing process was?	1	2	3	4	5

	Not very trustworthy		Average		Very trustworthy
How much do you feel you can trust the test results?	1	2	3	4	5

	Not very secure		Average		Very secure
How secure did you feel during the testing process?	1	2	3	4	5

	Not very stressful		Average		Very stressful
How stressful was the testing process?	1	2	3	4	5

	Not very easy		Average		Very easy	
If you needed further care, how easy was it to access it?	1	2	3	4	5	Did not need it

A4. *(If answered Yes in question A1)* Did you feel you could understand the result of your test?

1. Yes
2. No
3. I do not know

A4ai. *(If answered Yes in question A4, version of question for arm 1,2 and 4)* What do you think have helped you to understand the result of your test (select all that apply)?

1. The printed instructions for use that came with the HCV self-test
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand

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4. Being able to communicate with the selftest.ge team
5. Other; specify: _____

A4aii. *(If answered No in question A4, version of question for arm 1,2 and 4)* Why do you think you were unable to understand the result of your test? Select all that apply

1. The printed instructions for use that came with the HCV self-test were not easy to understand
2. Video instructions on how to perform a self-test was not easy to understand
3. Communication with the selftest.ge team were not easy to understand
4. Others; specify: _____

A5. *(If answered Positive, Invalid or Don't know in question A1aii)* Did you feel you knew what steps you needed to take to be further linked to hepatitis C care after you got the result of your test?

1. Yes
2. No

A6. *(If answered No in question A5)* What do you think would have helped you to know what steps you need to take to be further linked to care?

1. A list of clinics near me that provide HCV care with their contact information
2. More information on how community-based organizations near me could help me navigate how to be linked to care
3. A video explaining how I could get linked to care
4. Others; specify:_____

A7. In the future, where would you prefer to be tested for hepatitis C?

1. By myself at home
2. At home with someone I trust
3. By myself at a healthcare clinic
4. In a community centre by community-based organization staff
5. In a healthcare clinic by a healthcare worker
6. In a pharmacy by a healthcare worker
7. No preference
8. Prefer not to get tested for hepatitis C
9. Other; specify: _____

A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and instructions on how to do it?

4. Yes
5. No
6. Don't know

A8a. *(If answered Yes in question A8)* If yes, how often do you think you would test yourself?

1. More than once every 6 months
2. Once every 6 months
3. Once a year
4. Once every 2 years
5. Don't know

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6. Others, specify:_____

A1d. *(If answered Yes to question A1, Positive in question A1a and No in question A1d in Follow-up survey #1, this will be the first question for them in this Follow-up survey #2. After questions A1d and A1e have been answered by this group in Follow-up survey #2, they will proceed to section B. This question is also for those who answered Positive in question A1a in Follow-up survey #2; for this group, they will proceed through the rest of section A following skip patterns based on their answers)* Have you taken further steps for hepatitis C care after your positive test?

Please select all that applies

1. Yes, have gone for confirmation test
2. Yes, have had doctor consultation and completed additional testing
3. Yes, have started treatment
4. Others, specify: _____
5. No, I do not plan to take further steps

A1e. *(If answered Yes, have gone for confirmation test or Yes,* , have had doctor consultation and completed additional testing *and have started treatment in question A1d)* What was the result of your confirmation test?

1. I have hepatitis C viremia
2. I do not have hepatitis C viremia
3. Have not been told the results yet
4. Others, specify: _____

A1i. *(If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d)* Where did you go for this further hepatitis C care?

(select from drop down list the name of the facility

(For participants who live in Tbilisi)

1. Tbilisi ID Hospital
2. Neo Lab clinic
3. Hepa clinic
4. Other: _____

(For participants who live in Batumi)

1. Batumi Imedi HRS
2. Batumi ID hospital
3. Batumi Mary time hospital
4. Other: _____

SECTION B – RISK BEHAVIORS

B1. How many times have you or your partner(s) used a condom during sexual contact in the last month?

1. I have not had sexual contact in the last month
2. Always
3. Often
4. Sometimes
5. Never used

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B2. In the last month, have you taken any substance by snorting it?

1. Yes
2. No

B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?

1. Yes
2. No

B4. In the last month, have you injected unprescribed drugs?

1. Once
2. More than once
3. Never

B4a. (*If answered Once or More than once to question B4)* Within the last month, how often did you inject drugs?

1. Once a month
2. Several times a month
3. Once a week
4. 2-3 times a week
5. 4-5 times a week
6. Once a day
7. Several times a day
8. Don't know

B4b. (*If answered Once or More than once to question B4)* In the past month, have you ever used a needle/syringe that was used by somebody else before?

1. Yes
2. No
3. Don't know

B4c. (*If answered Yes to question B4b)* If you have used a needle/syringe that was used by somebody else before in the past month, how many people share it with you?

1. __ (fill in the number of people you shared with)
2. Don't know

SECTION C – Help us to make HCV testing accessible to everyone who needs it, your opinion counts!

Please let us know how we can improve HCV testing and care services - your feedback will help to guide how these services can best serve the people in Malaysia:

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