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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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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

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Word count: 3390 (max. 4000)

### 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 groups 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

### 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.

### INTRODUCTION

The World Health Organization (WHO) estimates that 58 million people globally have chronic hepatitis C virus (HCV) infection.<sup>1</sup> 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.<sup>1</sup> 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 for HIV, as well as specific studies on HCVST performance, usability, acceptability and user values and preferences.<sup>2-6</sup>OMA 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 ,<sup>7</sup> with the burden of infection largely within the PWID population (numbering over 52,250 in 2017).<sup>89</sup> Prior to the implementation of a national elimination programme in 2015,<sup>78</sup> the seroprevalence in PWIDs in Georgia ranged from 50– 92%, depending on region.<sup>10-13</sup> The programme has been successful in identifying and linking people with HCV to care,<sup>8</sup> 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.<sup>14</sup> Here we describe the protocol of an randomized controlled trial (Georgian IRB Ethics Approval Number: IRB# 2021-049, clinicaltrials.gov: <u>NCT04961723</u>) 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 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 I 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.

### **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<sup>®</sup> 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 th
	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 t 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.

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.<sup>15</sup> 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. 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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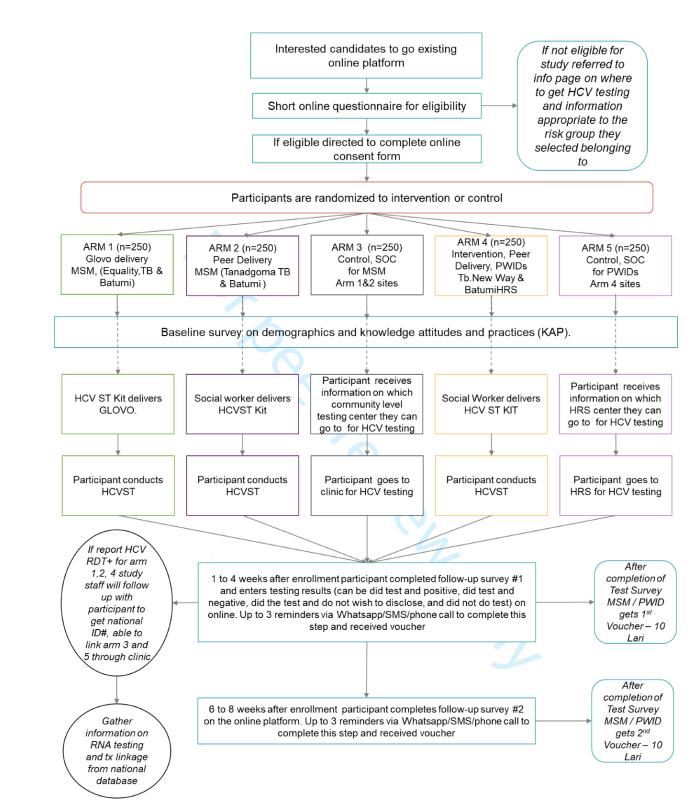
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Figure 1. Study design

### Figure 2. Social harms monitoring structure



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

2	
3 4 5 6	INDIVIDUAL LEVEL
7 8 9	Community members (users of HCV ST)
10 11 12 13	Report via Whatsapp/Viber/SMS/Email/Phone call
14 15 16	COMMUNITY LEVEL
17 18 19 20	Community stakeholder's group led by liaison officer
21 22 23	Follow up to address and provide support. Reports of harm aggregated into monthly reports
24 25 26 27	INSTITUTIONAL LEVEL
28 29 30 31	Steering group led by NCDC consisting of Batumi Imedi, Equality Movement, Tanadgoma, Tbilisi New Way
32 33 34	
35 36 37 38	
39 40 41	
40 41 42 43 44	
40 41 42 43 44 45 46 47 48	
40 41 42 43 44 45 46 47 48 49 50 51	
40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55	
40 41 42 43 44 45 46 47 48 49 50 51 52 53 54	

## 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.

### 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.

**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

1	
2	
3 4	6. Hepa clinic
5	7. Other:
6	
7	(For participants who live in Batumi)
8	
9	1. Batumi Tanadgoma center
10 11	2. Batumi Equality movement
12	3. Batumi Imedi HRS
13	4. Batumi ID hospital
14	5. Batumi Mary time hospital
15	6. Other:
16	
17 18	
19	
20	A1f. (If answered Negative in question A1aii, for arm 1,2, and 4 only) If you had tested positive
21	for hepatitis C, what do you think your next steps would have been?
22	1. To go to a community-based organization for more information and
23	advice
24 25	2. To go to a healthcare clinic for a confirmation test
25	<ol><li>To go to a hospital for a confirmation test</li></ol>
27	4. I would not do next step
28	5. Don't know
29	6. Others, specify:
30	A1g. (If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only) Have
31 32	you taken any further step to get a second test done?
33	1. Yes, have gone to a community-based organization for more
34	information and advice
35	<ol><li>Yes, have gone to a clinic and asked for another test</li></ol>
36	3. No, I have not made next step
37	4. Others, specify:
38 39	Adda (15 and and 10 in succession Adda) If you do not see the angula term when a 10
40	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
41	<ol> <li>Did not want to test/was not interested</li> <li>Forgot to get tested</li> </ol>
42	3. Afraid of testing
43	4. Did not have time
44	5. Transportation was too expensive
45 46	6. Others, specify:
47	
48	
49	
50	A2a (version of question for arm 2 and 5 group) Did you ack anyong any question about process
51	A2a. ( <i>version of question for arm 3 and 5 group</i> ) Did you ask anyone any question about process of hepatitis C testing?
52 53	1. Yes, online through the support offered on selftest.ge platform
54	2. Yes, online through searching the internet
55	3. Yes, person who performed the test
56	4. Yes, friend or family member
57	
58 59	4
60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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? 122 3 4 5
Not very trustworthy Average Very trustworthy How much do you feel you can trust the test results?
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)?

2	
3	1. The printed instructions for use that came with the HCV self-test
4	<ol> <li>Video instructions on how to perform a self-test</li> </ol>
5	
6	3. Being able to communicate with the selftest.ge team
7	4. Other; specify:
8	A4aii. (If answered No in question A4, version of question for arm 1,2 and 4) Why do you think
9	you were unable to understand the result of your test? Select all that apply
10	
11	1. The printed instructions for use that came with the HCV self-test
12	were not easy to understand
13	2. Video instructions on how to perform a self-test was not easy to
14	understand
15	3. Communication with the selftest.ge team were not easy to
	understand
16	
17	4. Others; specify:
18	
19	A5. (If answered Positive, test did not work or Don't know in question A1aii) Did you feel you
20	knew what steps you needed to take to be further linked to hepatitis C care after you got the
21	result of your test?
22	
23	1. Yes
24	2. No
25	A6. (If answered No in question A5) What do you think would have helped you to know what
26	steps you need to take to be further linked to care?
27	1. A list of clinics near me that provide HCV care with their contact
28	
29	information
30	2. More information on how community-based organizations near me
31	could help me navigate how to be linked to care
32	<ol> <li>A video explaining how I could get linked to care</li> </ol>
33	4. Others; specify:
34	
	AZ In the future, where would you prefer to be tested for benetitie C2
35	A7. In the future, where would you prefer to be tested for hepatitis C?
36	1. By myself at home
37	2. At home with someone I trust
38	3. By myself at a healthcare clinic
39	4. In a community centre by community-based organization staff
40	5. In a healthcare clinic by a healthcare worker
41	
42	
43	7. No preference
	<ol> <li>Prefer not to get tested for hepatitis C</li> </ol>
44	9. Other, specify:
45	
46	A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and
47	instructions on how to do it?
48	
49	1. Yes
50	2. No
51	3. Don't know
52	
53	A8a. (If answered Yes in question A8) If yes, how often do you think you would test yourself?
54	1. More than once every 6 months
55	2. Once every 6 months
56	3. Once a year
57	
58	6
59	
60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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2	
3	4. Once every 2 years
4	5. Don't know
5	6. Others, specify:
6	· · · · · · · · · · · · · · · · · · ·
7	A1d. (If answered Positive in question A1ai or A1aii) Have you taken further steps for hepatitis
8 9	C care after your positive test? Please select all that applies
9 10	1. Yes, have gone for confirmation test
10	2. Yes, have had doctor consultation and completed additional
12	testing
13	<ol><li>Yes, have started treatment</li></ol>
14	4. others, specify:
15	5. No, I do not plan to take further steps
16	
17	A1e. (If answered Yes, have gone for confirmation test or Yes, have completed further testing
18	and have started treatment in question A1d) What was the result of your confirmation test?
19	1. I was confirmed active chronic Hepatitis C (viremia)
20	2. I do not have active chronic hepatitis C (viremia)
21 22	3. Have not been told the results yet
22	4. Do not want to disclose
24	5. Others, specify:
25	Ati (If anoward Vac have going for confirmation test or Vac have completed further
26	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
27	care?
28	(select from drop down list the name of the facility
29	(Select normalop down instance of the idenity
30 21	(For participants who live in Tbilisi)
31 32	1. Tbilisi ID Hospital
33	2. Neo Lab clinic
34	3. Hepa clinic
35	4. Other:
36	
37	(For participants who live in Batumi)
38	1. Batumi Imedi HRS
39	2. Batumi ID hospital
40 41	3. Batumi Mary time hospital
41	4. Other:
43	
44	SECTION B – RISK BEHAVIORS
45	SECTION B - RISK BEHAVIORS
46	B1. How many times have you or your partner(s) used a condom during sexual contact in the last
47	month?
48	1. I have not had sexual contact in the last month
49	2. Always
50	3. Often
51 52	4. Sometimes
53	5. Never used
54	
55	B2. In the last month, have you taken any substance by snorting it?
56	1. Yes
57	
58	7
59	For near review only - http://bmionen.hmi.com/site/about/quidelines.yhtml
<u> </u>	FOI DEEL ΓΕΥΓΕΜ ΟΠΙΧ - ΠΤΠ'//ΠΜΙΟΠΕΡ ΠΜΙ COM/SITE/3ΠΟΙΤ/ΟΙΙΙΟΔΙΙΝΔς ΥΝΤΜΙ

1	
2	
3	2. No
4	
5	B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?
6	
7	1. Yes
8	2. No
9	
10	B4. In the last month, have you injected unprescribed drugs?
11	1. Once
12	2. More than once
13	3. Never
14	
14	B4a. (If answered Once or More than once to question B4) Within the last month, how often did
16	you inject illicit drugs?
17	1. Once a month
18	2. Several times a month
19	3. Once a week
20	4. 2-3 times a week
21	5. 4-5 times a week
22	6. Once a day
23	7. Several times a day
24	8. Don't know
25	
26	B4b. (If answered Once or More than once to question B4) In the past month, have you ever
27	
28	used a needle/syringe that was used by somebody else before?
29	1. Yes
30	2. No
31	3. Don't know
32	
33	B4c. (If answered Yes to question B4b) If you have used a needle/syringe that was used by
34	somebody else before in the past month, how many people share it with you?
35	1 (fill in the number of people you shared with)
36	2. Don't know
37	Z. DOITTRIOW
38	
39	
40	
41	SECTION C – Help us to make HCV testing accessible to everyone who needs it, your
42	opinion counts!
43	
44	Please let us know how we can improve HCV testing and care services - your feedback will help
45	to guide how these services can best serve to Georgia population.
46	
40	
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58	8

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

1	
1	
2	
3	7. Other:
4	
5	
6	
7	(For participants who live in Batumi)
8	
	1. Batumi Tanadgoma center
9	2. Batumi Equality movement
10	3. Batumi Imedi HRS
11	4. Batumi ID hospital
12	
13	5. Batumi Mary time hospital
14	6. Other:
15	
16	
17	A1f. (If answered Negative in question A1aii, for arm 1,2, and 4 only) If you had tested positive
18	for hepatitis C, what do you think your next steps would have been?
19	
	1. To go to a community-based organization for more information and
20	advice
21	<ol><li>To go to a policlinic for a confirmation test</li></ol>
22	<ol> <li>To go to a healthcare clinic for a confirmation test</li> </ol>
23	4. I would not do next step
24	5. Don't know
25	
26	6. Others, specify:
27	
28	
29	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?
30	1. Yes, have gone to a community-based organization for more
31	information and advice
32	
33	2. Yes, have gone to a clinic and asked for another test
34	<ol><li>No, I have not made next step</li></ol>
35	4. Others, specify:
36	
37	A1h. (If answered No in question A1g) If no, why not?
38	1. Did not want to test/was not interested
39	
	2. Forgot to get tested
40	3. Afraid of testing
41	4. Did not have time
42	5. Test was too expensive
43	6. Others, specify:
44	······································
45	
46	
47	
48	A2a. (version of question for arm 3 and 5 group) Did you ask anyone
49	any question about hepatitis C testing?
	1. Yes, online through the support offered on selftest.ge platform
50	2. Yes, online through searching the internet
51	
52	
53	4. Yes, friend or family member
54	5. Yes; others, specify:
55	6. No
56	
57	
58	10
59	
60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

	<ul> <li>question for arm 1) Did you ask anyone any question about hepatitis C testir</li> <li>1. Yes, online through the support offered on selftest.ge platform</li> </ul>
	2. Yes, online through searching the internet
	3. Yes, friend or family member
	<ol> <li>Yes; others, specify:</li> <li>No</li> </ol>
A2c. (version of	question for arm 2 and 4) Did you ask anyone any question about hepa
C testing?	
Ū	1. Yes, online through the support offered on selftest.ge platform
	2. Yes, by asking the peer deliver who dropped of my test
	<ol> <li>Yes, online through searching the internet</li> <li>Yes, friend or family member</li> </ol>
	5. Yes; others, specify:
	6. No
	Yes in question A1) How would you rate the hepatitis C testing you were offe owing categories? Please rate 5 point scale from 1 (weakest) to 5 (stronge
in each or the roll	owing categories? Please rate 5 point scale from 1 (weakest) to 5 (stronges
	Not very easy Average Very easy
How easy was the	e testing process? 1 2 3 4 5
	nient Average Very convenient
How convenient v	was the testing process? 1 2 3 4 5
<b>.</b>	
Not yory privato	
Not very private How private did v	
	Average Very private ou think the testing process was? 1 2 3 4 5
How private did y	
How private did y Not very trustwo	ou think the testing process was? 1 2 3 4 5
How private did y Not very trustwo How much do you	ou think the testing process was?12345rthyAverageVery trustworthy u feel you can trust the test results?12345
How private did y Not very trustwo How much do you Not very secure	ou think the testing process was?12345rthyAverageVery trustworthy u feel you can trust the test results?12345AverageVery secureVery secure12345
How private did y Not very trustwo How much do you Not very secure	ou think the testing process was?12345rthyAverageVery trustworthy u feel you can trust the test results?12345
How private did y Not very trustwo How much do you Not very secure How secure did y	ou think the testing process was?       1       2       3       4       5         rthy       Average       Very trustworthy       1       2       3       4       5         a feel you can trust the test results?       1       2       3       4       5         Average       Very secure       1       2       3       4       5         ou feel during the testing process?       1       2       3       4       5
How private did y Not very trustwo How much do you Not very secure How secure did y Not very stressfu	ou think the testing process was?       1       2       3       4       5         rthy       Average       Very trustworthy       1       2       3       4       5         a feel you can trust the test results?       1       2       3       4       5         Average       Very secure       1       2       3       4       5         ou feel during the testing process?       1       2       3       4       5
How private did y Not very trustwo How much do you Not very secure How secure did y Not very stressfu	ou think the testing process was?       1       2       3       4       5         rthy       Average       Very trustworthy       1       2       3       4       5         a feel you can trust the test results?       1       2       3       4       5         Average       Very secure       1       2       3       4       5         ou feel during the testing process?       1       2       3       4       5         Il       Average       Very stressful       1       2       3       4       5
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy	ou think the testing process was?       1       2       3       4       5         rthy       Average       Very trustworthy       1       2       3       4       5         a feel you can trust the test results?       1       2       3       4       5         Average       Very secure       1       2       3       4       5         ou feel during the testing process?       1       2       3       4       5         al       Average       Very stressful       5       5       5         s the testing process?       1       2       3       4       5
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth	ou think the testing process was?       1       2       3       4       5         rthy       Average       Very trustworthy       1       2       3       4       5         Average       Very secure       1       2       3       4       5         Average       Very secure       1       2       3       4       5         ou feel during the testing process?       1       2       3       4       5         at Average       Very stressful       5       5       5       5         at Average       Very easy       1       2       3       4       5         er care, how easy was it to access it?       1       2       3       4       5
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth	ou think the testing process was?       1       2       3       4       5         rthy       Average       Very trustworthy       1       2       3       4       5         Average       Very secure       1       2       3       4       5         Average       Very secure       1       2       3       4       5         ou feel during the testing process?       1       2       3       4       5         al       Average       Very stressful       5       5       5         al       Average       Very easy       4       5         er care, how easy was it to access it?       1       2       3       4       5         Yes in question A1)       Did you feel you could understand the result of your test       5       5       5
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth	ou think the testing process was?       1       2       3       4       5         rthy       Average       Very trustworthy       1       2       3       4       5         Average       Very secure       1       2       3       4       5         Average       Very secure       1       2       3       4       5         ou feel during the testing process?       1       2       3       4       5         at Average       Very stressful       5       5       5       5         at Average       Very easy       1       2       3       4       5         er care, how easy was it to access it?       1       2       3       4       5
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth	ou think the testing process was?       1       2       3       4       5         rthy       Average       Very trustworthy       1       2       3       4       5         Average       Very secure       1       2       3       4       5         Average       Very secure       1       2       3       4       5         ou feel during the testing process?       1       2       3       4       5         al       Average       Very stressful       5       5       5         al       Average       Very easy       5       5       5         er care, how easy was it to access it?       1       2       3       4       5         Yes in question A1)       Did you feel you could understand the result of your tes       1.       Yes
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth	ou think the testing process was? 1 2 3 4 5 Thy Average Very trustworthy a feel you can trust the test results? 1 2 3 4 5 Average Very secure tou feel during the testing process? 1 2 3 4 5 Average Very stressful s the testing process? 1 2 3 4 5 Average Very easy er care, how easy was it to access it? 1 2 345 Did not need it Yes in question A1) Did you feel you could understand the result of your tes 1. Yes 2. No
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth A4. <i>(If answered</i>	<pre>ou think the testing process was? 1 2 3 4 5 rthy Average Very trustworthy u feel you can trust the test results? 1 2 3 4 5 Average Very secure ou feel during the testing process? 1 2 3 4 5 If Average Very stressful s the testing process? 1 2 3 4 5 Average Very easy er care, how easy was it to access it? 1 2 345 Did not need it Yes in question A1) Did you feel you could understand the result of your tes 1. Yes 2. No 3. I do not know ed Yes in question A4, version of question for arm 1,2 and 4) What do you the </pre>
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth A4. <i>(If answered</i>	<pre>ou think the testing process was? 1 2 3 4 5 thy Average Very trustworthy u feel you can trust the test results? 1 2 3 4 5 Average Very secure ou feel during the testing process? 1 2 3 4 5 th Average Very stressful s the testing process? 1 2 3 4 5 Average Very easy er care, how easy was it to access it? 1 2 3 4 5 th Yes in question A1) Did you feel you could understand the result of your test 1. Yes 2. No 3. I do not know ed Yes in question A4, version of question for arm 1,2 and 4) What do you th to understand the result of your test (select all that apply)?</pre>
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth A4. <i>(If answered</i>	<pre>ou think the testing process was? 1 2 3 4 5 thy Average Very trustworthy u feel you can trust the test results? 1 2 3 4 5 Average Very secure ou feel during the testing process? 1 2 3 4 5 If Average Very stressful s the testing process? 1 2 3 4 5 Average Very easy er care, how easy was it to access it? 1 2 3 4 5 If Yes in question A1) Did you feel you could understand the result of your test 1. Yes 2. No 3. I do not know ed Yes in question A4, version of question for arm 1,2 and 4) What do you th to understand the result of your test (select all that apply)? 1. The printed instructions for use that came with the HCV self-test </pre>
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressful How stressful was Not very easy If you needed furth A4. <i>(If answered</i>	ou think the testing process was? 1 2 3 4 5 thy Average Very trustworthy a feel you can trust the test results? 1 2 3 4 5 Average Very secure ou feel during the testing process? 1 2 3 4 5 at Average Very stressful is the testing process? 1 2 3 4 5 Average Very easy er care, how easy was it to access it? 1 2 345 Did not need it Yes in question A1) Did you feel you could understand the result of your tess 1. Yes 2. No 3. I do not know at Yes in question A4, version of question for arm 1,2 and 4) What do you the to understand the result of your test (select all that apply)? 1. The printed instructions for use that came with the HCV self-tess 2. Video instructions on how to perform a self-test was not easy
How private did y Not very trustwor How much do you Not very secure How secure did y Not very stressfu How stressful was Not very easy If you needed furth A4. ( <i>If answered</i>	<pre>ou think the testing process was? 1 2 3 4 5 thy Average Very trustworthy u feel you can trust the test results? 1 2 3 4 5 Average Very secure ou feel during the testing process? 1 2 3 4 5 If Average Very stressful s the testing process? 1 2 3 4 5 Average Very easy er care, how easy was it to access it? 1 2 3 4 5 If Yes in question A1) Did you feel you could understand the result of your test 1. Yes 2. No 3. I do not know ed Yes in question A4, version of question for arm 1,2 and 4) What do you th to understand the result of your test (select all that apply)? 1. The printed instructions for use that came with the HCV self-test </pre>

1	
2 3	
4	<ol> <li>Being able to communicate with the selftest.ge team</li> <li>Other; specify:</li> </ol>
5	5. Other; specify:
6	A4aii. (If answered No in question A4, version of question for arm 1,2 and 4) Why do you think
7	you were unable to understand the result of your test? Select all that apply
8 9	1. The printed instructions for use that came with the HCV self-test
10	were not easy to understand
11	2. Video instructions on how to perform a self-test was not easy to
12	understand
13	3. Communication with the selftest.ge team were not easy to
14	understand 4. Others; specify:
15 16	4. Others, specify
17	A5. (If answered Positive, Invalid or Don't know in guestion A1aii) Did you feel you knew what
18	steps you needed to take to be further linked to hepatitis C care after you got the result of your
19	test?
20	1. Yes
21	2. No
22 23	AQ /// an answer of Alls in an and in ACIVA// at the answer thick are added to be a descent to be an and at
24	A6. (If answered No in question A5) What do you think would have helped you to know what
25	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
26	information
27	2. More information on how community-based organizations near me
28 29	could help me navigate how to be linked to care
30	3. A video explaining how I could get linked to care
31	4. Others; specify:
32	
33	A7. In the future, where would you prefer to be tested for hepatitis C?
34	<ol> <li>By myself at home</li> <li>At home with someone I trust</li> </ol>
35 36	3. By myself at a healthcare clinic
37	4. In a community centre by community-based organization staff
38	5. In a healthcare clinic by a healthcare worker
39	6. In a pharmacy by a healthcare worker
40	7. No preference
41 42	8. Prefer not to get tested for hepatitis C
42	9. Other; specify:
44	A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and
45	instructions on how to do it?
46	4. Yes
47	5. No
48 49	6. Don't know
50	
51	A8a. (If answered Yes in question A8) If yes, how often do you think you would test yourself?
52	1. More than once every 6 months
53	<ol> <li>Once every 6 months</li> <li>Once a year</li> </ol>
54 55	4. Once every 2 years
56	5. Don't know
57	
58	12
59	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
60	Tor peer review only intep.//binjopen.binj.com/site/about/guidelines.xittini

6. Others, specify:\_\_\_\_\_

A1d. (If answered Yes to question A1, Positive in question A1a and No in question A1d in Followup 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

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- 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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3	
4	B2. In the last month, have you taken any substance by snorting it?
5	1. Yes
6	
7	2. No
8	
9	B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?
10	1. Yes
11	2. No
12	
13	B4. In the last month, have you injected unprescribed drugs?
14	1. Once
15	2. More than once
16	3. Never
17	J. INEVEL
	DAT (If any set of the set of the set of the DAMER's the last much have the set of the s
18	B4a. (If answered Once or More than once to question B4) Within the last month, how often did
19	you inject drugs?
20	1. Once a month
21	2. Several times a month
22	3. Once a week
23	4. 2-3 times a week
24	5. 4-5 times a week
25	6. Once a day
26	7. Several times a day
27	8. Don't know
28	0. Bon ( Know
29	B4b. (If answered Once or More than once to question B4) In the past month, have you ever
30	
31	used a needle/syringe that was used by somebody else before?
32	1. Yes
33	2. No
34	3. Don't know
35	
36	B4c. (If answered Yes to question B4b) If you have used a needle/syringe that was used by
37	somebody else before in the past month, how many people share it with you?
38	
39	1 (fill in the number of people you shared with)
40	2. Don't know
41	Z. Don't know
42	
43	SECTION C – Help us to make HCV testing accessible to everyone who needs it, your
44	
45	opinion counts!
46	
47	Please let us know how we can improve HCV testing and care services - your feedback will help
48	to guide how these services can best serve the people in Malaysia:
49	
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58	14

# 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
- <u>#1</u> Descriptive title identifying the study design, 1
   population, interventions, and, if applicable, trial
   acronym

# Page 35 of 44

BMJ Open

1 2	Trial registration	<u>#2a</u>	Trial identifier and registry name. If not yet	2
3 4 5			registered, name of intended registry	
6 7	Trial registration:	<u>#2b</u>	All items from the World Health Organization Trial	2
8 9 10 11	data set		Registration Data Set	
12 13 14	Protocol version	<u>#3</u>	Date and version identifier	2
15 16	Funding	<u>#4</u>	Sources and types of financial, material, and other	13
17 18			support	
19 20 21	Roles and	<u>#5a</u>	Names, affiliations, and roles of protocol	13
22 23	responsibilities:		contributors	
24 25 26	contributorship			
27 28 29	Roles and	<u>#5b</u>	Name and contact information for the trial sponsor	1
30 31	responsibilities:			
32 33	sponsor contact			
34 35 36 37	information			
38 39	Roles and	<u>#5c</u>	Role of study sponsor and funders, if any, in study	10
40 41	responsibilities:		design; collection, management, analysis, and	
42 43	sponsor and funder		interpretation of data; writing of the report; and the	
44 45 46			decision to submit the report for publication,	
47 48			including whether they will have ultimate authority	
49 50 51			over any of these activities	
52 53	Roles and	<u>#5d</u>	Composition, roles, and responsibilities of the	10 and 11
54 55	responsibilities:		coordinating centre, steering committee, endpoint	
56 57 58	committees		adjudication committee, data management team,	
59 60	F	or peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

			and other individuals or groups overseeing the trial,	
1 2				
3 4			if applicable (see Item 21a for data monitoring	
5 6			committee)	
7 8 9 10	Introduction			
10 11 12	Background and	<u>#6a</u>	Description of research question and justification for	4
13 14	rationale		undertaking the trial, including summary of relevant	
15 16			studies (published and unpublished) examining	
17 18 19			benefits and harms for each intervention	
20 21 22	Background and	<u>#6b</u>	Explanation for choice of comparators	5
22 23 24	rationale: choice of			
25 26	comparators			
27 28				
29 30	Objectives	<u>#7</u>	Specific objectives or hypotheses	7 and 8
31 32 33	Trial design	<u>#8</u>	Description of trial design including type of trial (eg,	4 and 7
33 34 35			parallel group, crossover, factorial, single group),	
36 37			allocation ratio, and framework (eg, superiority,	
38 39			equivalence, non-inferiority, exploratory)	
40 41	Mathaday			
42 43	Methods:			
44 45	Participants,			
46 47	interventions, and			
48 49 50	outcomes			
51 52	Study setting	<u>#9</u>	Description of study settings (eg, community clinic,	4 and 5
53 54 55			academic hospital) and list of countries where data	
56 57				
58 59		For peer ro	eview only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	
60			wew only integrating openion from site about guidelines. And in	

1 2			will be collected. Reference to where list of study	
3 4			sites can be obtained	
5 6 7	Eligibility criteria	<u>#10</u>	Inclusion and exclusion criteria for participants. If	5
7 8 9			applicable, eligibility criteria for study centres and	
10 11			individuals who will perform the interventions (eg,	
12 13 14			surgeons, psychotherapists)	
15 16 17	Interventions:	<u>#11a</u>	Interventions for each group with sufficient detail to	7
18 19	description		allow replication, including how and when they will	
20 21 22			be administered	
23 24	Interventions:	<u>#11b</u>	Criteria for discontinuing or modifying allocated	n/a there are
25 26	modifications		interventions for a given trial participant (eg, drug	no
27 28 29			dose change in response to harms, participant	modificaitons
30 31 32			request, or improving / worsening disease)	
33 34	Interventions:	<u>#11c</u>	Strategies to improve adherence to intervention	6
35 36	adherance		protocols, and any procedures for monitoring	
37 38 39			adherence (eg, drug tablet return; laboratory tests)	
40 41 42	Interventions:	<u>#11d</u>	Relevant concomitant care and interventions that	n/a
42 43 44 45	concomitant care		are permitted or prohibited during the trial	
46 47	Outcomes	<u>#12</u>	Primary, secondary, and other outcomes, including	7 and 8
48 49 50			the specific measurement variable (eg, systolic	
50 51 52			blood pressure), analysis metric (eg, change from	
53 54			baseline, final value, time to event), method of	
55 56			aggregation (eg, median, proportion), and time point	
57 58 59			for each outcome. Explanation of the clinical	
60		For peer rev	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1 2 3 4			relevance of chosen efficacy and harm outcomes is strongly recommended	
5 6 7 8 9 10	Participant timeline	<u>#13</u>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits	6
11 12 13 14			for participants. A schematic diagram is highly recommended (see Figure)	
15 16 17 18 19 20 21	Sample size	<u>#14</u>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions	8 and 9
22 23 24 25 26 27 28 29	Recruitment	<u>#15</u>	supporting any sample size calculations Strategies for achieving adequate participant enrolment to reach target sample size	9
30 31 32	Methods:			
33 34 35	Assignment of			
36 37	interventions (for			
38 39	controlled trials)			
40 41 42	Allocation:	<u>#16a</u>	Method of generating the allocation sequence (eg,	6 and 7
41 42 43	Allocation: sequence	<u>#16a</u>	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of	6 and 7
41 42 43 44 45 46		<u>#16a</u>		6 and 7
41 42 43 44 45 46 47 48	sequence	<u>#16a</u>	computer-generated random numbers), and list of	6 and 7
41 42 43 44 45 46 47 48 49 50	sequence	<u>#16a</u>	computer-generated random numbers), and list of any factors for stratification. To reduce predictability	6 and 7
41 42 43 44 45 46 47 48 49	sequence	<u>#16a</u>	computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned	6 and 7
41 42 43 44 45 46 47 48 49 50 51 52	sequence	<u>#16a</u>	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	6 and 7

1 2	Allocation	<u>#16b</u>	Mechanism of implementing the allocation	7
3 4	concealment		sequence (eg, central telephone; sequentially	
5 6 7	mechanism		numbered, opaque, sealed envelopes), describing	
7 8 9			any steps to conceal the sequence until	
10 11			interventions are assigned	
12 13 14	Allocation:	<u>#16c</u>	Who will generate the allocation sequence, who will	6 and 7
15 16	implementation		enrol participants, and who will assign participants	
17 18 19			to interventions	
20 21 22	Blinding (masking)	<u>#17a</u>	Who will be blinded after assignment to	7
22 23 24			interventions (eg, trial participants, care providers,	
25 26			outcome assessors, data analysts), and how	
27 28 29	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
30 31		<u>// // 0</u>	permissible, and procedure for revealing a	n/a
32 33	emergency			
34 35	unblinding		participant's allocated intervention during the trial	
36 37	Methods: Data			
38 39	collection,			
40 41 42	management, and			
43 44	analysis			
45 46	Data collection plan	#18a	Plans for assessment and collection of outcome,	9 and 10
47 48 49	·		baseline, and other trial data, including any related	
50 51			processes to promote data quality (eg, duplicate	
52 53			measurements, training of assessors) and a	
54 55			description of study instruments (eg, questionnaires,	
56 57			laboratory tests) along with their reliability and	
58 59 60	F	or peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	
50				

Page 40 of 44

1			validity, if known. Reference to where data	
2 3			collection forms can be found, if not in the protocol	
4 5			,,	
6 7	Data collection plan:	<u>#18b</u>	Plans to promote participant retention and complete	6
8 9	retention		follow-up, including list of any outcome data to be	
10 11			collected for participants who discontinue or deviate	
12 13 14			from intervention protocols	
15 16	Data management	<u>#19</u>	Plans for data entry, coding, security, and storage,	9 and 10
17 18 19			including any related processes to promote data	
20 21			quality (eg, double data entry; range checks for data	
22 23			values). Reference to where details of data	
24 25			management procedures can be found, if not in the	
26 27 28			protocol	
29 30	Statistics: outcomes	#20a	Statistical methods for analysing primary and	7 and 8
31 32	Statistics. Outcomes	<u>#20a</u>		
33 34			secondary outcomes. Reference to where other	
35 36			details of the statistical analysis plan can be found,	
37 38 39			if not in the protocol	
40 41	Statistics: additional	<u>#20b</u>	Methods for any additional analyses (eg, subgroup	n/a
42 43	analyses		and adjusted analyses)	
44 45 46	Statistics: analysis	<u>#20c</u>	Definition of analysis population relating to protocol	n/a
47 48	population and		non-adherence (eg, as randomised analysis), and	
49 50 51	missing data		any statistical methods to handle missing data (eg,	
52 53			multiple imputation)	
54 55 56 57 58	Methods: Monitoring			
59 60	Fo	or peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Data monitoring:	<u>#21a</u>	Composition of data monitoring committee (DMC);	11
2 3 4	formal committee		summary of its role and reporting structure;	
5 6			statement of whether it is independent from the	
7 8 9			sponsor and competing interests; and reference to	
10 11			where further details about its charter can be found,	
12 13			if not in the protocol. Alternatively, an explanation of	
14 15 16			why a DMC is not needed	
17 18 19	Data monitoring:	<u>#21b</u>	Description of any interim analyses and stopping	n/a
20 21	interim analysis		guidelines, including who will have access to these	
22 23			interim results and make the final decision to	
24 25 26			terminate the trial	
27 28	Harms	<u>#22</u>	Plans for collecting, assessing, reporting, and	8
29 30 31			managing solicited and spontaneously reported	
32 33			adverse events and other unintended effects of trial	
34 35			interventions or trial conduct	
36 37 38	Auditing	#23	Frequency and procedures for auditing trial conduct,	n/a
39 40	Additing	<u> <del>π</del></u> 20	if any, and whether the process will be independent	n/a
41 42			from investigators and the sponsor	
43 44 45				
45 46 47	Ethics and			
48 49	dissemination			
50 51 52	Research ethics	<u>#24</u>	Plans for seeking research ethics committee /	2 and 11
52 53 54	approval		institutional review board (REC / IRB) approval	
55 56				
57 58				
59 60		For peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Protocol	<u>#25</u>	Plans for communicating important protocol	11
3 4	amendments		modifications (eg, changes to eligibility criteria,	
5 6 7			outcomes, analyses) to relevant parties (eg,	
7 8 9			investigators, REC / IRBs, trial participants, trial	
10 11 12			registries, journals, regulators)	
13 14	Consent or assent	<u>#26a</u>	Who will obtain informed consent or assent from	5
15 16 17			potential trial participants or authorised surrogates,	
18 19			and how (see Item 32)	
20 21 22	Consent or assent:	<u>#26b</u>	Additional consent provisions for collection and use	n/a
23 24	ancillary studies		of participant data and biological specimens in	
25 26 27			ancillary studies, if applicable	
28 29	Confidentiality	<u>#27</u>	How personal information about potential and	10
30 31 32			enrolled participants will be collected, shared, and	
33 34			maintained in order to protect confidentiality before,	
35 36			during, and after the trial	
37 38 39	Declaration of	#28	Financial and other competing interests for principal	13
40 41	interests	<u></u>	investigators for the overall trial and each study site	
42 43			invooligatoro for the overall that and oder olday one	
44 45	Data access	<u>#29</u>	Statement of who will have access to the final trial	13
46 47			dataset, and disclosure of contractual agreements	
48 49 50			that limit such access for investigators	
51 52 53	Ancillary and post	<u>#30</u>	Provisions, if any, for ancillary and post-trial care,	6
53 54 55	trial care		and for compensation to those who suffer harm from	
56 57			trial participation	
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1 2	Dissemination	<u>#31a</u>	Plans for investigators and sponsor to communicate	11
3 4	policy: trial results		trial results to participants, healthcare professionals,	
5 6 7			the public, and other relevant groups (eg, via	
7 8 9			publication, reporting in results databases, or other	
10 11			data sharing arrangements), including any	
12 13 14			publication restrictions	
15 16 17	Dissemination	<u>#31b</u>	Authorship eligibility guidelines and any intended	13
18 19	policy: authorship		use of professional writers	
20 21 22	Dissemination	<u>#31c</u>	Plans, if any, for granting public access to the full	13
23 24	policy: reproducible		protocol, participant-level dataset, and statistical	
25 26	research		code	
27 28 29 30	Appendices			
31 32 33	Informed consent	<u>#32</u>	Model consent form and other related	16 and 17
34 35	materials		documentation given to participants and authorised	
36 37 38			surrogates	
39 40	Biological	<u>#33</u>	Plans for collection, laboratory evaluation, and	n/a
41 42	specimens		storage of biological specimens for genetic or	
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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.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
<b>Primary Subject Heading</b> :	Public health
Secondary Subject Heading:	Diagnostics, Gastroenterology and hepatology
Keywords:	Public health < INFECTIOUS DISEASES, World Wide Web technology < BIOTECHNOLOGY & BIOINFORMATICS, Hepatology < INTERNAL MEDICINE

# SCHOLARONE<sup>™</sup> 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

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Word count: 3390 (max. 4000)

# 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 groups will receive a HCVST kit delivered by anonymized courier. Participants in the poet 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

# 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.

#### INTRODUCTION

The World Health Organization (WHO) estimates that 58 million people globally have chronic hepatitis C virus (HCV) infection.<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>2-6</sup>@ 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,<sup>7</sup> with the burden of infection largely within the PWID population (numbering over 52,250 in 2017).<sup>89</sup> Prior to the implementation of a national elimination programme in 2015,<sup>78</sup> the seroprevalence in PWIDs in Georgia ranged from 50– 92%, depending on region.<sup>10-13</sup> The programme has been successful in identifying and linking people with HCV to care,<sup>8</sup> 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.<sup>14</sup> Here we describe the protocol of an randomized controlled trial (Georgian IRB Ethics Approval Number: IRB# 2021-049, clinicaltrials.gov: <u>NCT04961723</u>) 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**.

#### 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 Disease: 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 I 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 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

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<sup>®</sup> 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.

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

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

	intervention groups compared with the control groups (margin 20%).	<ul> <li>and control groups will be compared (three comparisons):</li> <li>Arm 1 (intervention) vs. A (control) for MSM,</li> <li>Arm 2 (intervention) vs. A (control) for MSM</li> <li>Arm 4 (intervention) vs. A (control) for PWID.</li> </ul>
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 res y/n) is defined overall (as primary analysis) a for visit 1 (as additional analysis). The proportion of test positives p <sub>pos</sub> will be calculated among all patients with test resul (=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/u defined overall (as primary analysis) and for 1 (as additional analysis). The proportion of patients referred p <sub>ref</sub> will be calculated amo all patients with positive test results as well 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 analys The proportion of patients treated $p_{trt}$ will b calculated among all patients with positive to results as well as among all MITT and PP patients. The comparisons will refer to proportion with number with patients with a positive test re- 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 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 <b>Error! Reference sou</b> <b>not found.</b> , if not stated otherwise] will be reported either in absolute numbers and

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

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. 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).

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.<sup>15</sup> 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.

# 

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.

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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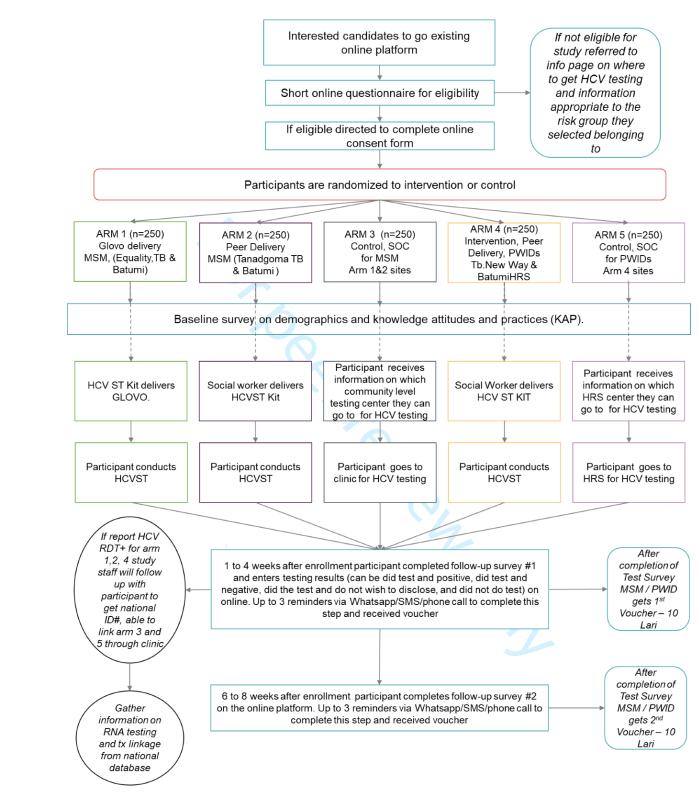
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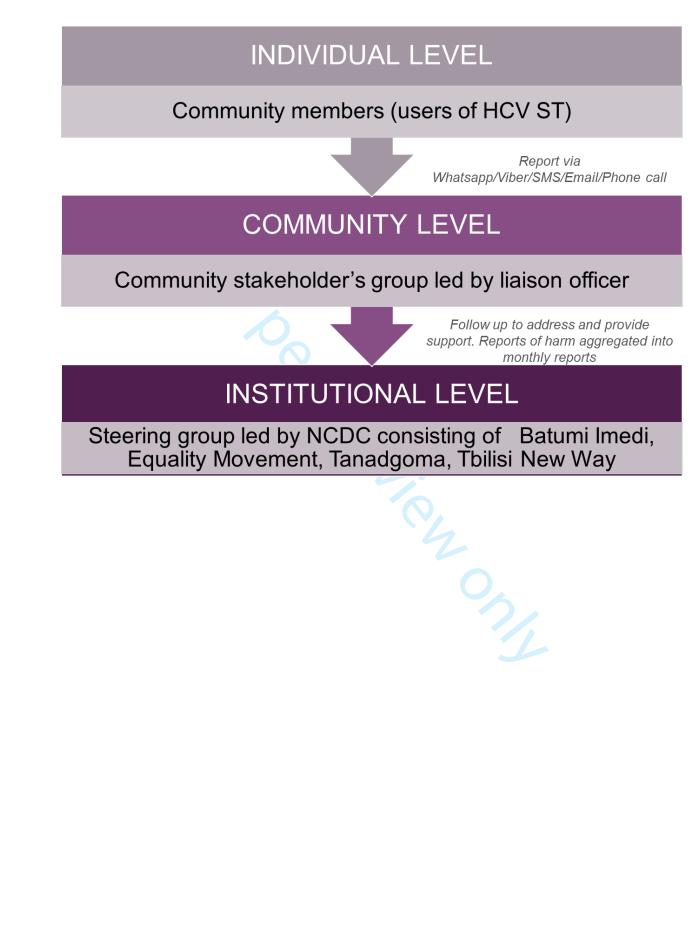
# FIGURE LEGENDS

Figure 1. Study design

Figure 2. Social harms monitoring structure



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



1	
2	
3	Supplementary Annex 1
4	Study information form and informed consent form
5	•
6 7	Hepatitis C Study Information Sheet
8	Title of Study
9	Randomized controlled trial of home-based hepatitis C self-testing in key populations
10	in Georgia
11	Participating Organizations
12	NCDC, Equality Movement, Tanadgoma, Tbilisi New Way HRS, Batumi Imedi HRS, Foundation for Innovative New Diagnostics
13 14	Introduction
15	Hepatitis C is a liver infection caused by a virus that can lead to serious liver damage, cancer,
16	and even death. You are being invited to take part in this study to help understand different
17	ways people can be tested for hepatitis C.
18	Purpose
19	The purpose of this study is to evaluate different models of hepatitis C testing
20 21	Study Procedures
21	If you take part in the study, you will only have to sign the consent form, take two surveys, and
23	consider getting tested for hepatitis C. You will be randomly selected for testing models: a) to
24	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.
25	If you are selected for the hepatitis c self-test it is a simple procedure using oral fluids. If you
26	are selected for the hepatitis C self-test group you will either be placed in the group that gets the
27	hepatitis C self test delivered by Glovo delivery or be placed in the group that will have the test
28 29	delivered to your house by a peer outreach worker or a social worker
30	Your information will be reviewed by the study personnel and grouped with all other persons in
31	the study.
32	Benefits
33	As a participant in this study, you may learn if you have been exposed to hepatitis C or not and
34	be offered care and treatment if you have hepatitis C. Risks
35 36	There is minimal discomfort with hepatitis C testing. There is a minimal risk that you could
37	encounter social harms from this study.
38	Framed in the study the observational team is set up to identify any social harm associated with
39	participation in the study and testing. They will give you recommendations and to get the
40	appropriate services as needed.
41	You can contact the study coordinator for the information how to contact this group (The phone
42 43	numbers will be provided by Arms)
44	
45	Compensation and Costs
46	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
47	and another phone credit voucher of 10 GEL when the finish the second study survey. You will
48	receive the phone credits to the phone number that you provide on the online platform
49 50	approximately 7 days after you complete each survey. You will be offered hepatitis C testing but
51	are not required to be tested for hepatitis C to receive compensation.
52	Confidentiality
53	All information collected about you during the course of this study will be stored without any
54	personal identifiers. No one will be able to match you to your information. No one will be able to
55 56	determine your identity in the frame of the study. Only study personnel will have access to the
56 57	information.
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60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

# 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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2 3			
4	Supplementary Annex 2		
5	PARTICIPANT FOLLOW-UP SURVEY #1		
7 8 9 10	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		
11 12 13 14 15 16	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.		
17 18 19	SECTION A – STUDY TESTING AND FOLLOW-UP		
20 21 22 23	<ul> <li>A1. Did you complete the hepatitis C testing that was offered to you as part of this study?</li> <li>1. Yes</li> <li>2. No</li> </ul>		
24 25 26	A1ai. ( <i>if answered Yes to question A1, version of question for arm 3 and 5</i> ) What was the result? 1. Positive 2. Negative		
27 28 29	<ol> <li>Don't know, have forgotten</li> <li>Do not want to disclose</li> </ol>		
30 31 32	A1aii. (if answered Yes to question A1, version of question for arm 1,2 and 4) What was the result?		
33 34 35	<ol> <li>Positive</li> <li>Negative</li> <li>Test did not work</li> </ol>		
36 37 38	<ol> <li>Don't know, could not read the test</li> <li>Do not want to disclose</li> </ol>		
39 40 41	A1b. ( <i>If answered No to question A1)</i> If no, why not? 1. Did not want to test/was not interested 2. Forgot to get tested		
42 43 44 45 46	<ol> <li>Afraid of testing</li> <li>Did not have time</li> <li>Others, specify:</li> </ol>		
47 48 49	A1c. (If answered Yes for question A1, for arm 3 and 5 only) Where did you go to get the hepatitis C test done?		
50 51 52 53 54	(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		
55 56 57 58	<ol> <li>Tbilisi ID Hospital</li> <li>Neo Lab clinic</li> </ol>		
59 60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml		

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3	6. He	pa clinic
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8	(For participants whe	o live in Batumi)
9		
10		tumi Tanadgoma center
11		tumi Equality movement
12		tumi Imedi HRS
13		tumi ID hospital
14		tumi Mary time hospital
15	6. Otł	her:
16		
17		
18		
19 20		
20 21		uestion A1aii, for arm 1,2, and 4 only) If you had tested positive
22		nk your next steps would have been?
23		go to a community-based organization for more information and
24	advice	
25		go to a healthcare clinic for a confirmation test
26		go to a hospital for a confirmation test
27		rould not do next step
28		n't know
29	6. Oth	hers, specify:
30	Ma (If anyward toot did not u	vork or Don't know in quastion Alaii, for arm 1.2 and 4 anhy) House
31		vork or Don't know in question A1aii, for arm 1,2 and 4 only) Have
32	you taken any further step to ge 1. Ye	is, have gone to a community-based organization for more
33		n and advice
34 35		s, have gone to a clinic and asked for another test
36		b, I have not made next step
37		hers, specify:
38	4. 01	ners, speeny.
39	A1h (If answered No in questic	on A1g) If you do not made any next step, why not?
40		d not want to test/was not interested
41		rgot to get tested
42		raid of testing
43		d not have time
44		ansportation was too expensive
45		hers, specify:
46		······; •······························
47 49		
48 49		
50		
51	A2a. (version of question for arr	<i>m</i> 3 and 5 group) Did you ask anyone any question about process
52	of hepatitis C testing?	
53		s, online through the support offered on selftest.ge platform
54	2. Ye	s, online through searching the internet
55		s, person who performed the test
56		s, friend or family member
57		
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3	5. Yes; others, specify:
4	6. No, I have not asked the question
5	,
6	A2b. (version of question for arm 1) Did you ask anyone any question about process of hepatitis
7	C testing?
8	1. Yes, online through the support offered on selftest.ge platform
9	2. Yes, online through searching the internet
10	3. Yes, friend or family member
11	4. Yes; others, specify:
12	5. No, I have not asked the question
13	5. No, i have not asked the question
14	ADD (version of evention for own 0 and 1) Did you call anyone any evention about honetitic
15	A2c. (version of question for arm 2 and 4) Did you ask anyone any question about hepatitis
16	C testing?
17	1. Yes, online through the support offered on selftest.ge platform
18	2. Yes, by asking the peer deliver who dropped of my test
19	<ol> <li>Yes, online through searching the internet</li> </ol>
20	<ol> <li>Yes, friend or family member</li> </ol>
21	5. Yes; others, specify:
22	<ol><li>No, I have not asked the question</li></ol>
23	
24	A3. (If answered Yes in question A1) How would you rate the hepatitis C testing you were offered
25	in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)
26	
27	Not very easy Average Very easy
28	How easy was the testing process? 1 2 3 4 5
29	
30	Not very convenient Average Very convenient
31	How convenient was the testing process? 1 2 3 4 5
32	
33 34	Not very private Average Very private
35	How private did you think the testing process was? $472345$
36	
37	Not very trustworthy Average Very trustworthy
38	How much do you feel you can trust the test results? 1 2 3 4 5
39	
40	
41	Not very secure Average Very secure
42	How secure did you feel during the testing process? 1 2 3 4 5
43	
44	Not very stressful Average Very stressful
45	How stressful was the testing process? 1 2 3 4 5
46	Not very easy Average Very easy
47	If you needed further care, how easy was it to access it? 1 2 3 4 5
48	Did not need it
49	
50	
51	A4. (If answered Yes in question A1) Did you feel you could understand the result of your test?
52	1. Yes
53	2. No
54	
55	A4ai. (If answered Yes in question A4, version of question for arm 1,2 and 4) What do you think
56	have helped you to understand the result of your test (select all that apply)?
57	

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 10 The printed instructions for use that came with the HCV self-test 1. 11 were not easy to understand 12 Video instructions on how to perform a self-test was not easy to 2. 13 understand 14 Communication with the selftest.ge team were not easy to 3. 15 understand 16 17 4. Others; specify: 18 19 A5. (If answered Positive, test did not work or Don't know in guestion A1aii) Did you feel you 20 knew what steps you needed to take to be further linked to hepatitis C care after you got the 21 result of your test? 22 1. Yes 23 2. No 24 25 A6. (If answered No in question A5) What do you think would have helped you to know what 26 steps you need to take to be further linked to care? 27 A list of clinics near me that provide HCV care with their contact 1. 28 information 29 More information on how community-based organizations near me 2. 30 could help me navigate how to be linked to care 31 A video explaining how I could get linked to care 3. 32 Others; specify: 4. 33 34 A7. In the future, where would you prefer to be tested for hepatitis C? 35 By myself at home 36 1. 37 2. At home with someone I trust 38 3. By myself at a healthcare clinic 39 4. In a community centre by community-based organization staff 40 5. In a healthcare clinic by a healthcare worker 41 6. In a pharmacy by a healthcare worker 42 7. No preference 43 8. Prefer not to get tested for hepatitis C 44 9. Other, specify: 45 46 A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and 47 instructions on how to do it? 48 1. Yes 49 2. No 50 3. Don't know 51 52 A8a. (If answered Yes in question A8) If yes, how often do you think you would test yourself? 53 1. More than once every 6 months 54 2. Once every 6 months 55 3. 56 Once a year 57 58 6 59 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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2 3 4. Once every 2 years 4 5. Don't know 5 6. Others, specify: 6 7 A1d. (If answered Positive in question A1ai or A1aii) Have you taken further steps for hepatitis 8 C care after your positive test? Please select all that applies 9 Yes, have gone for confirmation test 1. 10 Yes, have had doctor consultation and completed additional 2. 11 testing 12 3. Yes, have started treatment 13 4. others, specify: 14 No, I do not plan to take further steps 5. 15 16 A1e. (If answered Yes, have gone for confirmation test or Yes, have completed further testing 17 and have started treatment in guestion A1d) What was the result of your confirmation test? 18 19 1. I was confirmed active chronic Hepatitis C (viremia) 20 2. I do not have active chronic hepatitis C (viremia) 21 3. Have not been told the results yet 22 Do not want to disclose 4 23 5. Others, specify:\_\_\_\_\_ 24 25 A1i. (If answered Yes, have gone for confirmation test or Yes, have completed further 26 testing and have started treatment in question A1d) Where did you go for this further hepatitis C 27 care? 28 (select from drop down list the name of the facility 29 30 (For participants who live in Tbilisi) 31 1. Tbilisi ID Hospital 32 2. Neo Lab clinic 33 Hepa clinic 3. 34 4. Other: 35 36 37 (For participants who live in Batumi) 38 Batumi Imedi HRS 1. 39 2. Batumi ID hospital Batumi Mary time hospital 40 3. 41 Other: 4. 42 43 44 **SECTION B – RISK BEHAVIORS** 45 46 B1. How many times have you or your partner(s) used a condom during sexual contact in the last 47 month? 48 1. I have not had sexual contact in the last month 49 2. Always 50 3. Often 51 4. Sometimes 52 5. Never used 53 54 B2. In the last month, have you taken any substance by snorting it? 55 1. Yes 56 57 58 7 59

- 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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4	Supplementary annex 3:
5	PARTICIPANT FOLLOW-UP SURVEY #2
6 7	
8	STUDY ID: automatically linked and date and timestamped by the platform
9	SURVEY DATE: automatically generated/timestamped by the platform
10	
11	INFORMATION TO PARTICIPANTS
12	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
13	C testing in Georgia.
14 15	
15	SECTION A – STUDY TESTING AND FOLLOW-UP
17	
18	A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
19	1. Yes
20	2. No
21	
22	A1ai. (if answered Yes to question A1, version of question for arm 3 and 5) What was the result?
23 24	1. Positive
24	2. Negative
26	3. Don't know, have forgotten
27	4. Do not want to disclose
28	A1aii. (if answered Yes to question A1, version of question for arm 1,2 and 4) What was the
29	result?
30	1. Positive
31 32	2. Negative
32 33	3. Test did not work
34	4. Don't know
35	5. Do not want to disclose
36	
37	A1b. (If answered No to question A1) If no, why not?
38	<ol> <li>Did not want to test/was not interested</li> </ol>
39	2. Forgot to get tested
40 41	3. Afraid of testing
41	4. Did not have time
43	5. Others, specify:
44	A1c. (If answered Yes for question A1 for arm 3 and 5 only) Where did you go to get the hepatitis
45	C test done?
46	
47	(select from drop down list the name of the facility)
48 49	
49 50	(For participants who live in Tbilisi)
51	1. Tbilisi Tanadgoma center
52	2. Tbilisi Equality movement center
53	3. Tbilisi New Way HRS
54	4. Tbilisi ID Hospital
55	5. Neo Lab clinic
56 57	6. Hepa clinic
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3	7. Other:
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6	(Ear participanto who live in Potumi)
7	(For participants who live in Batumi)
8	
9	1. Batumi Tanadgoma center
10	<ol><li>Batumi Equality movement</li></ol>
11	<ol><li>Batumi Imedi HRS</li></ol>
12	<ol><li>Batumi ID hospital</li></ol>
13	5. Batumi Mary time hospital
14	6. Other:
15	
16	
10	A1f. (If answered Negative in question A1aii, for arm 1,2, and 4 only) If you had tested positive
18	for hepatitis C, what do you think your next steps would have been?
19	1. To go to a community-based organization for more information and
20	advice
21	2. To go to a policlinic for a confirmation test
22	<ol> <li>To go to a healthcare clinic for a confirmation test</li> </ol>
23	4. I would not do next step
24	5. Don't know
25	6. Others, specify:
26	
27	
28	Ala (If answored test did not work or Den't know in question Alaii for arm 1.2 and 4 only) Have
29	A1g. (If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only) Have
30	you taken any further step to get a second test done?
31	1. Yes, have gone to a community-based organization for more
32	information and advice
33	<ol><li>Yes, have gone to a clinic and asked for another test</li></ol>
34	<ol><li>No, I have not made next step</li></ol>
35	4. Others, specify:
36	
37	A1h. (If answered No in question A1g) If no, why not?
38	1. Did not want to test/was not interested
39	2. Forgot to get tested
40	3. Afraid of testing
41	5
42	4. Did not have time
43	5. Test was too expensive
44	6. Others, specify:
45	
46	
47	
48	A2a. (version of question for arm 3 and 5 group) Did you ask anyone
48 49	any question about hepatitis C testing?
49 50	1. Yes, online through the support offered on selftest.ge platform
	2. Yes, online through searching the internet
51 52	3. Yes, person who performed the test
52	
53	
54	5. Yes; others, specify:
55	6. No
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A2b. (version of question for arm 1) Did you ask anyone any question about hepatitis C testing? Yes, online through the support offered on selftest.ge platform 1. 2. Yes, online through searching the internet 3. Yes, friend or family member Yes; others, specify: 4. 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? 2 3 5 **-** 1 4 Not very private Average Very private How private did you think the testing process was? 2 5 3 4 1 Not very trustworthy Average Very trustworthy How much do you feel you can trust the test results? 1 2 3 5 4 Not very secure Average Very secure How secure did you feel during the testing process? 1 2 3 5 Not very stressful Average Very stressful How stressful was the testing process? 2 3 5 1 Not very easy Average Very easy If you needed further care, how easy was it to access it? 2 345 Did not need it 1 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)? The printed instructions for use that came with the HCV self-test 1. 2. Video instructions on how to perform a self-test was not easy to understand Communication with the selftest.ge team were not easy to 3. understand 11 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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 The printed instructions for use that came with the HCV self-test 1. were not easy to understand Video instructions on how to perform a self-test was not easy to 2. understand Communication with the selftest.ge team were not easy to 3. understand Others; specify: \_\_\_\_\_ 4. 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 More information on how community-based organizations near me 2. 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? By myself at home 1. 2. At home with someone I trust 3 By myself at a healthcare clinic 4. In a community centre by community-based organization staff In a healthcare clinic by a healthcare worker 5. In a pharmacy by a healthcare worker 6. 7. No preference Prefer not to get tested for hepatitis C 8. 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? More than once every 6 months 1. 2. Once every 6 months 3. Once a year 4. Once every 2 years 5. Don't know

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2 3	
4	6. Others, specify:
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6	A1d. (If answered Yes to question A1, Positive in question A1a and No in question A1d in Follow-
7	up survey #1, this will be the first question for them in this Follow-up survey #2. After questions
8	A1d and A1e have been answered by this group in Follow-up survey #2, they will proceed to
9	section B. This question is also for those who answered Positive in question A1a in Follow-up
10	survey #2; for this group, they will proceed through the rest of section A following skip patterns
11	based on their answers) Have you taken further steps for hepatitis C care after your positive
12	test?
13	Please select all that applies
14	1. Yes, have gone for confirmation test
15	2. Yes, have had doctor consultation and completed additional testing
16	3. Yes, have started treatment
17	4. Others, specify:
18 19	5. No, I do not plan to take further steps
20	Ata (If anoward Vap, have gone for confirmation test or Vap, have had destar consultation
20	A1e. (If answered Yes, have gone for confirmation test or Yes, , have had doctor consultation
22	and completed additional testing and have started treatment in question A1d) What was the
23	result of your confirmation test?
24	1. I have hepatitis C viremia
25	<ol> <li>I do not have hepatitis C viremia</li> <li>Have not been told the results yet</li> </ol>
26	
27	4. Others, specify:
28	A1i. (If answered Yes, have gone for confirmation test or Yes, have completed further
29	testing and have started treatment in question A1d) Where did you go for this further hepatitis C
30	care?
31	(select from drop down list the name of the facility
32 33	(For participants who live in Tbilisi)
34	1. Tbilisi ID Hospital
35	2. Neo Lab clinic
36	3. Hepa clinic
37	4. Other:
38	
39	(For participants who live in Batumi)
40	(For participants who live in Batumi)
41	
42	1. Batumi Imedi HRS
43	2. Batumi ID hospital
44	<ol><li>Batumi Mary time hospital</li></ol>
45 46	4. Other:
40 47	
47	SECTION B – RISK BEHAVIORS
49	
50	B1. How many times have you or your partner(s) used a condom during sexual contact in the last
51	month?
52	1. I have not had sexual contact in the last month
53	2. Always
54	3. Often
55	4. Sometimes
56	5. Never used
57 58	42
58 59	13
60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2

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:

**BMJ** Open

# 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

Page 36 of 45

1 2	Trial registration	<u>#2a</u>	Trial identifier and registry name. If not yet	2
3 4 5 6 7 8 9 10 11 12 13			registered, name of intended registry	
	Trial registration:	<u>#2b</u>	All items from the World Health Organization Trial	2
	data set		Registration Data Set	
	Protocol version	<u>#3</u>	Date and version identifier	2
14 15 16 17	Funding	<u>#4</u>	Sources and types of financial, material, and other	13
18 19			support	
20 21	Roles and	<u>#5a</u>	Names, affiliations, and roles of protocol	13
22 23 24	responsibilities:		contributors	
24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39	contributorship			
	Roles and	<u>#5b</u>	Name and contact information for the trial sponsor	1
	responsibilities:			
	sponsor contact			
	information			
	Roles and	<u>#5c</u>	Role of study sponsor and funders, if any, in study	10
40 41	responsibilities:		design; collection, management, analysis, and	
42 43	sponsor and funder		interpretation of data; writing of the report; and the	
44 45			decision to submit the report for publication,	
46 47 48			including whether they will have ultimate authority	
49 50			over any of these activities	
51 52 53	Roles and	<u>#5d</u>	Composition, roles, and responsibilities of the	10 and 11
54 55 56	responsibilities:		coordinating centre, steering committee, endpoint	
50 57 58	committees		adjudication committee, data management team,	
59 60	F	or peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

Page 3	7 of 45		BMJ Open	
1			and other individuals or groups overseeing the trial,	
2 3 4			if applicable (see Item 21a for data monitoring	
4 5 6			committee)	
7 8 9 10	Introduction			
11 12	Background and	<u>#6a</u>	Description of research question and justification for	4
13 14	rationale		undertaking the trial, including summary of relevant	
15 16 17			studies (published and unpublished) examining	
17 18 19			benefits and harms for each intervention	
19 20 21	Background and	#6b	Explanation for choice of comparators	5
22 23	rationale: choice of			
24 25 26 27 28 29 30	comparators			
	Objectives	<u>#7</u>	Specific objectives or hypotheses	7 and 8
31 32	Trial design	<u>#8</u>	Description of trial design including type of trial (eg,	4 and 7
33 34 35			parallel group, crossover, factorial, single group),	
36 37			allocation ratio, and framework (eg, superiority,	
38 39			equivalence, non-inferiority, exploratory)	
40 41 42	Methods:			
43 44 45	Participants,			
46 47	interventions, and			
48 49 50	outcomes			
51 52 53	Study setting	<u>#9</u>	Description of study settings (eg, community clinic,	4 and 5
54 55 56 57			academic hospital) and list of countries where data	
58 59 60	F	or peer re	eview only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

Page	38	of 45
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1			will be collected. Reference to where list of study	
2 3 4			sites can be obtained	
5 6 7	Eligibility criteria	<u>#10</u>	Inclusion and exclusion criteria for participants. If	5
7 8 9			applicable, eligibility criteria for study centres and	
10 11			individuals who will perform the interventions (eg,	
12 13 14			surgeons, psychotherapists)	
15 16 17	Interventions:	<u>#11a</u>	Interventions for each group with sufficient detail to	7
17 18 19	description		allow replication, including how and when they will	
20 21 22			be administered	
23 24	Interventions:	<u>#11b</u>	Criteria for discontinuing or modifying allocated	n/a there are
25 26	modifications		interventions for a given trial participant (eg, drug	no
27 28 29			dose change in response to harms, participant	modificaitons
30 31			request, or improving / worsening disease)	
32 33 34	Interventions:	<u>#11c</u>	Strategies to improve adherence to intervention	6
35 36	adherance		protocols, and any procedures for monitoring	
37 38 39			adherence (eg, drug tablet return; laboratory tests)	
40 41 42	Interventions:	<u>#11d</u>	Relevant concomitant care and interventions that	n/a
42 43 44	concomitant care		are permitted or prohibited during the trial	
45 46 47	Outcomes	<u>#12</u>	Primary, secondary, and other outcomes, including	7 and 8
48 49			the specific measurement variable (eg, systolic	
50 51 52			blood pressure), analysis metric (eg, change from	
52 53 54			baseline, final value, time to event), method of	
55 56			aggregation (eg, median, proportion), and time point	
57 58			for each outcome. Explanation of the clinical	
59 60		For peer rev	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 3			relevance of chosen efficacy and harm outcomes is strongly recommended	
4 5 7 8 9	Participant timeline	<u>#13</u>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits	6
10 11			for participants. A schematic diagram is highly	
12 13 14			recommended (see Figure)	
15 16 17	Sample size	<u>#14</u>	Estimated number of participants needed to achieve	8 and 9
18 19			study objectives and how it was determined,	
20 21			including clinical and statistical assumptions	
22 23 24			supporting any sample size calculations	
25 26	Recruitment	<u>#15</u>	Strategies for achieving adequate participant	9
27 28 29			enrolment to reach target sample size	
30 31 32	Methods:			
33	Assignment of			
34 25				
35 36	interventions (for			
35 36 37 38 39	-			
35 36 37 38 39 40 41	interventions (for	<u>#16a</u>	Method of generating the allocation sequence (eg,	6 and 7
35 36 37 38 39 40 41 42 43	interventions (for controlled trials)	<u>#16a</u>	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of	6 and 7
35 36 37 38 39 40 41 42 43 44 45 46	interventions (for controlled trials) Allocation:	<u>#16a</u>		6 and 7
35 36 37 38 39 40 41 42 43 44 45 46 47 48	interventions (for controlled trials) Allocation: sequence	<u>#16a</u>	computer-generated random numbers), and list of	6 and 7
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50	interventions (for controlled trials) Allocation: sequence	<u>#16a</u>	computer-generated random numbers), and list of any factors for stratification. To reduce predictability	6 and 7
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49	interventions (for controlled trials) Allocation: sequence	<u>#16a</u>	computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned	6 and 7
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52	interventions (for controlled trials) Allocation: sequence	<u>#16a</u>	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	6 and 7
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55	interventions (for controlled trials) Allocation: sequence	<u>#16a</u>	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	6 and 7

Page 40 of 45

1 2	Allocation	<u>#16b</u>	Mechanism of implementing the allocation	7
3 4	concealment		sequence (eg, central telephone; sequentially	
5 6 7	mechanism		numbered, opaque, sealed envelopes), describing	
7 8 9			any steps to conceal the sequence until	
10 11			interventions are assigned	
12 13 14	Allocation:	<u>#16c</u>	Who will generate the allocation sequence, who will	6 and 7
15 16	implementation		enrol participants, and who will assign participants	
17 18 19			to interventions	
20 21 22	Blinding (masking)	<u>#17a</u>	Who will be blinded after assignment to	7
23 24			interventions (eg, trial participants, care providers,	
25 26 27			outcome assessors, data analysts), and how	
28 29	Blinding (masking):	<u>#17b</u>	If blinded, circumstances under which unblinding is	n/a
30 31 32	emergency		permissible, and procedure for revealing a	
33 34	unblinding		participant's allocated intervention during the trial	
35 36	Methods: Data			
37 38	collection,			
39 40 41	management, and			
42 43	analysis			
44 45	anaiyələ			
46 47	Data collection plan	<u>#18a</u>	Plans for assessment and collection of outcome,	9 and 10
48 49 50			baseline, and other trial data, including any related	
50 51 52			processes to promote data quality (eg, duplicate	
53 54			measurements, training of assessors) and a	
55 56			description of study instruments (eg, questionnaires,	
57 58			laboratory tests) along with their reliability and	
59 60	F	or peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1			validity, if known. Reference to where data	
2 3			collection forms can be found, if not in the protocol	
4 5 6	Data collection plan:	<u>#18b</u>	Plans to promote participant retention and complete	6
7 8 9	retention		follow-up, including list of any outcome data to be	
10 11			collected for participants who discontinue or deviate	
12 13			from intervention protocols	
14 15 16	Data management	<u>#19</u>	Plans for data entry, coding, security, and storage,	9 and 10
17 18			including any related processes to promote data	
19 20 21			quality (eg, double data entry; range checks for data	
22 23			values). Reference to where details of data	
24 25			management procedures can be found, if not in the	
26 27 28			protocol	
29 30	Statistics: outcomes	#20a	Statistical methods for analysing primary and	7 and 8
31 32	olalistics. outcomes	<u>#200</u>	secondary outcomes. Reference to where other	
33 34				
35 36			details of the statistical analysis plan can be found,	
37 38 39			if not in the protocol	
39 40 41	Statistics: additional	<u>#20b</u>	Methods for any additional analyses (eg, subgroup	n/a
42 43	analyses		and adjusted analyses)	
44 45 46	Statistics: analysis	<u>#20c</u>	Definition of analysis population relating to protocol	n/a
47 48	population and		non-adherence (eg, as randomised analysis), and	
49 50	missing data		any statistical methods to handle missing data (eg,	
51 52 53			multiple imputation)	
54 55 56	Methods: Monitoring			
57 58				
59 60	Fo	or peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Data monitoring:	<u>#21a</u>	Composition of data monitoring committee (DMC);	11
3 4	formal committee		summary of its role and reporting structure;	
5 6 7			statement of whether it is independent from the	
7 8 9			sponsor and competing interests; and reference to	
10 11			where further details about its charter can be found,	
12 13			if not in the protocol. Alternatively, an explanation of	
14 15 16 17 18 19			why a DMC is not needed	
	Data monitoring:	<u>#21b</u>	Description of any interim analyses and stopping	n/a
20 21	interim analysis		guidelines, including who will have access to these	
22 23			interim results and make the final decision to	
24 25 26			terminate the trial	
20 27 28	Harms	<u>#22</u>	Plans for collecting, assessing, reporting, and	8
29 30			managing solicited and spontaneously reported	-
31 32			adverse events and other unintended effects of trial	
33 34 35			interventions or trial conduct	
36 37				
38 39	Auditing	<u>#23</u>	Frequency and procedures for auditing trial conduct,	n/a
40 41			if any, and whether the process will be independent	
42 43			from investigators and the sponsor	
44 45 46	Ethics and			
47 48 49	dissemination			
50 51	Research ethics	<u>#24</u>	Plans for seeking research ethics committee /	2 and 11
52 53	approval		institutional review board (REC / IRB) approval	
54 55				
56 57 58				
59 60	F	or peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1	Protocol	#25	Plans for communicating important protocol	11
2 3	amendments	<u></u>	modifications (eg, changes to eligibility criteria,	
4 5 6	amenaments			
7 8			outcomes, analyses) to relevant parties (eg,	
8 9 10			investigators, REC / IRBs, trial participants, trial	
10 11 12			registries, journals, regulators)	
13 14	Consent or assent	<u>#26a</u>	Who will obtain informed consent or assent from	5
15 16			potential trial participants or authorised surrogates,	
17 18 19			and how (see Item 32)	
20 21 22	Consent or assent:	<u>#26b</u>	Additional consent provisions for collection and use	n/a
23 24	ancillary studies		of participant data and biological specimens in	
25 26 27			ancillary studies, if applicable	
28 29	Confidentiality	<u>#27</u>	How personal information about potential and	10
30 31 32			enrolled participants will be collected, shared, and	
33 34			maintained in order to protect confidentiality before,	
35 36			during, and after the trial	
37 38	Declaration of	#20	Einancial and other competing interacts for principal	13
39 40		<u>#28</u>	Financial and other competing interests for principal	13
41 42	interests		investigators for the overall trial and each study site	
43 44 45	Data access	<u>#29</u>	Statement of who will have access to the final trial	13
46 47			dataset, and disclosure of contractual agreements	
48 49 50			that limit such access for investigators	
51 52	Ancillary and post	<u>#30</u>	Provisions, if any, for ancillary and post-trial care,	6
53 54 55	trial care		and for compensation to those who suffer harm from	
55 56 57			trial participation	
58 59				
60	F	or peer re	view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Dissemination	<u>#31a</u>	Plans for investigators and sponsor to communicate	11
3 4	policy: trial results		trial results to participants, healthcare professionals,	
5 6 7			the public, and other relevant groups (eg, via	
8 9			publication, reporting in results databases, or other	
10 11			data sharing arrangements), including any	
12 13 14			publication restrictions	
15 16 17	Dissemination	<u>#31b</u>	Authorship eligibility guidelines and any intended	13
18 19	policy: authorship		use of professional writers	
20 21 22	Dissemination	<u>#31c</u>	Plans, if any, for granting public access to the full	13
23 24	policy: reproducible		protocol, participant-level dataset, and statistical	
25 26 27	research		code	
28 29 30	Appendices			
31 32 33	Informed consent	<u>#32</u>	Model consent form and other related	16 and 17
34 35	materials		documentation given to participants and authorised	
36 37 38			surrogates	
39 40	Biological	<u>#33</u>	Plans for collection, laboratory evaluation, and	n/a
41 42 43	specimens		storage of biological specimens for genetic or	
44 45			molecular analysis in the current trial and for future	
46 47			use in ancillary studies, if applicable	
48 49 50 51	Notes:			
52 53	11b: n/a there are no modifications The SPIRIT Explanation and Elaboration paper is distributed			
54 55 56 57	under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was			
58 59 60 For peer review only - http://bmjop			view only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1	completed on 07. August 2021 using https://www.goodreports.org/, a tool made by the
2 3	EQUATOR Network in collaboration with Penelope.ai
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57	EQUATOR Network in collaboration with Penelope.ai
58 59 60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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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.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
<b>Primary Subject Heading</b> :	Public health
Secondary Subject Heading:	Diagnostics, Gastroenterology and hepatology
Keywords:	Public health < INFECTIOUS DISEASES, World Wide Web technology < BIOTECHNOLOGY & BIOINFORMATICS, Hepatology < INTERNAL MEDICINE

# SCHOLARONE<sup>™</sup> Manuscripts

**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

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Word count: 3529 (max. 4000)

#### 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 groups 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

## 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.

#### INTRODUCTION

The World Health Organization (WHO) estimates that 58 million people globally have chronic hepatitis C virus (HCV) infection.<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>2-6</sup>CEAA 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 ,<sup>7</sup> with the burden of infection largely within the PWID population (numbering over 52,250 in 2017).<sup>89</sup> Prior to the implementation of a national elimination programme in 2015,<sup>78</sup> the seroprevalence in PWIDs in Georgia ranged from 50– 92%, depending on region.<sup>10-13</sup> The programme has been successful in identifying and linking people with HCV to care,<sup>8</sup> 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.<sup>14</sup> Here we describe the protocol of an randomized controlled trial (Georgian IRB Ethics Approval Number: IRB# 2021-049, clinicaltrials.gov: <u>NCT04961723</u>) 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**.

#### 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 Disease 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 I 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 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 1 ว

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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

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<sup>®</sup> 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.

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

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

1 2		
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12 13	Secondary	<u> </u>
14 15 16 17 18 19 20 21 22 23	To assess the impact of HCV self-testing on the number of HCV antibody positive individuals who are aware of their status	Nur the pos of t vs c
24 25 26 27 28 29 30 31 32 33	To assess the impact of HCV self-testing on linkage and completion of HCV RNA confirmatory testing in HCV antibody positive individuals	Nur the pos refe con inte
34 35 36 37 38 39 40 41 42 43 44	To assess the impact of HCV self-testing on treatment initiation in HCV RNA positive individuals eligible to start treatment	Nur the par the
46 47 48 49 50 51 52 53 54 55 56	To assess the acceptability and feasibility of HCV self- testing at baseline and after study participation. Information about knowledge, attitudes, and practices related to	Ana pro
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intervention groups compared with the control groups (margin 20%).	<ul> <li>and control groups will be compared (three comparisons):</li> <li>Arm 1 (intervention) vs. Arm 3 (control) for MSM,</li> <li>Arm 2 (intervention) vs. Arm 3 (control) for MSM</li> <li>Arm 4 (intervention) vs. Arm 5 (control) for PWID.</li> </ul>
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 <sub>pos</sub> 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.
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.
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 <sub>trt</sub> 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).
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 <b>Error! Reference source</b> <b>not found.</b> , if not stated otherwise] will be reported either in absolute numbers and
	the control groups (margin 20%). Number and estimate of the proportion of HCV antibody positive participants made aware of their status in the intervention vs control groups 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 Number and estimate of the proportion of HCV RNA positive participants who start treatment in the intervention vs control groups Analysis of survey responses using

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.

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

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.<sup>15</sup> 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.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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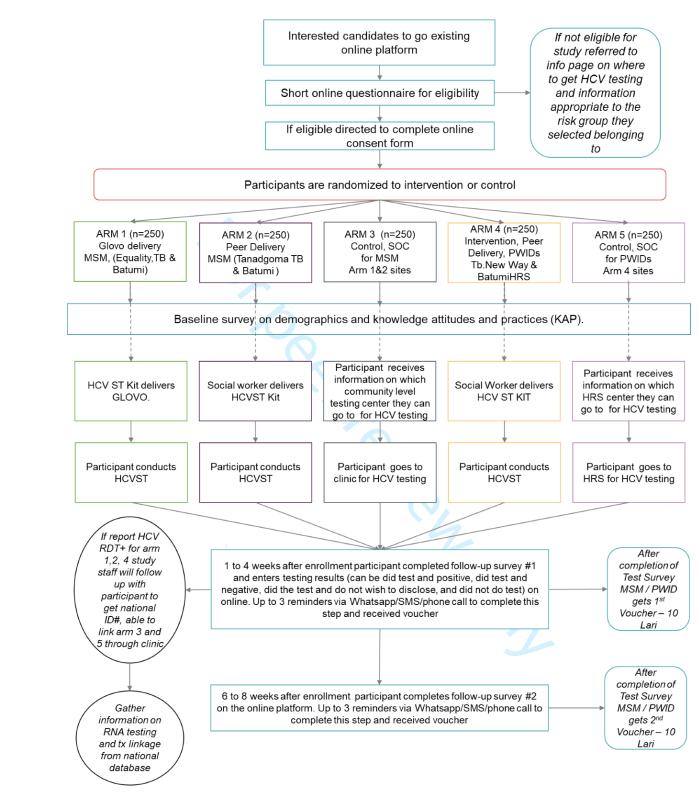
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# FIGURE LEGENDS

Figure 1. Study design

Figure 2. Social harms monitoring structure



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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3	Supplementary Appendix
4	Supplementary Annex 1 Study information form and informed consent form
5	Study mormation form and mormed consent form
6	Hepatitis C Study Information Sheet
7	Title of Study
8 9	Randomized controlled trial of home-based hepatitis C self-testing in key populations
9 10	in Georgia
11	Participating Organizations
12	NCDC, Equality Movement, Tanadgoma, Tbilisi New Way HRS, Batumi Imedi HRS, Foundation
13	for Innovative New Diagnostics
14	Introduction
15	Hepatitis C is a liver infection caused by a virus that can lead to serious liver damage, cancer,
16	and even death. You are being invited to take part in this study to help understand different
17	ways people can be tested for hepatitis C.
18 19	Purpose
20	The purpose of this study is to evaluate different models of hepatitis C testing <b>Study Procedures</b>
21	If you take part in the study, you will only have to sign the consent form, take two surveys, and
22	consider getting tested for hepatitis C. You will be randomly selected for testing models: a) to
23	either receive a hepatitis C testing kit delivered to your home or b) receive information about
24	how to get tested for hepatitis C at a local clinic or community center.
25	If you are selected for the hepatitis c self-test it is a simple procedure using oral fluids. If you
26 27	are selected for the hepatitis C self-test group you will either be placed in the group that gets the
28	hepatitis C self test delivered by Glovo delivery or be placed in the group that will have the test
29	delivered to your house by a peer outreach worker or a social worker
30	Your information will be reviewed by the study personnel and grouped with all other persons in
31	the study.
32	Benefits
33	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.
34 35	Risks
36	There is minimal discomfort with hepatitis C testing. There is a minimal risk that you could
37	encounter social harms from this study.
38	Framed in the study the observational team is set up to identify any social harm associated with
39	participation in the study and testing. They will give you recommendations and to get the
40	appropriate services as needed.
41 42	You can contact the study coordinator for the information how to contact this group (The phone
43	numbers will be provided by Arms)
44	Companyation and Costa
45	<b>Compensation and Costs</b> There are no costs to you for participation in this study. All participants will receive a phone
46	credit voucher of 10 GEL for completion of the first follow up questionnaire to enter test result
47	and another phone credit voucher of 10 GEL when the finish the second study survey. You will
48 49	receive the phone credits to the phone number that you provide on the online platform
50	approximately 7 days after you complete each survey. You will be offered hepatitis C testing but
51	are not required to be tested for hepatitis C to receive compensation.
52	Confidentiality
53	All information collected about you during the course of this study will be stored without any
54	personal identifiers. No one will be able to match you to your information. No one will be able to
55	determine your identity in the frame of the study. Only study personnel will have access to the
56 57	information.
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60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

## 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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3	Supplementary Annex 2
4 5	
6	PARTICIPANT FOLLOW-UP SURVEY #1
7	These forms will be previded to the participants in Coorgian language
8	These forms will be provided to the participants in Georgian language STUDY ID: automatically inputted and date and timestamped by the platform
9	SURVEY DATE: automatically generated/timestamped by the platform
10 11	
12	INFORMATION TO PARTICIPANTS
13	This questionnaire will be anonymized before being analyzed and your name will
14	never appear in the database. Your answers will be used to better understand hepatitis
15	C testing in Georgia.
16	
17	
18 19	SECTION A – STUDY TESTING AND FOLLOW-UP
20	A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
21	1. Yes
22	2. No
23	
24	A1ai. (if answered Yes to question A1, version of question for arm 3 and 5) What was the result?
25 26	1. Positive
26 27	2. Negative
28	<ol><li>Don't know, have forgotten</li></ol>
29	4. Do not want to disclose
30	
31	A1aii. (if answered Yes to question A1, version of question for arm 1,2 and 4) What was the result?
32	1. Positive
33 34	2. Negative
35	3. Test did not work
36	4. Don't know, could not read the test
37	5. Do not want to disclose
38	
39	A1b. (If answered No to question A1) If no, why not?
40 41	1. Did not want to test/was not interested
41 42	2. Forgot to get tested
43	3. Afraid of testing
44	<ol> <li>Did not have time</li> <li>Others, specify:</li> </ol>
45	5. Others, specify
46	
47	A1c. (If answered Yes for question A1, for arm 3 and 5 only) Where did you go to get the hepatitis
48 49	C test done?
49 50	(select from drop down list the name of the facility)
51	(For participants who live in Tbilisi)
52	1. Tbilisi Tanadgoma center
53	2. Tbilisi Equality movement center
54	3. Tbilisi New Way HRS
55 56	4. Tbilisi ID Hospital
56 57	5. Neo Lab clinic
57	3
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60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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3	6.	Hepa clinic
4	7.	Other:
5	1.	
6		
7	<i>_</i>	· · · · - · ·
8	(For participants	s who live in Batumi)
9		
	1.	Batumi Tanadgoma center
10	2.	Batumi Equality movement
11	3.	Batumi Imedi HRS
12	4.	Batumi ID hospital
13	 5.	•
14		Batumi Mary time hospital
15	6.	Other:
16		
17		
18		
19		
20	A1f. (If answered Negative	in question A1aii, for arm 1,2, and 4 only) If you had tested positive
21		think your next steps would have been?
22		To go to a community-based organization for more information and
23	advice	
24		
25	2.	To go to a healthcare clinic for a confirmation test
26	3.	To go to a hospital for a confirmation test
27	4.	I would not do next step
28	5.	Don't know
29	6.	Others, specify:
30	A1a (If answered test did n	ot work or Don't know in question A1aii, for arm 1,2 and 4 only) Have
31	you taken any further step t	
32		
33	1.	Yes, have gone to a community-based organization for more
34		ation and advice
35	2.	Yes, have gone to a clinic and asked for another test
36	3.	No, I have not made next step
37	4.	Others, specify:
38		
39	A1h. (If answered No in qu	estion A1g) If you do not made any next step, why not?
40	1.	Did not want to test/was not interested
41	2.	Forgot to get tested
42	3.	
43		Afraid of testing
44	4.	Did not have time
45	5.	Transportation was too expensive
46	6.	Others, specify:
47		
48		
49		
50	A2a (version of question fo	<i>r arm 3 and 5 group)</i> Did you ask anyone any question about process
51	of hepatitis C testing?	r ann o and o group, bid you ask anyone any question about process
52		Vac anling through the current efferred an adjust as relations
53	1.	Yes, online through the support offered on selftest.ge platform
54	2.	Yes, online through searching the internet
55	3.	Yes, person who performed the test
56	4.	Yes, friend or family member
57		
58		4
59		
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2	
3	5. Yes; others, specify:
4	6. No, I have not asked the question
5	,
6	A2b. (version of question for arm 1) Did you ask anyone any question about process of hepatitis
7	C testing?
8	1. Yes, online through the support offered on selftest.ge platform
9	2. Yes, online through searching the internet
10	3. Yes, friend or family member
11	4. Yes; others, specify:
12	5. No, I have not asked the question
13	5. No, i have not asked the question
14	ADD (version of evention for own 0 and 1) Did you call anyone any evention about honetitic
15	A2c. (version of question for arm 2 and 4) Did you ask anyone any question about hepatitis
16	C testing?
17	1. Yes, online through the support offered on selftest.ge platform
18	2. Yes, by asking the peer deliver who dropped of my test
19	<ol> <li>Yes, online through searching the internet</li> </ol>
20	<ol> <li>Yes, friend or family member</li> </ol>
21	5. Yes; others, specify:
22	<ol><li>No, I have not asked the question</li></ol>
23	
24	A3. (If answered Yes in question A1) How would you rate the hepatitis C testing you were offered
25	in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)
26	
27	Not very easy Average Very easy
28	How easy was the testing process? 1 2 3 4 5
29	
30	Not very convenient Average Very convenient
31	How convenient was the testing process? 1 2 3 4 5
32	
33 34	Not very private Average Very private
35	How private did you think the testing process was? $472345$
36	
37	Not very trustworthy Average Very trustworthy
38	How much do you feel you can trust the test results? 1 2 3 4 5
39	
40	
41	Not very secure Average Very secure
42	How secure did you feel during the testing process? 1 2 3 4 5
43	
44	Not very stressful Average Very stressful
45	How stressful was the testing process? 1 2 3 4 5
46	Not very easy Average Very easy
47	If you needed further care, how easy was it to access it? 1 2 3 4 5
48	Did not need it
49	
50	
51	A4. (If answered Yes in question A1) Did you feel you could understand the result of your test?
52	1. Yes
53	2. No
54	
55	A4ai. (If answered Yes in question A4, version of question for arm 1,2 and 4) What do you think
56	have helped you to understand the result of your test (select all that apply)?
57	

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 10 The printed instructions for use that came with the HCV self-test 1. 11 were not easy to understand 12 Video instructions on how to perform a self-test was not easy to 2. 13 understand 14 Communication with the selftest.ge team were not easy to 3. 15 understand 16 17 4. Others; specify: 18 19 A5. (If answered Positive, test did not work or Don't know in guestion A1aii) Did you feel you 20 knew what steps you needed to take to be further linked to hepatitis C care after you got the 21 result of your test? 22 1. Yes 23 2. No 24 25 A6. (If answered No in question A5) What do you think would have helped you to know what 26 steps you need to take to be further linked to care? 27 A list of clinics near me that provide HCV care with their contact 1. 28 information 29 More information on how community-based organizations near me 2. 30 could help me navigate how to be linked to care 31 A video explaining how I could get linked to care 3. 32 Others; specify: 4. 33 34 A7. In the future, where would you prefer to be tested for hepatitis C? 35 By myself at home 36 1. 37 2. At home with someone I trust 38 3. By myself at a healthcare clinic 39 4. In a community centre by community-based organization staff 40 5. In a healthcare clinic by a healthcare worker 41 6. In a pharmacy by a healthcare worker 42 7. No preference 43 8. Prefer not to get tested for hepatitis C 44 9. Other, specify: 45 46 A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and 47 instructions on how to do it? 48 1. Yes 49 2. No 50 3. Don't know 51 52 A8a. (If answered Yes in question A8) If yes, how often do you think you would test yourself? 53 1. More than once every 6 months 54 2. Once every 6 months 55 3. 56 Once a year 57 58 6 59 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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Page 26 of 34

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3	4. Once every 2 years
4	5. Don't know
5	6. Others, specify:
6 7	
8	A1d. (If answered Positive in question A1ai or A1aii) Have you taken further steps for hepatitis
9	C care after your positive test? Please select all that applies
10	1. Yes, have gone for confirmation test
11	2. Yes, have had doctor consultation and completed additional
12	testing
13	3. Yes, have started treatment
14	4. others, specify:
15	5. No, I do not plan to take further steps
16 17	A10 (If answard Vac have gone for confirmation test or Vac have completed further testing
17	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?
19	1. I was confirmed active chronic Hepatitis C (viremia)
20	2. I do not have active chronic hepatitis C (viremia)
21	3. Have not been told the results yet
22	4. Do not want to disclose
23	5. Others, specify:
24	
25	A1i. (If answered Yes, have gone for confirmation test or Yes, have completed further
26	testing and have started treatment in question A1d) Where did you go for this further hepatitis C
27 28	care?
28	(select from drop down list the name of the facility
30	
31	(For participants who live in Tbilisi)
32	1. Tbilisi ID Hospital
33	2. Neo Lab clinic
34	3. Hepa clinic
35	4. Other:
36	(For portionante urba liva in Datumi)
37 38	(For participants who live in Batumi) 1. Batumi Imedi HRS
39	2. Batumi ID hospital
40	3. Batumi Mary time hospital
41	4. Other:
42	
43	
44	SECTION B – RISK BEHAVIORS
45	
46 47	B1. How many times have you or your partner(s) used a condom during sexual contact in the last
47 48	month?
49	<ol> <li>I have not had sexual contact in the last month</li> </ol>
50	2. Always
51	3. Often
52	4. Sometimes
53	5. Never used
54	DO is the last month, have very taken and extended by and the 10
55	B2. In the last month, have you taken any substance by snorting it?
56 57	1. Yes
57	7
59	
59 60	For peer review only - http://bmiopen.bmi.com/site/about/quidelines.xhtml

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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4	Supplementary annex 3:
5	PARTICIPANT FOLLOW-UP SURVEY #2
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7	STUDY ID: automatically linked and date and timestamped by the platform
8 9	SURVEY DATE: automatically generated/timestamped by the platform
9 10	
11	INFORMATION TO PARTICIPANTS
12	This questionnaire will be anonymized before being analyzed and your name will
13	never appear in the database. Your answers will be used to better understand hepatitis
14	C testing in Georgia.
15	SECTION A – STUDY TESTING AND FOLLOW-UP
16 17	SECTION A - STODI LESTING AND TOLLOW-OF
17	A1. Did you complete the hepatitis C testing that was offered to you as part of this study?
19	1. Yes
20	2. No
21	
22	A1ai. (if answered Yes to question A1, version of question for arm 3 and 5) What was the result?
23	1. Positive
24	2. Negative
25 26	<ol><li>Don't know, have forgotten</li></ol>
20 27	4. Do not want to disclose
28	
29	A1aii. (if answered Yes to question A1, version of question for arm 1,2 and 4) What was the
30	result?
31	1. Positive
32	<ol> <li>Negative</li> <li>Test did not work</li> </ol>
33	4. Don't know
34 35	5. Do not want to disclose
36	
37	A1b. (If answered No to question A1) If no, why not?
38	1. Did not want to test/was not interested
39	2. Forgot to get tested
40	3. Afraid of testing
41	4. Did not have time
42	5. Others, specify:
43 44	
44	A1c. (If answered Yes for question A1 for arm 3 and 5 only) Where did you go to get the hepatitis
46	C test done?
47	(as last from show list the same of the facility)
48	(select from drop down list the name of the facility)
49	(For participants who live in Tbilisi)
50	1. Tbilisi Tanadgoma center
51	2. Tbilisi Equality movement center
52 53	3. Tbilisi New Way HRS
54	4. Tbilisi ID Hospital
55	5. Neo Lab clinic
56	6. Hepa clinic
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3	7. Other:
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6	(For porticipante who live in Potumi)
7	(For participants who live in Batumi)
8	1 Dotumi Tonodromo contor
9	1. Batumi Tanadgoma center
10	2. Batumi Equality movement
11	3. Batumi Imedi HRS
12	4. Batumi ID hospital
13	5. Batumi Mary time hospital
14	6. Other:
15	
16	
17	A1f. (If answered Negative in question A1aii, for arm 1,2, and 4 only) If you had tested positive
18	for hepatitis C, what do you think your next steps would have been?
19	1. To go to a community-based organization for more information and
20	advice
21	2. To go to a policlinic for a confirmation test
22	3. To go to a healthcare clinic for a confirmation test
23	4. I would not do next step
24	5. Don't know
25	
26	6. Others, specify:
27	
28	
29	A1g. (If answered test did not work or Don't know in question A1aii, for arm 1,2 and 4 only) Have
30	you taken any further step to get a second test done?
31	1. Yes, have gone to a community-based organization for more
32	information and advice
33	<ol><li>Yes, have gone to a clinic and asked for another test</li></ol>
34	3. No, I have not made next step
35	4. Others, specify:
36	
37	A1h. (If answered No in question A1g) If no, why not?
38	1. Did not want to test/was not interested
39	
40	2. Forgot to get tested
41	3. Afraid of testing
42	4. Did not have time
43	5. Test was too expensive
44	6. Others, specify:
45	
46	
47	
48	A2a. (version of question for arm 3 and 5 group) Did you ask anyone
49	any question about hepatitis C testing?
50	1. Yes, online through the support offered on selftest.ge platform
51	2. Yes, online through searching the internet
52	3. Yes, person who performed the test
53	4. Yes, friend or family member
54	5. Yes; others, specify:
55	6. No
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A2b. (version of question for arm 1) Did you ask anyone any question about hepatitis C testing? Yes, online through the support offered on selftest.ge platform 1. 2. Yes, online through searching the internet 3. Yes, friend or family member Yes; others, specify: 4. 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? 2 3 5 **-** 1 4 Not very private Average Very private How private did you think the testing process was? 2 5 3 4 1 Not very trustworthy Average Very trustworthy How much do you feel you can trust the test results? 1 2 3 5 4 Not very secure Average Very secure How secure did you feel during the testing process? 1 2 3 5 Not very stressful Average Very stressful How stressful was the testing process? 2 3 5 1 Not very easy Average Very easy If you needed further care, how easy was it to access it? 2 345 Did not need it 1 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)? The printed instructions for use that came with the HCV self-test 1. 2. Video instructions on how to perform a self-test was not easy to understand Communication with the selftest.ge team were not easy to 3. understand 11 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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 The printed instructions for use that came with the HCV self-test 1. were not easy to understand Video instructions on how to perform a self-test was not easy to 2. understand Communication with the selftest.ge team were not easy to 3. understand Others; specify: \_\_\_\_\_ 4. 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 More information on how community-based organizations near me 2. 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? By myself at home 1. 2. At home with someone I trust 3 By myself at a healthcare clinic 4. In a community centre by community-based organization staff In a healthcare clinic by a healthcare worker 5. In a pharmacy by a healthcare worker 6. 7. No preference Prefer not to get tested for hepatitis C 8. 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? More than once every 6 months 1. 2. Once every 6 months 3. Once a year 4. Once every 2 years 5. Don't know

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2	
3	6. Others, specify:
4	
5 6 7 8	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
9 10	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
11 12	test?
13	Please select all that applies
14	1. Yes, have gone for confirmation test
15	2. Yes, have had doctor consultation and completed additional testing
16	3. Yes, have started treatment
17	4. Others, specify:
18	5. No, I do not plan to take further steps
19	
20	A1e. (If answered Yes, have gone for confirmation test or Yes, , have had doctor consultation
21 22	and completed additional testing and have started treatment in question A1d) What was the
23	result of your confirmation test?
24	1. I have hepatitis C viremia
25	2. I do not have hepatitis C viremia
26	3. Have not been told the results yet
27	4. Others, specify:
28	Ati (If anoward Vap, have some for confirmation test or Vap, have completed further
29	A1i. (If answered Yes, have gone for confirmation test or Yes, have completed further
30	testing and have started treatment in question A1d) Where did you go for this further hepatitis C
31	care?
32	(select from drop down list the name of the facility
33	(For participants who live in Tbilisi) 1. Tbilisi ID Hospital
34	2. Neo Lab clinic
35 36	3. Hepa clinic
30 37	4. Other:
38	
39	(For participants who live in Batumi)
40	(For participants who live in Batumi)
41	
42	1. Batumi Imedi HRS
43	2. Batumi ID hospital
44	3. Batumi Mary time hospital
45	4. Other:
46	
47	SECTION B – RISK BEHAVIORS
48 49	
50	B1. How many times have you or your partner(s) used a condom during sexual contact in the last
51	month?
52	1. I have not had sexual contact in the last month
53	2. Always
54	3. Often
55	4. Sometimes
56	5. Never used
57	
58 50	13
59 60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
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	<ul><li>B2. In the last month, have you taken any substance by snorting it?</li><li>1. Yes</li><li>2. No</li></ul>
	<ul> <li>B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?</li> <li>1. Yes</li> <li>2. No</li> </ul>
	<ul> <li>B4. In the last month, have you injected unprescribed drugs?</li> <li>1. Once</li> <li>2. More than once</li> <li>3. Never</li> </ul>
S C F	B4a. ( <i>If answered Once or More than once to question B4</i> ) 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. ( <i>If answered Once or More than once to question B4</i> ) 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. ( <i>If answered Yes to question B4b</i> ) 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(fill in the number of people you shared with) 2