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Testing a persuasive health communication intervention (PHCI) for emergency department patients who declined rapid HIV/HCV screening: a randomised controlled trial study protocol

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ABSTRACT

Introduction Previous studies have shown that substantial percentages of emergency department (ED) patients in the USA recommended for HIV or hepatitis C (HCV) decline testing. Evidence-based and cost-effective interventions to improve HIV/HCV testing uptake are needed, particularly for people who inject drugs (PWIDs) (currently or formerly), who comprise a group at higher risk for these infections. We developed a brief persuasive health communication intervention (PHCI) designed to convince ED patients who had declined HIV/HCV testing to agree to be tested. In this investigation, we will determine if the PHCI is more efficacious in convincing ED patients to be tested for HIV/HCV when delivered by a video or in person, and whether efficacy is similar among individuals who currently, previously or never injected drugs.

Methods and analysis We will conduct a multisite, randomised controlled trial comparing PHCIs delivered by video versus in person by a health educator to determine which delivery method convinces more ED patients who had declined HIV/HCV testing instead to be tested. We will stratify randomisation by PWID status (current, former or never/non-PWID) to permit analyses comparing the PHCI delivery method by injection-drug use history. We will also perform a cost-effectiveness analysis of the interventions compared with current practice, examining the incremental cost-effectiveness ratio between the two interventions for the ED population overall and within individual strata of PWID. As an exploratory analysis, we will assess if a PHCI video with captions confers increased or decreased acceptance of HIV/HCV testing, as compared with a PHCI video without captions.

Ethics and dissemination The study protocol has been approved by the institutional review board of the Icahn School of Medicine. The results will be disseminated at international conferences and in peer-reviewed publications.

Trial registration number NCT05968573.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Adult emergency department patients who had declined routine HIV/hepatitis C (HCV) screening will be eligible for this investigation.
⇒ Participants, stratified by their injection-drug use (IDU) history, will be randomly assigned to receive a persuasive health communication intervention (PHCI) delivered either by video (with or without captions) or in person by a health educator.
⇒ Analyses will compare the efficacy of the two PHCI delivery methods in increasing acceptance of HIV/HCV screening, as stratified by participant IDU history.
⇒ The study will also perform an incremental cost-effectiveness ratio analysis to assist in assessing the value of video versus in-person delivery method of the PHCI.

INTRODUCTION

The US Centers for Disease Control and Prevention recommends that US emergency departments (EDs) conduct HIV and hepatitis C (HCV) screening.[1–4] A major impediment to the success of ED-based HIV/HCV screening in the USA is that a substantial percentage of ED patients recommended for testing or otherwise at risk for HIV or HCV,[5–12] or later diagnosed with these infections,[13–15] decline testing. However, there are no evidence-based behavioural interventions that successfully persuade ED patients who had initially declined HIV/HCV screening instead to agree to be tested.

To address this gap in evidence-based behavioural interventions, we developed, with stakeholder assistance (ED patients, ED medical staff and health educators), a persuasive health communication intervention (PHCI) designed to convince ED patients who had declined HIV/HCV screening to agree to be tested.[16] After creating the PHCI and subsequently conducting pilot testing of

it in the ED, we were concerned that the PHCI might not be as efficacious for people who inject drugs (PWIDs), a group who had not been a part of the stakeholders in the development of the PHCI. Because PWIDs are at higher risk of acquiring HIV/HCV, frequently receive care at US EDs, and should be offered HIV/HCV testing in EDs, it was important to be certain that the PHCI was as efficacious for current and former PWIDs as for those who never injected drugs (non/never PWIDs). To address this need, we enlisted the assistance of 10 current or former PWIDs receiving care at the Mount Sinai Beth Israel Hospital ED, a hospital that provides medical care to a community with a high prevalence of injection-drug use (IDU). These PWID ED patients provided feedback on how to ensure that the PHCI content not only would be acceptable and respectful to current and former PWIDs but also would convince those who initially declined HIV/HCV screening to be tested for these infections. The modifications included two insertions in the PHCI relevant to IDU, regarding the common modes of transmission and safe sexual and IDU practices to prevent transmission.

We also changed the order of two components of the PHCI, moving the component of the PHCI describing what would be lost by not getting tested prior to the component describing what could be gained by getting tested. We based this decision from feedback from the Mount Sinai Beth Israel ED PWID patients, our belief that this order of presentation might further increase the intervention's ability to convince people to be tested for HIV/HCV, and the fear appeal theory.[17] Fear appeal theory argues that a threat first needs to be considered, and then efficacy of action to take must be perceived in the face of that threat before effective action will be taken against that threat. Otherwise, attempts will be made to control fear by denying the legitimacy of the threat. In this case, the loss-framed messages arguably emphasise a threat, whereas the gain-framed messages arguably present the efficacy of the recommended action.

Challenges in delivering the PHCI could limit the widespread usage of the PHCI for routine ED HIV/HCV testing. Extant or external staff serving in the ED as HIV/HCV test counsellors, health educators or in a similar role could deliver the PHCI. However, most EDs do not have staff functioning in these roles, and when they do, likely do not have daily, full-day staff coverage. As a result, only patients presenting to EDs that have these staff and visit the ED when these staff are present could receive the PHCI. Therefore, we considered that the PHCI might be delivered instead by video. Videos have several potential advantages over in-person delivery of an intervention, including providing content in a uniform manner and enabling presentation of the intervention at any time and to multiple patients in parallel. To permit delivery of the PHCI by video, we prepared a video depicting two actors using the PHCI. One actor portrayed a physician delivering the PHCI, and the other actor portrayed an ED patient who had declined HIV/HCV testing. By the end of the PHCI video, the patient agrees to be tested for HIV/HCV.

When preparing the PHCI video, we engaged in a debate among the investigator team about the value of simultaneously displaying text summarising key points from the PHCI (i.e., captions, similar to closed captioning) as presented by the physician acting in the video. A potential advantage of captions in the video is that it might enhance viewer understanding of and reinforce the key points presented. On the other hand, the captions might distract viewers from listening to the dialogue as they attempt to read the key points. We concluded that evaluating the usage of captions versus no captions in the video delivery of the PHCI as an exploratory aim was a worthwhile additional goal for this project.

In this manuscript, we describe our multisite, randomised controlled trial (RCT) designed to evaluate the efficacy of the PHCI in convincing ED patients who initially declined HIV/HCV screening to agree to be tested for these infections. The RCT aims to evaluate whether the PHCI was more efficacious when delivered by video or in person by a health educator and whether its efficacy differed based on IDU history (current PWID, former PWID or never injected drugs (non/never PWID)). As an exploratory aim, the RCT will also assess whether or not the efficacy of the PHCI video is enhanced or diminished by captions displaying key points. In addition to examining the efficacy of PHCI, the RCT will also examine its cost-effectiveness. Although prior studies have concluded that ED-based programmes that screen for HIV or HCV are cost-effective,[18–20] there have not been studies examining the health economics of ED-based screening for both HIV and HCV, nor any that have evaluated ED-based behavioural interventions designed to increase HIV/HCV screening.[21]

Aims and objectives

The primary aims of this RCT are to determine which delivery form of the PHCI (video or in person by a health educator) persuades more adult ED patients who initially declined HIV/HCV screening to instead be tested for these infections (Aim 1); better persuades current PWID, former PWID or never/non-PWID ED patients who initially declined HIV/HCV screening to be tested (Aim 2); and has greater relative value overall and among current PWID, former PWID, and never/non-PWID ED patients, based on cost-effectiveness analysis (Aim 3). As an exploratory aim, we will also examine whether using a video with captions confers increased or decreased acceptance of HIV/HCV testing, as compared with a video without captions.

METHODS AND ANALYSIS

Trial design

This investigation is a three-strata (current PWID, former PWID and never/non-PWID), three intervention arms (video-delivered PCHI without captions, video-delivered

PCHI with captions or health educator-delivered PHCI) (1:1:1 allocation), parallel-design RCT. Randomisation to each intervention arm within strata occurs at the participant level separately at each study site, as opposed to randomisation to arms within strata across all study sites.

Trial population and setting

We will conduct this RCT at four EDs in The Mount Sinai Hospital Health System in New York, New York, USA (The Mount Sinai Hospital, Mount Sinai Morningside, Mount Sinai Queens and Mount Sinai West). Adult patients receiving medical care at these EDs who decline HIV/HCV screening will be potentially eligible for enrolment. RCT inclusion criteria are as follows (1): age≥18 years old; (2) speak English or Spanish; (3) able to provide informed consent for study participation; (4) not known to be coinfected with both HIV and HCV (per electronic health record (EHR) review and patient report); (5) not already participating in another HIV or HCV study; and (6) not been tested for both HIV and HCV within the prior twelve months (per EHR review and patient report).

Interventions

PHCI content

The final PHCI content is presented in five successive components: information, education, loss, gain and call to action. Figure 1 provides the PHCI content according to its seven components.

PHCI delivered by health educators

At Mount Sinai Health System EDs participating in the RCT, health educators, who are extant members of the ED staff, will deliver the PHCI in person to participants randomly assigned to that study arm. Health educators will receive 5 hours of role-play training with study staff in preparation to deliver the PHCI as part of the RCT. They will have laminated copies of the PHCI to refer to when delivering the PHCI to trial participants. Study staff or

Element	Content
Information	I'd like to encourage you to get tested for hepatitis C and HIV today. Testing is easy and fast. You'll get your test results quickly. If your test results show that you are infected, you'll have additional tests to confirm your diagnosis.
Education	Hepatitis C and HIV are infections that can spread from person to person through sex and injection drug use. Hepatitis C can cause liver damage and even liver cancer. HIV damages the body's immune system that protects us from diseases. When the immune system is damaged by HIV, it leads to AIDS. When someone has AIDS, they can become seriously ill. Getting tested is necessary because you might be infected with hepatitis C or HIV and not even know it.
Loss	What do you lose by not getting tested? If you don't get tested, you won't know if you have Hepatitis C or HIV. Not knowing if you're infected can be stressful. Plus, if you don't get tested today, you delay your chance to treat these infections now and become healthier. You'll also lose the chance to keep your loved ones and others from getting infected.
Gain	What do you gain by getting tested for hepatitis C and HIV? You'll know if you're infected or not. If you are infected, we can help you get highly effective treatment. There is a cure available for hepatitis C. Although there is no cure for HIV, people living with HIV who get treatment can expect to live as long as an average person. Getting tested today helps you take control of your health. It also encourages you to take necessary precautions, such as having safer sex and not sharing injection needles, to prevent spreading these infections to those close to you.
Common concerns	Everyone should be tested for hepatitis C and HIV, even if you don't believe you're at risk for these infections. Getting tested won't make you stay in the emergency department any longer. Your results will be kept strictly confidential. And no matter what your test results are, we'll continue to treat you with dignity and respect. If your test results do show that you are infected, we'll help you get effective treatment. You'll also get the support you need to cope with the challenges of having hepatitis C and HIV.
Patient questions	Do you have questions about the information I gave you or questions on why you should be tested for hepatitis C and HIV?
Call to action	We have quick and easy tests that you can have right now. Will you agree to be tested?

Figure 1 HIV/hepatitis C testing persuasive health communication intervention content in seven components: information, education, loss, gain, common concerns, patient questions and call to action.

a telephone-based translator will provide translation for Spanish-speaking participants for health educators not fluent in the Spanish language.

PHCI videos (with and without captions)

The PHCI video depicts two actors portraying an encounter in the ED in which a female physician delivers the PHCI to a male patient who has declined HIV/HCV screening. At the end of the video, the patient agrees to be tested for HIV/HCV. The English-language version of the video is 2.49 min in length, and the Spanish-language version is 3.14 min. For each language (English and Spanish), there are separate versions of the video with and without captions. The captions display key points of the PHCI as they are spoken by the physician in the video. Online supplemental 1 and 2 provide the video script by language and the captions. The videos are equivalent in content and in the portrayed setting of a clinical encounter in an ED, except for language and presence or absence of captioning. The same actors perform as physician and patient in all videos, speaking English or Spanish, as applicable to their respective videos.

Exemplification theory[22] and social cognitive theory[23] are the two behavioural theories that help explain how this design of the PHCI video enable it to be persuasive. Per exemplification theory,[22] viewing the physician and patient in this manner is effective because of the vivid and impactful nature of the personal interaction they demonstrate. According to social cognitive theory,[23] individuals are able to model behaviour through observational learning. The patient in the PCHI video demonstrates the behaviour we wish other patients to emulate—acceptance of HIV/HCV testing.

Study staff preparation for RCT

We will train study staff clinical research coordinators (CRCs) on the trial procedures prior to study initiation. CRCs will engage in at least 40 hours of didactic instruction and role-playing on identifying potential study participants, verifying study eligibility, providing informed consent, enrolling participants and gathering and securing study data. We will also conduct a brief pilot study at one of the participating Mount Sinai Health System EDs to further train CRCs in their duties, as well as finalise study procedures before commencing the RCT. We will directly observe CRCs as they recruit and enrol participants and conduct the study procedures. We will provide retraining of CRCs, as needed.

RCT procedures

Participant selection

As part of routine practice at the Mount Sinai Health System EDs participating in the RCT, ED nurses initiate HIV/HCV screening for all adult patients able to provide consent. Nurses indicate in the EHR which patients declined screening. Adult ED patients who declined HIV/HCV screening are the target population for this investigation. CRCs will review the EHRs of patients present in the ED during data collection periods and determine which patients declined HIV/HCV screening and are otherwise potentially study eligible, per study eligibility criteria. The CRCs will approach those whose EHR the triage nurses noted had declined HIV/HCV screening and appear to meet study eligibility criteria to confirm their study eligibility. For those confirmed as study eligible, the CRCs first will verify that they had in fact declined HIV/HCV screening and then continue study procedures according to the outcome of that verification process (figure 2):

1. Patients who verify having declined HIV/HCV screening: the CRCs will explain the purpose and steps involved in the RCT to those who verify that they had declined HIV/HCV screening at ED triage and ask them to consent to participate. For patients who agree

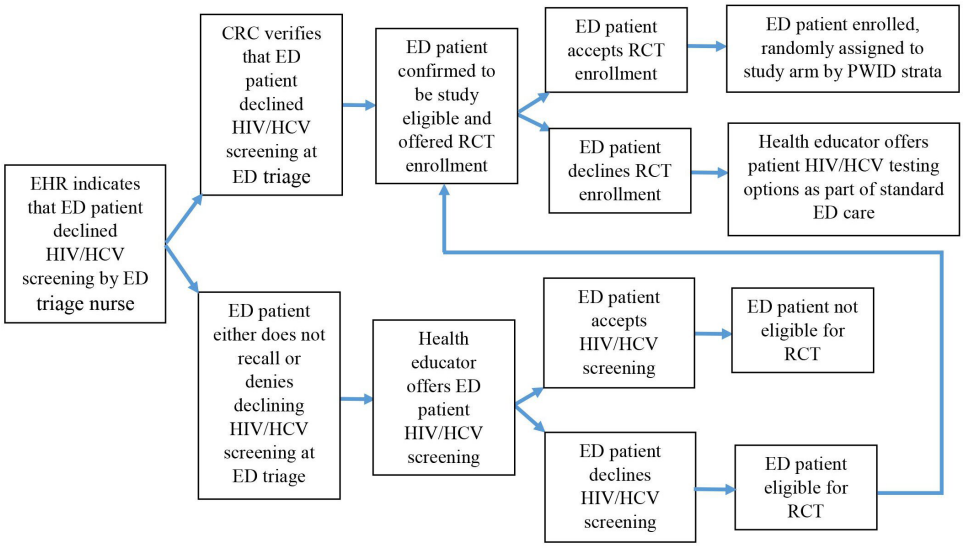

Figure 2 Verification of declination of HIV/HCV screening to confirm study eligibility. CRC, clinical research coordinator; ED, emergency department; EHR, electronic health record; HCV, hepatitis C; PWID, people who inject drug; RCT randomised controlled trial.

to participate in the RCT, the CRCs will proceed with study enrolment. For those who decline to participate in the RCT, the CRCs will thank those patients for their time. The health educator will approach those patients who decline participation in the RCT, not as part of a study, but as part of the ED's routine practice to encourage them to be tested for HIV/HCV. The health educators will inform them about their HIV/HCV testing options, in the ED or elsewhere. Such patients may elect to be tested for HIV/HCV in the ED not as part of the study. We will monitor how often this outside of the RCT testing occurs.

2. Patients who do not verify having declined HIV/HCV screening: CRCs will determine through further discussion with patients who do not verify that they had declined HIV/HCV screening at ED triage whether they either (1) do not recall being offered HIV/HCV screening or (2) did not in fact decline HIV/HCV screening. For the ED patients who do not recall being offered screening, the CRCs will coordinate with the health educator who will present/represent the HIV/HCV screening offer to the patient. For the patients who then after this offer decline screening, the CRCs will follow the procedures outlined above for those who verified having declined HIV/HCV screening (i.e., offering enrolment in the RCT). Health educators will otherwise proceed with the ED's routine practice for those who indicate they wish to be tested and therefore are ineligible for the RCT.

The CRCs will record on the study tablet computers the demographic characteristics of all ED patients whose EHRs were reviewed for study eligibility. They will record the number of ED patients screened for study eligibility, reasons for study ineligibility, HIV/HCV testing acceptance or declination and acceptance or declination of the invitation to participate in the RCT and reasons for declining.

Enrolment procedures

CRCs will obtain verbal informed consent for participation in the first portion of the RCT, which involves delivery of the PHCI and limited data gathering via the study questionnaire from participants without personal identifiers. As part of the informed consent process, CRCs will notify participants that they will be asked in private about their IDU history, and per their responses, they will be assigned to one of three strata in the RCT: (1) current PWIDs, (2) former PWIDs or (3) never/non-PWIDs. We will use questions about IDU that we adapted from the WHO's Alcohol, Smoking, Substance Involvement Screening Test and our prior research:[18 21] "I would like to ask you if at any time in your life if you injected any drug for non-medical use, such as heroin, cocaine, crystal meth, steroids or other drugs. For this question, I am not asking you about vaccinations or drugs you injected or received for medical treatment, such as insulin. Have you ever injected drugs for non-medical use?" If yes: "When was the last time you injected drugs?"

Because asking about IDU could be perceived by PWIDs as stigmatising, the question about IDU will be posed privately along with the explanation that their answer will be used solely for study assignment. Prior to posing this question, the CRCs will review the EHR for mention of current or former IDU. If the participant denies IDU yet their EHR mentions it, the CRC will politely ask, "OK. I just want to check. Did you ever inject drugs? Your medical record mentions that you might have at one time." Unless the EHR definitively indicates current or prior IDU (e.g., skin abscesses related to IDU), the participant's self-described IDU status will be used for cohort assignment.

Randomisation procedures

After obtaining informed consent, the CRCs will randomly assign participants (1:1:1 allocation) to either the (1) video-delivered PCHI arm without captions, (2) video-delivered PCHI arm with captions or (3) health educator-delivered PHCI arm, as stratified by IDU history (current PWID, former PWID or never/non-PWID). We will use the computer-based random selection service offered by Interrand, Inc. for randomisation assignment. Interrand will use block randomisation with varying block sizes, not known to the research staff, to ensure equal assignment to the intervention arms as stratified by IDU history at each study site. CRCs will retrieve the random assignment through the company's weblink after each study enrolment.

Intervention delivery

After obtaining informed consent from participants, the CRCs will initiate delivery of the PHCI according to each participant's randomisation assignment:

1. Video-delivered PHCI arms (video with or without captions): the CRCs will introduce the participant to the health educators and briefly remind the participant what will be occurring. The health educator will show the assigned PHCI video (video with or without captions, based on random assignment) on a tablet computer. Participants will be provided with earbuds to listen to the video's audio components. The CRCs will observe for protocol deviations (e.g., if the participant did not watch the video) and record the time elapsed during video watching (noting interruptions for patient care or other reasons).
2. Health educator-delivered PHCI arm: the CRCs will introduce the participant to the health educator and briefly remind the participant of what will be occurring. The health educator will deliver the PHCI per the study protocol. The CRCs will record the time elapsed in delivering the PHCI (noting interruptions for patient care or other reasons).

After the PHCI (whether video delivered or health educator delivered), the health educator will ask each participant whether he/she will agree to be tested for HIV, HCV or both infections. Participants eligible for testing for HIV and HCV may elect to be tested for only one of these infections, although testing for both will be offered.

Participants already known to be infected with either HIV or HCV or who were tested within the past year for either infection will not be asked to be tested for that infection. All participants regardless of being tested will afterwards proceed with the participant questionnaires.

Participant HIV/HCV risk questionnaire and intervention persuasiveness questionnaires

At the end of their involvement in the study and, if tested, prior to receiving their HIV/HCV test results, all participants will be asked to complete the study's brief participant questionnaires. These questionnaires ask participants about their common risk factors for HIV and HCV, reasons for accepting or declining HIV/HCV screening after the PHCI and how much the PHCI persuaded them to be tested for HIV/HCV (online supplemental 3). To ensure privacy when participants answer these questions and increase the veracity of their responses, the HIV/HCV risk factor questionnaires will be self-administered via audio-computer assisted self-interviewer using headphones on tablet computers.

Recording of HIV/HCV counselling time/effort

For Aim 3 (cost-effectiveness determination), CRCs will observe and record data on the time and effort expended by health educators performing HIV/HCV screening, as well as delivering the PHCI either in person or via video.

HIV/HCV testing procedures

Mount Sinai Health System EDs offer all patients HIV/HCV testing with verbal consent as permitted by New York State law. In addition to verbal consent for HIV/HCV testing, participants who agree to be tested will be asked to provide written consent to permit study staff to: (1) obtain each participant's final test results, (2) solicit and record multiple means of contact information to assist in linkage to care efforts, and (3) facilitate linkage to care for those whose test results are positive. Written consent will only be requested from participants who agree to be tested for HIV/HCV and will be obtained after they complete the participant HIV/HCV risk questionnaire and intervention persuasiveness questionnaire.

As is standard care at the study site hospitals, HIV/HCV testing is performed from phlebotomised samples using the Abbott Alinity HIV Ag/Ab Combo assay and HCV antibody test. Testing is performed at the hospital's central laboratory. ED health educators provide post-test counselling and support for patients whose test results are positive. These patients are provided with linkage to follow-up care at HIV or HCV specialty clinics in the Mount Sinai Health System or other patient-preferred locations.

Data analysis

Enrolment summary and comparison of participants at baseline

Using the CONSORT approach,[24] we will report the ED patients whose EHRs were reviewed for possible study inclusion and those approached, enrolled, consented and randomly assigned to the three PHCI delivery arms per IDU history strata. We will compare demographic characteristics among (1) study eligible versus not study eligible patients based on EHR review, (2) study eligible versus not study eligible patients through the CRCs' in-person assessment, (3) patients randomly assigned to the three PHCI delivery arms, stratified by IDU history, and (4) patients who completed the study (i.e., completed all parts of the study through the participant HIV/HCV risk questionnaire and intervention persuasiveness questionnaire) versus dropped out. We will compare groups and assess the adequacy of the randomisation procedure using Pearson's X^2 or Fisher's exact test for categorical variables and Student's t-test for normally distributed or Wilcoxon's test for non-normally distributed continuous variables. If necessary, a regression analysis or propensity score-weighted analysis will be performed to adjust for chance imbalances in covariates between study arms.[25] A two-tailed, α=0.05 significance level will be used for all analyses.

Primary aims analysis

Intention-to-treat analyses will be used. HIV/HCV screening acceptance will be compared using two-sample tests of binomial proportions by study arm (PHCI delivered by health educator versus PHCI videos combined—with or without captions) independent of IDU history cohort strata (Aim 1).

Although we are planning for three strata based on IDU history (current PWID, former PWID or never injected drugs (non/never PWID)), we anticipate that current PWIDs comprise a smaller subpopulation of our ED patients than former PWIDs, and a much smaller subpopulation than non/never PWIDs. Therefore, we expect that we will need to combine the current and former PWIDs into one population for the Aim 2 primary analysis. We will, however, endeavour to recruit as many current PWIDs as former PWIDs to permit comparing these groups to each other and to non/never PWIDs.

To assess HIV/HCV screening acceptance across IDU history cohorts (Aim 2), we will calculate testing acceptance for the PHCI videos combined (with or without captions, collapsed into one study arm) versus PHCI delivered in person by the health educators for current/former PWIDs (p1) and never/non-PWIDs (p2), as well as their difference (Δ=p1 p2) and its one-sided 95% CI (C, ∞). We will use an absolute difference of 5% as the non-inferiority margin. We will conclude that the screening acceptance is non-inferior for current/former PWIDs as compared with never/non-PWIDs if the lower limit CI is greater than 5%.

Secondary and exploratory analyses

To help understand which delivery form of the PHCI works better among certain subpopulations, we will conduct logistic regression analyses, with HIV/HCV screening acceptance as the outcome. We will use the Least Absolute Shrinkage and Selection Operator method to assist us with model selection by identifying important predictor variables. We will conduct similar secondary

analyses comparing PHCI study arms (independent of and within each IDU history cohort) by HIV and/or HCV infections identified, and infected persons linked to care. We will consider log-linear models for comparing prevalence for these secondary analyses based on sample size of outcomes. In an exploratory analysis, we will repeat the primary analyses separating the two video study arms (video with or without captions) and comparing them to each other and to the health educator arm.

Cost-effectiveness analysis

We will evaluate the cost-effectiveness of the PHCI from the local health system perspective, an established method,[26–28] to estimate the value of PHCI screening for HIV/HCV. The first step is a detailed microcosting analysis to estimate all costs associated with implementing the intervention, including staff time, materials and other costs. The second step will compare the costs to the effectiveness outcomes of the intervention, including test uptake and new cases detected.

Intervention microcosting

We will collect detailed data on each intervention step: first, costs of starting up the intervention; next, costs associated with the day-to-day operations of each intervention arm in current PWIDs, former PWIDs and never/non-PWIDs. We will estimate (1) average time spent conducting the intervention (screening by counsellors and setting up the video), (2) actual salaries paid to those delivering the health educator-based PHCI, (3) cost of any additional services used by intervention staff and (4) any additional training or other differential costs. We will estimate these costs for each arm and additionally stratify by IDU status. All costs estimates will be calculated in 2024 dollars with 95% CIs.

Endpoints for cost-effectiveness analyses

The endpoints of the trial serve as the measures of effectiveness used in the cost-effectiveness analysis: (1) persuading individuals to agree to HIV/HCV screening, and (2) detecting HIV/HCV infections that would otherwise be missed. Next, we will use generalised linear models (GLMs) to estimate the predicted number of persuaded individuals and subsequent detected infections as a function of the intervention arm, with 95% CIs around each estimate.[29]

Cost-effectiveness

The comparative performance of the interventions will be measured as the relative difference in the cost for each effectiveness outcome attained: persuading a patient to be screened for HIV/HCV after previously declining, and detecting an additional case of HIV/HCV attributable to the intervention. We will calculate a cost per test administered and cost per case identified by dividing the total cost for each intervention by the total number of HIV/HCV tests agreed to and cases of HIV/HCV detected. Next, to compare the relative value of each intervention when both are available, we will calculate the incremental cost-effectiveness ratio for each intervention from the perspective of a local health system. We will divide the difference in predicted mean costs in each

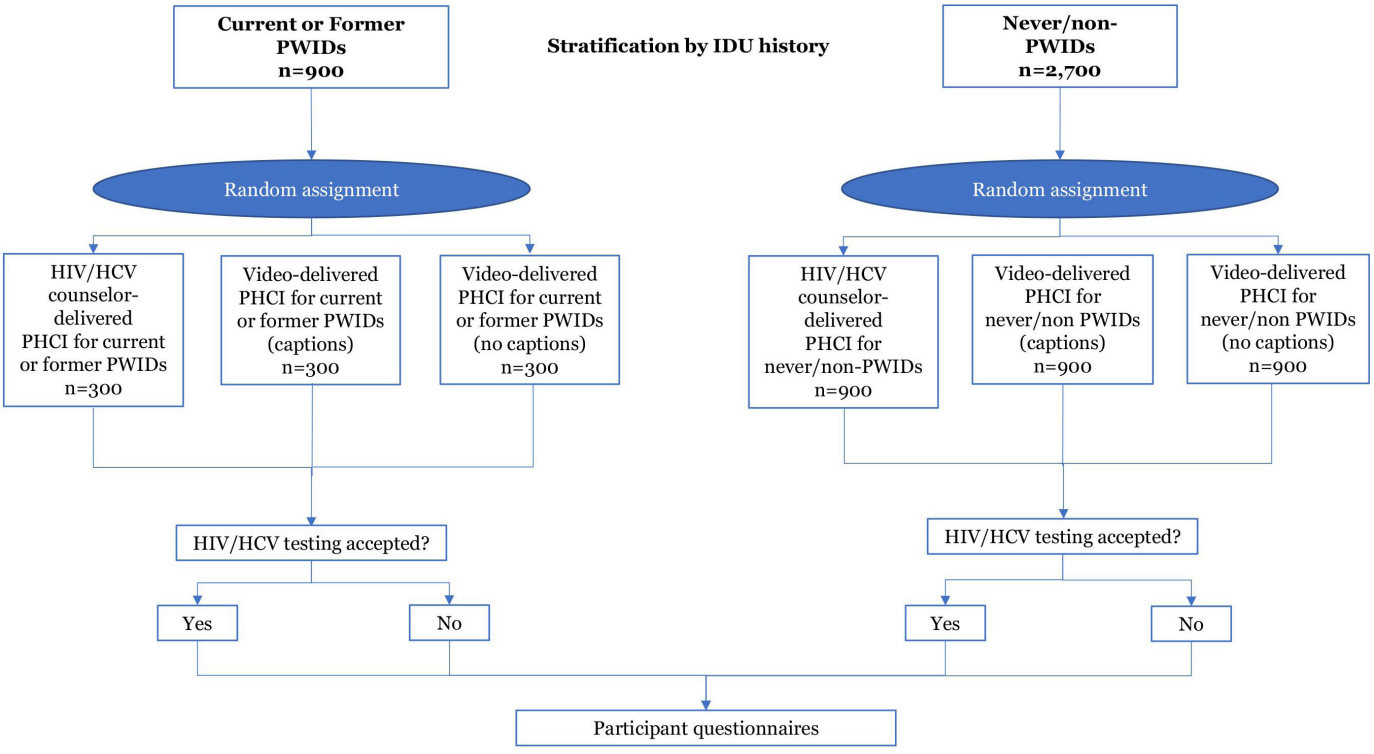

Figure 3 Expected RCT sample size by PWID strata and study arm. HCV, hepatitis C; IDU, injection-drug use; PHCI, persuasive health communication intervention; PWID, people who use injection drugs; RCT, randomised controlled trial.

arm by the difference in the predicted mean effectiveness measures.

Sensitivity analyses

We will conduct sensitivity analyses to ensure the robustness of our analytic approach and to improve generalisability. First, we will assess the goodness of fit of the distributional and link assumptions in our GLM predictive models with Park and Pregibon link tests.[30] Next, we will account for uncertainty in our estimates by assessing the cost-effectiveness across the 95% CIs of the predicted mean cost and effectiveness estimates, using a tornado diagram to summarise uncertainty within each intervention arm IDU subgroup. Finally, we will evaluate the impact of local IDU prevalence on total intervention cost and effectiveness by conducting analyses over a range of IDU prevalence from 0% to 100%, leveraging our predictive model of effectiveness and IDU-specific microcosting estimate.

Sample size

Our sample size estimates will be predicated on addressing Aims 1 and 2. Our R34 pilot study found ≈30% HIV/HCV testing acceptance in the PHCI video arm. For the Aim 1 analysis, to compare HIV/HCV screening acceptance by PHCI delivery method (video versus in-person health educator) without regard to IDU history/PWID strata, we will assume an effect size of at least a 10% absolute difference between the PHCI video arms combined (with or without captions, collapsed into one arm) (30%) versus the health educator-delivered PHCI study arm (20%) (α=0.05, power 0.80%). We will need at least 300 participants/study arm (PHCI video arms combined, in-person health educator arm) to have adequate power for the study to test for this effect size. To permit the exploratory comparisons by type of PHCI video (with or without captions) versus the in-person health educator study arm, we will recruit equal numbers of participants into each of the PHCI video arms. Thus, we will recruit n=300 in each of the PHCI video arms, producing a combined n=600 participants in the two PHCI video arms (figure 3).

To assess HIV/HCV screening acceptance (PHCI video arms combined versus PHCI delivered in person by health educator) across PWID cohorts (Aim 2), we will use a non-inferiority comparison, which requires a larger sample size. However, as noted previously, given that current PWIDs comprise a smaller population of ED patients than former PWIDs and never/non-PWIDs, we are limited by the anticipated sample size for this group. We will anticipate combining the current and former PWIDs into one group for these analyses, unless recruitment for current PWIDs exceeds our expectations. To accommodate a non-inferiority comparison across IDU history cohorts, we will recruit threefold more never/non-PWIDs than current/former PWIDs. With a minimum sample size of n=300 current/former PWIDs (combined PWID groups) and n=900 never/non-PWIDs, we will have adequate sample size to compare HIV/HCV screening uptake across these IDU history cohorts (power 0.80, non-inferior margin 5%).

Patient and public involvement

As described in the introduction section, patients and other stakeholders were involved in the development of the PHCI,[16] and PWID assisted in the revision of the PHCI to ensure its appropriateness for PWID. Otherwise, patients and the public are not involved in the study design, execution or analysis. There are no plans to disseminate the study findings directly to participants.

ETHICS, MONITORING AND DISSEMINATION

The study protocol has been reviewed and approved by the institutional review board of the Icahn School of Medicine (STUDY-22-01162). A data safety monitoring board required by the funding agency (National Institute on Drug Abuse) was formed. There are no plans for interim analyses, stopping guidelines or auditing procedures. Knowledge translation and dissemination of study findings will occur through presentations at national and international conferences, lectures for clinicians and health professionals and publications in peer-reviewed journals. The RCT dataset will be available after planned analyses are complete.

Trial status

The RCT has begun enrolment. Enrolment began on 25 January 2024 and is expected to end by 8 December 2027 unless extended.

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Contributors RCM is responsible for the overall content as guarantor, accepts full responsibility for the finished work and the conduct of the study, had access to the data and controlled the decision to publish. NH, MAC, TL, JM, EC, RS and BW contributed to the protocol development and revision and to the production of the protocol manuscript.

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