Protocol Title:
Understanding and Intervening with Heavy Drinking Among Patients with HIV and HCV: Clinical Trial

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7649

Clinic:
Leiber Research Clinic

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Cover Sheet

Choose ONE option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes.
I am submitting an annual continuation without modifications

Division & Personnel

Division

What Area Group does the PI belong to?
Epidemiology & Population Science
What Division/Department does the PI belong to?
Division of Translational Epidemiology
Within the division/department, what Center or group are you affiliated with, if any?
Substance Dependence Research Group

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York

State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.

consultant: Scott Friedman, MD, Mount Sinai

Application for Continuation of Research

Status

Current Status of Study:
All research interventions were completed. Only data analysis is ongoing.

Summary of Experiences to Date

Please provide a summary of scientific progress of the study and the experience of research participants, to date. This requirement is designed to allow for the investigator and the IRB to reassess the study's risks and benefits in terms of developments in the field, changing practice patterns, and new IRB policies and procedures.
Recruitment and data collection are now complete. We had 45 individuals consent into the trial and 31 participants complete one or more study sessions. We have just completed data collection. Although we would have liked to continue recruitment to reach our n=60 goal, we were delayed in finding a clinic and launching data collection, had delays in recruitment efforts, and were only able to recruit about half of the desired sample size. The data have not yet been analyzed, but anecdotally, participants have told us that they have found the study to be helpful in decreasing their drinking. Although these comments often came from intervention participants, even some control participants expressed appreciation for the study, which got them to think about their drinking. We are requesting this continuation for data analysis only.

Funding

Have there been any changes in funding status since the prior approval?
No
Have the principal investigator and other investigators made all required disclosures of financial interest in the study sponsor/product?
Yes

Summary

Have there been any study findings, recent literature, or untoward events occuring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation?
Yes
Please indicate how the new information affects the study's risk/benefit analysis and comment on whether consent form changes are necessary.
COVID-19 would raise risks for in-person data collection. Because of this, all study sessions have been conducted remotely, consistent with NYSPI guidelines, in response to the pandemic. No participant

activities have been done in-person since the NYSPI directive to shift to remote data collection. Data collection is now complete. No changes to the CF are indicated given that risks were minimized through a shift to remote research and because data collection is now complete.
Have there been any serious adverse events (serious and/or unanticipated problems involving risks to subjects or others at this site which occured in the past year)?
No
Have all study staff with a significant role in the design or implementation of the human subject components of this study received required training in human research subject protections?
Yes
Is the study covered by a certificate of confidentiality?
Yes
Certificate expiration date (mm/dd/yyyy)
NA

Overall Progress

Approved sample size
5 formative / 5 pretest / 80 trial
Total number of participants enrolled to date
5 formative / 7 pretest enrolled (5 completed baseline) / 45 trial
Number of participants who have completed the study to date
5 formative / 5 pretest / 31 trial (31 completed 1 or more study appts, 14 withdrawn/discontinued before baseline as detailed below, data collection now closed)
Have there been any significant deviations from the anticipated study recruitment, retention or completion estimates?
Yes
Describe actions taken or planned to address these problems.
For the trial we anticipated consenting n=80 participants of which n=60 would complete baseline. However due to delays in finding a clinic and in recruitment, and the impending end-of-grant, we were only able to consent n=45 into the study, of whom n=31 completed at least one study session. Although we made every effort to maximize our recruitment, we were unable to recruit more in the timeframe of grant funding.
Comments / additional information
The K23 grant was originally funded through 1/30/20, was extended to 6/30/20 in a first NCE, and is now extended until 9/30/20 through a second NCE. Although this will allow for time for data analysis, it does not accommodate continued recruitment.

Sample Demographics

Specify population
formative research - HIV/HCV co-infected heavy drinkers
Total number of participants enrolled from this population to date
5 consented / 5 engaged in study sessions
Specify population #2
pretest - HIV/HCV co-infected heavy drinkers
Total number of participants enrolled from this population to date

7 consented / 5 engaged in study sessions
Specify population #3
trial - HIV/HCV co-infected heavy drinkers
Total number of participants enrolled from this population to date
45 consented / 31 engaged in study sessions
Gender, Racial and Ethnic Breakdown

Formative Research Participants (n=5)

	African Am/Black	Hispanic/Latino	White	Other/Multiple	Total
Male	5	0	0	0	5
Female	0	0	0	0	0
Transgender	0	0	0	0	0
Total	5	0	0	0	5

Pretest Participants (n=7)
* One participant discontinued study.
** One participant was withdrawn from the study.

	African Am/Black	Hispanic/Latino	White	Other/Multiple	Total
Male	6*	0	0	0	6
Female	1**	0	0	0	1
Transgender	0	0	0	0	0
Total	7	0	0	0	7

Trial Participants (consented n=45)
* n=5 discontinued from study, n=2 withdrawn from study.
** n=2 discontinued from study, n=1 withdrawn from study.
*** n=1 discontinued from study, n=3 withdrawn from study.

	African Am/Black	Hispanic/Latino	White	Other/Multiple	Total
Male	24*	6***	2	0	32
Female	11**	1	0	0	12
Transgender	1	0	0	0	1
Total	36	7	2	0	45

Summary of Current Year's Enrollment and Drop-out

Number of participants who signed consent in the past year
45
Did the investigator withdraw participants from the study?
Yes
Circumstances of withdrawal:
Participants consent into the study before completing final eligibility screening; their participation in the study is contingent on passing this final screening. Therefore, meeting exclusion criteria at this point requires withdrawing them from study participation.

Trial: One participant was disqualified from the study after health information request confirmed that participant did not have a history of Hepatitis C infection (an inclusion criterion), despite participant's initial self-report. Five participants were disqualified based on high-risk exclusion criteria, as assessed after consent per protocol (n=4 were at risk for alcohol withdrawal and n=1 affirmed anti-psychosis medication). Risk was assessed according to protocol, appropriate resources were provided, and no emergency referrals were needed.
Did participants decide to discontinue study involvement?
Yes
Circumstances of discontinuation:
Trial: Eight participants consented into the study but could not be scheduled for their baseline appointment despite repeated efforts to contact them and in many cases repeated no-shows. Aside from these 8 participants who did not attend baseline and the 6 withdrawn from the study (enumerated above), all participants completed baseline. Efforts were made to retain participants following baseline, but some were lost to follow-up because they either could not be reached, no-showed, or chose not to attend. However, 31 completed at least one study session. Data collection is now closed.

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

✓ Psychiatric Assessment
✓ Collection of Biological Specimens
✓ Psychotherapy Trial
✓ Audio or Videotaping
✓ Internet-based Data Collection or Transmission

Population

Indicate which of the following populations will be included in this research

✓ Adults
✓ Individuals with HIV/AIDS

✓ Substance Users

Research Support/Funding

Will an existing internal account be used to support the project?
No
Is the project externally funded or is external funding planned?
Yes
Select the number of external sources of funding that will be applicable to this study

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?
Yes
Select one of the following
The grant/contract is currently funded
Source of Funding
Federal
Institute/Agency
National Institute on Alcohol Abuse and Alcoholism
Grant Name
Understanding and intervening with heavy drinking among patients with HIV and HCV
Grant Number
K23AA023753
Select one of the following
Single Site
Business Office
RFMH
Does the grant/contract involve a subcontract?
No

Study Location

Indicate if the research is/will be conducted at any of the following
✓ NYSPI
✓ Other Columbia University Medical Center Facilities
This protocol describes research conducted by the PI at other facilities/locations
No

Lay Summary of Proposed Research

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Among patients with HIV, especially those also infected with HCV, heavy drinking is associated with significant risks to health. However, little is known about how to best intervene with co-infected heavy drinkers, a particularly high risk group for whom targeted intervention has not been developed. Therefore, I propose to test a newly developed drinking-reduction intervention for patients with both HIV and HCV, which combines components of successful interventions developed for HIV and for liver disease patients.

We will recruit 80 HIV/HCV co-infected drinkers from HIV primary care in order to ensure 60 eligible and enrolled trial participants, which should yield an adequate final sample size of 45 participants completing the study. Participants will be randomly assigned to an intervention or control condition, while ensuring that equal numbers of individuals with alcohol use disorder are assigned to each condition. The intervention condition will receive brief in-person sessions with a counselor and will be asked to use a smartphone app daily to keep track of drinking and other health behaviors for two months. The intervention sessions will include information about HIV, HCV and alcohol, and the counselor will give the participant information about their liver function and alcohol use to try to motivate them to drink less. The control condition will simply be asked to drink less and will be given pamphlets with general information on HIV, Hepatitis C, and drinking from educational websites on HIV/HCV co-infection. We will then evaluate whether the intervention condition was more effective at reducing drinking than the control condition.

Background, Significance and Rationale

Background, Significance and Rationale
Patients with HIV have high rates of heavy drinking and alcohol problems, and face serious medical consequences from this use. Some research suggests that alcohol can increase viral load and decrease CD4 (cluster of differentiation 4; e.g., T helper cells) count, although this literature is conflicting. It also increases risk for liver damage, as does hepatitis co-infection, making liver disease a leading cause of death for patients with HIV. Patients with alcohol problems are also less adherent to antiretroviral therapy (ART), and some intentionally skip ART to try to avoid hepatotoxic effects of combining ART with alcohol. Some studies also show alcohol's interference with other aspects of engagement in HIV care.

Approximately 25% of HIV-infected patients are co-infected with HCV. Although HCV alone can lead to liver damage, HIV accelerates this progression, as does heavy drinking. Further, individuals with HCV who drink heavily may be less likely to access HCV medication. Despite serious health risks associated with alcohol use, some research suggests that HIV/HCV patients drink more than HIV mono-infected patients.

Growing recognition of alcohol-related harm in HIV patients has stimulated the development of drinking reduction interventions for HIV-infected heavy drinkers, some of which have been successful. Some interventions for HCV mono-infected drinkers and liver disease patients have also shown promise. Yet we know of no successful interventions that target HIV/HCV co-infected patients, a group with elevated drinking and particularly high consequences of drinking. Interventions for HIV patients address HIV health but do not address liver fibrosis, which is an urgent threat to survival for co-infected patients. Interventions for liver disease patients discuss fibrosis to motivate drinking reduction, but neglect HIV and important

topics such as ART adherence. Given that the drinking interventions for HIV and liver disease patients both effectively target drinking in medical patients, albeit through attention to different medical issues, such approaches can and should be integrated to provide an intervention that best meets the needs of patients with both HIV and HCV, a particularly high-risk group.

Specific Aims and Hypotheses

Specific Aims and Hypotheses

The aim is to pilot test a newly adapted intervention for HIV/HCV co-infected patients that integrates features from existing interventions for HIV patients and liver disease patients.

Primary Hypothesis:
At end-of-treatment (60 days) and 30 days after treatment (90 days), mean drinks per drinking day will be lower in the intervention (Clinician's Guide + HealthCall for HIV/HCV) than in the educational control condition.
Secondary Hypotheses:
At end-of-treatment (60 days) and 30 days after treatment (90 days), other measures of alcohol use (drinking frequency, maximum quantity, frequency of binge drinking and intoxication) with be lower, and readiness to change drinking and self-efficacy to change drinking will be higher, in the intervention (Clinician's Guide + HealthCall for HIV/HCV) than in the educational control condition.

Exploratory analyses:
Determine whether intervention efficacy differs between these with and without alcohol dependence, and between those with and without alcohol use disorder.

Description of Subject Population

Sample #1

Specify subject population
Formative Research - HIV/HCV co-infected heavy drinkers
Number of completers required to accomplish study aims
5
Projected number of subjects who will be enrolled to obtain required number of completers
5
Age range of subject population
18-99 (inclusive)

Sample #2

Specify subject population
Pretest - HIV/HCV co-infected heavy drinkers
Number of completers required to accomplish study aims
5
Projected number of subjects who will be enrolled to obtain required number of completers
5
Age range of subject population
18-99 (inclusive)

Sample #3

Specify subject population
Trial - HIV/HCV co-infected heavy drinkers
Number of completers required to accomplish study aims
We will recruit 80 participants to ensure that 60 meet eligibility criteria and agree to participate. A final sample size of 45 (assuming 75% retention from 60 enrolled patients) is adequate for detecting large differences (d=0.85) with 80% power.
Projected number of subjects who will be enrolled to obtain required number of completers
80
Age range of subject population
18-99 (inclusive)

Gender, Racial and Ethnic Breakdown

I will recruit co-infected patients regardless of gender and race/ethnicity. We recently conducted a brief survey at the CUMC/NYP HIV clinic, which provides data on the expected demographic breakdown of the co-infected patients at this clinic. For those with HIV/HCV, 80% were male, 18% female, and 2% transgender, a realistic approximation of what to expect for this study. Of these co-infected participants (who were invited to endorse as many racial/ethnic identities as applied), 56% identified as Black, 26% as Hispanic, 15% as White, 10% as Native American, and 8% as Other, again a realistic approximation of what we can expect in the proposed study. We are also expecting to recruit co-infected patients through RecruitMe, Craigslist, and newspaper advertisements which will expand our recruitment catchment area to the entire NYC area and reflect greater diversity.

This largely mirrors nationally representative data published by the Centers for Disease Control and Prevention (CDC) on HIV-infected injection drug users (a close approximation of the HIV/HCV co-infected population), wherein 19% were female and 81% male, with a very similar racial/ethnic breakdown (48% Black, 27% Hispanic/Latino, 20% White, 5% other/multiple races). Therefore, we can have confidence that our results will be generalizable to the HIV/HCV co-infected population at large.

Description of subject population

The following table describes the types of participants that will be a part of each sample population. Each type of participant reflects the four recruitment methods we will use to identify patients for this study (see Recruitment Procedures).

Recruitment Method	Types of Participants	Study Population		
		Formative Research	Pretest	Trial
(1)	Patients who present to the CUMC/NYP clinic for care and are identified as potentially eligible by the recruiter and referred to the research team for formal screening	X	X	X
(2)	Patients identified as potentially eligible by the recruiter from a database (of previous participants interested in clinic research) and referred to research team for formal screening	X	X	X
(3)	Interested patients who call the research team directly for formal screening after referral from flyers or advertisements.	X	X	X
(4)	Interested patients in the NYC area who self-refer through RecruitMe and agree to be contacted by the research team for formal screening.			X

Recruitment Procedures

Describe settings where recruitment will occur

Participants will be recruited in the following settings:

(1) at an HIV primary care clinic where they are receiving treatment (Comprehensive Health Program, New York Presbyterian Hospital, Harkness Pavilion, 180 Fort Washington, 6th Floor, New York, NY 10032) and

(2) through advertisement on RecruitMe, an online based recruitment tool, where interested potential participants can provide their contact information to the research team for formal screening.
- A flyer will be distributed at various HIV clinics and social service agencies and a listing will be posted on Craigslist as well to direct patients to this RecruitMe posting.
- We will also advertise in the AM New York and Metro New York newspapers in effort to increase visibility and expand recruitment efforts further in the NYC area (please see attached advertisement text).
- A Google ad will also be run to target potential participants who search for key words related to our study (please see attached google ad example).

How and by whom will subjects be approached and/or recruited?

We will use four recruitment methods to identify potentially eligible participants as described below. Once identified, all potentially eligible participants will be formally screened by the research coordinator.

An existing study recruiter who is employed by the Columbia University Department of Infectious Diseases (Christian A. Vivar Ramon, uni=cav2138 through 07/26/19; replaced by Megan K. Urry, uni=mku2102) regularly screens patient medical records as they present to the clinic for care and approaches them for various studies being conducted in the Comprehensive Health Program. The recruiter is able to approach patients about their interest in various studies by speaking with participants directly or speaking with the patient's providers who gauge the patient's interest before the recruiter meets with them for screening.

For our study the recruiter will maintain a tracking list of all potentially eligible co-infected HIV and Hepatitis C clinic patients which will ensure our recruitment efforts are comprehensive and not redundant. The recruiter will maintain this list through preliminary screening of clinic medical records and will use it to track patients who:
- have already screened for the study,
- have already enrolled in the study,
- have yet to be screened and have an upcoming scheduled clinic visit (cross referenced with the clinic's scheduling list) where they can be screened.
- have yet to be screened, but do not have an upcoming scheduled clinic visit.

(Recruitment method 1) - *patients who present at the clinic for care, where one of two scenarios will occur:*

- The recruiter will approach potential participants by review of their medical records and gauge their interest by briefly explaining the study. If they are interested, the potential participant will fill out a *Consent-to-Contact Form* that will be given to the research coordinator. The recruiter will then call the research coordinator, who will conduct a brief phone screen *(see script)* immediately to determine eligibility, or call the participant within one week to complete screening if preferred. If eligible, the research coordinator will coordinate a time with the participant to obtain informed consent and finalize screening as detailed further in the Inclusion/Exclusion Criteria.
- The recruiter will manage a calendar using the tracking list described to record when potentially eligible co-infected patients are scheduled for a clinic visit. The calendar will contain no PHI so that the research coordinator can use it to determine when she should speak with scheduled patient's provider. When speaking with the provider, the research coordinator will request that the provider gain the patient's verbal consent to allow the research coordinator to meet with the patient for an on-site screening during their visit. If verbal consent is obtained, the research coordinator will explain the study, complete the brief phone screen in-person, and schedule the informed consent either directly afterward or at mutually agreeable time. If a patient misses their scheduled visit, the recruiter will mail out an opt-in letter (described in recruitment method 3) to gauge the patient's interest instead.

(Recruitment method 2) - *patients from the database of previous participants of clinic research who have agreed to be contacted for future studies*

- The recruiter is also able to maintain a database of patients who have participated in other studies and have agreed to be contacted for future studies at the clinic. The recruiter will review the database and identify patients who may be potentially eligible.
- The recruiter will use the *Recruiter Phone Script and Verbal Consent* form to call the patient and assess their interest in the study.
- If interested, the recruiter will gain verbal consent from the potential participant using the form and provide it to the research coordinator to conduct a brief phone screen *(see script)* to determine eligibility
- If eligible, the research coordinator will schedule an informed consent appointment at the clinic and then finalize screening.

The recruiter may also provide interested potential participants the contact information for research study staff, so that interested potential participants may call the research coordinator directly for initial phone screening after obtaining verbal consent.

(Recruitment Method 3) - Referrals via flyers in CUMC/NYP clinic

- In addition, we will advertise the study to patients through flyers in the waiting room of the CUMC/NYP clinic.
- We will also utilize an opt-in letter (see attached) which will be mailed out by the recruiter to patients who may be potentially eligible, but do not have a scheduled upcoming clinic visit where they can be screened in-person. We will include a copy of the Key Information page of the Informed Consent so that patients have a chance to learn more about the study and if interested, may contact the research coordinator directly for screening.
- We will also distribute the flyers during staff meetings where we will describe the study to make the staff aware that some of their patients may be participating and invite referrals.
- Patients who self-refer from these methods will call the research coordinator, whose number is provided on the flyer.
- During the call the research coordinator will request verbal consent and conduct a brief phone screen *(see script)* to determine eligibility.
- If eligible, the research coordinator will schedule an informed consent appointment at the clinic and then finalize screening.

(Recruitment Method 4 - for trial only) - *RecruitMe - web-based advertisement to patients in NYC metro area*

- If they are found eligible, the potential participant will provide their contact information (name, email, phone number).
- Once contact information is obtained, the research coordinator will call the participant and request verbal consent using the *RecruitMe Phone Screening and Script* to conduct a brief phone screen to determine eligibility.
- If the potential participant is found eligible, they will be scheduled for an informed consent appointment at the NYSPI offices and will finalize screening.
- Those who call the research coordinator directly and who are not CUMC/NYP patients, will also be directed to the study's website to complete prescreening through RecruitMe.

- Flyers will be distributed to various HIV clinics and social service agencies in the NYC area to inform potentially eligible participants of the study and to direct them to our RecruitMe posting. Permission from sites will be obtained and documented to the IRB prior to posting. If requested, we will visit the clinics and agencies/organizations to speak with providers about the study to help increase its visibility. We will also allow providers to include information about our study and flyer in announcements and newsletters they produce and publish as part of their outgoing materials. Additionally we will allow providers to post our flyers at their agencies and clinics where they would be accessible to interested potential participants who would be directed on how to screen further for eligibility.
- In addition to the flyer distribution, we will post a listing on Craigslist to advertise recruitment for our study. The listing will direct interested potential participants to visit RecruitMe or to call directly to complete screening (please see attached Craigslist listing example).
- To further maximize our recruitment efforts, we will also place advertisements in the AM New York and Metro New York newspaper and place targeted Google ads in an effort to reach our target population.
- We will also include the research team's phone number in the flyer, newspaper advertisements, Craigslist listing, and Google ad which will allow potential participants to call us directly for screening, in order not to exclude those without internet access and/or the computer literacy required to use RecruitMe. We will follow the "RecruitMe Phone Screening and Script" for such participants and will conduct risk assessment according to the RecruitMe protocol for outside patients (not affiliated with CUMC/NYP).

How will the study be advertised/publicized?

Please see above for our recruitment process, including recruitment through an official recruiter at the CUMC/NYP clinic, use of flyers, advertisements in the newspapers, opt-in letters, and referrals from providers. The study will also be advertised on the internet through RecruitMe, a web-based recruitment tool, to reach patients of other clinics who are eligible in the NYC area, as described above.

To inform potential participants of the RecruitMe advertisement, we will post flyers (see attached) in various HIV clinics and agencies throughout the NYC area as well as a listing in the volunteers section of Craigslist.org, targeted Google ads, and advertisements in the AM New York and Metro New York newspapers. See attached confirmations from each approved location:

* *Hep Free NYC* (https://hepfree.nyc/category/research/) – a network of providers in NYC dedicated to improving health outcomes for people at risk for or living with Hepatitis B and C

* *Callen-Lorde Community Health Center*
- Callen-Lorde: 356 West 18th St, New York, NY 10011
- Callen-Lorde Bronx: 3144 3rd Ave, Bronx, NY 10451
- Thea Spyer Center: 230 West 17th St, New York, NY 10011

* *Montefiore Medical Center - The Center for Positive Living/Infectious Diseases Clinic*
- Family Care Center, 3rd Floor 3444 Kossuth Avenue Bronx, NY 10467

** Cornell Clinical Trials Unit*
- Chelsea Clinic: 53 West 23rd Street, 6th Floor New York, NY 10010
- Uptown Clinic: 525 East 68th Street, Baker 24 New York, NY 10065

** Alliance for Positive Change*
- The Alliance Headquarters: 64 W. 35th St, 3rd Floor, New York, NY 10001
- The Alliance CASA Washington Heights: 2036 Amsterdam Ave, New York, NY 10032
- The Alliance Keith Haring Harlem Center: 315 East 104th St, East Harlem, NY 10029
- The Pelham Grand: 1870 Pelham Parkway South, Bronx, NY 10461
- The Alliance Luis & Lillian Outreach Center: 150 First Avenue, New York, NY 10009
- The Alliance Lower East Side Harm Reduction Center: 25 Allen St, New York, NY 10002

Do you have ads/recruitment material requiring review at this time?
Yes
Does this study involve a clinical trial?
Yes
Please provide the NCT Registration Number
NCT03652675

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
No

Inclusion/Exclusion Criteria

Name the subject group/sub sample
Trial - HIV/HCV co-infected heavy drinkers (PRIMARY SAMPLE: see below for modifications used in formative and pretest work)
Create or insert table to describe the inclusion criteria and methods to ascertain them

Please note: The trial will be the primary sample used to assess intervention efficacy of this study. The study start up consisting of the formative research and pretest used modifications of this primary criteria as explained below.

	Inclusion Criteria:	Determined by:
(1)*	Age 18 through 99 (inclusive)	*Recruitment method 1 & 2*: Recruiter who will check patients' medical chart *Recruitment method 3 &4*: Research coordinator at time of phone screen
(2)*	HIV infection	
(3)*	Ever been diagnosed with HCV infection (regardless of treatment status; including active or remitted infection)	

(4)	Recent (last 12 months) liver panel results available	*Recruitment method 1 & 2*: Recruiter may note status of (4) if available *All methods*: research coordinator will query at time of phone screen .
(5)	During prior 30 days, ≥4 drinks in one day at least once**	*All methods:* Research coordinator at time of phone screen
(6)*	Can speak and read in English	
(7)*	Current and regular HIV care in the NYC metro area	

*Items (1), (2), (3), (6), and (7) will also be determined at prescreening for participants enrolled through RecruitMe.
**We define heavy drinking as 4+ drinks (regardless of gender), following the precedent of a recent drinking reduction trial in HIV primary care (Hasin et al., 2013, PMID: 23432593).

We do NOT require prior drinking reduction or cessation as an inclusion criterion. Requiring participants to cut down or stop drinking to be eligible for the study defeats the purpose of the study, which is to provide an intervention to help participants make this change. The intervention uses screening and brief intervention to increase motivation, desire, and effort to decrease drinking among those who are not help-seeking but who are at high risk for drinking-related harm. Participants will be informed that this study is designed to help them drink less; therefore, they can choose not to participate if they find this disagreeable.

Create or insert table to describe the exclusion criteria and methods to ascertain them

	Exclusion Criteria:	Determined by:
(1)	Participation in ongoing HealthCall study at Montefiore Hospital	*All methods*: Research coordinator at time of phone screen will ask about their participation in that research study.
(2)	Potential participant has definite plans to leave the greater New York metropolitan area during study period	*All methods:* Research coordinator who will ask if they have definite plans to leave the NYC area in the next four months at time of phone screen.
(3)	Potential participant is psychotic, suicidal, or homicidal	*Method 4:* Research coordinator and PI at time of phone screen. *All methods*: All participants who provide informed consent also complete a brief electronic high-risk screening. The research team member will review these results in-session to determine risk status (described further below).
(4)	Potential participant is at-risk for developing alcohol withdrawal symptoms	*All methods*: Research team member who will conduct a modified CIWA-Ar assessment if participant reports regular heavy drinking (see below).

To determine (3) participants will be assessed through a high-risk screening and the research team will take appropriate steps to ensure that all potential participants can be referred immediately to care if they identify having psychotic, suicidal, or homicidal behaviors.

Potential participants identified through RecruitMe (recruitment method 4) will complete high risk screening twice:

1. At time of phone screening to minimize risk of including at-risk participants. Potential participants will only be invited to schedule an informed consent session if they pass screening. *2. At time of informed consent* to ensure that such participants do not have any recently developed risk symptoms. If these participants report being at risk, they will be promptly referred to the PI who will be on-site.
Unlike participants recruited directly from the CUMC/NYP HIV clinic, which is within the CUMC campus where the NYSPI offices are located, participants identified through RecruitMe have established HIV care elsewhere outside of this campus. It will be important to ensure that participants identified through RecruitMe are managed immediately if they report risk symptoms because it will be logistically difficult for the research team to provide hands-on, immediate referral to their providers, such as is the case for participants recruited directly from the clinic (please see further below for details). Participants identified from RecruitMe will be informed during phone screening that they will be asked questions to assess whether they may be in danger to themselves or others and if so, a referral to emergency or crisis services may be made.

Participants identified through recruitment method 1, 2, or 3 will also be patients of the CUMC/NYP clinic. If they report risk after completing screening at time of informed consent, the research staff member will immediately alert clinic staff about ineligible participants due to suicidal/homicidal ideation or psychosis, so that these issues can be appropriately managed. This risk assessment will be conducted at the CUMC/NYP clinic, allowing for prompt and immediate referral. The clinic has a same day "walk- in" provider available for emergency referrals Monday-Friday (when recruitment will occur), as well as dedicated mental health providers including a psychiatrist and social workers. We will utilize these resources in the event of an emergency during the screening assessment and will also speak with the participant's primary provider if possible

The following screening questions consisting of items from The Structured Clinical Interview for DSM (SCID) Psychotic Screen module and Addiction Severity Index (ASI) items for suicide (also adapted for homicide), will be asked of participants to determine this high-risk status during the screening following the informed consent. The steps described below detail the procedures that will take place in case a participant identifies such risk.

PSYCHOSIS:		
Question:	In the past 12 months, did a doctor or other health professional tell you that you had schizophrenia or a psychotic illness or episode?	In the past 12 months, has a doctor or other health professional given you medication for schizophrenia or a psychotic illness or episode?
Score:	0 = No	0 = No

	1 = Yes	1 = Yes
SCORING/MANAGEMENT:		
Participant identified from CUMC/NYP clinic (recruitment method 1,2,3)	*In-person high risk screen following informed consent:* An affirmative response to either item will exclude the participant from the study and require referral to the clinic.	
Participant identified from RecruitMe (recruitment method 4)	*At time of phone screen:* If a participant answers "Yes" to either items above, the research coordinator will inform the PI immediately and encourage the participant to contact their treating provider about any questions or concerns or to call 911 in case of an emergency. If the potential participant is clearly presenting psychotic symptoms and appears at risk during the call, the PI will speak with the participant and conduct a 911 three-way call to ensure that they are connected to emergency crisis services immediately. *In-person high risk screen following informed consent:* An affirmative response to either item will exclude the participant from the study. If the participant is at immediate risk and presents with active psychotic symptoms, the staff member conducting the session, will inform the PI immediately who will confirm risk and participant will be walked over to the Comprehensive Psychiatric Emergency Program/Department @ CUMC - 630 West 168th Street New York, NY 10032 for immediate care. If participant is not at immediate risk or does not present with psychotic symptoms, they will be provided crisis referrals and encouraged to call NYC Well or their provider for further care.	

SUICIDE:	
Item:	Choose the one statement that best describes the way you have been feeling during the past 2 weeks including today.
Score:	Statement:
0	I don't have any thoughts of killing myself
1*	I have thoughts of killing myself but I would not carry them out
2*	I would like to kill myself
3*	I would kill myself if I had the chance
SCORING/MANAGEMENT:	
Anything above a 0 will require a discussion with the research staff member, who will gather more information to determine the participant's ideation and intent, and who will draft a clinical	

note documenting this discussion, outcome, and action taken.		
Participant identified from CUMC/NYP clinic (recruitment method 1,2,3)	*In-person high risk screen following informed consent:*	
	1*	Individuals endorsing a 1 but who clearly demonstrate no intent will be allowed to continue in the study but will also be referred to the clinic providers. Individuals endorsing a 1 but who verbally state intent will be excluded from the study and referred to their providers.
	2*	Individuals who endorse a 2 will be referred immediately to their provider, and the PI will be notified immediately of this occurrence. The participant will be excluded from the study unless the research coordinator and provider agree that the participant demonstrates no intent.
	3*	Individuals endorsing a 3 will be excluded from the study, referred immediately to their provider, and the PI will be notified immediately of this occurrence.
Participant identified from RecruitMe (recruitment method 4)	*At time of phone screen:* If a participant scores a (1) (2) or (3) they will be ineligible, and staff will inform the PI immediately. PI will determine if participant is at immediate risk of harming themselves by confirming if they have current thoughts and intent to carry out the act. If so, the PI will conduct a three-way call to NYC Well (Crisis Intervention) 1-888-692-9355. If the participant sounds to be in immediate danger, a three-way call to 911 emergency services will be made instead by the PI. If a participant presents as having thoughts of self-harm, but is not at immediate risk (does not have current thoughts or intent), the participant will be encouraged to call NYC Well (Crisis Intervention) on their own to be connected to care.	
	In-person high risk screen following informed consent:	
	1*	Individuals endorsing a 1 but who clearly demonstrate no intent will be allowed to continue in the study but will also be referred to the PI. If participant does not have intent, they will be encouraged to seek further care from their provider or encouraged to call NYC Well and provided with referrals. Individuals endorsing a 1 but who verbally state intent will be excluded from the study and referred immediately to the PI for an in-person discussion and the participant will be walked over to the Comprehensive Psychiatric Emergency Program/Department for immediate care.
	2*	Individuals who endorse a 2 will be referred immediately to the PI for an in-person discussion and excluded from the study unless the PI agrees that the participant demonstrates no intent. If intent is present, the research staff member will escort the participant to immediate care as described above.
	3*	Individuals endorsing a 3 will be excluded from the study, referred immediately to the PI and the research staff member will escort the participant to immediate care as described above.

HOMICIDE:	
Item:	Choose the one statement that best describes the way you have been feeling during the past 2 weeks including today.
Score:	Statement:
0	I don't have any thoughts of killing anyone
1*	I have thoughts of killing someone but I would not carry them out
2*	I would like to kill someone
3*	I would kill someone if I had the chance
SCORING/MANAGEMENT:	
Identical to the scorning/management of the suicidality question for all recruitment methods.	

If participants are found to be eligible following the high-risk screening, they will be assessed for criterion (4) where we will follow the example set by previous studies using HealthCall in the research group. We will use an initial gateway question to assess regular heavy drinking followed by a modified CIWA-Ar instrument to assess alcohol withdrawal symptoms in the past 30 days to determine if the participant may be at such risk during participation in the intervention ("In the past 30 days, did you drink 4 or more drinks a day, on 8 or more days?"). The following steps and procedures will be taken below.

SCORING/MANAGEMENT– An affirmative response, requires the participant to be assessed using the CIWA-AR instrument (modified to measure symptoms in the past 30 days). Participants who have a score of 10 or more and report having 2 or more co-occurring symptoms will be ineligible and referred to seek alcohol detox. Participants recruited from the CUMC/NYP clinic, will be brought to the attention of their providers, while participants identified through RecruitMe will be encouraged to speak to their providers and given a referral guide for alcohol treatment services. Participants who do not meet this exclusion will be eligible to participate in the study.

Inclusion/Exclusion Criteria #2

Name the subject group/sub sample
Formative Research - HIV/HCV co-infected heavy drinkers - Sample 1
Create or insert table to describe the inclusion criteria and methods to ascertain them

All inclusion criteria described for the trial participants apply to the formative research participants except for criterion (4). Liver panel results are not needed in order to get participants' feedback on the intervention content. Formative research phase participants are not enrolled in the trial itself.

Create or insert table to describe the exclusion criteria and methods to ascertain them

All exclusion criteria described above for the trial participants apply to the formative research participants, except for criteria (1) and (4).
- Formative research participants can be included regardless of their previous participation in HealthCall, given that their outcomes will not be used to determine intervention efficacy.
-This criteria (4) was introduced later in the study for additional participant protection.

Inclusion/Exclusion Criteria #3

Name the subject group/sub sample
Pretest - HIV/HCV co-infected heavy drinkers
Create or insert table to describe the inclusion criteria and methods to ascertain them
All inclusion criteria described for the trial participants (sample 3) apply to pretest participants (sample 2).
Create or insert table to describe the exclusion criteria and methods to ascertain them
All exclusion criteria described for the trial participants apply to the pretest participants except for criterion (4), which was introduced later in the study for additional participant protection.

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers
Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)
No
Waiver or alteration of consent
Yes
Waiver of documentation of consent
Yes
Waiver of parental consent
No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?
No
Describe procedures used to obtain consent during the screening process

We have requested a waiver for the study recruiter to obtain verbal consent from potential participants, identified through the database (recruitment method 2), to provide their contact information to the study staff (described in the recruitment procedures) so that the research coordinator may conduct a brief phone screen. We have previously requested a waiver for this brief phone screen conducted by the research coordinator to determine eligibility for participants recruited through methods 1 and 2. Participants recruited

through methods 3 and 4 do not require such a waiver as they are considered self-referrals where the participant contacts the research coordinator directly to screen further for the study.

Describe Study Consent Procedures

The study recruiter will screen potential participants' medical records (recruitment method 1) as they appear at the clinic for care or (recruitment method 2) through the database described in the recruitment procedures. For potential participants identified through recruitment method (1) the recruiter will approach potentially eligible participants and explain the study, have the participant complete a *Consent-to-Contact Form*, and call our research coordinator for those who are interested. Additionally, screening may also take place on-site at the clinic if providers gain interested potential patient's verbal consent to have the research coordinator meet them for screening. The research coordinator will ask several screening questions by phone (if applicable) (see Inclusion/Exclusion criteria section) and will also ask for voluntary demographic information. If likely eligible, the research coordinator will come on site to the clinic, obtain written informed consent, and then conduct the final screening for risk (psychosis, suicidality, homicidality, alcohol withdrawal symptoms), providing further referrals if needed. This will provide the final determination for eligibility. This screening/consent session will take place the day of the participant's appointment if possible, at a time convenient for the participant and provider, in an available office in the clinic. If the referral cannot be made on that day, a later appointment will be scheduled for screening/consent to be conducted at the clinic. For recruitment method (2), the recruiter will use the *Recruiter Phone Screen and Verbal Consent* (see script) to call the potential participant, assess their interest in the study, and obtain verbal consent to allow the research coordinator to contact the potential participant and conduct the phone screen described above (or the potential participant can call the research coordinator directly for the phone screen). If likely, eligible, the research coordinator will schedule the potential participant for an appointment at the clinic and will obtain written consent and conduct final screening for risk (psychosis, suicidality, homicidality, alcohol withdrawal symptoms) for final determination for eligibility as described above.

Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Consent Form

Justification for Waiver or Alteration of Consent

Waiver of consent is requested for the following

Waiver of consent is requested for (1) the verbal consent documented by study recruiter allowing research coordinator to contact potential participant for brief phone screening, (2) the brief phone screening conducted by the research coordinator after the potential participant is identified by the recruiter through medical records.

Explain why your research can not be practicably carried out without the waiver or alteration

(1) Waiver for *Recruiter Phone Script and Verbal Consent (used for recruitment method 2)*
This waiver is required because the role of the CUMC recruiter is limited to only recruitment and referral, after which further screening can only be conducted by this NYSPI study team. This waiver will allow the

recruiter to obtain verbal consent over the phone from potential participants identified through the database (described in the recruitment methods) so that the research coordinator can contact them for further screening. This further screening will be conducted by phone and requires the waiver of consent described in (2).

(2) Waiver for *Phone Screening and Script* (*waiver applicable for recruitment method 1 and 2*)
The recruiter will identify potentially eligible participants by their medical records, and will introduce the study and assess interest. The recruiter works for the clinic in this screening capacity and is not assigned formal research activities for this study (such as completing the screening process or obtaining informed consent). The research coordinator is responsible for these research tasks, but is located in another building and will not be immediately available, especially because the recruiter will be approaching potential participants during brief pockets of time (i.e., before their appointment, after their appointment but before lab testing). Therefore, the screening must be done immediately by phone by the research coordinator (after receiving verbal consent). This brief screening will consist of a short list of simple questions, with the more intensive risk assessment conducted later, after informed consent, when the research coordinator is on-site at the clinic and able to facilitate prompt referral in the instance of risk.

Describe whether and how subjects will be provided with additional pertinent information after participation

(1) Waiver for *Recruiter Phone Script and Verbal Consent (used for recruitment method 2)*
The waiver described for the verbal consent documented by the recruiter welcomes potential participants to inquire about any questions they have for the recruiter before consenting to be contacted by study staff for a phone screen. After providing this consent, potential participants are encouraged to learn more about the study during the phone screen where they will be able to ask questions and provided information on participation expectations if they are found eligible.

(2) Waiver for *Phone Screening and Script* (*waiver applicable for recruitment method 1 and 2*)
Given that the phone screening for eligibility conducted by the research coordinator consists of a short list of simple questions, there is no further pertinent information that needs to be given after participation. The important information is that the questions will be used to assess eligibility; this is stated before the screening is conducted and before the potential participant is asked to give verbal consent. In case the potential participant has any further questions that we have not anticipated, we have included a prompt asking for questions before the verbal consent is requested.

Waiver of Documentation of Consent

Would the consent form signature be the only link between the subject's identity and the research data?
Yes
Is breach of confidentiality the main study risk?
No
Describe the study component(s) for which waiver of documentation is requested.

We are requesting a waiver of documentation for the verbal consent obtained by the provider for potentially eligible patients as described in recruitment method 1. We described that the research coordinator would be using the calendar of upcoming scheduled co-infected patient visits (withheld of PHI) to speak with the provider directly before a patient visit and request that they gain the patient's verbal consent to meet with the research coordinator during their visit for an in-person screening.

- In order to protect the identities of potential participants and to prevent a potential breach of confidentiality, the research coordinator currently does not collect PHI at time of screening unless the potential participant is found to be eligible or if their consent to contact is obtained and documented previously by the recruiter. If the provider were to document such verbal consent, it would create an unnecessary link between the subject's identity and screening data where none has been created previously or will be created for other participants who screen for the study in the future.
- Requiring the provider to document such verbal consent would not only be time consuming, but would also be redundant as the research coordinator would meet face-to-face with the interested potential participant shortly after for screening at which time she would obtain and document verbal consent from the participant again.
- Although we request a waiver of documentation for the verbal consent obtained by the provider, the research coordinator would still continue to obtain verbal consent at time of screening as described previously and will continue to ensure that participants are given the opportunity to make informed decisions.

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Elliott, Jennifer
Hasin, Deborah, PHD
Lerias, Doukessa
Radecka, Olga
Type in the name(s) not found in the above list

Mahnoor Ali (see CITI training uploaded)

Study Procedures

Describe the procedures required for this study

STUDY START-UP: FORMATIVE RESEARCH AND PRE-TEST

Formative research will involve sitting down with 5 participants, reviewing intervention content, letting them try out the smartphone app, and inviting their feedback on the intervention (content, session style/approach, smartphone content). We will discuss adaptations made for HIV/HCV, and content relevant to HCV infection, and invite their feedback on whether it is useful and understandable. Feedback will be used to finalize intervention content. Formative research participants will be contacted post-study participation by phone to retrospectively collect demographic information to ensure that such data is collected consistently and recorded for future descriptive reporting purposes. These participants have agreed to be contacted by study staff for future research and will be given an opportunity to choose to disclose requested demographic information on a voluntary basis.

A pre-test will involve running 5 participants through the 60-day intervention, and inviting feedback in the same topic areas as in formative feedback. We will monitor the assessments and smartphone app for any technical problems that can be fixed prior to the trial itself. We will use this pre-test to make finishing touches to our intervention and study protocol, and finalize the content of both.

TRIAL PROCEDURES

(1) Explanation of the study and consent
Individuals who appear potentially eligible by the CUMC/NYP clinic recruiter's screening of the medical records or screening through database (recruitment method 1 and 2 as described in the recruitment procedures) and report interest in participating will speak briefly with the research coordinator by phone, who will be trained in human subjects' protections and will ask several simple questions to determine inclusion/exclusion criteria. Individuals who call as a self-referral via flyer or provider (recruitment method 3) will call the research coordinator directly to complete this described phone screening. The research coordinator will meet potential participants at the clinic to obtain informed consent and conduct additional screening for alcohol use disorder status (needed for randomization), as well as psychosis, suicidality, and homicidality, and risk of developing alcohol withdrawal symptoms (final exclusion criteria). Participants ineligible due to psychosis, suicidality, homicidality, and/or being at risk of developing alcohol withdrawal symptoms will be immediately brought to the attention of clinic providers so that they can be appropriately managed; will receive brief advice on alcohol reduction, and referral for help with alcohol abuse if desired or clearly indicated. Eligible participants will be scheduled for a baseline session at either the clinic or the NYSPI offices (722 W168th St 2nd Floor offices [Substance Dependence Research Group] New York, NY 10032), pending space constraints.

In order to obtain participants' health information from their medical records, clinic staff advised that their standard practice of disclosing health information requires written authorization from participants in accordance to HIPAA and CUMC procedures. To comply with this requirement, eligible participants who are patients of the CUMC/NYP clinic will sign an authorization form at time of informed consent allowing clinic staff to disclose requested health information from medical records to research team.

Individuals who appear potentially eligible after being identified through RecruitMe (recruitment method 4), will complete a phone screening with the research coordinator to determine inclusion/exclusion criteria. If found eligible a member of the research team* will meet potential participants at the NYSPI offices to obtain informed consent as described above. Participants found to be ineligible due to psychosis, suicidality, homicidality, and/or risk of developing alcohol withdrawal symptoms will be immediately brought to the

attention of the PI and will be escorted to the Comprehensive Psychiatric Emergency Program/Department @ CUMC - 630 West 168th Street New York, NY 10032 for immediate care. Participants found to be ineligible due to being at risk of developing alcohol withdrawal symptoms will be encouraged to speak to their providers and provided a referral list to seek alcohol treatment services. Eligible participants will be asked to obtain their medical record information from their providers, as it is required to conduct the study baseline session. Participants will be asked to bring a copy of their lab reports (of results requested in the health information request form) from their provider's office or will be provided a double-sided document with the health information request form on one side and a letter to their provider informing them why the information is requested and how to complete the form (see attached). Participants will be scheduled for baseline once they can provide such lab reports or agree to a date by which they will have completed the health information request form.

* Please note the research team includes: the PI, the research coordinator, and two study counselors all of whom are also persons designated to discuss and document consent for this study.

(2) Randomization

After participants complete the screening assessment, the research team member will be able to determine alcohol use disorder status from the responses. The research team member will provide the counselor or PI with the participant identification number (ID; assigned consecutively) and alcohol use disorder status. The counselor or PI will then randomize participants using pre-determined blocked lists created by a biostatistician, in order to balance treatment groups across alcohol use disorder status (the research coordinator will not randomize in order to remain blind to condition). Randomization lists were generated (in R software) and provided by biostatistician Adam Ciarleglio, PhD on May 4, 2018.

(3) Intervention and Control groups

Prior to scheduled baseline appointments and once written HIPAA compliant authorization is obtained from participants recruited from CUMC/NYP, research staff will request clinic staff to record and report participants' health information from their medical records (see measures table for requested indicators) and will request any updates to this health information prior to follow-up appointments. Participants identified from RecruitMe will be asked to assist in collecting their medical record information from their providers before scheduling the baseline appointment and prior to any follow-up appointments. Participants will be randomly assigned to the one of the following conditions which will be facilitated by a study counselor* (approximately 30 participants each, 60 total):

* Please note: the PI will substitute for the role of study counselor or research coordinator to meet staffing needs when other research team members are not available.

-Intervention condition. The intervention is an adaptation of the National Institutes of Health (NIH) Clinician's Guide (CG; NIAAA, 2007) in conjunction with the previously tested HealthCall smartphone app program (Hasin et al., 2013; Hasin et al., 2014). Participants assigned to this group will be scheduled for a brief meeting (~20 minutes) with a counselor to discuss alcohol use, liver function, and HIV medication adherence. The counselor will give the participant feedback on risks related to their drinking and alert them of elevations in liver inflammation according to indicators obtained from their medical records, help set a drinking goal, and make suggestions to help with reducing alcohol use, if the participant chooses. The participant will also receive a pamphlet on drinking, HIV, and HCV. They will then be introduced to

HealthCall, a smartphone app designed to help keep track of their drinking, reasons for drinking/abstaining, medication adherence, drug use, condom use during sex, and mood, through short daily use*. The participant will be provided with a study smartphone equipped with a calling plan and access to HealthCall during the time of the study. Participants will be shown how to use HealthCall and will have the chance to practice using it. Over the next 30 days, participants will be asked to use HealthCall daily. Each use lasts 2-3 minutes. At the end of the 30 days, participants will meet with a counselor for a 10-minute interview. At the interview, participants will be given a graph showing the results of HealthCall daily use and the counselor will explain and discuss the graph. The counselor will also ask about any changes in alcohol use and give feedback on drinking. Participants will then be asked to continue using HealthCall for the next 30 days. At the end of those 30 days the counselor will meet with participants for another 10-minute interview to go over the updated graph, and to discuss alcohol use and goals.

*Components of HealthCall (questions reference yesterday's behavior):
-Greeting
-Whether alcohol was consumed (yes/no)
-Type of alcohol consumed (beer, malt liquor, wine, hard liquor, pre-mixed coolers)
-Size of alcohol unit consumed (for conversion to standard drinks)
-Quantity of alcohol units consumed
-Level of desire to drink
-Commitment to reducing drinking
-Whether participant thought about sessions with counselor and drinking reduction goal
-Reasons for drinking or not drinking
-Offer to view drinking graph
-Use of other drugs (yes/no; how many times)
-What proportion of HIV medication was taken
-Reasons HIV medication was taken or missed
-Alcohol interference with medication adherence
-Any sexual activity (yes/no); if yes, whether they used a condom
-Overall perceived health, stress level, anger, depression, rating of day overall
-Drinking reduction tip
-Thank participant, invite them to call counselor if needed and continue using app

-Control condition. At baseline, participants will receive brief advice to decrease drinking and a request to spend 20 minutes in the session, observed by the counselor, reviewing an educational pamphlet on drinking, HIV, and HCV. At 30 and 60 days, participants will be asked about their drinking, and again receive advice to decrease drinking. This condition will provide (a) similar exposure time as CG+HealthCall at baseline, (b) brief counselor contact at 30 and 60 days, (c) the same message to decrease drinking, and (d) access to health information. However, the control condition, a realistic approximation of standard-of-care in many places, does not provide in-depth counselor sessions with feedback informed by liver indicators and HealthCall data, the active components of CG+HealthCall for HIV/HCV. This condition was chosen to indicate if CG+HealthCall for HIV/HCV is an improvement over standard-of-care, an important distinction to determine if it warrants further study and eventual dissemination.

-Assessments will precede counselor sessions, and will occur at baseline, 30 days, 60 days, and 90 days (90 days is assessment-only and includes no counselor sessions for either condition). Assessment questionnaires

will be self-administered electronically with the exception of the Timeline Followback and assessment of alcohol use disorder and dependence, which will be administered by the research coordinator or a research team member. The research coordinator/team member will supervise all assessments and answer questions as needed. Efforts will be made to keep the research coordinator/team member blind to condition to minimize potential bias in assessment.

-Breath and urine samples will be collected at all assessment periods, although participants may refuse to provide them without jeopardizing study involvement. Submitted papers using this data may receive requests to examine the association between biological (breath, urine) markers with self-reported use. Although breathalyzer and urine test methods are subject to limitations, they are less expensive and disruptive to participants' lives than other methods of biological assessment (such as alcohol ankle bracelets) and provide some data that can be used to validate participants' self-reports (i.e., the blood alcohol content [BAC] would be expected to be positive at a higher rate for daily drinkers; the urine tests would be expected to yield positive results at higher rate among those with higher frequency of drug use). This method also provides comparability with other HealthCall studies conducted by the Substance Dependence Research group.

Study appointments may occur at either the CUMC/NYP clinic or the NYSPI offices, depending on space availability. Study appointments that occur at the NYSPI offices (address specified above), will take place in the research coordinator's study office or another study room if needed. The participant will be set up at a computer desk with a chair where they can comfortably complete tablet assessments. If the participant agrees to provide urine and breathlyzer samples, the breathalyzer test will be conducted in the study room and the participant will be escorted to the nearest private restroom to collect the urine specimen, while the research coordinator or member of the research team waits outside of the restroom. Study appointments conducted at the clinic will be set up similarly (using research rooms or "talk rooms") depending on the space constraints. These rooms are set up similarly to the NYSPI office study rooms and have a desk and chair available to the participant.

Although study visits may occur at the NYSPI offices, the close proximity of the NYSPI offices to the CUMC/NYP clinic (i.e., five-minute walk) will facilitate prompt referral and escort to the clinic in the case of risk or emergency for participants who have established care there. (Such emergencies are not anticipated given that risk screening will occur at the screening appointment, which will be held on site at the clinic.) For participants who have established care elsewhere, Comprehensive Psychiatric Emergency Program/Department @ CUMC - 630 West 168th Street New York, NY 10032 is also located in this area allowing staff to escort participants in case of risk of emergency. Only study staff will be engaged in research activities with participants at the clinic (please note that the recruiter will only be identifying potential subjects and introducing the study to them).

You can upload charts or diagrams if any

Criteria for Early Discontinuation

Criteria for Early Discontinuation

Loss of the study smartphone.

Suicidality, homicidality, and psychosis are not part of our ongoing assessment battery and are assessed only at screening. However, it is possible that the research coordinator or counselor could observe signs of psychosis, or that they could hear the participant make a comment about suicidality or homicidality during study appointments. In the event of evidence of suicidality, homicidality, or psychosis, or concern that the participant's life is in acute danger, the research coordinator or counselor will proceed as described: (1) providers of participants referred from the CUMC/NYP clinic will be immediately alerted so that they may manage their patients. When study appointments are conducted at the NYSPI offices, participants considered at risk will be referred and escorted to the clinic site located a brief 5-minute walk away from the NYSPI offices. For participants identified from RecruitMe, the PI will be immediately alerted so that she may assess the participant and if considered at risk, the participant will be escorted to the Comprehensive Psychiatric Emergency Program/Department @ CUMC - 630 West 168th Street New York, NY 10032, which is also located a brief 5-minute walk away from the NYSPI offices. If it is clear that the participant is in acute distress, he/she will be discontinued from the study. If deemed to be not at risk, they will be permitted to continue participation.

The PI's mentors and co-investigators Deborah Hasin, PhD, and Efrat Aharonovich, PhD, have conducted several previous studies of HealthCall with HIV participants (N>600). Although they have disqualified participants who may be at risk of developing alcohol withdrawal symptoms from participating, they have not discontinued participation early in participants whose drug or alcohol use changes because some fluctuation in alcohol or drug use is common in early stages of recovery and because these participants generally don’t seek or accept referral to further treatment. Rather, if alcohol or drug use worsens, they offer brief advice to decrease dangerous behavior and referral to relevant treatment facilities (e.g., Alcoholics Anonymous [AA], rehabilitation, therapy) and encourage participants to follow through, and offer them the option of remaining in the study, allowing participants the possibility of benefiting subsequently from the treatment. For participants whose medical issues require hospitalization, they offer the option to resume participation in the study after they are discharged from the medical hospitalization. Referral in case of emergency is facilitated by the proximity to the clinic and emergency services, as outlined above. These procedures, which will be used for the present study, are designed to maximize protection and benefit to the participants, while enabling us to observe what happens to study participants after referral to additional drug and alcohol treatment, or after their return from medical hospitalization. If the participant reports unsafe sexual behavior, they will also receive brief advice to decrease dangerous behavior but will not be removed from the study.

Blood and other Biological Samples

Please create or insert a table describing the proposed collection of blood or other biological specimens Participants will be asked to use a breathalyzer to determine BAC, and to provide urine samples for drug testing. No blood samples will be collected, although HIV and liver function indicators will be collected from participants' medical records (see assessment table). Participants recruited from CUMC/NYP will sign a “HIPAA Compliant Authorization for Release of Medical Information and Confidential HIV Related Information”, so that clinic staff can disclose and collect information from medical records to research team. Participants identified from RecruitMe will be asked to assist in collecting their medical chart

abstracted HIV and liver function indicators from their providers before being scheduled for their baseline sessions.

Assessment Instruments

Create a table or give a brief description of the instruments that will be used for assessment
Please see attached amended measures/assessment table.
Please attach copies, unless standard instruments are used

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
No
Treatment to be provided at the end of the study

Participants will not receive additional intervention at end of study.

After the 90 day follow-up evaluation, if participants are seeking additional treatment, they will be encouraged to speak with social workers at the clinic, and/or will be referred to other alcohol treatment programs in the institution or elsewhere in participant's communities.

Clinical Treatment Alternatives

Clinical treatment alternatives
There will be two conditions in the trial. One will consist of the in-person Clinician's Guide (tailored for HIV/HCV) with HealthCall. The other is an educational control condition. Other accepted psychosocial methods to treat drinking and alcohol problems are cognitive behavioral therapy, motivational interviewing, and self-help groups such as AA.

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period
Data can be linked to participants' identity. Data will not include identifying information and will be identified by a subject ID number only. All data will be entered and maintained in a secured clinical trials electronic database and coded with a unique identifier assigned to each participant. Identifying information linked with subject study ID numbers will be kept in separate secured files in locked cabinets and will be available only to selected clinic and research staff members who need to interact with the participants and/or track study progress. This information will also be available to State and institutional regulatory personnel (who may review records as part of routine audits).

Participants are heavy drinkers. Therefore, it is possible that their drinking may become problematic at some point during the study. However, the intervention (and even the advice/education control condition) is likely to minimize the risk of such an occurrence, as compared with patients not enrolled in the study (who are likely receiving no intervention to decrease drinking). Efforts will be taken to monitor for adverse events and refer participants to needed care, as discussed below.

Participants may experience discomfort during assessment, in responding to questions about alcohol, liver disease, or HIV, perhaps by realizing as a result of the assessment that their drinking is harming their health. However, this is a legitimate concern and during the study such distress may help motivate them to reduce their drinking which will be beneficial to them. We will take steps to minimize the risk of discomfort, but participants will have the option to discontinue participation or skip distressing questions.
Describe procedures for minimizing risks
-Recruitment procedures will ensure that participants understand and agree to the informed consent (e.g., research coordinator or research team member will discuss content, informed consent will include quiz).
-Participants will be informed of alternative treatments for alcohol problems and provided referrals as indicated or requested, and encouraged to speak with their HIV providers and/or social workers at the clinic about their needs, questions, and concerns.
-While every possible step will be taken to minimize risk of discomfort occurring in the first place, consent documentation will make it clear that participants may refuse to continue with the study at any time or may refuse to answer particular questions without penalty.
-The clinical status of participants will be reviewed regularly during weekly supervision of the study counselor with the PI. Any adverse events will be evaluated to determine if the participant should be removed from the study and/or referred for more intensive treatment, and will be promptly reported to the IRB.
-Confidentiality will be protected by various means, including coded records, password protection, encryption of electronic data, and storing signed consent forms in locked cabinets.

Methods to Protect Confidentiality

Describe methods to protect confidentiality

In the trial, all records will be kept confidential. All paper records and material with identifying information will be kept in a locked filing cabinet at the HIV clinics while participants are involved in the study, and then transferred to a locked filing cabinet in our offices at Psychiatric Institute (722 West 168th Street, Suite 228 or 241). Identifying information (including name and phone number) for all potential participants prior to enrollment will be destroyed if they decide to not complete further screening or are found to not be eligible.

Access to HealthCall on the smartphone is secured with a personal pin number known only to the participant and study personnel (as necessary). After participants complete their daily responses to HealthCall, the information is automatically transmitted in encrypted form, without personal identifiers, to a password-protected server. Study data on this server will only be accessible by the Principal Investigator and study personnel. Access to these data is protected through two levels of login/password security. If data

uploading is not immediately possible because no wi-fi connectivity is available, then uploading is reattempted when wi-fi connectivity becomes available.

HealthCall data consists entirely of numeric codes keyed to alphanumeric indexes that are not of human-readable value. All electronic data from the participants' HealthCall application data entry will be saved to the database without their names or other identifying information.

Electronically stored data from study assessments and other study data will not include identifying information and will be identified by a subject ID number only. The database linking participants' names to IDs will be securely stored and independent of other study databases.
Will the study be conducted under a certificate of confidentiality?
Yes, we have already received a Certificate of Confidentiality

Direct Benefits to Subjects

Direct Benefits to Subjects

Participants in the intervention condition may benefit by decreasing their drinking, as the intervention was adapted from other evidence based, effective interventions. However, it is also possible that they will not benefit from the intervention.

Although the control condition will receive brief advice and educational materials, this will likely not be substantially different than standard-of-care.

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
Yes
Please describe and indicate total amount and schedule of payment(s).
Include justification for compensation amounts and indicate if there are bonus payments.

Participants will receive round-trip MetroCard at all appointments to compensate travel (value: $5.50). Participants will receive compensation in ClinCard payments and will be compensated according to the phase of the study they enroll in and what appointment they attend.

Participants enrolled in the *formative research* will receive a total of $25 for their one-session commitment.

Participants enrolled in the *pre-test* can earn up to a total of $95 and a smartphone or $195.
- $10 at consent/enrollment
- $25 at baseline
- $25 at 30-day assessments
- $35 and a smartphone or $135 at 60-day assessments (please see below)

Participants enrolled in the *trial* can earn up to a total of $180 and a smartphone or $280.
- $20 at consent/enrollment
- $40 at baseline
- $40 at 30-day assessments
- $40 and a smartphone or $140 at 60-day assessments (please see below)
- $40 at 90-day assessments

Participants in the intervention condition may keep the smartphone used in the study or receive $100 in ClinCard payment if they choose to return it. Control participants will also be offered either a smartphone or $100 in ClinCard payment. Intervention participation will not be incentivized, as intervention in clinic settings is not paid.

References

References
Hasin DS, Aharonovich E, Greenstein E. (2014). HealthCall for the smartphone: technology enhancement of brief intervention in HIV alcohol dependent patients. Addict Sci Clin Pract., 17, 9.

Hasin, DS, Aharonovich E, O'Leary A, Greenstein E, Pavlicova M, Arunajadai S, Waxman R, Wainberg M, Helzer J, Johnston B. (2013). Reducing heavy drinking in HIV primary care: a randomized trial of brief intervention, with and without technological enhancement. Addiction, 108, 1230-40.

National Institute on Alcohol Abuse and Alcoholism. (2007). Helping Patients Who Drink Too Much: A Clinician's Guide. Accessed 2/2/18 at https://www.niaaa.nih.gov/guide.

Uploads

Upload the entire grant application(s)
Upload copy(ies) of unbolded Consent Form(s)
Upload copy(ies) of bolded Consent Form(s)
Upload copy(ies) of recruitment materials/ads to be reviewed
Upload a copy of Certificate of Confidentiality
Upload copy(ies) of the HIPAA form
hipaa 8-17-18.pdf
Upload any additional documents that may be related to this study

New York State Psychiatric Institute (NYSPI)
Authorization to Use or Disclose Health Information during a Research Study

Protocol Number: 7649 **Principal Investigator:** Jennifer C Elliott, PhD

Name of Study: Understanding and intervening with heavy drinking among patients with HIV and HCV: Clinical trial

Before researchers can use or share any identifiable health information ("Health Information") about you as part of the above study (the "Research"), the New York State Psychiatric Institute (NYSPI) is required to obtain your authorization. You agree to allow the following individuals and entities to use and disclose Health Information about you as described below:

- New York State Psychiatric Institute (NYSPI), your doctors and other health care providers, if any, and
- The Principal Investigator and his/her staff (together "Researchers"). Researchers may include staff of NYSPI, the New York State Office of Mental Health (OMH), Research Foundation for Mental Hygiene, Inc. (RFMH), and Columbia University (CU), provided such staff is a part of the study, and
- Providers of services for the Research at CU, NYSPI and/or RFMH, such as MRI or PET, or Central Reference Laboratories (NKI), if indicated in the consent form**.**

1. The Health Information that may be used and/or disclosed for this Research includes:

☑ All information collected during the Research as told to you in the Informed Consent Form.
☑ Health Information in your clinical research record which includes the results of physical exams, medical and psychiatric history, laboratory or diagnostic tests, or Health Information relating to a particular condition that is related to the Research.
☑ Additional information may include:

Health information in your medical chart which includes the results of laboratory/diagnostic tests and medication history relating to your HIV and Hepatitis C infections.

2. **The Health Information listed above may be disclosed to:**

☑ Researchers and their staff at the following organizations involved with this Research:
New York State Psychiatric Institute/Columbia University

☑ The Sponsor of the Research,
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
and its agents and contractors (together, "Sponsor"); and
☑ Representatives of regulatory and government agencies, institutional review boards, representatives of the Researchers and their institutions to the level needed to carry out their responsibilities related to the conduct of the research.
☐ Private laboratories and other persons and organizations that analyze your health information in connection with this study

☐ Other (family members or significant others, study buddies, outside agencies etc.) Specify:

3. By giving permission to release your Health Information as described above, you understand that your Health Information may be disclosed to individuals or entities which are not required to comply with the federal and state privacy laws which govern the use and disclosure of personal Health Information by NYSPI. This means that once your Health

Information has been disclosed to a third party which does not have to follow these laws (e.g., a drug company or the Sponsor of the Research), it may no longer be protected under the HIPAA or NYS Mental Hygiene Law requirements but is subject to the terms of the consent form and may be subject to other state or federal privacy laws or regulations.

4. Please note that:

- You do not have to sign this Authorization form, but if you do not, you may not be able to participate in the study or receive study related care. You may change your mind at any time and for any reason. If you do so, you may no longer be allowed to participate in the study. If you withdraw this Authorization the research staff and the Sponsor, if this is sponsored research, may still use or disclose Health Information containing identifying information they already have collected about you as needed to maintain the reliability of the research. Any request to withdraw this Authorization must be made in writing to (enter name and contact information below):

  Jennifer C Elliott, PhD; 1051 Riverside Drive, Box 123, New York NY 10032

- While the Research is going on, you may not be allowed to review the Health Information in your clinical research record that has been created or collected by NYSPI. When this research has been completed you may be allowed to see this information. If it is needed for your care, your Health Information will be given to you or your Doctor.

5. This Authorization does not have an end date.

6. You will be given a copy of this form after you have signed it.

I agree to the use and disclosure of Health Information about me as described above:

_____ _____

Signature of Participant/ Legal Representative Date

_____

Printed Name of Participant

_____

Relationship of Legal Representative to Participant (if applicable)

We also ask you or your legal representative to initial the statements below:

☐ **I have received a copy of the NYSPI/OMH Notice of Privacy Practices.**