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# Peer Outreach Point-of-Care Testing as a Bridge to Hep C Care

**Submission date**
05/09/2018

**Recruitment status**
No longer recruiting

**Registration date**
29/10/2018

**Overall study status**
Completed

**Last Edited**
06/12/2021

**Condition category**
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Studies have shown that people who use drugs are both interested in Hepatitis C virus (Hep C virus, HCV) treatment and have the same treatment success rate seen in clinical trials. However, most people who use drugs do not know whether they have the virus and even fewer are engaged in care or ever treated. Testing for HCV requires a blood test. The delay involved in waiting for lab results and going back to the doctor to get the results can prevent people taking the test. Many people who use drugs have damaged veins which can make taking blood painful or impossible.
Point-of-care (on-the-spot) testing provides immediate information on HCV status and allows the healthcare worker to explain treatment options then and there. This test uses only a small drop of blood from a finger-prick and results are available in 20 minutes. In addition, it requires minimal training to administer and can be performed by people who are not doctors or nurses. This study will investigate the effect of point-of-care testing on whether people who use drugs will take up HCV treatment.

Who can participate?
People aged over 18 years who have ever injected drugs and have not been tested for HCV in the past 6 months and have not previously been treated for HCV infection.

What does the study involve?
Peer workers with experience of drug use and HCV infection will do outreach in the community to contact people at risk of HCV infection. Peer workers will ask for informed consent and will conduct a short survey to collect basic information about the person and their HCV virus testing history. They will provide a brief educational discussion regarding HCV transmission and treatment, and the availability of HCV treatment and support resources through the Toronto Community Hep C Program.
At the end of each interaction, participants will be randomly assigned to receive a point-of-care test or treatment as usual (i.e. referral to the Hep C Program nurses for blood work at a health centre). Participants who are randomized to receive the point of care testing will receive post-test counseling.
Those who are seen at least once by a Hep C Program treatment nurse will be compared among who receive the point-of-care test with those who do not receive the point of care test.

What are the possible benefits and risks of participating?
Participants may find it satisfying to know their HCV status, which may lead them to seek treatment they would not have if they did not know their status, and they may find it satisfying to know that they are contributing to knowledge generation and program development. Participants may experience emotional or psychological discomfort as a result of knowing their HCV status, and being asked about personal health experiences and/or life events that may have been difficult. To minimize this risk, the ORWA will be able to direct them to support at the health centres.

Where is the study run from?
South Riverdale Community Health Centre, Toronto, Canada.

When is the study starting and how long is it expected to run for?
May 2018 to October 2019

Who is funding the study?
Solutions - East Toronto's Health Collaborative

Who is the main contact?
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# Contact information

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Public

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## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

## Study information

### Scientific Title
Peer Outreach Point-of-Care Testing as a Bridge to Hep C Care

### Acronym
POC Outreach Study

### Study objectives
Point-of-care (POC) HCV antibody testing by peer outreach workers will further improve client engagement in care beyond peer outreach alone; as demonstrated by the proportion of clients seen by the peer outreach workers who later engage with a program treatment nurse for HCV assessments compared with the control group.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Michael Garron Hospital Research Ethics Board, 12/09/2018, 765-1809-Inf-40

### Study design
Randomized controlled trial

### Primary study design

Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Community

## Study type(s)
Screening

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

## Health condition(s) or problem(s) studied
Hepatitis C virus infection

## Interventions
Participants will be randomized using an online random number generator to each of the two study arms after receiving HCV education and information. The peer outreach workers will receive a weekly allotment of outreach packages pulled from increments of 100 from the entire sample size. The group assignments will be hidden and attached to each outreach package. Assignment will not be known to the peer outreach workers and will only be revealed after enrollment and baseline survey have taken place.

Half of participants will be assigned to the intervention group and will receive immediate point-of-care (POC) hepatitis C antibody testing. The other half will act as the control and will be offered 'testing as usual' - referral to program nurses for blood work. Outreach workers will be blind to the group assignment until after HCV education/information is presented to participants.

POC testing requires minimal training to administer and can be performed by lay people outside of traditional health care settings. A drop of blood from a finger prick is mixed with a buffer solution and inserted into a device to test for HCV antibodies. There is no laboratory involved, and tests can be performed quickly and easily in the community. The entire testing (including wait time for result) takes about half an hour. The OraQuick® HCV test will be used as part of this study. This test is a proven and approved test; we are using this test to measure its impact on engagement in care.

Data will be collected via chart review from participant’s medical records at each of the program’s partner sites using the HCV Care Data Collection Tool. The data to be collected and used for this purpose is antibody positivity status, completion of blood RNA test, completion of ultrasound, HCV genotype, presence of advanced (F3/4) fibrosis, treatment start date, length of treatment, HCV medication prescribed, treatment completion status and reason why uncompleted, sustained virologic response (SVR), reason for treatment not initiated.

Demographics and health care access history will be collected at baseline. Baseline data will be collected via an Outreach Testing Study Questionnaire administered by a research assistant.

These surveys will rely on self-report and do not use standardized measures but include questions that align with the Canadian Community Health Survey and have been used extensively in our studies we have undertaken.

### Intervention Type
Other

### Primary outcome measure
The proportion of clients seen by the outreach workers who had a HCV RNA test completed by the TCHCP treatment nurse compared with the control group. Primary Outcomes will be measured 6 months after the data collection stage, between May and July 2019; this outcome will be measured by calculating the number of study participants who complete a HCV test with a program nurse within 6 months from the start of study enrollment, which we anticipate will take 3 months to complete.

### Secondary outcome measures
1. Proportion of: participants who are newly diagnosed
2. Proportion of participants who meet other evaluation goals (phlebotomy, fibrosis assessment, ultrasound)
3. Rate of treatment initiation within 6 months of assessment
All secondary outcomes will be measured in the 6 months following the participant's enrollment into the study.

### Overall study start date
01/05/2018

### Completion date
31/10/2019

## Eligibility

### Key inclusion criteria
1. 18 years or older
2. Lifetime history of injection drug use

### Participant type(s)
Mixed

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
400

### Total final enrolment
381

### Key exclusion criteria
1. Currently on HCV treatment
2. Have a Sustained Virological Response (SVR) from HCV treatment in the past
3. Have had HCV testing in the past 6 months
Inclusion/exclusion criteria will be by self-report.

### Date of first enrolment
29/10/2018

### Date of final enrolment
14/02/2019

## Locations

### Countries of recruitment
Canada

### Study participating centre
**South Riverdale Community Health Centre**
955 Queen Street East
Toronto
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## Sponsor information

### Organisation
South Riverdale Community Health Centre

### Sponsor details
955 Queen Street East
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Canada
M4M 3P3

### Sponsor type
Hospital/treatment centre

### Website
www.srchc.ca

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Solutions - East Toronto's Health Collaborative

# Results and Publications

### Publication and dissemination plan
A central focus of this project will be the development of practice recommendations, the dissemination of findings to community stakeholders, and public education. The TCHCP has previously published six articles documenting program outcomes and will submit project findings for publication. Team members regularly present at workshops and conferences, including an annual two-day training event which brings all of the 16 community-based, multidisciplinary provincial HCV treatment teams together. Findings from this project will be shared at this event and other relevant meetings/conferences. A plain language report will be created and shared with front line workers and people living with/at risk for HCV at a workshop event(s) held at least one of the program's Health Centres. Findings will be disseminated through the South Riverdale Community Health Centre newsletter for people who use drugs. The TCHCP will use its established network of professional contacts to arrange meetings with health care providers across Toronto, Canada to discuss our findings.

### Intention to publish date
31/10/2020

### Individual participant data (IPD) sharing plan
Data will be stored in a secure repository and will be available on reasonable request. Any paper data from the study will be kept at South Riverdale Community Health Centre in a secure area for a period of 5 years after study completion and then destroyed. Electronic data, including the master list identifying study participants, will be kept on a password-protected computer and as a password-protected file. Participants are notified of this in the consent process.

### IPD sharing plan summary
Stored in repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 14/05/2020 | 06/12/2021 | Yes | No |