

# The HALT Hepatitis study

<b>Submission date</b> 19/10/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/10/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hard-to-reach groups are defined by lifestyle factors that render engagement with healthcare services problematic; they include homeless persons, people who inject drugs and ex-prisoners. These groups are at risk of a range of infectious diseases, often due to living conditions, injecting drug use, alcoholism, chaotic lifestyle factors, and generally poor physical and psychiatric health. Exposure to, and prevalence (percentage of a population affected with the disease at a given time) of, tuberculosis, hepatitis B virus (HBV) and hepatitis C virus (HCV) among the hard-to-reach is known to be high. The same factors that put individuals at risk of infection can also create barriers to passive presentation for diagnosis and adherence to treatment, including within the healthcare system. Therefore, support mechanisms are often needed to help people through the clinical process after they test positive for an infection. This study aims to determine whether screening and peer support for HCV or HBV infected individuals in hard-to-reach groups is effective and cost-effective.

### Who can participate?

Males or females over 16 years old who are homeless or substance abusers

### What does the study involve?

If found to be positive for HCV participants are randomly allocated to either peer support and accompanied referrals or supported during clinical diagnostic and treatment by normal care. If found to be positive for HBV participants are allocated to either peer support and accompanied referrals.

### What are the possible benefits and risks of participating?

Participants are offered the opportunity to be tested for HIV, HBV and HCV. Individuals benefit from knowing their infection status and from engagement with the healthcare system if found to be positive. No risks are foreseen.

### Where is the study run from?

University College London (UK)

### When is the study starting and how long is it expected to run for?

January 2013 to June 2015

Who is funding the study?  
Department of Health (UK)

Who is the main contact?  
Prof. Ibrahim Abubakar  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Ibrahim Abubakar

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## Additional identifiers

**Protocol serial number**  
12/0445

## Study information

**Scientific Title**  
The HALT study: effectiveness of testing for, and treatment of, hard-to-reach groups for hepatitis B virus and hepatitis C virus in England

**Study objectives**  
Providing peer support and accompanied referrals to hard-to-reach individuals infected with hepatitis C virus (HCV) or B virus (HBV) will increase the likelihood of a full diagnosis and treatment completion, where appropriate.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
NRES Committee London, Brent, 21/02/2013, ref: 13/LO/0077

**Primary study design**  
Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Hepatitis C virus (HCV) or B virus (HBV)

**Interventions**

Current interventions as of 06/02/2014:

Screening of hard-to-reach individuals, random allocation of those infected with HCV to either peer support and accompanied referrals or normal care, allocation of those infected with HBV to peer support and accompanied referrals.

Previous interventions:

Mobile screening of hard-to-reach individuals, random allocation of those infected with HCV or HBV to either peer support and accompanied referrals or normal care.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Current primary outcome measures as of 06/12/2012:

1. Cost effectiveness evaluation of the interventions
2. Successfully reaching an appropriate clinical endpoint for those HCV infected

Previous primary outcome measures until 06/12/2012:

1. Cost effectiveness evaluation of the interventions
2. Successful completion of full HCV clinical diagnosis

**Key secondary outcome(s)**

Current secondary outcome measures as of 06/12/2012:

1. Sustained virological response to HCV treatment
2. Successfully reaching an appropriate clinical endpoint, full diagnosis and commencement of treatment, where appropriate, for those HBV infected
3. Proportion of hard-to-reach with adequate immune response to HBV vaccine
4. Factors influencing lack of vaccine uptake

Previous secondary outcome measures until 06/12/2012:

1. Sustained virological response to HCV treatment
2. Successful full HBV clinical diagnosis and commencement of treatment
3. Proportion of hard-to-reach with adequate immune response to HBV vaccine
4. Factors influencing lack of vaccine uptake

**Completion date**

30/06/2015

# Eligibility

## Key inclusion criteria

Homeless or substance misusing individuals

## Participant type(s)

Other

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Key exclusion criteria

1. Individuals unable to give informed consent
2. Under 16 years of age

## Date of first enrolment

01/01/2013

## Date of final enrolment

01/07/2014

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

University College London

London

United Kingdom

WC1E 6JB

# Sponsor information

## Organisation

University College London (UK)

ROR

<https://ror.org/02jx3x895>

## Funder(s)

### Funder type

Government

### Funder Name

Department of Health Policy Research Programme (UK), ref: 015/0306

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results for participants with chronic HCV infection	01/04/2019	24/10/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No