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The HALT Hepatitis study

Submission date 19/10/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/11/2012	**Overall study status** Completed	
Last Edited 24/10/2019	**Condition category** Infections and Infestations	

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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures

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

Overall study start date
01/01/2013

Completion date
30/06/2015

Eligibility

Key inclusion criteria
Homeless or substance misusing individuals

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
660

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
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
WC1E 6JB

Sponsor information

Organisation
University College London (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.ucl.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results for participants with chronic HCV infection	01/04/2019	24/10/2019	Yes	No
HRA research summary			28/06/2023	No	No