

Contingency management targeting increased completion of hepatitis B (Hep B) vaccination amongst people in treatment for heroin dependence

Submission date
04/02/2011

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
01/04/2011

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
21/08/2014

Condition category
Mental and Behavioural Disorders

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NIHR CSP ref.: 52665

Study information

Scientific Title

Cluster randomised controlled trial of contingency management targeting increased completion of hepatitis B (Hep B) vaccination amongst people in treatment for heroin dependence

Acronym

CONMAN hep B

Study objectives

The use of incentives will increase the take-up and completion of Hep B vaccination when compared to a control condition (TAU) in which no incentives are offered.

The formal null hypothesis is that: there will be no difference in take-up and completion between groups of patients offered or not offered incentives.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North London REC 2, 27/09/2010, ref: 10/HO724/56

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Addiction opiate dependence

Interventions

In accordance with best clinical practice all sites will offer patients the 'super-accelerated vaccination schedule' (comprising three injections at 1, 7 and 21 days) (Department of Health, 2006; 2007). The vaccination schedule offered in each site will be identical. The treatment offered will differ only in terms of the absence/presence (and type) of adjunctive incentive schedule as follows:

Group A (Experimental Group):

Vaccination with fixed incentive schedule (CM-fixed): Service-users receive up to an aggregate total of £30 comprising in vouchers comprising 3 x £10 vouchers given at each of 3 vaccination injections (days 1, 7 and 21).

Group B (Experimental Group):

Vaccination with escalating incentive schedule (CM-escalating): Service-users receive up to an aggregate total of £30 in vouchers which escalate in value at each of the 3 successive vaccination injections (i.e. £5, £10 and £15 vouchers at days 1, 7 and 21 respectively).

Group C (Control Group):
Vaccination without incentive.

The hepatitis B vaccine should be delivered in line with existing service protocols at all sites. Delivery of the incentive will be complimented by appropriate positive verbal reinforcement to the patient which emphasises the positive benefits of the vaccination, provides appreciative feedback for their attendance at the appointment and recognition that the patient has taken a positive step in attending for treatment and complying with appointment times.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hepatitis B (Hep B) vaccination

Primary outcome(s)

Successful completion of the three Hep B vaccination injections (days 1, 7 and 21) within 28 days. Participants will be defined as completers if they receive all three injections by day 28.

Key secondary outcome(s)

1. On-time attendance
2. For those who do not complete, the proportion of vaccination doses received

Completion date

31/07/2011

Eligibility

Key inclusion criteria

1. Aged greater than 18 years, either sex
2. New episode of opiate treatment (within first 2 months)
3. Previous, current, or at risk of engaging in risk behaviour (i.e. injecting drug use)
4. Willing to receive vaccination
5. Willing to provide informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Pregnant or breastfeeding
2. Received prior hepatitis B vaccination course
3. Current or past hepatitis B infection

Date of first enrolment

14/02/2011

Date of final enrolment

31/07/2011

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Addictions Department**

London

United Kingdom

SE5 8AF

Sponsor information**Organisation**

South London & Maudsley NHS Foundation Trust and Kings College London (UK)

ROR

<https://ror.org/015803449>

Funder(s)**Funder type**

Government

Funder Name

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?
Results article	results	12/07/2014		Yes	No