

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

Registration date

01/04/2011

Overall study status

Completed

Last Edited

21/08/2014

Condition category

Mental and Behavioural Disorders

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof John Strang

Contact details

Addictions Department
National Addiction Centre
Institute of Psychiatry
Addiction Sciences Building
4 Windsor Walk
Denmark Hill
London
United Kingdom
SE5 8AF
+44 (0)20 7848 0819
john.strang@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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

Overall study start date

14/02/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

n = 192 (total); 64 per trial intervention

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**

England

United Kingdom

Study participating centre**Addictions Department**

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

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

Sponsor details

c/o Jenny Liebscher
SLaM R&D Office
Room W 1.08
Institute of Psychiatry
De Crespigny Park
Denmark Hill
London
England
United Kingdom
SE5 8AF
+44 (0)20 7848 0251
jenny.liebscher@kcl.ac.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.kcl.ac.uk/index.aspx>

ROR

<https://ror.org/015803449>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0707-10149)

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	12/07/2014		Yes	No