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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
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)

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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