ISRCTN00746242 https://doi.org/10.1186/ISRCTN00746242

An intervention to reduce sexual risk after Post-Exposure Prophylaxis for HIV following Sexual Exposure (Project PEPSE)

Submission date	Recruitment status	[_] Prospectively registered
06/01/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/01/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/05/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Carrie Llewellyn

Contact details
Division of Public Health & Primary Care
Brighton & Sussex University Hospitals NHS Trust
Village Way
Falmer
Brighton
United Kingdom
BN1 9PH
-
c.d.llewellyn@bsms.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11436

Study information

Scientific Title
Multicentre RCT and economic evaluation of a psychological intervention together with a leaflet to reduce risk behaviour amongst men who have sex with men (MSM) prescribed post-exposure prophylaxis for HIV following sexual exposure (PEPSE)

Acronym
PEPSE

Study objectives
Men who have sex with men (MSM) are most affected by HIV in the UK and they are increasingly likely to engage in risky sexual behaviour. One to one behavioural interventions, such as motivational interviewing (MI) have been recommended to reduce HIV in high risk groups by National Institute for Health and Clinical Excellence (NICE) in the UK, as part of current STI/HIV service provision. MSM who receive a preventative regimen of HIV treatment after potential sexual exposure to HIV (PEPSE) are at particularly high risk of later acquiring HIV and therefore could greatly benefit from targeted risk reduction interventions, so as to reduce the likelihood of further risk behaviour, subsequent infection and costs to the National Helath Service (NHS) in the UK.

Aims:
1. Examine whether MI is effective in reducing risky sexual behaviour in MSM prescribed PEPSE compared to usual treatment.
2. Examine whether motivational interviewing increases adherence to PEPSE and whether the intervention could represent value for money to the NHS.

HIV is a condition affecting both length and quality of life, even with highly effective treatments. Therefore, a relatively low-cost intervention for MSM that is effective in reducing the likelihood of risky sexual behaviour and further HIV infections will not only directly benefit recipients, but also the wider MSM community and the NHS as a whole.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee South East Coast, Surrey, 14 July 2011 ref: 11 /LO/0718

Study design
Preventative, interventional randomised 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Infectious diseases and microbiology

Interventions
RCT conducted in Brighton and London is proposed. Participants will be MSM who have been prescribed PEP after sexual exposure.

Those randomised to receive the intervention will receive two telephone administered sessions of motivational interviewing (MI) augmented by information and skills training. Each telephone session will be a maximum of 30 minutes long. The second session will contain similar content to the first but will reiterate and build on the risk reduction motivation from session 1. In the case of drop-out between the 2 intervention sessions, a dose-response can then be assessed. The interventionist will initially assess individual risk behaviours and any informational, motivational or skill deficits which have contributed to maintenance of participants.

This group will be compared to a treatment as usual control group. Individuals will be followed up for one year to determine whether the intervention has long term effects on sexual behaviour. Value for money will be estimated by conducting an economic evaluation, where the costs and health outcomes of the interventions are compared.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The proportion of risky sexual practices measured at 3, 6 and 12 months after the end of treatment

Secondary outcome measures
No secondary outcome measures

Overall study start date
03/01/2012

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Men who have sex with men (MSM)
2. Minimum age =16 years
3. A prescription for PEP after sexual exposure
4. Attending a Genito-Urinary Medicine (GUM) clinic
5. Willing and able to give written, informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
UK Sample Size: 250

Total final enrolment
175

Key exclusion criteria
The following groups of patients will be excluded: those that do not consider themselves to be MSM, patients under the age of 16 years, people who have received previous psychological support from a clinical psychologist in relation to their sexual risk taking; people with learning difficulties; people unable to read study materials; people with no means of communication acceptable to the patient; people who are seeking PEP after sexual assault.

Date of first enrolment
03/01/2012

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Public Health & Primary Care
Brighton
United Kingdom
BN1 9PH

Sponsor information

Organisation
Brighton & Sussex University Hospitals NHS Trust (UK)

Sponsor details
Clinical Investigation and Research Unit (CIRU)
Royal Sussex County Hospital
Eastern Road
Brighton
England
United Kingdom
BN2 5BE
+44 (0)1273 696 955
ciru.reception@bsuh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.bsuh.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
NIHR - Research for Patient Benefit (RfPB) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
26/10/2019

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?
Protocol article	protocol	22/03/2012		Yes	No
Results article	results	23/05/2019	24/05/2019	Yes	No