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

<b>Recruitment status</b> No longer recruiting	Prospectively registered		
	[X] Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	Individual participant data		
	No longer recruiting  Overall study status  Completed		

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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## 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

**BN1 9PH** 

United Kingdom

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

## 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
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### 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