

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

Submission date 06/01/2012	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 06/01/2012	Overall study status Completed	☒ Protocol
Last Edited 24/05/2019	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ 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

Protocol serial number

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 Health 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

Primary study design

Interventional

Study design

Preventative, interventional randomised trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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**

United Kingdom

England

Study participating centre

Division of Public Health & Primary Care

Brighton

United Kingdom

BN1 9PH

Sponsor information**Organisation**

Brighton & Sussex University Hospitals NHS Trust (UK)

Funder(s)**Funder type**

Government

Funder Name

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

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