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Positive Voices: National Survey of People with HIV

Submission date
11/10/2013

Recruitment status
No longer recruiting

Registration date
11/10/2013

Overall study status
Completed

Last Edited
16/03/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The number of people living with human immunodeficiency virus (HIV) [PLHIV] in the UK is estimated at 100,000 in 2012, due to effective HIV treatment and ongoing new HIV diagnoses. There is a need to better understand the patterns of risk behaviour in PLHIV, the prevalence of HIV-associated co-morbidities, and attitudes and satisfaction with current models of care, in order to plan HIV prevention, treatment and care services.

Who can participate?
HIV+ individuals aged 18+ attending NHS HIV specialist services will be eligible to take part.

What does the study involve?
The project will utilise the national census of HIV positive individuals in care [SOPHID] as a national sampling frame to invite a random sample of PLHIV to complete an online questionnaire. Topics covered will include: sexual and drug taking behaviours; co-morbidities and risk behaviours associated with chronic disease; use of health services; quality of life; satisfaction with care; and attitudes and experiences toward living with HIV.
The project will be carried out in two phases. In Phase 1, we will use mainly qualitative methods with patients, clinic staff, and other key informants to develop and validate the survey tool and explore the acceptability and feasibility of a variety of incentives targeting clinics and patients to improve survey response rates. In Phase 2, the survey will be conducted in twenty clinics. In the initial small study, two interventions will be studied (incentive and recruitment method).
Incentive method: Patients will be randomly allocated to one of four incentives:
1. Control - no incentive
2. Offer of health information
3. A prize draw for gift vouchers
4. Offer of health information plus a prize draw for gift vouchers
Recruitment method, Clinic level randomisation - clinics will be randomised to recruit either : a) a pre-defined randomly selected list of patients sent from Health Protection Agency OR b) all patients attending clinic during a specified time period.

What are the possible benefits and risks of participating?
There are no direct benefits for patients who participate, unless the patient is randomly

allocated to receive health information or entry into a prize draw. The indirect benefits are contributing to the evaluation and improvement of their HIV services. The risks of participating are minimal, but the survey includes questions of a sensitive nature and therefore patients may feel some distress or discomfort. Patients are free to quit the survey at any time, and details of local HIV support organisations will be provided.

Where is the study run from?
The study is run from Public Health England in London.

When is the study starting and how long is it expected to run for?
The qualitative work of Phase 1 will recruit from July - October 2013. Phase 2 (the initial small study) will start recruitment in November 2013 until October 2014.

Who is funding the study?
National Institute for Health Research (UK).

Who is the main contact?
Meaghan Kall, Survey Coordinator
meaghan.kall@phe.gov.uk

Study website
http://www.ucl.ac.uk/voices

Contact information

Type(s)
Scientific

Contact name
Miss Meaghan Kall

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14460

Study information

Scientific Title
Development and Implementation of Positive Voices: the National Survey of People Living with HIV

Acronym
Positive Voices

Study objectives
The main objectives of the study are to:
1. Evaluate the method of delivering the survey with the highest response rate
2. Identify differences between survey respondents and non-respondents

Protocol can be found at: http://www.ucl.ac.uk/silva/voices/pdfs/protocol

On 06/06/2014 the anticipated end date was changed from 01/04/2014 to 31/10/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Harrow Research Ethics Committee, 28/03/2013, ref: 13/LO/0279

Study design
Observational and interventional two tiered factorial randomised controlled trial; Design type: Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Patient information can be found at: http://www.ucl.ac.uk/silva/voices/pdfs/Patient_Information_Sheet

Health condition(s) or problem(s) studied
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions

Incentive, Patients will be randomised to one of four incentive packages in a factorial design:
1. Control - no incentive
2. Offer of health information
3. A prize draw for gift vouchers, or
4. Offer of health information plus a prize draw for gift vouchers
Recruitment method, Clinic level randomisation - clinics will be randomised to recruit either : a) a pre-defined randomly selected list of patients sent from Health Protection Agency OR b) all patients attending clinic during a specified time period

The total duration of intervention varies by clinic recruitment method. Clinics assigned to recruit from a pre-selected list of patients will run the study for 4 months. Clinics assigned to recruit sequential attendees, will run the study for 2 months. There will be no follow up with patients after this time.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Response rates; Timepoints: Which method of incentivising clinics and participants achieves the highest response rate.
Assessed at the end of the study. For example, response rates will be calculated by counting the total number of survey responses, the total number of survey invitation slips returned by the clinics, and retrospectively counting the actual number of HIV+ patients who attended during the study period.

Secondary outcome measures
1. Assess whether response rates among the various risk groups and age groups are representative of the national HIV population (+/10%).
2. Assess key determinants of variation in response rates by risk group, age group, geography, and clinic size.

Assessed at the end of the study.

Overall study start date
25/07/2013

Completion date
31/10/2014

Eligibility

Key inclusion criteria
Phase 1: Focus Group Discussion & Cognitive Interviews:
1. HIV positive
2. Male and female, aged 18 and over
3. Accessing care at an NHS HIV clinic

Phases 2 & 3: Pilot and Full Survey:
1. HIV positive
2. Male and female, aged 18 and over
3. Accessing care at an NHS HIV clinic
4. Reported to SOPHID in the previous calendar year

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 1366

Key exclusion criteria
Phase 1: Focus Group Discussion & Cognitive Interviews:
1. Unable to speak English
2. Participant declines audio recording of the discussion (for focus group discussions only)

Phases 2 & 3: Pilot and Full Survey:
Unable to complete online questionnaire due to language or literacy

Date of first enrolment
25/07/2013

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Infections
London
United Kingdom
NW9 5EQ

Sponsor information

Organisation
Public Health England (UK)

Sponsor details
Biosafety Unit
CEPR, Porton Down
Salisbury
United Kingdom
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Elizabeth.Coates@phe.gov.uk

Sponsor type
Government

Website
http://www.hpa.org.uk/

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Public Health Research; Grant Codes: CHPR-2011-006

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?
HRA research summary			28/06/2023	No	No