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Feasibility of a trial of risk reduction in sexual health clinics

Submission date
17/07/2015

Recruitment status
No longer recruiting

Registration date
05/08/2015

Overall study status
Completed

Last Edited
28/03/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sexually transmitted infections (STIs) continue to represent a major public health challenge in the UK. Research is required to identify brief, pragmatic, labour non-intensive interventions that can be tailored to the level of risk of the individual attending any of a range of different sexual health (SH) services. In order to test the feasibility of conducting a study of targeted risk reduction interventions at sexual health services, the aim of this study is to find out what is currently done within these settings, and whether potential interventions would be appropriate and desirable to both providers and patients. This study will be mapping the current practice of sexual risk reduction interventions in UK SH clinics, and identifying best practice, exploring opportunities and challenges to the delivery of candidate risk reduction interventions in SH clinics, and testing an evidence-based intervention package.

Who can participate?
Service managers, doctors, nurses, health advisors and psychologists working at sexual health services including genito-urinary medicine (GUM), contraceptive and sexual health (CASH) or Brook clinic, and patients aged 16 or older attending a GUM, CASH or Brook clinic.

What does the study involve?
The plan is to carry out formative work, followed by a pilot feasibility study. The formative work consists of five interlinked activities, collecting information from both service providers and service users. Interviews are conducted with service providers and patients to gain an understanding of current approaches and attitudes to risk assessment in SH services and behavioural interventions, and the resources available and used for this. This information is used to design a web-based survey which is sent to all SH service providers. A patient survey is conducted where patients are asked to indicate their preferences for the design of various candidate risk reduction interventions. Finally, focus groups are used to find out how previously identified interventions can be appropriately adapted to use in the NHS. These activities provide candidate interventions, and indicate opportunities for introducing them and the challenges to consider. In the pilot feasibility study the package of targeted interventions is introduced to test the feasibility of conducting a full study. Clinics are randomly allocated to either the intervention group or the control group. Intervention clinics introduce the intervention package, and interviews and process measures are used to look at the challenges and opportunities in

delivery. The control group do not receive any interventions. Service users are recruited from both intervention and control clinics and followed-up to determine the feasibility of collecting STI outcomes following recruitment in clinics.

What are the possible benefits and risks of participating?
Service provider participants receive information on their current practices for risk assessment and reduction, and determining the resources currently spent and available for this activity. During the pilot, providers receive training for the intervention package. Patient participants may benefit from receiving part of the intervention package; those who attend control clinics or are part of the formative research are contributing to research that may benefit them indirectly by informing appropriate interventions for sexual risk reduction. In addition, patient participants for interviews and focus group discussions receive compensation for their time. The potential risks and burdens to patient participants are limited, but they could include some distress during interviews if they are uncomfortable with the topic being discussed. During the consent process, it is made very clear that participants do not need to answer any questions they are uncomfortable with and can stop their involvement at any point. In the focus group discussions, participants are grouped together based on sexual orientation, gender and age to make participants more comfortable discussing their thoughts on sexual health services. For all participants, there is some burden on their time.

Where is the study run from?
Central and North West London NHS Trust and Brighton and Sussex University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2015 to December 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Carina King
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Contact information

Type(s)
Scientific

Contact name
Dr Carina King

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Additional identifiers

Protocol serial number
18925; HTA 12/191/05

Study information

Scientific Title
Sexual risk reduction interventions for patients attending sexual health clinics; feasibility to conduct an effectiveness trial (Sante project)

Study objectives
Sexually transmitted infections (STIs) continue to represent a major public health challenge in the UK. Research is required to identify brief, pragmatic, labour non-intensive interventions that can be tailored to the level of risk of the individual attending any of a range of different sexual health (SH) services. In order to test the feasibility of conducting a trial of targeted risk reduction interventions at sexual health services, we need to understand what is currently done within these settings, and whether potential interventions would be appropriate and desirable to both providers and patients. This study will be mapping current practice in UK SH clinics with respect to delivery of sexual risk reduction interventions and identifying best practice, exploring opportunities and challenges to the delivery of candidate risk reduction interventions in SH clinics.

Added 08/02/2017:
This study will also pilot an evidence-based intervention package.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Chelsea and Westminster REC, 19/05/2015, ref: 15/LO/0690
2. Chelsea and Westminster REC, 16/05/2016, ref: 16/LO/0673

Study design
Pilot trial; Observational; Design type: Mixed-methods

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions

Current interventions as of 08/02/2017:
The plan is to carry out 5 interlinked activities during the formative work, and then a pilot feasibility study. The formative work consists of:
1. Semi-structured interviews with service providers to understand current practice and resources
2. A web-based survey of all SH service providers to ascertain opportunities and barriers to intervention delivery
3. Semi-structured interviews with service users to understand clinic experience and intervention preferences
4. A patient survey (a discrete choice experiment) to determine preferences candidate risk reduction interventions
5. Focus group discussions to elicit stakeholder opinions on how previously identified interventions can be appropriately adapted to the NHS setting
These activities will provide candidate interventions, and indicate opportunities for implementing them and the challenges to consider. Following this, the package of interventions (a brief 1:1 consultation with a healthcare professional, and a digital intervention) will be piloted. Both quantitative and qualitative outcomes will be used to determine the feasibility of conducting a cluster randomized controlled trial of targeted sexual risk reduction interventions within sexual health clinics in England.

Clinics will be randomized to be either control or intervention sites. The intervention being piloted is a package of evidence-based targeted sexual risk reduction activities. The package consists of a triage algorithm to stratify patients into high and low risk categories for STI diagnosis, those who meet the criteria for high risk will be offered an additional brief (25-40 minutes) 1 to 1 session with a health advisor during their clinic visit. All service users, regardless of their triage outcome will be sign-posted to a digital intervention, which they can complete in their own time. The control group will not receive any interventions. During the pilot, a sub-sample of service users from both intervention and control clinics will be recruited for a follow-up at 6 weeks. This follow-up will include a brief questionnaire and STI screen.

Previous interventions:
The plan is to carry out 5 interlinked activities, collecting information from both service providers and service users. Semi-structured interviews are conducted with service providers and patients to gain an understanding of current approaches and attitudes to risk assessment in SH services and behavioural interventions, and the resources available and used for this (ACTIVITIES 1 & 3). This information will be used to inform the design of a web-based survey which will be sent to all SH service providers (ACTIVITY 2). A patient survey (a discrete choice experiment) will be conducted, where patients are asked to indicate their preferences for the design of various candidate risk reduction interventions (potential candidate interventions are being identified from a systematic literature review) (ACTIVITY 4). Finally, focus groups are used to elicit stakeholder opinion on how previously identified interventions can be appropriately adapted to the NHS setting (ACTIVITY 5). These activities will provide candidate interventions, and indicate opportunities for implementing them and the challenges to consider.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measures as of 08/02/2017:
Acceptability of the intervention package to users and HCP as measured by:

1. Proportion of service users who attend the clinic that are scored by triage tool
2. Proportion of those who score high who are offered the intervention
3. Proportion of those who are offered the intervention who take up the intervention
4. Proportion who take up the intervention who complete the intervention
5. Reasons for not completing the intervention from service users
6. Acceptability of the intervention from the provider perspective
The primary outcome measures will be measured using mixed-methods throughout the period of the pilot intervention. The process data will be collected during the service users attendance at the sexual health clinic, and recorded in the electronic patient record. Qualitative data will be collected from both service users and service providers throughout the pilot period.

Previous primary outcome measures:
Feasibility of delivering targeted interventions in sexual health settings; Timepoint(s): December 2016

Key secondary outcome(s))
Added 08/02/2017:
Feasibility and resources required within the clinic, measured by:
1. The total time spent by service users within the clinical service, compared to normal
2. Total number of service users seen and STIs diagnosed, compared to normal
3. Average consultation time, compared to normal
4. Number of patients seen by health advisors, compared to normal
5. Extra HCP time required for the intervention
These outcome measures will be measured throughout the pilot period, from data routinely collected by the clinic's electronic patient record system.

Feasibility of active follow-up in an RCT, measured by:
1. Proportion of service users who consented to the follow-up
2. Proportion of service users who were contactable at 3 months
3. Proportion of service users for whom there was a follow-up STI screen
These outcome measures will be measured at the point of patient recruitment in the clinic and at a 6-week follow-up contact.

Completion date
31/08/2017

Eligibility

Key inclusion criteria
Service providers:
1. Any of service manager and professional members of the multidisciplinary team (doctors, nurses, health advisors, psychologists)
2. Working at sexual health services including: Genito-urinary medicine (GUM), contraceptive and sexual health (CASH) or Brook clinic

Patients:
1. Attendance at a GUM, CASH or Brook clinic
2. 16 years or older

Target Gender: Male & Female ; Lower Age Limit 16 years

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Service providers:
1. In post for less than 3 months

Patients:
1. Younger than 16 years
2. Lacking capacity to give informed consent
3. Unable to speak English

Date of first enrolment
09/07/2015

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Central and North West London NHS Trust
United Kingdom
NW1 2PL

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
United Kingdom
BN1 6AG

Study participating centre

Croydon Health Services NHS Trust
United Kingdom
CR9 2RS

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
United Kingdom
SW10 9NH

Study participating centre
County Durham and Darlington NHS Foundation Trust
United Kingdom
DL3 6JL

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK); HTA/12/191/05

Results and Publications

Individual participant data (IPD) sharing plan
The ethical approval and patient consent does not include publication of participant-level data. The individual qualitative interview and focus group discussion data is not felt to be appropriate to store in a public repository. For quantitative data from the patient questionnaires, participant

web-surveys and routine clinical patient records, this aggregated data can be made available upon request following approval by the Principal Investigator and the signing of a data sharing agreement, which has been approved by the appropriate ethical committees.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No
Results article	results	01/03/2019		Yes	No
Abstract results	oral presentation	01/06/2016		No	No
Basic results		18/09/2018	18/09/2018	No	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Poster results	poster presentation	01/06/2016		No	No
Poster results	poster presentation	01/06/2016		No	No