Protocol

Sexual health risk reduction interventions – the Santé Project

Full project title: Sexual risk reduction interventions for patients attending sexual health clinics; feasibility to conduct an effectiveness trial

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Project summary:

We will conduct a brief systematic review of sexual risk reduction behavioural interventions focussing on UK relevant evidence to identify a suite of effective behavioural interventions that can be combined to meet user's needs and are deliverable from SH clinic settings (Objective 1&2). We will review existing sexual risk assessment/triage tools using data reported to Public Health England (PHE) from SH clinics to develop/refine a tool that identifies individuals at increased behavioural risk (Objective 3). We will carry out a mixed methods study to describe sexual risk reduction practices in SH clinics in the UK and identify opportunities for intervention. This will include a survey of interventions offered in SH clinics, supplemented by key informant interviews among clinic staff (Objective 4). We will conduct interviews and discrete choice experiments among the potential target groups, to explore their experience and preferences for risk reduction interventions (Objective 5). Building on the results of the above work, we will propose individualised packages of behavioural interventions. The feasibility of delivery will be tested among clinic attendees and staff, while the user groups will provide feedback on the acceptability of the intervention overall and according to characteristics including age, gender, orientation, culture and ethnicity (Objective 6). A study will be undertaken to assess the acceptability and feasibility of implementation of this package of interventions and engagement with the elements of the interventions (Objective 7), and feasibility of conducting a RCT and collecting follow-up measures to assess the effectiveness of the intervention packages (Objective 8). The cost of the implementing the intervention will be estimated (Objective 9), and finally the triage tool and intervention manuals will be refined to ensure the fidelity of the interventions, and a trial design proposed for a full evaluation, if deemed feasible (Objective 10).

Background

STIs continue to represent a major public health challenge in the UK. This is reflected in this commissioned call for the preliminary work required prior to the commissioning of a definitive study of the effectiveness of brief interventions to reduce sexual risk behaviour. Such interventions, while tested individually and in most cases showing a modest but consistent positive effect, have not been implemented systematically in a way that could have a population level impact in the UK. An additional challenge is that any implementation can only be sustainable if it can be delivered at minimal overall cost; this is not a time when substantial investment of additional resources across a large number of services is realistic. In this context, research is required now 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 services. The characteristics of those in the higher risk groups will differ by clinic setting, gender, sexual orientation and other factors which will need to be incorporated into the intervention model. Finally, what is needed at this time is a test of the feasibility of conducting a definitive trial of effectiveness, incorporating an economic analysis.

Glossary

Throughout the protocol the term sexual health (SH) clinics is used to describe all types of clinical settings commissioned to provide sexual health services. This includes genitourinary medicine (GUM) clinics, sexual and reproductive health (family planning) clinics, and integrated contraception and sexual health services (CASH). Service users, or users, describe people who use SH clinics and health care providers (HCP) for the staff who provide the SH services.

Aims and objectives

The project addresses the research question:

What is the feasibility of a randomised controlled trial of an individualised package of sexual risk reduction interventions offered at various points in the clinical care pathways within SH clinics (genitourinary medicine, contraception, and integrated sexual health clinics)?

The aims of the project are therefore:

1. To develop and pilot a package of evidence-based sexual risk reduction interventions for those at most risk, that can be implemented in SH services. The suite of interventions will be matched to service user's needs and developed alongside a triage method for identifying the appropriate target groups.
2. To assess the feasibility of testing the effectiveness of this individualised package of behavioural interventions in a randomised controlled trial (RCT) against usual care.

Specific objectives are as follows:

1. To review existing evidence relevant to the UK on the nature and efficacy of brief and self-delivered sexual risk reduction interventions.
2. To identify a suite of interventions of known effectiveness that can be delivered and combined to meet individual users needs.
3. To develop a sexual risk assessment/triage tool to identify service users' level of sexual risk and thus individualise packages of behavioural interventions to user's need.
4. To describe current practice in UK SH clinics with respect to delivery of sexual risk reduction interventions and identify best practice.
5. To explore opportunities and challenges to the delivery of candidate risk reduction interventions in SH clinics.
6. Using stakeholder input, to select, adapt and manualise an evidence-based suite of interventions that can be combined and delivered to meet individuals' needs.
7. To determine the acceptability, feasibility and deliverability of the individualised intervention packages in different SH clinical settings.
8. To assess the feasibility of testing the effectiveness of this individualised package of behavioural interventions in a randomised controlled trial (RCT) against usual care.
9. To estimate the cost and resource implications of implementing the individualised intervention packages in different SH settings.
10. To refine a manual of the intervention packages and to outline a feasible trial design (if feasibility is supported).

Interventions to be assessed:

The selection of the suite of interventions will be informed by evidence on effectiveness, acceptability, feasibility and sustainability derived from a rapid literature review, building on existing reviews, and will use risk-reduction opportunities at several points in a clinical pathway.

Pending the results of the review in WP1, we anticipate that it will involve the following:

1. A triage step that stratifies individuals' sexual risk and thus allows an individualised package of interventions to be offered, tailored to the individual's needs according to a schema.

2. A package of intervention(s) that may comprise just one, or several components (or none in the case of those classified as at low risk).

3. Selection of a package of interventions with different modes of delivery, such as, but not limited to, group delivered (e.g. waiting room videos), self-delivered (e.g. interactive digital interventions), and clinician delivered (one-to-one motivational interviewing).

Interventions will be adapted from existing interventions as required, and selected for deliverability within existing resources and clinical pathways. The suite of interventions will be developed in conjunction with other initiatives to reduce STI incidence such as enhanced recall, designed to increase STI and HIV testing among those clinic attendees who have had an STI diagnosis or reported high risk sexual behaviours, and improved and facilitated partner notification, to reduce re-infection rates and detect undiagnosed infection in the community.

Research plan

Design and organisation of the project:

The project is a multi-stage mixed method study design that will incorporate a systematic review, secondary analysis of national surveillance data; interviews and surveys with clinic staff; semi-structured interviews, a discrete choice experiment and focus groups with clinic attendees; monitoring of intervention offering, uptake, and completion, and follow-up questionnaires; and capturing the clinical resources used. In order to achieve this, the study will be organised in 6 overlapping work packages.

The work packages (WP) are summarised as follows, with further details of each below:

WP1: A systematic review of sexual risk reduction behavioural interventions focussing on UK relevant evidence (Objective 1 & 2).

WP2: Develop a sexual risk assessment/triage tool to identify individuals at increased risk in sexual health settings (Objective 3).

WP3: A mixed methods study to describe sexual risk reduction practices and preferences in SH clinics in the UK and to identify opportunities for intervention (Objective 4 & 5).

WP4: To select and adapt a suite of evidence based interventions suitable for delivery in sexual health setting and acceptable to patients and staff (Objective 6).

WP5: To pilot the interventions, assess their acceptability, practicality, and cost of implementation; to assess the feasibility of a future randomised control trial (Objective 7-9).

WP6: To refine the triage tool, and manuals of the interventions to ensure that the triage tool can be incorporated into routine care (or derived from routinely collected data) and to ensure the fidelity of the interventions; to outline the trial design for a full evaluation (Objective 10).

The work packages and the corresponding objectives that they will address are detailed below:

Work Package 1

Objective 1: To review existing evidence relevant to the UK on the nature and efficacy of brief and self-delivered sexual risk reduction interventions

Objective 2: To identify a suite of interventions of known effectiveness that can be delivered and combined to meet individual users needs

Study design: A systematic review of the literature.

Inclusion and exclusion criteria: The inclusion and exclusion criteria will reflect the focus on intervention settings in the UK, or those with similar healthcare systems. It will include both interventions that can be delivered in sexual health clinics, (e.g. waiting room videos, brief one-to one behavioural interventions, such as motivational interviewing or cognitive behavioural interventions), and those that can be introduced in a clinic and then self-administered at home (e.g. interactive digital interventions).

Search strategy: The review by Scott-Sheldon included only RCTs carried out in the USA in STD clinics from 1989 to early 2009. The review will therefore need to have a broader scope, i.e. include non-US studies from high and middle income countries. The review will be restricted to RCTs. The review will start with a scoping review, after which the detailed review protocol will be finalised.

Peer-reviewed articles will be located using the following computerised databases: Cochrane Infectious Diseases Group trials register, Centre for Reviews and Dissemination (CRD), Database of Abstracts of Reviews of Effectiveness (DARE), MEDLINE, EMBASE, Web of Science, IBSS, LILACS, PsycINFO. Searches will cover the period 2000 to 2014. The database searches will be supplemented by scanning the reference lists of included papers.

We will use the latest standard criteria (CONSORT and STROBE) to assess quantitative study quality (Schulz et al 2010; von Elm et al 2008). All papers will be appraised independently by two reviewers. Where agreement is not obtained papers will be referred to a third reviewer.

Data extraction: A data extraction template will be developed focusing upon generic issues relating to design, definitions of standard care, barriers to uptake, characteristics of interventions (explicit/implicit operationalisation of theory) and populations, key aspects of process evaluation, and economic issues. We do not intend to search for full economic evaluations, but rather we will abstract relevant economic data from the identified studies, where reported. This will give us some indication of intervention costs. Analyses of intervention effectiveness will be recorded in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) (Moher et al, 2009)).

Outcomes: The focus is on interventions that are designed to reduce sexual risk and so primary outcome measures will include reduction in a biological marker of sexual risk, for example incident HIV/STIs, or unwanted pregnancy, or a well validated behaviour measure (e.g. condom use, number of sexual partners). Length of follow-up and duration of effect will be recorded. Other outcomes of importance in informing the selection of front running interventions will be the resource implications, and acceptability to target groups.

Outputs: A suite of candidate interventions to be selected and adapted (in WP4) on the basis of outputs from WP3. These candidate interventions will be selected on the basis of effectiveness and deliverability within SH clinics and will be analysed in terms of their specified behaviour change objectives, underpinning mechanisms of change model, corresponding change techniques and implementation strategies in accordance with IM. The review will be registered on the PROSPERO database.

Work Package 2:

Objective 3: To develop a sexual risk assessment/triage tool to identify service users' level of sexual risk and thus individualise packages of behavioural interventions to users' need.

Study design: Sexual risk assessment/triage tools will be developed to identify individuals at increased risk of STIs and HIV, through the analysis of routinely collected demographic, clinical and behavioural data that is entered into electronic patient records (EPR) as part of routine care in SH services and captured in the Genitourinary Medicine Clinic Activity Dataset (GUMCAD).

Statistical analysis of GUMCAD the latest version of which (GUMCADv3) will link individuals' socio-demographic, geographical, clinical and behavioural data with their incident or prevalent STIs (including HIV) will be undertaken to determine which factors best predict subsequent STI acquisition. GUMCAD is a pseudo-anonymised patient-level electronic dataset which collects information on diagnosis made and other commissioned services provided by genitourinary medicine (GUM) clinics (level 3 services). The extension of GUMCAD to include information from other commissioned non-GUM sexual health services (level 2 services such as enhanced GPs, integrated contraception and sexual health services, young people's services e.g. Brook clinics, and other third sector or volunteer sectors services) is being rolled out (GUMCADv2). Collection and reporting of GUMCADv2 (n=570) from all level 2 and 3 services to PHE is mandatory; this therefore will be the **study population and setting** for this component of the analysis.

The **data collected** in GUMCADv2 includes basic demographic information (age, gender, self-defined ethnicity, country of birth, and sexual orientation) and residence (lower-level super output area of residence [LSOA] based on postcode), clinic information (which clinic and type of appointment), clinical information including all tests, vaccinations and diagnoses made for all patients seen. The STI diagnoses recorded include gonorrhoea or chlamydia including complicated and uncomplicated by site of infection), trichomonas, syphilis (including stage), genital herpes (primary or recurrent), genital warts (primary or recurrent), HIV and other blood borne viruses, and whether or not the patient was a contact of partner with an STI.

GUMCADv3 has been enhanced by the addition of key behavioural variables covering sexual risk and drug and alcohol use. These variables are based on those that the British Association for Sexual Health and HIV (BASHH) specialists recommend should be recorded as part of a routine sexual health consultation and those identified through on-going research on behavioural risk markers for subsequent HIV acquisition in MSM (Desai and Burns). The wording for these key behavioural questions has been informed by the National Survey of Sexual Attitudes and Lifestyles (Natsal). The behavioural data will be collected as part of the routine clinical history taken from the service user by the health care provider (HCP) and then reported back to PHE. This

provides the opportunity for developing STI risk algorithms using data on individual level self-reported (to HCP) sexual behaviour (including condom use), drug and alcohol use and previous STI diagnosis as well as socio-demographic and health service related data.

A sexual risk hierarchy will be defined using the data from GUMCADv3. Outcomes will be divided into low, medium and high risk based on the following assumptions; that infections characterised by a high proportion of symptomatic cases need higher risk sexual behaviour patterns for transmission to be maintained (Glaiser, 2006), and that in MSM the transmission of pharyngeal and urethral gonorrhoea and chlamydia can be sustained in the absence of unprotected anal intercourse.

- Low risk: no STI diagnosis
- Medium risk: chlamydia, trichomonas, or new episode of genital herpes, or new episode of genital warts only in heterosexual men and women. Pharyngeal or urethral chlamydia and gonorrhoea, or new episode of genital herpes or new episode of warts in MSM.
- High risk: more than one incident infection, gonorrhoea, syphilis and new HIV diagnoses in heterosexual men or women; rectal gonorrhoea, chlamydia, LGV, or syphilis, new hep C, or a new HIV diagnosis in MSM

Data analysis: Ordinal regression models to identify a parsimonious model of the key predictors of sexual risk according to the hierarchy above and thus the variables that an algorithm should take into account. These models will be informed by a social determinants framework (Monteiro et al 2005, Stenger et al 2013), which acknowledges the role of contextual factors, socio-demographic and geo-spatial (residence as well as clinic attended), in addition to self-reported sexual behaviour and drug and alcohol use to identify people at risk. The analysis (and thus the resulting models) will be disaggregated by gender, ethnicity and sexuality. The algorithm will be developed on a random sample of half the GUMCADv3 pilot dataset and then validated for performance on the remaining half.

Sample size: GUMCADv3 pilot data is being collected from 10 clinics, a mixture of types across England, from August 2013. The total number of patients seen annually in these clinics is approximately 140,000 with approximately 35,000 new STIs diagnosed. The large dataset will provide high power to detect associations and validate potential algorithms.

Outputs: the outputs of WP2 will include: A risk assessment tool which can be delivered via EPR. The acceptability and feasibility of the tool to identify individuals at three levels of risk in clinical settings will be piloted during WP5.

Work Package 3:

Objectives 4*:* To describe current practice and preferences in UK sexual health (SH) clinics with respect to delivery of sexual risk reduction interventions and identify best practice.

Objective 5: To explore opportunities and challenges to delivery of candidate risk reduction interventions in SH clinics

Study design: A series of linked studies using mixed methods: key informant interviews, semi-structured interviews with service users, a national internet-based survey of service leads, and a discrete choice experiment among service users, as follows:

i. Key informant interviews: to be conducted by telephone. The **target population** from whom a purposive sample will be taken comprises HCP, including service leads, health advisors, and clinicians (doctors and nurses). The **settings** will include 15 clinics purposively selected to include a range of type, size, location, and client mix. A **sample** of n=30 will be recruited to complete semi-structured interviews exploring the following themes (to be informed by WP1 and 2):

- the types and extent of triage methods in use and who does it.
- the behavioural interventions delivered and who delivers it (including 1:1 structured discussion to address risk taking as per NICE guidelines).
- the organisation of staff, time and resources spent on risk reduction interventions.
- the acceptability and feasibility of introducing a triage tool and the candidate interventions.

ii. Semi-structured interviews with patients: to be conducted as face-to-face interviews with a purposive sample of a **target population** of young men and women, and MSM, recruited at different points in the clinic pathway, with and without a diagnosed STI, and from **settings** comprising a range of clinic types and locations, from a range of ages and ethnicities. A **sample** of n=30 will be recruited to explore the following themes

- experience of the clinical service on the day- including the pathways of care
- attitude towards risk assessment
- own perception of their sexual risk
- experience of behavioural interventions in the past
- preference for behavioural interventions, if any

iii. Internet survey: a brief (10 minute) web-based survey. The **target population** will be SH clinic service leads who report to GUMCADv2 (n=570). It will be informed by the data emerging from the qualitative study with clinic staff in order to provide an overview of clinic practice in the UK. In order to maximise the response rate there will be liaison with the British Association of Sexual Health and HIV (BASHH), as the survey data will provide an opportunity to audit risk reduction strategies in sexual health settings, as per NICE guidelines. **Data collected** will include:

- clinic staff size and distribution
- distribution of clinical tasks amongst staff groups
- the proportion of clinics that conduct a risk assessment on patients
- the staff groups that are involved in the risk assessment.
- the proportion of clinics which deliver 1:1 structured discussion to address risk, as per NICE guidelines
- the staff groups that deliver the intervention and the training that they have
- types of interventions used, behaviour change techniques used and delivery modes
- the proportion of patients who receive this intervention
- the resource allocated to these interventions

For the purpose of **data analysis**, all interviews will be recorded and transcribed; content analysis will be conducted independently by a minimum of two researchers and discrepancies in coding will be resolved through discussion until a consensus is reached. Analysis will be conducted using the framework approach. This deductive approach to qualitative analysis allows for a more structured approach to data collection based on pre-determined aims and objectives. Software (NVivo version 10) will be used to synthesise and code the data within a thematic matrix to enable elucidation of conceptual associations. Both pre-determined concepts used for developing the topic guides as well as emergent themes arising from the data will inform the process of identifying the key thematic categories to be used in data coding, which will then be used to index and chart findings. The internet survey will be analysed using simple descriptive statistics, adjusted for clinic type, and location.

iv. Discrete Choice Experiment: We will explore patient preferences for the provision of risk reduction interventions using a Discrete Choice Experiment (DCE). DCEs have been used extensively in health economics as a method for assessing patients' preferences regarding the design of healthcare services (Ryan et al, 2008), including STI services (Miners et al 2012, Llewellyn et al, 2012). The DCE study will help determine how the intervention should be delivered to patients (for example, 1:1 or group based interventions and whether the intervention should be delivered by someone of the same sex). The intervention content, however, will be determined through the results of the systematic review and other WPs, not the DCE.

DCEs are a method based on the premise that services can be described in terms of their attributes (or characteristics) and that an individual's preference, and therefore choice, of service is based on a combination of these attributes. It is generally thought to be more realistic than directly asking individuals to state their preferences as it requires them to make choices and implicitly 'trade-off' different service or intervention designs. A particular advantage of this approach is that unlike the interviews with key informants and patients, it will produce quantitative evidence on preferred intervention designs in terms of desirable combinations of constituent components. For example, it might be that individuals are willing to 'receive' an intervention that takes a relatively long time to complete, or involves repeat 'doses', if it is delivered 1:1 rather than through a group environment. Or perhaps individuals are more likely to agree to attend a behavioural intervention if they know the intervention is being run by a person of the same sex or sexual orientation. DCE data can also be analysed to assess whether preferences vary by observable characteristics such as age and sex. Thus it will be possible to determine whether preferences, and therefore the intervention design, should differ by sub populations.

In summary, the proposed DCE will involve four stages:

1. Identification of the key issues of importance (attributes and attribute levels) to patients in terms of elements of delivering the intervention based on literature review (WP1) and the results from WP3 parts i-iii.

2. Constructing the DCE questionnaire using a fully factorial design to limit the number of questions respondents need to complete.

3. Gain ethical approval and administer the DCE instrument

4. Analyse the data using appropriate regression techniques given the precise DCE design, and determining the relative importance of the different intervention characteristics.

Data collected: The attributes covered by the questionnaire will be informed by the literature review. Attributes and levels will be combined in choice scenarios which the respondents will be asked to choose from. A fractional factorial design (FFD) will be used to create a questionnaire of manageable size while remaining optimal from a statistical perspective (Ryan et al, 2008).

Target population and setting: DCEs are not amenable to conventional power calculations, in part because designing the questionnaire (a prerequisite for determining power) is an integral part of the research process. However, other studies using DCE to assess patient preferences for healthcare have typically included 200 participants (Ngene, 2012). Based on previous questionnaire return rates from similar research at sexual health clinics at least 250 participants will be recruited from 6 clinics. Subject to ethical approval, individuals will be recruited from both GUM and CASH clinics. Individuals will be eligible if they are between 16-25 years of age or MSM as they represent the 'high risk' groups of primary interest. No other inclusion or exclusion criteria will be applied but individuals will be asked to provide information regarding variables such as age and other risk factors, at the time of completing the DCE questionnaire. Individuals will be asked to participate in the study by research nurses at the clinics, and to complete a paper based version of the instrument there and then. If individuals do not want to complete the questionnaire at the time, they will be offered the opportunity to complete it online. All data will be collected anonymously.

Analysis of the DCE will depend on the exact design, but it is likely to be by random effects logistic regression. Odds ratios and 95% Confidence Intervals (CI) will be used to estimate the relative importance of each attributes level. Preferences for different intervention designs (i.e. combinations of the different attributes) can and will also be presented by presenting the probability individuals would choose one intervention design over another. In order to determine whether preferences differ by respondent characteristics, a second regression model will include interactions between DCE attributes and respondent characteristics (e.g. age, gender, ethnicity and sexual orientation).

Outputs*:* the outputs of WP3 will include: (i) a report describing current practice for risk assessment and intervention in UK sexual health settings; (ii) a list of the candidate interventions and their design that appear popular and deliverable in sexual health settings for further evaluation in WP4 and 5.

Work Package 4:

Objective 6: Using stake holders input, to select, adapt and manualise an evidence-based suite of interventions that can be combined and delivered as intervention packages to meet individuals' needs.

Study design: The systematic review from WP1 and the clinical opportunities and user preferences identified in WP3 will be used through a process of Intervention Mapping to select and guide adaptation of a suite of interventions.

A suite of deliverable interventions will be identified and categorised in terms of the particular behaviour change outcomes and self-regulatory skills that they have been found to change effectively. These can then be matched to deficits and behaviour change needs in service users. Candidate interventions will be analysed into their component parts drawing on IM design methods and assessed – and where necessary adapted – for use in UK clinics using a variety of delivery modes including, for example, sexual health clinic waiting rooms (e.g.,

informational videos), one-to-one clinic appointments (e.g., motivational interviewing and skills training), group-based interventions and self-delivered interventions (including interactive digital interventions). For those categorised by the triage tool as at highest risk, one-to-one interventions (e.g. motivational interviewing) are likely to be offered as recommended by NICE (NICE, 2007a). Intervention components are likely to consist of: techniques to provide persuasive information about health consequences, consolidate self-protective values, norms and motivation, set personal goals, promote in-context self-regulation (including if-then planning), undertake self-monitoring and self-assessment, teach persuasive negotiation skills, as well as development of condom-related behavioural skills including accessing, carrying, and using condoms and lubricant, and making condoms more sexually exciting. In addition, where not currently specified by existing interventions, components can be added that enhance motivation to change and other techniques recommended by NICE to be effective at eliciting behaviour change (e.g. intervention components that increase self-efficacy and norms, including peer practices and approval) (NICE behavioural interventions NICE, 2007b). It is envisaged that 'best bet' interventions will be adapted for use with the high risk target groups and amended with PPI and staff input through the use of Focus Groups. For example, existing interventions may be adapted to ensure feasibility of faithful delivery in clinic settings or to optimise maintenance of behaviour change by including the addition of follow up contact where this is supported by evidence provided by WP1, or support partner notification.

Each intervention package will be guided by a manual which will define specific and replicable modes of delivery with underlying behaviour change mechanisms. As there is a need to translate effective behaviour change interventions from research settings to clinical practice, the manual would provide recommendations for the implementation in a clinical context. Finally, constructing guidelines for monitoring the reliability and validity of the interventions will increase the fidelity of the interventions and will be an additional strength of this work.

Intervention Mapping consists of 6 iterative steps: (1) needs assessment, (2) mapping of intervention objectives (i.e., main outcomes) onto psychological, behavioural and environmental determinants or change processes, (3) selecting techniques and strategies to modify the determinants of behaviour based on an understanding of change processes, (4) selection and construction of intervention components and materials, (5) planning for intervention adoption, implementation and sustainability and (6) planning evaluation including process and outcome evaluation methods and instruments. This process will be applied across all work packages. The systematic review (WP1) review will clarify the needs of clinic users and staff in identifying potentially effective interventions and intervention components as well as potential change mechanisms that may be critical to intervention effectiveness. We will also identify pre-existing intervention materials which appear to be effective (in relation to our main outcomes) in UK clinic settings in order to identify 'best bet' techniques and strategies. This work will help inform the analyses of existing risk reduction clinic practices (WP3). Outputs from WP1, 2 and 3 will provide the evidence base for stage 4 of the IM package that is, selecting and adapting a suite of evidence-based interventions suitable for delivery in UK sexual health clinics (WP4). As this process proceeds, the feasibility study of an RCT (WP5) will be detailed, together with a manual allowing replication of the intervention construction and implementation practices (WP6).

Stage 4 of the intervention mapping process (WP4) will comprise focus groups with current and/or previous service users, a PPI advisory group, sexual health advisors and clinicians. These will be used at the beginning of the IM procedure (months 1-3) to present the front running candidates for inclusion in the intervention suite and to stimulate discussions about: how best to adapt to each group; feasibility of delivery; likely uptake, etc. and thus inform the on-going IM process.

Target population and setting:
Service User input: A sampling framework, using quota sampling based on sexual orientation, age and gender will be applied, including MSM and young heterosexuals aged ≥ 16 years old, to create four distinct groups in order to gain a broad range of opinions. Approximately 6-8 participants (n=24-32 in total) will be recruited to attend each focus group which will last 45 to 60 minutes. These groups are formed so that participants from our target communities with a high prevalence of STIs are able to share their thoughts and feelings freely amongst participants with similar experiences of sexual health provision. Eligible participants from our PPI group, in Brighton and in one London SH clinic (where researchers are based) will be invited to attend one of four focus groups being held at local community venues.

Health Care Provider (HCP) input: Four additional groups to will provide input from potential service providers (n=24-32). Two groups will be run with Sexual Health Advisors (one in Brighton and one in London) and two groups with HCP from GUM clinics or integrated contraception and sexual health services (again in Brighton and London).

Data collection: Discussions will be facilitated by two researchers trained in focus group methodology and will be transcribed verbatim by an external medical transcription service. Non-HCP participants will receive £20 as recompense in line with similar studies.

Data Analysis The transcripts will be analysed using a Framework Analysis approach (Ritchie and Spencer, 1994). This assists accurate reporting of individual experiences and opinions as well as the meanings attached to them, whilst maintaining predefined objectives (Pope et al, 2000). See WP3 for details.

Outputs: Manualised packages of interventions suitable for delivery in the context of existing sexual health services including clear guidelines on (1) which behavioural and self-regulatory needs and deficits each intervention is able to address and (2) what counts as faithful delivery in context including "must have" and must not have rules. Manualisation will be completed in WP6.

Work Package 5:

Objectives 7: To determine the acceptability and feasibility of implementing the individualised package of interventions in different SH clinical settings,

Objectives 8: To assess the feasibility of testing this individualised package of behavioural interventions in a randomised controlled trial against usual care.

Objectives 9: To estimate the cost and resource implications of implementing the individualised intervention packages in different SH settings.

Study Design: It is envisaged that the best design for a definitive RCT would be cluster randomisation. We therefore propose to determine feasibility by conducting pilot implementations in a small number of clinics (n=6) representative of the range of sexual health services, without randomisation. Three further clinics will act as pilots for the control sites where patients will continue to receive standard of care, but consent to obtain follow-up outcome data will be sought. Outcomes will be assessed using a mix of qualitative and quantitative methods. As the collection of data used for triage is expected to be incorporated into routine care (data being collected routinely to meet the PHE requirements for behavioural surveillance) this data will be available for control and intervention sites.

Target population: Patients attending the pilot clinics and eligible for triage during a 6 month pilot period.

Inclusion criteria: Men and women, aged 16 and over, attending the pilot SH clinics with a new clinical episode
Exclusion criteria: Under 16, do not or are unable to consent

Settings: Nine clinics (6 intervention and 3 control pilot clinics) have been chosen as the minimum number to represent the range of sexual health clinical settings in the UK, within the constraints of resources (all have agreed in principle to participate). Clinics in and out of London have been included. All clinics will have access to at least a limited EPR facility, which is required to meet the PHE national surveillance requirements.
Large London GUM clinic – The Mortimer Market Centre; high proportion of MSM; ethnically diverse
Large non-London GUM clinic – The Royal Sussex County Hospital; high proportion of MSM.
Medium-sized London GUM clinic - Archway Centre; large proportion ethnic minorities; small proportion of MSM
Medium-sized London GUM clinic - Kings College Hospital; ethnically diverse; small proportion MSM; fully integrated sexual health and contraception service.
Brook Advisory Service – three London clinics to be included (Euston, Southwark and Lambeth); primarily contraception services but provide level 2 sexual health services.
Small and medium-sized non-London GUM clinics – Swindon and Whittal Street, Birmingham.

Interventions: As developed in WP 4, it is expected that the package of interventions will include group delivered (e.g. waiting room videos), self-delivered (e.g. interactive digital interventions), clinician delivered (one-to-one motivational interviewing). Clinical staff will be trained on site by the research team in interpreting the triage results, and delivering the intervention.

Recruitment and sampling: Recruitment will take place in the 4 GUM clinics for 2 months and in the 2 Brook clinics for 3 months. All patients attending the clinic during the recruitment period will be provided with information that the clinic is piloting a new risk assessment tool which will help clinicians decide whether to offer interventions to reduce health risks associated with sexual behaviour. The information will make clear that, if they are advised to take part in a particular intervention, they can choose to accept the intervention, or not. All eligible patients attending the intervention and control clinics during the recruitment period will be asked by the clinician at the beginning of the consultation, prior to triage, whether or not they would consent to being approached after 3 months for telephone follow-up interview. If the risk assessment tool indicates a medium or high risk then the patient will be eligible to be offered an appropriate package of intervention(s). If the intervention advised is an interactive digital intervention, they will use a password to access the intervention via a website, on a computer in the clinic, and to access the intervention at home. If it is a face-to-face or telephone intervention they will be referred accordingly. The triage tool will be incorporated into the EPR systems of the participating clinics, so that all clinic attendees will be subject to this risk assessment and the result automatically recorded.

Data collection and follow-up: Once users are referred to a package of intervention their clinic ID will be their unique identifier. The unique identifier automatically generates a notification when a participant starts and finishes any part of the intervention (see figure 1). The proportions in the different steps of figure 1 will be extracted from the clinic EPR systems. A purposive sample of n=30 users who were offered the intervention but did not accept or dropped out at any point will be invited to participate in a semi-structured telephone interview exploring the reasons for not accepting the intervention or dropping out. A further n=30 semi-structured interviews with HCP (clinicians and health advisors) will be conducted exploring their experience of the intervention.

A sample of the users who agree to telephone follow-up will be contacted by phone by a research nurse, three months after their appointment. The study aims and objectives will be explained and verbal consent for a telephone interview taken. The research nurse will conduct a brief telephone interview, collecting data on their experience of attending the clinic and the intervention (if they received it), sexual risk behaviour, whether or not they have been to an SH clinic and/or had an STI diagnosed since their clinic appointment and preferred mode of follow-up: e.g. clinic appointment or postal STI sampling kit. Based on their preferred choice of follow-up either a clinic appointment will be arranged or postal GC/CT sampling kit will be dispatched (figure 3)

In order to describe the impact of the intervention on the flow of users through the clinic and resource allocation clinic operations in the run up to the pilot, during the pilot and after the pilot will be observed. Based on the timings entered into the electronic patient records and aggregate clinic activity data to extract the following: Total time spent by service users in clinic, total number of service users seen, number of STIs diagnosed; average consultation time with clinician; and health advisors work load.

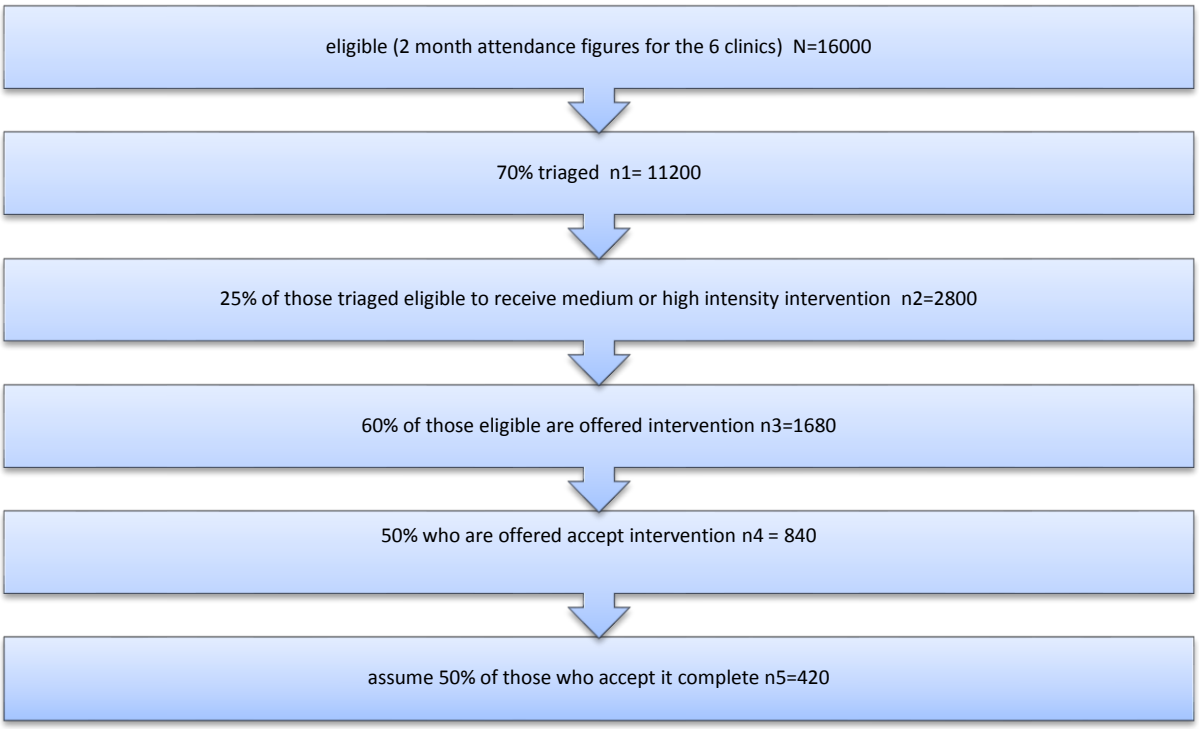

Figure 1: Flow chart for feasibility of the intervention with estimated proportions at each stage.

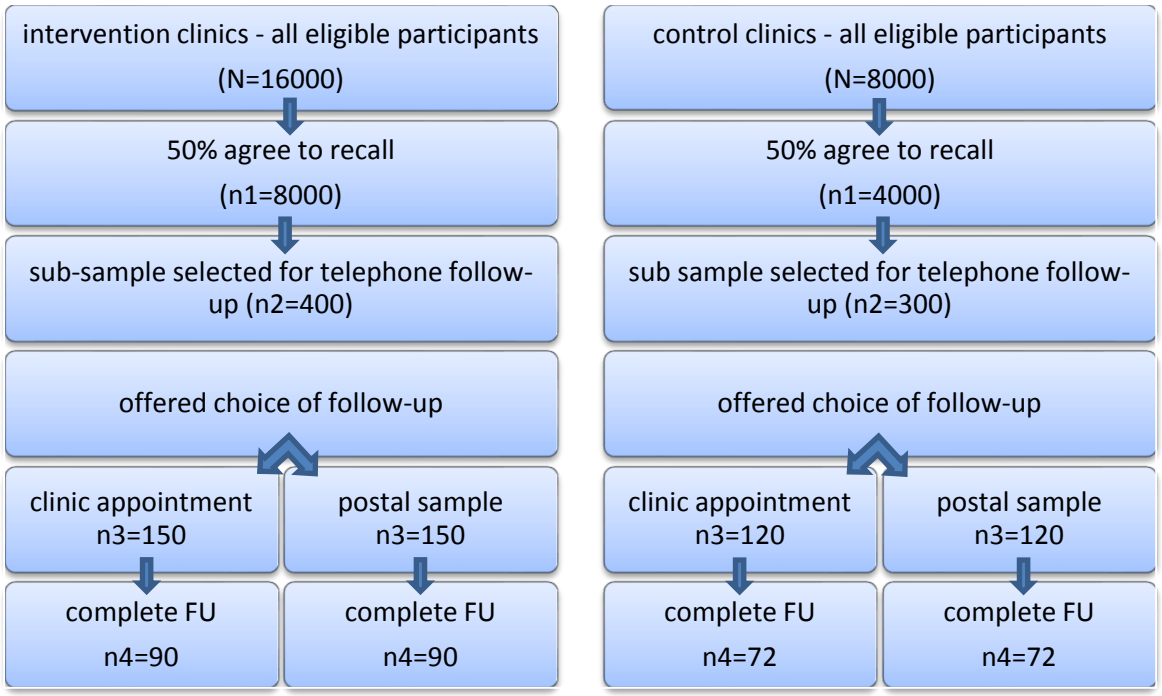

Figure 2: Flow chart for follow-up study

Study outcomes:

Acceptability of the intervention to users and HCP
1. Proportion of service users who attend the clinic that are scored by triage tool
2. Proportion of those who score high or medium 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
6. Reasons for not completing the intervention from the qualitative study of participant
7. Acceptability of the intervention from the qualitative study of the staff

Feasibility and resource outcomes:
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

Feasibility of active follow-up in an RCT
1. Proportion of service users who consented to the follow-up
2. Proportion of service users who were contactable at 3 months and complete the telephone interview
3. Proportion who had been for a STI screen or agreed to follow-up testing
4. Proportion of service users for whom there was a follow-up STI screen

Data analysis/ sample size: To investigate the feasibility of the intervention and understand the processes involved five measures will be collected: (i) the proportion of attendees triaged, among whom (ii) the proportion classified as medium or high risk, among whom (iii) the proportion offered the intervention, among whom (iv) the proportion that accept it, and among whom (v) the proportion who complete the intervention. All of these will be extracted from the EPR and calculated for each of the six centres implementing the intervention to see how this varies, and we will test for a difference in each between GUM clinics and Brook clinics by chi-squared test.

The sample size is estimated from proportion (v) as this uses the smallest denominator. It also determines the number of participants who experienced the intervention. A total of 16000 patients attending the trial sites during the feasibility study period will be triaged leading to at least 400 completing the intervention (see figure 1), from among at least 800 accepting it, based on the above estimates. This sample size allows proportion (v) to be estimated with expected 95% confidence interval of 46 to 54%, and assuming 200 accept the intervention in Brook clinics and 600 at GUM. This provides over 80% power to detect a difference in completion such as 44 vs. 56% between these clinic types.

To investigate the feasibility of collecting the follow-up data envisaged for the main trial we will ask attendees whether they will agree to telephone follow-up. We will then, in a subsample of 400 from implementation site clinics and 300 from the control clinics, conduct telephone follow-up and calculate (i) the proportions opting for either a return visit to the clinic, or to be sent a kit for home sampling, and (ii) from among the two groups calculate the proportion completing follow-up (i.e. returning to clinic or returning a kit for testing). We will compare these proportions between GUM and Brook, and between clinics implementing the intervention and control, and between groups opting for a clinic appointment or home sampling. Analysis will use chi-squared test and logistic regression, to examine these differences jointly.

This sample size, if the overall follow-up is assumed to be around 60%, gives a 95% confidence interval of 56 to 64%. Assuming at least 150 select each follow-up method at intervention clinics and 120 at control clinics then we will have over 80% power to detect a difference of 53 vs. 67% in completed follow-up, and a difference of 54 vs. 66% between intervention and control clinics. Qualitative data will be analysed as in WP3

Economic analysis: An assessment will be made of the (incremental) costs of delivering the package of interventions, by recording the resources, such as staff time, that are required to deliver the interventions during the feasibility study and by applying appropriate NHS unit costs. Interviews with health care professionals, service manages and commissioners will be undertaken if necessary to supplement the data collection exercise. The overall output would be an estimate of the per-patient cost of delivering the intervention and the cost that would be required to fund the intervention in a fully powered RCT. The intention would be to perform a full economic evaluation if a full RCT of the intervention is later commissioned.

Work Package 6

***Objective 10*:** To refine the manual of the intervention package and to outline a feasible trial design (if feasibility is supported).

Manual development: Complete specification of the intervention package(s), standard operating procedures, and potential staff and cost implications will be developed for the different intervention packages in different setting. An associated training tool and post-training assessment for clinicians and health advisors will be developed, informed by the training of clinical staff during the trial. The manual and the training are expected to be interactive, web based components with the potential for refresher training to be added in.

Design of a proposed RCT: This is likely to comprise a cluster randomised control trial with a combination of active follow-up, supplemented by routinely collected clinical and surveillance data. Feasibility challenges will be reported. If a trial is deemed unfeasible, alternative evaluation methods will be proposed.

Project outputs

1. Systematic review of brief sexual risk reduction interventions for high risk groups in a UK clinical setting.

2. A risk score algorithm adapted to SH-clinics and compatible with EPR systems to guide selection of intervention packages appropriate to particular health service users in accordance with their risk profile, and the service in which they are seen.

3. Development of an evidence-based tool kit of sexual risk reduction interventions, tailored to different high risk individuals.

4. Development of manuals for delivering the interventions in appropriate contexts (e.g., in clinic and at home) with fidelity strategies embedded.

5. An estimate of the feasibility of implementing the interventions in different clinical settings

6. Estimates of the cost of implementing the intervention package

7. Identification of a group of interested stakeholders, including service users (PPI), service providers (health advisors and service leads), other stakeholders (voluntary sector and commissioners) who can oversee the development of the next stage, e.g. RCT and the implementation and scale up of the intervention.

8. A trial design for a full evaluation and estimate of the feasibility of delivery of the trial

9. Plain English report for participants and service users.

10. Publications in peer-reviewed journals (to include feasibility/developmental work written up for publication).

11. Best Practice Guidelines for staff involved in delivering interventions

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