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Abstract

Sexual risk reduction interventions for patients attending sexual health clinics: a mixed-methods feasibility study

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Background: Sexually transmitted infections (STIs) continue to represent a major public health challenge. There is evidence that behavioural interventions to reduce risky sexual behaviours can reduce STI rates in patients attending sexual health (SH) services. However, it is not known if these interventions are effective when implemented at scale in SH settings in England.

Objectives: The study (Santé) had two main objectives – (1) to develop and pilot a package of evidence-based sexual risk reduction interventions that can be delivered through SH services and (2) to assess the feasibility of conducting a randomised controlled trial (RCT) to determine effectiveness against usual care.

Design: The project was a multistage, mixed-methods study, with developmental and pilot RCT phases. Preparatory work included a systematic review, an analysis of national surveillance data, the development of a triage algorithm, and interviews and surveys with SH staff and patients to identify, select and adapt interventions. A pilot cluster RCT was planned for eight SH clinics; the intervention would be offered in four clinics, with qualitative and process evaluation to assess feasibility and acceptability. Four clinics acted as controls; in all clinics, participants would be consented to a 6-week follow-up STI screen.

Setting: SH clinics in England.

Participants: Young people (aged 16–25 years), and men who have sex with men.

Intervention: A three-part intervention package – (1) a triage tool to score patients as being at high or low risk of STI using routine data, (2) a study-designed web page with tailored SH information for all patients, regardless of risk and (3) a brief one-to-one session based on motivational interviewing for high-risk patients.

Main outcome measures: The three outcomes were (1) the acceptability of the intervention to patients and SH providers, (2) the feasibility of delivering the interventions within existing resources and (3) the feasibility of obtaining follow-up data on STI diagnoses (primary outcome in a full trial).

Results: We identified 33 relevant trials from the systematic review, including videos, peer support, digital and brief one-to-one sessions. Patients and SH providers showed preferences for one-to-one and digital interventions, and providers indicated that these intervention types could feasibly be implemented in their settings. There were no appropriate digital interventions that could be adapted in time for the pilot; therefore, we created a placeholder for the purposes of the pilot. The intervention package was piloted in two SH settings, rather than the planned four. Several barriers were found to intervention implementation, including a lack of trained staff time and clinic space. The intervention package was theoretically acceptable, but we observed poor engagement. We recruited patients from six clinics for the follow-up, rather than eight. The completion rate for follow-up was lower than anticipated (16% vs. 46%).

Limitations: Fewer clinics were included in the pilot than planned, limiting the ability to make strong conclusions on the feasibility of the RCT.

Conclusion: We were unable to conclude whether or not a definitive RCT would be feasible because of challenges in implementation of a pilot, but have laid the groundwork for future research in the area.

Trial registration: Current Controlled Trials ISRCTN16738765.

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Contents

List of tables

List of figures

List of boxes

List of abbreviations

aOR	adjusted odds ratio
app	application
AttA	attitudinal arguments
BASHH	British Association for Sexual Health and HIV
BIC	Bayesian information criterion
BSA	behavioural skills argument
BSMS	Brighton and Sussex Medical School
CI	confidence interval
CLOGIT	conditional logistic
CUST	condom use skills training
DCE	discrete choice experiment
DHSC	Department of Health and Social Care
EPR	electronic patient record
FPA	Family Planning Association
GMFA	Gay Men Fighting AIDS
GP	general practitioner
GUM	genitourinary medicine
GUMCAD	genitourinary medicine clinic activity data set
HA	health advisor
HCP	health-care provider
HIV	human immunodeficiency virus
ID	identification
IM	intervention mapping
IST	interpersonal skills training
LCM	latent class model
MI	motivational interviewing
MMC	Mortimer Market Centre
MSM	men who have sex with men
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NormA	normative argument
NPV	negative predictive value
OR	odds ratio
PEP	post-exposure prophylaxis
PHE	Public Health England
PMG	Project Management Group
PPI	patient and public involvement
PPV	positive predictive value
PrEP	pre-exposure prophylaxis
PSC	Project Steering Committee
RCT	randomised controlled trial
RSB	risky sexual behaviour
SH	sexual health
SMT	self-management skills training
STI	sexually transmitted infection
THT	Terrence Higgins Trust
TIA	threat-inducing argument
UCL	University College London
WP	work package

Plain English summary

Reducing sexually transmitted infections (STIs) is a public health priority. Those most likely to be diagnosed with a STI are young people (aged 16–25 years) and men who have sex with men. Studies in other countries have shown that interventions aimed at changing sexual behaviour (e.g. increasing condom use) can reduce the chance of getting new STIs in patients attending sexual health (SH) clinics. However, it is not clear if these interventions will work in English sexual health clinics, or if they could be implemented within existing resources. This study aimed to find out if effective interventions could be adapted to an English setting and tested this in a randomised trial.

The scientific literature was searched for potential interventions and 33 trials were found. Effective methods included videos, digital web-based interventions, self-testing kits and talking sessions (e.g. counselling). Patients and providers were asked which interventions were acceptable and preferences for digital and one-to-one talking interventions were found. Providers suggested that these were feasible to deliver. Data routinely collected from patients (e.g. number of partners) were used to select patients at a higher risk of having a STI, a computerised risk score calculation was developed, and the highest risk group was directed to a one-to-one counselling intervention. There were no appropriate digital interventions available; therefore, a stand-in web page was created to signpost users to appropriate SH resources. This was offered to all patients.

The intervention package was piloted in two SH settings rather than the planned four because of a lack of clinic staff time and space. It was planned to follow up a subset of patients from all eight clinics 6 weeks after their visit to collect information on STI diagnoses. Patients were recruited from six clinics, but only 16% of patients completed the survey and returned a sample.

It was not possible to conclude definitively whether or not a randomised trial is feasible because of challenges in implementation and recruitment.

Scientific summary

Background

Sexually transmitted infections (STIs) continue to represent a major public health challenge in the UK, with 417,584 diagnoses in 2016. Although there have been reductions in the numbers of cases of gonorrhoea and genital warts, there was a 12% increase in syphilis diagnoses, and chlamydia incidence has remained stable. Despite having a national network of open-access clinics for the treatment of STIs, and improved diagnostics, infection rates remain high. STIs particularly affect subgroups of the population, with young people (aged 16–25 years) and men who have sex with men (MSM) having the highest rates of infection. A variety of factors contribute to the risk of STIs: lack of knowledge about STIs, low self-efficacy, poor condom use, peer norms and a lack of sexual negotiation skills. This led the Department of Health and Social Care to develop a Sexual Health Framework, which recommends the prioritisation of prevention and support for behaviour change, alongside increased access to sexual and reproductive health services, particularly for those most vulnerable to poor sexual health (SH).

Multiple behavioural interventions have been trialled and, in most cases, shown to have a modest but consistently positive effect, but they have not been implemented systematically in a way that could have a population-level impact in the UK. There is a lack of evidence about how they can be implemented, in which context, by whom and for whom. A clearer understanding of the factors that influence implementation in particular settings is needed. As funding for health care is under pressure, providing substantial additional resources across a large number of services is unrealistic, and, therefore, the implementation of new interventions needs to focus on identifying brief, pragmatic, non-labour-intensive interventions that can be tailored to the level of risk of the individual attending any of a range of different SH services. Implementation should be achievable through the reallocation of existing resources, not substantial new investment.

Objectives

The overall aim of the Santé project, developed in response to a commissioned call, was to determine the feasibility of a randomised controlled trial (RCT) of an individualised package of sexual risk reduction interventions, to be offered within routine clinical care pathways in SH clinics. This aim was addressed through 10 objectives:

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 the user's needs
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 develop a manual of the 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 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).

Methods

The project was a multistage, mixed-methods study, which included developmental work and a pilot cluster RCT, and comprised six packages of work using the methodological approach of intervention mapping.

The developmental work included three main strands of work to inform the intervention package design: (1) a systematic review of sexual risk reduction behavioural interventions focusing on UK-relevant evidence, (2) the development of a sexual risk triage tool to identify individuals at increased risk of STI diagnosis (3) a mixed-methods study to describe sexual risk reduction practices and preferences in SH clinics and to identify opportunities for intervention. Using the evidence generated from these activities, we selected and adapted evidence-based intervention components to develop and manualise a one-to-one intervention. We sought feedback from patients and health-care providers (HCPs) on the design and content of the intervention.

We conducted a pilot cluster randomised trial to investigate the feasibility of implementing the intervention package, its acceptability and the feasibility of obtaining the outcome data necessary for a full RCT. The pilot was designed to include four intervention and four control clinics, including level 2 and level 3 services. A subset of patients was recruited from intervention and control clinics, to be followed up 6 weeks later for a web survey and STI screen. The STI screen was either offered as a postal self-sample kit sent to the patient's home, or patients could return to the clinic for a screen. The screen included chlamydia and gonorrhoea tests. The web survey collected information about participants' recent clinic visit, including any interventions received.

In the intervention clinics, process data were collected from the electronic patient record (EPR) system or study data collection tools to monitor engagement with the intervention. Interviews and focus group discussions were conducted with patients and HCPs to gain feedback on the acceptability and feasibility of the intervention delivery.

Results

Developmental work

We identified 33 RCTs in a systematic review, of which 24 provided evidence of some significant impact on sexual behaviours, reflected in increased testing for STIs or reduced STI rates. Interventions included videos, digital online interventions, peer-group-delivered interventions, talking interventions such as counselling, and the provision of self-sampling kits for STI testing. Feedback from both patients and providers indicated that talking interventions, such as brief motivational interviewing sessions, and digital interventions were considered acceptable to service users and desirable by HCPs. HCPs also indicated that these intervention approaches could feasibly be delivered within their clinical settings.

We developed an intervention package consisting of three components: (1) a triage tool to score patients as being at high or low risk of STI using routine data, (2) a digital intervention (web page) for all patients, regardless of risk (low-intensity intervention) and (3) a brief one-to-one consultation based on motivational interviewing for high-risk patients (high intensity). There were no appropriate online interventions that were available or that could be adapted for the pilot; therefore, we created a placeholder for the purposes of the pilot.

Pilot intervention

We enrolled eight pilot trial sites in four categories, level 2 (non-specialist SH services) and small, medium and large level 3 clinics (providing specialist SH services, all genitourinary medicine clinics), and allocated these as four intervention and four control sites. Neither of the level 2 services (one intervention and one control) was able to implement the protocol. Among the remaining three intervention sites, the intervention package was implemented fully in one, partially in one and was not able to be piloted in the third. Principal barriers to site participation included recommissioning of services during the period of the pilot, lack of staff capacity or space, or other changes such as the implementation of a new EPR system or relocation of the clinic. A search for replacement clinics for those unable to deliver was unsuccessful.

The triage process was completed by 612 eligible patients in the intervention sites. The triage threshold was set to select 5% of young people and 15% of MSM as being at high risk, based on the model development process. However, when implemented, considerably more than this (19% of young people and 29% of MSM) were selected. Of those triaged as high risk, 18% attended the one-to-one session and 0.4% of clinic attendees (both high and low risk were eligible) were tracked as having visited the web page.

Patient and provider participants in the qualitative interviews and focus group discussions gave positive feedback about the one-to-one sessions, with health advisors feeling that it was similar to, and reinforced, their current roles, and patients who attended stated that they found it acceptable. There were mixed views of the triage process, particularly from HCPs; there were difficulties in implementing the triage process within the clinic EPR systems in a reasonable time scale, so alternative processes had to be used (self-completion tablet-computer questionnaires on arrival in the clinic). Participants felt that the principle of a web-based intervention was good, but neither HCPs nor patients had actively engaged with this part of the intervention package, which was limited by our inability to offer a fully functioning intervention.

Pilot follow-up

We recruited 406 patients to test whether or not it was possible to collect follow-up data at 6 weeks. This comprised a web survey and STI screen (by self-sampling and return by post). Of those enrolled, 273 (67%) were young people and 133 (33%) were MSM. Two hundred and twenty-eight (56%) participants did not participate in the web survey or return a self-sample kit and 64 (16%) completed both. Young people were less likely to complete the web survey [0.39, 95% confidence interval (CI) 0.25 to 0.61] or complete a STI screen (0.45, 95% CI 0.29 to 0.72) than MSM. Among young people, women were more likely to participate than men, and there were significant differences in follow-up rates by clinic, even when the age, gender and ethnicity of the participant were taken into account. Among MSM, no demographic factors were significantly associated with response, although there were trends towards older and white MSM being more likely to respond than younger and non-white MSM.

Conclusions

There are existing evidence-based interventions that could benefit patients attending UK SH services. We adapted and manualised a brief one-to-one intervention that was acceptable to staff and patients, although we had very limited opportunity to pilot it in clinics. However, digital online interventions, although acceptable and more easily deliverable at scale, were not available to pilot. They required more adaptation than was possible within the remit of this project, and a commitment to longer-term maintenance and updates. A mechanism to triage patients as part of routine care was developed, but before large-scale testing it would require more engagement by software suppliers so that it could be incorporated into EPR systems. During piloting, we found some evidence to support the acceptability of the combined intervention package, but encountered multiple challenges in both the feasibility of implementation and conduct of a trial. Follow-up rates for the outcome measure were lower than anticipated. Therefore, we conclude that undertaking a cluster RCT of the proposed intervention package would be very difficult in the environment of current SH service provision in England. In addition to the

challenge of limited resources and service reorganisation, there is a change in the model of care being commissioned, with a shift away from face-to-face consultation in favour of self-testing and online patient pathways. Although there is agreement that there is a need for behavioural interventions, including one-to-one interventions for the highest risk groups, the heterogeneity of services means that implementation of a large-scale national trial would be challenging. Digital interventions could be implemented in conjunction with new care pathways for STI testing, but these have not been widely commissioned. Further developmental work is required to see how behavioural interventions can be incorporated into the new models of service delivery. Alternative evaluation designs will probably be required to provide evidence of efficacy and cost-effectiveness at that point.

Trial registration

This trial is registered as ISRCTN16738765.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Background, aim and overview

Background

Sexually transmitted infections

In 2012, there were 448,422 new diagnoses of sexually transmitted infections (STIs) in England.[1] This declined to 417,584 diagnoses in 2016, mostly cases of gonorrhoea and genital warts. However, a concurrent 12% increase in syphilis diagnoses was seen, and chlamydia incidence has remained stable.[2] There was also a considerable decline in the number of new human immunodeficiency virus (HIV) diagnoses between 2015 and 2016, with a 23% reduction among men who have sex with men (MSM) largely attributed to increased HIV testing and pre-exposure prophylaxis (PrEP).[3,4]

Despite improved diagnostics, widespread service provision for the treatment of curable STIs in England and greater emphasis on partner notification, infection rates remain high. STI rates are particularly high in subgroups of the population, with young adults (aged 16–25 years) and MSM having the highest rates of infection.[1,2] Many STIs in young people will go undiagnosed, and, for young women in particular, this may have consequences for their future fertility and consequent costs for the health service. Individuals may be at risk for a variety of reasons, such as lack of knowledge about STIs, low self-efficacy (lacking belief that one can successfully meet a goal or perform a particular task such as negotiating the use of condoms) and poor condom use and/or sexual negotiation skills. Risk-taking may also be influenced by peer group norms. Some groups of young people, often characterised by factors associated with the broader determinants of social and health inequalities (e.g. education and literacy), are disproportionately affected by STIs.[5]

This has led the Department of Health and Social Care (DHSC) to develop a Sexual Health Framework,[6] which recommends the prioritisation of prevention and support for behaviour change, alongside access to sexual and reproductive health services, particularly for those most vulnerable to poor sexual health (SH). This is especially crucial in the context of increasing antibiotic resistance, for example in gonorrhoea,[2] the prevention of which is as important as effective treatment if we are to bring transmission rates down.

Sexual health services

Sexual health services are provided through a range of clinics in England, including general practitioner (GP) practices, genitourinary medicine (GUM) and contraception clinics, young people's services (including third-sector providers such as the health-care charity Brook) and pharmacies. The types of care that these different providers can offer varies. Level 3 services (e.g. GUM clinics) provide the full range of STI testing, treatment and management for all patient groups, usually with contraceptive services, in which case they are referred to as integrated SH services. Level 2 services (e.g. some community SH services, Brook or enhanced GP services) provide more limited STI testing and the management of uncomplicated or asymptomatic infections. Level 1 services offer limited STI screening for asymptomatic patients only.[7]

Since 2013, the commissioning of NHS services for SH has changed, becoming more complex and fragmented. Most services are now commissioned by local authorities as part of their remit to provide public health services. NHS England remains responsible for HIV treatment and care, but also commissions some components of SH, such as national screening programmes. Clinical Commissioning Groups also have a role through their responsibility for commissioning primary care services.[8–10] Clinics that provide sexual and reproductive health services offer an opportunity to engage those at risk in sexual risk reduction interventions.[11,12] However, introducing complex triage and sexual risk reduction interventions into busy clinical settings on a large scale, essential if there is to be a population-level impact, is challenging and will have resource implications. It is imperative to show that a complex intervention is clinically effective and deliverable, as well as cost-effective, in a sufficient proportion of the diverse range of services provided in England.

Risk groups and behaviours

Young people and MSM are at higher risk of STIs. MSM specifically are at risk of HIV infection, with more than one-third of newly diagnosed HIV cases in Western Europe being among MSM.[13] In addition to age and sexual orientation, several demographic, geographical and behavioural characteristics that are associated with an increased risk of STIs have been identified. This potentially allows for targeted provision of prevention services to subgroups at highest risk of STI acquisition.

Among young people, factors associated with an increased risk of a STI diagnosis include multiple partners, previous STI diagnosis and reported lack of condom use. In England specifically, the relative level of deprivation and the geographical region where someone lives are also associated with STI risk.[2,14,15] Similar patterns are seen among MSM, with associations with multiple partners and geographical variations observed.[16,17] There are also differences in STI diagnoses according to ethnicity, with gonorrhoea rates being considerably higher among black ethnic minorities.[18] In addition, the use of drugs during sex ('chemsex') is a pronounced risk factor among MSM groups, although it is also seen as a risk in heterosexual groups.[16,19,20] Information about these factors is often routinely collected within SH services as part of taking a clinical history and could, therefore, be used as part of triage processes.

Risk reduction interventions

Behaviour change interventions seek to promote changes in behaviour patterns associated with STI acquisition. The white paper *Healthy Lives, Healthy People*[21] emphasises a commitment to behaviour change approaches as a solution to reducing preventable illness and death. Research has shown that behaviour change interventions can help people adopt health-promoting behaviour patterns, including safer sex practices.[22,23] However, intervention effectiveness varies in relation to intervention type and target audience.[24,25] Attendance at a SH clinic provides an opportunity for intervention delivery at a potentially 'teachable moment', when people are primed to think about their sexual behaviour and the consequences for their health.[26]

Sexual risk reduction interventions are complex interventions, which need to be integrated into routine service provision alongside STI testing and treatment, repeat testing and partner notification. These interventions can take a number of forms and have different objectives, such as increasing knowledge of STIs, changing cognitive antecedents such as attitudes and/or beliefs (including normative beliefs), or increasing self-efficacy.[27] The mode of delivery can vary widely. The US Centers for Disease Control and Prevention community guide[27] concluded that community-based individual-, group- and community-level interventions can be effective in reducing the risk of STIs in MSM. Digital approaches, such as applications (apps) or online interactive interventions, have also be shown to be effective and offer novel delivery that can be done outside the clinic environment.[28] Other intervention formats, such as waiting room videos, can be provided to all clinic attendees, although they may need to be adapted to different clinic settings; the videos have been shown to reduce incident STIs.[29] However, there is also evidence that tailoring interventions to individuals' preferences and needs leads to greater uptake and makes the interventions more likely to be effective.[30]

As clinic resources are limited, the use of triage or risk assessment can ensure that more resource-intensive interventions are targeted at those who need them most, or those for whom the intervention has been designed and who are more likely to find it effective. As electronic patient record (EPR) systems become more widely used within clinical settings, using the coded data collected as part of routine care to inform a triage algorithm could provide a mechanism to target different risk groups with appropriately tailored risk reduction support.

Evidence gap

Currently, multiple interventions have been trialled, but there is a lack of clarity about which intervention would best be implemented in which context, by whom and for whom. Therefore, a clear understanding of the factors that influence implementation in particular contexts is needed. In addition, such interventions, although 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 be achieved only if it can be delivered at minimal overall cost. As funding for health-care services, particularly those commissioned by local authorities, is under pressure, any demand for additional resources across a large number of services is unrealistic. In this context, research is required to identify brief, pragmatic, non-labour-intensive interventions that can be tailored to the level of risk of the individual attending any of a range of different SH services. The characteristics of those in the higher-risk groups will differ by clinic setting, gender, sexual orientation and other factors that will need to be incorporated into the intervention model. The Health Technology Assessment (HTA) call that led to the work described in this report was intended to address a first, important, step by determining whether or not it would be feasible to conduct a definitive trial of effectiveness of brief behavioural interventions in SH services, incorporating the development of triage processes to ensure that the interventions were most efficiently delivered to those most likely to benefit, and whether or not such a strategy would meet cost-effectiveness criteria.

Aim

The overall aim of the Santé project was to determine the feasibility of a randomised controlled trial (RCT) of an individualised package of sexual risk reduction interventions offered within routine clinical care pathways in SH clinics. This addresses two key aims:

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 users' needs and developed alongside a triage method for identifying target groups.
2. To assess the feasibility of testing the effectiveness of this individualised package of behavioural interventions in a RCT against usual care.

Objectives

The aims were addressed through 10 specific objectives:

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 the users' needs
4. to describe current practice in UK SH clinics with respect to the 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 develop a manual of the 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 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).

Project overview

The project was a multistage, mixed-methods study design that incorporated a systematic review; a secondary analysis of national surveillance data; interviews and surveys with clinic staff; semistructured interviews, a discrete choice experiment (DCE) 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 was organised into six overlapping work packages (WPs), summarised in *Figure 1*:

1. a systematic review of sexual risk reduction behavioural interventions focusing on UK-relevant evidence (objectives 1 and 2)
2. development of a sexual risk assessment/triage tool to identify individuals at increased risk in SH settings (objective 3)
3. a mixed-methods study to describe sexual risk reduction practices and preferences in SH clinics in the UK, and to identify opportunities for intervention (objectives 4 and 5)
4. the selection and adaptation of a suite of evidence-based interventions suitable for delivery in SH settings and acceptable to patients and staff (objective 6)
5. a pilot study of the feasibility of implementing interventions to assess their acceptability, practicality and cost of implementation, and to comment on the feasibility of a future RCT (objectives 7–9)
6. the refinement of 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, and an outline of the trial design for a full evaluation (objective 10).

The project focused on understanding factors that influence the implementation of interventions in complex SH clinic settings, from both patient and provider perspectives. We used co-creation approaches to intervention identification and adaptation with health advisors (HAs), clinicians and service users as an essential part of ensuring that the intervention would be acceptable and deliverable. We followed the Medical Research Council revised guidance[31,32] on developing and evaluating complex interventions, taking the results of the systematic review and selecting and developing the most promising package of interventions to reduce sexual risk. The National Institute for Health and Care Excellence (NICE) and the DHSC recommend user input when designing services,[33] as it leads to services that are more responsive to the needs of users as services are less likely to be designed inappropriately and more likely to be used.

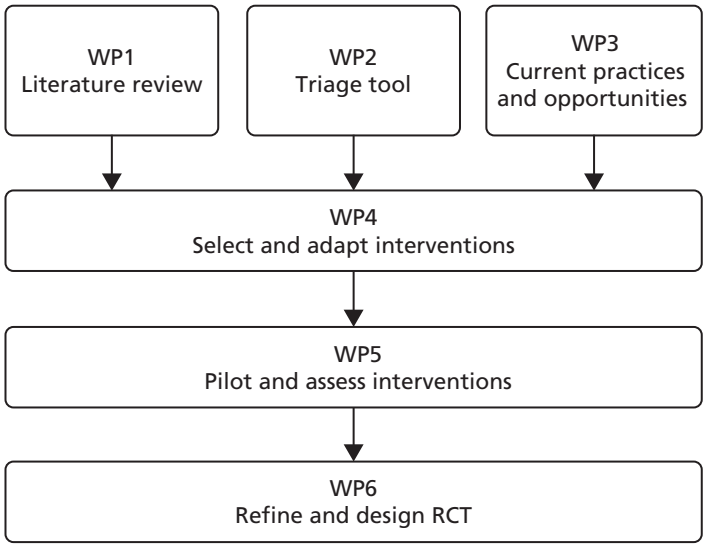

FIGURE 1 Work package overview.

The methodological steps to delivering the objectives set out earlier were informed by the intervention mapping (IM) approach to intervention design.[34] The IM approach is iterative and can be described as six steps (*Box 1*). As described, the views of stakeholders, including service users and staff who deliver interventions, are captured and are vital to the successful design and implementation of interventions that are acceptable, practically feasible and sustainable over time.[35] Co-creation of interventions with stakeholders is integral to the IM approach.[34] Although in part already defined by the project brief, the project included a consideration of the needs of the population and identified specified behaviour change outcomes corresponding to those needs. Regulatory processes underpinning specified behaviour changes were identified from relevant research and matching change techniques were selected.

In the case of the interventions, it was anticipated that, as these were to be selected from those for which efficacy evidence already existed, we would be able to select practical intervention components designed to change defined behaviour regulation processes that work in situ.

This IM process facilitates the identification of primary and secondary outcome measures, specified as needs and target behaviour changes, thus anticipating the evaluation design. Prototype interventions should be tested and adapted to ensure the fidelity of delivery in context prior to finalising an intervention manual.

The IM process combines an ecological approach with participation from all stakeholders, a focus on specification of the underlying mechanism (in a clear logic model) and a research-based approach to ensuring the fidelity of implementation. A key part of this process is to identify change techniques (e.g. Abraham and Michie,[36] Abraham,[37] Michie and Johnston[38]), modes of delivery and delivery competencies that maximise intervention effectiveness in real-world contexts.[39] All of this underpinned the approach taken to deliver the project.

Project management

Structured oversight of the project was conducted by a Project Steering Committee (PSC), with an independent chairperson, and was convened in accordance with guidelines for the National Institute for Health Research (NIHR) HTA programme. This committee also served the function of the Data Monitoring Committee.

The Project Management Group (PMG), chaired by the chief investigator, oversaw the work of all WPs. It agreed the details of project set-up and the design, initiation and supervision of the study. Each WP had a working group responsible for the day-to-day management of the work, and these groups reported to the PMG monthly.

BOX 1 Intervention mapping: iterative steps applied to the Santé Project

1. Needs assessment (predetermined partly by commissioned brief and partly by WP1 and WP3).
2. Mapping of intervention objectives (i.e. main outcomes) on to psychological, behavioural and environmental determinants or change processes (WP4).
3. Selecting techniques and strategies to modify the determinants of behaviour based on an understanding of change processes (WP4).
4. Selection and construction of intervention components and materials (WP4).
5. Planning for intervention adoption, implementation and sustainability (WP5).
6. Planning evaluation, including process and outcome evaluation methods and instruments (partly by WP5).

Patient and public involvement

We embedded patient and public involvement (PPI) into the research programme at key points, including at the proposal development stage. It was essential that the developed intervention packages were endorsed by service users; therefore, PPI and service user input throughout the proposal was sought for the translation of the research outcomes into improvements in current service provision. We set up a PPI group specifically for this project and liaised with the group throughout the project. The PPI group (including our target groups of young people and MSM) helped in writing and approved the patient information sheets for this study.

Ethics

Ethics approval for the study was granted by Westminster National Research Ethics Committee (reference number 15/LO/0690) for work conducted in WPs 3 and 4, and the Chelsea National Research Ethics Committee (reference number 16/LO/0673) for work conducted in WP5. The use of data in WP2 was approved by Public Health England's Associate Caldecott Guardian. The anonymised data were collected as part of a pilot of enhanced routine STI surveillance, and their use was not considered to require an ethics review. All service user participants provided written informed consent for interviews, focus group discussions and surveys. Health-care providers provided written informed consent for focus group discussions, verbal consent for interviews and implied consent for web surveys. Process data from clinics were anonymised, and posters informing service users that the clinic was currently part of a study were displayed informing participants that they could opt out of their process data being used in analysis.

Chapter 2 Work package 1: systematic literature review

Background

A 2010 meta-analysis[30] of sexual risk reduction interventions suggested that behavioural interventions are effective, with moderate effect sizes, and should be implemented widely to reduce the population burden of STIs, including HIV. However, this review focused solely on US-based intervention studies within STI clinics. An earlier UK review[40] of behavioural interventions in GUM clinics included 14 trials, but 12 were conducted in the USA.

Potential interventions could include those delivered in the clinic setting, such as brief one-to-one motivational interviews, or beyond the clinic setting, such as interactive digital interventions. A recent review[41] of interactive digital interventions has confirmed that they can be effective in improving knowledge about SH and suggest that they influence sexual behaviour positively; however, evidence of an effect on STI rates was lacking. Other systematic reviews of interventions have been limited to particular groups, such as adolescents,[42–46] HIV-positive individuals,[47] older adults[48] and MSM,[49] or have focused on only condom promotion[50] or HIV risk.[51]

There was a need to update these systematic reviews to include brief interventions that could be delivered in the wider range of SH services available in the UK (e.g. GUM, contraception and SH, and Brook services), focusing on the highest risk groups of MSM and young people. Some of this chapter is based on Long *et al*.[52]

Aim

The aim of this review was to identify evidence-based, waiting-room-delivered, self-delivered and brief-health-care provider (HCP)-delivered interventions that evaluated effectiveness against reducing risky sexual behaviour (RSB) or incidence of STIs in both young people and MSM.

Methods

A review protocol was developed and set out the methods used in the review (PROSPERO registration number CRD42014014375). The review was conducted in 2015.

Search strategy

The search strategy was developed in MEDLINE (via Ovid) and adapted for use in other databases. The search used a RCT filter to identify methodologically relevant studies. Search terms were identified by consulting literature, and an iterative search process was used to ensure an appropriate balance of sensitivity and specificity. Medical subject heading (MeSH) terms used in the original MEDLINE search were translated for use in other databases as necessary.

The following databases were searched: MEDLINE (via Ovid), PsycINFO (via Ovid), EMBASE (via Ovid), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (via EBSCO host), Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE) (via The Cochrane Library) and HTA (via The Cochrane Library). All searches were conducted in October 2014. Further searching of retrieved studies and relevant systematic reviews was carried out by hand. The database search results were exported and managed using EndNote [(version X5) Clarivate Analytics (formerly Thomson Reuters), Philadelphia, PA, USA] and deduplicated using the software and manual checking. A full search strategy is presented in *Appendix 1*.

Study selection

We considered only individual and cluster RCTs. Relevant studies were identified in two stages using predefined eligibility criteria. Titles and abstracts were examined independently by two researchers (LL and RP) and screened for possible inclusion. Disagreements were resolved by discussion. Full texts of the identified studies were obtained. Two researchers (LL and RP) examined these independently for inclusion or exclusion. Gwet's AC1 statistic was calculated to assess inter-rater reliability[53] and disagreements were resolved by discussion. A third reviewer was available if necessary.

Inclusion criteria

Population

Young people aged 16–25 years or MSM groups.

Study design

Randomised controlled trials of brief interventions for reducing sexual risk that could be implemented in SH clinics in the UK were considered. Within this definition, interventions were divided into those that involved one session of < 30 minutes and those that involved between two and six 30-minute sessions. The analysis was restricted to RCTs to increase the likelihood that evidence of effects would be robust.

Intervention

Interventions in the following settings were included: social networking sites, primary care, emergency care settings, community treatment settings (e.g. GUM and SH clinics) and educational settings (including schools and colleges). Waiting-room, self-delivered, clinician-delivered and digital interventions were included.

Outcome

Biological (e.g. STI incidence), sexual behaviours (e.g. condom use or number of sexual partners), testing (e.g. home-based, appointment booking and clinic visits). Outcomes were measured at a minimum of 60 days' follow-up. (Note that we included studies that did not show statistically significant effects on primary or secondary outcomes.)

Setting

The UK and other high-income settings.

Exclusion criteria

Population

Studies focused exclusively on victims of sexual or domestic abuse or violence; those in prison, psychiatric facilities or nursing homes; or individuals/communities with no fixed address.

Study design

Studies without a randomised control group; animal models; narrative reviews, editorials and opinions; non-English-language papers; and reports published as meeting abstracts only, or when insufficient methodological details were reported to allow critical appraisal of study quality. Systematic literature reviews were not included in the review, but their reference lists were searched for relevant RCTs. Studies published prior to 2000 were excluded.

Intervention

All non-tailored interventions (e.g. social marketing campaigns providing free access to condoms), interventions for adherence to medical treatment (e.g. adherence to antiretroviral therapies), interventions for couples and family/parent-centred interventions.

Outcome

Only psychological changes evaluated, such as attitude change, or a follow-up of < 60 days.

Setting
Low- or middle-income settings.

Critical appraisal
The methodological quality of each paper was assessed using the Cochrane 'risk of bias' tool.[54] The tool includes six key criteria against which potential risk of bias is judged: adequacy of allocation sequence generation; adequacy of allocation concealment; blinding of participants, personnel or outcome assessors; completeness of outcome data; selectivity of outcome reporting; and other biases. Quality was assessed by one reviewer, and checked by a second. Any discrepancies were discussed and resolved and reviewed by a third reviewer.

Data extraction
Data on the study design, setting, population, intervention, outcomes and results were collected using a standardised data extraction form. Data were extracted by one reviewer and 50% checked for accuracy by the second reviewer.

Analysis
Findings of each RCT were summarised alongside a narrative synthesis. The summaries qualitatively examined the range of results and potential associations with effect size. Additional potential moderators or mediators that we examined included characteristics of the interventions (e.g. degree of tailoring), intervention components (e.g. condom use skills training) and population (sex, sexual orientation and coexisting conditions). Intervention components were categorised into 10 categories based on Albarracín *et al.*,[25] summarised in *Box 2*. The 10 intervention component categories were normative arguments (NormAs), attitudinal arguments (AttAs), behavioural skills arguments (BSAs), any kind of information, threat-inducing arguments (TIAs), condom use skills training (CUST), interpersonal skills training (IST),

BOX 2 Intervention strategies

Definitions of intervention strategies used in this systematic review based on the Albarracín *et al.* categorisation:[25]

- Normative arguments: NormAs about the support of condom use by friends, family members or partners – 'other people are doing it, other people will approve of you doing this'.
- Attitudinal arguments: for example, the discussions of the positive implications of using condoms for the health of the partners and for the romantic relationship, the pros and cons of using condoms, whether the consequences of using condoms will be good or bad.
- Behavioural skills arguments: what to do when partners do not want to use a condom; when recipients or their partner is sexually excited, and when alcohol or drugs are involved; verbal description, for example, instruction about how to put on a condom.
- Any kind of information: factual information (i.e. mechanisms of HIV, HIV transmission and HIV prevention).
- Threat-inducing arguments: for example, discussions about the recipient's personal risk of contracting HIV or other STIs, and fear-based arguments based on –
  - perceived susceptibility to a STI: 'you are the type of person who will get this'
  - perceived severity of STI: 'it will harm you/you will die'.
- Condom use skills training: for example, practice with unwrapping and applying condoms.
- Interpersonal skills training: for example, role playing of interpersonal conflict over condom use and initiation of discussions about protection.
- Self-management skills training: self-monitor goals (e.g. practice in decision-making while intoxicated, avoidance of risky situations).
- HIV/STI counselling and testing: involves the administration of a seropositivity test as well as the type of counselling in place.

NormA, normative argument.

self-management skills training (SMT), condom provision and HIV/STI counselling and testing. Components were independently coded for each intervention description by one reviewer and 50% were independently coded by a second reviewer. Gwet's AC1 statistic was calculated to assess inter-rater reliability.[53]

Results

The search yielded 17,916 unique publications (*Figure 2*). Titles and abstracts of all publications were screened by two independent reviewers. Inter-reviewer agreement, assessed with Gwet's AC1 statistic,[53] was nearly perfect (99% agreement; AC1 = 0.99) for study screening and selection. Eighty-four articles were identified for full-text screening and 33 studies were included in the review. Data were extracted and rated on all the intervention strategies by one reviewer and a second reviewer extracted 50% of the data independently; inter-rater reliability was excellent (80.6% agreement; AC1 = 0.86).

Study descriptions

Of the 33 studies included, 23 were focused on young people and 10 were focused on MSM groups. The majority of studies were based in the USA, including all 10 of the MSM and 16 of the young people studies; other young people studies were from the UK ($n = 3$), Australia ($n = 2$) and the Netherlands ($n = 1$) and Denmark ($n = 1$). A summary of the studies is presented in *Table 1*.

Many interventions were culturally tailored to a target group, usually based on age, gender, sexual orientation or ethnicity, and the types of interventions evaluated were very heterogeneous. The majority of interventions were aimed at reducing high-risk sexual behaviours (e.g. condomless sex or multiple partners) and maximising protective behaviours. Many interventions provided basic information about STIs and commonly included risk assessment, hands-on skills training in condom use, problem solving, decision-making, goal-setting and communication around safe sex. Five studies also included additional testing components.[60,69,73,74,83] Intervention delivery variously used print, mail, computer or video-based formats but also included face-to-face counselling with varying levels of intensity, from one short session up to 2 hours' contact time.

The most commonly reported outcome was condom use or unprotected sex, alongside other self-reported behavioural outcomes (16/23 young people and 9/10 MSM studies). Twelve studies reported on at least one STI outcome (9/23 young people and 3/10 MSM studies), with chlamydia and gonorrhoea being the most frequent.[56,60,61,63,64,69,71,73,76,81,82] STIs diagnosed at the recruitment or baseline visit were treated, and, therefore, any bacterial infections diagnosed at follow-up were considered new infections. For studies that included viral infection outcomes, only infections after baseline assessment were counted in the results. Most of the studies collected their own samples at follow-up, and many supplemented this with medical record reviews.

Overall, 24 of the 33 RCTs reported some effectiveness against either the primary or secondary outcomes. We retained non-effective studies in the review to allow a comparison of those strategies that did not work. A reduction in STI incidence was reported in half of the relevant young people studies (four out of eight studies), and 8 of the 16 to report on behavioural outcomes found a beneficial effect. Of the three trials that reported STI outcomes in MSM, none showed any effect,[69,81,82] but the majority of those reporting on behavioural outcomes reported beneficial results for at least one measure.

Young people

The trials were generally considered to be of fair to good quality, with some exceptions. Two studies[67,72] were judged to be at risk of selection bias because of poor randomisation procedures, two reported[72,76] inadequate allocation concealment procedures, two[60,67] had a high risk of reporting bias and two[67,71] were at high risk of attrition bias because of incomplete outcome data.

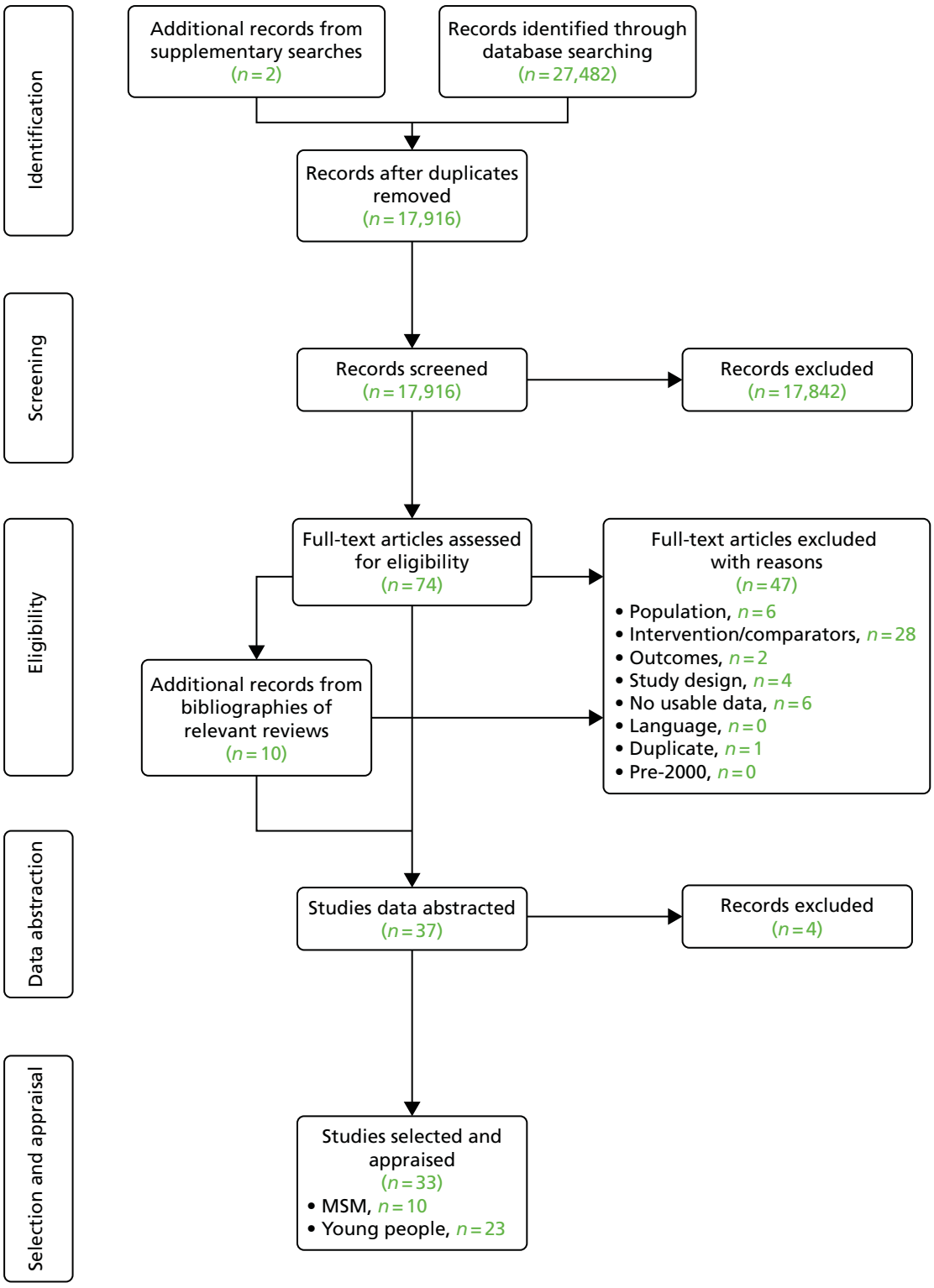

FIGURE 2 The PRISMA flow chart of studies included in the systematic review. Reprinted from *Preventative Medicine*, **91**, Long L, Abraham C, Paquette R, Shahmanesh M, Llewellyn C, Townsend A, Gilson R, Brief interventions to prevent sexually transmitted infections suitable for in-service use: a systematic review, pp. 364–82, 2016,[52] with permission from Elsevier.

TABLE 1 Summary of included studies of interventions

Study		Participants		Intervention				Outcomes		
Study first author and date	Setting	Number	Population	Mode of delivery	Intensity	Duration (days)	Intervention strategies	Outcomes	Effectiveness	Follow-up (months)
Young people										
Apoola (2011)[55]	UK Community substance misuse service	Total = 54 Intervention = 27 Control = 27	Men and women aged < 20 years	Oral swab HIV, hepatitis B and C tests	One session[4]	2	STI	Test uptake	↑ Testing (100% vs. 18.5% HIV testing)	N/A
Bolu (2004)[56]	USA Public STI clinics	Total = 4328 Intervention = 1447 Control = 1443	Men and women aged < 25 years	Tailored brief one-to-one counselling and HIV test counselling	Two sessions (2 × 20 minutes)	7–10	STI	STI	↓ STI incidence in those < 20 years old (OR 0.53; 95% CI 0.32 to 0.86)	12
Booth (2014)[57]	UK School-based settings	Total = 253 Intervention = 145 Control = 108	Men and women aged 16–24 years	Short video and posters, followed by talks and repeated video	One session (approximately 15 minutes)	1	NormA, AttA, Info, CUST	Test uptake	↑ Attitude to testing (aOR 1.53; 95% CI 1.06 to 2.22)	N/A
Bull (2012)[58]	USA Online	Total = 1578 Intervention = 942 Control = 636	Men and women aged 16–25 years	Social media [Facebook (Facebook, Inc., Menlo Park, CA, USA)] page	8-week content cycle	180	NormA, Info, BSA	Condom use	↑ Condom use (68% vs. 56% control, at 2 months)	2, 6
Calderon (2011)[59]	USA Urban Emergency Department	Total = 200 Intervention = 100 Control = 100	Men and women aged 15–21 years and HIV negative	HIV pre-test video	One session (4 minutes)	1	STI	Knowledge Testing	↑ HIV knowledge score (79% vs. 66%) ↑ HIV testing (51% vs. 22% in control)	N/A
Chacko (2010)[60]	USA Urban reproductive health clinic	Total = 376 Intervention = 192 Control = 184	Women aged 16–22.5 years	Tailored one-to-one MI	Three sessions (2 × 30–50 minutes; 1 × 15 minutes)	180	NormA, AttA,	Testing STI	No effect	6, 12

Study		Participants		Intervention				Outcomes		
Study first author and date	Setting	Number	Population	Mode of delivery	Intensity	Duration (days)	Intervention strategies	Outcomes	Effectiveness	Follow-up (months)
Cook (2007)[61]	USA Community-based setting	Total = 403 Intervention = 211 Control = 209	Women aged 15–24 years	Home testing kit	Kits at 6, 12 and 18 months	540[3]	Info	Test uptake STI	↑ Testing (RR: 1.38; 95% CI 1.23 to 1.55)	12, 24
Crawford (2014)[62]	UK STI clinics	Total = 212 (Number in groups not presented)	Men and women aged 19–25 years	Leaflet and tailored one-to-one counselling, by telephone or face to face	One session (< 30 minutes)	1	Info	Alcohol Condom use	No effect	6
Downs (2004)[63]	USA Urban health centres	Total = 300 (Number in groups not presented)	Women aged 14–18 years	Video	Four sessions 1 × 30 minutes; 3 × 15 minutes)	180	Atta, Info, BSA, IST, NormA	STI Condom use Knowledge	↓ STI (OR of STI in control: 2.79, *p*-value: 0.05) ↑ Abstinence	1, 3, 6
Gottlieb (2004)[64]	USA STI clinics	Total = 1766 (Number in groups not presented)	Men and women aged 14–40 years	Brief one-to-one general risk reduction counselling	Two sessions (20 minutes each)	NR	STI	STI	↓ Chlamydia incident infections	3, 6, 9, 12
Grimley (2005)[65]	USA Hospital and adolescent clinic	Total = 275 Intervention = 137 Control = 138	Women aged 14–23 years	Tailored one-to-one session	Three sessions (15 minutes each)	90	NormA, AttA, Info, BSA, SMT	Douching cessation	↓ In douching (OR of stopping: 3.49; 95% CI 1.66 to 7.32)	6, 12
Kang (2012)[66]	Australia Online	Total = 704 Intervention = 211 Control = 493	Men and women aged 16–25 years	Personalised e-mails	Variable	180	Info[16]	Testing Condom use	↑ Chlamydia testing (53% vs. 31%)	6
Klein (2011)[67]	USA Online	Total = 178 Intervention = 91 Control = 87	Women aged 14–19 years	Tailored internet-based session	Two sessions (1 hour each)	1	NormA, Info, BSA, CUST, IST	Condom use Knowledge	↑ Condom use (51% vs. 71%, pre–post) ↑ Knowledge in both groups	3

continued

TABLE 1 Summary of included studies of interventions (*continued*)

Study		Participants		Intervention				Outcomes		
Study first author and date	Setting	Number	Population	Mode of delivery	Intensity	Duration (days)	Intervention strategies	Outcomes	Effectiveness	Follow-up (months)
Mevissen (2011)[68]	Netherlands Online	Total = 218 Non-tailored = 81 Tailored = 67 Control = 70	Men and women aged 18–25 years	Tailored internet-based session	One session	1	NormA, AttA, Info, BSA, TIA	Condom use Testing Perceptions	↑ Condom use (0.88 vs. 0.43 mean)	3
				Non-tailored internet-based session	One session	1	NormA, AttA, BSA, TIA Info	Condom use Testing Perceptions	↑ Condom use (0.62 vs. 0.43 mean)	3
Metsch (2013)[69]	USA STI clinics	Total = 1258 Intervention = 638 Control = 620	Men and women aged < 25 years	Tailored one-to-one counselling and HIV testing	One session (20–40 minutes)	1	STI, CP, Info	STI Condom use Sexual risk	↓ Number of partners (IRR: 0.76; 95% CI 0.69 to 0.84)	6
Norton (2012)[70]	USA University of Connecticut	Total = 198 HIV group = 37 STI group = 42 Pregnancy group = 37	Men and women aged > 18 years	Multimedia DVD on HIV	One session (60 minutes)	1	NormA, Info, BSA	Condom use Sexual risk	No effect vs. control	1, 2
				Multimedia DVD on STIs or pregnancy	One session (60 minutes)	1	NormA, Info, BSA	Condom use Sexual risk	↑ Condom use (OR 0.19 vs. HIV) ↓ Inconsistent condom use (OR 0.42 vs. HIV)	1, 2
Østergaard (2000)[71]	Denmark School-based setting	Total = 5487 Intervention = 2603 Control = 2884	Women aged 15–19 years	Chlamydia home test kit	One test	365	Info, STI	STI	↓ Chlamydia prevalence (2.9% vs. 6.6%)	12
Proude (2004)[72]	Australia Family practice	Total = 312 Intervention = 156 Control = 156	Men and women aged 18–25 years	Brief advice about safe sex and condoms	One session	1	Info, BSA, CP	Sexual risk Perception	No effect	3

Study		Participants		Intervention				Outcomes		
Study first author and date	Setting	Number	Population	Mode of delivery	Intensity	Duration (days)	Intervention strategies	Outcomes	Effectiveness	Follow-up (months)
Roye (2007)[73]	USA Planned Parenthood sites	Total = 400 Video = 88 Counselling = 81 Combined = 84 Control = 84	Black and Latina women aged 15–21 years	Video and brief one-to-one counselling	One session (40 minutes)	1	BSA, TIA, IST	Condom use	↑ Condom use	3, 12
Scholes (2007)[74]	USA Group Health Cooperative	Total = 8820 Intervention = 2940 Control = 2940	Men aged 21–25 years	Home testing kit (letter and test request card)	One session	NR	Info, STI[23]	Test uptake	↑ Testing (RR 5.6; 95% CI 3.6 to 8.7)	4
				Home testing kit (letter and sampling kit)	One session	NR	Info, STI[23]	Test uptake	↑ Testing (RR 11.1; 95% CI 7.3 to 16.9)	4
Scholes (2003)[75]	USA Managed care settings	Total = 1210 Intervention = 596 Control = 614	Women aged 18–24 years	Self-help magazine and condoms; tailored feedback newsletter and condoms	Two tailored rounds	180	CP, Info, CUST	Condom use	↑ Condom use any partner (aOR 1.86; 95% CI 1.32 to 2.65), primary partner (aOR 1.97, CI 1.37 to 2.86)	3, 6
Shrier (2001)[76]	USA Hospital and adolescent clinic	Total = 123 Intervention = 60 Control = 63	Women aged < 24 years	Video, tailored one-to-one counselling, condoms and information	Four sessions (approximately 37 minutes)	180	NormA, AttA, Info, BSA, TIA, CUST, IST, SMT, STI	Condom use Attitudes Knowledge	↑ Condom attitude score (7.9 vs. 8.3) ↓ Non-main partner (25 vs. 10%)	1, 3, 6, 12
Suffoletto (2013)[77]	USA Emergency Department	Total = 52 Intervention = 23 Control = 29	Women aged 18–25 years engaged in hazardous drinking and risky sex behaviours	Tailored weekly risk reduction text messages	Weekly for 3 months	90	AttA, Info, TIA, SMT	Condom use	↑ Condom use (20% to 53% pre–post intervention)	3

continued

TABLE 1 Summary of included studies of interventions (*continued*)

Study		Participants		Intervention				Outcomes		
Study first author and date	Setting	Number	Population	Mode of delivery	Intensity	Duration (days)	Intervention strategies	Outcomes	Effectiveness	Follow-up (months)
MSM studies										
Carpenter (2010)[78]	USA Online	Total = 199 Intervention = 99 Control = 100	MSM aged 18–30 years	Online training modules	Seven tutorials (approximately 2 hours each)	7	AttA, Info, BSA, SMT, NormA	Condom use	↓ Risky sex in both study arms	3
Coffin (2014)[79]	USA Community	Total = 326 Intervention = 162 Control = 164	MSM aged ≥ 18 years; substance users	Personalised cognitive counselling and HIV test	One session (30–50 minutes) and booster	1	STI, SMT	Sexual risks Substance use	↓ Unprotected receptive anal sex (RR = 0.57; 95% CI 0.33 to 1.01)	3, 6
Hirshfield (2012)[80]	USA Online	Total = 3092 Video = 1874 Web page = 609 Control = 609	MSM aged 18–81 years	Internet-based video and HIV prevention information	Two videos, one of 9 and one of 5 minutes	1	BSA, SMT	Test uptake Condom use	↓ Unprotected anal sex (OR = 0.61; 95% CI 0.48 to 0.77)	2
					Web page	1	Info	Test uptake Condom use	↓ Unprotected anal sex (OR = 0.42; 95% CI 0.27 to 0.66)	2
Metcalf (2005)[81]	USA Public STI clinics	Total = 138 Intervention = 70 Control = 68	MSM aged 15–39 years	Brief one-to-one counselling	Two sessions and booster (20 minutes)	180	STI, SMT	STI Sexual risk	No effect	3, 6, 9, 12
Metsch (2013)[69]	USA STI clinics	Total = 1074 Intervention = 529 Control = 545	MSM aged ≥ 18 years	Tailored one-to-one counselling and HIV testing	One session (20–40 minutes)	1	STI, CP, Info	STI Condom use Sexual risk	↑ STI incidence in intervention group (aRR: 1.41; 95% CI to 1.05 to 1.90) ↓ Unprotected sex (IRR: 0.71; 95% CI 0.61 to 0.83)	6
Milam (2014)[82]	USA University clinical sites	Total = 179 Intervention = 90 Control = 89	HIV-infected MSM aged >18 years	Internet-based tailored messaging	Monthly messages	360	NormA, BSA	STI Condom use	↓ Unprotected sex in both study arms	Monthly (1–12 months)

Study		Participants		Intervention				Outcomes		
Study first author and date	Setting	Number	Population	Mode of delivery	Intensity	Duration (days)	Intervention strategies	Outcomes	Effectiveness	Follow-up (months)
Mustanski (2013)[83]	USA Online	Total = 102 Intervention = 50 Control = 52	HIV-negative MSM aged 18–24 years	'KIU!' 3 online modules	2 hours	90	NormA, AttA, Info, BSA, SMT	Condom use HIV attitude	↓ Unprotected anal sex at 3 months (RR: 0.56)	1.5, 3
Outlaw (2010)[84]	USA Community services	Total = 188 Intervention = 96 Control = 92	African American MSM aged 18–26 years	Community MI and HIV testing	30 minutes	7–10	STI, CP	Test uptake	↑ HIV testing (49% vs. 20%)	N/A
Rosser (2010)[85]	USA Online	Total = 650 Intervention = 337 Control = 313	MISM aged >18 years	'Sexpulse' web page	Completed 7 days after enrolment	1	NormA, BSA, SMT	Condom use	↓ Unprotected anal sex at 3 months (aRR: 0.84; 95% CI 0.70 to 1.01)	3, 6, 9, 12
Young (2013)[86]	USA Online	Total = 112 Intervention = 57 Control = 55	African American and Latino MSM aged >18 years	Social media (Facebook) page and home testing	Kit offered every 4 weeks	90	STI, Info	Test uptake Condom use	↑ HIV testing (44% vs. 20%)	3

↑, increased; ↓, decreased; aOR, adjusted odds ratio; aRR, adjusted relative risk; CI, confidence interval; CP, condom provision; DVD, digital versatile disc; Info, information; KIU!, Keep It Up!; MI, motivational interviewing; MISM, men who use the internet to seek sex with men; N/A, not applicable; NR, not reported; OR, odds ratio; RR, relative risk.
The total number refers to the total participants in the study but in some, not all participants were relevant to our analysis.

Several of the RCTs specifically targeted women, with 10 of the 23 studies not including men, and only a single trial limited to sexually active young men.[74] Four RCTs recruited from STI clinics,[56,62,64,69] with two of these trials reporting reductions in STIs,[56,64] and two were based within schools.[57,71]

Four out of five video interventions designed for young people (with or without counselling) were found to be beneficial for reducing STIs,[63] reducing RSB[63,73,76] or increasing STI test uptake.[59] Of the three video-based interventions that reduced RSB, all employed BSAs and IST strategies.[63,73,76] Three of the seven brief one-to-one counselling interventions were found to be beneficial, either increasing STI test uptake[55] or reducing STIs,[56,64] with both of these studies including HIV/STI testing as part of the intervention package. Four digital interventions, out of the six included, were successful in either reducing RSB through BSAs or NormA strategies[58,67,68] or increasing STI test uptake.[66] The three home testing interventions were found to be beneficial for either increasing STI test uptake[61,74] or reducing STIs.[71] Of the two interventions that used printed materials, one reduced RSB,[75] specifically unprotected sex. However, several of the studies reported no impact on either primary or secondary outcomes, and many reported effects only in secondary outcomes or were too underpowered to present subanalyses.

Men who have sex with men

Overall, included studies were considered to be of fair to good quality. One trial[82] was deemed to be at risk of selection bias because of poor randomisation procedures, and one study[84] was at high risk of both attrition bias and detection bias because of poor blinding of outcome assessment and incomplete outcome data.

Four out of 10 trials were limited to younger MSM,[78,81,83,84] two of the studies specifically included Latino or African American men only,[84,86] one addressed substance-using MSM[79] and one included HIV-positive MSM only.[82] Five out of six digital interventions designed for MSM were beneficial, for either reducing RSB[78,82,83,85] or increasing STI test uptake.[86] There was no evidence that any of the digital interventions reduced STI incidence. All of the four digital interventions found to reduce RSB in MSM[78,82,83,85] employed NormAs and BSAs, alongside SMT[78,83,85] and information provision.[78,83] Three of the four one-to-one counselling interventions were beneficial, for either reducing RSB[69,79] or increasing STI test uptake;[84] all of these included HIV/STI testing.

One study[69] investigating a 25-minute pre-HIV test session within a clinic setting found a significant increase in the overall incidence of STIs in MSM, with higher rates among those who received the intervention than in the control group [adjusted relative risk 1.41, 95% confidence interval (CI) 1.05 to 1.90].

Discussion

We found 33 RCTs that met our inclusion criterion of evaluating a brief behavioural intervention for improving SH outcomes among young people and MSM. A number of interventions trialled were effective at improving testing, reducing self-reported risk behaviours (such as condomless sex) and decreasing STI diagnoses (*Table 2*). However, the effect sizes seen were generally small, the types of interventions and outcomes evaluated suggested that there is still a lack of evidence for certain approaches to improving SH behaviours, and one study demonstrated a negative intervention impact.[69]

Reducing risky sexual behaviours

The majority of trials in both young people and MSM populations involved either digital interventions or one-to-one counselling. Digital interventions were found to be effective for reducing RSB in half of the trials among young people and in two-thirds of participants in MSM studies. The successful digital interventions in both young people and MSM employed NormAs and BSAs.[58,67,68,78,82,83,85] In addition, successful digital interventions in both high-risk populations employed information in five trials[58,67,68,78,83] and SMT in three trials.[78,83,85] Successful interventions provided most or all of the following: arguments about the support for condom use by friends, family members or partners; information about STIs, such as prevalence, transmission and how to reduce the risk for transmission; help in identifying personal risk for STIs; training in common

TABLE 2 Summary of intervention effectiveness

Intervention	Young people ($n = 23$)			MSM ($n = 10$)		
	Number of trials	Effective trials	Improved outcome	Number of trials	Effective trials	Improved outcome
Digital	6	3	RSB	6	4	RSB
			STI test uptake		1	Test
One-to-one counselling	7	2	STI incidence	4	2	RSB
			STI test uptake		1	Test
Video	5	3	RSB			
		1	STI incidence			
		1	STI test uptake			
Printed materials	2	1	RSB			
Home test kit	3	1	STI incidence			
		2	STI test uptake			

behaviour change processes, such as problem solving, decision-making and goal setting; and training in communication surrounding condom use and safe sex.

Two out of four trials of one-to-one counselling showed an improvement in RSB among MSM, whereas none of the seven trials of one-to-one counselling in young people found this to be effective for this outcome. Although the sample of studies is too small to draw statistical inferences, these findings could indicate a difference between the two groups regarding the effectiveness of these interventions on risky SH behaviour, with MSM appearing to respond better to both one-to-one counselling and digital interventions than young people. However, the difference in effectiveness may be related to the nature of the intervention strategies employed. Although both NormAs and behavioural skills training were successfully employed in digital interventions for both MSM and young people to reduce RSB, the successful digital interventions for MSM also used information and SMT (in addition to NormAs and BSAs), and this may have accounted for their success.

Video interventions were effective for reducing RSB in three out of the five RCTs,[63,73,76] and those that were successful contained behavioural skills training and IST, and two used TIAs.[63,73,76] One intervention involving printed materials was successful in reducing sexual behaviour in young people, using condom provision, information and CUST.[75]

However, both the video and printed material interventions were conducted only for young people, with no RCTs involving either conventional (non-online) videos or printed materials targeting MSM. This presents a potential opportunity for developing interventions involving video and printed materials tailored to a MSM population to reduce RSB. However, it should be noted that one MSM trial used a video format within an online digital intervention,[80] and this was not found to be effective for any of the outcomes of interest in our review.

Reducing sexually transmitted infection incidence

None of the MSM interventions reported success in reducing STI diagnoses. Both of the one-to-one interventions that reduced the incidence of STIs in young people consisted of a brief counselling session plus a HIV/STI test,[56,64] whereas one-to-one counselling did not reduce STIs in any of the four trials conducted with MSM.[69,79,81,84]

One out of five trials of video interventions aimed at young people showed an improvement in STIs, employing AttAs, information, behavioural skills training and IST.[63] One out of three trials of home test kits showed an improvement in STIs in young people, delivering information alongside the test kit.[71] Again, neither of these intervention formats was trialled in MSM populations.

Increasing sexually transmitted infection testing

One digital intervention targeting MSM[86] and one targeting young people[66] were found to increase STI test uptake. Interventions that were successful provided information, including information about testing, with one providing personalised advice by e-mail. Similar findings were observed for one-to-one counselling, with only one trial for young people and one trial for MSM being found to be effective in increasing STI test uptake; both tests included oral swab tests.[55,84] In video interventions developed for young people, one of the five trials was effective for increasing STI test uptake; the successful video was specifically designed to replace one-to-one counselling before a HIV test.[59]

More promising, however, were interventions involving home test kits. Two of the three trials using this methodology effectively increased testing, and both included information and instructions on using the test kit.[61,74] It is notable that no RCTs involving home test kits were found for MSM, suggesting a potential opportunity for developing such interventions tailored to a MSM population. *Table 3* summarises the successful strategies used within RCTs that showed evidence for improved outcomes, and strategies for which there was weaker evidence (potential strategies).

Recommendations for intervention development

Existing evidence suggests that digital interventions for both MSM and young people should contain NormAs, BSAs and information in order to maximise impact on RSB and STI test uptake. In addition, SMT may be usefully employed to reduce RSB. One-to-one counselling interventions for both MSM and young people should contain HIV/STI testing as part of the intervention, with trials to date showing that this can

TABLE 3 Summary of features associated with programme effectiveness

		Successful strategies		Potential strategies	
Outcome	Intervention	Young people	MSM	Young people	MSM
Reduce RSB	Counselling		HIV/STI testing		
	Digital	NormA, BSA	NormA, BSA		SMT, Info
	Video	BSA, IST		TIA, AttA, Info	
	Home test kit				
	Printed materials			CP, Info, CUST	
Reduce STI incidence	Counselling	HIV/STI testing			
	Digital				
	Video	AttA, Info, BSA, IST			
	Home test kit			HIV/STI testing	
	Printed materials				
Increase STI test uptake	Counselling	HIV/STI testing	HIV/STI testing		
	Digital	Info	Info		
	Video	HIV/STI testing			
	Home test kit	Info			
	Printed materials				

increase STI testing, reduce STIs and reduce RSB. However, these interventions have not been widely evaluated in different geographical and demographic populations, so some caution is needed in assuming that these benefits will be realised in this population.

There was more evidence that diverse intervention formats are used among young people, and video-based interventions also containing behavioural skills training, IST, AttAs, information and HIV/STI testing could improve RSB, STIs and STI test uptake. In addition, TIAs, AttAs and information may be usefully employed to reduce RSB. Home testing kits should contain information in order to improve STI test uptake, and the act of testing may be usefully employed to reduce STIs.

Given the lack of RCTs of conventional (non-online) video interventions, home test kits and printed materials for the MSM population identified in this systematic review, opportunities exist for developing such interventions. We would cautiously recommend using the strategy components described above in any new intervention design for MSM, while accepting the need for further adaptation and piloting.

Challenges for intervention adaptation

Many of the successful interventions were tailored to gender or ethnicity groups, with half of the young people studies targeting Latina or African American women. Therefore, taking these interventions out of this cultural and demographic context may change both their efficacy and acceptability. This is a particular challenge for the young heterosexual male group, as very few interventions were designed specifically for this group. Interventions such as that developed by Roye *et al.*[73] were designed with input from the specific patient group they were targeting (i.e. young African American women), which make them less likely to be appropriate as an 'off-the-peg' intervention for use in the UK. So, although some interventions may be desirable or acceptable in principle, we anticipate that considerable adaptation may be needed.

Metsch *et al.*[69] found an increase in STI incidence among MSM in the one-to-one pre-HIV testing intervention group (12.5% control vs. 18.7% intervention). Conflicting efficacy within intervention formats or between subgroups, such as MSM or young people, could lead to negative results when adapted to a different context or setting.

Strengths and limitations

A key strength of this review is that it began with a broad search for RCTs of behavioural interventions in both young people and MSM. However, despite the extensiveness of the search, with > 17,000 articles screened, young heterosexual males were found to be under-represented in the literature, with only one RCT focused exclusively on this group.[74] This could reflect a publication bias, or a lack of research into this particular risk group. Several of the RCTs did not assess STI outcomes, but reported risk behaviours as the primary outcome. The outcomes are self-reported and could suffer from social desirability bias, and, therefore, should be interpreted with caution. In addition, several of the studies reported on multiple secondary outcomes, and lacked power to assess them, and did not account for multiple hypothesis testing.[87] This may have resulted in some of the weak statistical associations observed. However, it also poses the potential for interventions presented for adaptation and scale-up to have modest effects. We included studies in the review that showed no effect, allowing us to examine whether or not there was consistent evidence for an intervention format or strategy being successful.

The diverse range of settings in which the RCTs were performed could have influenced our conclusions. The quality and availability of resources, such as counselling, which are routinely offered could affect the efficacy of the trials; when usual care is extremely minimal, a relatively brief intervention might improve it suffeciently to show a benefit. However, other settings, in which routine care is more comprehensive, may show a smaller effect or no effect at all. This limits the generalisations we can make, particularly for the MSM studies, as these were all conducted in the USA.

Many of the RCTs identified in this review use specific gender and ethnic samples, and the diversity of these groups must also be taken into account when considering the generalisability of the review findings. For example, one study was restricted to HIV-positive MSM,[82] who may react differently to intervention approaches from HIV-negative MSM. We found very few studies conducted in the UK, and only one within a UK SH setting.[62]

Length of follow-up may have resulted in the apparent lack of impact seen on some sexual behavioural outcomes. It was notable that some interventions showed short-term improvement in outcomes, which was not seen later in the follow-up period.[58,73,85] This is confirmed by other evidence that suggests that the effect associated with an intervention may diminish with time after the intervention delivery.[23,88] Therefore, our assessment may have excluded potentially effective intervention approaches that lacked longer-term impacts. Such approaches might be effective in the longer term if repeatable.

Conclusion

A number of interventions that have the potential to be adapted for use in routine SH settings within the UK were identified. Intervention formats, such as videos, self-testing kits, one-to-one counselling sessions, and various forms of digital interventions (e.g. social media and e-mails), could all be appropriate candidates and showed limited but significant effectiveness in increasing testing and reducing risky behaviours and STIs. Despite the diversity of the interventions, there were common themes within the successful interventions, such as using BSAs that can be used to guide intervention adaptation.

Chapter 3 Work package 2: triage tool development

Background

The use of data-driven triage tools, developed using predictive statistical models, is relatively common in both primary and secondary clinical care.[89] They are used to target individual care based on key risk characteristics found at the population level, such as the Framingham risk score, which has been widely used to support treatment decisions for cardiovascular disease.[90] In SH, triage is commonplace.[91,92] Clinics often stratify patients according to symptoms, behavioural risks and demographics to receive different services such as 'quick checks' or safeguarding.[93,94] These triage processes tend to be a dichotomous decision based on predefined criteria, which may not necessarily take into account risk behaviours or identify patients most in need of interventions.[95]

Since 2009, SH clinics in England have provided data to a mandated surveillance system for SH episodes, the Genitourinary Medicine Clinic Activity Data Set (GUMCAD).[96,97] This data set contains 12 variables that include demographics and any tests and diagnoses related to that episode of care. This has allowed spatial trends in STIs to be monitored over time; however, it lacks information on risk behaviours, which would allow for more detailed risk stratification.

In order to facilitate a more in-depth understanding of STI epidemiology in England, Public Health England (PHE) enhanced the GUMCAD to include numbers of partners, drug and alcohol use, prior GUM clinic visits and partner notifications in GUMCADv3.[98,99] The British Association for Sexual Health and HIV (BASHH) recommends that all these variables are recorded as part of a patient consultation, and they are therefore intended to be feasible for collection in routine care.[100] The GUMCADv3 reporting system was piloted in two phases, with revisions made in phase 2 based on clinic feedback and data quality issues from phase 1.

A population-level, data-driven approach to triage, based on the risk of a STI diagnosis, has not yet been applied to the UK setting. In order to test a model of delivery of a behavioural intervention that is tailored to the risk profile and characteristics of the target population, we therefore developed a data-driven triage tool that could be integrated into service systems and processes.

Aim

The aim was to develop a triage tool based on clinical data routinely collected within SH clinics in England, in order to stratify patients according to their risk of STI diagnosis and thereby direct service users to tailored behavioural interventions individualised to their needs. Separate models were to be developed for the MSM and young people groups because of the different risk types and relative importance of behavioural and demographic data.

Method

We conducted secondary data analysis of the nationally mandated GUMCADv2 data from 2013 to 2015 and the second phase of the GUMCADv3 pilot, conducted in 2015–16. Analysis of the phase 1 GUMCADv3 pilot is not presented as this version of the surveillance system was superseded by the phase 2 version.

Data sets

Surveillance (Genitourinary Medicine Clinic Activity Data Set v2)

This is a national mandatory reporting data set for England: all level 2 and level 3 SH services are required to submit their SH patient episodes to PHE. It covers an estimated 600 services (including SH services) and reports STI diagnoses. The data set contains 12 variables (*Table 4*): demographics, attendance information and any episode activity and diagnoses. Data from the reporting periods quarter 1 (2013) to quarter 3 (2016) were used. This data set is referred to as 'v2' throughout.

TABLE 4 Genitourinary medicine clinic activity data set variables available for triage tool analysis

Question	Format
Surveillance	
Gender	Categorical
Age at attendance (derived from date of birth)	Continuous
Self-defined ethnicity	Categorical
Country of birth	Categorical
Deprivation index (derived from lower-layer super output area of residence)	Continuous
Self-identified sexual orientation	Categorical
SHHAPT or READ codes of the diagnoses and/or service received	Categorical
Enhanced surveillance	
Number of partners in the past 3 months	Categorical
How many were new partners? (heterosexual and WSW only)	Categorical
Did you/your partner use a condom the last time you had penetrative (vaginal or anal) sex? (heterosexual only)	Categorical
Have you had anal (receptive or insertive) sex with a known HIV-positive partner in the past 3 months? (MSM only)	Categorical
Have you had any condomless anal sex (receptive or insertive) in the past 3 months? (MSM only)	Categorical
Have you had any receptive condomless anal intercourse in the past 3 months? (MSM only)	Categorical
Was alcohol use assessed?	Categorical
Was alcohol use documented as problematic?	Categorical
Have you used recreational drugs in the past 3 months?	Categorical
Did you take amphetamine/speed, benzodiazepines, cannabis, cocaine, crack, crystal meth, E/MDMA, GHB/GBL, heroin, ketamine, legal high, m-cat, methadone, poppers, solvents/glue or other?	Binary (yes)
Did you inject any recreational drug in the past 3 months?	Categorical
Did you share equipment with anyone when injecting drugs?	Categorical
Were you under the influence of recreational drugs (before or during sex) the last time you had sexual intercourse?	Categorical
Have you ever attended another GUM service?	Categorical
Have you been diagnosed with a STI in the past year?	Categorical
Did you have chlamydia, gonorrhoea, herpes, LGV, non-specific genital infection, syphilis, warts or other	Binary (yes)
When did you last have a HIV test?	Categorical, LGV

E/MDMA, ecstasy/methylenedioxymethamphetamine; GBL, gamma butyrolactone; GHB, gamma-hydroxybutyrate; LGV, lymphogranuloma venereum; m-cat, mephedrone; SHHAPT, sexual health and HIV activity property type; WSW, women who have sex with women.

Enhanced surveillance (Genitourinary Medicine Clinic Activity Data Set v3 pilot 2)

This data set was generated by PHE during a pilot conducted from July 2015 to June 2016 in five SH clinics: Bedford (Brook), Bristol (GUM), Croydon (GUM), Barnet (GUM) and Southend (GUM). This data set contains the same 12 variables from v2 and an additional 18 questions on recent sexual behaviours, drug and alcohol use, and previous diagnoses and attendance (see *Table 4*). This data set is referred to as 'v3p2' throughout.

Definitions

Young person: any attendance among all women, and men who have no report of sex with men and self-report as heterosexual, aged 16–25 years.

Men who have sex with men: any attendance among men who have any report of sex with men, or self-report as bisexual or homosexual, of any age.

Attendance: any first attendance within an episode of care.

Outcome: any new diagnosis of HIV, syphilis, gonorrhoea, chlamydia, hepatitis, lymphogranuloma venereum, trichomonas or herpes. Recurrent herpes and warts infections and non-specific genital infections were excluded.

Data management

The v2 data undergo routine data cleaning processes by PHE; details of this process are available on request from PHE ('GUMCADv2 Specifications Manual_v3_23_09_2014') (Hamish Mohammed, Public Health England, 23 September 2014). The v3 data were cleaned for inconsistencies between demographic and reported sexual behaviours (e.g. a female heterosexual reported as having female sex partners), drugs reports (e.g. no reported drug use and sharing injecting equipment) and previous SH attendances and diagnoses. During the cleaning, a positive response to any question about high-risk behaviour was given more weight than any contradictory negative response; for example, if an individual reported 'no' to drug use in the previous 3 months but gave a positive response to subsequent questions about the use of cannabis, then the answer to 'any drug use' would be changed to 'yes' and the answer to questions about cannabis use would be left unchanged. In the case of discrepancies between gender, sexual orientation and types of partners, gender and partner type were prioritised. For example, a heterosexual male reporting male partners would be classified as MSM within the model. Cases with multiple items of conflicting data were excluded.

The core v2 variables were still reported through the routine v2 system for the pilot clinics; the v3 pilot data were submitted separately to PHE. The clinic code, patient identification (ID) and attendance date were used to merge the two data sets. Checks for discrepancies in demographic information between v2 and v3 data sets were conducted and resolved on a case-by-case basis; cases with inconclusive cleaning were excluded from analysis. If patients from the v3p2 data set were merged with a v2 record, demographic variables were compared to test for possible biases in the subset of patients available for analysis. All cleaning, merging and data management was carried out using Stata® (StataCorp LP College Station, TX, USA) version 13.

Selection of candidate predictors

The predictor variables investigated were those available in the data set. The behavioural and risk variables included in the v3p2 data set were based on those recommended for sexual history taken by BASHH in 2013 and are well supported in the literature as being indicators of STI risk.[100] The variables were split into demographic and behavioural variables. Demographic variables included age, deprivation, prior GUM visits, prior STI diagnosis (including specific infections), ethnicity, country of birth, sexual orientation, gender and HIV status. Behavioural variables included number of sexual partners, new partners, condom use, problematic alcohol use and drug use, and unprotected anal intercourse and sex with known HIV-positive partners in MSM. Depending on the number of observations and degrees of freedom in the models, variables were recategorised between models.

All of these variables were considered in the model development; however, exclusion for reasons of missing data or low prevalence (e.g. < 5%) was undertaken following the initial description. Variables with missing data may introduce bias if the data are not missing at random (e.g. if patients are less likely to disclose risky behaviours, or there are differences in reporting quality between clinics), and if they are not frequently available then including them in a triage tool might be impracticable.[101] There are several approaches to dealing with missing data. For variables with limited missing data (< 25%), which are assumed to be missing at random, multiple imputation is recommended, as it preserves sample size.[102] However, including missing data as a distinct category may be a more pragmatic approach, as complete data collection within a routine clinical setting may not be realistic, and missing data are unlikely to be missing completely at random. This was our primary analysis approach.

To protect against overfitting, a general rule is to have 10 outcome events (i.e. STI diagnoses) per degree of freedom in the development model (i.e. predictor variable).[103] Lower priority or highly correlated candidate predictors were removed to reduce the number of degrees of freedom when possible and necessary.[103]

Developing the prediction model

The primary outcome was the binary composite variable of STI diagnosis. Multivariable logistic regression was used to develop the triage tool. The primary models were developed in the v3p2 data set, one for MSM and one for young people.

We used a full model approach, with all predefined variables included regardless of statistical association in univariate analysis.[101,104] We conducted a sensitivity analysis using a forward stepwise approach to explore whether or not a more parsimonious model could be used. All variables were binary or categorical, except age and deprivation score (derived from the patient's postcode). Continuous variables were investigated for non-linear relationships with the outcome and categorised if appropriate. Data reduction within the categorical variables (e.g. ethnicity) was undertaken based on data patterns and substantive knowledge.

The regression coefficients were used to calculate an individual's probability of STI diagnosis using the following equations (*Box 3* presents a worked example):

$$\text{Log odds of STI} = \text{model intercept} + (\text{variable value} \times \text{coefficient}) + \ldots. \quad (1)$$

$$\text{Patient's odds of STI} = e^{(\text{patient's log odds value})} \quad (2)$$

$$\text{Probability of STI} = [\text{odds}/(1 + \text{odds})] \times 100. \quad (3)$$

Model performance

Model performance was evaluated using several statistical tests. The Hosmer–Lemeshow goodness of fit test was carried out to measure model calibration,[105] despite its limitations.[106] Model discrimination was tested using the *c*-statistic [area under the receiver operating characteristic curve (AUROC)].[101,107] The *c*-statistic and the pseudo-R^2 were the main parameters for determining if the model was effective at predicting the outcome of interest. A *c*-statistic of > 0.7 is generally considered reasonable model discrimination for a clinical tool, and one of > 0.8 is considered strong discrimination; 0.5 indicates that the model is no better than chance at predicting the outcome.[108] The Bayesian information criterion (BIC) was used to determine the most parsimonious model in sensitivity analyses, with lower values favouring model selection.

We compared different probability thresholds with the patient's true outcome to give sensitivity, specificity, positive predictive values (PPVs) and negative predictive values (NPVs). External validation, when the regression equation is tested in a district data set, is recommended as an independent assessment of the model performance to assess the extent of overfitting and the resulting optimism of its performance.[109]

BOX 3 Worked example of the triage tool

The model regression equation is used to calculate the patient log odds, using the following equations:

Patient's log odds of STI diagnosis = constant + (var_1 × $coefficient_1$) + . . . + (var_i × $coefficient_i$)

Patient's odds of STI diagnosis = $e^{(\text{patient's log odds value})}$

Probability of STI diagnosis = [odds/(1 + odds)] × 100

Taking the young person models:

Log odds of STI diagnosis = –2.34 + (south Asian × –0.32) + (other Asian × –0.06) + (black Caribbean × 0.98) + (other black × 0.45) + (other white × 0.28) + (mixed white & black × 0.61) + (mixed other × –0.13) + (other ethnicity × –0.37) + (missing ethnicity × –0.16) + (born Africa × –0.42) + (born Asia × –0.86) + (born Europe × 0.03) + (born Americas × –0.26) + (born other × –0.12) + (born missing × –0.24) + (age 18–19yrs × –0.26) + (age 20–21yrs × –0.21) + (age 22–23yrs × –0.36) + (age 24–25yrs × –0.48) + (deprivation 2nd × –0.10) + (deprivation 3rd × –0.004) + (deprivation 4th × –0.18) + (deprivation 5th × –0.22) + (missing deprivation × 0.13) + (prior chlamydia × 1.30) + (1 partners × 0.77) + (2–4 partners × 0.92) + (> = 5 partners × 0.95) + (missing partners × 0.40) + (new partner × 0.37) + (new partner missing × 0.64) + (condom use × –0.69) + (missing condom use × –1.04)

Take the example of a black Caribbean, 19-year-old female, who lives in an area in the second quintile of deprivation. She was diagnosed with chlamydia in the previous 12 months, has had two partners in the previous 3 months, of whom one was new. She used a condom at last sex. In this case, the regression equation for this patient would look like:

Log odds of STI diagnosis = –2.34 + (black Caribbean × 0.98) + (born UK × 0) + (age 18–19yrs × –0.26) + (deprivation 2nd × –0.10) + (prior chlamydia × 1.30) + (2–4 partners × 0.92) + (new partner × 0.37) + (condom use × 0)

Log odds of STI diagnosis = 0.87

Patient's odds of STI diagnosis = $e^{(0.87)}$

Patient's odds of STI diagnosis = 2.39

Probability of STI diagnosis = [2.39/(3.39)] × 100

Probability of STI diagnosis = 70.5%

This is therefore an example of a very high-risk patient, with the model predicting a 70.5% likelihood of them being diagnosed with a STI.

External validation was not conducted because of the limited sample size of the v3p2 pilot; however, it was discussed that external validation could be done as part of the WP5 (see *Chapter 6*) pilot implementation.

Sensitivity analyses

We conducted sensitivity analyses in order to test assumptions about our primary modelling approach. We assessed a model that included only demographic data to determine how much added value the additional behavioural information provides; this also allowed us to investigate whether or not demographics at the national level had different relationship directions and magnitudes of effect to the smaller v3p2 data set.

Missing data, which were included as a distinct category in the primary model, were compared with imputed models to give us more information on pragmatic implementation. A categorised missing approach was adopted to reflect the real-world nature of routine data, and because we made the assumption that data were not missing at random and, therefore, may contain predictive value in themselves. Finally, a full model where all a priori defined variables were included was compared with a forward stepwise regression approach.

Results

Data description

During the pilot period from July 2015 to June 2016, a total of 28,514 episodes of care were reported. *Table 5* describes the key demographic variables between those with and those without enhanced behavioural data. The patients recorded in the v3p2 data set were similar in terms of ethnicity, age and gender to those with only basic surveillance for the same time period. There were considerably higher levels of missing sexual orientation information in the enhanced data set (16% vs. 7%), and lower numbers of homosexual or bisexual patients (6% vs. 13%). This probably reflects the fact that the pilot sites do not include any of the clinics with higher proportions of MSM clients, such as Dean Street or Brighton.

TABLE 5 Description of demographic variables in the GUMCAD surveillance and enhanced surveillance data sets

Variables	Enhanced surveillance ($N = 23,107$), *n* (%)	Surveillance only ($N = 5407$), *n* (%)
Gender		
Male	9419 (41)	2252 (42)
Female	13,613 (59)	3155 (58)
Missing	3 (0)	
Sexual orientation		
Heterosexual	17,761 (77)	4314 (80)
Bisexual	1034 (4)	493 (9)
Homosexual	540 (2)	202 (4)
Missing	3772 (16)	398 (7)
Ethnicity		
White	16,197 (70)	3544 (66)
Asian	1124 (5)	282 (5)
Black	3732 (16)	967 (18)
Mixed	1374 (6)	374 (7)
Other	233 (1)	49 (1)
Missing	447 (2)	191 (4)
Age (years)		
< 25	8990 (39)	1781 (33)
25–34	8665 (38)	1964 (36)
35–44	3293 (14)	898 (17)
45–64	2007 (9)	696 (13)
≥ 65	151 (1)	68 (1)

Following cleaning of the merged data set, there were 9530 non-MSM young people recorded in the v3p2 pilot, of whom 1005 had a STI diagnosis (10.6%). This is very similar to the STI diagnosis rate seen in the national surveillance data set during the same time period (10.8%). There were 1448 MSM records in the v3p2 data set, with 318 STI diagnoses (22.0%). This was higher than the nationally reported rate of 14.9%. This allows up to 100 and 32 degrees of freedom in the young person and MSM models, respectively, to avoid overfitting.

Young people and MSM differed from the general surveillance population and from each other (*Table 6*). The proportion of young women in the data set was higher than in the general clinic population (69% vs. 59%) and the MSM population in the data set was older than in the overall clinic population and more likely to be of white ethnicity (82% vs. 70%). The number of partners reported by young people generally reflected the general population, but MSM reported a higher proportion of multiple partners, with 15% reporting five or more partners in the previous 3 months compared with 3% of the general pilot clinic population. They also had a lower number of missing data for this variable. MSM reported double the rate of drug use of young people (14% vs. 7%) and considerably lower rates of missing data for this variable (31% vs. 52%). This supports the assumption that data were unlikely to be missing at random, with either MSM being more likely to disclose drug use or providers being more likely to ask MSM patients about drug use.

TABLE 6 Description of GUMCAD enhanced surveillance data

Variables	Total (*N* = 23,103), *n* (%)	Young people (*N* = 9530), *n* (%)	MSM (*N* = 1448), *n* (%)
Demographic			
Gender			
Male	9491 (41)	2983 (31)	1448 (100)
Female	13,612 (59)	6547 (69)	–
Age (years)			
< 20	2938 (13)	2628 (18)	77 (5)
20–24	6052 (26)	6902 (82)	297 (21)
25–34	8664 (38)	–	562 (39)
35–44	3291 (14)	–	262 (18)
45–64	2007 (9)	–	213 (15)
≥ 65	151 (1)	–	37 (3)
Sexual orientation[a]			
Heterosexual	17,758 (77)	7809 (82)	51 (4)
Bisexual	540 (2)	120 (1)	299 (21)
Homosexual	1034 (4)	27 (0)	963 (67)
Missing	3771 (16)	1574 (17)	135 (9)
Location of birth			
UK	15,682 (68)	6813 (71)	1049 (72)
Europe	2095 (9)	643 (7)	153 (11)
Africa	1134 (5)	309 (3)	40 (3)
Americas	821 (4)	217 (2)	43 (3)
Asia	289 (1)	51 (1)	19 (1)
Other	618 (3)	190 (2)	54 (4)
Missing	2464 (11)	1307 (14)	90 (6)

continued

TABLE 6 Description of GUMCAD enhanced surveillance data (*continued*)

Variables	Total ($N = 23,103$), *n* (%)	Young people ($N = 9530$), *n* (%)	MSM ($N = 1448$), *n* (%)
Ethnicity			
White British	13,639 (59)	6072 (64)	1003 (69)
White, other	2554 (11)	785 (8)	185 (13)
South Asian	661 (3)	201 (2)	33 (2)
Other Asian	463 (2)	165 (2)	36 (2)
Black Caribbean	1353 (6)	448 (5)	28 (2)
Other black	2379 (10)	991 (10)	54 (4)
White and black mixed	826 (4)	418 (4)	31 (2)
Other mixed	548 (2)	249 (3)	38 (3)
Any other	233 (1)	79 (1)	17 (1)
Missing	447 (2)	122 (1)	23 (2)
Deprivation quintiles			
Lowest	4731 (20)	1744 (18)	294 (20)
Quintile 2	6019 (26)	2364 (25)	354 (24)
Quintile 3	4257 (18)	1768 (19)	259 (18)
Quintile 4	4291 (19)	1937 (20)	273 (19)
Highest	2917 (13)	1363 (14)	213 (15)
Missing	888 (4)	354 (4)	55 (4)
Previous STI diagnosis[b]			
No	21,526 (93)	8795 (92)	1329 (92)
Yes	1577 (7)	735 (8)	119 (8)
Behavioural			
Number of partners[c]			
None	1068 (5)	365 (4)	73 (5)
Zero	10,893 (47)	4336 (46)	410 (28)
One	4037 (17)	1660 (17)	506 (35)
Two to four	649 (3)	206 (2)	215 (15)
Five or more	6456 (28)	2963 (31)	244 (17)
Missing			
No	–	2658 (28)	–
Yes	–	2663 (28)	–
Missing	–	4209 (44)	–
Condom use last sex			
No	–	3881 (41)	–
Yes	–	2014 (21)	–
Missing	–	3635 (38)	–
Anal sex with known HIV +ve partner[c]			
No	–	–	786 (54)
Yes	–	–	124 (9)
Missing	–	–	538 (37)

TABLE 6 Description of GUMCAD enhanced surveillance data (*continued*)

Variables	Total (*N* = 23,103), *n* (%)	Young people (*N* = 9530), *n* (%)	MSM (*N* = 1448), *n* (%)
Condomless anal sex[c]			
No	–	–	419 (29)
Yes	–	–	535 (37)
Missing	–	–	494 (34)
Receptive condomless anal sex[c]			
No	–	–	138 (10)
Yes	–	–	350 (24)
Missing	–	–	960 (66)
Problematic alcohol use			
No	4558 (20)	1890 (20)	192 (13)
Yes	203 (1)	102 (1)	22 (2)
Missing	18,342 (79)	7538 (79)	1234 (85)
Drug use[c]			
No	10,212 (44)	3860 (41)	795 (55)
Yes	1537 (70)	686 (7)	199 (14)
Missing	11,354 (49)	4984 (52)	454 (31)

a These relate to females only in the young people, and in the MSM group, self-reported heterosexuals who reported same sex male partners were included in the MSM group.
b Within the previous 12 months.
c Within the previous 3 months.
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Young person model

Variable selection

Deprivation was included as quintiles, based on the UK indices of multiple deprivation[111] derived from the patient's postcode. Age was included in the model as a categorical variable; plotting the relationship between age and STI diagnosis showed that the association was not linear. We described the number of prior STI diagnoses reported, both longitudinally and from patient report. Within this cohort of young people, there were very few non-chlamydia prior diagnoses, and we therefore included prior chlamydia infection only in the model. Ethnicity and location of birth contained a large number of categories, 15 and 9, respectively, adding 23 degrees of freedom to the model. Many of the categories contained < 5% of the patient population; therefore, these variable categories were collapsed to ensure that there were more balanced categories for modelling. Drug use and problematic alcohol use were excluded because of high numbers of missing data, and sexual orientation was excluded for having too little heterogeneity.

Table 7 describes the variables and categories that were included in the primary analysis.

Primary model

The primary model categorised missing data, retaining all records in the model (*Table 8*). The model included 34 degrees of freedom and therefore met the required 10 outcomes per degree of freedom. Among young people, females were less likely to have a STI diagnosis [odds ratio (OR) 0.71, 95% CI 0.62 to 0.83] than males, and being older was associated with lower odds of STI diagnosis. Being of black or mixed white and black ethnicity was associated with higher odds of STI diagnosis than being white British.

TABLE 7 Variables and their definitions in the primary young person's model

Variable	Categories
Demographic	
Gender	Male (reference), Female
Ethnicity	White (reference), white other, South Asian, Asian other, black Caribbean, black other, white and black mixed, mixed other, other, missing
Location of birth	UK (reference), Europe, Africa, Americas, Asia, other, missing
Prior chlamydia diagnosis	No (reference), yes – within the past year
Age (years)	16–17 (reference), 18–19, 20–21, 22–23, 24–25
Deprivation score	Quintiles – least deprived (reference)
Behavioural	
Number of partners	None (reference), one, two to four, five or more, missing
New partners	No (reference), yes, missing
Condom use	No (reference), yes, missing

TABLE 8 Full multivariable logistic regression model for STI diagnosis in the current visit in young people

Variable	OR	Coefficient	*p*-value	95% CI
Gender				
Male	1.00			
Female	0.71	–0.34	0.000	0.62 to 0.83
Ethnicity				
White British	1.00			
White, other	1.33	0.28	0.099	0.95 to 1.86
South Asian	0.73	–0.32	0.308	0.39 to 1.35
Asian, other	0.94	–0.06	0.854	0.49 to 1.80
Black Caribbean	2.65	0.98	0.000	2.01 to 3.50
Black, other	1.57	0.45	0.000	1.25 to 1.97
White and black mixed	1.85	0.61	0.000	1.39 to 2.45
Mixed, other	0.88	–0.13	0.596	0.55 to 1.41
Other	0.69	–0.37	0.409	0.29 to 1.66
Missing	0.85	–0.16	0.661	0.42 to 1.73
Location of birth				
UK	1.00			
Europe	1.03	0.03	0.881	0.72 to 1.47
Africa	0.66	–0.42	0.046	0.44 to 0.99
Americas	0.77	–0.26	0.234	0.50 to 1.18
Asia	0.42	–0.86	0.262	0.09 to 1.90
Other	0.89	–0.12	0.695	0.48 to 1.62
Missing	0.78	–0.24	0.033	0.62 to 0.98

TABLE 8 Full multivariable logistic regression model for STI diagnosis in the current visit in young people (*continued*)

Variable	OR	Coefficient	*p*-value	95% CI
Age (years)				
16–17	1.00			
18–19	0.77	–0.26	0.050	0.59 to 1.00
20–21	0.81	–0.21	0.107	0.63 to 1.05
22–23	0.70	–0.36	0.006	0.54 to 0.90
24–25	0.62	–0.48	0.000	0.48 to 0.80
Deprivation quintile				
1 (highest)	1.00			
2 (high)	0.91	–0.10	0.325	0.74 to 1.10
3 (medium)	1.00	–0.004	0.973	0.80 to 1.24
4 (low)	0.84	–0.18	0.126	0.67 to 1.05
5 (lowest)	0.80	–0.23	0.090	0.61 to 1.04
Missing	1.14	0.13	0.464	0.80 to 1.61
Previous chlamydia				
No	1.00			
Yes	3.66	1.30	0.000	2.88 to 4.65
Number of partners				
Zero	1.00			
One	2.16	0.77	0.011	1.19 to 3.91
Two to four	2.51	0.92	0.003	1.36 to 4.64
Five or more	2.58	0.95	0.008	1.28 to 5.22
Missing	1.49	0.40	0.149	0.87 to 2.57
New partners				
No	1.00			
Yes	1.45	0.37	0.000	1.19 to 1.77
Missing	1.89	0.64	0.000	1.38 to 2.60
Condom use				
No	1.00			
Yes	0.50	–0.69	0.000	0.41 to 0.62
Missing	0.35	–1.04	0.000	0.25 to 0.50

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Behavioural risks included prior chlamydia diagnosis (OR 3.66, 95% CI 2.88 to 4.65), multiple partners in the prior 3 months and having a new partner. Condom use at last sex was protective (OR 0.50, 95% CI 0.41 to 0.62).

The model had reasonable performance, with a pseudo-R^2 of 7.8% and a *c*-statistic of 0.703. The Hosmer–Lemeshow test showed good model fit (*p*-value = 0.1602). The model predicted probabilities range from 1% to 75%, with a mean of 12%. Using a risk cut-off point of 15%, one would refer 19% of patients, with a sensitivity of 42% and specificity of 84% (*Table 9* and *Figure 3*).

TABLE 9 Sensitivity, specificity, PPV and NPV values for different risk prediction thresholds in the young person's model

Prediction threshold (%)	STI ($n = 1005$)	No STI ($n = 8525$)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Correctly classified (%)	% referred
> 5	905	6411	90.0	24.8	12.4	95.5	31.7	76.8
> 10	673	3118	67.0	63.4	17.8	94.2	63.8	39.8
> 12	581	2304	57.8	73.0	20.1	93.6	71.4	30.3
> 15	425	1385	42.3	83.8	23.5	92.5	79.4	19.0
> 18	309	861	30.8	89.9	26.4	91.7	83.7	12.3
> 20	252	605	25.1	92.9	29.4	91.3	85.8	9.0
> 30	112	192	11.1	97.8	36.8	90.3	88.6	3.2

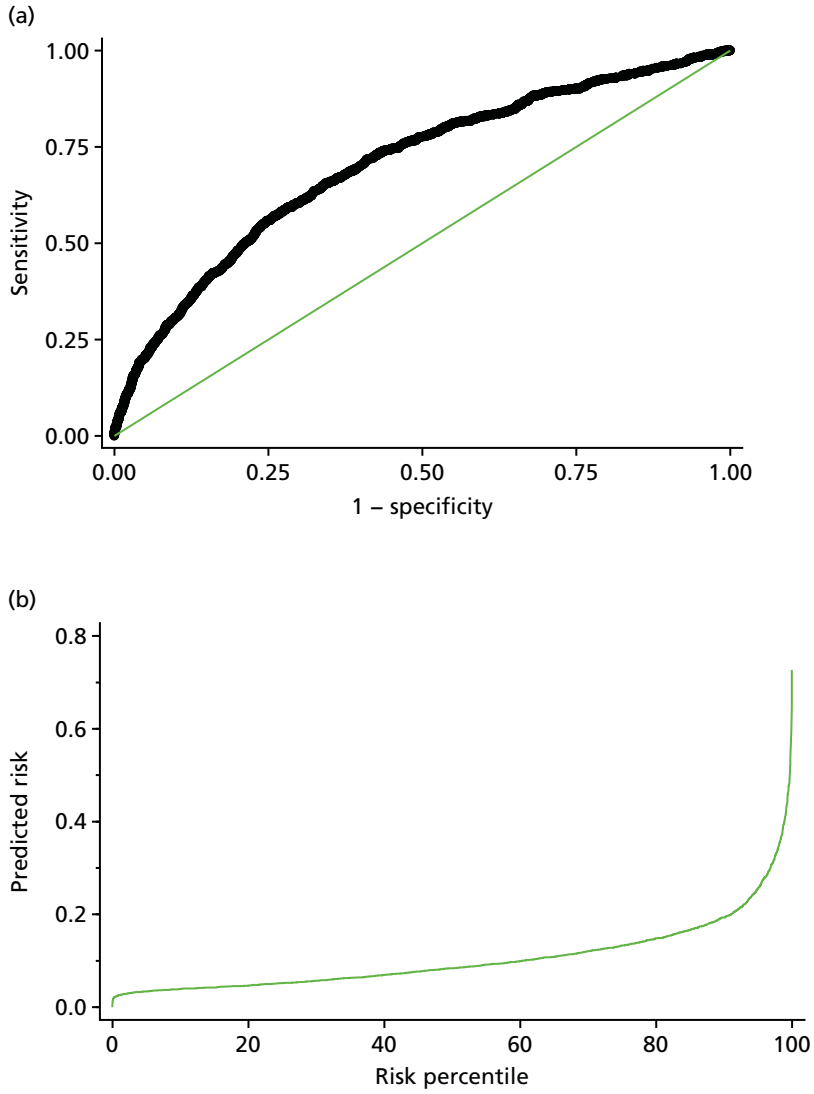

FIGURE 3 Model performance graphs for the primary young people's model. (a) Receiver operating characteristic curve of STI diagnosis, *c*-statistic = 0.7026, and (b) linear prediction (log odds) of STI diagnosis. This article was published in *EClinicalMedicine*, vol. 4–5, King C, Hughes G, Furegato M, Mohammed H, Were J, Copas A, *et al.*, Predicting STI diagnoses amongst MSM and young people attending sexual health clinics in England: triage algorithm development and validation using routine clinical data, pp. 43–51, Copyright Elsevier 2018.[110]

Sensitivity analyses

A model fitted using a forward stepwise approach, using a *p*-value threshold of 0.2, did not exclude any of the variables and therefore had the same model performance.

A model was fitted using multiple imputation. The following variables underwent 10 imputation rounds using chained equations: location of birth, ethnicity, deprivation, number of partners, new partners and condom use. The model had a pseudo-R^2 of 6.6% and a *c*-statistic of 0.688; the predicted risks ranged from 1% to 68%. Overall, this showed worse discrimination than the model that included categorised missing values.

A model including demographic data only, and fitted using the v2 data set (1,045,373 observations), showed considerably poorer model performance, with a pseudo-R^2 of 1.4% and a *c*-statistic of 0.590. The predicted risk of STI diagnosis was limited, ranging from 2% to 24%, reflecting poor discrimination. A typical high-risk individual based on demographics alone would be an 18- to 19-year-old black Caribbean male, born in Europe and living in an area of high deprivation (predicted risk 23%).

Men who have sex with men model

Variable selection

Similarly to the young person's model, within the MSM model, age and deprivation were included as categorical variables, and ethnicity and country of birth were reduced to fewer categories because of the lack of heterogeneity within the sample. Within this cohort of MSM, a variety of prior STI diagnoses were reported, including HIV, syphilis, chlamydia and gonorrhoea. Many of these contained too few records to be included as individual predictors; therefore, a single binary variable indicating STI in the prior 12 months was used. Problematic alcohol use was excluded for having too many missing data.

Table 10 summarises the variables in all the models from this point forward.

TABLE 10 Variables and their definitions in the primary MSM model

Variable	Categories
Demographic	
Ethnicity	White (reference), white other, South Asian, Asian other, black Caribbean, black other, white and black mixed, mixed other, other, missing
Location of birth	UK (reference), Europe, Africa, Americas, Asia, other, missing
STI diagnosis	No (reference), yes – within the past year
Age (years)	< 20 (reference), 20–24, 25–34, 35–44, 45–64, ≥ 65
Deprivation score	Quintiles – least deprived (reference)
Behavioural	
Number of partners	None (reference), one, two to four, five or more, missing
Condomless anal sex	No (reference), yes, missing
Known HIV-positive partner	No (reference), yes, missing
Any drug use in the prior 3 months	No (reference), yes, missing

Primary analysis

The model was fitted, using categorised missing values, with 36 degrees of freedom and may therefore be overfitted (*Table 11*). In the MSM model, the only significant demographic predictors of STI diagnosis were being of South Asian ethnicity (OR 2.53, 95% CI 1.05 to 6.10) and being born in Europe (OR 2.46, 95% CI 1.26 to 4.78). Significant behavioural risks included having had condomless anal sex in the previous 3 months (OR 1.95, 95% CI 1.39 to 2.73) and any drug use in the prior 3 months (OR 1.89, 95% CI 1.31 to 2.74).

The model had reasonable performance, with a pseudo-R^2 of 7.0% and a *c*-statistic of 0.676. The Hosmer–Lemeshow test showed good model fit (*p*-value = 0.224). The model predicted probabilities range from 3% to 71%, with a mean of 16%. Using a risk score threshold of 30% would result in one in five patients being classified as being at high risk of STI diagnosis, with a sensitivity of 38.7% and specificity of 84.8% (*Table 12* and *Figure 4*).

Sensitivity analyses

Using a forward stepwise approach to the model, with a *p*-value threshold of 0.2, excluded age, deprivation quintile, number of partners and ethnicity. This model was favoured according to the BIC statistic, but had a poorer discrimination (*c*-statistic = 0.658) and model fit (pseudo-R^2 = 5.8%); BIC tends to favour parsimonious models, that include fewer explanatory variables.

TABLE 11 Full multivariable logistic regression model for STI diagnosis in the current visit in MSM

Variable	OR	Coefficient	*p*-value	95% CI
Ethnicity				
White British	1.00			
White, other	0.67	–0.40	0.236	0.35 to 1.30
South Asian	2.53	0.93	0.039	1.05 to 6.10
Asian, other	1.43	0.36	0.518	0.48 to 4.21
Black Caribbean	0.57	–0.56	0.307	0.20 to 1.67
Black, other	0.98	–0.02	0.957	0.47 to 2.03
White and black mixed	0.76	–0.28	0.569	0.29 to 1.97
Mixed, other	1.19	0.17	0.676	0.53 to 2.70
Other	1.05	0.04	0.947	0.28 to 3.90
Missing	1.99	0.69	0.159	0.76 to 5.20
Location of birth				
UK	1.00			
Europe	2.46	0.90	0.008	1.26 to 4.78
Africa	1.00	0.002	0.995	0.42 to 2.42
Americas	1.43	0.36	0.417	0.60 to 3.40
Asia	1.23	0.21	0.737	0.37 to 4.16
Other	0.88	–0.13	0.796	0.33 to 2.32
Missing	0.65	–0.43	0.185	0.35 to 1.23

TABLE 11 Full multivariable logistic regression model for STI diagnosis in the current visit in MSM (*continued*)

Variable	OR	Coefficient	*p*-value	95% CI
Age (years)				
< 20	1.00			
20–24	0.75	–0.28	0.364	0.41 to 1.39
25–34	0.79	–0.24	0.409	0.44 to 1.39
35–44	0.63	–0.47	0.141	0.34 to 1.17
45–64	0.55	–0.59	0.076	0.29 to 1.06
≥ 65	0.41	–0.89	0.117	0.13 to 1.25
Deprivation quintile[a]				
1 (highest)	1.00			
2 (high)	0.93	–0.07	0.708	0.63 to 1.36
3 (medium)	0.87	–0.14	0.504	0.57 to 1.32
4 (low)	1.08	0.08	0.716	0.72 to 1.63
5 (lowest)	0.66	–0.41	0.094	0.41 to 1.07
Missing	1.15	0.14	0.709	0.56 to 2.35
Previous STI				
No	1.00			
Yes	1.40	0.33	0.150	0.89 to 2.20
Number of partners				
Zero	1.00			
One	1.24	0.21	0.604	0.55 to 2.76
Two to four	1.30	0.26	0.524	0.58 to 2.93
Five or more	1.70	0.53	0.219	0.73 to 3.97
Missing	1.01	0.01	0.976	0.44 to 2.36
Unprotected anal intercourse				
No	1.00			
Yes	1.95	0.67	0.000	1.39 to 2.73
Missing	0.89	–0.12	0.758	0.43 to 1.86
Known HIV-positive partner				
No	1.00			
Yes	1.52	0.42	0.065	0.98 to 2.37
Missing	1.15	0.14	0.681	0.59 to 2.22
Drug use in prior 3 months				
No	1.00			
Yes	1.89	0.64	0.001	1.31 to 2.74
Missing	1.29	0.25	0.210	0.87 to 1.91

a Deprivation quintiles based on the Index of Multiple Deprivation.

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TABLE 12 Sensitivity, specificity, PPV and NPV values for different risk prediction thresholds in the MSM model

Prediction threshold (%)	STI ($N = 318$), n	No STI ($N = 1130$), n	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Correctly classified (%)	% referred
> 10	308	1018	96.9	9.9	23.2	91.8	29.0	91.6
> 15	262	714	82.4	36.8	26.8	88.1	46.8	67.4
> 18	227	531	71.4	53.0	30.0	86.8	57.0	52.3
> 20	209	452	65.7	60.0	31.6	86.2	61.3	45.6
> 25	157	294	49.4	74.0	34.8	83.9	68.6	31.1
> 30	123	172	38.7	84.8	41.7	83.1	74.7	20.4
> 35	86	111	27.0	90.2	43.7	81.5	76.3	13.6

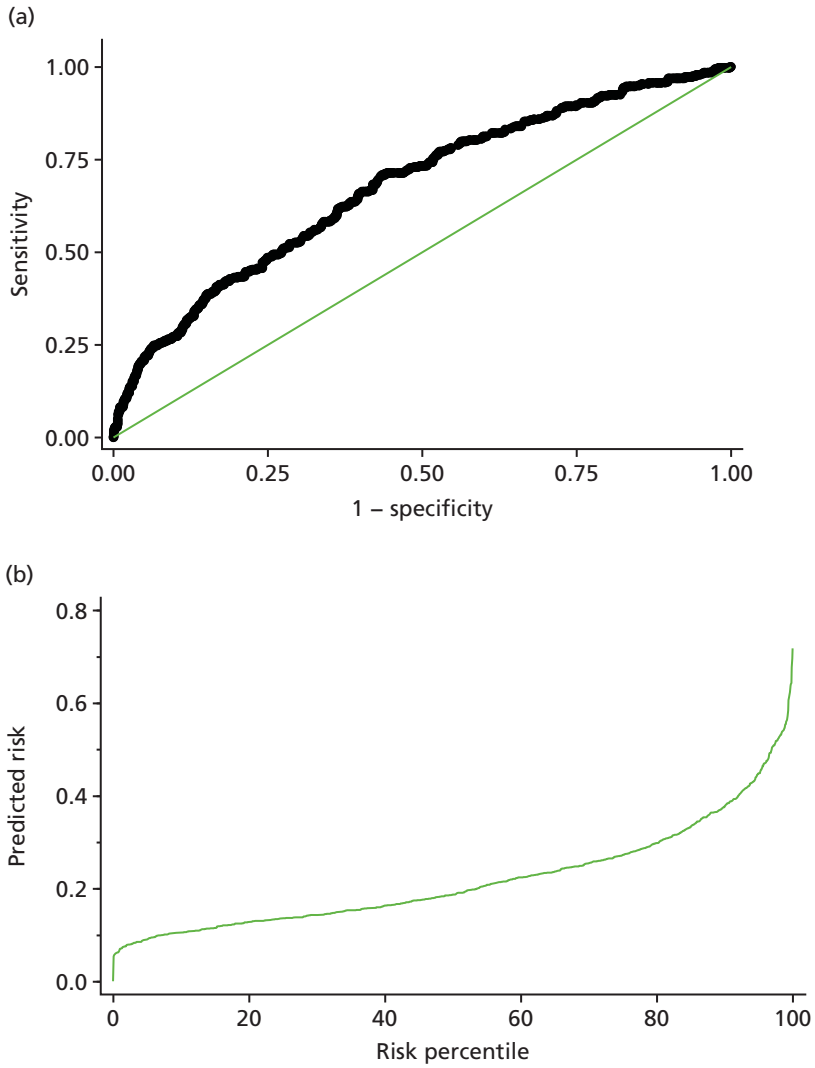

FIGURE 4 Model performance graphs for the primary MSM model. (a) Receiver operating characteristic curve of STI diagnosis, *c*-statistic = 0.676; and (b) linear prediction (log odds) of STI diagnosis. This article was published in *EClinicalMedicine*, vol. 4–5, King C, Hughes G, Furegato M, Mohammed H, Were J, Copas A, *et al.*, Predicting STI diagnoses amongst MSM and young people attending sexual health clinics in England: triage algorithm development and validation using routine clinical data, pp. 43–51, Copyright Elsevier 2018.[110]

A model was fitted using multiple imputation, which underwent 10 imputation rounds using chained equations of location of birth, ethnicity, deprivation, number of partners, sex with a known HIV-positive partner, condomless anal sex and drug use in the prior 3 months. The model had a pseudo-R^2 of 6.8% and a *c*-statistic of 0.676; the predicted risks ranged from 4% to 71%. This model showed very similar performance and discrimination to the model that included categorised missing data, and similar direction and magnitude of relationships with the outcome.

A model including demographic data with only the v2 data set (245,863 observations) showed very poor model performance, with a pseudo-R^2 of 0.5% and a *c*-statistic of 0.553. The range of predicted risk of STI diagnosis was limited (7–23%), reflecting poor discrimination. A typical low-risk individual based on demographics alone would be a South Asian aged > 65 years living in an area of low deprivation who was born in Asia (predicted risk 7%). This is contradictory to the v3p2 model, in which being South Asian was one of the main risks for STI diagnosis.

Discussion

We developed two triage tools, one each for young people and MSM groups, based on routinely collected demographic and limited behavioural data as part of a pilot implementation of GUMCADv3. Overall, both models showed borderline reasonable, but not good, performance, with the young person's model (*c*-statistic = 0.706) having slightly better performance than the MSM model (*c*-statistic = 0.676). A *c*-statistic of > 0.7 is generally considered the threshold for a diagnostic to be clinically reasonable. The inclusion of STI history and behavioural data was crucial to model performance, with models based on demographic data showing very poor performance (*c*-statistic = 0.590 and 0.553 for young people and MSM, respectively).

Young people

The young person's model identified several significant predictors of STI diagnosis, as well as protective factors, such as being female, being > 17 years of age and reporting condom use at last sex. This agrees with previously published literature, which has also found older age and condom use to be associated with lower risk of STI diagnosis in other settings.[112–114] Similarly, multiple partners and prior diagnoses are established risks for STIs among young people.[15,113,115] The finding that young people of black ethnicity (including black Caribbean) or mixed white and black ethnicity are at higher risk of STI diagnosis agrees with previous findings from the UK.[116,117] Among young people, possible explanations for this association may be around different levels of SH knowledge, and therefore behaviours, among younger and black ethnic minorities.[118]

Applying the young person's model as a triage tool within a clinical setting requires a threshold to be set, with patients having a score above the threshold categorised as being at 'high risk of STI diagnosis' and those below the threshold as 'low risk of STI diagnosis'. The risk predictiveness curve (see *Figure 3*) shows that most young people were relatively low risk, with predicted risk rising sharply from 20% to 75% in only 10% of the population. Using a predicted risk threshold of > 20%, in which the slope of the curve rises steeply, results in a sensitivity of 25% and specificity of 93%. Applying a lower threshold of > 15% improves the sensitivity to 42% and reduced the specificity to 84%; however, this would double the number of patients classified as being at 'high risk of STI diagnosis' (9% vs. 19%). Although this lower threshold increases sensitivity, the feasibility of delivering a brief intervention to one in five young people may not be possible.

Men who have sex with men

The MSM model identified only four significant predictors of STI diagnosis: being of South Asian ethnicity (OR 2.53), being born in mainland Europe (OR 2.46), having had condomless anal sex in the previous 3 months (OR 1.95) and drug use in the prior 3 months (OR 1.89). The use of drugs has been reported as a risk for STI diagnosis by multiple studies,[16,20,119] so this finding would be expected. However, the lack of association seen between number of partners and STI diagnosis contradicts multiple studies that have found it to be a significant risk,[16,17,120] as was found in young people. In fact, when we used a forward

stepwise modelling approach, the number of partners was not retained in the model; nor was age, deprivation or ethnicity. Compared with other reports of risks for different STIs in the UK, the finding that being of South Asian ethnicity is a significant risk was unexpected.[121] This may be the result of small numbers of observations ($n = 33$); a handful of cases in this group could result in a significant relationship.

The risk predictiveness curve for the MSM model (see *Figure 4*) showed a more consistent increase in risk of STI diagnosis across the population, suggesting that MSM are more likely than young people to be at high risk when the increase is concentrated in a small proportion of the population. Half of MSM have a predicted risk of a STI of > 20%, which explains why the discrimination of this model is poorer than that of the young person's model. Using a predicted risk threshold of > 30% would result in 20% of the MSM clinic population being classified as having a 'high risk of STI diagnosis', with a sensitivity of 39% and specificity of 89%. A threshold of > 20% would give a better balance of sensitivity and specificity (66% and 60%, respectively), but would result in 46% of patients being at 'high risk of STI diagnosis'.

Implementation challenges

A key challenge of implementing risk scores for triaging in real-world clinical settings is the need to balance sensitivity, specificity and available resources. The aim of this pilot study was to demonstrate the feasibility of triaging patients into different behavioural risk reduction interventions, and crucially, using existing clinical resources. Therefore, the decision about what threshold to use when operationalising the triage is probably driven more by the proportion of patients classified as high risk than by optimising either the sensitivity (identifying more true positives) or specificity (identifying fewer false positives). Based on this being the priority, a risk threshold of 20% for young people and of 30% for MSM may be the best balance between resources, sensitivity and specificity.

A potential challenge for this approach, assuming that all high-risk patients would be referred to an intervention that requires a level of clinic resources, would arise if clinic populations differ dramatically in terms of their demographics and sexual behaviours. A clinic that sees mostly lower-risk patients, for example mostly women of white or Asian ethnicity aged > 18 years, would probably classify less than the expected 9% of high-risk patients. In comparison, a clinic attended by more young black men would probably classify > 9% as high risk, resulting in an unequal burden on resources.

Strengths and limitations

In general, the young people and MSM populations were representative of the wider clinic populations from the five pilot sites in terms of location of birth, deprivation and ethnicity. MSM patients tended to have lower levels of missing data than young people and general populations; therefore, it is likely that the two populations used in the model development reflect the wider population of these clinics. However, these clinics may not be representative of national GUM clinic attendance. The STI rate among the subsample of MSM specifically was higher than the nationally reported rate for the same time period (22% vs. 15%, respectively), although it does not include data from any of the higher-risk London clinics with large MSM populations.[18] The pilot clinics were all located in the south of England, and, therefore, the demographic profile of patients within models is unlikely to be generalisable nationally.

A limitation of the v3p2 data set is the number of missing data within the behavioural variables. Although the behavioural variables are recommended as part of the BASHH guidelines[100] and are intended to be feasible for collection in routine care, in practice this may not be the case. The number of missing data differs between young people and MSM, suggesting that clinical staff did not address these questions to patients at random but, rather, selected whom they asked and recorded data for based on personal characteristics. For example, a young woman attending a GUM clinic for contraception may be less likely to have her recent sexual behaviour recorded than one attending for a STI screen. We found that drug use was much more likely to have been recorded in MSM than in the general population (49% vs. 31%, respectively), perhaps reflecting an awareness of chemsex being a common high-risk behaviour in MSM. As it is reasonable to assume that the missingness is not random and that there are several mechanisms that could lead to this missingness, our primary models would not have accounted for this. Improving data

completeness for the limited behavioural data across the whole clinic population would probably improve model performance and discrimination. This would also allow for additional variables to be included in the triage tool, such as problematic alcohol use.

We did not conduct any internal validation of either model; therefore, we cannot comment on how well the model would generalise to a different data set. The young person's model, with 1005 outcomes and 34 degrees of freedom, met the rule of thumb to prevent overfitting that there should be 10 outcome events per degree of freedom. The MSM model, however, was fit with 36 degrees of freedom for 318 outcomes; therefore, it is likely to be overfitted, despite having poorer performance. External validation was planned during the pilot feasibility trial implementation, providing a more robust method of model validation than internal validation.[109]

Conclusion

Triaging patients into high- or low-risk groups based on routinely collected data within SH clinics showed reasonable discriminatory ability; however, at a minimum, basic behavioural data are needed to improve the discrimination of these models. The ability to include additional, or more complete, behavioural data would probably improve performance further. The models were developed using the only data set available at this time, from a pilot that included a small sample of clinics that were not representative of all clinics in the UK (e.g. larger London clinics with a high proportion of high-risk patients were not included). Although the work demonstrated that developing such a tool was possible to a minimal threshold of clinical utility, further refinement and external validation is needed to improve the performance of the tool and assess the real-world applicability of this approach.

Chapter 4 Work package 3: current opportunities, barriers, and preferences for behavioural interventions

Background

Attendance at a SH clinic provides an opportunity to deliver interventions at a potentially 'teachable moment'. In line with this, NICE recommends that high-risk groups, including young people and MSM, undergo risk assessment at SH services.[17] It is recommended that those considered as being at high risk receive a brief, structured one-to-one risk reduction intervention.[122] There is currently a lack of evidence from the UK as to how patients are being triaged in clinics, what criteria are being used to determine risk and what interventions are being offered. Considering the range of potential evidence-based interventions identified in WP1,[52] understanding what is currently offered as the standard of care across diverse services is important.

Taking account of the views of stakeholders, including service users and staff who deliver interventions, is vital to the design and implementation of interventions that are acceptable, practically feasible and sustainable over time.[35] Cocreation of interventions with stakeholders is important to the IM approach to intervention development and adaptation.[123] This iterative process combines an ecological approach with the participation of all stakeholders, a focus on specification of the underlying mechanisms (in a clear logic model) and a research-based approach to ensuring fidelity of implementation. A key part of this process is to refine modes of delivery and delivery competencies that maximise intervention effectiveness in real-world contexts.[39] Understanding service user and provider preferences for different intervention approaches and the motivation for these preferences forms part of the IM process. This part of the project therefore used qualitative and quantitative methods to obtain evidence to inform the IM process.

Aim

To describe current practice in SH clinics with respect to triage and the delivery of sexual risk reduction interventions, and to explore opportunities and challenges to the delivery of candidate risk reduction interventions.

Method

We conducted a mixed-methods study with HCPs and service users, using four phases of data collection.

Key informant provider interviews

Key informant interviews were conducted with a range of service providers to explore the current use of triage methods and behavioural interventions in SH services in England. We explored respondents' views of the opportunities and challenges to the delivery of sexual risk reduction interventions within existing resources in SH services.

Participant selection

We purposively recruited a range of HCPs to include service leads, HAs, doctors and nurses. Providers were targeted to reflect different types of clinics, sizes, geographic locations and client mixes. Selection of clinics was done through individual contacts and through random selection from the list of clinics provided by PHE, which was done in Stata. In total, we aimed to conduct 30 interviews.

Recruitment
Interviews were pre-booked following an invitation sent by e-mail. Participants were contacted up to three times by e-mail before they were considered as not interested in taking part.

Data collection
The interviews were conducted by telephone. Interviews lasted approximately 30 minutes in total, and consent was taken verbally at the start. The interviews were audio-recorded and transcribed by a professional service (Way With Words, London, UK).

Analysis
Analysis used the framework approach, a deductive approach that allows for a more structured approach to data analysis based on predetermined aims and objectives as well as accommodating emerging themes. Content analysis was conducted independently by two researchers (CK and AR) and themes were agreed through discussion until consensus was reached. Both predetermined concepts used for developing the topic guides and emergent themes arising from the data informed the process of identifying the key thematic categories to be used in data coding.[124,125]

Web-based service provider survey
A brief web survey was conducted with SH service providers to determine current triage and intervention strategies in use across England, and the resources that are available for these. The content of the web survey was informed by findings from the analysis of the key informant provider interviews, and, therefore, the survey was conducted sequentially to the interviews.

Study population
All SH services that report to the PHE GUMCADv2 reporting system were eligible to participate, that is level 1, 2 and 3 services within England. An estimated 570 services were reporting to PHE at the time of the survey, and a list of clinic contacts was provided by PHE. A supplementary list of clinic contacts was provided by Tom Nadarzynski [Brighton and Sussex Medical School (BSMS), 18 November 2015, personal communication] and used to update contact information.

Data collection
Providers were sent an e-mail containing study information and the link to the web survey. Up to five e-mail reminders were sent over a 6-month period (December 2015–June 2016): three generic and two personalised e-mails. The link to the survey was also distributed in the delegate packs at the BASHH 2016 annual conference. The survey was developed in Opinio (Version 7.3, Opinio, ObjectPlanet, Oslo, Norway), which is hosted on University College London (UCL) servers, and was designed to take 10 minutes. The survey was piloted by two independent clinicians who work in level 3 services to check for understanding and language. No personally identifiable information was collected.

Analysis
The survey was analysed using descriptive statistics, adjusted for clinic type and location. All analysis was done using Stata 13.

Semistructured interviews with patients
Interviews with service users were conducted to gain an understanding of patient perceptions of risk and patients' attitudes towards different risk reduction interventions, to inform acceptable and desirable interventions.

Participant selection
We purposively sampled young men and women and MSM who were attending NHS SH services. The recruitment framework categorised MSM by age and young people by age and gender, with equal recruitment across two clinic sites. We targeted 15 heterosexual young people and 20 MSM (total = 35).

Recruitment
Participants were recruited from two SH clinics: Claude Nicol Centre, Brighton, and Mortimer Market Centre (MMC), London. Participants were approached in the clinic waiting room and given a study information sheet to read before deciding to take part. Participants were offered a £20 high street voucher as a thank you for taking part. Interviews were scheduled to take place either on the day of recruitment or at a future time.

Data collection
Interviews were conducted by researchers in person within the clinical setting. Interviews were designed to last 30 minutes, and were piloted with members of the PPI group to check for understanding and sensitivity. Written consent was taken prior to the interview starting, and the interviews were audio-recorded and then transcribed using a professional service.

Analysis
We used the same analysis methodology as described for the HCP interviews.

Patient discrete choice experiment
We conducted a cross-sectional DCE, to assess patient preferences for risk reduction interventions. DCEs are based on the premise that services can be described in terms of their 'attributes' and 'levels' (or characteristics) and that an individual's preference, and therefore choice, of service is based on a combination of these characteristics. Information from WP1 and both provider and patient interviews was used to define the key issues of importance (attributes and attribute levels) that may influence patients' preference.

Study population and sample size
We recruited young people and MSM who were attending a NHS SH clinic, aiming for a representative sample of attenders within these groups. DCEs are not amenable to conventional power calculations in advance of developing the instrument. However, other studies using DCE methods to assess preferences for health care have typically included 200 participants.[126] As we planned subanalyses in young people and MSM, we aimed to recruit 350 participants.

Recruitment
Patients were recruited from three SH clinics: Claude Nicol Centre, Brighton; MMC, London; and Archway, London. Participants were approached in the clinic waiting room and given a study information sheet to read before deciding to take part.

Instrument design
The questionnaire used a 'labelled' rather than generic design. Four modes of brief behavioural intervention were included in the final design: 'talking' to someone [meaning talking therapies such as counselling and motivational interviewing (MI)], an 'e-mail or text containing health advice', an 'online session by yourself' or an 'online group session' (*Table 13*). A fifth option, 'opt out', was also offered. The attributes included type of contact, type of activity involved in each session, length and number of sessions, and the person who mediates the sessions. Note, however, that each attribute was not necessarily applicable to each intervention; for example, a person is not needed to mediate an e-mail/text-based intervention. The number of sessions (one to six) and their length (15 minutes to 1 hour) were deliberately small to reflect the brief nature of the interventions shortlisted.

The pilot questionnaire was generated using an orthogonal approach and set to 12 choice tasks given 12 degrees of freedom in the design using the NGene V1 software (ChoiceMetrics, Sydney, NSW, Australia). It was completed by 24 clinic attendees. The pilot design required participants to make two choices per DCE question. The first included an 'opt-out' option; this was omitted in the second (referred to as a 'forced choice' question). This two-stage approach was included to evaluate the concern that a large number of participants would 'opt out'. However, the forced choice question was removed from the final design, as only a minority of responses indicated a preference not to participate. The final instrument was produced using a d-efficient approach using priors from the pilot. Participants were asked to complete all 12 DCE questions.

TABLE 13 Discrete choice experiment attributes and levels

Attribute	Options				
	E-mail or text containing health advice	Online session by yourself	Online group session	Talking with at least one person	Opt out
Type of contact	E-mails or texts from a NHS service containing health information	Interactive online information including videos and quizzes	A Facebook (Facebook, Inc., Menlo Park, CA, USA) group chat or Twitter (Twitter, Inc., San Francisco, CA, USA) (or similar online social media)	One-to-one telephone conversation, one-to-one face-to-face meeting in clinic, group face-to-face meeting in clinic	N/A
Type of session	Reading e-mails/ texts	Typing questions and responses	Read/watch online and ticking boxes via a web page or application	Talking	N/A
Length of each session	N/A	Up to 15, 30 or 60 minutes	Up to 15, 30 or 60 minutes	Up to 15, 30 or 60 minutes	N/A
Number of sessions	N/A	One, two or three or four to six	One, two or three or four to six	One, two or three or four to six	N/A
Person who mediates the session	N/A	N/A	A health counsellor, nurse or peer	A health counsellor, nurse or peer	N/A

N/A, not applicable.

Eight versions of the questionnaire were produced, in each of which the order of the DCE options and questions was different.

Data collection

Once patients had signed a consent form, they were given the paper questionnaire and asked to complete this while in the waiting room. The questionnaire was designed to take 10 minutes. Participants were asked to provide limited demographic and risk behaviour information, including age, gender, ethnicity and sexual orientation. The questionnaire was piloted with patients in one clinic to check for understanding. Data were entered into a Microsoft Access® 2013 (Microsoft Corporation, Redmond, WA, USA) database.

Data analysis

Analysis used conditional logistic (CLOGIT) and latent class models (LCMs). CLOGIT models were the basic form of analysis, but because the results are presented for the 'average' respondent, they do not address issues of heterogeneity. LCMs address heterogeneity by assuming that the population of interest consists of a number of prespecified latent classes with a probability that each individual belongs to each class. Likely 'membership' of each class is estimated as a function of prespecified covariates: born in the UK (yes/no), having tested for a STI within the past year (yes/no), previously diagnosed STI (yes/no) and risk group (heterosexual 16–20 years of age, heterosexual 16–25 years of age, MSM 16–25 years of age, MSM 26–50 years of age and MSM $\geq$ 51 years of age). The number of classes was determined by selecting the number of classes in the model with the lowest BIC and examination of the standard errors on the coefficients.

All results are presented as ORs and 95% CIs based on robust standard errors given that each participant provided multiple responses. All attribute levels were dummy coded (1 for group membership, 0 otherwise) except when estimating the alternative specific constants (ASCs). The ASCs represent the extent to which people prefer one of the intervention options or opting out when all other factors are disregarded. That is, they indicate the strength of preference for each individual label. For the ASCs, effects coding was used (1 for group membership, –1 otherwise) to avoid confounding with the base levels on the main attributes. 'E-mail or texts' was used as the reference option in all analyses. Statistical analyses were performed using Stata 14 and NLOGIT 5 (NLOGIT 5, Econometric Software Inc., New York, NY, USA); the scenario evaluation was undertaken using Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA).

Results

Key informant provider interviews

A total of 40 HCPs were individually contacted by e-mail, and 26 telephone interviews were subsequently completed. Those interviewed included clinical leads, nurse practitioners and HAs, from level 2 and 3 services both inside and outside London (*Table 14*).

Current services

Most staff reported a mixture of appointment and walk-in services, with clinics varying in how patient pathways are set up. Level 2 services, many of which are nurse led, have set clinic times for specific procedures (e.g. coil fitting) that can require involvement of different specialties and are therefore appointment based. Self-check-in and booking was mentioned by staff from two GUM clinics:

> *Before they see the doctor or the nurse, there will be a, sort of, kiosk that will ask them pertinent questions in a way just to save time. So the majority of the history taking, if you like, will be done on the, sort of, electronically by patients.*
>
> *Doctor, level 3*

Several clinic staff reported having specific services and pathways for young people and MSM groups. The age cut-off for 'young' varied from 16 to 19 years, and the change in the pathways included additional questions, assessments for vulnerability and speaking to a HA:

> *An MSM who's in his 20s or 30s, whatever, with symptomatic, so we have a policy of do-not-turn-away, we need to see that person and treat them.*
>
> *Nurse, level 3*

Other services were offered by participating clinics, with little standardisation in how the services were set up; these included contraceptive clinics, drug and alcohol services, psychological services and condition-specific (e.g. warts) services. Referrals to external services also varied between clinics, including GUM services (by level 2 clinics), sexual assault or domestic abuse, drug and alcohol services, charities [such as London Friend or the Terrence Higgins Trust (THT)] and other clinical specialties (e.g. psychosexual).

A variety of triage methods and their purposes were described by staff from different clinics. Examples of how triage rules varied included 'MSM with greater than X number of partners' (Doctor, level 3) or 'Somebody who is displaying a sexual behaviour where there is multiple partner change' (Doctor, level 3). Not all clinics had set rules, with triage lacking standardisation:

> *Well we have guidelines. We have sort of GUM guidelines, departmental guidelines, but it's down to the individual doctor or nurse, seeing the patient, to decide whether someone should see the health advisor.*
>
> *Doctor, level 3*

TABLE 14 Health-care provider participants in key informant interviews

Level	Number	Job title, *n*	Location, *n*
2	8	Nurse, 5; doctor, 3	London, 3; non-London, 5
3	18	HA, 7; nurse, 1, doctor, 10	London, 9; non-London, 9

One participant reported having an electronic triaging system, similar to the proposed approach in this project:

> *The system, the way it's devised, does flag up to say this patient needs to see a health advisor because of risk A and B and it lists it down for you, what the clinician in the room has ticked.*
>
> *HA, level 3*

Clinic staff reported offering a range of SH promotion and risk reduction interventions, some more formally than others. Many of these activities were not specifically funded, but were done within existing resources:

> *So we just get paid as a level 2 sexual health screen regardless of whether we offer an intervention or not.*
>
> *Nurse, level 2*

Informal interventions included condom distribution and general health promotion messages, which were reported as being done by all clinic staff:

> *I mean, I think, really, sexual health promotion is just sort of integral to every kind of consultations so, in a way, some degree of sexual health promotion should be happening in every consultation.*
>
> *Doctor, level 3*

Various national campaigns were being delivered by clinics, such as the C-card initiative,[127] and the Sex Positive campaign by Brook.[128] More formal risk reduction interventions focused on one-to-one sessions and outreach or educational services. One-to-one sessions in level 3 services were generally performed by HAs or counsellors, rather than all clinical staff:

> *So to a certain extent, the majority of staff have had some training in motivational interviewing [. . .] if someone starts to need more intensive motivational interviewing interventions, they're referred to the health advisors.*
>
> *Doctor, level 3*

The one-to-one intervention method mentioned most often was MI. Brook specifically reported a longer 6-week educational programme about self-esteem and SH.

Proposed triage

The proposed Santé approach was generally seen as something that was done already, and this resulted in some respondents not being sure of the utility:

> *. . . we already have, well, it's not a tool, but we have a means to ask people, so if anything was going to be developed that had a chance of being used it would have not to increase the length of time.*
>
> *Doctor, level 3*

However, this led others to state that it could be acceptable:

> *I think that would work because we do triage forms which give us a little bit of a clue.*
>
> *HA, level 3*

Potential barriers to the proposed triage included increasing the time needed with patients, how well the score would perform, training required in using it, how the patient referral would work, and issues in adapting EPR systems. On the other hand, several opportunities were highlighted, such as the perceived benefits of standardisation and accurate prediction, ease of having an EPR-based system, and potential patient acceptability.

Proposed interventions

We presented the following intervention types to the HCPs, and asked for both the opportunities and barriers to potentially implementing them in their setting: videos in the waiting room, group sessions, online resources, including mobile phone 'apps', and single and multiple one-to-one sessions.

Health-care professionals gave mixed opinions on videos, with the practical ease of implementing them and having a potentially receptive and captive audience given as opportunities:

> *It's an easy way for people to kind of . . . people aren't doing very much, so it's quite a good time to kind of drill it in.*
>
> *HA, level 3*

However, there were concerns over the lack of targeting and appropriateness for diverse waiting rooms:

> *. . . we have a very heterogeneous waiting room for the walk-in clinic, you know. The challenge, I guess, would be how you target that, or do you have a number of different ones for different risk groups.*
>
> *Doctor, level 3*

Patient group sessions as an intervention format were, on the whole, not well received (e.g. 'I think that's a non-starter' – HA, level 3). The barriers to using group sessions focused on resource issues, with a lack of appropriately trained staff, staff time and clinic space, and general disruption to the clinic running smoothly being potential issues. HCPs also anticipated low patient acceptance:

> *. . . personally, if I was a patient, I'd run out screaming if somebody tried to get me to do some group work when I'm sitting in a clinic that I might feel slightly uncomfortable about, anyway.*
>
> *Nurse, level 3*

Positive aspects to group sessions were highlighted, although were mostly assigned to specific risk groups and support group models. Another positive aspect was being opportunistic and engaging with patients while they are at the clinic:

> *Catch them while they're waiting you know, they haven't got anywhere to go.*
>
> *Nurse, level 2*

One HCP reported offering a group intervention and another reported that they had done so in the past.

Some clinic staff reported that they referred patients to online resources and apps; specific examples included dedicated online education tools for psychosocial issues. There was generally a positive attitude to using digital interventions, across staff and clinic types. The main barriers concerned patient motivation and uptake and a current lack of tools to which to refer patients:

> *There's so much else to distract them on the internet, but unless it's something they enjoy doing, the learning is not going to happen unless it's couched in a very user-friendly, quick, vehicle.*
>
> *Doctor, level 3*

Opportunities for digital interventions included their accessibility, perceived patient preference and minimal staff delivery time required:

> *We have quite an IT-savvy patient group, I would say, so something like that might appeal.*
>
> *HA, level 3*

> *Yeah, well, they love apps. I mean we suggest apps. I'm quite an elderly nurse now but even I know to suggest apps.*
>
> *Nurse, level 2*

Brief one-to-one sessions of MI were mentioned as something that was offered by all the GUM and Brook clinics that we engaged with. However, it was also an intervention that providers highlighted had a lot of challenges. One participant identified a lack of evidence as a challenge; this was raised more frequently for MI than for other intervention types. The current needs associated with one-to-one sessions focused on costs and staff resourcing:

> *So I think the clinical time, availability of time in the clinic is probably the biggest challenge.*
>
> *Doctor, level 3*

Patient motivation was also viewed as a barrier, that is, whether or not the patient would be open to the intervention:

> *With behavioural interventions, if people are referring into that service, if you've got to work out whether the patient is really ready for this intervention, because if the patient is not ready for it, it's just no point doing it.*
>
> *HA, level 3*

The main opportunity that was raised for one-to-one sessions was the flexibility that these offer, and the ability to tailor sessions to individual risks and needs. Many of the HCPs expressed that they felt that the brief sessions were effective, even if this is hard to demonstrate:

> *Yes I know that's probably not the most cost-efficient. But I think that's probably the most effective method of risk reduction, because it is tailored to the actual patient's needs and you have time to explore what their risk is.*
>
> *HA, level 3*

Similar opportunities and barriers were raised around a series of one-to-one sessions, with HCPs highlighting the constraints of time and resources available in clinic to deliver these:

> *Yes, that's a great idea, but we've never had capacity to do that.*
>
> *HA, level 3*

There was a perception that this was a good intervention format and that it could be effective, provided that patients were motivated:

> *But if it's something that perhaps is reserved for people who are seen as particularly high risk, and particularly amenable to this sort of intervention, then it would have a place.*
>
> *Doctor, level 3*

Implementation challenges

Financial and staffing constraints were raised frequently as barriers to the delivery of current services, as well as being an anticipated barrier for delivering novel triage pathways or interventions. One approach currently taken to limited budgets was self-sampling:

> *All this quick checking and self-assessment has started as a result of changes in funding and competition in sexual health services [. . .] that's where that's all heading.*
>
> *HA, level 3*

There was a perception that commissioners focused on treatment rather than prevention for STIs and that evidence was needed for a service to be commissioned:

> *Commissioners, I think, will not fund anything that hasn't been shown to be effective. And so I think you'll have to demonstrate in some way that it is effective and not just that it's acceptable.*
>
> *Doctor, level 3*

Continuity of care was deemed both important and lacking by HCPs, with issues associated with how services are commissioned:

> *. . . one of the problems that we face, generally, is that drug and alcohol services generally tend to be borough-based, and all the patients we see come from everywhere.*
>
> *Doctor, level 3*

Additional services or improvements that were desired by HCPs included outreach for homeless people and sex workers, improved drug services, community education and post-exposure prophylaxis (PEP) follow-up pathways.

Provider web survey

We received 100 responses, representing 145 clinical services, of which 82 (82%) were complete. The majority of responses were from level 3 services (80%), and three were from level 1 services. Respondents included clinical leads (41%), doctors (37%), HAs (8%) and nurses (8%). Respondents had been working within their service for an average of 10 years (range 0–31 years). The overall response rate was 25%, with a higher response rate among level 3 services (31%).

Current services

Two respondents reported not offering any health promotion or risk reduction intervention services, both of whom worked in level 3 services. *Table 15* describes the services currently being offered by SH services in England.

The least common health promotion activities offered were videos and apps, whereas leaflets and brief one-to-one sessions were relatively common in both level 2 and 3 services at the time of the survey in 2015/16. Five respondents reported previously showing educational videos; reasons for stopping included lack of funding ($n = 3$), no observed impact ($n = 1$) and the materials no longer being available ($n = 1$). Lack of funding was cited as the reason for one clinic ceasing to offer an app, and another for ceasing an online intervention. HCPs cited a lack of trained staff time as the main reasons for stopping in clinics that previously offered 'talking interventions' (i.e. one-to-one, multiple sessions of MI and group sessions).

Triage

The majority of clinic staff (77%) reported triaging on the basis of SH risk; this was less common in level 2 services (68% vs. 84%). No respondents reported using an automated (or algorithm-based) triage decision; rather, a nurse, doctor or HA always made the decision, along with patient input. Comments in the free-text section about an automated system were mixed, with many reporting that it is 'not necessary', but others stating that it would be useful, for example: 'a good thing as long as not too long and time consuming'. HCPs were asked what three factors they considered most important for assessing patient risk of STIs.

TABLE 15 Summary of interventions currently delivered by SH providers

	Level, *n* (%)	
Intervention	1 and 2 ($N = 20$)	3 ($N = 80$)
Leaflets	15 (75)	65 (81)
Educational videos	1 (5)	3 (4)
Online learning materials	5 (25)	8 (10)
Mobile app	0 (0)	2 (3)
Brief one-to-one sessions	11 (55)	56 (70)
Multiple sessions of MI	2 (10)	38 (48)
Group sessions	5 (25)	7 (9)

Sexual orientation, number of recent partners and the types of sexual activity reported (e.g. condomless sex) were the most commonly selected factors, and this was consistent between level 2 and 3 services. These are all variables included in the GUMCADv3 tool.

Overall, 14 responses stated that the SH service did not have any EPR system [level 2 = 2 (13%), level 3 = 12 (18%)]. Of those with EPR systems, 45 (55%) reported having it amended, of whom one-quarter stated that it was very difficult to do; 9% said that they were not able to amend their system despite trying to do so.

Intervention barriers and opportunities

Of the interventions not currently offered by clinics, the most desired by level 3 services were online learning materials (67%) and mobile 'apps' (64%). Group sessions were the least popular, with only 18% of level 1 and 2 services and 23% of level 3 clinics expressing any desire to offer them (*Table 16*).

For those interventions that clinic staff expressed an interest in delivering, the main barriers to and motivations for delivery are presented in *Table 17*. Most of the barriers were related to funding and staff time for delivery, whereas the motivations were around potential effectiveness and uptake (rather than practical reasons). This suggests that if digital or video-based interventions were developed, clinics would be able (and want) to deliver these.

TABLE 16 Number of clinics reporting a desire to deliver, or not deliver, different intervention types

	Level 1 and 2, *n* (%)		Level 3, *n* (%)	
Intervention	Desired	Not desired	Desired	Not desired
Educational videos	30 (46)	11 (17)	30 (46)	11 (17)
Online learning materials	40 (67)	6 (10)	40 (67)	6 (10)
Mobile app	41 (64)	3 (5)	41 (64)	3 (5)
Brief one-to-one sessions	5 (33)	2 (13)	5 (33)	2 (13)
Multiple sessions of MI	13 (42)	2 (6%)	13 (42)	2 (6)
Group sessions	14 (23)	29 (48)	14 (23)	29 (48)

Note
The percentages are calculated based on the number of clinics not already providing this service.

TABLE 17 The main barriers and motivations for intervention formats in level 1, 2 and 3 clinics

Intervention	Barriers (%)	Motivations (%)
Educational videos	Lack of funding for development (37)	Captive patient audience (37)
Online learning materials	Lack of funding for development (61)	Minimal staff time (33)
Mobile app	Lack of funding for development (65)	Potential patient uptake (47)
Brief one-to-one sessions	Time constraints (50)	Widely appropriate for patients (38)
Multiple sessions of MI	Lack of funding for staff (50)	Perceived effectiveness (50)
Group sessions	Lack of trained staff time (38)	Encourages peer learning (50)

Note
Percentages are calculated based on the number of clinics that expressed an interest in delivering this intervention format.

Trial feasibility

Respondents were asked if they would be interested in taking part in a cluster RCT of brief behavioural interventions, and whether or not being randomised at the clinic level would be acceptable. Nearly half of the clinics (48%) expressed an interest in trial participation, but only 40% reported being comfortable with randomisation. There was no statistical difference between level 2 and level 3 clinics (38% vs. 41%, respectively).

Semistructured interviews with patients

We recruited 35 service users: 15 young heterosexuals and 20 MSM. A description of the participants is presented in *Table 18*.

The service users we recruited were visiting the clinics for a range of reasons, including routine checks, results and treatment (including as part of partner notification), or because they had symptoms. The reasons were similar between MSM and young people, with regular attenders in both groups. Some reported being motivated to attend because they were anxious, especially with regard to symptoms or a recent 'risky' event.

Risk perception

We asked participants about their self-perception of sexual risk, as a way to introduce the concept of our proposed triage approach and to gain an insight into potential barriers to triage. Trust, or lack of trust, of a sexual partner was frequently associated with service users' perceptions of their sexual risk, driving sexual risk behaviour decisions such as using condoms; this was common among both young people and MSM.

TABLE 18 Description of participants in service user semistructured interviews

Characteristic	Participants	
	Young people ($N = 15$)	MSM ($N = 20$)
Gender, *n*		
Male	7	N/A
Female	8	N/A
Age group (years)		
16–20	8	
16–25		7
21–25	7	
26–50		6
> 51		7
Ethnicity, *n*		
White British	10	11
White, other	3	2
Black African	1	
Asian British	1	
Black British		2
Black, other		1
Chinese		1
Missing		3

N/A, not applicable.

The concept of causal and regular partners was much more common among MSM, and the types of sexual behaviours practised within these partnerships were different; for example, not using a condom was something done only in a relationship. Young people discussed different levels of trust between people they knew and, for example, someone they met via the dating app Tinder (Match Group, LLC, Dallas, TX, USA).

Use of condoms, a major aspect of risk perception in young people, was reported as being influenced by peers. Young women specifically discussed an inability to negotiate the use of condoms, or were described by young men as not negotiating condoms:

> *. . . it would be a big rarity if a girl basically asked me to put on a condom.*
>
> *Male, 21–25 years*

There was a perception that peers were not using condoms and that normalised the behaviour; concern about pregnancy was more of a motivation for their use than STI risk. For MSM, on the other hand, condom use was seen as a matter of preference. Condom use was also circumstantial, and non-use was often seen as a one-off event:

> *I like to class myself as someone who is safe with sex but I am not perfect.*
>
> *MSM, 16–25 years*

Other factors that shaped how people felt about their personal risk included drug and alcohol use, and perceptions about the general prevalence of STIs in the population and in overseas partners.

Risk was seen as dynamic by both groups and was related to relationship status, age or maturity, and a personal scare experienced by either the individual or someone they know. Common views were that being in a relationship is associated with lower risk and that risk decreases with age: 'I'd like to think that the older people do get the more kind of cautious and aware of STIs they are' (female, 16–20 years). In the case of young people more specifically, university was seen as a distinct period of taking more risks, but that this risk was self-limited during this period. In MSM, self-esteem was specifically mentioned as affecting risk behaviours:

> *. . . if your self-esteem is quite low, it's quite possible to engage in un-safer practice than if your self-esteem is quite high.*
>
> *MSM, 26–50 years*

Proposed triage

We asked participants about being offered services based on standardised risk assessment, and they had mixed views. Positive aspects of triaging included the process of having a score acting as an intervention in itself, as it may raise awareness about risks that service users had not considered previously:

> *. . . it's something that people might not like, but you, kind of have to know, it's better to know.*
>
> *Female, 21–25 years*

Participants' trust of HCPs also meant that they would listen to them, as they were seen as knowing best, although this would rely on the triage being well explained (no 'technical jargon') and trusted:

> *. . . you're a registered health-care professional, so I trust your reasoning.*
>
> *Female, 16–20 years*

It was acknowledged that triage might act as a 'shock factor', and that, despite not being supportive of it at the time, service users might 'reflect' afterwards, although this would not necessarily lead to behaviour change:

> *I wouldn't consider changing my behaviour actually, I would just see it as, yes, a warning.*
>
> *MSM, 16–25 years*

Concerns raised with triage included anxiety associated with a classification of 'high risk'. Alternatively, telling users something they already knew was considered redundant:

> *. . . either way I'm going to get tested, so I don't know why they tell people really.*
>
> *Female, 21–25 years*

Some MSM expressed concern that they were pigeonholed simply based on being MSM and belonging to a particular demographic group:

> *. . . with gay culture being so sleazy you just sort of expect to be high risk all the time.*
>
> *MSM, 16–25 years*

Onward referral based on triage raised concerns that services should be available to everyone, with the denial of services or rigidity of referrals criteria not liked. However, many noted that the offer of supportive services was positive and that service streamlining made sense.

Proposed interventions

Similar to the HCP interviews, we asked participants for their thoughts on different intervention formats and any preferences for waiting room videos, group sessions, online materials and apps or one-to-one sessions. Service users raised multiple concerns about videos in the waiting room, suggesting that they would make people feel awkward in mixed waiting rooms or increase their anxiety:

> *. . . having had sex with 20 different people last night, they don't need a video saying 'don't be promiscuous'.*
>
> *MSM, 16–25 years*

Opportunities, however, focused on the notion that education is good, and a SH setting is the correct setting for SH education:

> *Why not?' Information is a good thing. It's a sexual clinic, so that's why people are there, to talk about sex.*
>
> *MSM, 26–50 years*

Recommendations about content included that text information or statistics would be desirable and short advert or campaign-type clips would be acceptable, but that content should not be graphic.

Group sessions were not viewed favourably, with many participants stating that they would not take part despite seeing the role that they could have. Privacy and confidentiality were the primary concern with this intervention format, as many did not want to talk about SH in a group despite considering themselves open:

> *. . . you share funny stories with your friends, and I do talk about sex quite a lot with my friends, but not about this part.*
>
> *Female, 21–25 years*

Among MSM this was seen as an issue particularly if someone is shy or isolated:

> *. . . they cannot talk at home, they cannot talk at school, and they cannot talk in church and they cannot talk to their own best friends, so they are not going to start talking here.*
>
> *MSM, 26–50 years*

These concerns were associated with the group or other situations not being appropriate to their circumstances, and a belief that there would be judgement about lifestyle. MSM were also concerned about the possibility of bumping into someone they knew, and about HIV status affecting how someone might participate. On the other hand, the ability to learn from others' experiences was seen as valuable.

Generally, having some form of digital-based intervention (e.g. website, social media or app) was positively viewed, although respondents felt differently about the various formats. Although all participants expressed concerns about apps, this was more an area of concern for young people, who typically reported sharing mobile phones, with friends and family often looking at them, or leaving mobile phones out 'on the table':

> *. . . people use my phone, so they would know my business.*
>
> *Female, 16–20 years*

The apps were considered somewhat redundant if there was a website available:

> *. . . most information I can find it online, I don't need an app just for that [. . .] it's not like you need to check it every day.*
>
> *MSM, 16–25 years*

In favour of apps, however, were their convenience and immediacy, especially if they could do more than just provide information (e.g. book appointments or provide remote clinical consultation), or if they could give wider health information. Social media were less popular, with concerns over Facebook (Facebook, Inc., Menlo Park, CA, USA) or Twitter (Twitter, Inc., San Francisco, CA, USA) not being anonymous and therefore lacking privacy:

> *I wouldn't share my, as much personal information as if I come here and I talk to someone.*
>
> *Female, 21–25 years*

However, some MSM said that they had followed online pages about SH and had seen adverts about SH promotion advertised through Facebook. More specifically, MSM-targeted apps or websites such as Grindr (Grinder LLC, West Hollywood, CA, USA) were suggested as good places to have SH information. Online formats were viewed as convenient as they could be accessed as and when needed; however, there was a concern that they needed to be a reliable source to ensure anonymity.

One-to-one 'chatting' interventions were well received, and most participants indicated that these were their favoured option. The face-to-face aspect and the element of human interaction were considered important ('the thing about, you know, chatting to a human is, they're receptive', male, 16–20 years), and the ability to ask questions in a tailored session. The need for the session and what people expected to get out of it was related to their trust in the HCP, for both the referral and what they would share in the session. Negative aspects of this intervention were the possibility of being embarrassed, not seeing it as being needed and being inconvenient. Most participants said that between 15 and 30 minutes would be a good duration. Carrying out sessions over the telephone received mixed reactions, with many saying that they preferred face-to-face contact and the privacy afforded by a clinic, whereas others saw value in the convenience:

> *You get to speak to a real person, you can do it from the comfort of your own home.*
>
> *Female, 21–25 years*

Patient discrete choice experiment

A total of 368 eligible patients completed the questionnaire and 90% (331/368) completed all 12 DCE questions, resulting in 21,495 DCE observations overall. Of the respondents, 43% were MSM and 50% were young people; compared with GUMCADv2 data from the clinics during recruitment, the sample was broadly demographically representative, although there were slightly more young MSM (aged 16–25 years) and fewer MSM aged 26–50 years. Fifty-two per cent of the sample were recruited from Brighton, 62% were born in the UK and 59% were male; six respondents identified as transgender. Forty-six per cent of respondents had had a previous STI diagnosis, with 22% having three or more STI tests in the previous 12 months and 22% having had no tests.

Twenty per cent of respondents (71/368) chose one particular intervention consistently (*Table 19*). However, there was minimal evidence to suggest that a particular attribute level dominated participants' choices. None or only a small proportion of respondents always chose the option with the shortest duration (up to 15 minutes, 0/368), the fewest number of sessions (5/368) and sessions organised by nurses (10/368) or by other HCPs (5/368). These findings suggest that respondents were 'trading' between different intervention options, which is an important requisite if DCE studies are to be useful.

Conditional (fixed-effects) logistic regression analysis

'Talking' was chosen as the most preferred intervention option on 40% of occasions. The next most frequently chosen option (27% of responses) was the 'e-mail or text'-based design. The opt-out option was preferred on < 10% of occasions (*Table 20*).

The CLOGIT model explained more of the variation in the data than a model with no independent variables (likelihood ratio chi-squared test, $p < 0.0001$). McFadden's pseudo-R^2 was 0.13, indicating that the model fitted the data moderately well.[129] It also predicted 42% of choices correctly, and the signs on the model

TABLE 19 Dominant responses from 368 participants

Choice	*n* (%)
Talking	28 (7.6)
Online one to one	1 (0.3)
Online group	2 (0.5)
E-mail or text	34 (9.2)
Opt out	6 (1.6)

TABLE 20 Actual versus predicted results

		Predicted *n* (%)	
Choices	Actual *n* (%)	CLOGIT	LCM
Talking	1740 (40.5)	3225 (75.0)	2071 (62.5)
Online one to one	547 (12.7)	0	179 (5.4)
Online group	519 (12.1)	0	35 (1.0)
E-mail or text	1148 (26.7)	1074 (25.0)	856 (25.8)
Opt out	345 (8.0)	0	171 (5.2)
Total	4299	4299	3312[a]

a The LCM includes only responses in which demographic data were complete.

coefficients were logical, offering a degree of plausibility to the underlying model (e.g. people preferred shorter to longer sessions).

The analysis showed that respondents generally preferred interventions over 'opting out' (*Table 21*), with 'talking' interventions being the most clearly favoured option (OR 1.45, 95% CI 1.35 to 1.57, vs. 'e-mail or text'). Face-to-face group sessions were generally preferred less than individual face-to-face sessions (OR 0.66, 95% CI 0.57 0.78) or 'one-to-one telephone calls', although the latter comparison did not achieve statistical significance (OR 0.87, 95% CI 0.73 to 1.02). Respondents generally preferred fewer sessions to more sessions, and shorter sessions were more highly valued than longer sessions. Respondents indicated a strong preference for sessions to be facilitated by HCPs rather than by peers (OR 0.53, 95% CI 0.46 to 0.60), but they did not express a clear preference on the type of HCP.

Latent class model

Three classes were identified for the LCM, which predicted a higher proportion of correct choices than the CLOGIT analysis [73% (2419/3312)] and was more flexible in terms of the options it predicted. None of the sociodemographic variables was predictive of class membership, and these were therefore omitted from the final model.

Participants in the classes were similar in terms of how they valued the number and length of sessions, the choice of facilitator and whether or not meetings were one to one or group based. However, they differed in terms of their preferred intervention method (*Figure 5*). Participants who were more likely to be in a LCM class 1 (60%) favoured 'talking' interventions, although all other options were preferred to 'nothing'. Those who were more likely to be in class 2 (14%) had a general preference for 'opting out', although their next strongest preference was for 'talking' interventions. Respondents who were more likely to be in class 3 (26%) demonstrated a preference for 'e-mail or text'-based interventions over any other option.

TABLE 21 Conditional (fixed-effects) logistics regression analysis results

	Dummy coded			Effects coded		
Choice	OR	95% CI	*p*-value	OR	95% CI	*p*-value
Online group[a]	–	–	–	0.42	0.38 to 0.47	< 0.001
Online one to one[a]	–	–	–	0.44	0.40 to 0.49	< 0.001
Talking[a]	–	–	–	1.45	1.35 to 1.57	< 0.001
None[a]	–	–	–	0.30	0.26 to 1.34	< 0.001
Face-to-face group	–	–	–	0.66	0.57 to 0.78	< 0.001
One-to-one telephone call	0.87	0.74 to 1.02	0.08	–	–	–
Number of sessions						
Two or three	0.76	0.68 to 0.84	< 0.001	–	–	–
Four to six	0.60	0.54 to 0.66	< 0.001	–	–	–
Duration of sessions (minutes)						
15–30	0.85	0.77 to 0.93	0.001	–	–	–
31–60	0.59	0.53 to 0.66	< 0.001	–	–	–
Nurse	1.01	0.90 to 1.15	0.76	–	–	–
Peer	0.53	0.46 to 0.60	< 0.001	–	–	–

a Alternative specific constants indicating the strength of preference for individual labels relative to 'e-mails or texts'.

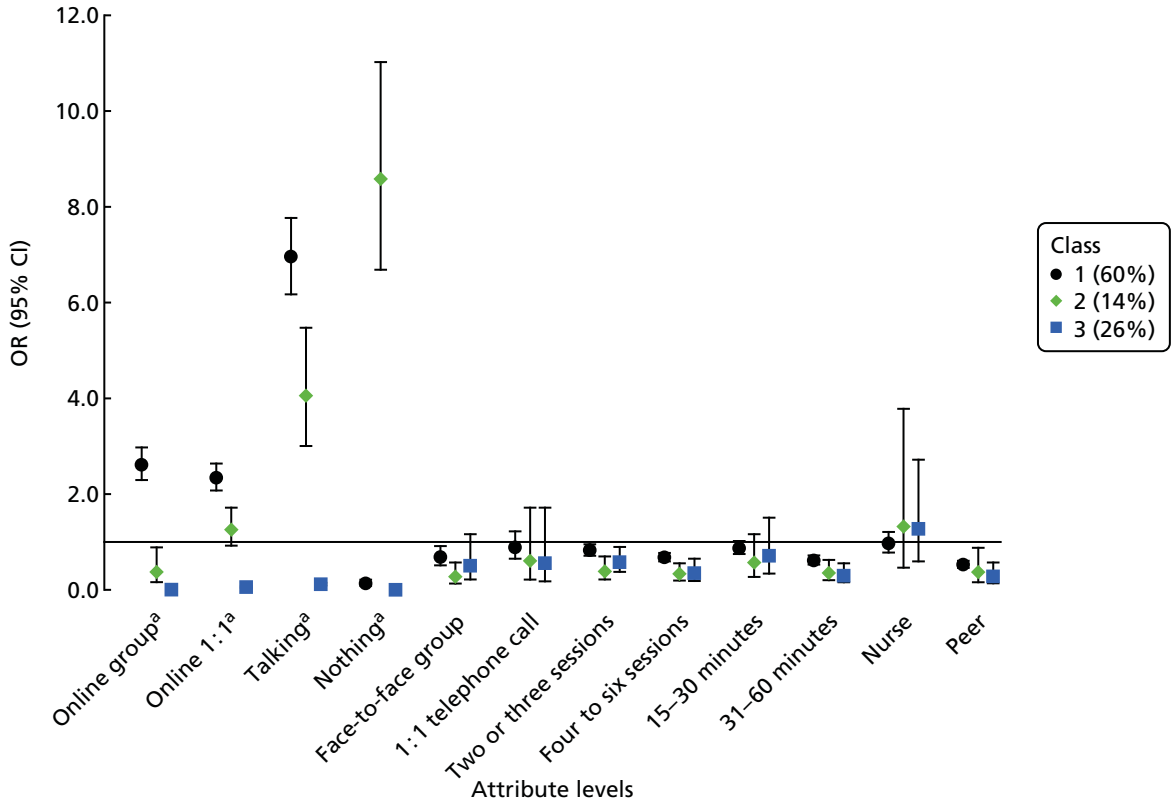

FIGURE 5 Latent class model results. a, ORs are effects coded, otherwise they are dummy coded; label percentages indicate the proportion of respondents likely to be in each class; log-likelihood –3,547; McFadden's pseudo-$R^2 = 0.33$. Reproduced from Miners A, Llewellyn C, King C, Pollard A, Roy A, Gilson R, *et al.* Designing a brief behaviour change intervention to reduce sexually transmitted infections: a discrete choice experiment. *Int J STD AIDS* (vol. 29, iss. 9), pp. 851–60,[130] copyright © 2018 by SAGE Publications. Reprinted by permission of SAGE Publications, Ltd.

Discussion

We conducted a mixed-methods assessment of current triage and sexual risk reduction interventions offered through SH clinics and the acceptability and feasibility of the brief interventions identified in the literature review. We found agreement between HCPs and service users in terms of intervention acceptability and preferences, and identified key barriers and potential opportunities related to the delivery of brief behavioural interventions in SH clinics.

Current practice

We found that most services at the time of interview and the web survey (September 2015–June 2016) reported to offer some form of sexual risk reduction intervention. Most of these took the form of brief one-to-one sessions conducted in clinics, delivered by HAs in GUM clinics and by nurses in Brook clinics. Staff in smaller level 2 services, such as in enhanced GP services, reported seeing mostly uncomplicated and low-risk patients, and referral to GUM services was the primary approach to intervention. In addition, clinics that reported that they did not currently offer brief one-to-one sessions viewed them as a desirable intervention, with the main barriers being resourcing (trained staff and staff time). This is in line with NICE recommendations that high-risk patients should be offered brief sessions.[122] Brief one-to-one sessions were seen by HCPs as being effective, acceptable to patients and allowing for the tailoring of interventions; notably, patients concurred that the 'human factor' and tailoring of a one-to-one was important.

Similarly, three-quarters of clinics in the web survey reported conducting some form of triaging of patients based on sexual risk. However, no service reported using a standardised triage based on risk modelling, as we proposed in this study, and triaging embedded into EPR systems was again not common. As triaging

is already routine practice, many HCPs viewed it as acceptable; this also meant that many HCPs commented that they did not see the point of a model-based triage. Although clinical risk scores, based on predictive modelling of population data, have been implemented in some specialties (e.g. cardiology,[131] intensive care medicine[132]), they have not be rolled out in SH previously. In order to change SH clinic pathways to triage based on models rather than clinical experience or expert opinion, strong evidence and HCP engagement would probably be required.

Opportunities

Several opportunities for risk reduction interventions were raised by both HCPs and service users. First, service users showed a preference for having any intervention over having no intervention, with < 10% of patients in the DCE opting for no intervention. Similarly, HCPs saw the role of SH services as prevention, and not just treatment. This supports risk reduction interventions are being acceptable in general.

There was agreement between HCPs and service users around brief one-to-one sessions being generally preferred. During interviews with HAs, many said that they felt that one-to-one sessions were beneficial to patients, although they acknowledged that patient motivation was important, and that they were part of a HA's role. These 'talking' interventions were the most preferred by service users, based on the DCE, with fewer sessions, shorter sessions and HCP facilitation being preferred. As clinic resources were raised as a potential challenge to delivery of interventions, conducting a single brief session would suit both service providers and users.

Again, digital interventions were seen as favourable by both service providers and users, although the reasoning for finding this intervention type acceptable differed. HCPs mentioned the fact that digital interventions are not resource intensive and noted perceived patient preference. Service users highlighted the convenience of online interventions, and many reported having gone online to find information before attending the clinic.

Barriers

The main barriers raised by HCPs revolved around resourcing and patient motivation, whereas the key concerns of service users related to privacy and the need or usefulness of an intervention. During the course of this study, changes to the commissioning of SH services were ongoing, with an overall decrease in SH service funding nationally. These decreases were not consistent across local authorities, with some reductions in services as high as 20%, alongside an overall increase in GUM attendances.[133,134] One area that was highlighted as suffering from these cuts to funding was the number of HA positions within GUM clinics. The role of HAs includes partner notification as well as delivering sexual risk reduction interventions. At the time of data collection, services highlighted a lack of staff time and a lack of staff trained in MI as key barriers to delivering risk reduction interventions. With ongoing cuts to funds and services, it could be anticipated that these resource constraints would persist, and even increase, making a currently feasible intervention unfeasible.

The need for privacy was crucial for service users, and this was reflected in the preferences for intervention types (i.e. group, social media and peer-led interventions) being less favourable. Also important to service users was trust in HCPs, and the need for any interventions, especially digital interventions, to be seen as NHS supported or endorsed. Other studies have also found that trust in online resources is important to patients,[135,136] and, therefore, any digital intervention would need to be seen as trustworthy. Based on the literature review in WP1 (*Chapter 2*), none of the digital interventions was developed in the UK or within the NHS. This may prove a barrier to engagement if service users deem these digital interventions to be untrustworthy.

Many clinics reported having EPR systems (86%); however, the type of system used was not universal, which may prove a challenge to the implementation of a standardised, model-based triage approach. EPR providers were diverse, and there were different clinic experiences in adapting these systems. In order to trial an EPR-based triage adaptations would need to be made to multiple systems and would be limited to clinics with functioning systems – a potential bias.

Based on the clinic staff interviewed and web survey responses, we observed a high level of heterogeneity in current services offered, triaging pathways and resourcing. The aim of this project was to determine the feasibility of delivering a package of brief behavioural interventions within existing resources in a SH clinic setting. Therefore, a key barrier that we can anticipate in determining feasibility is whether or not different types of services (e.g. level 3 and level 2) and services commissioned by different local authorities, which have different funding structures, would be able to deliver these types of interventions. This would be a challenge both to intervention delivery and intervention evaluation.

Strengths and limitations

In both service user and service provider interviews, we reached data saturation regarding intervention opportunities and barriers, despite not reaching the targeted sample of 30 interviews with providers. We were unable to recruit the predetermined number of level 2 providers, and, therefore, this service type had less representation than we had planned. The interviews with providers and service users were conducted by three female researchers, which may have influenced the responses, especially of MSM or young men. However, we saw agreement in reasons for preferences between young women, men and MSM, and also with service providers. We also saw agreement between the qualitative interviews and the quantitative surveys conducted (triangulation), adding strength to our conclusions.

The response rate for the web survey was poor, and, therefore, the results may not be representative of SH services nationally. We attempted several methods to improve the response rate to the survey, including personalised e-mails and dissemination at a national SH conference. Neither of these approaches resulted in significantly increased responses. We contacted clinics directly by e-mail, using a list of contacts provided by PHE and supplemented by a list compiled during a Doctor of Philosophy project. We found that many of the e-mail addresses were no longer in use as staff had moved on, that the person indicated was not an appropriate primary contact for the clinic or that there was no contact e-mail available. Particular examples of no contact being possible were services that had been tendered by local authorities to private companies or charities [e.g. all services run by Virgin Care (London, UK)]. Therefore, several clinical services were unlikely to have been reached, and these may not be representative of other services (e.g. tendered to a private provider or with high staff turnover).

A limitation of the DCE was that the alternative specific constant odds ratios were generally large in comparison with the attribute levels. This suggests either that the intervention characteristics are generally less important to people than the overall format or that important attributes and levels were omitted from the design. The attributes and levels were selected on the basis of the qualitative interviews and were therefore based on evidence. We chose not to estimate whether people were more willing to, for example, spend 30 minutes talking with someone than answering questions online when all other factors were held constant (so-called alternative specific parameters). This meant that the estimated parameters, such as the duration of each session, were common across the intervention options. However, it is possible that people would value their time differently depending on the intervention type that they are considering. Third, a number of options, such as having videos in clinics and distributing leaflets containing health advice, were excluded from the final DCE design, despite being in the literature review. Videos were omitted based on the interviews and, therefore, the results of the DCE are driven by the validity of the findings from the service user interviews.

Conclusion

Clinics across England, at the time of data collection, offered a range of risk reduction interventions, with one-to-one MI being the most common and most desired service on offer. However, contrary to guidelines, high-risk individuals were not being provided with additional risk reduction interventions uniformly, and we found a high level of heterogeneity between services. We found similar preferences and concerns raised by providers and service users about different intervention formats. One-to-one sessions were viewed favourably as an intervention format, with the ability for tailoring being very important. This was followed by digital intervention approaches, which were seen as convenient. Videos, which were found to be effective in reducing STIs and risky behaviours and increasing testing in the systematic review, were viewed with mixed feelings by both providers and service users. Finally, peer-based interventions were not popular, for both logistical reasons by providers and privacy concerns by service users.

Chapter 5 Work package 4: choosing and adapting the components of the intervention

Background

As anticipated in the methodological plan (*Figure 6*), at this stage in the project the following had been completed: obtaining the views of stakeholders, including service users and staff who deliver interventions, and conducting a review of available interventions. We knew what interventions were potentially acceptable, practically feasible and sustainable over time.[35]

Having completed WPs 1, 2 and 3 we had the basis for the next step in the IM process: to complete the intervention selection. This would allow the manualisation of the one-to-one component of the intervention package, although, as discussed above, the digital intervention was not immediately available.

Aim

The aim of this work package was to select, adapt, if required, and manualise an evidence-based suite of interventions that could be combined and delivered as intervention packages to meet individual needs.

Method

Intervention mapping

This work package brought together the three central steps in the IM, as set out below:

1. mapping of intervention objectives (i.e. main outcomes) on to psychological, behavioural and environmental determinants or change processes
2. selecting techniques and strategies to modify the determinants of behaviour based on an understanding of change processes
3. selecting and constructing intervention components and materials.

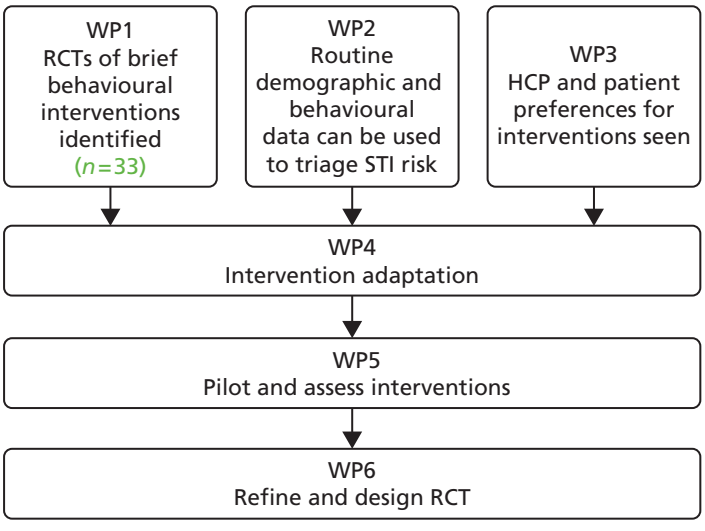

FIGURE 6 Summary of the work packages contributing to the IM process.

The process had begun with the systematic review (*Chapter 2*), which was used to identify potentially effective intervention components and change mechanisms that may be critical to intervention effectiveness. We identified pre-existing intervention materials that appeared to be effective in reducing STIs and RSB that would be appropriate for UK clinic settings in order to identify 'best bet' techniques and strategies. Findings from WP3 (*Chapter 4*), from both service providers and users, were used to prioritise intervention approaches and components according to preference, probable engagement and pragmatic resource constraints.

Decisions on the intervention package design and components were made through a series of face-to-face group discussions with the intervention development team (CL, CA, AR, MS, CK, LC, JB, SA and AP), and feedback was sought from the PPI group. Three meetings were held as part of this iterative adaptation process, supported by ongoing broader discussion with the PSC and PMG.

Service user input

Focus group discussions and semistructured interviews were conducted with service users, to present candidate interventions and to stimulate discussions about how best to adapt to each group, the feasibility of delivery and probable uptake, and, therefore, to inform the ongoing IM process. Candidate interventions for discussion were shortlisted by the intervention development team and shared with the PPI group prior to seeking service user input.

Participant selection

We used a sampling framework, with quota sampling based on sexual orientation, age and gender (including MSM and young people) to gain a broad range of opinions. Four groups were defined: MSM aged < 25 years, MSM aged > 25 years, young heterosexual women and young heterosexual men. Approximately six to eight participants (n = 24–32 in total) were invited to attend each group.

Recruitment

Participants were recruited from the SH service and community settings through posters and leaflets for group discussions. Young heterosexual men were purposefully approached and recruited from SH clinics for individual interviews because of a lack of uptake for group discussions. All participants were recruited in Brighton for pragmatic reasons.

Data collection

Written consent was taken prior to the focus group discussions or interviews starting, and all discussions were anonymous. Each focus group discussion was planned to last 45–60 minutes. Discussions were facilitated by two researchers trained in focus group methodology (AR and AP) and were transcribed verbatim. Interviews were planned to be 30 minutes and were conducted by a single researcher (AR, CK or Sarika Desai). Patient participants received £20 as recompense in line with current practice.

Analysis

We used the same analysis approach as described in *Chapter 4* (i.e. content analysis, using a framework approach).

Manualisation

The intervention package was manualised to 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 provides recommendations for implementation in a clinical context, such as role-play examples. A training plan was developed as part of the intervention manual in collaboration with clinical staff.

The manual was shared with the management team, PPI group and steering committee for feedback, and shared with clinical staff from MMC, Archway, the Claude Nicol Centre and Brook services for feedback.

Results

Selecting intervention components

Intervention types were selected using the preferences of service providers and users presented in WP3 (*Chapter 4*) and by prioritising behaviour change needs according to the overall objective of adapting a package of interventions that would lead to a reduction in STIs. The conclusions of the prior work that set the scene for this stage in the project can be summarised as follows:

- There is evidence that a range of intervention formats, including brief MI sessions, digital interventions, educational videos and home testing kits, can lead to moderate reductions in STIs and RSBs.
- Delivery of SH promotion tailored to risk was mostly acceptable to providers and patients, and model-based triage algorithms showed moderate discrimination.
- One-to-one talking and online interventions were acceptable to service users and seen as feasible by HCPs; however, resource limitations favoured fewer and shorter sessions (brief behaviour change interventions).
- Waiting room videos, group sessions and peer-led interventions were undesirable and posed resource and pragmatic challenges.

Based on these broad conclusions, this part of the IM process focused on brief one-to-one sessions only for patients considered to be at higher risk, as this would be resource intensive, and a digital intervention for all patients regardless of risk, as a low-resource intervention. Evidence generated to this point suggested that this approach would be both acceptable and feasible within the current NHS SH environment. Further refinement and adaptation of existing interventions is presented below.

Brief one-to-one consultation

Reasons for choosing this intervention included:

- it being one of the effective approaches identified in the WP1 systematic review
- it being a clear front-runner from the process of WP3
- it being already in place, with most of the clinics interviewed currently offering these
- most participants having favourable opinions about it
- it needing to be conducted in a personal and private space.

In the case of MSM, three effective trials used a one-to-one approach with counselling, MI and personalised cognitive counselling.[69,79,84] Two effective interventions among young people used this approach;[56,73] one trial included both young people and MSM.[56] The intervention manuals were available for three[73,79,84] out of these five effective trials. Through round table discussion, the conclusions from WP3 were used to refine and select the intervention components from these trials to make decisions about the format and content of sessions. For example, personalisation was considered important to patients, and, therefore, this influenced the decision about how the session would be structured. We decided that the one-to-one approach would use the most appropriate components of all the available manuals for both MSM and young people, and apply these to the needs of both groups. This was based on the finding that, generally, the needs, risk perception motivations and preferences for delivery were similar between young people and MSM. It also supports the flexible nature of the one-to-one approach.

In the interests of equitable delivery, the intervention was designed to be offered to all service users at high risk, regardless of their motivational assessment, a key barrier to delivery raised by providers and service users. The focus of the sessions would then initially be on identifying 'what aims need to be achieved in this session and how to achieve them', including a checklist of conversation topics and their level of motivation. Consultation tasks might include risk assessment (e.g. patients' individual risk level, the kind of problems they encounter) and provide normative or attitudinal information based on their risks. In the case of those who are already motivated, that is those who understand their risks and want to change their behaviour,

this process could be skipped and the focus changed to 'what you can do', for example use condoms. The sessions would draw on MI principles but not attempt to deliver MI per se. The lack of trained staff time was a key barrier to the delivery of interventions. It was therefore concluded that the intervention should be consistent with MI principles, but without requiring intensive MI skills training. This would make it more likely to be feasible.

We sought service user input on the session duration and proposed that the intervention would be a single session designed to last 20–45 minutes, dependent on need and motivation. The decision to have a single session was based on the need for the intervention to be pragmatic and able to be delivered within existing resources. Service users also suggested that multiple sessions would be a barrier to patient attendance and engagement. We acknowledge that service users may be referred for health promotion or partner notification on future clinic visits; even though we decided on a single session, we planned for these to be adaptable and that additional booster sessions could be offered through the use of action plans to be included in patients' records on an EPR system. These decisions and the overall design attempt to standardise what many HCPs reported they were already doing, and adds evidence-based structured elements to enhance this.

Motivational interviewing is a collaborative, goal-oriented style of communication with particular attention given to the language of change. It is designed to strengthen personal motivation for, and commitment to, a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion. We prioritised a focus on listening for Change Talk within Motivational Interviewing (DARN-C).[137] Identifying and working with patients' change talk is essential for moving from exploration and motivation to directional change. The consultation was intended not to add additional consultations to the clinic service, but rather to provide a way of structuring usual discussions with high-risk clinic attendees as identified in a standardised way by the triage algorithm.

Brief one-to-one manualisation

In order to provide a pragmatic, effective and time-efficient intervention, the one-to-one consultation was structured to suit HAs' existing experience with MI by providing a sequence of five linked key steps (*Figure 7*) that target specific needs and provide a menu of effective intervention strategies (*Box 4*).

Digital online intervention

Reasons for choosing this intervention type included:

- It being one of the effective intervention types identified in the systematic review.
- It being favourable to service providers because of the limited demand on available resources.
- It being favourable to service users because of the convenience. However, participants were worried about the confidentiality of an app on their phone and therefore generally preferred websites.
- Some clinics were already referring participants to websites and/or are in the process of developing digital services.

Intervention mapping identified effective trials that used some form of digital intervention: three trials[58,63,68] that were effective in young people and five[8,80,83,85,86] that were effective in MSM. However, of these eight trials, intervention materials were available for only two (*Figure 8*). None of the effective interventions identified in WP1 is currently available online. The Downs *et al.*[63] website was developed in the USA and uses videos to present relationships and SH education, but at the time of our study this web page was being updated and charged individual users for access. The need to adapt the page to a NHS setting, the individual user fees and cultural differences in the content were barriers to its use. The second intervention with available content was from Mevissen *et al.*,[68] which consisted of a virtual clinic consultation. However, the virtual clinic was developed in the Netherlands; adaptation would have required considerable resources to translate the content into English and adapt it to the NHS setting, and it was not available free of charge for research use.

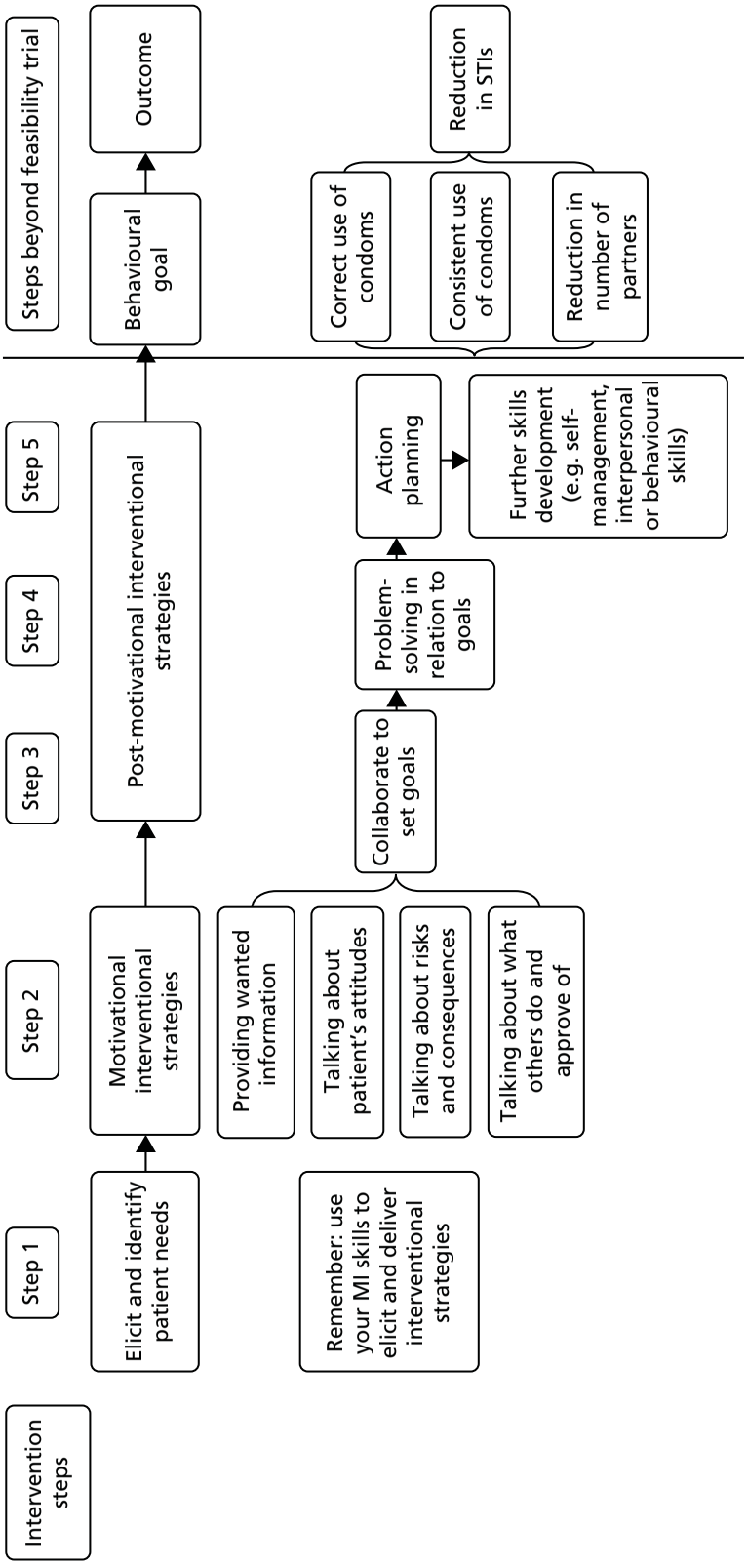

FIGURE 7 Santé task list: leading the patient through change. The five-step pathway for young people and MSM (based on strategies described in *Box 2*).

BOX 4 Effective intervention strategies

Step 1: eliciting and identifying the patient's current needs.

Step 2: matching needs to any of the motivational intervention strategies we have provided, for example using supplemented MI techniques to provide information, talk about the patient's attitudes, talk about risks and consequences, and/or talk about what others do and approve of.

Step 3: collaborating with the patient to set specific goals.

Step 4: engaging the patient in barrier identification and problem-solving in relation to their goals (overcoming barriers).

Step 5: setting specific action plans and discussing self-management approaches helpful to goal enactment and further skills development, such as increasing self-efficacy/ability, enhancing condom use skills and/or increasing self-management using If–Then planning.

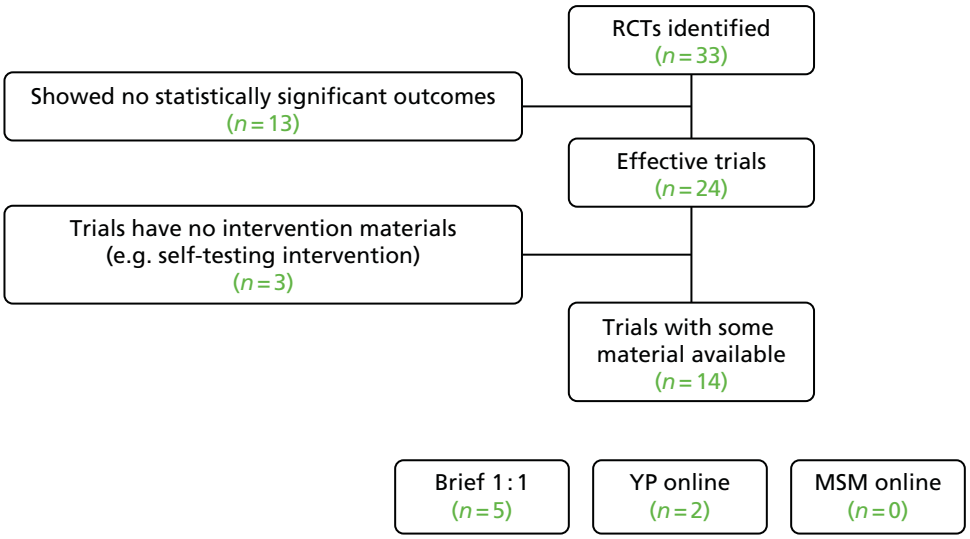

FIGURE 8 Summary of RCTs available for adaptation in the IM process. YP, young people.

Therefore, there were no evidence-based digital interventions that could be used 'off the shelf'. We consequently decided to develop a web page that could function as a portal to selected web resources, and be piloted to measure acceptability and engagement, although this would not be an evidence-based risk reduction intervention. We decided that this would include customised links to trusted web resources, which would tailor content to users via brief demographic screening questions, as the personal aspect was important to service users. Placeholders from legitimate bodies (e.g. NHS Choices) were discussed for inclusion, and we sought recommendations from HCPs and our PPI group.

Intervention refinement and service user feedback

All three aspects of the suite of interventions (triage process, one-to-one intervention, online intervention) were detailed in a manual, which presented technical behavioural language in user-friendly terms suitable for clinical staff to use with their patients. This was then taken to service user focus groups, HAs and the PMG for their input. Three focus groups were successfully completed with MSM of all ages and young women, in community settings. We were unable to recruit young heterosexual men to a focus group discussion; therefore, we recruited them to semistructured interviews within the clinic, successfully completing four interviews (*Table 22*).

TABLE 22 Summary of service user focus group discussion and interview participants

Group	Number	Age range (years)	Sexual orientation (*n*)	Ethnicity (*n*)
MSM > 25 years	5	26–46	Gay (4)	White British (5)
			Bisexual (1)	
MSM < 25 years	4	18–21	Gay (3)	White British (4)
			Bisexual (1)	
Young men	4	16–22	Heterosexual (4)	White British (3)
				Asian (1)
Young women	5	18–21	Heterosexual (5)	White British (5)

The processes of triage, one-to-one motivational interviews and online intervention strategies were presented for discussion. Owing to the lack of availability of trialled online intervention materials, we presented printouts of home pages from a range of health promotion web services that were known to be reputed, were recommended by our PPI group or included relevant intervention components, alongside those identified from the systematic review. The following web pages were presented to young people: Seventeen Days (www.seventeendays.org),[63] Family Planning Association (FPA) (www.fpa.org.uk), The Mix (www.themix.org.uk), Brook (www.brook.org.uk) and NHS Choices (www.nhs.uk). The following were presented to MSM: THT (www.tht.org.uk), Gay Men Fighting AIDS (GMFA) (www.gmfa.org.uk), Men's Safer Sex (www.menss.co.uk),[138] and NHS Choices.

Triage process

Most participants felt that the offer of a one-to-one intervention could be appropriate and acceptable (especially to 'others' and 'the younger ones'), but was contextualised with significant considerations when participants spoke of their own perspectives. At least two participants, both young males, were anxious that the offer of an intervention by a HCP would be 'scary' and make them feel 'stressed'. However, such an offer was felt to be more acceptable when a diagnosis underlined the relevance and value of the offer. When offering an intervention was seen to be normal practice, and was conducted confidentially, this was seen to reduce the anxiety of being specified:

> *It depends if you're being singled out or if it's the same for everyone . . . If they say, because of X, Y and Z, we think this and it's done in a normal, generic way – that will be more relevant.*
>
> *MSM, > 25 years group*

The most frequent factor cited as a positive influence on the acceptability of an offer was patients' perception of the value of or need for an intervention. Motivating factors were identified or articulated as perception of risk (and potential impact of infection), a STI diagnosis and recognition of the clinic's supportive and person-centred approach ('not just tick a few boxes'). Across MSM and young people there were repeated expressions of the desire for services that addressed them as individuals with specific and distinct needs. Participants also speculated that the refusal by some patients to engage with personal risks would be a key factor in their response to the offer of an intervention, and this was considered to be a greater concern for younger patients, particularly according to older MSM.

One-to-one consultation

The offer of a HA appointment was considered acceptable by participants, but was seen to be viable only when the patient recognised that there was sufficient need or value and that the content would be relevant. Participants expressed little appreciation of the value or purpose of speaking to a HA in the absence of an immediate and explicit need, such as a STI diagnosis.

Younger participants in particular discussed the value of and preferences for the timing of a HA intervention. There were diverse and divided opinions across and within groups, but most said that they would prefer that an intervention would start straight away, primarily because of other demands on their time. Younger participants also acknowledged the risks of forgetting and not coming back, and not wanting to provide telephone numbers to clinics.

The ideal length of a HA consultation, according to participants, varied between 20 minutes and 1 hour, with most participants suggesting around 30 minutes to be appropriate and acceptable. Web-based interaction with HAs, such as private webchat or telephone interactions as an alternative to face-to-face appointments, was popular with all groups. However, the older MSM group specifically valued speaking one to one on the telephone, whereas the younger groups tended to prefer webchat interactions.

There were mixed responses to the provision of written 'action plan' cards as part of an intervention. Although the value of clarification and a reminder of key points was identified, some participants found the cards 'nannyish', and several participants suggested that paper versions (even at credit card size) would be easily lost or discarded because of confidentiality concerns. The provision of the same information by text message was considered a more effective and preferred method.

Digital online intervention

Participants across all demographics valued the internet as a source of immediate, accessible information, but it was not typically identified as an arena for exploring sexual behaviour. However, participants clearly expressed a desire for interactive content over static information, which would enable them to ask questions specific to their individual needs. The screening page offered as an example (which asked for age, sex and sexual orientation) was acceptable and valued by all groups and interviewees. However, any use of login details was seen as frustrating and off-putting.

There was a high level of respect for NHS web content across all groups, and it was considered reliable and factual. This, however, went hand in hand with a prevalent perception that NHS web pages would also be wordy, static and unengaging: '. . . the NHS is gloriously boring and matter of fact' (MSM, > 25 years). There was widespread recognition that a risky degree of unreliable information exists on the internet; however, the availability of interactive content (The Mix and Brook's 'text/web chat') appeared to over-ride concerns about the reliability of information on these (mostly) unfamiliar sites. Younger participants expressed enthusiasm for the youth-focused presentation of these sites, and the opportunity to ask questions via text/webchat appeared to over-ride or displace previously expressed caution about reliability.

The MSM focus groups were shown the following web pages: THT, GMFA, NHS Choices ('Sexual health for gay and bisexual men', www.nhs.uk/live-well/sexual-health/sexual-health-for-gay-and-bisexual-men/) and Men's Safer Sex.[138] Familiarity with some of these sites may have influenced responses, but a key issue that was raised repeatedly by participants was the need for them to personally identify with sites. The site for men of any sexual orientation was largely dismissed because of the prominent image of a woman's lips, but was thought potentially useful to younger bisexual men or men not fully embracing a gay identity: 'This definitely looks predominantly targeted to straight people' (MSM, > 25 years).

Participants appeared to be less engaged with sites that primarily offered static information and advocated more dynamic content. The description of risks as 'slip-ups' in the site for men of any sexual orientation was appreciated as an alternative to 'risk' when discussing future experience, and the use of narrative to engage readers was briefly raised in the older MSM group. But even in this group there was little understanding of or interest in behaviour change interventions and most discussion centred on websites as sources of information:

> *. . . that is, for most people, what happens. They slip up. And they may get a reminder to plan, so I go, 'all right, yes.' Because, again, it's for that person to kind of go, 'All right, yes, I've got to plan this.'*
>
> *MSM, > 25 years*

The THT page was largely dismissed and disregarded by MSM participants as being visually too busy and oriented to the charity's fundraising needs:

> *THT is clearly about health fundraising. That first page is just saying to me, 'We're a charity', and I would not have even thought about going to there for social advice.*
>
> *MSM, > 25 years*

The GMFA page was acceptable to some, but others (especially younger participants) considered the presentation of a man in underwear too sexual:

> *. . . going back to the idea again, of wanting to be represented; I am put off by the whole beautiful people thing and to me, it just seems too sexy to be educational.*
>
> *MSM, > 25 years*

The young people were shown the following web pages: FPA, Brook, NHS Choices ('Live Well: Sexual health' www.nhs.uk/common-health-questions/sexual-health/), The Mix and Seventeen Days (women only). Preferences did not differ greatly between male and female participants. The FPA site was dismissed in the female group with little comment and the male one-to-one interviews took little notice of this page, referring only to its potential to provide factual information, and its off-putting status as a charity:

> *Like maybe, people will get the wrong idea of, 'Oh I have to donate something to the cause', or something. For me personally if I see something, 'oh charity, oh no, I need to avoid it'.*
>
> *Young person, male*

Interactive opportunities were more popular than static information pages, and the option of a web chat facility on the Brook home page was enthusiastically focused on by both men and women for two key reasons: the flexibility to contact someone at the patient's convenience and the arm's-length method of engagement, which was frequently cited as preferable to meeting a HA:

> *I personally think the web chat would be like the best. Being able to just go straight on it and just have a professional writing back to you, like with an answer because, obviously, you can search all day and still not have an answer for something. So I think that is the best.*
>
> *Young person, female*

'The Mix' page was popular with the young female group and most male interviewees. It was seen as being addressed specifically to younger people, and this targeted relationship was a significant motivator of interest. One young male participant was familiar with this site as it was promoted in his school. Positive discussion focused on key aspects, including its varied content addressing diverse aspects of younger people's lives (mental health, STIs, contraception, pornography). The home page tabs 'Your Voices' and 'Mental Health' were each mentioned as a valuable feature, despite their content not being visible in the single page presented to the focus group:

> *It's got everything on it. It's not just banging one thing. It's got drugs and alcohol and everything.*
>
> *Young person, male*

The home page of the Seventeen Days website, which was shown only to the women's groups, was swiftly dismissed for the lack of apparent interaction and immediacy of the narrative format and content, and the discussion moved on to the value of getting quick answers to STI-related issues:

> Respondent 2: *Yes, and they [Seventeen Days] could be talking about all stuff that you didn't want to even discuss.*

Respondent 1: *Yes, you just wanted to know one thing and that could be at the end. Maybe too much to go through.*

Young people, female

Manual refinement

Feedback from service users was combined with feedback from the PPI and the PMG, and the opinions were used to inform the intervention manual, to produce the final version of a manualised intervention package for piloting (Intervention Manual; see (www.jounalslibrary.nihr.ac.uk/programmes/hta/1219105).

Triage

The first step of the intervention package is the application of the triage algorithm presented in WP2 (see *Chapter 3*). To balance clinic resources with sensitivity and specificity, the risk threshold was set to refer approximately 15% of MSM and 5% of young people. The triage was designed to be conducted through the clinic EPR system by any member of clinical staff seeing a patient.

Online material

Feedback from service users indicated that a screening page used to direct users to more tailored online material was acceptable and addressed the desire for services to feel personalised. The proposed links received mixed opinions, so we reviewed the links with further input from the PPI group. The final lists of links included were, for young people, The Mix, MenSS[138] and BISH (www.bishuk.com) and, for MSM, THT, GMFA and NHS Choices. Multiple approaches were proposed for advertising and referring service users to the web pages that we recommended, for example sending a link to patients as part of appointment reminder text messages, displaying posters in clinic waiting rooms with the web link and encouraging HCPs to direct patients to the web page during appointments. All of these methods were included in the intervention manual.

One-to-one consultation

The approach proposed to service users during this phase was deemed acceptable in discussions across the wider project team and was not amended based on feedback.

Discussion

Through an iterative process we summarised and synthesised the evidence from WPs 1, 2 and 3 and consulted with service users and providers to develop the early stages of an intervention manual. The underlying ethos of the Santé consultation was based on the collaborative, well-researched MI approach recommended for use in sexual behaviour change by NICE and the Society of Sexual Health Advisers.[139] The approach of using an intervention package in which a more resource-intensive consultation is focused on those at higher risk of a STI diagnosis was designed to be deliverable within existing resources and current clinic structures.

Acceptability of one-to-one sessions

There were two overarching contextual factors that came from the qualitative feedback with service users: that services are private and non-judgemental, and that participants can identify with the content . The one-to-one consultation was designed to be adaptable to individuals with differing needs and motivations, thereby addressing the desire for services to feel personalised and tailored. However, a contradiction was identified, with the offer of a health promotion appointment with a HA sometimes being off-putting if it was seen to specify the individual patient. Systematic triaging, which could be viewed as ‘box-ticking’, was off-putting when it was seen as impersonal, and so this raises questions around how triaging could be conducted in a way that indicates the value of a personalised intervention, while also avoiding the anxiety that being specifically targeted could provoke.

Challenges of digital

Despite several digital interventions being included in the systematic review, and both service users and providers showing some preferences for this intervention format, we could not locate any materials that could be used for piloting. One of the two studies trialled with young people for which some materials were available[63] required individual user licences, with significant cost implications, and the other[68] had a considerable number of components in Dutch only. Extensive effort was put into contacting authors of other studies that reported effective digital interventions, with the intention of adapting any potential resources to the needs of this study. If the Santé intervention package were to go to a full trial, a digital intervention would need to be developed or currently available options would need to be revisited. A scoping review had found 19 digital interventions for young people that had been tested for effectiveness, raising questions about how to access, evaluate, regulate and sustain such interventions that quickly become obsolete.[28,140] With digital formats requiring ongoing maintenance, software updates and site management, the potential for off-the-shelf approaches to interventions is limited without wider investment and infrastructure.

The feedback from service users about the various examples of online SH information and interventions revealed preferences for certain formats, which would be important in the development of future online interventions. Notably, from WP3 service users demonstrated a preference for websites rather than mobile apps. Magazine-style websites that featured SH among a range of other youth-oriented content (e.g. abortion, family life, friendship, pregnancy, drug/alcohol, parenthood, safe sex) were valued by young male and female participants as appropriate and engaging. It may be that this magazine style of website is the only format that will cause younger participants to move beyond a focus on information-finding, and it considers the potential for explorations of experience and behaviour. Interactive formats, such as web chat (as offered by the Brook website), were preferred by younger groups as they enable engagement with services at the user's convenience, with the additional advantages of personal distance and anonymity provided by the web interface. Charity SH websites (THT, FPA) were considered off-putting because of assumptions that these sites are focused on raising money and are unlikely to meet their needs. MSM groups stated that the oversexualised presentation of web content (e.g. GMFA) diluted confidence in the content and diminished engagement with the website. Therefore, an interactive resource that contains both information and behaviour change approaches and has varied but relevant non-sexualised content could be most acceptable to service users.

Limitations

In addition to the limitations discussed with the digital intervention, we were unable to recruit young male heterosexual participants to take part in a focus group discussion. This was especially challenging in the face of cuts to youth services and, after several attempts to recruit individuals and access existing youth groups; this method was replaced with one-to-one interviews, recruited and conducted in STI clinics. In addition, all participants of group discussions and interviews were recruited from Brighton, and, therefore, their feedback may not be relevant to young people or MSM in London or other parts of England. The decision to recruit from Brighton only was a pragmatic one, with the aim to gain rapid feedback rather than comprehensive feedback on the intervention package. Further service user input on the acceptability of the intervention package was planned for the pilot study (see *Chapter 6*).

Conclusion

Despite there being multiple trialled interventions with evidence of effectiveness, there were challenges in accessing the required materials to adapt them for piloting. This was particularly notable for online digital interventions, with only two of the digital interventions identified in the review being accessible, and therefore we used stand-in digital content in our pilot study. Both one-to-one consultations and online interventions were in principle acceptable to service users as approaches to sexual risk reduction. A key feature for MSM and young people was the need for any intervention to be appropriately tailored to their specific needs.

Chapter 6 Work package 5: pilot feasibility trial

Background

Work packages 1–4 were designed to establish whether or not there are evidence-based brief interventions that could feasibly be adapted for use in SH settings in England, be delivered within existing resources and be shown to have an impact on high-risk behaviour and STI diagnoses (*Figure 9*). We found that both 'talking' interventions, such as brief MI sessions, and digital interventions were acceptable to service users and desirable for HCPs, and therefore these were the foci of our IM process. We developed an intervention manual for the pilot, using co-creation with service users, providers and the project management team.

A pilot study was used to gather information about the feasibility and acceptability of conducting a RCT in order to provide information on recruitment, implementation and potential effect sizes.[141,142] In this case, the pilot was used to investigate whether or not the adapted one-to-one intervention can be implemented as planned in a routine SH setting and if service users are inclined to engage with the intervention package. The proposed methodology of a cluster RCT also needed to be piloted, as this requires both clinic and service user engagement.

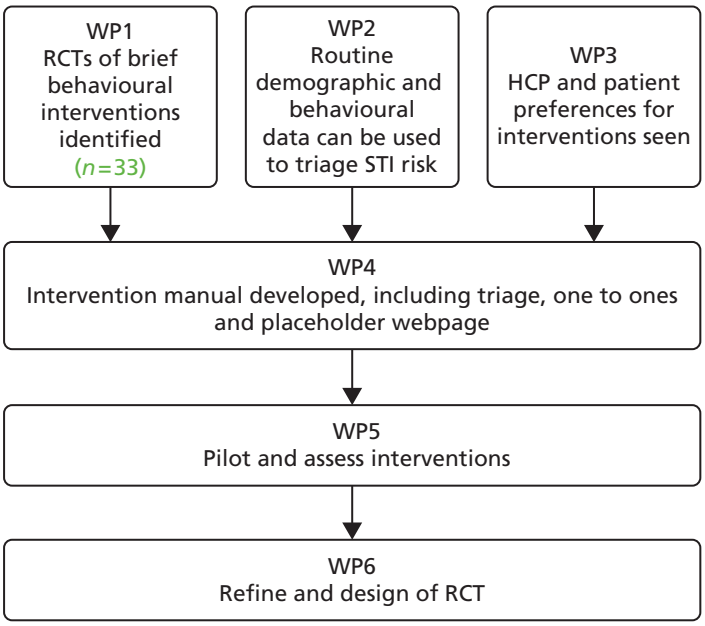

FIGURE 9 Summary of WPs 1–4.

Aim and objectives

To pilot the intervention package within existing clinic resources, and to assess the acceptability and feasibility to both HCPs and service users. Specifically, we aimed to address the following objectives regarding trial and intervention feasibility and acceptability:

1. Acceptability of the intervention to users and HCPs –

    i. proportion of eligible service users who attend the clinic that were assigned a score by the triage tool
    ii. proportion of those who were classified as high risk who were offered the intervention
    iii. proportion of those who were offered the intervention who took it up
    iv. proportion who took up the intervention who completed it
    v. reasons for not completing the intervention from the qualitative study of participants
    vi. acceptability of the intervention from the qualitative study of the staff.

2. Feasibility of delivering the interventions –

    i. the total time spent by service users within the clinical service compared with normal
    ii. total number of service users seen and STIs diagnosed, compared with normal
    iii. average consultation time compared with normal
    iv. number of patients seen by HAs compared with normal
    v. extra HCP time required for the intervention.

3. Feasibility of obtaining follow-up outcome data –

    i. proportion of eligible service users who consented to the follow-up
    ii. proportion of eligible service users who were contactable at 6 weeks and complete a questionnaire
    iii. proportion who complete follow-up tests.

Method

We conducted a prospective pilot of a cluster RCT across multiple SH clinics in England from March to May 2017 (*Figure 10*). The pilot included implementing the intervention package, follow-up of service users to obtain biological outcome data, and qualitative feedback from service providers and users.

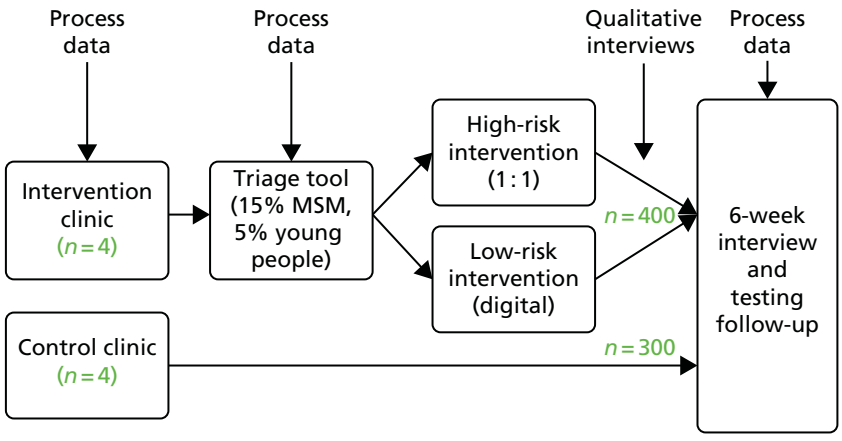

FIGURE 10 Overview of the pilot trial protocol.

Intervention pilot

We planned to include eight clinics in the pilot, four intervention and four control sites. Clinics were purposefully selected to take part and included level 2 and level 3 services located in different cities across England. The study was registered on the NIHR portfolio, which allows sites to volunteer to take part. In a full trial, allocation to intervention or control would be randomised, but this was not required in the pilot to determine feasibility.

Participants

All MSM and young people attending the clinics during the pilot period were eligible to be triaged and offered the appropriate intervention. Service users who lacked capacity to self-complete the triage (e.g. could not read English) were excluded; however, a member of the research team was present to help with any technical barriers to using the triage assessment tool.

Intervention

The intervention consisted of three components, as described in more detail in *Chapter 5* (triage, online intervention, one-to-one intervention). Participants in the intervention clinics were triaged using a risk prediction tool, which was self-completed on a stand-alone tablet computer. The triage result code was printed on a ticket and participants were asked by a member of study staff to give the ticket to the HCP they saw. Based on their risk score, participants were eligible to be offered one or both interventions:

1. High intensity – patients who scored highly in the triage algorithm for sexual risk were eligible to be offered the high-intensity intervention. This was a brief one-to-one session with a trained member of the health-care team (expected to be a HA in GUM clinics). This intervention was designed to be delivered in a single session, lasting up to 45 minutes, and on the same day as the participant's clinic visit.
2. Low intensity – this was offered to all patients, whether they scored above or below the threshold for referral for the high-intensity intervention. This was a web page designed specifically for the pilot trial, containing targeted SH information that could be accessed either during the clinic visit or at home later (www.santeproject.com – note that this web page is no longer active).

Service users in control clinics received standard care, which could include the offer of a behavioural intervention, for example a consultation with a HA.

In the intervention clinics, the HCP whom patients saw for their appointment could decide whether or not to refer a 'high-risk' user to the high-intensity intervention. The triage tool was set to refer approximately 15% of MSM service users and 5% of young people. This meant that MSM with a predicted risk of STI diagnosis of > 24% and young people with a predicted risk of > 22% were classified as high risk, based on the development data set used in WP2. These thresholds were deemed to be feasible in terms of the numbers of service users being referred, and giving a reasonable balance between sensitivity and specificity.

The project protocol and intervention package were presented to all clinical staff in intervention clinics during a routine staff meeting. Participating HAs had a training session (designed to be 2 hours) on the intervention manual, including the use of role play.

Data collection

Triage data were self-completed by service users and were collected using Android tablets through a custom-built ODK Collect (ODK Development Team, version 1.4) form. The variables collected were the same as those presented in *Table 6*. Anonymised data were uploaded to a secure server. Data about the one-to-one intervention process were recorded in the EPR system in Brighton and on paper forms in Archway. Engagement with the digital component of the intervention package was monitored using Google Analytics (Google Inc., Mountain View, CA, USA) during the pilot period. Process data for the number of service users attending the clinics during the pilot period, when available, were collected within the clinic existing EPR system.

Sample size

Based on historical clinic patient data on attendances provided as part of the GUMCAD data return, we estimated that a total of 5500 eligible patients would attend four clinics during the 1-month intervention period (*Figure 11*). Based on 70% of patients in the intervention period being triaged, an average of 10% being eligible for the high-intensity intervention, and 60% then being offered interventions, we expected 231 patients to be offered the high-intensity intervention. Assuming that 50% (expected 95% CI 44% to 57%) accepted the intervention, and then 50% completed it, we estimated that 58 patients would complete the intervention. The assumptions for the proportions triaged, offered and accepting the intervention were purposefully conservative to reflect the potential for poor engagement with the trial from HCPs and service users.

Analysis

We planned to describe the proportion of patients who went through each phase of the intervention process, comparing clinic types and patient demographics, adjusted for clustering at the clinic level. All analyses were conducted in Stata 14.

Interviews and focus group discussions

Telephone interviews with service users were conducted to explore (1) the reasons for not accepting the intervention or not engaging with the intervention process and (2) how their triage score matched their perception of risk.

Group discussions were held with service providers to explore potential challenges to intervention implementation and any feedback on acceptability.

Participant selection

We sampled young men and women and MSM who were attending SH services and completed the triage process. We sequentially recruited service users who scored as 'high risk', aiming to recruit 24 service users across two clinics. HCPs were purposefully recruited from participating clinics to represent both HAs and other clinical staff, with two focus group discussions planned for each participating site.

Recruitment

Service user participants were recruited from participating clinics. They were approached in the clinic waiting room and given a study information sheet to read before deciding to take part. Participants were

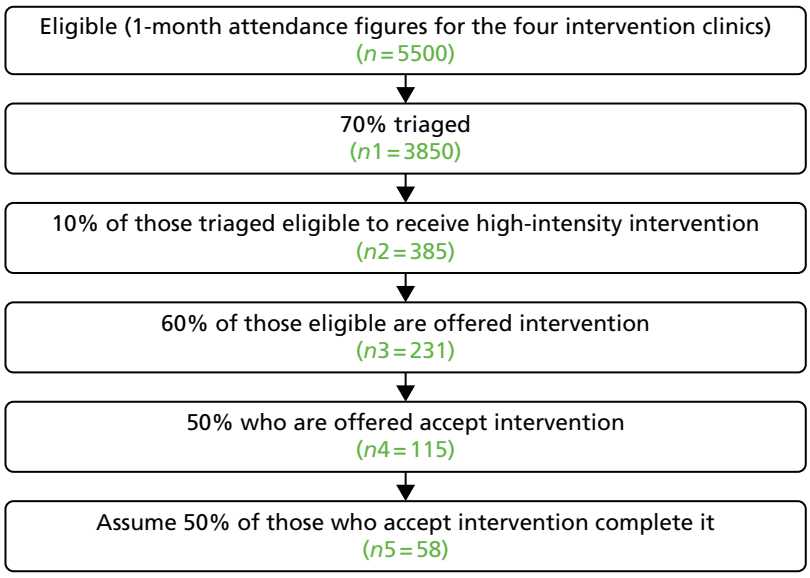

FIGURE 11 Flow chart for patient flow through the clinic.

offered a £20 high street voucher for taking part. Interviews were either scheduled to take place on the day of recruitment or scheduled for a future time by telephone.

Health-care providers were e-mailed to invite them to take part in a group discussion. When there was not enough interest to form a group, individual interviews were conducted.

Data collection

Interviews were by telephone and group discussions were conducted within the clinical setting. Interviews were designed to last 20 minutes, and the group discussions 45 minutes. Written consent was taken at the point of recruitment for service users and prior to the discussion starting for providers. Interviews and discussions were audio-recorded and then transcribed using a professional service.

Analysis

We used the same analysis methodology as described in *Chapter 4*.

Follow-up

We recruited a subset of patients from intervention and control clinics to be followed up 6 weeks after their clinic visit with a web survey and STI screening. The STI screening was either through a postal self-sample kit sent to patients' homes, or patients returned to the clinic for a 'quick check' screen. The screen included chlamydia and gonorrhoea, with a urine sample for men and vaginal swab for women. The web survey collected information about their recent clinic visit, including any interventions received.

Participant selection

All young people and MSM attending the recruitment clinics during set time periods were eligible for recruitment. There were no sample targets in terms of demographics.

Recruitment

Participants were approached in clinic waiting rooms and given information about the study by a member of the study team or clinic staff. Recruitment was conducted in specified time blocks at clinics until enough patients consented. The patient's preference for returning to the clinic or being sent a postal self-sample kit was recorded and patients self-completed information about their age, ethnicity, sexual orientation and contact details. The clinic patient ID was used as an anonymised study ID that could be linked to clinic records for processing results. The process was standardised across intervention and control clinics, and information posters were displayed in all clinics. A total of 75 and 100 patients were targeted for recruitment from control and intervention clinics, respectively (*Figure 12* – n2).

Data collection

Recruitment data were collected using Android tablets, through a custom-built ODK Collect survey form. Encrypted data were uploaded to a secure server. The follow-up web survey was created using SnapSurvey (Snap Surveys, London, UK), with no identifiable information requested. Patients were e-mailed the survey link up to three times. For the follow-up STI screen, patients either posted a self-collected sample, which was then processed by The Doctors Laboratory (London, UK), or returned to the clinic. The results were e-mailed to a NHSMail e-mail account, and patients were sent negative results via text message from a study telephone number. Any positive results were sent to the study co-ordinator at the recruiting clinic for follow-up and treatment in accordance with local protocols. All follow-up data were entered into a Microsoft Access 2013 database and processed using Stata 14.

Analysis

We described the frequencies and proportions, by clinic, age group, sex and ethnicity for each stage of the follow-up. Proportions were compared using chi-squared tests and multivariable logistic regression.

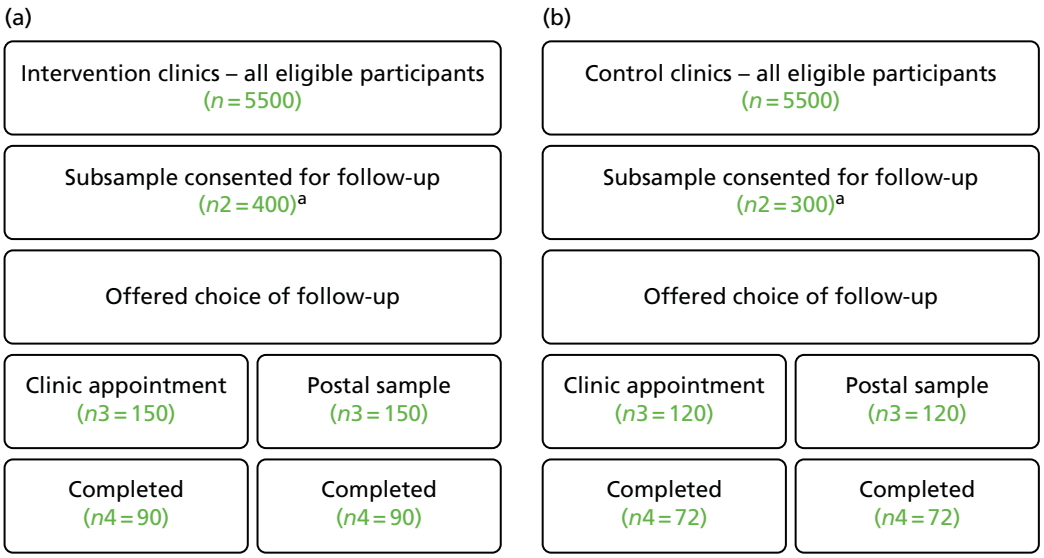

FIGURE 12 Sample size for patient follow-up at 6 weeks. a, *n*2 = total for all participating clinics; therefore, 400/4 = 100 in intervention clinics and 300/4 = 75 in control clinics. (a) Intervention clinics and (b) control clinics.

Results

Clinic participation

We planned to include four intervention and four control clinics in the pilot (*Figure 13*), with all eight sites recruiting patients to the follow-up STI screen and the four intervention clinics implementing the complete manualised intervention. Inclusion in the pilot study was discussed with 13 potential sites over a 6-month period. Three sites agreed to be control clinics: Croydon, Durham, and Chelsea and Westminster. Another three agreed to be intervention clinics: MMC, Archway and the Claude Nicol Centre. Both MMC and the Claude Nicol Centre have large MSM patient populations, and Archway serves a predominantly young and deprived patient population. At each site, a single site lead was identified to support the implementation, and this was either the clinical lead or a HA.

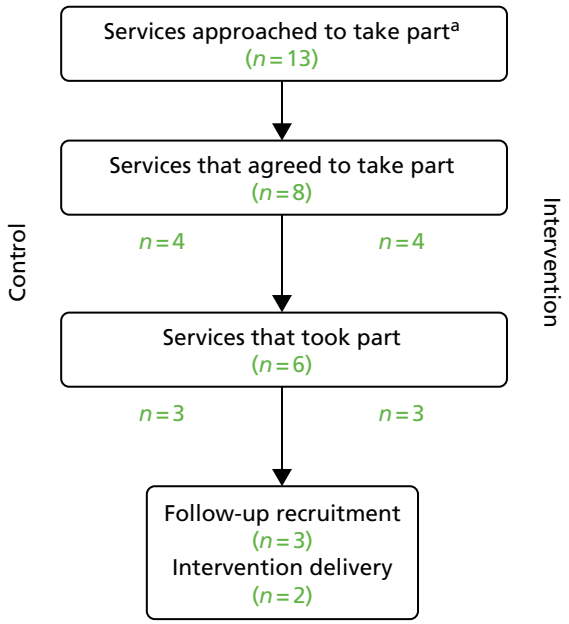

FIGURE 13 Clinic participation in the pilot feasibility study. a, The project was on the Clinical Research Network portfolio, meaning that it was visible to all services, these services could contact the study co-ordinator to take part.

Among the intervention sites, we were unable to pilot the intervention package at MMC despite its initial agreement, and it was piloted only partially at Archway (*Figure 14*). We had discussed the implementation with the clinic lead, health psychologist and HAs over a 6-month period before determining that it was not feasible. Reasons given for the inability to implement the intervention focused on the lack of staff resources and physical space in the clinic to see patients for a one-to-one session. This had not been raised initially when the sites were selected, but the pilot study period coincided with the retendering of SH services in London, which resulted in a substantial reduction in the size of the service commissioned. At MMC, we tried to mitigate the issue of staff time by offering bank shifts and overtime payments and recruiting temporary HAs as research assistants. None of these approaches was successful in securing additional resources within the time available for the pilot.

We were unable to include any level 2 services within the pilot. One service provider (Brook) was willing to participate following discussions with its clinical lead and the London and South East service manager. We identified three potential sites in total, both inside and outside London. In the event, there were insurmountable problems that prevented both piloting the intervention and recruiting patients for follow-up. These included implementation of a new EPR system, lack of clinic space for recruitment or intervention delivery, lack of staff capacity to deliver the intervention package, lack of clinic capacity to process additional test results, loss of one contract leading to the closure of a clinic, and relocation of staff. We contacted four alternative level 2 services, all of which were unable to take part because of concurrent recommissioning or lack of capacity.

Intervention pilot

Triage

The original proposal aimed to embed the triage tools developed in WP2 within the EPR systems of clinics for the pilot trial. We discussed this proposal with two different EPR software providers [MillCare (Belper, UK) at Brighton and RioMed (Eastleigh, UK) at MMC and Archway], but these companies were unable to implement the triage within either of these systems.

In Brighton, the feedback from the EPR provider was that the implementation of a triage tool as we developed would be feasible, but would take considerable coding and configuration and a minimum of 6 months' development and testing. Therefore, we did not pursue adaptation of the EPR at Brighton because of the time constraints. It was also noted that the EPR provider raised concerns over our approach, as, despite the triage tool parameters having already been collected within the EPR system, the real-time processing would be computationally intensive (e.g. deprivation quintile is derived from a patient's postcode).

At MMC and Archway, the EPR provider indicated that the implementation of the triage within the system was achievable and anticipated 3 months to develop and pilot the system. Concerns regarding the coding or configuration were not raised. Over an 8-month period the EPR provider developed three iterations of the triage; however, none of these was deemed practical, with issues of double data entry, burdensome navigation through the patient record and the removal of compulsory fields. Therefore, we were unable to pilot test the triage within the EPR system at these sites. This indicates that, were this to be pursued, a programme of software development would need to be supported and funded by the NHS provider.

For the purposes of the pilot trial, we developed a stand-alone Android tablet-based system using open-source software (ODK Collect). This altered the patient pathway from that originally proposed: the triage tool was self-completed by patients prior to their appointment, rather than being conducted as part of the consultation with a HCP. This system was in place for 1 month before the pilot began so that it could be integrated into the clinic and to allow providers to become familiar with the study protocol.

The triage tool was completed 1064 times, representing 16% of patient attendances during the pilot trial period. Sufficient information to complete the triage process was provided by 1030 (97%) patients, of whom 612 (59%) were either young or MSM. As study staff asked service users to complete the triage

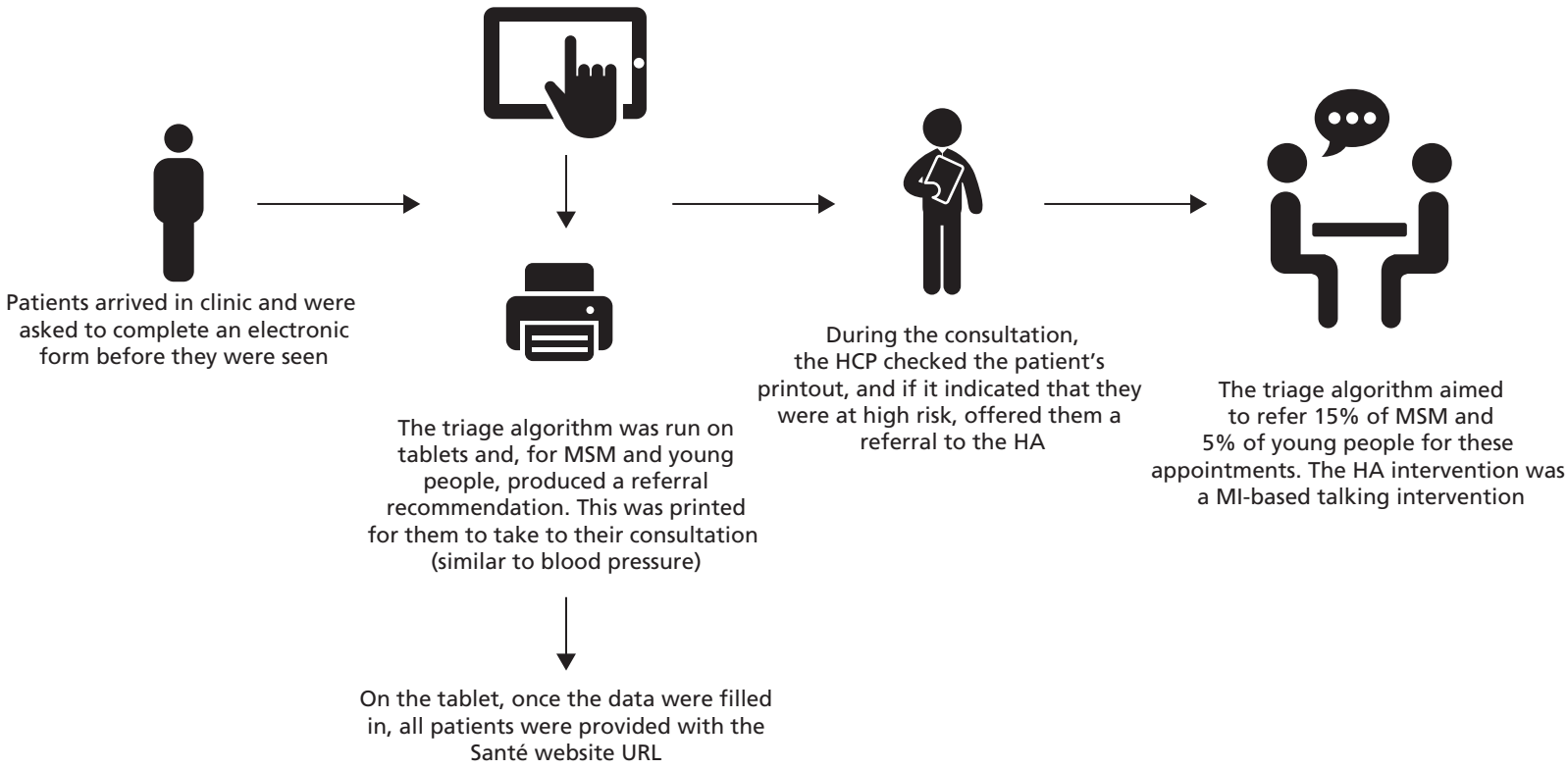

FIGURE 14 Schematic of the pilot Santé intervention patient pathway.

prior to their clinical appointment, we were unable to distinguish our target groups and, therefore, aimed to have all patients take part. In both settings, a higher proportion of young people than of MSM was triaged (*Table 23*).

The triage tool was set to a risk referral threshold that we had planned would identify 5% of young people and 15% of MSM to be at high risk, based on the model performance from WP2. However, at both sites, the triage process identified a considerably higher proportion than this (*Table 23*). Notably, there was a higher proportion of high-risk young people at the Archway clinic and a higher proportion (and attendance in general) of high-risk MSM in the Brighton clinic. These risk profiles of the two clinics is not necessarily surprising and probably reflects that the demographics and sexual history of participants in the pilot trial differ from those of participants included in the development data set. There was also a lower number of missing sexual history and behaviour data in the pilot than in the WP2 data set, and this may have changed the triage tool's performance. The threshold for defining a high-risk patient could be adjusted for clinics according to the capacity to provide a high-risk intervention, but this poses specific challenges for a standardised approach to triaging.

Santé web page

During the pilot period, the project web page was advertised in four ways in both pilot clinics: posters displayed information about it in the clinic waiting rooms, the web address was printed on the triage tickets, HCPs in the clinics were informed about the web page and it was printed on the action plan cards given during the one-to-one sessions.

A total of 24 unique users visited the web page during the pilot, out of a potential 6805 patients (0.4%), with one visitor returning. On average, visitors stayed on the web page for 38 seconds, and stayed on the home page. Two users accessed the web page using a mobile phone, and all other site visits were from computers. *Figure 15* demonstrates the age and gender of the site visitors.

TABLE 23 Summary of the triage process during the pilot trial

	Site, *n* (%)	
Group	Brighton (*N* = 925)	Archway (*N* = 139)
Young people		
Clinic attendances	1472	365
Triage completed	306 (21)	50 (14)
High risk	50 (16)	17 (34)
Low risk	256 (84)	33 (66)
High-risk patients who attended one to one	10 (20)	3 (18)
MSM		
Clinic attendances	2369	88
Triage completed	246 (10)	10 (11)
High risk	71 (29)	2 (20)
Low risk	175 (71)	8 (80)
High-risk patients who attended one to one	11 (15)	1 (50)

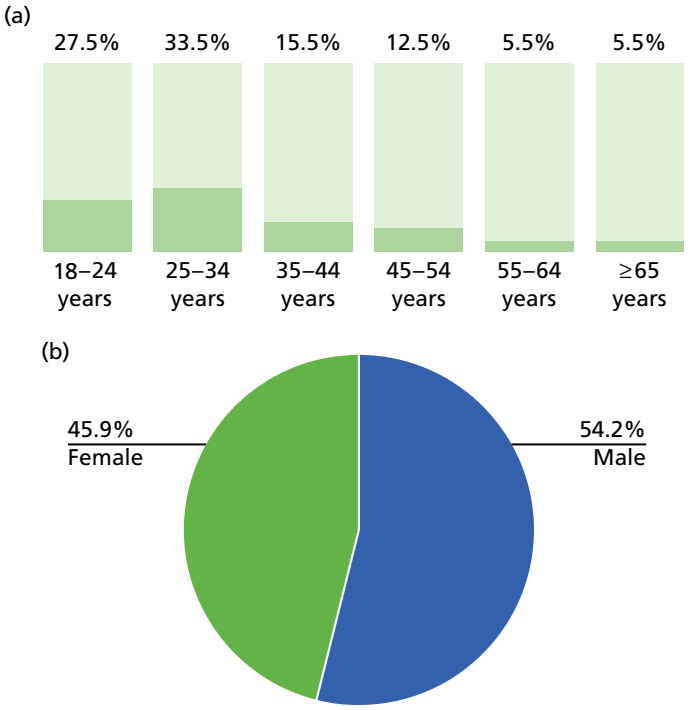

FIGURE 15 Age and gender of the Santé web page visitors (derived from Google Analytics). (a) Age, 100% of total sessions; and (b) gender, 100% of total sessions.

One to one

At Archway, one HA agreed to work additional bank shifts during the piloting period, meaning that we could deliver the intervention package 2 days per week during May 2017. In Brighton, the HAs implemented the intervention as part of their routine practice from 2 May to 2 June 2017. Training was delivered in two brief (1-hour) sessions at Brighton with the whole HA team present, and in a single session at Archway (1 hour). The training included an overview of the study protocol, an explanation of the intervention manual, and brief role-play exercises using the five steps of the one-to-one consultation and action plan cards.

In Brighton, the EPR system was adapted to include information about whether or not the patient had been triaged, referred for the one to one and accepted. Of the 552 eligible patients who completed the triage process, records for 168 (30%) were entered into the EPR system, with this proportion being slightly higher for young people than for MSM (31% vs. 24%, respectively). A total of 21 (0.6%) potentially eligible patients (see *Table 23*) were recorded as having completed a one-to-one session; this represents an average of one patient per day. However, it is possible that more patients completed the one-to-one but were not recorded in the EPR. In the HA comments recorded within the EPR system, sessions took 5–15 minutes, but this was reported in only a few records. More general comments on the content of the sessions, of which examples are given below, showed that they covered a range of topics and that patients had a range of motivation around behaviour change:

> *Has made patient realise that it is important to know potential partners well and use condoms, especially in early stages of a relationship.*
>
> *Young person, Brighton*

> *Triaged wrongly as high risk; one episode of UPAI [unprotected anal intercourse] for which he accessed PEP. No other UPAI. No [chemsex]. Consistent condom use and informed.*
>
> *MSM, Brighton*

> *Discussed risk taking as part of PEP discussion. Patient acknowledges risk behaviour and it is usual for him to make decision of knowing partners. Due to alcohol this did not happen this time. Patient not choosing to make changes to this behaviour at this time.*
>
> *MSM, Brighton*

At Archway, of the 60 eligible patients who completed the triage, 19 (32%) were high risk and four (7%) completed the intervention. The four sessions were recorded as taking approximately 30 minutes each, but the intervention steps and action planning were conducted in only 3 minutes. The content of the sessions was reported as including condom use, peer pressure around risk behaviours such as drugs and contraception with young people, and PrEP, PEP and general STI knowledge in MSM. Among those who were triaged as high risk but did not attend the one-to-one session, reasons for non-attendance included the patients not waiting for the appointment, issues with the referral process in the clinic and HCPs not feeling that a referral was warranted.

Service user qualitative feedback

A total of 16 interviews were completed with the 24 service users who consented (*Table 24* and *Box 5*). We were unable to complete eight of the planned interviews as participants did not answer our calls or they declined to take part when we subsequently contacted them. We contacted individuals up to three times, by either telephone call or text message, before deeming them lost to follow-up. Reasons for participants presenting to the SH clinic were routine check ($n = 7$), contraception ($n = 4$), treatment ($n = 3$) and because they were concerned about a recent contact with a sexual partner and their STI results ($n = 2$).

Triage and referral to the one-to-one session

All the participants were recruited in participating clinics following their completion of the self-triage; participants indicated that the triage process was acceptable, although many appear not to have understood its purpose. Overall, they felt comfortable with the questions being asked (i.e. demographic and recent sexual behaviours) and found that filling in the questions on the tablet computer was straightforward. One of the main advantages was that the tablet was felt to be quick to complete and could save time. The discretion afforded by self-completion was also mentioned, but not as a key issue.

TABLE 24 Service user participants in pilot study qualitative feedback

Characteristic	Young people	MSM
Location		
London	5	2
Brighton	4	5
Age (years)		
< 18	2	
< 25		3
18–21	3	
25–50		3
22–25	4	
> 50		1
Ethnicity		
White	4	5
Black	2	
Asian	1	1
Mixed	2	
Other		1

BOX 5 Case studies

'Jeff'

Jeff (MSM, aged 21 years) had come in for his regular 3-monthly HIV test and was referred to the HA to talk about PEP. He had never seen a HA before and was curious; although he had to wait some time, he wanted to do it then and there. Their conversation covered STIs other than HIV and he decided to have a full STI screen after their discussion. Jeff explained how this clinic visit was very different from usual: 'Because to start with there was the tablet experience, filling in and then getting a ticket and then being informed about the health advisor and then actually talking to that health advisor. Yes, it was really different because usually it would just be going to the room with the doctor and then getting a finger prick done and that's it, yes.' His action plan had included doing some research around STIs and PEP, and he had followed through on this and intended to have regular full screening in future.

'Kelly'

Kelly (female, aged 18 years) had just been diagnosed with a STI and valued the opportunity to talk to someone, although the HA did not feel that it was appropriate to do an intervention with her because her anxiety was high: 'So, I was quite happy just to talk to someone and just ask questions about it, because I wasn't really sure. And I had seen a health advisor before, and it was quite helpful.' She had seen a HA before to discuss changes she might like to make, and although she felt a bit judged, she felt it had changed her mind about what she was doing. On this occasion, speaking to the HA helped calm her down and made her realise that everything was OK.

'Emma'

Emma (female, aged 17 years) had come in for treatment and welcomed the opportunity to see the HA and get more information. She had kept her action plan and thought that it was a good idea. She thought that the discussion was useful and had also visited the website.

Although one participant raised a concern about whether or not the questions took all the relevant information about sexual risks into account (MSM, > 50 years), no one objected to being referred to a HA based on the triage tool. However, although conceptually acceptable, there was little evidence that the ticket-based system we piloted in lieu of an integrated EPR-based system was feasible. Only half the participants we interviewed gave the ticket to the HCP they saw – reasons for this failure were confusion about an unfamiliar process and forgetting, for example 'We're a bit distracted when we're there' (MSM, > 50 years).

There were mixed experiences among those participants who successfully passed their triage ticket to the HCP. For example, a young female participant (25 years old) came in for contraception and did not expect to talk about sexual risk. Some patients felt that the triage ticket prompted a helpful discussion about new sexual partners and could result in them agreeing to have a STI test. Others, however, reported that their HCP did not seem to want the ticket or discuss sexual risk, whereas others spoke briefly with the HCP about sexual risk: 'I gave it to, like, my doctor, and she, did a little talk on sexual health and stuff' (female, aged 22 years). Patients who did not give the tickets to their HCP generally reported discussing sexual risk with their HCP regardless.

Many of the patients who had come for contraception or routine check-ups neither expected nor were offered any health promotion interventions, such as leaflets or referral to a HA. Among patients who were

referred to a HA based on the triage tool, reasons for accepting a referral varied, including the opportunity to talk about PEP or to have a general discussion about SH and risk behaviours:

> *I found it reassuring that there are services in place that would be, looking out for potential relapses with people that come into that clinic.*
>
> *MSM, 25–50 years*

> *I think that was good because I feel, if I hadn't given her the slip, I might not have been told to go to the health person. I think that was good for me, just to speak to someone else as well.*
>
> *Female, 18–22 years*

Santé website

Although there was no indication that patients found the idea of the Santé website unacceptable, only one of the interview participants (who had also attended the HA one to one) had visited the web page. The young woman who visited the web page (18 years old) said she went to the website for additional information and was happy to do both a one-to-one session and visit a web page. Other participants reported wanting to find specific information from the internet; a young woman (21 years old), for example, had searched to find out more about her treatment but had not visited the intervention website.

A few participants indicated that they might check a website on their mobile phones while waiting for their appointments but would not go back to it afterwards. However, none of the participants had visited the website using the link advertised on posters in the clinics or the tickets, and most had not noticed the information printed on the ticket. Barriers to this were poor understanding that the ticket contained relevant information and not having the skills or facility to scan the QR code on their mobile phones. One young woman stated that she might have been interested in checking the website but the HCP took the ticket from her. Participants reported not seeing the posters among all the displayed information and being too distracted or busy reading or talking while they waited. Texting the web link (e.g. with the appointment reminder) was suggested as a more effective way to promote a website.

One-to-one session

Very few of the participants we interviewed were referred to see the HA as intended. Participants who had previous reported experience of one-to-one sessions typically saw them as worthwhile, giving them motivation to change and even resulting in behaviour change:

> *It was something that I was already thinking but it just pushed a bit more.*
>
> *Female, 20 years*

Participants were generally open to the idea of a one-to-one session with a HA. Only one young woman (aged 21 years) said that she was always asked to see a HA about her drinking and consistently declined as she does not consider it to be a problem. Some participants wanted a clear reason for seeing the HA and would be motivated to ask to talk to someone if they had specific questions or concerns. Others thought that they would accept the opportunity to talk to a HA if it was recommended to them, although this sometimes raised anxious concerns:

> *I think I'd be a bit nervous as to why they recommended me to one, but, like, I would go. If they're recommending me to go see one, then I would.*
>
> *Female, 17 years*

Other barriers to attending a HA referral included time and the gender of the HA; for example, a young woman (aged 25 years) said that she would be more inclined to talk to a HA if it was a quick discussion, and wanted the HA to be the same gender as her.

Health-care provider qualitative feedback

We had planned to conduct focus group discussions with both HAs and other clinical staff from Archway and Brighton to get feedback on how the intervention was implemented and experience from service perspectives. Two group sessions were held in Brighton and included three HAs and four other clinical staff. Recruitment from the London clinics was more difficult, with two doctors and one psychologist who had not been directly involved in the triage or the intervention taking part. Their comments remain speculative. An individual interview was conducted with the HA from Archway who had taken part in the pilot.

Triage

The value and effectiveness of the triage algorithm was questioned by most participants, who generally considered this to be a 'blunt' and diluted alternative to the more sensitive interpersonal, face-to-face risk assessment. Among HAs there was suspicion and lack of confidence in the capacity of the triage tool to accurately predict risk or need:

> *As a system, I don't think it works and it's not the same as having someone in front of you with it and then, kind of, ascertaining the best way for using instincts.*
>
> *Brighton, Doctor*

> *I think it's a completely different kind of experience and I think it depends what your measures or outcomes are, because I think sometime we'll see a person in clinic, they'll have a really good experience with us, it will be a really human experience and actually they might then come back a month later and tell us about something completely different that they hadn't mentioned at the first visit because they feel safe, they've had a good experience. Whereas that is quite a, sort of, impersonal . . .*
>
> *London, HA*

The HAs' experiences of the pilot led them to feel that the tool had sometimes referred patients who were subsequently assessed to have not needed referral and failed to refer patients whom they subsequently identified as high risk. Conversely, the Brighton HA group also stated that many of the patients referred via the triage tool were patients from the waiting room who had already been booked in to see the HAs. This was seen to both assert the effectiveness of the triage tool in identifying appropriate patients and undermine the purpose and value of the tool:

> *And I think we're picking up the ones anyway that would engage, so they're the ones that, kind of, tend to be known to us and they engage and they're getting through to us in other ways. And the people that won't engage are the people that won't engage, no matter what triage system you're using.*
>
> *Brighton, HA*

There was a further challenge to this method in the routine practice in Brighton, where all individuals < 18 years old are routinely screened and receive a thorough assessment. This raised questions regarding the context of the pilot, as the role of an additional triage assessment was not clear:

> *And with the young people they have an assessment anyway, really thorough from a safeguarding perspective, so all under 18s and that bring up anything and everything to do with risk. So that's going to happen anyway, when they're in the room. So, I don't think you need something on top of that, with regards to young people, do you?*
>
> *Brighton, HA*

Several advantages or opportunities offered by the triage tool were also discussed, including the potential for the triage tool to enable patients to highlight a risk profile or other issues that they might not feel able

to raise face to face. This private disclosure was seen as avoiding a potentially embarrassing discussion with a member of staff:

> *So, what I'm saying is they may say something different to the consultant, nurse, whoever they see, and they may be saying what they really feel [overtalking]. If you see what I mean? Because sometimes it's easier to do this than it is to talk to someone face to face. So, it's tricky, yes, you're going to get that I think.*
>
> *London, HA*

The Brighton HA group also revealed that the piloted triage tool was potentially more effective than the current process of asking patients to tick key risk assessment questions on a form at reception.

Another potential advantage of a systematised triaging that the London group proposed was the process and structure that it could provide to new members of staff who might lack confidence and skills. The systematised triage was thought to prompt staff to both identify and refer patients who come in for non-STI issues but who have risk profiles that would otherwise go unassessed:

> *I suppose a good thing is that it might make a clinician think more about a patient, particularly if they're repeat attenders for something, and they think that they're really settled and stable and don't need any intervention, this might actually pick it up. So, it might make people explore things more as opposed to thinking, 'Oh, this person's a repeat attender for something,' it might make them look into it more.*
>
> *London, HA*

> *I rarely see the contraception service patients even though we're supposed to be integrated service. So, I would say it really helped clinicians to identify that. But the whole assessment was still down to them: do they feel this person would need to be referred?*
>
> *London, HA*

Santé website

We had limited feedback on the Santé web page as consenting participants either were not aware of it or had not used it. At least two of the Brighton HAs were not aware that a Santé website existed, and none of the others made reference to having used the Santé website. There was some brief discussion about the potential value of referral to websites:

> *. . . there are some aspects or some topics maybe that people feel OK to do online, but I think in the area that we're in, in sexual health it's such a sensitive issue . . . it's quite a vulnerable position to be in to start talking about . . . So, when it comes to online, I'm not sure how that will translate, but for some people that might be just what they want, because for them, maybe talking doesn't help them or they don't feel it benefits them, and it might be a starting point for some people online.*
>
> *London, HA*

One-to-one sessions

This feedback focused on the HA experience, as the non-HA staff had little experience of the intervention. HAs from Brighton and the London HA interviewee made conflicting comments about their use of the one-to-one sessions, stating that 'It's what we do anyway,' but also commenting that the manual provided useful structure and format for these interventions. HAs in Brighton also discussed their existing use of MI as part of their routine work, although they acknowledged the limited amount of MI training that the HA staff had received. Much of the training had taken place many years ago, and HAs subsequently asked the study team for additional training in MI.

Two of the Brighton HAs stated that they were concerned about the limitations of the intervention manual and felt that it repeated what was already part of their routine practice. They had therefore ignored it ('I must admit I didn't really use it'), whereas another Brighton HA participant referred to the value of the manualised MI approach for the structure it provided:

> *I like the part when it gets to the work, I like the MI, I like just being able to, kind of, code or prove what you're doing or, I'm not saying that very well, but measuring what we do somehow.*
>
> *Brighton, HA*

The London HA interviewee in particular valued the manual for its structure and the focus on goal setting, which they felt guided their approach and focused attention on action planning. They also suggested that the focus on action plans provided structure for patients too:

> *. . . just having to do it 100%, thinking about it 100% and doing it 100% was more how it, kind of, focused the consultations, so that it helped to elicit three goals that the person wants, so, it really made the consultation more structured actually . . . I think in the normal run of the clinic that wouldn't be the same way which we would deal with it. So, it, made it more structured for me personally.*
>
> *London, HA*

Although the London HA welcomed the use of the credit-card-sized action plans, none of the Brighton HAs had used the cards or appeared to be aware of them. As with attitudes towards the manual, the Brighton HAs described a tension between routine practice already being similar to the intervention process and the action plans not being acted on:

> *It's what we would do anyway. The couple of times that I have done it I've forgotten to do an actual action plan, because I wouldn't necessarily do that.*
>
> *Brighton, HA*

Again, the London HA interview identified advantages in the structure that the intervention and action plans provided, and related these to both the HAs and the patients:

> *I thought it was a very comprehensive tool, I really did, and a very comprehensive tool, it just, highlighted the bits that you needed to do; and, as I say, the action plan I think was really for me the best part of it.*
>
> *London, HA*

Implementation barriers

A number of implementation barriers were raised during discussions, including the ticketed triage process and limited staff training. The use of tickets was seen to be a key 'leakage' point at which both patients and staff lost potential referrals. The tickets, which were a workaround in place of the initially planned integrated EPR system planned, were seen as confusing to patients, and they were lost, abandoned or ignored by patients and were lost or forgotten by staff. The use of these tickets was introduced as a workaround because of the delays and technical barriers to adapting EPR systems, and this was seen to have introduced several significant barriers to the pilot trial implementation. Integration into the EPR system was identified as a valuable solution that would have avoided many of these 'leakage' points:

> *I found them screwed up on the lab floor, stuffed in between people's notes, sometimes in the wrong place. Or people just randomly putting notes on my desk, you know, 'Do I give this to you, what do I do with it?'*
>
> *Brighton, HA*

> *I think, yes, people who would've been referred to me . . . basically, because there were few issues with just getting everybody understanding what to do with that bit of paper.*
>
> *London, HA*

The engagement of doctors, nursing staff and HAs in briefings and training about the conduct of the trial appears to have been inconsistent, fractured and of limited impact. Although all participants said that they found ways to make things work, patients were lost to the study because of confusion about the triage tickets, and the intervention manual was not always read or properly applied by HAs. Among the HAs there was considerable variation in the engagement with the trial, and questionable skills/capacity of HAs to administer a MI intervention. The capacity of many HAs to deliver MI was questioned by some HAs themselves and by participants in the London group:

> *I think MI is often talked about as something that everyone does, and I think everyone can do it but equally it can be a very filtered, watered down version of what could be most useful. So I think it's good to make sure if you are offering it, that it's being done by somebody that's really experienced in doing it.*
>
> *London, Psychologist*

Although most staff in the two pilot clinics had been informed about the pilot's aims and objectives and all HAs had been through some training on the intervention manual, concerns were raised about the effectiveness of the briefings and training. In the Brighton discussions, a senior nurse had joined the clinic after the pilot had begun and highlighted the necessity of effective, ongoing introductions for new staff. This was also recognised to be an issue for junior doctors, who may arrive after initial briefings:

> *I think if the staff that are seeing them [patients] have a grip of the basic principles of the study, that's more persuasive than them just going, 'Oh, I'm not really sure it's something to do with offering you an intervention if you're a high risk.' There's consistency, isn't there? Everyone saying the same thing, in the same sort of way.*
>
> *Brighton, Doctor*

The triage and intervention were generally accepted as viable in these busy clinic environments, and the trial appeared to have had only a very limited impact on the day-to-day clinic work. Even HAs appear to have found the trial and intervention to have been acceptable within their workload, although this may be related to their opinion that most referrals were of patients they would already have expected to see and the limited numbers of triaged patients who actually made it through to HA appointments. The Brighton HA group suggested that the 'Brighton Express' clinic for those aged < 18 years, which provides routine and thorough face-to-face assessment of the needs of younger patients, would have been negatively affected by the trial.

Follow-up study

In both intervention and control clinics, service users were recruited for a follow-up survey and screening at 6 weeks. The follow-up involved a short web questionnaire and either completion of a self-sample kit to be returned by post or a return to the clinic for a routine STI screening. The initial target was 700 patients from eight clinics; as only six clinics took part, the recruitment target was revised down to 525 patients. We had originally projected that 180 out of 400 patients from intervention clinics, and 144 out of 300 patients from control clinics, would complete follow-up (*Figure 12*). A total of 406 patients consented to follow-up; recruitment was not achieved at three clinics because of a lack of eligible patients and low consenting rates (*Figure 16*).

Of the 406 patients who consented, 273 (67%) were young and 133 (33%) were MSM. Overall, 228 (56%) participants did not participate in the web survey or return a self-sample kit and 64 (16%) completed both follow-up activities. MSM were more likely than young people to participate in the web survey, to return a self-sample or to complete both parts of the follow-up (29% vs. 10%).

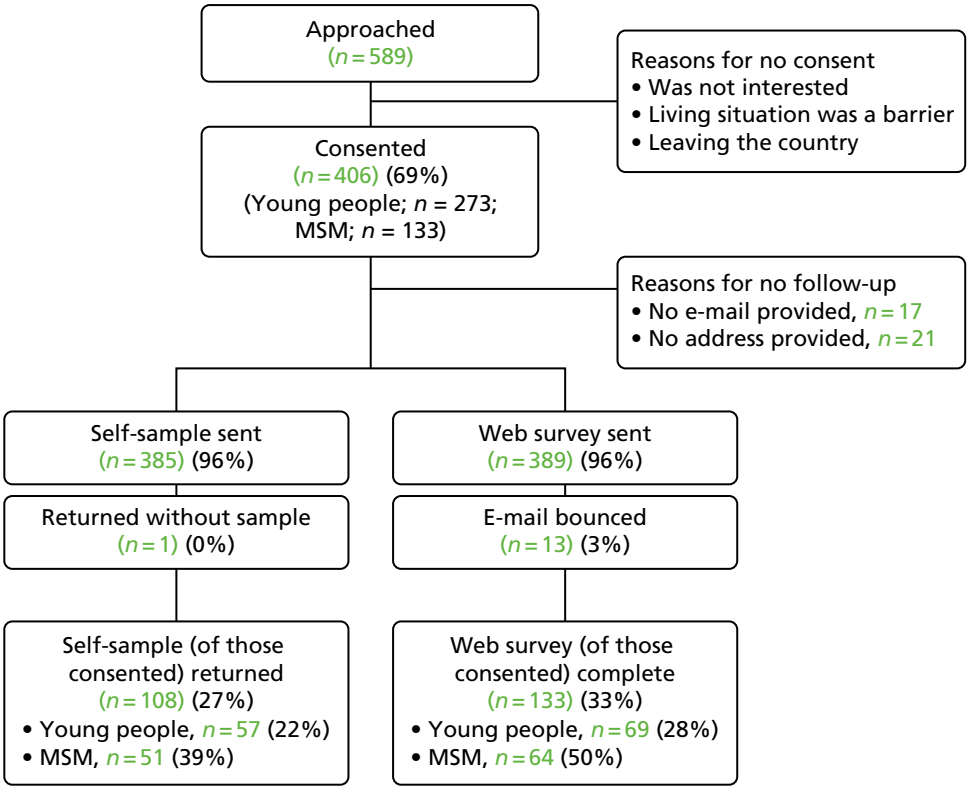

FIGURE 16 Recruitment and follow-up summary.

The patients recruited for follow-up represented 2% of all eligible attendees attending the clinics during the study period (*Table 25*). Young people whom we recruited were generally representative in terms of age, gender and sexual orientation; however, our sample had a larger number of young people of black ethnicity. The MSM population whom we recruited was generally younger than the overall MSM patient population and had a higher proportion of bisexual men. We under-recruited from MMC compared with the other clinics.

Web survey

A total of 990 e-mails were sent out to 389 service users. Thirteen (3%) e-mails bounced as the e-mail address provided by the service user was incorrect (see *Figure 16*). Of the 376 service users who received the link, 133 (35%) completed the survey, and an additional 17 (5%) participants started but did not complete the survey. On average, participants responded to the third e-mail reminder and took a median of 2 minutes to complete the survey.

Young people were significantly less likely to complete the web survey than MSM (OR 0.39, 95% CI 0.25 to 0.61), and the overall completion rate ranged between clinics from 36% at Archway to 19% at Croydon. *Table 26* presents factors associated with survey completion in MSM and young people.

Among young people, women were more likely to respond to the web survey than men [adjusted odds ratio (aOR) 4.35, 95% CI 1.59 to 11.88]. Participants recruited from Croydon were significantly less likely to respond, even when the age, gender and ethnicity of the participant were taken into account (aOR 0.22, 95% CI 0.07 to 0.66). In MSM, no demographic factors were identified that predicted whether participants were more or less likely to respond to the web survey, although there were trends towards older and white MSM responding. Interestingly, MSM from Croydon had the highest response rate.

Sexually transmitted infection screen

We offered two options for the 6-week follow-up: returning to clinic for a 'quick check' or being posted a self-sample kit. Typically, 'quick check' STI screening appointments involved the completion of a very short questionnaire, self-collection of samples and minimal interaction with clinic staff. In some of the clinics we

TABLE 25 Summary of participants recruited for follow-up and the general clinic populations

	Young people, *n* (%)		MSM, *n* (%)	
Characteristic	Total (*N* = 6216)[a]	Recruits (*N* = 273)	Total (*N* = 5738)[a]	Recruits (*N* = 133)
Gender				
Male	1444 (23)	67 (25)		
Female	4772 (77)	206 (75)		
Age (years)				
16–20	1890 (30)	87 (32)	149 (3)	9 (7)
21–25	4326 (70)	186 (68)	610 (11)	25 (19)
26–35			1639 (29)	43 (32)
36–45			1504 (26)	29 (22)
> 45			1836 (32)	27 (20)
Ethnicity				
White	4296 (70)	179 (66)	4485 (78)	102 (77)
Mixed	455 (7)	25 (9)	228 (4)	11 (8)
Asian	331 (5)	11 (4)	350 (6)	7 (5)
Black	568 (9)	52 (19)	192 (3)	6 (5)
Other	566 (9)	6 (2)	483 (8)	7 (5)
Sexual orientation				
Heterosexual	5759 (93)	245 (90)		
Homosexual	25 (0)	2 (1)	5286 (92)	113 (85)
Bisexual	404 (7)	25 (9)	452 (8)	20 (15)
Clinic				
Archway	1667 (27)	64 (23)	386 (7)	11 (8)
Brighton	2134 (34)	50 (18)	1952 (34)	49 (37)
Chelsea	968 (16)	38 (14)	1532 (27)	36 (27)
Croydon[a]		64 (23)		12 (9)
Darlington	292 (5)	31 (11)	37 (1)	3 (2)
MMC	1155 (19)	25 (9)	1831 (32)	22 (17)

a Data from Croydon were not available.

were unable to offer a 'quick check' appointment because of limitations with the booking system. Of the 406 participants recruited, 385 opted for the postal self-sample kits and provided address details. The return rate was higher among those who were sent kits (27%) than among those who opted to return to the clinic (3/21, 14%). Among the 108 participants who were successfully screened, there were two positive tests for chlamydia and no gonorrhoea diagnosed. We aimed to send the self-sample kits at 6 weeks following recruitment into the study; on average samples were returned at a median of 9 weeks (IQR 8–11 weeks).

TABLE 26 Multivariate analysis of demographic predictors of web survey completion in MSM and young people

	Young people ($N = 273$)		MSM ($N = 133$)	
Characteristic	Completed, *n* (%)	aOR[a] (95% CI)	Completed, *n* (%)	aOR[b] (95% CI)
Gender				
Male	7 (12)	1.00		
Female	62 (33)	4.35 (1.59 to 11.88)		
Age (years)				
16–20	27 (36)	1.00	3 (38)	1.00
21–25	42 (24)	0.57 (0.29 to 1.11)	12 (50)	2.54 (0.33 to 19.62)
26–35			9 (21)	0.56 (0.08 to 4.01)
36–45			19 (68)	6.34 (0.77 to 52.27)
> 45			21 (78)	5.40 (0.67 to 43.26)
Ethnicity				
White	47 (30)	1.00	58 (59)	1.00
Mixed	3 (14)	0.34 (0.08 to 1.44)	0 (0)	
Asian	1 (10)	0.27 (0.03 to 2.41)	1 (14)	0.13 (0.01 to 1.39)
Black	14 (27)	2.13 (0.82 to 5.52)	2 (33)	0.37 (0.04 to 3.68)
Other	4 (67)	9.42 (1.34 to 66.41)	3 (43)	0.70 (0.12 to 4.01)
Sexual orientation				
Heterosexual	57 (26)	1.00		
Homosexual	1 (50)	3.09 (0.18 to 52.65)	53 (48)	1.00
Bisexual	11 (50)	2.92 (1.08 to 7.93)	11 (58)	3.10 (0.74 to 12.98)
Clinic				
Archway	22 (34)	1.00	5 (45)	1.00
Brighton	16 (32)	0.73 (0.29 to 1.82)	25 (53)	0.82 (0.14 to 4.92)
Chelsea	11 (29)	1.13 (0.43 to 2.96)	15 (42)	0.45 (0.08 to 2.66)
Croydon	7 (11)	0.22 (0.07 to 0.66)	7 (58)	2.93 (0.30 to 28.72)
Darlington	7 (23)	0.24 (0.68 to 8.71)	1 (50)	1.13 (0.04 to 34.11)
MMC	6 (24)	1.33 (0.41 to 4.40)	11 (52)	0.76 (0.11 to 5.16)

a Adjusted for gender, age, ethnicity, sexual orientation and clinic.
b Adjusted for age, ethnicity, sexual orientation and clinic.

Young people were significantly less likely to return the self-sample kit than MSM (OR 0.45, 95% CI 0.29 to 0.72), and the overall completion rate ranged between clinics from 34% in MMC and Chelsea to 15% in Darlington. *Table 27* presents factors associated with survey completion in MSM and young people.

Among young people, the only factor significantly associated with completing a STI screen was being female (aOR 3.32, 95% CI 1.32 to 8.38); the association with being older was borderline. Among MSM, although no associations were statistically significant, there was again a trend towards older MSM being more likely than younger MSM to complete the screen (63% in those > 45 years vs. 0% in those aged 16–20 years).

TABLE 27 Multivariate analysis of demographic predictors of STI screen completion in MSM and young people

	Young people (*N* = 273)		MSM (*N* = 133)	
Characteristic	Completed, *n* (%)	aOR[a] (95% CI)	Completed, *n* (%)	aOR[b] (95% CI)
Gender				
Male	7 (12)	1.00		
Female	50 (26)	3.32 (1.32 to 8.38)		
Age (years)				
16–20	13 (16)	1.00	0 (0)	
21–25	44 (25)	2.04 (0.97 to 4.28)	8 (33)	1.00
26–35			13 (30)	0.7 (0.23 to 2.37)
36–45			13 (45)	1.21 (0.35 to 4.12)
> 45			17 (63)	2.03 (0.58 to 7.16)
Ethnicity				
White	39 (23)	1.00	45 (44)	1.00
Mixed	6 (24)	1.11 (0.37 to 3.30)	3 (27)	0.68 (0.14 to 3.20)
Asian	1 (10)	0.27 (0.03 to 2.40)	0 (0)	
Black	10 (20)	1.11 (0.43 to 2.84)	0 (0)	
Other	1 (20)	1.55 (0.14 to 16.81)	3 (43)	0.95 (0.19 to 4.78)
Sexual orientation				
Heterosexual	49 (21)	1.00		
Homosexual	1 (50)	4.11 (0.23 to 73.35)	45 (40)	1.00
Bisexual	7 (30)	1.83 (0.65 to 5.12)	6 (30)	0.71 (0.21 to 2.34)
Clinic				
Archway	10 (19)	1.00	3 (30)	1.00
Brighton	11 (23)	1.21 (0.42 to 3.48)	22 (45)	1.40 (0.29 to 6.83)
Chelsea	12 (32)	2.48 (0.88 to 6.99)	13 (36)	1.06 (0.21 to 5.40)
Croydon	11 (17)	1.06 (0.38 to 3.00)	5 (42)	3.90 (0.41 to 37.47)
Darlington	5 (17)	1.23 (0.34 to 4.44)	0 (0)	
MMC	8 (32)	3.10 (0.94 to 10.25)	8 (36)	1.18 (0.21 to 6.70)

a Adjusted for gender, age, ethnicity, sexual orientation, clinic.
b Adjusted for age, ethnicity, sexual orientation, clinic.

Discussion

We conducted a pilot feasibility study to determine the acceptability of our intervention package, the feasibility of implementing the package and the feasibility of conducting a subsequent cluster RCT. We encountered multiple challenges in both trial and intervention feasibility, but found some evidence to support acceptability; however, we also faced challenges in collecting all the data that we had planned to use to assess acceptability and feasibility. *Table 28* summarises the pilot trial objectives and specific outcomes that we intended to collect and those that we actually managed to collect.

Intervention acceptability

The intervention package consisted of three components: the triage, the web page and the one-to-one consultation. The first step, triage, was conducted on tablet computers, with study staff asking patients on arrival to complete it before their appointment. This was a resource-intensive approach to triage and we captured only 16% of patients who attended during the pilot period, and could not reliably capture the

TABLE 28 Summary of pilot trial outcomes planned and measured

Planned objective and measure	Measurement status	Comments
Acceptability of the intervention to users and HCPs		
Proportion of eligible service users who attend the clinic who were assigned a score by the triage tool	Collected as planned (*Table 23*)	These data were collected through the tablet triage and compared with the total attendances recorded in the clinic EPR system
Proportion of those who were classified as high risk who were offered the intervention Proportion of those who were offered the intervention who took it up Proportion who took up the intervention who completed it	Partially collected (*Table 23*)	These data were collected through the table triage system and then linked to the clinic EPR system in Brighton and to paper forms in Archway. This linkage relied on HCPs asking for the triage ticket and then filling in information during the consultation, and this was incomplete for a proportion of service users, limiting our conclusions
Reasons for not completing the intervention from the qualitative study of participants	Collected as planned (*Service user qualitative feedback*)	We conducted 16 interviews with service users, identifying barriers to attending the one-to-one sessions and accessing the web page
Acceptability of the intervention from the qualitative study of the staff	Partially completed (*Health-care provider qualitative feedback*)	We conducted focus group discussions and interviews with HCPs from Archway and Brighton, and identified barriers to and opportunities for the intervention in these two settings
Feasibility of delivering the interventions		
The total time spent by service users within the clinical service compared with normal	Data not collected	We did not collect any baseline data from the clinics on attendances or duration of consultations. Therefore, we did not have anything to compare the pilot period with. We were also unable to collect data on consultation durations from the EPR system
Total number of service users seen and STIs diagnosed, compared with normal	Data not collected	
Average consultation time compared with normal	Data not collected	
Number of patients seen by HAs compared with normal	Partially collected (*Table 23*)	
Extra HCP time required for the intervention	Partially collected (*Intervention pilot*)	Health advisors were asked to record how long the one-to-one session lasted in the EPR system. These data were incomplete
Feasibility of obtaining follow-up outcome data		
Proportion of eligible service users who consented to the follow-up Proportion of eligible service users who were contactable at 6 weeks and complete a questionnaire Proportion who complete follow-up tests	Collected as planned (*Figure 16* and *Table 25*)	These data were collected by study staff and then compared with all attendances as recorded by the clinic EPR. We were unable to make this comparison for one clinic, which did not provide its EPR data

number of patients who refused to take part. However, those patients who did engage with the triage process completed it 97% of the time – this suggests that the process was acceptable and that the tablet-based self-triage was usable. This was supported by the interviews with patients, who generally found this process to be acceptable and the types of questions asked unsurprising. This is similar to the findings from other self-triage evaluations in SH that have found the process, whether using pen and paper, electronic devices or being completed online, was acceptable.[93,143] There is also evidence to suggest that self-triage could elicit more reliable information about sexual risk than face-to-face assessments.[144] However, the difference in completeness of data between the pilot and the triage development data set may have resulted in the tool

not performing as anticipated. Further work to externally validate or refine the model using different clinic populations would be required before the value of standardised implementation could be determined.

The acceptability was less consistent among health-care staff. HCPs expressed particular concern over the ability of the triage tool to identify accurately whom they perceive to be 'high risk'. At the same time, there were questions about the value of having a tool if it was identifying patients who would already be flagged as being at 'high risk'.

Although in principle the concept of a web page was acceptable to patients and providers, engagement with the intervention web page was extremely limited, demonstrating a disconnect between acceptability and uptake. This may have been because of the short period for the pilot, so that it had not been well embedded into the operation of the clinic. However it is a common theme in internet-based digital interventions, with effectiveness closely linked to engagement and reach,[28] and more methods for sharing the web page with patients could have been employed.[145]

The one-to-one session was commented on by both patients and providers, suggesting that this was an acceptable approach, although this was not based on first-hand experience for most of the participants. Of those who should have been referred for the one-to-one intervention, only 18% were recorded as having completed it, which raises questions about actual acceptability. Not all HAs who delivered the one-to-one sessions were positive about them. Some considered it to be something that they already did and, therefore, questioned the need for the manualised approach. This would probably cause challenges in terms of fidelity of delivery of the implementation across services and individual providers, if HAs considered the intervention only a reinforcement of their current practice.

Intervention feasibility

We were unable to collect our originally proposed metrics for intervention feasibility (*Table 28*); however, we collected several different types of data about the ability and willingness of clinics to pilot the intervention package. We had planned to pilot in four clinics and specifically aimed to engage a level 2 service. Although Brook agreed to the pilot and gave high-level support for the project, we encountered several practical limitations and were ultimately unable to include them. These barriers were mainly related to resources rather than to the acceptability of the structure of the intervention. Similarly, the two London GUM clinics agreed to the pilot but were unable to implement it. They raised significant issues with staffing and clinic space. In order to conduct a trial in these settings, resources would need to be provided.

Brighton was able to implement the intervention package, mostly within existing clinic resources, suggesting that not all SH services are experiencing the same level of resource constraint. In Brighton, members of clinical staff (including a HA) were part of the PMG, and this continued engagement may have been one of the reasons for engaging with the pilot. In a large cluster RCT it would be essential to engage both management and health-care staff at potential sites to improve the chance of the trial being successful.

Although incorporating the triage tool in the EPR systems in Brighton and Archway was theoretically possible, we were unable to demonstrate feasibility (and therefore acceptability) of this approach within the timescale and resources of this study. This limited our ability to monitor process data on the number of patients triaged, referred and who attended. It also made the patient pathway less seamless, with HCPs needing to be engaged enough with the intervention to ask patients for their triage slip and then refer them to a HA if indicated. We had envisaged that the EPR systems would run the triage without prompts and then inform the HCP during the consultation of the result, without the provider needing to remember. We are unable to comment on whether or not this approach would have improved provider engagement with the intervention process; however, the system piloted would not support a larger trial.

Trial feasibility

We worked on the premise that a full trial would be cluster randomised and powered to detect a reduction in STI diagnoses. In order to test the feasibility of this trial design, we recruited a subset of

patients from intervention and control sites to be followed up 6 weeks after recruitment. We did not recruit the 700 planned patients, partly because of our inability to engage with all eight clinics we had originally planned. However, we also recruited fewer patients within clinics for a range of reasons. For example, some patients were ineligible because they were in the country only temporarily, whereas others lived with their partner or parents and did not want to share their contact information in case this resulted in accidental disclosure of their clinic attendance.

In addition, of those who did consent to be followed up, return rates for both the web survey and STI screen were lower than we had projected. Approximately one-third of participants engaged with the follow-up process, and there were differences in the characteristics of those who engaged. MSM were more likely to engage than young people, heterosexual women were more likely to engage than heterosexual men and older MSM were more likely to take part than younger MSM. In a trial, these differences could bias the primary outcome. In addition, there were differences in both recruitment and follow-up rates between clinics, with Croydon having lower follow-up rates in young people but higher rates in MSM, after adjusting for other factors. This suggests that there may other factors involved that we have not captured. In a cluster randomised design it would be important to understand how clinic features influenced both the trial implementation as well as ascertainment of the primary outcome. These pilot data suggest that this could be problematic.

Strengths and limitations

A key strength of the pilot was the inclusion of clinics from different geographical locations, with different patient characteristics and risk behaviours. This meant that data, although limited, were likely to include different perspectives and experiences from both HCPs and patients. We were able to pilot the intervention package effectively in only two clinics, which is also a limitation. As the clinics implemented the intervention differently, we are unable to directly compare their experiences or generalise to SH services in England, considering the diversity of standard practice observed across services. In particular, we were unable to draw conclusions about trial feasibility and intervention acceptability in level 2 services.

The interviews and focus group discussions with patients and HCPs included some participants who had not had any interaction with the intervention package, or had not realised that they were part of an intervention. Therefore, some of the views expressed were more theoretical than based on experience. We were aiming to understand the barriers to delivering the intervention, and the reasons for the intervention being acceptable or not. Although some participants provided concrete examples from their experience, many were able to provide opinions based only on a description of what was offered.

We recruited a large number of participants to the follow-up study, albeit fewer than planned (406/700), meaning that the descriptive analyses lacked power. We found very few statistically significant factors associated with completing follow-up. Similarly, with only two clinical services implementing the intervention pilot, it is not possible to fully understand the potential differences between clinic types.

Conclusion

We were able to pilot the intervention package and recruit patients to be followed up for a STI screen 6 weeks after their visit to a SH clinic. However, we observed considerable barriers both to implementing the intervention and conducting the follow-up. These implementation barriers included the inability to recruit a level 2 service to take part in the pilot, not being able to adapt an EPR system to include the triage process and a lack of trained staff time to deliver the one-to-one session. The 6-week follow-up suffered from lower than expected recruitment and completion rates, although differences in the types of patients who completed follow-up were noted. These differences could influence interpretation of the results of a trial powered for STI outcomes. In spite of these challenges, we found that the intervention was generally perceived as acceptable.

Chapter 7 Work package 6: determination of the feasibility of a randomised controlled trial, and further recommendations

Introduction

The systematic review (WP1) confirmed that there are several interventions that have shown modest but significant effects on sexual behaviour and STI outcomes. Both service users and service providers expressed a preference for one-to-one and digital interventions. Clinics indicated that these types of interventions have been, or could be, feasibly delivered within their settings. The specification and manualisation of the one-to-one intervention, which required more development work than expected, was nonetheless completed, and pre-trial evaluation by service providers and users was positive. However, attempts to execute a pilot trial highlighted major service-level feasibility challenges. Implementing the triage tool, albeit not in its fully developed form because of insufficient data being available to refine the model, was hampered by unresponsive and inflexible IT systems and support. But the biggest challenge was the inability of services to deliver. This can be summarised as being caused by a combination of 'bad timing' and a service provision environment undergoing unprecedented upheaval, with an almost universal demand from commissioners that providers accommodate a reduction in funding for services.

Work package 6 was designed to include the development of an outline protocol for a cluster RCT, based on the elements developed and tested in the Santé project to that point. However, in the light of the findings of the pilot, our conclusion is that the postulated cluster RCT as a whole is not feasible at the current time. Nonetheless, there are important outputs from the project that could lead to the implementation and evaluation of an important public health intervention.

Method

The data from each of the work packages were reviewed and synthesised by the PMG and a consensus was arrived at regarding the feasibility of a RCT. Discussions on the data collected related to the intervention package acceptability and intervention and trial feasibility. Conclusions in respect of each of these were agreed and presented to the PSC and PPI groups for input and feedback.

Results and discussion

One-to-one behavioural intervention

Throughout the project there was support from SH service users for behavioural interventions, and more specifically for HCP-based talking interventions. This is consistent with the framework published by the DHSC,[6] which prioritises prevention through behaviour change, alongside access to sexual and reproductive health services. Brief one-to-one sessions are already a recommended activity within SH services, and, therefore, our intervention package could capitalise on existing best practice by providing an evidence-based structured intervention. However, despite being supported by providers and desired by patients, there was limited engagement with the one-to-one intervention in the small number of settings in which it was trialled, and there was resistance from clinics to implementing the pilot because of a lack of resources. As a result, we did not obtain as much evidence for the feasibility of delivery as we had hoped. Any future trial or implementation should include a further pilot of the acceptability and feasibility of delivery, and consider the costs of delivery and potential cost–benefit.

Digital intervention

The concept of a digital intervention was popular with service users and providers. The systematic review identified a number of digital interventions for which there was at least some evidence of efficacy; however, there was none that could be included in the pilot. The interventions were unavailable for a variety of reasons including licensing issues, being offline or in non-current format, or being out of date or culturally or linguistically inappropriate. We used a placeholder to try to measure potential engagement, but other aspects of the pilot trial implementation limited the utility of available data.

A digital intervention places the least demand on clinic resources. We postulated that the digital intervention would be the best option in terms of deliverability for the majority of service users who are at lower risk. There is still a need to demonstrate that it could be delivered and engaged with by a sufficient proportion of those at risk to have a population-level impact on STI rates.

Triage tool

The analysis of GUMCADv3 data led to a predictive model that could be implemented as an automated triage tool. The work in WP2 demonstrated that such a tool is feasible and, with further behavioural data, easily refined so as to improve its performance. Implementing the tool for the pilot was not optimal, requiring alternative methods of data collection that were less robust and more demanding of resources, at least in the short period available for the trial. Although there was scepticism from some service providers, others could see the value of a systematic evaluation of risk that could also be used to direct users to different STI screening pathways. It could also be easily adapted for use in conjunction with online access to STI testing. The wider application of this technology means that it is more likely to be supported and prioritised for implementation.

We found this to be contradictory, as the pilot provided an opportunity to generate an evidence base on the value of these types of interventions, which could then be used to support their continued implementation and commissioning. We found that the role of HAs differed between clinics, and that many of these differences were the result of local commissioning decisions, rather than based on local patient needs or staff skills. In order for our intervention package to be successfully delivered within SH clinics using existing resources, a commitment from commissioners to support these sorts of services would be required. However, we were unable to generate the evidence that commissioners would probably need to make the decision to support these services. This is a considerable issue if research into behavioural interventions in SH services assumes a certain level of existing resources.

Randomised controlled trial feasibility

Overall, based on the experience of trying to implement the pilot and the data collected, we concluded that trialling this intervention package using a cluster RCT approach is not feasible in existing SH services. Of the several factors identified, some could be mitigated if funding for the intervention delivery was met by the trial (including the HA and clinic staff time, adaptation of the digital intervention and implementation of the triage tool in clinic EPR systems). However, as the intervention effect size would still be likely to be small, the cost-effectiveness may still rely on delivering the eventual service within existing resources. With the immediate constraints on resources for SH services nationally, the case for prioritising this prevention strategy is difficult to make without the evidence for the very study that cannot be delivered.

Other concerns with conducting a cluster RCT were highlighted. First, we found considerable variability in services, in terms of their current resources (which was particularly apparent with clinics going through recommissioning and the impact that this had on their resourcing), patient pathways and interventions that they currently offer. This was an issue for multiple reasons:

- Standardising clinic pathways and services to the degree required for a trial would be challenging, meaning that local adaptations to the intervention package would probably be needed. The inability to ensure standardised implementation would undermine the evaluation.

- The intervention may not be sufficiently different from standard care to demonstrate any intervention effect, as many clinics currently offer some form of one-to-one session or refer patients to online resources. As control sites would need to be able to offer their current minimum standard of care, a well-resourced control clinic with MI-trained HAs may not be materially different from an intervention clinic.

Second, there were concerns about whether a standardised triage tool, developed using national-level data should be applied in all clinic settings. We found a higher proportion of high-risk patients in the pilot sites than had been seen in the data set used to develop the tool. This is not surprising, as the proportion of MSM, for example, attending clinics varies substantially. If only a fixed, and small, proportion of patients can be offered the one-to-one intervention, there could be substantial inequality in who is offered the intervention package between services, or unfeasible numbers of patients requiring intervention in some clinics. This could have an impact on the overall effect of the intervention at each of the clinics and have significant design implications.

Third, the rate of follow-up completion was much lower than would be needed for a trial, and there were differences in those clinic attendees who agreed to take part and those who completed the STI screen compared with those who did not. This suggests that the primary outcome measure in a cluster RCT could suffer from material biases.

Finally, we encountered significant research and development barriers during the project, which resulted in delays to starting the pilot study, and this may have been one reason for the resulting poor engagement from clinics. Certainly the available time to complete the pilot was reduced and it was not possible to accommodate, for example, postponing implementation of the pilot until after a clinic moved, or a new IT system was implemented. During the period of the project, the process for gaining national and local ethics approvals changed, with the new system aiming to decrease the amount of local approvals required for multisite projects. However, our experience of the process did not reflect this, with each pilot site required different documentation, checks and time to process. These delays also affected sponsor approval. Overall, it took 9 months to complete the research and development process for the pilot, which involved liaising with only five NHS trusts. A large cluster RCT would require considerably more clinics to be involved, and, at present, delivering that represents a risk to the project. Any delay would also incur research staff costs and run the risk, as in this pilot, of a clinic no longer being able to deliver the intervention during this period.

Alternative designs

We had initially planned that any large trial for the intervention package would need to be cluster randomised, because the intervention required a service-wide change in clinic practice and procedure. However, as we determined that there were significant difficulties with this design, several related to the clusters themselves, two alternative designs were considered, which do not rely on cluster-level randomisation.

Individual randomisation

Elements of the intervention package could be well suited to individual randomisation, such as the triage being randomly applied to different patients. However, there are still concerns about contamination between the intervention and control patients because of the service-wide nature of the intervention. Employing study staff to deliver the intervention could mitigate this risk but would have cost implications, and this implementation method would need piloting.

Step-wedge roll-out

As the intervention package was in principle acceptable and used evidence-based elements, the intervention package could be routinely implemented within clinics, if commissioners agreed to support it. A stepped-wedge trial, which did not involve randomisation or the need for the level of standardisation that a RCT would require, could allow for some adaptation of the intervention within each clinic. If this was combined with changes to GUMCAD, as currently being implemented for the Impact trial of HIV

PrEP,[146] then the outcome measures could be collected as part of routine data collection. This would allow for an evaluation of real-world implementation. However, this approach would be unable to establish the effect size, and requires funding agreement from commissioners.

We did not conclude that either of these alternative designs would be feasible for a trial within existing resources. Either would require additional developmental work and piloting.

Further developmental work and recommendations

To realise the potential to implement the intervention package, or elements of it, there are key areas that require further development.

Digital intervention

A digital risk reduction intervention would need to be developed or adapted from one of the trialled interventions for which materials are available. Following the development process, additional piloting work would be needed to improve and incentivise engagement, for example in terms of the processes used in the pilot (e.g. specific text message promotion).

One-to-one session

One concern with the one-to-one session, which was supported by our pilot work, is that because it is similar to HA's current practice there may be issues with intervention fidelity. Furthermore, different SH providers have different levels of training. Some MI training is required, but it is not universally provided, even to HAs. Extensive training was considered unfeasible within current clinics' resources for the pilot. We designed the training to be pragmatic within existing clinic resources, assuming a baseline level of MI experience among staff, which was not always found. Additional work would be needed to evaluate how well this training module could be implemented, the gaps it would leave and how well those HCPs implemented the intervention session, rather than defaulting to their usual practice.

Electronic patient record-based triage tool

Although implementing the triage tool within clinic EPRs seems feasible, we were unable to actively demonstrate this within the pilot. A key challenge in this was communicating how the triage should be presented in the front end of the system (i.e. what the HCP interacts with). Therefore, further work that includes the participation of clinical staff and engages with multiple different EPR providers would be needed. An important aspect of this would be how to standardise, to a sufficient level, both the ways in which the data are captured and processed and the end-user experience. In addition, further work on the external validation or refinement of the triage tool is needed, using more complete data to demonstrate whether it could be usefully rolled out either in clinics or in online pathways.

Follow-up

Because of the relatively poor follow-up rates, further investigation and piloting of different methods (e.g. telephone call reminders) and potential incentives (e.g. vouchers for samples returned) to improve follow-up rates would be needed. Specifically, these would need to assess whether heterogeneity in follow-up increased or decreased by location and type of clinic, as well as the service user demographics.

Economic evaluation

We had intended to estimate the cost of delivering the intervention package as part of the pilot trial but were unable to collect the data we needed to do this. At the outset, it was envisaged that the intervention would be delivered within existing resources by reallocation of staff time, in particular from existing work with patients. As such, an economic analysis might be less useful. However, it was clear that, to deliver the intervention, existing resources were not sufficient and an economic evaluation is needed. One of the main barriers we faced in conducting the pilot trial was delivering the one to one, and having a clear understanding of what resources a clinic would require to deliver the intervention package could have improved our ability to make conclusions on feasibility.

Dissemination

Further communication between service providers, commissioners and service users is needed if the proposed intervention approach is to be trialled or undergo further piloting. A barrier we faced was the disconnect between service providers' and users' preference for risk reduction and what commissioners were prioritising for funding. We plan to disseminate the findings from this project to both service providers and commissioners, through this report, academic publications and conference presentations, to encourage this communication.

Chapter 8 Conclusion

Summary of main findings

Our key findings from this feasibility study were as follows:

- Evidence-based brief behavioural interventions that could be appropriate to SH clinics in the UK are available, but there are considerable barriers to the implementation of sustainable digital interventions and additional infrastructure would be needed if this approach were to be pursued. A more intensive, but still brief, one-to-one intervention based on the results of published trials was specified and could be deliverable.
- Both HCP-delivered talking interventions and online interventions were more desirable than other intervention formats, and were considered acceptable to providers and patients during piloting. However, the assessment of acceptability was limited in the project because of limited implementation.
- Risk of a STI diagnosis could be predicted with reasonable accuracy using a limited number of routinely collected demographic and behavioural data; however, this approach to triage was met with contradictory opposition by some HCPs and EPR software providers. The acceptability of conducting self-triage by patients could provide opportunities in the context of online patient pathways.
- During the course of the project, recommissioning and reductions to SH clinic resources and staffing resulted in considerable challenges to involving clinics in the pilot. This was especially pronounced in level 2 services, which, despite high-level support and interest in the project, were unable to take part. Plans for future work in this area will need to consider the full resource implications of implementing and evaluating brief behavioural interventions.
- Participant recruitment for a 6-week follow-up demonstrated biases in those who agreed to participate and those who completed the follow-up, raising concerns about the ability to conduct a large-scale trial with STI outcomes. Different approaches to incentivising participants should be considered going forward.

Overall conclusion

We conclude that a cluster RCT of the Santé intervention package would be very difficult to undertake in SH services in England at the present time. However, we are limited in our ability to draw a more definitive conclusion on feasibility, primarily because of the smaller than expected number of services that took part in the pilot study. In the literature review we found RCTs of behavioural interventions that had been successfully undertaken. However, a large-scale pragmatic cluster RCT could be delivered only if the resources were available for the interventions. At the time of this study, resource limitations and major service reconfigurations meant that there were neither the resources nor the necessary service engagement to deliver such a trial.

With limited resources and service reorganisation, there is a shift in the focus of commissioning away from face-to-face consultation and towards self-testing and online patient pathways. Although there is agreement that there is a need for behavioural interventions, including one-to-one sessions for the highest risk groups, the heterogeneity of services means that the design and implementation of a large-scale national trial would be challenging. Digital interventions could be implemented in conjunction with new care pathways for STI testing, but these have not been widely commissioned. Further developmental work is required to see how behavioural interventions can be incorporated into the new models of service delivery. Alternative evaluation designs are likely to be required to provide evidence of efficacy and cost-effectiveness at that point.

This project has wider lessons for SH services. We found that both staff and patients valued the human interaction of one-to-one consultations, with patients particularly concerned that services should be tailored to their specific and varied needs. Reducing the flexibility of the response in SH services and replacing it with standardised online pathways may risk disengaging patients and reduce the opportunity to exploit teachable moments in the clinical setting. On the other hand, lower-cost alternative models of service delivery for the majority of low-risk patients may lead to resources being released for the delivery of more intensive behavioural interventions for those most at risk. Online and remote testing models will provide an opportunity to exploit digital interventions, although, as we found, these will require further development.

The recommissioning and service reorganisation that coincided with the period of this study was a considerable barrier to effective piloting of the intervention package. Further development of the proposed intervention package and a commitment to funding the intervention during its evaluation would be required if the potential for this approach to reducing STI rates is to be realised.

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Carina King (Senior Research Associate, Infectious Disease Epidemiology) was the overall project co-ordinator, responsible for the day-to-day running of the project. She led the write-up of the final report.

Carrie Llewellyn (Reader, Applied Behavioural Medicine) was the co-chief investigator, leading WP4 and substantially contributing to the overall design and delivery of the remaining work packages.

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Andrew Copas (Reader, Statistics) was a co-investigator and the project statistician. He contributed to the overall study design and WP5 design, and contributed to the remaining WPs.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 MEDLINE search strategy (work package 1)

1. exp Health Promotion/
2. exp Health Education/
3. exp Sex Education/
4. exp Preventive Health Services/
5. exp Preventive Medicine/
6. exp Primary Prevention/
7. Public Health/
8. exp Social Medicine/
9. exp Behavior Therapy/
10. exp Health Behavior/
11. exp Sexual Behavior/
12. exp risk reduction behavior/ or exp risk-taking/ or exp condoms/
13. exp unsafe sex/
14. exp safe sex/
15. exp sexual abstinence/
16. exp Sex Education/ or exp sexology/
17. ((prevent$ or reduc$ or educat$ or promot$ or increas$ or decreas$ or facilitat$ or barrier$ or encourag$) adj2 (sex$ or HIV or STI or STIs or STD$)).ab,ti.
18. Attitude to health/ or health knowledge, attitudes, practice/
19. OR
20. exp Sexually Transmitted Diseases/
21. exp chancroid/ or exp chlamydia infections/ or exp lymphogranuloma venereum/ or exp gonorrhea/ or exp granuloma inguinale/ or exp syphilis/
22. exp HIV infections/ HIV*.ti,ab. /acquired immuno deficiency syndrome/ Acquired Immunodeficiency Syndrome/
23. Herpes Genitalis/
24. Condylomata Acuminata/
25. (HPV or human papilloma$).ab,ti.
26. ((genital or venereal) adj2 wart$).ab,ti.
27. (STI or STIs or STD or STDs).ab,ti.
28. (Sexual$ transmit$ adj3 (infect$ or disease$)).ab,ti.
29. OR
30. exp Adolescent/
31. (young$ adj2 (men or man or woman or women or female$ or male$ or people or person)).ab,ti.
32. (teenage$ or adolescen$ or youth or youths).ab,ti.
33. exp men/
34. ((gay adj2 man) or men).ti,ab.
35. (men$ adj6 men).ab,ti.
36. OR
37. 19 and 32 and 39-41. randomized controlled trial.pt.
38. controlled clinical trial.pt.
39. random$.ti,ab.
40. control$.ab,ti.
41. (effectiveness or trial).ti.
42. placebo.ab,ti.
43. one to one intervention$.ti,ab.
44. intervention$.tw.
45. ((control$ or experimental or compar$) adj2 (Group$ or trial$ or study or studies or evaluat$ or condition))

EME
HS&DR
HTA
PGfAR
PHR

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