

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

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Scientific summary

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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.

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