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The clinical effectiveness of behaviour change interventions to reduce risky sexual behaviour after a negative HIV test in men who have sex with men (MSM): a systematic review

Contact name and numbers

Sponsor	**Institute Director, Institute for Applied Health Research**
Principle Investigator	Professor Paul Flowers Professor of Sexual Health Psychology Institute for Applied Health Research School of Health and Life Sciences Glasgow Caledonian University Cowcaddens Road Glasgow G4 OBA Phone: +44 (0)141 331 8617 **Email: P.Flowers@gcu.ac.uk**
Co-Investigators	Professor Olivia Wu, Glasgow University Olivia Wu (Olivia.Wu@glasgow.ac.uk) Dr Dan Clutterbuck, Chalmers Centre (daniel.clutterbuck@nhs.net) Dr Karen Lorimer, Glasgow Caledonian University (K.Lorimer@gcu.ac.uk) Professor Sharon Hutchinson, Glasgow Caledonian University (Sharon.Hutchinson@gcu.ac.uk) Professor Lawrie Elliott Napier University (l.elliott@napier.ac.uk) Dr Lisa McDaid Glasgow University (lisa.mcdaid@glasgow.ac.uk) Dr Ann Sullivan, Chelsea and Westminster Hospital NHS Foundation Trust (ann.sullivan@chelwest.nhs.uk) Dr Michael Rayment, Homerton University Hospital, NHS Foundation Trust, (michaelrayment@nhs.net)

List of Abbreviations

Abbreviations	Explanation
AIDS	Acquired immunodeficiency syndrome
ART	Anti-retroviral treatment
BCT	Behaviour change techniques
CCT	Controlled clinical trial
HAART	highly active antiretroviral therapy
HIV	Human immunodeficiency virus
MSM	Men who have sex with men
PLWHIV	People living with HIV
PrEP	pre exposure prophylaxis
RCT	Randomised controlled trial

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Background and Rationale

New diagnoses among MSM in the UK have been increasing since 2007 with 3,010 reports in 2011 (48% of all new diagnoses), representing an all-time high (HPA 2012). Annual UK population treatment costs in 2006 were £483 million, rising to £683 million when taking into account community care costs (Mandalia et al., 2010). Average annual treatment costs across all stages of HIV infection in the UK in 2006 ranged from £18,087 for people living with HIV (PLHIV) on mono-therapy, to £32,322 for those on quadruple-or-more antiretroviral therapies (ART); projected annual cost were between £721 and £758 million by 2013 (Mandalia et al., 2010). It has been estimated that each infection prevented would save between £280,000 and £360,000 lifetime treatment costs (HPA 2011). Transmission of HIV among MSM is on-going in the UK, and remains substantial. Within the last year new biomedical approaches to prevention, such as pre exposure prophylaxis (PrEP) have become available to negative MSM in the USA, and in the UK it is proposed that home testing for HIV will be legalised in early 2014. These advances in biomedical HIV prevention have reinvigorated behavioural approaches to HIV prevention.

There is clear evidence-based guidance available concerning the need and general scope of individual-level behavioural change interventions, much of it produced by the project team (e.g., Clutterbuck et al., 2012; Flowers et al., 2012). There is a systematic review evidence base, which has assessed the effectiveness of behavioural approaches to HIV prevention (e.g., Herbst et al., 2007, Johnson et al., 2008, Berg 2009), and this indicates 'what works' – the overall effectiveness of interventions at reducing risks for HIV when compared with usual care (Sullivan et al., 2012). Many of these reviews analysed the effectiveness of interventions delivered at the individual level, which on the face of it seems to suggest there is no current need to repeat these analyses, particularly if there have not been high quality up-to-date published trials since 2008 that would warrant a re-run of these searches and review update. There are, however, a variety of gaps and recent innovations that suggest an up-to-date evidence synthesis is now warranted.

Firstly, there is a lack of very specific direction concerning which interventions, or which elements of effective interventions, should be employed therein (Lorimer et al., 2013). Within the field of HIV prevention amongst MSM there is a history of analysing the effectiveness of interventions according to gross categories of delivery method (e.g., group based vs. individual level) rather than examining the components that moderate intervention effects. For example, Herbst *et al.,* (2007) systematically reviewed the effectiveness of individual-, group- and community-level HIV behaviour change interventions for adult MSM, and included four studies of individual-level interventions with 4,689 participants. The review indicated the effectiveness of individual-level behaviour change interventions for HIV prevention, but it, along with others (Herbst et al., 2005, Johnson et al., 2008, Berg 2009), fails to elucidate what works best, in which context, how and with whom. They also include evidence from pre-1997, prior to the introduction of antiretrovirals (for example, 24 of the 44 interventions included in a 2008 Cochrane review were conducted pre-1997; Johnson et al., 2008). The widespread availability of highly active antiretroviral therapy (HAART) from 1996/97 transformed the meaning of HIV infection from fatal disease to a chronic manageable condition (Flowers et al., 2001), radically changing the perceived severity of HIV and calling into question the transferability of evidence across the history of the epidemic.

Secondly, there is also little information concerning the viability of exploring a range of intervention delivery options, or the use of interventions within the growing range of settings in

which HIV testing is now offered. Although, evidence is beginning to filter through: exploratory research suggests acceptability towards rapid HIV testing at home (Chen et al., 2010); a review is currently underway exploring the effect of modifiers (e.g. location of testing, population, link to treatment etc.) on rapid HIV testing and treatment outcomes (Pottie et al., 2011); and a report that non-clinic approaches to HIV prevention interventions, involving the Internet, are as efficacious as face-to-face approaches (Noar et al., 2009), but this is a rapidly changing landscape in which evidence is quickly outdated (for example, as MSM move from using one website to another, affecting feasibility and acceptability assessments of interventions, particularly for those operating within the MRC's guidance on developing complex interventions adhering to each step; Craig et al., 2008).

Thirdly, the National Institute for Health and Care Excellence (NICE) guidelines regarding HIV testing are increasingly dated and do not go far enough in terms of specifying details of behavioural interventions (NICE 2011). These reasons may, in part, help explain the current poor provision of behavioural interventions to MSM reporting significant levels of HIV risk within the UK (Desai et al., 2013).

Fourthly, we believe there is an historical imperative to restrict our focus on intervention studies conducted after ART became widely available in the UK, hence altering the context in which an HIV diagnosis may be seen by an individual (i.e., a radical shift to a manageable chronic condition) and the subsequent major changes in HIV testing policy and behaviour in the UK, which followed circa 2000.

Below we detail how our initial scoping review suggests the need for a review process which balances scientific rigour with a pragmatic focus upon the need for clear direction in terms of intervention development. We argue that, given the current state of the available evidence synthesis and the urgent need for more specific guidance tailored to an ever more complex world of HIV prevention and HIV risk-related behaviour, we need both an inclusive focussed mixed method evidence review and a team of subject experts to identify candidate interventions.

Rationale for a focus on behaviour change techniques

Behavioural change techniques are described as '*the smallest component compatible with retaining the postulated active ingredients that is, the proposed mechanisms of change, and can be used alone or in combination with other BCTs'* (Michie and Johnson, 2012, p3). There is growing evidence of the feasibility and value of using BCT taxonomies to review behaviour change interventions (e.g., Michie et al., 2009). Within the field of HIV prevention amongst MSM there is a history of analysing the effectiveness of interventions according to gross categories of delivery method (e.g., group based vs. individual level) rather than examining the components that moderate intervention effects. Heterogeneity within pooled outcome data is also commonly reported (e.g., Avenell et al., 2004) suggesting the need for much more detailed analysis of intra-intervention factors. To date there has been very little domain specific developments of BCTs in relation to HIV risk reduction and no specific examination of the literature regarding MSM and HIV risk behaviours (the SHARP-ICCS taxonomy focussed upon general populations and condom use; Abraham et al., 2011). We propose to extract all the available data concerning the role of BCTs within the existing evidence of effectiveness of individual level interventions amongst MSM which address HIV risk reduction rather than condom use alone (see inclusion criteria and outcome section below). We propose to conduct a series of further analyses to elucidate new and useful knowledge for further research and intervention development. These are concerned with the associations of the number, clustering and role of individual BCTs with effectiveness, the role of theory in relation to effectiveness and, given the growing evidence from other domains that interventions using BCTs predicted by theory are more effective than those that are not we propose to examine whether theory

congruent BCTs are more effective than those which are not (Dombrowski et al., 2012, Taylor et al., 2012).

Research aim and objectives

Research question: What is the clinical effectiveness of behaviour change interventions to reduce risky sexual behaviour after a negative HIV test in men who have sex with men (MSM)?

The specific objectives are to:

- Conduct a systematic review of the effectiveness of behaviour change interventions to reduce risky sexual behaviour after a negative HIV test in MSM;
- Conduct a network meta-analysis to assess which particular component or components: (1) the mode of delivery, (2) the number of BCTs, (3) the type of BCTs and (4) theory-congruent clusters of BCTs, are effective in reducing HIV risk related behaviour;
- Organise and host an expert event to enable the synthesis and translation of findings.

Research Plan

Design and theoretical/conceptual framework

The research is an evidence synthesis, which will consist of a systematic review, meta-analysis of direct, indirect and networked evidence with embedded BCT taxonomy and theory coding analyses (details below). By using network meta-analysis, multiple comparisons (of interventions or components of interventions) can be compared simultaneously in one analysis, while preserving the randomised structure of the evidence (Welton et al., 2009).

Health technologies being assessed

The specific health technology focus of this proposal is individual motivational behaviour change interventions, and their component parts (i.e., BCTs), offered in HIV testing, to MSM who test negative. They can be brief individual, single or multisession, delivered anywhere, in any modality. Particular attention will be paid to any control groups (no interventions, standard of care, alternative interventions), modes of delivery, dose effects, and to the risk assessment criteria applied for inclusion, in order to inform the design and application of candidate interventions.

Thus, given the complexity of the field in relation to established and concurrent technologies we propose to focus within the evidence pertaining to individual level interventions alone and to focus on the rigorous extraction of novel information within this literature.

Study eligibility criteria

Types of population

MSM of any age, ethnicity, who have tested for HIV and received negative results. Studies that focus exclusively on commercial sex workers; trans people; victims of sexual or domestic abuse or violence; intravenous drug users; those in prison, psychiatric facilities or nursing homes; or individuals with no fixed address will be excluded as these groups have distinct needs beyond the scope of the review. Following Johnson et al., (2008) we will include only

studies in which MSM constituted at least one-third of the study sample (e.g., HIV-seronegative) or were specifically targeted by the intervention. When other populations are included, we will either obtain outcome data for the MSM subset or reduce the study weight to reflect only the proportion who were MSM.

Types of intervention

Individual-level, motivational interview-based interventions designed to promote sexual risk reduction and thereby to reduce transmission of HIV. There will be no restriction on the type of intervention setting or mode of delivery or MSM population (e.g., recreational drug/alcohol users).

Brief*, individual-level behaviour change interventions aiming to reduce HIV risk related behaviour that assess the effectiveness at follow-up at least once from baseline will be considered. Particular attention will be paid to examining dose effects and the numbers of times that interventions are delivered.

**We define brief as any therapeutic or preventive consultation of short duration (one to five sessions) undertaken by a health-care professional, general practitioner, nurse or other trained professional. We will consider even the briefest interventions (e.g., 30 min) as long as they meet the inclusion criteria.*

Outcomes – all short, medium and long-term outcomes:

- Behavioural – approaches which are known to reduce the risk of HIV acquisition; condom use across all time periods; approaches such as negotiated safety; the uptake and adherence to PrEP; or combinations of the above;
- Biological - HIV/STI incidence;
- Learning - HIV/STI knowledge; condom application skills;
- Cognition - condom use self-efficacy; condom-related attitudes or beliefs; HIV/STI risk perception; negotiated safety self-efficacy, PrEP self-efficacy;
- Economic – All outcomes relating to cost-effectiveness analysis (e.g., costs; outcomes relating to health benefits such as quality adjusted life years, life years, or disability adjusted life years).

Types of study

We will include randomised controlled trials (RCTs) for evidence of effectiveness and economic evaluations for evidence of cost-effectiveness (including cost-effectiveness, cost–utility and cost–benefit analyses).

Studies with the following control conditions will be eligible for inclusion in the review:

- Participants were on a waiting list to receive the intervention under study;
- Participants continued to receive 'usual care';
- Participants received a lesser dose or only some of the core components of the intervention under study (minimal intervention);
- Participants received an entirely different intervention from that under study.

Study design - All comparative studies comparing two or more interventions, i.e., RCTs or controlled clinical trials (CCTs) will be considered for inclusion in the review. In addition, all economic evaluations (e.g., cost-effectiveness analysis; cost-utility analysis; cost benefit analysis) will also be considered.

Search Strategy

Existing search strategies from previous guidelines and systematic reviews will be examined and a revised strategy will be developed through consultation with a subject librarian. We anticipate a four-part search strategy: firstly, we will search electronic bibliographic databases for published work (these will include CINAHL, Cochrane Library, Embase, MEDLINE and PsychINFO); secondly, we will search "grey" literature for work that is not published in books or journals (e.g., recent conference abstracts or CDC websites); thirdly, we will search trials registers for ongoing and recently completed trials, and; finally, we will search reference lists of published studies, conduct citation searches of key studies (tracked through Web of Science), contact the authors of included studies for further information where necessary (for example, training manuals, intervention manuals, detailed descriptions, fidelity measures), and seek input from the project advisory group. All databases will be searched from 2000; no language restrictions will be applied.

We will develop a sensitivity-maximising search strategy to locate relevant studies, but will employ a sensitivity- and precision-maximising version instead if the former retrieves an unmanageable number of references (Glanville et al., 2006). Relevant search filters, for specific study designs, identified by the InterTASC Information Specialists Sub-Group (ISSG) will be incorporated into the search strategy (https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/home/search-filters-by-design). The specifications of the electronic search will involve controlled vocabulary (e.g., MeSH or indexing terms) and keywords in four areas: (1) HIV, AIDS, or sexually transmitted disease (infection); (2) prevention research methods (e.g., intervention, evaluation, education); (3) sex risk behaviours and biological outcomes; and (4) target population (e.g., MSM).

Inclusion and exclusion criteria will be applied successively to titles and abstracts by one reviewer. Full reports will be obtained for those studies that appear to meet the criteria or where there is insufficient information from the title and abstract. Full reports will be assessed by two reviewers independently. Disagreements will be resolved through discussion and recourse to a third reviewer if necessary (the lead applicant or one of the co-applicants). A PRISMA-style flow chart will be used to document the numbers of studies included and excluded at each stage of the review.

Data Extraction and Assessment of Risk of Bias

We will extract data from all full text studies that fulfil the inclusion criteria. Any further discrepancies will be resolved by discussion or by adjudication by a third reviewer (the lead applicant or one of the co-applicants).

A standardised framework will be devised, and data extraction will be undertaken by one reviewer and checked by a second reviewer. We will describe all studies that meet the inclusion criteria, in terms of:

Study design: Trial design and quality, data collection methods, modes and techniques; validity of tools; adherence to protocol (we will attempt to retrieve protocols from searches, including by contacting authors); statistical and other analyses.

Participants (intervention and control): Demographic characteristics (e.g., age, ethnicity)

Intervention: Setting and recruitment methods; components of the intervention (including BCTs employed), details of modes of delivery and any other aspects of content; frequency, intensity

and duration of the intervention; theoretical framework employed in intervention design (see below)

Outcomes – all short, medium and long-term outcomes (described above). Data from intention to treat analysis will be preferred over results from analysis of completers only.

Cost-effectiveness outcomes – all data relating to cost-effectiveness analysis will also be recorded. This will include the type of economic evaluation undertaken (i.e. cost-effectiveness analysis, cost-utility analysis, or cost benefit analysis) and a description of the model used. In addition, intervention costs, incremental cost per HIV infection averted, incremental cost per quality-adjusted life years (QALY) saved, or incremental cost per disability-adjusted life years (DALY) saved for each intervention compared with the comparator will also be recorded.

The risk of bias in individual studies will be assessed using the Cochrane Collaboration's risk of bias assessment (Higgins et al., 2011). The Cochrane assessment requires a judgement to be made by the review authors on the likely risk of bias arising from trial design: methods of randomisation sequence generation and allocation concealment; blinding; adequate assessment of incomplete data; comparability of groups at baseline; and whether treatments were adequately described. We will not exclude any studies but will provide a narrative discussion, highlighting the strengths and limitations of the evidence base.

Synthesis of Results

Classification of behavioural change techniques

Description of behavioural change intervention content will be coded, using a 93-item revised version of the Taxonomy of generally applicable BCTs proposed by (Michie et al., 2009). Inter-rater reliability of identified BCTs will be assessed using Cohen's κ statistic.

Theory coding

The Theory Coding Scheme (TCS) suggested by Michie and Prestwich (2010) will be applied. This focuses upon 19 items categorising the role of theory within interventions across 6 dimensions, including coding whether a theory or model was mentioned, how theories were used in intervention design, how intervention evaluations tested theory, and the implications of the results for future theory development (Michie and Prestwich 2010).

Treatment fidelity

A 30-item Treatment Fidelity Checklist (Borrelli 2011) will be applied to intervention descriptions/manuals to assess whether methodological strategies are in place with regard to the following five areas: study design (7 items); interventionist training (7 items); intervention delivery (9 items); intervention receipt (5 items); and intervention enactment (two items). Percentage scores for each section will reflect the proportion of items with evidence of at least one treatment fidelity strategy. An overall summary score of ≥80% will represent an intervention with a high treatment fidelity rating (Borrelli et al., 2005).

Statistical methods

Individual study characteristics and outcomes will be summarised and presented in an evidence table. Narrative synthesis of evidence will be carried out on the cost-effectiveness data. Where appropriate data are available, pairwise meta-analysis of behavioural change

interventions will be carried out, based on the random effects model (DerSimonian and Laird 1986); this is based on the assumption that the effects being estimated in the included studies are not identical, but follow the same distribution. For dichotomous outcomes, odds ratios, and for continuous outcomes, standardised mean difference, with 95% confidence intervals will be calculated. Statistical heterogeneity and the extent of inconsistency between the study findings will be investigated and assessed using the Higgins I^2 and the variance estimate τ^2. Funnel plots will be used to examine potential publication bias and small study effects. In addition, graphical augmented funnel plots will be used to assess the robustness of the findings of the meta-analysis by estimating the potential impact of future additional evidence on the current meta-analysis (Langan et al., 2012).

In order to examine the potential relationship between the mode of delivery, BCT and theory-congruent clusters, and treatment effects, pairwise and indirect comparisons of the components of the interventions (according to the proposed coding described above) will be carried out. Indirect comparisons require any two treatments to have a common comparator, or a link through a chain of comparisons. In other words, a chosen baseline treatment can be indirectly compared to another treatment, provided there is at least one "connecting" comparison. For example, consider three treatments labelled A, B and C. If we let d_{AC} denote the direct comparison of treatment A with treatment C, and d_{BC} denote the direct comparison of treatment B with treatment C, then a crude estimate for the relative (indirect) comparison of treatment A with treatment B could be $\hat{d}_{AB} = d_{AC} - d_{BC}$. Therefore, given the known direct evidence of the effect of treatments A and B compared to treatment C, we can indirectly estimate the effect of treatment A compared to treatment B, where treatment C is the "connecting" treatment.

Subsequently, we will use Bayesian random effects network meta-analysis based on minimally informative prior distributions, to incorporate both direct and indirect evidence into our analysis. This will follow the general principles set out by the International Society for Pharmacoeconomics Outcomes Research (ISPOR) Taskforce (Hoaglin et al., 2011, Jansen et al., 2011). For trials with multiple arms, an adjustment will be made in the analysis to account for the correlation between the effect estimates for each pair of arms within each trial. We will report the median of the posterior distribution along with 95% credible intervals (95%CrI). In addition, treatments were ranked to provide a probability of each treatment being considered the best in each outcome. Three sets of starting values were used, which will be burnt-in until convergence is reached (approximate 5000 Markov Chain Monte Carlo iterations), based on the Gelman-Rubin-Brooke statistic. A further 20,000 iterations will be run and the sampled values were used to estimate posterior means and credible intervals for response probabilities and odds ratios. We also explore the effect of using different priors was investigated for the variance distributions, since it has been suggested that, with small amounts of data, results may be sensitive to the chosen priors

Where appropriate, random effects meta-regression will also be undertaken in the pairwise and network meta-analysis (Dias et al., 2013) to examine potential confounders and effect modifiers. We acknowledge that meta-regression based on aggregate data and study-level covariates generally suffer from low power; therefore, we will ensure only a small number of covariates (selected based on sound clinical rationale) are used. All analysis will be performed using Stata release 11 (StataCorp) and WinBUGS 1.4.3 (MRC Biostatistics Unit 2007).

Synthesis of findings and identification of candidate interventions

There are two steps involved within our overarching synthesis of the evidence and the identification of candidate interventions. Firstly, the results of the systematic review will be

presented using the PRISMA reporting guidelines (Moher et al., 2009), including a PRISMA checklist and flowchart. We will develop an appropriate presentation of results of the network meta-analysis according to the ISPOR Taskforce guidance', and simultaneously illustrate the relative strengths and weakness associated with each BCT, theory congruent BCTs and named intervention. This matrix will detail the patterning of effectiveness at various levels. At this point in time it is not possible to specify exactly the level of detail that will be available as this is constrained by both the number of studies identified and the willingness of key researchers to share intervention descriptions and manuals. We anticipate the matrix will include evidence of effectiveness at the level of the named interventions described within the literature); and given the results of the network meta-analysis, effectiveness at the various levels of BCTs and modes of delivery.

Secondly, we will organize and hold a single day expert event to enable further analysis of candidate interventions in relation to real world feasibility and acceptability. This will also enable the translation of the findings of the systematic review into candidate intervention(s) ready for manualisation and a Phase III feasibility study. As part of the preparation for the event, each member of the advisory group will offered specific training by the team and be sent the matrix of results outlined above, and asked to digest and consider its implications for contemporary and future service provision. Within a specified design brief and proforma, they will be asked to individually develop an evidence based individual motivational behaviour change intervention for negative men concerning '*How to stay negative'*. Each member will be prepared to present it to the advisory group meeting for discussion, critique and collective development. They will be asked to detail the strengths and weakness of their approaches according to the following criteria:

- Is it evidence based with direct and auditable development clearly relating to the insights generated through the systematic review?
- Is it theory driven?
- Is it potentially suited (including acceptability) to a diverse range of MSM in the UK, for example those from different social, economic and ethnic backgrounds, those with disabilities, those working in the sex industry, and those with different sexual orientations e.g., bi-sexual?
- Could it be delivered in a way that encourages access and uptake, for example is delivered in community settings, or uses new technologies such as digital media?
- Does it fit with existing service provision in the UK, including that provided by the NHS, private providers and other sectors such as voluntary organisations, including acceptability by staff and across varied geographical areas (e.g., urban and rural settings)?
- Could it be delivered within existing budgets; if so, are their associate opportunity costs; if not, would the potential cost, including training, be prohibitive?
- Does it provide access to more specialist services such as STI treatment, and psychological support?

The morning session at the one-day expert event will be dedicated to the multiple presentations of these individual intervention ideas. Detailed records of emerging consensus, areas of disagreement and areas of innovation will be simultaneously systematically recorded. The afternoon session will involve the whole group, during which the ideas presented will be mapped and synthesized to identify candidate interventions.

Essential criteria

Candidate interventions must have demonstrable effectiveness (identified through in order of ranking, specific theory congruent BCTs, individual BCTs, clusters of BCTs, numbers of BCTs,

overall effectiveness), be cost effective, suitable to diverse HIV prevention approaches (not only the promotion of condom use), be fit for the future

Desirable criteria
Candidate interventions should be able to be easily implemented within a range of settings (without losing fidelity), be affordable, require minimal expert training, be delivered through self-care and via diverse modalities (smart phones) and be capable of implementation across diverse settings which include the patient's home setting.

This event is not being framed as dissemination: it is a crucial final stage of the synthesis; with the findings from this event being fed into the review work for the final report.

Dissemination and project outputs

We will develop a targeted multimedia engagement and dissemination strategy which focuses on the primary beneficiaries of this research: researchers working on intervention development and evaluation within this field: those commissioning services relating to interventions to reduce risky sexual behaviour; the growing range of testing and prevention providers, including healthcare professionals, policy makers and policy organisations, and; communities of gay and other MSM.

The results will be reported in a final report to the HTA programme. The report will clearly outline the methods used in the evidence synthesis and summarise the key findings, including the review of effectiveness and meta-analysis of direct, indirect and networked evidence with embedded behaviour change technique (BCT) taxonomy and theory coding analyses. This will provide evidence, which is currently lacking, of what works best, in which context, how and with whom. This information will extend the knowledge base and provide new understanding vital for future intervention development and evaluation and for service commissioning and delivery. At least one scholarly article will be prepared for publication in a peer-reviewed, open access journal.

Findings will be presented at clinical, non-clinical, and MSM-focussed national and international conferences. A briefing paper will be developed in an accessible language in various formats and circulated to key stakeholders via traditional and social media. We will work reciprocally with the project's Advisory Group to identify key stakeholders and their networks, in order to disseminate the final report, article(s) and briefing. We will disseminate findings to these and to the British HIV Association and British Association of Sexual Health and HIV (BASHH), and other stakeholders such as the National AIDS Trust, NICE, and HIV patient advocacy groups such as Terrence Higgins Trust and HIV Scotland. The project team have excellent well established links with all these groups. Public engagement and dissemination to gay and other MSM in the UK will be undertaken via community events such as regional Pride Festivals. We will use the Sexual Health Research Network (www.sexualhealthnetwork.org.uk), of which KL and LM are co-founding members, to engage with the UK research community, and others, including via blogs and podcasts (left open for comments).

Project timetable and milestones

The project timetable takes into account the average 35 days of annual leave (plus 10 public holidays) for the RA, and the festive period the project straddles, in order to set realistic and manageable timescales and milestones to ensure a thorough and high quality review.

	Month number											
	1 Aug	2 Sept	3 Oct	4 Nov	5 Dec	6 Jan	7 Feb	8 Mar	9 Apr	10 May	11 June	12 July
Finalise protocol and search strategy												
Conduct searches and screening												
Study selection and retrieval												
Contact authors and finalise data												
Data extraction												
Data analysis												
Expert event and final synthesis												
Write up and dissemination												

Patient and Public Involvement

Our advisory group will be constituted by both patients and other members of the public. We have invited negative and positive MSM onto the Advisory Group Board (the BASHH public panel has already agreed to assist) and have invited a variety of key stakeholders to also take part. We will draw upon our connections and good relationships with leading organisations within the field and have already asked for representation from the National AIDS Trust, Terrence Higgins Trust, Gay men fighting AIDS, Gay Men's Health. Should the proposal prove successful we will also ask HIV service commissioners in Scotland, England, Northern Ireland and Wales and HIV testing providers in urban rural and remote settings.

Patients and members of the public will be supported and mentored on a one to one basis by one of the co-applicants or fellow advisory group member, to ensure their voice is effectively heard and their experience is a positive one. To achieve this, four members of the public will be invited and supported on the project Advisory Group. They will be recompensed for their time, experience and expertise. These members will be recruited from Scotland, Glasgow (n=2) and England, London (n=2) from both clinical testing (n=2) and community testing (n=2) sites. Each will have tested for HIV within the previous year (this will be clear on the recruitment poster). We propose to recruit these members of the project advisory group through fliers and posters placed within testing sites and through a brief interview conducted by an interview panel consisting of one member of the research team in each location plus one member of the project advisory group. The interview will ensure that the person does not have previous professional experiences as a patient representative or involvement within other research teams and is aware of the responsibility, commitment, time frame and opportunities that being on the project Advisory group entails.

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