



Development of a social marketing/mass media intervention to increase HIV testing for gay & bisexual men and all MSM in Greater Glasgow & Clyde: Evidence synthesis and component analysis

STUDY PROTOCOL
V0.2

Start date: 01/10/2016
End date: 31/03/2017
Duration: 6 months

Purpose The purpose of the Protocol is to describe the study/project and provide information about the procedures for entering participants into the study/project. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary.

This protocol has been authorised by:


Laurence Moore	SPHSU Director		
Name	Role	Signature	Date
			03/11/16
Lisa McDaid	Chief Investigator		
Name	Role:	Signature	Date

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1. Summary

MSM are known to experience significant inequalities in health and wellbeing and are the group most at risk of HIV in the UK. An estimated one in five HIV-positive MSM is undiagnosed and delayed HIV diagnosis is associated with poorer health outcomes and treatment response, increased mortality and healthcare costs, and increased levels of onward transmission. UK national guidelines currently recommend that all MSM test annually and men at higher risk of HIV infection test more frequently, but most do not meet these recommendations. To address this issue, NHS Greater Glasgow & Clyde is planning to deliver a coordinated programme of social marketing interventions aimed at increasing HIV testing frequency among MSM. Social marketing is an approach used to develop activities aimed at changing or maintaining people's behaviour for the benefit of individuals and society as a whole, but evidence for the effectiveness of media campaigns on changing HIV testing behaviour is relatively limited. The project will develop an evidence-informed social marketing intervention to promote regular HIV testing to MSM and to combat HIV stigma as a barrier to testing. The project will conduct an evidence synthesis of existing evidence on social marketing and mass media interventions for HIV testing with MSM. Rather than to assess effectiveness per se, the purpose of the study is to identify patterns in delivery (i.e., mode of delivery) and programme (i.e., Behaviour Change Techniques (BCTs)) components within interventions (in line with the eight benchmark criteria for social marketing) associated with effectiveness. We will develop a matrix to synthesise the findings from each stage of the analysis, to inform development of a candidate intervention. This will then be taken forward in a second project (to follow and be funded separately) to synthesise expert opinion (MSM and those who work with them) on the candidate intervention to refine and optimise its components and behaviour change techniques and to manualise the intervention for further testing.

2. Introduction

2.1 Background

MSM are known to experience significant inequalities in health and wellbeing and a disproportionate burden of ill health in relation to sexual health, mental health and substance use when compared with the general population, and are the group most at risk of HIV in the UK; an estimated one in five HIV-positive MSM is undiagnosed [1, 2]. Delayed HIV diagnosis is associated with poorer health outcomes and treatment response, increased mortality and healthcare costs, and increased levels of onward transmission [3, 4]. UK national guidelines currently recommend that all MSM test annually and men at higher risk of HIV infection test more frequently, e.g., three-monthly [5]. We recently demonstrated that only half of UK MSM test annually and less than one quarter of MSM at risk meet the recommendation to test more frequently [6].

The media can be a powerful communication tool. However, evidence for the effectiveness of media campaigns on changing HIV testing behaviour is relatively limited [7]. Such interventions are rarely theoretically informed, rarely address any specificity within the behavioural domains of regular HIV testing, rarely incorporate appropriate behaviour change techniques (e.g. beliefs about consequences), rarely focus upon operationalizing population segmentation (infrequent testers at risk) and often focus more upon their aesthetics than their mechanism of action. The new evidence review for the NICE Guideline on HIV testing identified just two recent RCTs examining the effectiveness of mass media and communication campaigns on increasing HIV testing [8]. Both studies were conducted in the US and with women and provide only moderate evidence of the effectiveness in increasing HIV testing uptake [9, 10]. Our own evaluation of NHS Greater Glasgow & Clyde (GGC)'s Make Your Position Clear mass media campaign suggested partial support for the role of such campaigns in improving sexual health (men with mid or high campaign exposure were more likely to have tested for HIV in the previous six months) [11], but itself recognised the limitations of such mass media campaigns if/when run without the nuanced targeting that social marketing approaches advocate. Social marketing is an approach used to develop activities aimed at changing or maintaining people's behaviour for the benefit of individuals and society as a whole [12]. However, few studies have fully incorporated social marketing criteria and the 2011 Cochrane review called for more rigorous research designs and detailed process evaluation work to identify the social marketing intervention components that are most effective [7].

2.2 Rationale

NHS GGC's Steve Retson Project (SRP) is planning to deliver a coordinated programme of social marketing interventions aimed at increasing HIV testing frequency among MSM. They are keen to develop an evidence informed, theoretically-based intervention, which has a clear behavioural target, clear audience segmentation and entails appropriate behaviour change techniques. With regard to behavioural domain, NHS GGC recognises the need for a continued focus on regular and frequent HIV testing, stressing the benefits of knowledge of HIV status as noted above. They also want to support men (both population wide and as individuals) to be more open in their conversations about testing, re-testing and HIV status in order to inform sexual decision-making. We propose to work with NHS GGC to develop an evidence-informed social marketing intervention targeting MSM in relation to regular HIV testing.

The proposal is a clear fit to the Unit and the Relationships programme, and in particular the Communities theme. In the QQR, we said that we would examine how to engage gay communities in intervention research taking a community participative approach and this proposal fits with that aim and will compliment core-funded work to understand how to promote and capitalise on community engagement in the design and development of future interventions (as well as in further development and refinement of our method of stakeholder engagement for this purpose). The project capitalises on our expertise in MSM and HIV testing behaviours and our strong links with NHS GGC. The social marketing campaign is part of their larger reconfiguration of sexual health services for MSM and we are committed to working with NHS GGC to develop and evaluate components of their intervention. We will go on to seek funds to evaluation the social marketing and HIV testing intervention, an area for which there is little international evidence thus far. Ultimately, it will also feed into our work to inform a new, innovative and inclusive model of community-based health improvement to improve wellbeing and reduce multiple, interrelated health inequalities in sexual health, mental health and substance use among MSM.

2.3 Aims/Objectives/Research questions

AIM: To develop an evidence-informed social marketing intervention to promote regular HIV testing to MSM and to combat HIV stigma as a barrier to testing to be delivered in Greater Glasgow & Clyde

The objectives of this project are:

- To synthesis existing evidence on social marketing and mass media interventions for HIV testing with MSM

- To identify intervention components within social marketing and mass media interventions for HIV testing with MSM associated with effectiveness

3 Study Design/Methods

3.1 Study Design

The project will conduct an evidence synthesis of existing evidence on social marketing and mass media interventions for HIV testing with MSM. Rather than to assess effectiveness per se, the purpose of the study is to identify patterns in delivery (i.e., mode of delivery) and programme (i.e., Behaviour Change Techniques (BCTs)) components within interventions (in line with the eight benchmark criteria for social marketing) associated with effectiveness.

Stage 1. Systematic review of existing evidence on effective social marketing interventions for HIV testing with MSM

A Cochrane review of the impact of interventions on HIV/STI testing on MSM was published in 2011 [7]. The review found only two studies of multi-media social marketing interventions that increased HIV testing uptake and both were graded as low quality evidence. We will conduct a scoping review of academic research published since 2010 (the dates of the Cochrane review searches).

Search Strategy

A search strategy will be discussed, agreed among the Project Management Group and the searches will be conducted by the Information Scientist, Candida Fenton. We will use similar and standard MeSH search terms for HIV, MSM, and social marketing/mass media interventions as the Cochrane review [7]. Searches will be limited to academic databases: Medline, Embase, CINAHL, Web of Science and PSYCInfo. Medline covers US medical literature and Embase European. CINAHL covers nursing and allied health professional and Web of Science covers all high impact journal across the subject.

Inclusion criteria

Population: Studies in which MSM constitute at least one-third of the study sample or were specifically targeted by the intervention. Studies where the population is solely transgender will be excluded.

Interventions and comparators: all interventions that seek to change behaviour through non-interactive visual or auditory means. Including mass media, social marketing, multimedia, major poster and leaflet and radio campaigns and combinations of the above. Studies without comparators will be included.

Outcomes: HIV testing (only studies that report on HIV testing as an outcome, or the frequency of testing, will be included).

Study types: All study types including trials, cross-sectional designs and qualitative process evaluation.

Exclusion Criteria

Studies that do not meet the inclusion criteria above, those published prior to 2009, and in languages other than English will be excluded. Grey literature, books (chapters) and dissertations will be excluded.

Study Selection & Data Extraction

Inclusion and exclusion criteria will be applied to screen titles and abstracts by JR, with a 10% sample validated by NB. 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. The same process will be applied to full texts with discrepancies resolved through consensus and/or further discussion with LMCD/PF. A PRISMA-style flow chart will be used to document the numbers of studies included and excluded at each stage of the review. Search results will be recorded in endnote files, with separate folders created for included, excluded, and 'maybe' papers.

Only studies that meet the inclusion criteria will be included in the scoping review. We extract basic data on: study identifier (first author, location, year); study design (study type, method of recruitment, duration of follow up); outcome measures (specific details of the specificity of the HIV testing domain will be recorded); participant details (number of participants, age); and results. A minimum of three requests will be made to study authors for intervention manuals and study materials. If authors provide more than one source of information regarding their description of the intervention, the most detailed source will be used within this review. Databases will be collated and curated regarding the intervention materials which are available.

The initial data extraction tools will be piloted on 10% of the articles in the sample and reviewed by the Project Management Group (LMcD, NC, PF, JR, NB). Data extraction will initially be carried out by JR, with a 10% sample validated by NB. Discrepancies and difficulties will be resolved through consensus and/or further discussion with LMcD/PF.

Quality Appraisal

Included study quality will be appraised with the NICE quality appraisal checklist¹ for quantitative papers and the GATE² frame for qualitative papers to identify potential bias. Each paper will be assigned a score for internal and external validity, from ++ (high quality) to – (poor quality). Studies will be appraised by JR, with a 10% sample validated by NB. Papers will not be excluded on the basis of quality.

Stage 2. Social marketing/mass media component analysis

We will review and extract data on the nature of the intervention, including mode of delivery, media, use of imagery, content and tone. We will review and extract data on the reporting of the eight key characteristics of social marketing [12].

1. Behavioural goals
2. Customer orientation and pretesting
3. Theory
4. Insight driven
5. Segmentation/targeting
6. Motivational exchange
7. Competition
8. Methods mix (ie more than communication)

Reported barriers and facilitators to the use of each characteristic will also be recorded. JR will extract data, with a 10% sample checked and validated by NB. Discrepancies and difficulties will be resolved through consensus and/or further discussion with LMcD/NC/PF.

Stage 3. Behaviour Change Techniques analysis

¹ <https://www.nice.org.uk/process/pmg4/chapter/appendix-g-quality-appraisal-checklist-quantitative-studies-reporting-correlations-and>

² <http://ebm.bmj.com/content/11/2/35.extract>

We will review intervention descriptions and materials where available. We will extract data on the number of BCTs, the type of BCTs, and theory-congruent clusters of BCTs, using tools previously developed by PF.

Descriptions of behavioural change intervention content will be coded into BCTs using a 93-item revised version of the Behaviour Change Technique Taxonomy v1 as proposed by Michie et al., (2013) [13]. JR will code the BCTs, with a 10% sample checked and validated by NB. Disagreements and additional BCTs identified will be discussed and where agreement cannot be reached, PF will give a final rating on the discrepancies.

In order to examine the role of theory within interventions, the Theory Coding Scheme (TCS) of Michie and Prestwich (2010) will be adopted [14]. Critically, the approach does not analyse if theory-based interventions *per se* are more effective than those that are not based on theory. Instead, it seeks to examine exactly how theory has been operationalised at a number of levels within an intervention. It assesses how theory has informed the intervention, how theory has been used within the development of interventions, how theory or predictors have been used to select recipients for interventions and how BCTs are related to theories and theoretical constructs (providing a measure of theory congruent BCTs).

The first 11 items of the 19-item TCS will be used to assess the relationship between theory, target behaviours and their relationship to informing intervention development and implementation [14]. These items categorise the role of theory within interventions across a number of dimensions including whether a theory or model was mentioned, how theories were used in the intervention design and how intervention evaluations tested theory (e.g., tracking proposed mechanisms of behaviour change). TCS will be assessed by two independent reviewers. Disagreements will be resolved through discussion.

3.2 Settings

N/A

3.3 Participant Selection

N/A

3.4 Recruitment

N/A

3.5 Withdrawal and loss to follow up

N/A

3.6 Study Procedures

N/A

3.7 Data Collection

N/A

3.8 Data Analysis

All data will be tabulated and a narrative approach used to analyse and synthesise the data. There are a number of approaches to data synthesis, including integrative synthesis to primarily combine and summarise data and interpretative synthesis that aims to generate new concepts and theory [15]. Iterative analysis and discussion within the Project Management Group will be used to reach consensus. We will develop a matrix to synthesise the findings from each stage of the study to hypothesise on the theory of behaviour change and to develop and refine a logic model for the intervention. The matrix will provide a transparent account of how the different types of evidence are used to develop a candidate intervention.

A summary report will be prepared by the Project Management Group on the evidence synthesis, detailing the results of the social marketing/mass media component and BCT analyses. The report will include a brief description of the candidate intervention to be taken forward in the second project (to follow and be funded separately) to synthesise expert opinion (MSM and those who work with them) on the candidate intervention to refine and optimise its components and behaviour change techniques and to manualise the intervention.

4. Research Governance and Regulatory Issues

4.1 Ethical issues

Research Ethics Committee: N/A

Research Ethics Committee Reference: N/A

This project is an evidence synthesis of existing evidence on social marketing and mass media interventions for HIV testing with MSM. It involves no recruitment of participants or primary data collection.



If you **do not think that ethical approval is required for your study**, can you please indicate by ticking this box that you have consulted the relevant ethics committees or spoken to unit staff with expertise in ethics, i.e. Marcela Gavigan, Mark McCann or Gillian Fergie to confirm this.

4.2 Data Monitoring

Data for this study does not fall under the SPHSU Data Management Policy as data are not taken from study participants. Lisa McDaid is the PI and will be responsible for monitoring and quality assurance of procedures, including data collection, recording and analysis. Throughout the evidence synthesis, data extraction/analysis will initially be carried out by JR, with a 10% sample validated by NB. Discrepancies and difficulties will be resolved through consensus and/or further discussion with LMCD/PF/NC.

4.3 Data Management

As outlined above, SPHSU data management policies do not apply to evidence synthesis and a Data Management Plan is not required.

4.4 Data Storage and Retention

N/A

5 Project Management

5.1 Project Manager

A Project Manager is not required for the project and day to day organisation will be managed by Lisa McDaid, with administrative support from Natalie Owens.

Julie Riddell is the Research Assistant on this project, supported by Nicola Boydell, and will be primarily responsible for conducting the scoping review, data extraction and the social marketing and BCT analyses.

5.2 Project Management Group

The Project Management Group (PMG) will consist of the PI (Lisa McDaid), Co-Investigators (Paul Flowers and Nicky Coia), and Project Team members (e.g., staff employed on or contributing to the project³). The Project Team consists of the following members:

³ Candida Fenton and Nicola Boydell will only attend PMG meetings when contributing to the project.

Name	Division/Organisation
Julie Riddell	MRC/CSO SPHSU, Research Assistant
Nicola Boydell	MRC/CSO SPHSU, Research Assistant
Candida Fenton	MRC/CSO SPHSU, Information Scientist
Natalie Owens	MRC/CSO SPHSU, Administrative Assistant
Gemma Teal	Institute of Design Innovation, Glasgow School of Art, Design Researcher

The PMG is responsible for strategic direction and the day-to-day running of the trial and can make decisions appropriate to this role. PMG members will not formally sign a contract, but will be requested to agree to the remit of the PMG.

PMG Remit

The specific roles of the PMG are to:

- Attend PMG meetings and advise on availability for future meetings
- Input into and comment on the protocol, scoping review search strategy, data extraction tools, and other materials as required
- Promote the project
- Be involved in the day-to-day running of the project by supporting the PI and the Project Team
- Provide scientific or other expert guidance to the PI and Project Team on trial-based matters such as recruitment and retention strategies, process evaluation design, qualitative and quantitative analysis
- Maintain confidentiality of any project information that is not in the public domain
- Respond to project correspondence and any questions in a timely fashion
- Provide responses to any issues or concerns raised by the virtual Project Advisory Group
- Consider the implications of any recommendations made by the virtual Project Advisory Group
- Be aware of accumulating external evidence and assess its impact and relevance
- Input into the development of the project analysis plan
- Input into the interpretation and writing up of the project results

PMG Meetings

The Project Management Group will meet monthly, on average. Meetings will usually be held at the offices of SPHSU – ideally these should be face-to-face meetings but teleconferencing or videoconferencing facilities will be made available for members who are unable to attend in person. Meetings will be arranged by Natalie Owens. The TMG papers and agenda will be circulated before the meeting; TMG members who will not be

able to attend the meeting may pass comments to the PIs for consideration during the discussions. PMG meetings will be chaired by the PI (Lisa McDaid). On all issues, every effort should be made to achieve consensus. The role of the Chair is to summarise discussions and encourage consensus; it is therefore best for the Chair to give their own opinion last. Minutes of PMG meetings will be taken on the SPHSU template and a Decision Log will be created and maintained by Natalie Owens.

Members will be expected to send apologies in advance of any meeting they cannot attend. If a member neither attends nor sends apologies for a meeting, every effort should be made to ensure their availability for the next meeting. If a member does not attend nor send apologies for the following meeting, they will be asked if they wish to remain part of the PMG. If a member does not attend a third meeting in a row, they should be replaced, unless there are particular extenuating circumstances.

In addition, the PI will meet with the Project Team fortnightly to oversee the day-to-day running of the project.

All documentation circulated to PMG members should be considered confidential.

5.3 Advisory Group

A virtual advisory group will be set up to ensure methodological probity and to provide guidance. We will invite the following onto the group: a patient representative, i.e., a gay man; a sexual health clinician; an HIV testing research expert; and an expert in intervention development. They will be asked to contribute once during the study (at the end to advise on interpretation and development of the candidate intervention – March 2017).

5.4 Project Filing Structure

The SPHSU project filing and master file structure will be adhered to. In the first instance, the electronic project files will be kept on:

I:\programmes\relationships\Communities\Social Marketing_ S00084, and moved to the new SPHSU projects drive once it is available.

The hard copy project master file will be kept: by Lisa McDaid. Hard copy working project files will be kept: in a locked cupboard by Julie Riddell. An electronic copy of the project master file will be shared with the external co-investigators and a strict version control adhered to.

6. Dissemination

6.1 Communication method

This analysis will provide novel, highly specific, systematically generated knowledge capable of shaping intervention development with an understanding of effective BCTs and their relationship with theory.

The key communications channels are:

- Project report for NHS GGC
- Peer review publication on the evidence synthesis and intervention development
- Presentation at national behavioural medicine conference (e.g., UK Society for Behavioural Medicine)
- Presentation at international sexual health conference (e.g., International Society for STD Research)
- Social media (for dissemination of findings)

The study findings will inform two further funding proposals:

- i) CSO Small Grant application to synthesise expert opinion and manualise the candidate intervention (January 2017); and
- ii) Full Grant application for a pilot feasibility trial of the intervention (June 2017)

6.2 Publication Policy

All publications and presentations relating to the project will be authorised by the Project Management Group. Criteria for authorship will follow SPHSU authorship guidelines. The PI takes ultimate responsibility for deciding authorship and authorship order within these principles.

A publication policy will be prepared (to cover this project and the two proposals that follow) and will set out the criteria for authorship, approvals, format of acknowledgements and list of potential papers (to be reviewed and updated at PMG meetings, as required).

6.3 Public Engagement and Knowledge Exchange

At this stage, no specific public engagement or knowledge exchange activities are planned during the course of the six months study, but this will be kept under review by the PMG. Findings could be used to inform Participant and Public Involvement (PPI)

work alongside future proposals. Media and social media dissemination will be undertaken when disseminating findings.

7. Project Milestones / Timelines

The following sets out the key project milestones points when key decisions must be taken:

Tasks	Timeline	Milestones
Study set up <ul style="list-style-type: none"> • Protocol written • PAG recruited 	Weeks 1-3	<ul style="list-style-type: none"> • Protocol finalised • TMG/PAG set up / meeting dates agreed
Scoping review <ul style="list-style-type: none"> • Search strategy set up • Searches conducted • References screened 	Weeks 3-7	<ul style="list-style-type: none"> • Searches complete • References sources • Final inclusion agreed
Data extraction <ul style="list-style-type: none"> • Data extraction tools developed • Papers reviewed • Data extracted and validated 	Weeks 8-22	<ul style="list-style-type: none"> • Data extraction tools finalised • Basic data extraction completed and validated • Social marketing data extraction completed and validated • BCT data extraction completed and validated
Social marketing analysis <ul style="list-style-type: none"> • Social marketing data tabulated 	Weeks 9-14	<ul style="list-style-type: none"> • Social marketing data tabulated • Social marketing narrative summary prepared
BCT analysis <ul style="list-style-type: none"> • BCT data tabulated 	Weeks 15-22	<ul style="list-style-type: none"> • BCT data tabulated • BCT narrative summary prepared
Report writing <ul style="list-style-type: none"> • Write up of project methods and results • Intervention development 	Weeks 23-26	<ul style="list-style-type: none"> • Matrix of evidence synthesis prepared • Results written up • Brief description of candidate intervention prepared • Final report submitted
Grant application <ul style="list-style-type: none"> • Development grant for stage 2 • Outline grant for pilot feasibility study 	TBC	<ul style="list-style-type: none"> • Development grant proposal submitted • Outline proposal for pilot feasibility study submitted

A full project timeline is included in Appendix A.

8. Project Risk Assessment

The risks relevant to the project are recorded in the risk assessment form and contained in the initial Project Risk/Issue log on: I:\programmes\relationships\Communities\Social Marketing_ S00084.

The Risk Log will be reviewed and updated at PMG meetings.

9. References

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14. Michie, S. and A. Prestwich, *Are interventions theory-based? development of a theory coding scheme*. *Health Psychol*, 2010. **29**.
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Appendix A: Project Timeline

	October					November				December				January					February				March				
Week beginning	03 rd	10 th	17 th	24 th	31 st	7 th	14 th	21 st	28 th	5 th	12 th	19 th	26 th	2 nd	9 th	16 th	23 rd	30 th	6 th	13 th	20 th	27 th	6 th	13 th	20 th	27 th	
Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	
Design search strategy (JR/CF/LMcD)			■	■																							
Prepare protocol (JR/LMcD/PF)	■	■																									
Conduct searches (CF)				■		■																					
Screen titles/abstracts (JR)							■	■	■	■	■	■															
Screening validation (NB)							■			■																	
Source references (JR/NO)											■																
Design data extraction tools (JR/LMcD/PF)							■	■	■	■	■	■															
Data extraction (JR)												■		■	■	■	■	■	■	■	■	■	■	■	■	■	■
Extraction validation (NB)												■		■	■	■	■	■	■	■	■	■	■	■	■	■	■
Social marketing component analysis (JR/LMcD)																		■	■	■	■	■	■	■	■	■	■
BCT analysis (JR/PF)															■	■	■	■	■	■	■	■	■	■	■	■	■
Report/paper writing (JR/LMcD/PF)																							■	■	■	■	■
CSO grant application (LMcD/PF)														■	■	■	■	■	■	■	■	■	■	■	■	■	■
PMG meetings* (LMcD/PF/NC/JR/NO)								22 nd			13 th				11 th				9 th				6 th			27 th	
PMT meetings* (LMcD/JR)			■				■				■				■				■				■			■	

Xmas break

*Meetings to be attended by CF/NB/GT when required.

† PMG Meeting wb 27th March will be a half day meeting to review the matrix of finding to hypothesise on the theory of behaviour change and to develop and refine a logic model for the intervention.