# STASH (STis and Sexual Health): a peer-led intervention to prevent and reduce STI transmission and improve sexual health in secondary schools in UK

Submission date 25/02/2016	<b>Recruitment status</b> No longer recruiting
<b>Registration date</b> 24/05/2016	<b>Overall study status</b> Completed
Last Edited 10/07/2024	<b>Condition category</b> Infections and Infestations

- [X] Prospectively registered
- [X] Protocol
- [\_] Statistical analysis plan
- [X] Results
- [X] Individual participant data

## Plain English summary of protocol

#### Background and study aims

Young people in the UK report higher levels of unsafe sex than any other age group. As a result, they are at highest risk of getting, and passing on, sexually transmitted infections. Young people often lack awareness of the risks or are unsure how to protect themselves. They are also vulnerable to social pressure from friends and peers who seem more sexually experienced, and to popular beliefs that safer sex behaviour is 'uncool'. Youth peer-led interventions often involve peers 'teaching' friends or younger children. Peer educators often volunteer themselves for this role or are chosen by teachers; this type of selection tends to result in young people who are committed to school and who may find it difficult to relate to students who are disengaged and at highest risk. An alternative is to recruit young people from among those voted as most influential by their peers, and to train them not as peer educators but as peer supporters. These individuals then act as role models who change behavioural norms through social networks and other mechanisms of influence. This has been tried, with success, in a school-based anti-smoking intervention called ASSIST. Early research on the use of social media in promoting healthy behaviour is promising. Most UK teens are connected to online social networks; messages can spread rapidly; and social media provides an alternative to talking about sex directly, something many youth find embarrassing. We will build on components found to work well in ASSIST: recruiting influential peers, allowing knowledge and attitudes to spread via social networks, and using professionals to train peer supporters. However, this intervention focuses on sexual health, an older target group and utilises social media to spread messages. The main aim of this study is to find out whether this intervention is feasible, acceptable and implemented as intended. The study is not big enough to tell us whether the intervention works, but will let us to assess whether it is worth doing a larger trial, and if yes, how we should go about doing this.

#### Who can participate?

All S4 students (aged 14-16) at state-funded schools in the Lothian region of Scotland who have received or are currently receiving teacher-led sex RSHP (Relationships, Sexual Health and Parenting), regardless of their sexual experience or individual level of risk.

What does the study involve?

We identify and recruit the most influential students in fourth year (S4) of secondary school. These students attend a two-day training course run by specialist trainers. Over a defined period (between 4 and 10 weeks) they use social media and face-to-face interaction to influence sexual norms and behaviour among their peers. They are supported – through regular meetings and via social media – by the professionals who trained them. After a test in one school we implement the intervention in a further six schools, using the previous group of S4 students as controls; these students move to S5 before the intervention starts and are therefore not be exposed to it. We examine how the intervention was implemented by evaluating activities, and by talking to students, teachers and parents about their experience of being involved. We are interested in whether the intervention improves attitudes, knowledge, and risk-reduction skills, and whether these, in turn, delay first sex, increase condom use and improve the quality of sexual relationships. Peer supporters present the findings to their year group, teachers, and other professionals, and we write up the results for academic and policy audiences. If the intervention is successful, we will seek funds for a full-scale study.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? University of Glasgow (UK)

When is the study starting and how long is it expected to run for? January 2016 to December 2018

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Dr Kirstin Mitchell kirstin.mitchell@glasgow.ac.uk

## **Contact information**

**Type(s)** Public

**Contact name** Dr Kirstin Mitchell

ORCID ID http://orcid.org/0000-0002-4409-6601

## **Contact details**

MRC/CSO Social and Public Health Sciences Unit Institute of Health and Wellbeing, University of Glasgow Top Floor, 200 Renfield Street Glasgow United Kingdom G2 3QB +44 (0)141 353 7514 kirstin.mitchell@glasgow.ac.uk

## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers NIHR 14/182

## Study information

## Scientific Title

An exploratory study to test STASH (STis and Sexual Health), a peer-led intervention to prevent and reduce STI transmission and improve sexual health in secondary schools in UK

## Acronym

STASH

## **Study objectives**

The hypothesis of this exploratory study is that the STASH intervention will be feasible, acceptable (both to target group and stakeholders), and not inferior to existing provision of sex education in schools.

The hypotheses of the STASH intervention are:

 That secondary students, nominated as influential by their peers and trained as peer supporters, can effect improvements in sexual attitudes and behaviour among their peers.
 That social media provides an effective means through which peer supporters can disseminate positive sexual health messages

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

College of Medical Veterinary and Life Sciences (MVLS) Ethics committee, University of Glasgow, 23/08/2017, ref: 00160002

Study design

Intervention development and exploratory study

**Primary study design** Interventional

Secondary study design Non randomised study **Study setting(s)** School

Study type(s)

Prevention

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Prevention of sexually transmitted infections; sexual health and well-being

#### Interventions

Intervention development and exploratory study undertaken in two stages: Stage 1: Develop and formatively evaluate the intervention package, recruitment strategies and evaluation tools, pilot these in one school and make refinements Stage 2: Conduct an exploratory study in six schools in Scotland to include a feasibility trial and detailed process evaluation. This will be designed to assess whether progression criteria for a

subsequent full trial are met

The trial is multi-centre as the intervention will be delivered in 6 schools

Building on learning from ASSIST (an effective peer-led anti-smoking intervention), we will identify and recruit the most influential students in fourth year (S4) of secondary schools (aged 14 to 16) in Scotland. These students will attend a two-day training run by specialist trainers. Over a defined period (between 4 and 10 weeks) they will use social media and face-to-face interaction to diffuse information, norm change and support for healthy sexual behaviour among their peers. They will be supported – through regular meetings and via social media – by the professionals who trained them.

## Intervention Type

Behavioural

## Primary outcome measure

The main outcome is attainment of progression criteria to a potential subsequent full trial. The primary intervention outcome is frequency of unprotected sex. We will also assess the feasibility and acceptability of linkage to NHS data on STI diagnosis as a longer-term outcome.

## Secondary outcome measures

Secondary outcomes to be clarified during development stage but likely to include:

- 1. Self-reported STI diagnosis, testing and symptoms
- 2. Sexual behaviour
- 3. Relationship quality
- 4. Adherence to targeted behavioural norms
- 5. Perceptions about the behaviour of others
- 6. Knowledge of STI risk
- 7. Awareness and use of local sexual health services
- 8. STI prevention skills
- 9. Beliefs about capabilities

Process measures include feasibility, fidelity, acceptability and reach of the intervention, for example the proportion of nominated peer supporters who agreed to participate. We will assess the perceived value of peer supporters among students, the level of exposure to the intervention, and acceptability to teachers. We will also record the key costs of intervention adaptation, implementation and maintenance and we will assess the feasibility of measuring sexual quality of life and information on sexual health related health care resource use.

## Overall study start date

01/01/2016

## **Completion date**

31/12/2018

## Eligibility

## Key inclusion criteria

State-funded schools in the Lothian region of Scotland. All S4 students (aged 14-16; male and female) at eligible schools who have received, or are currently in receipt of teacher-led sex RSHP (Relationships, Sexual Health and Parenting), regardless of their sexual experience or individual level of risk.

## Participant type(s)

Healthy volunteer

**Age group** Child

**Lower age limit** 14 Years

**Upper age limit** 16 Years

**Sex** Both

**Target number of participants** 700 participants and 700 controls

# **Total final enrolment** 1376

## Key exclusion criteria

 Faith schools in which STASH principles conflict with religious principles/teaching on sex education
 Students in eligible schools who refuse their consent or whose parents/carers refuse consent

## Date of first enrolment

15/01/2017

Date of final enrolment 15/01/2018

## Locations

**Countries of recruitment** Scotland

United Kingdom

**Study participating centre University of Glasgow** MRC/CSO Social and Public Health Sciences Unit Top Floor 200 Renfield Street Glasgow United Kingdom G2 3QB

## Sponsor information

**Organisation** University of Glasgow (UK)

Sponsor details

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Glasgow Scotland United Kingdom G12 8QQ

**Sponsor type** University/education

ROR https://ror.org/00vtgdb53

## Funder(s)

**Funder type** Government

#### Funder Name

National Institute for Health Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type Government organisation

Funding Body Subtype

National government

Location United Kingdom

## **Results and Publications**

## Publication and dissemination plan

Detailed plans for dissemination of trial results to be confirmed at a later date. Indicative plans for dissemination are as follows:

1. Academic dissemination: Protocol to be published, open access in Journal of Behavioural Medicine (or equivalent). Outcome of the exploratory study to be published, open access, in a leading international journal. Process evaluation results published, open access, in journal such as Sexually Transmitted Infections. We will present details of the study design, intervention and baseline results at a national conference (such as UK Society of Behavioural Medicine). We will also disseminate findings via The Sexual Health Research Network for UK-based academic researchers.

2. Dissemination to key policy leads and practitioners: Key policy leads, including representatives from the Sex Education Forum and the Sexual Health and BBV team at the Scottish Government, will advise on effective dissemination to policy makers and practitioners.

3. We will seek to publish a plain English summary of key findings and policy recommendations on the Sex Education Forum website. We will seek invitations to speak at key stakeholder and practitioner events, such as those organised by the 'Wellbeing in Sexual Health and HIV' (WISHH) network (aimed at professionals working within sexual health and well being in Scotland) and the British Association of Sexual Health & HIV (BASHH).

4. Dissemination to the lay public: Where appropriate, press releases will accompany the publishing of academic articles. We will also make use of social media to disseminate results. We will seek to link with public events such as science festivals. Peer supporters at participating schools will be supported to present the results to their classmates during school assemblies.

## Intention to publish date

31/12/2019

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Scuay outputs							
Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?		
<u>Protocol file</u>	version v1.5	14/05/2018	06/06 /2018	No	No		
<u>Protocol article</u>	protocol	29/11/2018	30/11 /2020	Yes	No		
<u>Interim results</u> <u>article</u>	Feasibility results	01/11/2020	15/01 /2021	Yes	No		
<u>Interim results</u> <u>article</u>	Feasibility results	14/06/2021	17/06 /2021	Yes	No		
<u>Dataset</u>	Feasibility data	20/04/2021	12/04 /2023	No	No		
<u>Interim results</u> article	Intervention development and optimisation	11/04/2023	12/04 /2023	Yes	No		
<u>Results article</u>	opportunities and challenges	16/02/2021	10/07 /2024	Yes	No		