

DMP title

Project Name STASH Data Management Plan

Principal Investigator / Researcher Kirstin Mitchell

Project Data Contact Ross Forsyth [REDACTED]

Description The study aims to develop and test the feasibility and acceptability of a school-based intervention delivered by peer supporters (STASH; STis And Sexual Health) to prevent and reduce transmission of sexually transmitted infections (STIs) and improve the sexual health of secondary students aged 14-16 in UK.

Funder Medical Research Council

Institution University of Glasgow

0. Proposal name

0. Enter the proposal name

An exploratory study to test 'STASH', a peer-led intervention to prevent and reduce STI transmission and improve sexual health in secondary schools.

1. Description of Data

1.1 Type of Study

The study aims to develop and test the feasibility and acceptability of a school-based intervention delivered by peer supporters (STASH; STis And Sexual Health) to prevent and reduce transmission of sexually transmitted infections (STIs) and improve the sexual health of secondary students aged 14-16 in UK.

1.2 Types of Data

Quantitative, qualitative; generated by online baseline and follow up questionnaires and interviews. Notes will also be collected when observing the training sessions as they are delivered to the peer supporters.

1.3 Format and scale of the data

1.3.1 Peer supporter identification

The peer supporter identification process will ask all S4 pupils to identify which of their peers are most influential. This will be completed anonymously via hard copy and manually analysed to produce a list of the nominated most frequently. The top 20% of pupils who are nominated will be invited to take on the role of peer supporter.

Approx 1000 administrative forms will be completed as part of this process.

No of questions – 4

1.3.2 Baseline and follow up questionnaire

Seven schools in total will participate in the intervention. Average year size for West Lothian is 160; allowing for non-response of 15% due to pupil absence, the sample size across all 6 schools is approximately 700 intervention participants and 700 controls.

No of questionnaires – approx 700 participants and 700 controls at baseline and follow up.

No of questions within questionnaire – 60

An information sheet and opt out form will be supplied to all parents (approx 180).

This will be captured electronically via an online survey. Information captured here will include name, gender and date of birth. Participant and control data will be stored on the SPHSU SORD system.

A pupil list will be generated for each school. This will outline the name of the pupils the s4 year group for each school.

1.3.4 Peer supporter consent forms

Across the seven school, approximately 140 pupils will be recruited as peer supporters. These pupils will be given information sheets on the role of a peer supporter and will be asked to sign a physical opt in consent form before they take on this role. Parents of peer supporters will also fill in a physical opt in consent forms, to give their child permission to take on the role of peer supporter.

1.3.5 Process Evaluation -

The evaluation will assess intervention reach and fidelity, as well as feasibility and acceptability to peer supporters, target group and stakeholders, and provide key data regarding criteria for progression to a potential larger RCT. Evaluation to comprise:

- (1) Structured observation and evaluation of peer leader training to measure engagement/social interaction by peer supporters, document reactions to intervention, including concerns about role (feasibility and acceptability).
- (2) Semi-structured interviews with trainers.
- (3) Online questionnaire to all peer supporters, focusing on reasons for engagement/non-engagement, preferred communication approaches, perceived challenges and factors facilitating role, perceived response of peers (fidelity, acceptability, reach).
- (4) One focus group and 1-2 semi-structured paired interviews with peer supporters (2-4 schools) to amplify and explore issues identified in online questionnaire and explore how change (if perceived) is spread through social networks.
- (5) One focus group and 1-2 semi-structured paired interviews with student participants (in 2-4 schools), including high and low engagers to explore reasons for variation in participation/non-participation, discuss perceived value of different intervention components and acceptability/feasibility of longer-term follow-up (reach, feasibility and acceptability).
- (6) Stakeholder focus groups (school management/teachers and parents) in 2-4 schools (6 groups approx), to assess any changes to provision of sex education, acceptability issues, factors facilitating and hindering implementation, perceived impact on social groups/school culture, views on longer term follow-up, resources needed for sustained implementation (fidelity, acceptability, sustainability).
- (7) Project monitoring data on students nominated, recruited, attending training and participating in intervention by gender, socio-economic status and school engagement; review of minutes of meetings with stakeholders and training providers to document implementation decisions and issues (retention, fidelity and feasibility).
- (8) Monitoring of contemporaneous events such as relevant high coverage media stories using Google Alerts and relevant search term (potential confounding and contamination).
Data outputs: audio files (stored as MP3 files), anonymised verbatim transcripts (MS Office word) and NVivo outputs such as memos, text searches and node summaries.

2. Data collection / generation

2.1 Methodologies for data collection / generation

Questionnaires and interviews.

2.2 Data quality and standards

Adherence to UK Data Service guidance for recording, transcription and coding (see

<http://ukdataservice.ac.uk/manage-data/format/transcription.aspx> for examples). Quality checks at key stages to ensure transcriptions accurately represent verbal recordings, anonymised to remove personal information (in line with UK Data Protection Act), and coded appropriately, including double coding of a portion of transcripts. Published data will adhere to NICE quality guidelines (<http://www.nice.org.uk/article/pmg10/chapter/appendix-g-methodology-checklist-qualitative-studies>).

Validated questionnaires will be used as recommended by the Trial Management Group.

Range checks will be built in to the online questionnaire.

Questionnaire will be tested with SPHSU staff prior to release as well as with pupils in schools. The baseline/follow-up questionnaire will be pre-tested via cognitive interviews to test comprehension and acceptability of items.

Transcription of interviews will be conducted by Smallbiz, with whom the SPHSU have a non-disclosure agreement and appropriate data sharing protocols in place.

Digital recording of interviews will only begin once consent and personal information collected.

3. Data management, documentation and curation

3.1 Managing, storing and curating data

Managing, storing, curating data:

Data will be stored on the SPHSU's password protected, secure server, which is backed up daily. Only appropriate members of the STASH Trial Management Group members will have access to the data.

Resources

Network file sharing, available via Glasgow University

Study web page. Can be created via Glasgow University web site (My Glasgow/Share point).

7-Zip encryption software will be used, based on the recommendations made by IT at the start of data collection.

Data sent off site for transcription will be logged into and out of the unit and encrypted data will be sent via secure website transfer, and with support from the unit IT team.

In reporting findings we will ensure that any quotations reported do not reveal the identity of participants or schools.

Outputs:

Raw data files, STATA outputs, MPlus outputs and data analysis presented in tables and figures. Data for survey stored separately to any personal information the Unit may have about participants.

3.2 Metadata standards and data documentation

Intervention documentation and process data. Outputs: text (word) and numerical (excel spreadsheets). The study protocol will outline a systematic and unbiased record of events and ensure protection of privacy in line with UK Data Protection Act.

The project will follow UK Data Service recommendations for documentation of data (<http://ukdataservice.ac.uk/manage-data/document.aspx>), including implementation of appropriate file structure, labelling and data storage formats. Where appropriate will use the Data Documentation Initiative (DDI) specification tool to record metadata through the lifecycle of the project (<http://www.ddialliance.org/Specification/>).

3.3 Data preservation strategy and standards

All data will be kept in adherence to the SPHSU Data Archiving SOP.

This outlines the process for electronic numbering, applying a retention review date, process for retrieval.

Anonymised data will be converted into a format suitable for long-term access, as recommended by the UK Data Service and the Digital Curation Centre (<http://www.dcc.ac.uk>). These will be stored on Glasgow University's Secure Server for a minimum of 10 years following project completion, with data integrity checked every 2/3 years.

4. Data security and confidentiality of potentially disclosive personal information

4.1 Formal information/data security standards

The Unit works to ISO 27001, 27002 for information technology security according to the MRC policy. Specific policies applying to the data are described in the Unit policies on the Management of Research Data and on Working with Electronic Data and we abide by the MRC guidance on Personal Information in Medical Research. In particular, in relation to encryption, own cloud and password protection.

There is a risk that unauthorised users may gain access to data containing personal information. To reduce this likelihood, collection of identifying information will be kept to a minimum and user authentication and encryption will be applied throughout. Any printed transcripts used during analysis will be stored in a locked cabinet and destroyed when no longer needed.

Data transcripts will be anonymised (for instance by replacing student names with pseudonyms) and by removing geographical identifiers such as names of towns and schools. Storage of data described above is designed to protect confidentiality.

Consent forms will be stored separately from other data during data collection.

Where possible data will be labelled by ID only.

4.2 Main risks to data security

Identification of individual study members is the main security risk but every step is taken to reduce this risk: information that could be used to identify individuals is removed from the main data files, and are not accessed by researchers or shared externally. Such data include date of birth, full postcode, and uncoded verbatim data. When data are shared with external collaborators, the data requested are checked for possible statistical disclosure risk.

5. Data sharing and access

5.1 Suitability for sharing

- Yes

It will be sufficient to make these data available to other researchers via open access publication and on the UK Data Archive within 18 months of completion of the particular phase of data collection.

With regard to the baseline and follow up questionnaire data, the cleaned data set will be made available via UK Data Archive. With regard to the qualitative data, a set of extracted quotes will be made available, organised under relevant thematic headings. In order to safeguard the anonymity of research participants, full transcripts will not be made publicly available. Both these data sources will go online as soon as the relevant papers have been published.

Consent to share the data will be requested within the consent process. Data from participants who refuse to have their data shared will be removed prior to sharing.

5.2 Discovery by potential users of the research data

Information on STASH will be made available on the SPHSU website. Information on the availability of the data will be included in any publications.

5.3 Governance of access

The Principle Investigators (Professor Laurence Moore and Dr Kirstin Mitchell) will control permission to access the study data.

5.4 The study team's exclusive use of the data

The study team consists of the following. Access to the data will be provided through the Principle Investigators.

Principal Investigators:

Professor Laurence Moore and Dr Kirstin Mitchell

[REDACTED]

Co-Investigators:

Dr Lisa McDaid and Dr Sharon Simpson

[REDACTED]

Dr Sarah Barry

[REDACTED]

Dr Julia Bailey and Ms Rachael Hunter

[REDACTED]

[Redacted text block]

Professor Lawrie Elliott

[Redacted text block]

University of Glasgow project staff:

Mr Ross Forsyth, Project Manager
Dr Carrie Purcell, Research Associate

[Redacted text block]

[Redacted text block]

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions
Data will be anonymised. Consent will outline clearly, the potential for data to be shared with other genuine researchers.

5.6 Regulation of responsibilities of users
Data sharing agreement will outline the conditions of use.

6. Responsibilities

Laurence Moore and Kirstin Mitchell, Co-Principle Investigators
Responsible for overseeing the management of the data collection, analysis and security.

Rachael Hunter, Health Economist
Responsible for securely storing the health economic data and ensuring the confidentiality of the participants who volunteered this data.

Ross Forsyth, Project Manager
Responsible for the day to day management of questionnaire data collection and storage.

Carrie Purcell, Research Associate

Responsible for the management of the qualitative data gathered within the STASH project.

Alex McConnachie, Statistician

Responsible for the secure management of any data provided to the Robertson Centre for Biostatistics.

7. Relevant policies

7. Relevant institutional, departmental or study policies on data sharing and data security

Policy	URL or reference
Data Management Policy and Procedures	In development
SPHSU Archive SOP	In development
Data Sharing Policy	In development

8. Author and contact details

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

Ross Forsyth

Principle Investigator - Kirstin Mitchell,

[REDACTED]

[REDACTED]