

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



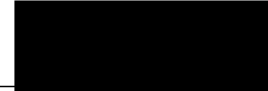
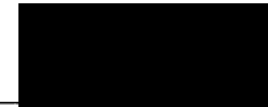
STASH

STATISTICAL ANALYSIS PLAN (SAP)

Study Title: STIs and Sexual Health
Short Title: STASH

Sponsor: University of Glasgow
Funded by: National Institute of Health Research Public Health Research Programme
Funder ref: 14/182/14
REC: College of Medical, Veterinary and Life Sciences Ethics Committee, University of Glasgow

Protocol Version: v1.4 Date: 17th November 2017
SAP Version: v1.0 Date: 2nd May 2018

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CONTENTS

1.	Introduction	4
1.1.	Study Background	4
1.2.	Study Design	4
1.3.	Sample Size and Power	4
1.4.	Study Population	5
1.4.1.	Inclusion Criteria	5
1.4.2.	Exclusion Criteria	5
1.5.	Study Objectives	5
1.5.1.	Acceptability and Feasibility	5
1.5.2.	Potential Primary and Secondary Outcomes	6
1.6.	Study Outcomes	7
1.6.1.	Grouping Variables	7
1.6.2.	Acceptability Outcomes	7
1.6.3.	Feasibility Outcomes	8
1.6.4.	Potential Primary Outcomes	9
1.6.5.	Potential Secondary Outcomes	9
1.6.6.	Effect Modifiers	10
1.6.7.	Social Network Analysis	10
1.7.	Statistical Analysis Plan (SAP)	10
1.7.1.	SAP Objectives	10
1.7.2.	General Principles	10
1.7.3.	Current Protocol	11
1.7.4.	Deviations To Those Specified In Study Protocol	11
1.7.5.	Software	11
2.	Analysis	12
2.1.	Study Populations	12
2.2.	Baseline Characteristics	12
2.2.1.	Student Characteristics	12
2.2.2.	School Characteristics	12
2.3.	Questionnaire Validation	12
2.3.1.	Identifying Questionnaire Domains	13
2.3.2.	Internal Consistency	13
2.4.	Outcome Analysis	13
2.4.1.	Acceptability and Feasibility Outcomes	13
2.4.2.	Potential Primary and Secondary Outcomes	13
2.4.3.	Social Network Analysis	14
2.4.4.	Additional Exploratory Analysis	14
2.5.	Identifying Outcomes for Future Trial	15
3.	Document History	15
4.	Tables	15

Glasgow Clinical Trial Unit
Statistical Analysis Plan (SAP)

5. Figures	15
6. Listings	15
APPENDIX A.....	16

1. INTRODUCTION

1.1. STUDY BACKGROUND

Young people in the UK are at the highest risk of STIs and report higher levels of unsafe sex than any other age group and this elevated risk is linked to a number of reasons such as lack of awareness, insufficient knowledge of protection and social norms which denigrate safer sexual behaviour and undermine the quality of intimate relationships. Also, STIs are associated with socio-economic inequality and early intervention is thought to prevent disadvantage leading to poor lifetime sexual health.

1.2. STUDY DESIGN

The intervention will be evaluated using an intervention development and exploratory study undertaken in two stages. This SAP is relevant only to stage 2.

At stage 2 an exploratory study in six schools will be conducted to include a feasibility trial and process evaluation to assess whether progression criteria for a subsequent full trial are met.

The study is a non-randomised design where students in S4 in the academic year 2016-2017 in all study schools completed the study evaluation measures at the end of S4. As they have not been exposed to the intervention, they will be used as a control arm to carry out comparisons with the intervention arm. The intervention will be delivered to students in S4 in the academic year 2017-2018 in all study schools and they will complete the study evaluation measures at the beginning and end of the 2017-2018 academic year and will constitute the intervention arm of the study.

Peer nomination questionnaires will be used to identify the most influential pupils to become peer supporters. They will undergo training facilitated by Fast Forward and the West Lothian Drug and Alcohol Service. Over a defined period (between 5 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. Participants in the study include all students in S4 in each of the study schools.

1.3. SAMPLE SIZE AND POWER

The study is not designed to identify an estimate of effect and thus a standard power calculation is not appropriate. The average year size for West Lothian is 160 pupils and allowing for a non-response of 15% due to pupil absence, sample size across all 6 schools is approximately 700 intervention participants and 700 control participants.

1.4. STUDY POPULATION

6 schools in the Lothian region will be recruited and the intervention will be delivered to all S4 (aged 14-16) students within these schools regardless of their sexual experience or individual level of risk.

1.4.1. INCLUSION CRITERIA

State funded schools in the Lothian region, Scotland. Faith schools will be included if they are willing to accept the intervention in full (including condom promotion as a strategy for STI prevention). All S4 students at the eligible schools who have received, or are currently in receipt of teacher-led sex education, regardless of their sexual experience or individual level of risk will be eligible.

1.4.2. EXCLUSION CRITERIA

Private schools will not be eligible to participate in the study.

1.5. STUDY OBJECTIVES

1.5.1. ACCEPTABILITY AND FEASIBILITY

The aim of the STASH study is to develop and test the feasibility and acceptability of a school-based intervention delivered by peer supporters to prevent and reduce transmission of sexually transmitted infections and improve the sexual health of secondary school students aged 14-16 in UK with the aim of determining if a larger scale trial is warranted.

The main objective of the study is to determine whether the study meets the predetermined progression criteria, which measure:

- Feasibility of the intervention and evaluation methods
- Acceptability of the intervention and evaluation methods to peer supporters, target group and the stakeholders.

The progression criteria are:

- Was it feasible to implement STASH in 4 of 6 schools?
 - green: proceed if 60% of nominated students are recruited and complete the training in each of 4 schools
 - amber: discuss if 50% of nominated students are recruited and complete the training in each of 4 schools
 - may not proceed if amber target achieved in <4 schools
- Was STASH acceptable to peer supporters in 4 of 6 schools?

- green: proceed if 60% of peer supporters who complete the training send ≥ 3 messages/have ≥ 3 conversations and attend ≥ 2 follow-up meetings, and 60% of peer supporters 'liked' the role, in each of 4 schools
- amber: discuss if 50% of peer supporters who complete the training send ≥ 3 messages/have ≥ 3 conversations and attend ≥ 2 follow-up meetings, and 45% of peer supporters 'liked' the role, in each of 4 schools
- may not proceed if amber target achieved in < 4 schools
- Was STASH acceptable to stakeholders and target group?
 - green: proceed if in each of 4 schools 60% of students exposed to STASH agree that the intervention was acceptable; no major acceptability issues raised by schools; and $< 15\%$ of peer supporters report that parents were unhappy about them being a peer supporter.
 - amber: discuss if in each of 4 schools 50% of students exposed to STASH agree that the intervention was acceptable; ≤ 2 acceptability issues raised by schools; and $< 20\%$ of peer supporters report that parents were unhappy about them being a peer supporter.
 - may not proceed if amber target achieved in < 4 schools
- Were the evaluation methods acceptable and feasible?
 - green: proceed if student response rates of $> 70\%$ at baseline and follow-up in each of 4 schools
 - amber: discuss if student response rates of $> 60\%$ at baseline and follow-up in each of 4 schools
 - may not proceed if amber target achieved in < 4 schools

1.5.2. POTENTIAL PRIMARY AND SECONDARY OUTCOMES

The study aims to determine key trial design parameters for a possible future large-scale trial, including key outcome measures, intra-cluster correlation and sample size.

The end outcomes for the trial are: delayed initiation/abstinence from sexual activity; and consistent condom use among those who are sexually active. We will consider a range of potential primary outcome indicators and the study will set an indicative primary outcome, for use in any subsequent trial. Given that sexual behaviour would be expected to increase from baseline to follow up due to maturation effects, the primary comparisons will be between

intervention and controls. Similar processes will assess a range of secondary outcomes. Effect modifiers will be explored to allow hypothesis generation in a future large-scale trial.

1.6. STUDY OUTCOMES

1.6.1. GROUPING VARIABLES

The main grouping variable will be study group, i.e. intervention vs control group.

For the purposes of assessing some of the outcomes, pupils will be categorised according to the following:

Intervention ID (intervention group only):

1. Peer supporter
2. Peer supporter drop-out (did training but did not complete role)
3. Nominee (nominated but did not attend training)
4. Student – other (none of the above)

Level of exposure (intervention group only):

1. Trained peer supporter
2. Student exposed (received at least one message or had at least one conversation or visited the STASH website)
3. Student unexposed

1.6.2. ACCEPTABILITY OUTCOMES

Progression criteria (overall and by school)

Intervention group only:

- Number of nominated students that are recruited
- Number of peer supporters who complete the training and send ≥ 3 messages/have ≥ 3 conversations and attend ≥ 2 follow-up meetings
- Number of peer supporters who report that they 'liked' the role
- Number of students exposed to STASH that agree that the intervention was acceptable
- Number of peer supporters who report that their parents were unhappy about them being a peer supporter

Intervention and control groups (overall and separately):

- Student response rates (any questions answered) to questionnaires at baseline and follow-up.

Other research questions (all students, unless otherwise stated):

- Is the questionnaire acceptable to students that have a lower academic attainment (for the sample overall and separately for study group, baseline only)?
 - Number of missed items by planned examinations (Nat 4 only versus combination of Nat 4/Nat 5 versus Nat 5 only) or other appropriate categorisation of planned exams
 - Number of missed items by intention to leave school.
- Is there any systematic bias in students who only complete one questionnaire? Appendix items 1-12, 14, 15, 17 and 18 will be compared by completion/non-completion of follow-up questionnaire, for the sample overall and separately by study group.
- Is the level of peer supporter engagement related to school climate (peer supporters only)?
 - Number of FB posts and conversations from follow-up questionnaire plus from PS questionnaire; intention to keep sharing messages after intervention ends; liked being a peer supporter by
 - My teachers are fair in dealing with students
 - I try hard in school
- What is the experience of peer supporters (peer supporters only)?
 - All variables in peer supporter questionnaire will be summarised overall and by gender and school.
- Is data linkage acceptable¹ and does it vary by key factors (for the sample overall and separately by study group, at both baseline and follow-up). Key factors that will be considered are appendix items 1, 2, 3, 5, 7-12, and 14-17.

1.6.3. FEASIBILITY OUTCOMES

Progression criteria (overall and by school)

Intervention group only:

- Number of nominated students who are recruited and complete the training

¹ Note that slightly different wording was used in control, baseline and follow-up questionnaires.

Intervention and control groups (overall and separately):

- Student response rates (any questions answered) to questionnaires at baseline and follow-up.

Other research questions:

- Representativeness of nomination results: What factors at baseline are associated with being nominated, taking up the role, completing and dropping out? Items 1-17 from the baseline characteristics listed in the appendix will be reported overall and by intervention ID.
- Who is exposed to the intervention? Items 1-17 from the baseline characteristics listed in the appendix will be reported overall and by level of exposure.

1.6.4. POTENTIAL PRIMARY OUTCOMES

Potential primary outcomes (variable names in Appendix) will be reported overall, by study group and by exposure:

- Condom use at last vaginal intercourse
- Condom/dental dam use at last oral sex
- Number of sexual partners in last 3 months and whether a condom was used
- Frequency of condom use in the last 6 months
- Proportion of students who have not have sex in the past 6 months or have not had sex at all

1.6.5. POTENTIAL SECONDARY OUTCOMES

Potential secondary outcomes (variable names in Appendix) will be reported overall, by study group and by exposure:

- STI prevention and sexual health related knowledge
- Ease of talking about sex with parents and friends
- Ease of talking about sex with a boyfriend/girlfriend
- Confidence in STI prevention skills
- 'Competence' at first intercourse/competence at last intercourse
- Sexual attitudes and adherence to sexual health norms
- Perception of whether others are sexually active
- Self-reported quality of intimate relationships
- Distress about sex life
- Use of internet and social media for finding sexual health information, sexting and viewing sexual images
- Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS)
- Conversations about STASH-related topics

- Self-esteem
- Self-reported sexual activity
- Knowledge of local sexual health services

1.6.6. EFFECT MODIFIERS

- Single item measures of:
 - gender
 - socio-economic status (SIMD, free school meal status)
 - ethnicity
 - educational attainment
 - religiosity
 - date of follow-up questionnaire completion
- Self-reported risk behaviours in peer group
- School climate and engagement
- Parental monitoring
- Sexual attraction and identity
- Self-regulation
- Importance of social media to social life
- Social network questions
- Exposure to intervention activities

1.6.7. SOCIAL NETWORK ANALYSIS

Research questions include:

- How many peer supporters and non-peer supporters name one or more friends who are not in the S4 year group?
- How many peer supporters said they shared STASH messages with people outside of their school?

1.7. STATISTICAL ANALYSIS PLAN (SAP)

1.7.1. SAP OBJECTIVES

The objective of this SAP is to describe the statistical analyses to be carried out for the STASH Study.

1.7.2. GENERAL PRINCIPLES

Continuous variables will be summarised by the number of observations, number of missing values, the mean and standard deviation, the median and inter-quartile range and the minimum and maximum values. Categorical variables will be summarised by the number of observations, number of missing values and the number and percentage of subjects that are in each of the categories.

Acceptability and feasibility outcomes will be presented with corresponding 95% confidence intervals where appropriate.

Missing data will not be imputed.

Schools will not be named in the analysis report but, where any results are broken down by school (eg. school characteristics), will be reported anonymously by school ID number.

1.7.3. CURRENT PROTOCOL

The current study protocol at the time of writing is version 1.4, dated 17/11/17. Future amendments to the protocol will be reviewed for their impact on this SAP, which will be updated only if necessary. If no changes are required to this SAP following future amendments to the study protocol, this will be documented as part of the Robertson Centre Change Impact Assessment processes.

1.7.4. DEVIATIONS TO THOSE SPECIFIED IN STUDY PROTOCOL

There are no deviations from the current study protocol.

1.7.5. SOFTWARE

The statistical software packages used will be R for Windows v3.3.1, SAS for Windows v9.3, or higher versions of these programs.

2. ANALYSIS

2.1. STUDY POPULATIONS

The study population is all pupils who provide consent to participate in the study and have provided any data.

2.2. BASELINE CHARACTERISTICS

2.2.1. STUDENT CHARACTERISTICS

Summaries of the following baseline characteristics will be provided overall and by study group. They will also be summarised separately for those who did not complete the follow-up survey as per the general principles in Section 1.7.2:

- Gender
- Age
- SIMD
- Residence
- Ethnicity
- Number of exams being taken
- Plans for leaving school
- Views on religion

Associations between baseline characteristics and successful follow-up (defined as completion of any items in the follow-up questionnaire) will be summarised and may be investigated using appropriate statistical tests and mixed effects logistic regression models, adjusting for clustering by school, and presented with corresponding 95% confidence intervals.

2.2.2. SCHOOL CHARACTERISTICS

- % Free school meals
- Total number of pupils
- Urban/rural
- National 5 exam results

2.3. QUESTIONNAIRE VALIDATION

This process will be carried out on the control data, to identify domains into which individual questionnaire items could be combined and to assess internal consistency. This will help inform the outcome measures to be used for a future RCT.

The results from this analysis will feed into the primary and secondary outcomes analyses, with identified domains being analysed as detailed in those sections.

2.3.1. IDENTIFYING QUESTIONNAIRE DOMAINS

Analysis of the control data will be carried out to assess the effectiveness of the questionnaire items and measures that are being used.

Principal Component Analysis (PCA) will be used to determine items that can potentially be dropped from the questionnaire in future and to combine individual questions into relevant domains. This will be applied to

1. All individual items
2. Items by question bank.

The results will be used to identify domains across the whole questionnaire, into which individual items could be combined, and also to assess whether some individual items could be dropped from question banks.

A separate PCA will be carried out on the set of potential primary outcomes to address whether a combined variable could be formed from the individual items.

2.3.2. INTERNAL CONSISTENCY

Cronbach's alpha will be calculated for each PCA domain to assess reliability of the domains and inform whether individual items should be dropped.

2.4. OUTCOME ANALYSIS

2.4.1. ACCEPTABILITY AND FEASIBILITY OUTCOMES

These will be summarised descriptively as detailed in Sections 1.6.2 and 1.6.3, according to the general principles in Section 1.7.2.

2.4.2. POTENTIAL PRIMARY AND SECONDARY OUTCOMES

To assess the effect of the intervention on the potential primary and secondary outcomes, mixed effect regression models will be fitted to each with a fixed effect for study group and a random effect for school.

Similar models will adjust for the effect modifiers to identify the factors that have an effect on the outcomes to indicate whether future studies should adjust for such factors.

The effect estimates and 95% confidence intervals (CI) will be reported for the intervention effect and any effect modifiers, for each of the models, allowing determination of the key trial design parameters for the future

randomised control trial (RCT). The within-school intraclass correlation coefficients for each of the outcomes will be reported to inform the sample size calculations for the future RCT.

These analyses will be carried out on:

1. All individual question items listed in Section 1.6.4 and 1.6.5;
2. All question banks containing those individual items (mean score across all constituent questions with data);
3. Outcome domains as identified by method 1 (across all items) in Section 2.3.1;
4. Outcome domains as identified by method 2 in Section 2.3.1 (within question bank).
5. Any outcome domain identified from the set of potential primary outcomes, as detailed in Section 2.3.1.

2.4.3. SOCIAL NETWORK ANALYSIS

To answer the social network analysis research questions, the following analyses will be conducted:

1. Calculate the percentage of outside network friends (this is the number of nominated friends that are not in S4 divided by the total number of nominated friends). This will be carried out on:
 - Each school
 - All control schools together
 - All intervention schools together
 - Whole sample population (control and intervention schools)
2. Number of peer supporters that said they had shared the STASH messages with people who are outside of their school.

2.4.4. ADDITIONAL EXPLORATORY ANALYSIS

The models in Section 2.4.2 may be extended to estimate the intervention effects within subgroups of the population using interactions between intervention and the effect modifiers specified in section 1.6.6, to determine if the intervention is more or less effective in these subgroups.

2.5. IDENTIFYING OUTCOMES FOR FUTURE TRIAL

Sensitivity to change of the potential primary outcomes and the outcome domains identified from the PCA will be assessed using mixed effects models fitted to the outcome values for the intervention group at baseline and follow-up, with a random intercept for school and a random slope for time. The sensitivity to change will be compared between potential primary and secondary outcomes using the magnitude of the random slope variance from each model.

No statistical tests will be carried out but the comparison will inform the choice of primary and secondary outcomes for the future trial. The completeness of the data and the prevalence of each potential outcome will also inform the choice of the outcomes.

3. DOCUMENT HISTORY

This is version 1.0 of the SAP for the STASH study, dated 2nd May 2018 and this is the initial version of this document.

4. TABLES

Dummy tables will be produced during the development of the statistical analysis programs for review and feedback. Approval of the content of the final statistical outputs will be a requirement for database lock.

5. FIGURES

Dummy figures will be produced during the development of the statistical analysis programs for review and feedback. Approval of the content of the final statistical outputs will be a requirement for database lock.

6. LISTINGS

No formal listings will be provided as part of the final analysis of the study. A copy of the final data in both raw and processed form will be provided at the end of analysis.

APPENDIX A.

Listed below are the items from the questionnaire that relate to the baseline characteristics and the potential primary and secondary outcomes.

Baseline characteristics

- 1) Gender
- 2) IMD (postcode)
- 3) Free School Meals (fsm)
- 4) Type of residence (reside)
- 5) Educational attainment (exam)
- 6) Age (derived from mnthyr)
- 7) Intention to leave school (leave)
- 8) Religiosity (relig)
- 9) Ethnicity (ethnic)
- 10) Identity (ident)
- 11) School Climate (climfair, climtalk, climval, climtrust, climenc, climclose, climtry)
- 12) Peer risks (peersex, peerlaw, peeralc, peercan)
- 13) Named by others as someone you can talk to about private things (derived variable using F1name-F6name. Full names in data will be replaced by subject IDs before data is received by statistician to prevent exposure to subject identifiable information and a variable will be created to determine if each subject has been named by a peer)
- 14) Talking to parents about sex (talkpar)
- 15) Talking to friends about sex (talkfren)
- 16) Wellbeing (EWopt, EWuse, EWrlx, EWprob, EWthink, EWclose, EWmind)
- 17) Sexual experience:
 - ever experienced oral sex (oralyes)
 - ever experienced sexual intercourse (intyes)
 - condom use at last sexual intercourse (intlastcdm)
- 18) Self-esteem (esteem, melike, melook)
- 19) Conversations about STASH related topics (chabod, chahelp, charel, chalgbt, chaready, chapress, chasti, chaup, chasxt, chawor)

Effect moderators

- 1) Parental monitoring (parhome, pardet, parcheck)
- 2) Sexual attraction and identity (attract, identity)
- 3) Self-regulation (regford, regwant, regres)
- 4) Importance of social media to social life (smimp, smout)
- 5) Exposure to intervention (Number of FB posts, number of STASH conversations: stash_sharing, role_liked)
- 6) Date of follow-up questionnaire completion

Potential Primary Outcomes

- Condom use at last vaginal intercourse
 - Intlstcdm, oralstcdm
- Condom/dental dam use at last oral sex
 - oralstcdm
- Number of sexual partners in the last 3 months and whether a condom was used
 - int3mpart, int3mcfreq, oral3mp, oral3mcdm
- Frequency of condom use in the last 6 months
 - int3mfreq, int3mcfreq
- Proportion of students who have not had sex in the past 6 months or have not had sex at all
 - intwhn, intyes, oralyes, oralwhn

Potential Secondary Outcomes

- Reasons for not having sex (intwhy and oralwhy)
- STI prevention and sexual health related knowledge
 - knwcdm, knwdam, knwsti, knwlaw, knwdoc, knwantb, knwcum, knwlube, knwclit
- Ease of talking about sex with parents and friends
 - talkpar and talkfrend
- Ease of talking about sex with a boyfriend/girlfriend
 - releasy
- Confidence in STI prevention skills
 - conrecog, contell, conshow, conget, conput, conref
- 'Competence' at first intercourse
 - int1stwill, int1stcont, int1stmet, int1streg, int1stmot
- 'Competence' at most recent intercourse
 - Intlastwill, intlastregret, intlastdrugs
- Sexual attitudes and adherence to sexual health norms
 - opgirl, opnude, opslut, opslutb, oporn, oppop, openjoy, opno, opagree, opfree, opdrunk, oprisk
- Perception of whether others are sexual active
 - sexest
- Self-reported quality of intimate relationships
 - prqfeel, prqhap, pretalk, prqang, prqpers, prqjeal, rqfeel, rqhap, rqtalk, rqres, rgang, rqpers, rqjeal
- Distress about sex life
 - distress
- Use of internet and social media for finding sexual health information, sexting and viewing sexual images
 - webinfo, webimag, webndsend, webndget, webndask, webndfor
- Short Warwick-Edinburgh Mental Well-Being Scale
 - EWopt, EWuse, EWrlx, EWprob, EWthink, EWclose, EWmind

Glasgow Clinical Trial Unit
Statistical Analysis Plan (SAP)

- Conversations about STASH related topics
 - chabod, chahelp, charel, chalgbt, chaready, chapress, chasti, chaup, chasxt, chawor
- Self-esteem
 - melike, melook, esteem
- Self-report sexual activity - kiss, gent, mstbte
- Anal sex ever and in last 6 months (anal, analwhn)
- Knowledge of local sexual health services
 - cdmwher, ecwher, contwher, advwher

Social Network Analyses

- Named friend not in S4 at their school (F1S4-F5S4)
- Shared STASH messages with people outside of my school (often_outside from Peer Supporter Questionnaire)