

STASH

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

STASH (STIs and Sexual Health) is funded by the National Institute of Health Research Public Health Research Programme.

Sponsor:	University of Glasgow, G12 8QQ
Funder:	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
ISRCTN ref:	TBA

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17/11/17

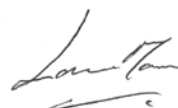
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General Information This protocol describes the STASH study and provides information about the procedures for entering participants into the study. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary, particularly following the development phase of the study. These will be circulated to the known Investigators in the study, but other collaborators are advised to contact the study staff in the Social and Public Health Sciences Unit (SPHSU) to confirm that they have the most up-to-date version of the protocol in their possession. Problems relating to the study should be referred, in the first instance, to the Principle Investigators at SPHSU.

Compliance This study will adhere to the conditions and principles outlined in the EU Directive 2001/20/EC, EU Directive 2005/28/EC and the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95). It will be conducted in compliance with the protocol, the Research Governance Framework for Health and Social Care (Department of Health 2008), the Data Protection Act 1998, and other regulatory requirements as appropriate.

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All queries should be directed to the Project Manager, Mr Ross Forsyth, who will direct the query to the most appropriate person.

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- 1) Table of behaviour change techniques
- 2) Guidance on Harms

Glossary of abbreviations

PI	Principal Investigator
CSO	Chief Scientist Office
ISRCTN	International Standard Randomised Controlled Trial Number
MRC	Medical Research Council
NHS	National Health Service
NIHR-PHR	National Institute of Health Research Public Health Research
QALY	Quality-adjusted Life Years
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SOP	Standard Operating Procedure
SPHSU	Social and Public Health Sciences Unit
TSC	Trial Steering Committee
TMG	Trial Management Group
PEG	Project Executive Group

1. Amendment history

Amend No.	Version no.	Date issued	Author(s) of changes	Details of changes made
1	0.3	21/1/16	KM	Changes from detailed project description approved by NIHR: - Recruitment of schools changed from Lothian-wide to West Lothian initially. - Faith schools excluded on the basis that key components of intervention content (e.g. promotion of condom use) would be inconsistent with messages promoted by schools. - Added paragraph on qualitative analysis; previously missing - In description of intervention, added sentence on designing website to house peer supporter manual/intervention content - Replaced text on study management with excerpt from the 'Study Management Plan' which gives more precise detail than the original DPD
2	0.6	11/2/16	KM	- Revised economic analysis , including changing outcome from SQoL to EQ-5DY - Progression criteria revised to be more conservative - Revised wording on recruitment of schools. Took out choice for parents to opt out of study as not practical
3	0.9	24/06/16	KM	Flowchart revised to reflect changes to project timetable, specifically that the STASH project can only be run in Autumn term, due to the timetabling of exams between January and June.

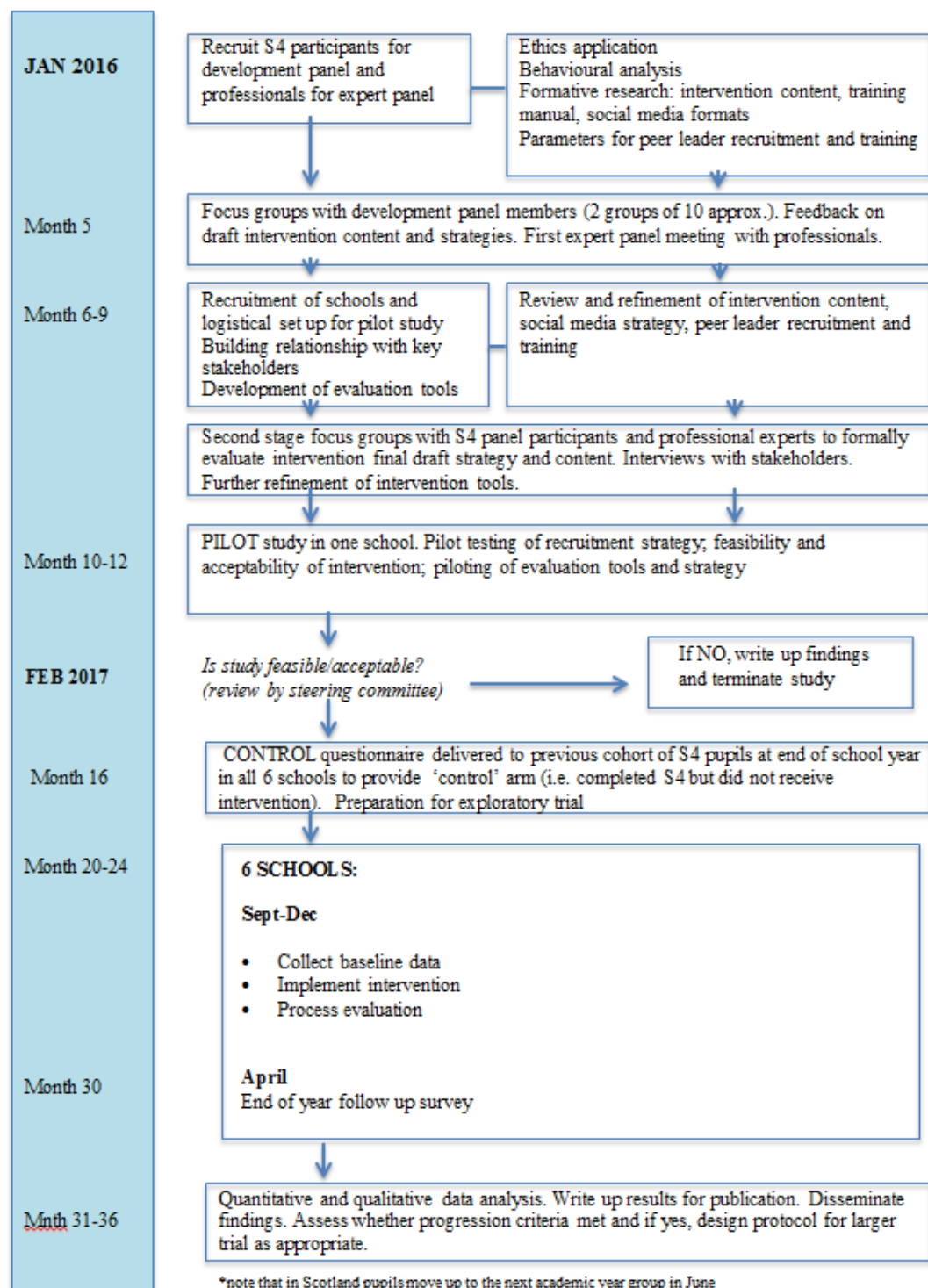
				• Minor changes to description of recruitment process in development phase, specifically on development of young people's panels. No longer specified that schools must be in Glasgow and Edinburgh areas. • Minor changes to description of intervention based on initial findings from development work; specifically on peer delivered activities and on acknowledgement of efforts of peers. • Added more detail on behaviour theories guiding intervention development to reflect work on the development of the intervention. Specifically, role of TDF clarified, and several relevant theories introduced: SDT; NPT; SCT; and social norms theory.
4	0.10	16/09/16	KM	• Minor changes to description of secondary outcomes to reflect the results of TMG discussion on measures for the questionnaire (EQ-5DY replaced by CHU-9; SWEMWS measure added; Rosenborg's self-esteem measure deleted) • Process evaluation interviews and groups revised downwards due to feasibility concerns. Now proposed that we conduct a basic process evaluation in all 6 schools and in-depth 'case study' evaluation in 2 to 4 schools. Cognitive interviews on outcome questionnaire reduced from 12 to 6 in number as felt that previous number was not realistic. Also, now that it is possible to track website engagement electronically,

				trainers will only monitor harms and not general engagement. Inserted updated theory of change, revised based on behavioural analysis and need to better reflect the mechanisms of change, and contextual influences
5	V1.2	22/05/17	KM/CP/SS/RF/SB/RH	- Protocol significantly revised to reflect the fact that intervention development stage now complete. Intervention development now written in past tense as brief report of what has been done. - Minor changes are in tracked change and major revisions are coded red (with old text deleted). - Major changes are: clarified that faith schools can be included if they agree to the intervention in full; progression criteria revised following agreement from TSC; refinements to recruitment process and study withdrawal; clarification and further detail on outcomes; updated programme theory of change and logic model; revised description of intervention to include changes made following pilot; refined plans for process evaluation; clarified and added detail to approach to dealing with harms.
6	V1.4	17/11/17	KM	Accepted all tracked changes; replaced programme theory with an updated version which reflects further work on this; following discussion and agreement with TSC and NIHR, revised the progression criteria. Main change was removal of outcome 5 (whether observed outcomes reflected

				benefit/harm). This was because of difficulty of setting meaningful thresholds, given wide confidence limits. In ethics section (17.3 Confidentiality), removed paragraph on circumstances in which confidentiality would be broken as questionnaire does not ask about any behaviours which could be considered safeguarding issues, and qualitative research is purely focused on experience of the intervention (no personal disclosures), so this paragraph now outdated. Safeguarding issues covered instead in the separate document: STASH Procedures Reporting of Harms to NIHR TSC v3.2.
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2. Study schema

STASH study FLOW diagram



3. Study summary

Rationale: Young people in the UK are at highest risk of STIs and report higher levels of unsafe sex than any other age group. Their elevated risk has been linked to lack of awareness, insufficient knowledge of how to protect themselves, and social norms which denigrate safer sexual behaviour and undermine the quality of intimate relationships. Research suggests that involving peer supporters in intervention delivery is acceptable to students and effective in reducing risk behaviours via ‘diffusion of innovation’, particularly where peer supporters are influential role models, chosen by peers. Interventions in which peer supporters work informally within their social networks offer a useful alternative to peer-led didactic teaching, which has shown limited effects. To date, there have been no UK school-based studies in which peer supporters utilise social media, despite research from elsewhere suggesting their potential.

Intervention: 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 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. They will be supported – through regular meetings and via social media – by the professionals who trained them.

Participants and methods: Stage one (now complete) involved formative evaluation of the intervention, including expert and student panels to advise on intervention design, and piloting of the intervention and evaluation instruments in one school. In stage two the revised intervention will be tested via exploratory study in 6 schools, with staged implementation and comparison with previous cohort of S4 students (controls). We will collect core process measures in all 6 schools, with extended measures in 2-4 schools. Basic evaluation will comprise: student evaluation of peer supporter training; interviews with trainers; peer supporter online questionnaire; social network analysis; project monitoring data; and analysis of relevant items from the follow-up questionnaire. The extended evaluation will include the above with the addition of: structured observation of peer supporter training; and paired/group interviews with trained peer supporters, non-peer supporter S4s and teachers.

Measures: The main outcome is attainment of progression criteria to a potential subsequent full trial. The primary effectiveness outcomes are delayed initiation/abstinence from sexual activity; and consistent condom use among those who are sexually active. We will also assess the feasibility and acceptability of linkage to NHS data on STI diagnosis as a longer-term outcome. Secondary outcomes include: STI prevention and sexual health related knowledge, Confidence in STI prevention skills, sexual attitudes and adherence to sexual health norms, and quality of intimate relationships. Process measures include feasibility, fidelity, acceptability

and reach of the intervention, for example the proportion of nominated peer supporters who agreed to participate, and the proportion of students in S4 not exposed to intervention activities. 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.

4. Introduction

4.1 Background

Existing research. Young people report higher levels of unsafe sex than any other age group and are also at highest risk of STI diagnosis [1]. STIs are associated with socio-economic inequality [1] and early intervention is required to prevent disadvantage converting to poor lifetime sexual health. Despite this, there is a lack of UK-based evidence on effective and cost-effective interventions to reduce STIs in young people.

A brief scoping review of sexual health interventions highlighted the following:

STI interventions targeting young people. Results from recent systematic reviews suggest modest impacts of conventional school based interventions. Picot and colleagues [2] systematically reviewed school-based skills building interventions for prevention of STIs. Twelve RCTs met inclusion and quality assessment criteria, including UK studies SHARE [3] and RIPPLE [4]. The reviewers found evidence of positive change in non-behavioural outcomes including knowledge and self-efficacy, and about half the studies reported a beneficial effect on at least one behavioural outcome (including condom use and sexual initiation). A parallel review of process data from these trials [5] suggested two key influences on outcome: fidelity, influenced by the extent to which the school had a supportive culture, a flexible administration and enthusiasm and expertise among those delivering the sexual health content; and acceptability and engagement, influenced by enthusiasm, credibility and expertise of intervention providers, and relevance and appeal to young people. Several reviews of sexual health interventions for young people have investigated factors associated with greater effect size [6-9] and found the following important: longer duration/greater intensity; focus on resilience and competencies (especially condom use); inclusion of behaviour change techniques (e.g. motivational training); emphasis on psychological correlates of risk; high quality training; recipient characteristics (e.g. age, risk profile), use of theory/formative research and supportive school environment. A recent systematic review [10] noted the diversity in approaches of effective interventions, suggesting that a range of effective mechanisms exist.

Peer-led interventions. Despite a significant literature, the effectiveness of peer-led approaches among young people is equivocal [11-15] and it has been described as ‘a method in search of a theory’ [16]. Recent systematic reviews [13, 15] suggest that some rigorously evaluated interventions have shown improvements in knowledge, attitudes and intentions, but almost none have had an impact on behaviour. Harden et al [17] identified five studies comparing the effectiveness of peer leaders to teachers in delivering the same intervention, of which two found peer leaders to be more effective than teachers. Peer leaders are thought to be less effective than adults at imparting factual information, and getting students involved in classroom activities but more effective at establishing conservative (non-risky) norms [11]. A formal teaching role may undermine credibility with peers [18] and may be less effective than informal social support work [12]. How peer educators are chosen and their reputation among peers is important [12,15,19]. Most studies rely on self-selection or teacher-selection, but both these strategies may result in educators who are not particularly credible and who find it difficult to reach high-risk students [19,20]. On the other hand, in the effective anti-smoking intervention ASSIST, despite initial doubts of students and staff, nomination of influential peers by students resulted in a diverse and representative group of peer leaders [19]. The STAND study used peer-nomination and diffusion of social norm change (though not using social-media) in a youth-focused sexual health intervention, and the approach was both acceptable and effective [21].

Use of social media. As a health promotion tool, social media has strong potential and its use is rapidly gaining currency [22]. There have been two recent systematic reviews of social media interventions in sexual health. Jones et al [23] reviewed 11 STI interventions targeting youth aged 15 to 24, and found evidence of impact on knowledge and weaker evidence of impact on risk behaviour. Swanton et al [24] reviewed 15 interventions, of which 6 were targeted at young people. They found significant impact on condom use and STI testing but with wide variation in effectiveness across study design. The studies included in these reviews mostly used text messaging or web-based interventions; only two used social networking sites (Facebook) and only one recruited existing social networks [25], though not networks within the same social system. Jones et al recommended that: interventions should use platforms that are popular with young people, that content should be interactive and visually appealing, and that interventions should seek to maximise engagement (e.g. via regular updates) and minimise burden (e.g. ease of use) [23]. Swanton et al also recommended interactive and personalised content, as well as development work with end-users to ensure that the intervention reflects the way social media is used [24].

Peer influence and social norms. A systematic review of predictors of adolescent initiation of sexual activity found that youth perception of social norms were stable predictors of sexual behaviour and intention [26]. Correcting misperceptions about what others do has been shown to reduce HIV risk behaviours in college students [27] and is supported by social norm theory [28].

Implications. We did not find any sexual health interventions involving peer-led use of social media within a school setting, suggesting that our proposed approach is novel. To be effective, the literature suggests that our intervention should: seek to minimise burden on schools; use social media platforms that are used by and appealing to young people; provide content that is interactive, visually appealing and relevant to their needs; involve end-users in the design; allow students to nominate their peer leaders, seek to augment rather than replace teacher-led provision; and let peer leaders influence normative attitudes and behaviours via informal contacts rather than didactic teaching.

4.2 Rationale for current study

Students in school represent a ‘captive audience’ and schools are particularly well placed to reach disadvantaged young people at higher risk of adverse sexual health outcomes, and before sexual attitudes and behaviours become entrenched [29]. Young people who cite school as their main source of information about sex are less likely to report unsafe sex and previous STI diagnosis [30]. The proportion citing school as their main source is increasing [31], but content and quality of provision of sex education in UK schools is variable [32]. Over two-thirds of young people report inadequate knowledge when they first felt ready for sex [31], suggesting significant room for improved delivery of school-based sex education.

The intervention builds on a peer-led smoking prevention intervention (ASSIST) in secondary schools, which recruited and trained ‘influential’ students (aged 12/13) as peer supporters to spread and sustain non-smoking norms through informal interactions with peers. A cluster RCT [33] found that smoking was reduced over a two-year period. The intervention has been recommended by NICE (PH23)¹ and is now disseminated under licence as DECIPHER-ASSIST. It has been successfully implemented in hundreds of schools, in over 30 areas in England, Wales and Scotland. As well as exploiting the efficacy of informal peer support delivered by influential students, the intervention also utilises professional trainers, thereby reducing burden on schools and increasing the potential for scalability and widespread adoption. While building on the theoretical approach underlying ASSIST [34] and its key intervention components (informal support by influential peers; external trainers), the STASH intervention will incorporate a number of significant differences and developments, with a focus on sexual health, an older age group and the use of social media in addition to face-to-face interactions.

As part of the pre-proposal development work, we conducted a patient and public involvement exercise (PPI), which found strong support for a combination of the ASSIST model augmented by a social media component. PPI participants said that social media is fundamental to their everyday interactions with friends. They perceived sex education at school to be largely

¹ <https://www.nice.org.uk/guidance/ph23/chapter/1-recommendations#recommendation-3-peer-led-interventions>. Accessed 22 April 2015

inadequate, expressed concern about discussing sexual matters with teachers and were enthusiastic about an intervention in which they could discuss sexual health with trained peers. Social media provides scope for rapid diffusion of messages, has potential for regular updates, visually appealing and interactive content, and is highly relevant to teenage social interaction. The approach is flexible, allowing peer supporters and participants to engage according to their interest, availability and comfort with different social media platforms. This flexibility also ensures that topics of importance to young people can be raised and addressed, even if outside the planned content. We expect that the natural overlap between online and face-to-face interaction will have a synergistic effect (e.g. friends talking about recent posts).

5. Study objectives

The aim of STASH is 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 and improve the sexual health of secondary school students aged 14-16 in UK.

By the end of the study (36 months), we will have:

1. Finalised the design of a school-based STI prevention intervention, in which influential peer supporters use online social networks and face-to-face interactions to influence norms, knowledge, competence and behaviour and promote use of sexual health services.
2. Assessed the recruitment and retention of peer supporters, as well as feasibility, and acceptability of the intervention among peer supporters, participants and key stakeholders.
3. Assessed the fidelity and reach of intervention delivery by trainers and peer supporters, including barriers to, and facilitators of, successful implementation.
4. Refined and tested the logic model and theoretical basis of the intervention.
5. Enhanced understanding of the potential of social media, when used by influential peers, to diffuse norm change and facilitate social support for healthy sexual behaviour.
6. Determined key trial design parameters for a possible future large-scale trial, including recruitment and retention rates and strategies, outcome measures, intra-cluster correlation and sample size.
7. Determined the key components of a future cost effectiveness analysis and tested data collection methods.
8. Established whether pre-set progression criteria are met and a larger scale trial is warranted. If criteria met, we will design the protocol for an RCT, including identification of required structures, resources and partnerships.

6. Study design

Intervention development and exploratory study undertaken in two stages, consistent with MRC guidance on the development and evaluation of complex interventions [35]:

Stage 1: Develop and formatively evaluate the intervention package, recruitment strategies and evaluation tools, pilot these in one school and make refinements (objectives 1-5);

Stage 2: conduct an exploratory study in six schools to include a feasibility trial and detailed process evaluation (see flow diagram). This will be designed to assess whether progression criteria for a subsequent full trial are met (objectives 2-8).

The protocol was substantially revised between v0.10 and v1.3 to report on progress against planned stage one activities, and to reflect changes to the intervention and evaluation design as a result of those activities.

7. Participant selection

The target group are S4 students (aged 14-16) who have received, or are currently in receipt of teacher-led sex education. All S4 students will be targeted, regardless of their sexual experience or individual level of risk.

S4 students (aged 14-16) are targeted because: (a) the median age of first sexual intercourse in UK is 16 [36], hence this is the school year prior to many students first having sexual intercourse and during which some students will engage in sexual activity for the first time. STI prevention messages will thus be timely and relevant; (b) Older students in S4 in Scottish schools (those born between 1st March and 30th September) are eligible to leave at the end of S4 and younger students (born between 1 October and the end of February) are eligible to leave at the start of the Christmas holidays during S5. Students from less affluent backgrounds are more likely to leave school during S4 and S5. S4 is the last school year in which this key group can be reached.

The intervention will be delivered in 7 state-funded secondary schools in Lothian region, Scotland (1 pilot; 6 study schools). Schools will be recruited on a first come, first served basis, while keeping mindful of the need to ensure variation in terms of school size, geographic location and area-deprivation.

Inclusion criteria: State funded schools in 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 (aged 14-16) at 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.

Exclusion criteria: Private schools.

8. Recruitment

8.1 Number of participants

The exploratory study is not designed to identify an estimate of effect and thus a standard power calculation is not appropriate. 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. This sample size should be sufficient to allow qualitative and quantitative progression criteria to be assessed and provide information on key parameters for the design of a future trial. It is premature to specify the required sample size for a future trial, but is nevertheless useful to have an indication of the likely size of such a trial. It is anticipated that a full trial would be cluster randomised, with school as the unit of randomisation. Assuming a mean school year size of 150 students and an effect size of 0.1, then a trial of between 15 and 25 schools per arm would have 80% power across a range of scenarios in which (1) intra-cluster correlation is assumed to be either 0.01 or 0.03; (2) there is one or two primary outcomes; (3) follow up rates vary between 75% and 85%.

8.2 Recruitment process

Schools will be recruited via a senior member of the relevant Education services (such as The Head of Education (Quality Assurance)). Following an initial meeting between the study team and Education Services, the Education services will contact school heads to alert them to STASH and introduce the study team. STASH project staff will initially contact school management teams by email and meetings will be arranged with those expressing interest in participation. Follow-up emails and calls will be made as necessary. Response rates, and any stated reasons for non-participation, will be recorded.

8.3 Informed consent

Schools who opt to participate will be asked to sign a research contract outlining responsibilities of the school and the researchers. Prior to the start of the intervention phase, S4 students and their parents will receive an information sheet telling them about the STASH study. Informed opt-in consent from the students will be required for all specific components of the research study, including questionnaires (opt-out for parents), interviews and focus groups; and from the peer supporters and their parents for them to participate in the training and take on the peer supporter role. Parental opt-out consent for the questionnaire is important since research over many years shows that the lower participation with opt-in consent is strongly biased away from the most vulnerable young people [37].

At all study stages, participants will be informed that they can withdraw from any research component at any time without prejudicing their experience at school. Research participants will be reassured that their answers will be treated in confidence. Researchers will only break

confidentiality if a disclosure in interview or questionnaire suggests that a young person might be at risk of serious harm or at risk of harming others (see section 13 on harms). The intervention website will include links to local and national referral services.

8.4. Randomisation

Given that the recruitment of schools to cluster randomised trials has been well established in many previous trials, we have opted to implement the intervention in all 6 study schools, rather than recruit a larger number of schools and randomise half to the control. The prior cohort of S4 students (i.e. those completing S4 in the year prior to the intervention) will complete the outcome questionnaire towards the end of their academic year (and prior to implementation of the intervention in the subsequent cohort of S4 students) and their data will be compared with the cohort of S4 students participating in the intervention. In this sense the prior cohort of S4 students will serve as controls and their 'treatment' is the usual provision of sex and relationships education in each school.

9. Withdrawal & loss to follow-up

On administration of the control questionnaire, and signature of the research contract, the school will be considered formally recruited to the study. Any school opting to discontinue with the study after this point will be considered a withdrawal.

To maximise retention, schools will be given £500 to compensate for disruption to school-life due to the questionnaire and process evaluation activities; plus £500 to compensate for staff time taken up by intervention activities (e.g. staff attendance at training).

The ASSIST evaluation achieved high response rates for their evaluation questionnaire (over 90% at each data collection point), and all schools were retained in the trial. Given the more sensitive nature of the topic, and older age group, we anticipate that compliance with the intervention and evaluation may be lower. We expect to achieve at least a 75% response rate for the baseline, follow up and control questionnaires

10. Outcome Measures

Primary outcome measures

The main study outcome is whether the study meets pre-set progression criteria. These criteria measure: the feasibility of the intervention; the acceptability of the intervention to peer supporters, the target group and stakeholders; and the potential benefit of the intervention compared to existing provision of sex education in schools (see table 1 below (note that criteria were revised following discussion with the TSC).

	Criteria	INDICATOR*	METHOD OF ASSESSMENT	RATIONALE
*GREEN=Very strong indication to proceed AMBER=Medium indication to proceed. Discuss with TSC and proceed with identified plan to improve performance on indicator in Phase III trial RED=Indication of doubt as to whether to proceed. Discuss with TSC, and only proceed if other indicators are amber/green and there is a clear mitigating strategy				
1	Was it feasible to implement STASH in 4 of 6 schools?	In each of 4 schools, 60% of nominated students are recruited and complete the training. In each of 4 schools, 50% of nominated students are recruited and complete the training Amber target achieved in fewer than 4 schools	Project monitoring data	Based on learning from ASSIST, 60% is estimated as the proportion required to ensure that peer supporters are representative and reach across the entire year group.
2	Was STASH acceptable to peer supporters in 4 of 6 schools?	In each of 4 schools 60% of peer supporters who complete the training, send three or more messages/have three or more conversations, and attend two or more follow-up meetings and 60% of peer supporters report that they 'liked' the role In each of 4 schools 50% who complete the training send three or more messages/have three or more conversations, and attend two or more follow-up meetings and 45% like role Amber target achieved in fewer than 4 schools	Facebook monitoring data Peer Supporter Questionnaire	We consider 60% a reasonable target given the sensitivity of the topic and challenge involved for peer supporters. 60% represents a majority while not providing an over-ambitious target, given that the intervention is new to schools and not institutionally embedded. We would expect role acceptability to increase with further iterations (e.g. in a full RCT) which lead to greater clarity and institutional support. We view 60% as a 'starting point' for this feasibility stage.
3	Was STASH acceptable to stakeholders	In each of 4 schools, 60% of students who are exposed to STASH agree that the intervention was acceptable.	Follow-up Questionnaire	We consider 60% a reasonable target given the sensitivity of the topic. 60%



	and target group?	No major acceptability issues raised by participating schools (identified via process evaluation or communication with school) Less than 15% of peer supporters report that parents were unhappy about them being a peer supporter In each of 4 schools, 50% rate intervention as acceptable Less than 20% of peer supporters report that parents were unhappy about them being a peer supporter One or two major acceptability issues raised by participating schools but mitigating strategy identified Amber target achieved in fewer than 4 schools Major acceptability issues raised by schools with no possible mitigating strategy	Process evaluation interviews Peer Supporter questionnaire	represent a majority and is realistic in the context of a feasibility study. Acceptability to teachers and school leadership will be assessed qualitatively, hence a focus on identification of major issues rather than a quantitative target.
4	Were the evaluation methods acceptable and feasible?	In each of 4 schools, student response rates of >70% at baseline and follow up In each of 4 schools, student response rates of >60% Amber target achieved in fewer than 4 schools	Baseline and Follow-up Questionnaires	We consider a response rate of 70% sufficient to undertake analysis, and feasible given that this cohort are undertaking public examinations at the end of the year. Response rates in the pilot were lower than expected for a school survey. Parental opt out has been very low and nearly all students in attendance complete the questionnaire, but due to the age group (and linked to area deprivation) there are students who are regularly absent (e.g. because they also attend other services).

The study will also set an indicative primary outcome, for use in any subsequent trial. Biological measurement of STIs provides the most reliable indicator of effectiveness but prevalence is too low within a short follow-up period in this age group to justify cost and ethical issues. Condom use during vaginal sex is the behaviour most amenable to change and frequency of unprotected intercourse is a commonly reported outcome in school-based interventions [7].

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 including: condom use at last vaginal intercourse; condom/dental dam use at last oral sex; number of sexual partners in last 3 months; number of sexual partners in last three months with no condom use; frequency of condom use in the last 6 months; proportion of students who have not had sex in past 6 months or have not yet had sex at all. 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.

We will assess the feasibility and acceptability of longer-term follow-up, including linkage to routine NHS data on STI diagnosis and use of sexual health services, subsequent to intervention exposure. This was successfully tried in RIPPLE [38]. We will explore this via discussion with colleagues with expertise in data linkage and via an item on acceptability to students in the questionnaire. Given that an explicit aim of the intervention is to strengthen links to sexual health services, we might expect to see an increase in service use over the longer term. An increase in STI diagnosis is more difficult to interpret; it might reflect improved uptake of services rather than an increase in risky behaviour. We will therefore explore acceptability and feasibility of validating service use data with an additional longer-term follow-up of students to measure risk-behaviour and help-seeking.

Secondary outcome measures

Informed by our theory of change, we will investigate a range of potential secondary outcomes. Measures for the survey include validated scales, items from validated scales and items from existing sexual health intervention evaluations (e.g. RIPPLE; SHARE; Sex Unzipped; Apause) and surveys (e.g. Natsal). Reliability of items will be assessed during the pilot. Measures are as follows:

- STI prevention and sexual health related knowledge, (drawn from, and adaptations of existing survey items).
- Ease of talking about sex with parents and friends (adapted Natsal measure)
- Confidence in STI prevention skills (adapted from range of existing survey items)
- 'Competence' at first intercourse using the 4-item Natsal Sexual Competence measure which includes items on willingness, acceptability of timing, autonomy and use of

contraception. Aggregate score represents extent to which first intercourse was competent in a public health sense [41]

- Sexual attitudes and adherence to sexual health norms (12 new items, adapted from range of existing survey items)
- Perception of whether others are sexually active.
- Self-reported quality of intimate relationships. 7-items newly designed items.
- Distress about sex life (Natsal-3 item)
- Self-reported use of internet and social media for finding sexual health information, sexting and viewing sexual images online (6 new items).
- Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS). 7-item scale measuring a broad concept of positive emotional well-being including psychological functioning, cognitive-evaluative dimensions and affective-emotional aspects [43]. Aggregate scores form a 'well-being index' with higher score representing greater well-being.
- Conversations about STASH-related topics (new items for STASH)
- Self-esteem (2 items from RIPPLE questionnaire, plus single-item global measure [39])
- Self-reported sexual activity.
- Knowledge of local sexual health services

Effect modifiers

- Single item measures of gender, socio-economic status (IMD, free school meal status), ethnicity, educational attainment (qualifications being studied and intention to leave school), religiosity.
- Self-reported risk behaviours in peer group (4-items from existing surveys)
- School climate and engagement (measured using selected items from the Beyond Blue 'School climate' scale, [42]),
- Parental monitoring. Three new items.
- Sexual attraction and identity (modified version of the Kinsey Scale; item from Natsal)
- Self-regulation. Three items drawn from the 36-item Adolescent Self-Regulatory Inventory [40]
- Importance of social media to social life (2 newly designed items)
- Social network questions, asking about up to 6 friends (time spent together; able to confide in person)
- Exposure to intervention activities and messages.

As for the primary outcome, the main comparisons will be between intervention and controls, since sexual behaviour would be expected to increase from baseline to follow up due to maturation effects.

Economic evaluation

- Detailed cost analysis of the intervention (including unit costs for the cost components)
- Identify any costs to students via the process evaluation
- Self-reported health related health care resource use (STI testing and treatment, contraception including out of pocket costs)
- We will assess the reliability of the Child Health Utility (CHU) 9D as a measure of student health-related quality of life (QALY) [44] and basis for conducting a within-trial cost-utility analysis. The CHU-9 is a validated, designed for children aged 7 to 11, with their input.

11. Study intervention

The intervention builds on components found to work well in ASSIST [33]: recruiting influential peers, allowing knowledge/attitudes to spread via social networks [34] and using professionals to train peer supporters. Novel aspects of the intervention - sexual health content and use of social media – were designed and refined during the development stage.

11.1 Theory of Change

The STASH intervention approach is underpinned by ‘Diffusion of Innovation’ Theory (Rogers 2002), which offers an explanation of how change occurs. In brief, this theory suggests that over time novel ideas and behaviours spread through members of a social system via communication channels. The pace of change is determined by the perceived relative advantage of the new idea, the degree to which the idea is compatible with the values, experiences and needs of early adopters, the ease with which new ideas/behaviours can be understood and tried out, and the degree to which newly adopted behaviours are visible to others. In STASH, peer supporters will serve as ‘early adopters’ or innovators’. Selected by members of their social system as trustworthy and credible, they have potential to act as models of change (making change visible) and to ‘sell’ the relative advantages of healthy sexual behaviour. They will be instrumental in helping to create an enabling social environment to support behaviour change and adoption of positive/healthy sexual norms (norm change).

Diffusion of Innovation Theory describes the overarching mechanism through which change occurs. In order to further articulate active ingredients, and determine the focus of intervention messages and behaviour change techniques, we drew on a range of well-established behaviour change theories. The key theories we have drawn on are described below, and a table in annex one lists the BCTs indicating how we are implementing them in STASH as well as the relevant theory they are associated with (from work by Michie et al [45]).

- Social Cognitive Theory (SCT) [46] which posits that people learn by observing others and that the reproduction of this behaviour is influenced by the personal (self-efficacy toward the behaviour), the behavioural (the response to the behaviour) and the environmental (factors that facilitate or inhibit practice of the behaviour). SCT emphasises the importance of self-efficacy, providing encouragement/reinforcement, social support, modelling behaviour, knowledge, skills and goal setting.
- Self Determination Theory (SDT) [47] highlights the centrality of three concepts; competence (to be in control and seek mastery), relatedness (to be connected to others) and autonomy (freedom to act), these are key to intrinsic (self) motivation to change. All of these are likely to be important in terms of the aims of this intervention.
- The Theory of Planned Behaviour (TPB) [48] emphasises the importance of attitudes, subjective norms and perceived behavioural control in shaping intention and behaviour.
- Information Motivation and Behaviour (IMB) [49] highlights information about risks and means of prevention, motivation to reduce risk and behavioural skills as key determinants of behaviour.

Finally, Normalisation Process Theory (NPT) will serve as a ‘sensitising tool’ to clarify potential barriers and facilitators to implementation in schools. [50]. NPT comprises 16 domains which account for key aspects of successful implementation of interventions. The theory was originally designed to explain how new ways of working are embedded in health care systems but several sub-domains are highly pertinent to successful implementation (e.g. key individuals driving the intervention forward; buy in from participants; intervention assessed as worthwhile) and are reflected in the STASH logic model.

11.2 Intervention components:

The intervention seeks to reduce the prevalence of STIs by targeting two key protective factors: abstinence/delay of sexual intercourse, and consistent condom use for those who are sexually active. It will be delivered in 5 stages:

(1) Nomination of peer supporters. All students in 4th year (Scottish S4; aged 14/15/16) will be asked to complete a peer nomination questionnaire. We will use the three questions used in ASSIST: (Who do you respect in S4 at your school? Who are good leaders in sports or other group activities in S4 at your school? Who do you look up to in S4 at your school?). In addition we will test several new recruitment questions. The 25% of young people receiving the most nominations, stratified by gender, will be invited to a recruitment meeting.

(2) Recruitment of peer supporters. A meeting will then be held with nominees in each school, in which the trainers explain the purpose of the intervention, role of peer supporter and answer questions. The aim is to recruit between 15% and 20% of the entire year-group to the role. If attendance at the recruitment meeting is poor, or if role uptake low or skewed significantly towards one gender, a second recruitment meeting may be held. Letters (information and consent forms) will be sent to parents/carers of all nominated students expressing interest in

participation. Peer supporters are then asked to provide their consent, and that of their parents, to their participation in training and intervention.

(3) Two-day peer supporter training in school time and at a venue outside of school. The training will be facilitated by Fast Forward and West Lothian Drug and Alcohol Service. It aims to: equip peer supporters with knowledge, skills and confidence required for the role; build motivation and enthusiasm for the role; and generate trust and rapport within the peer supporter group and between peer supporters and trainers. Drawing on the STASH theory of change, the training activities will focus on building sexual health knowledge and skills, understanding consequences and risk, building self-esteem and self-efficacy, reinforcing social support for healthy sexual norms, (competence), boosting intrinsic motivation and autonomy. Peer supporters will also be trained in skills required for the role such as listening and influencing skills; identifying and responding to sensitive disclosures, and signposting to sources of help. During the training, peer supporters will sign a code of conduct and will agree a plan to 'announce' the project to their year group (an assembly, video, bulletin are all options).

(4) Peer support work. The period in which peer supporters are active in their role is between 5 and 10 weeks. Intervention activities include: **(a) peer delivered activities:** education and persuasion to target determinants of behaviour identified in behavioural analysis. Peer supporters will establish a 'secret' Facebook group, comprising their friends and the STASH trainer. They will be encouraged to paste messages and links from the STASH website to this group, and to initiate face-to-face conversations centred on STASH messages. They will be encouraged to alert their friends to online and local sources of support and help. To ensure maximum reach, peer supporters will use 'STASH cards' to advertise a non-sharing version of the STASH website to students beyond their immediate friendship group and/or who are not members of their secret Facebook group. Peer supporters are supported by a trainer as well as an appointed contact teacher. As far as possible, peer supporters will be able to engage with intervention resources flexibly, for instance, they can choose which messages and links to share, and have the option of editing messages **(b) Trainer-led activities,** including: moderation of threaded discussions and monitoring of content; communication with peer supporters; Facilitating face-to-face follow-up meetings (weekly or fortnightly) with the peer leader group. **(5) Acknowledgment.** Peer supporters who complete the role will be provided with Glasgow of University certificates and, if they complete the online questionnaire, gift vouchers. Schools may also support peer supporters towards attainment of a credited Youth Achievement Award. Our PPI work suggests external recognition provides a strong incentive.

The training will be lead jointly by Fast Forward, a national youth health and wellbeing charity with specialist expertise in training peer educators, and West Lothian Drug and Alcohol Service, who have previously been involved in delivering ASSIST. The ASSIST study used personal diaries to track Peer Supporter activities but current work evaluating the ASSIST roll out in Scotland suggests that these do not provide a reliable record of actual activity (Fiona Dobbie, personal communication). Instead STASH will track online activity via Facebook monitoring data and

visits to the website, and via an online survey to Peer Supporters at the end of the intervention period.

Retention of Peer Supporters

Retention of peer supporters will be measured by role completion, defined as the proportion of peer supporters who attend both days of training, attend at least two follow-up meetings and send at least three messages. The ASSIST RCT achieved very high retention rates for their peer supporters; 99% of those trained agreed to continue the role and 84% submitted complete diaries at the end of the intervention period. Given the older age group (students in S4 sit national examinations) and more sensitive topic, we expect that slightly fewer will agree to continue the role after training, and that a smaller proportion (about 60%) of those who agree to the role, will complete it. We will employ a range of strategies to maximise peer supporter retention and response rate at follow-up including: developing high quality intervention materials, building collegiate and open relationships between project staff and school staff; building open and supportive relationships between trainers and peer supporters; using existing class sessions (rather than person time) for intervention activities and questionnaire completion; and avoiding periods of low attendance for data collection.

Gender, equality and diversity:

The target group (students aged 14-16) represents a cross-section of young people in this age group in UK (see section 6). As a broad-based sexual health intervention seeking to effect norm change, the intervention will promote respect for diversity in sexual orientation/preferences. We will emphasise to peer supporters that no individuals should be excluded from participation) on the basis of gender, ethnicity or disability status. Asking students to nominate influential peers has been shown to result in peer supporters who are representative of the year group [19] in terms of academic achievement and socio-economic status.

Gender stratification during the peer nomination exercise will ensure equal number of young men and women are invited to the recruitment meeting. PPI participants suggested that young women would be more likely to volunteer than young men. If the gender ratio of students agreeing to the peer supporter role in any school is greater than 65:35, we will work with the school to encourage more boys to take part, including a potential second recruitment meeting.

Peer supporters and participants will be encouraged to interact with whomever they feel most comfortable, regardless of gender; social networks often cross gender lines and PPI participants told us that choice of gender is important. An estimated 4% of pupils in Scottish state schools come from minority ethnic groups (www.gov.scot/resource/doc/933/0041854.pdf). We will monitor ethnicity and uptake of peer supporter role but given the small proportion of ethnic minority students, it is not feasible to increase representation without unduly interfering with

the nomination process. We will employ safety measures to ensure that any issues relating to gender, sexuality or ethnicity are quickly identified and addressed (see section 13 on harms).

12. Study procedures

Intervention development and exploratory study undertaken in two stages, consistent with MRC guidance on the development and evaluation of complex interventions [35]:

Stage 1: Develop and formatively evaluate the intervention package, recruitment strategies and evaluation tools, pilot these in one school and make refinements (objectives 1-5);

Stage 2: Conduct an exploratory study in six schools to include a feasibility trial and detailed process evaluation (see flow diagram). This will be designed to assess whether progression criteria for a subsequent full trial are met (objectives 2-8).

12.1 Stage 1 (Months 1-17): Intervention development, formative evaluation, pilot

In stage one, we developed and formatively evaluated the intervention. This stage had three overarching aims:

- 1) To identify the key intervention messages, behaviour change techniques and content of the peer supporter manual
- 2) To finalise the design of the STASH intervention approach and;
- 3) To refine and test the logic model and theoretical basis of the intervention

We followed a flexible and iterative four stage process to:

- define the problem;
- collate and synthesise evidence;
- identify key topics and messages and;
- refine intervention design.

This process involved the following activities: (1) scoping review of relevant academic literature; (2) consultations with the target group (two groups of S4 students at non-participating schools), relevant professionals (two half-day professional consultation sessions), a young people's advisory group; interviews with S4 teachers with PSE (personal and social education) or other pastoral responsibilities; (3) review of sexual health resources for professionals, and web resources targeted at young people (4) assessed the functionality and appropriateness of different social media platforms (e.g. Tumbler, Twitter, Whatsapp, Facebook) (5) refined key

aspects of intervention approach (nomination, recruitment, codes of conduct for participation) (6) worked with a website developer to design the website, and with Fast Forward/WLDAS to design the training manual (7) refined the logic model based on the intervention development work.

During this phase we also recruited a pilot school and secured informal agreement to participate from five further schools, identified/designed evaluation measures and tools; piloted the intervention and evaluation tools in one school, and undertook logistical preparations for the second stage of the trial.

Table 2 summaries the key research questions and sources of data consulted in stage one:

Table 2. Summary of sources of data in relation to intervention development research questions

Research Questions	Sub-questions	Sources of data
<i>What are the problems and drivers of problems?</i>	What do systematic and qualitative reviews say about this? What themes appear in young people's online communications (YouTube etc.)? What do young people themselves say? What should the key themes be?	1. Academic literature i) Systematic reviews (sex education, peer education) ii) Other relevant / key academic literature
<i>What is known to work?</i>	What are key features of a) peer-led sex education b) school-based interventions and c) social media interventions associated with effectiveness? What behaviour change strategies are effective and relevant to young people's sexual health?	2. Consultations iii) Young people's advisory group iv) Young people's development panel v) Professional panel vi) Interviews with teachers
<i>How might sexual health messages be best communicated?</i>	Which social media platforms are most appropriate for use in this intervention? What are the characteristics of influential online sites/personalities? What approaches to learning about sex health appeal to young people?	vii) Expertise and advice from TMG and TSC 3. Professional resources viii) Professional websites and web resources ix) Relevant grey literature, policy reports, strategies and guidance (including CfE) x) Young people's sites (influential bloggers)

		xi) Peer education and sex education manuals 4. Web sources targeting young people
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The methodology for each of the four main sources is described below:

Source one: Academic Literature

We undertook a scoping review via targeted searches of academic literature, including systematic reviews of interventions; reviews of evidence; and literature on behaviour change theories. This review also addressed barriers to and facilitators of young people's sexual health and behaviour, in specific relation to condom use, abstinence, and delayed timing of first sexual encounter.

Source two: Consultations on intervention design

Target population. We recruited two mixed gender groups of S4 (aged 14-16) students, with (10-14 participants in each) from two secondary schools outside the study area (one in Dundee and one in Aberdeen).

Within each school we sought approval of the head teacher and then worked with a key contact teacher in S4 to identify students for the panel. We asked teachers to advertise the voluntary panel role via student bulletins, registration classes and noticeboards as appropriate, and to circulate a parental 'opt-out' form to potential participants. Teachers were informed that we were interested in a broad range of students, in terms of attainment and socio-economic status. Two sessions were conducted with students at each school, one in June and September 2016. The first explored terminology and perceptions of key problems and drivers of problems, and the second focused on the draft content of the intervention materials.

We also convened a young people's advisory group in Glasgow in May 2016, with a group of volunteers from Scottish Sport Futures. The group provided an initial sounding board for our ideas for the intervention.

Professionals. Two professional panels were convened, in June 2016 and February 2017, at the MRC/CSO Social and Public Health Sciences Unit in Glasgow. A wide range of professionals – working in education, young peoples' sexual health, digital media, communication, and behaviour change – were recruited via the professional networks of the research team. In June

2016 participants reviewed and discussed the draft intervention components prior to the pilot, and in February 2017 the group reviewed the findings of the pilot, and suggested refinements.

Teachers. A parallel consultation was held with teachers, because it was difficult for them to attend the professional panel during term time. We conducted individual and paired interviews with secondary school S4 teachers with PSE (personal and social education) or other pastoral responsibilities (n=4), in schools likely to participate in the exploratory trial. We approached school senior management teams to introduce the study and gauge willingness to participate in the development stage of the trial. Those agreeing to participate were asked to identify two to three suitable volunteers to interview. Interviews explored the feasibility and acceptability of implementing the intervention in schools, potential for harms/unintended outcomes, and other contextual issues.

Each of these consultation sessions were audio recorded, informed consent having been obtained from participants at the outset. Data from each of these sessions were analysed alongside the scoping review and review of sexual health resources (as per Table two) and informed the content and format of the pilot intervention.

Sources three and four: Review of sexual health resources (professional and young people)

We consulted a range of relevant resources, as identified via the professional networks of the TMG, in the professional consultations, and by targeted searches. These included: professional websites which collate SRE information (eg. Sex Education Forum); manuals from other peer supporter and sexual health interventions (eg. ASSIST, SHARE); grey literature (third sector reports, summaries of policy/legislation); and sexual health and wellbeing web sources targeted at young people, which were reviewed for relevance, quality of content, design and authority.

Pilot study in one school – process evaluation

During months 10 to 12 we conducted a one-month pilot in one school. We tested the recruitment strategy, and recruited and trained peer supporters to deliver the intervention. We assessed the acceptability, feasibility, reach and fidelity of the intervention delivery via a small-scale process evaluation, and tested the evaluation measures and tools.

The purpose was to assess and refine the intervention materials and implementation mechanisms, and to identify specific feasibility and/or acceptability issues (see *STASH Process Evaluation Protocol*). The pilot process evaluation data collection comprised: semi-structured observational data of two-day peer supporter training; student evaluation of two-day peer supporter training; in-depth group discussion between trainers and research team immediately following two-day training; interviews with the three STASH trainers following intervention

delivery; online questionnaire completed by all trained peer supporters; friendship pair/group interviews with at least half of trained peer supporters, and with three general S4 participants; social network analysis (basic, using Facebook group membership data and social network questions from baseline questionnaire); analysis of items from follow-up questionnaire (items on exposure and effect modifiers); interviews with three teachers, including the STASH contact teacher and two other teachers with guidance responsibilities and some awareness of STASH; Facebook monitoring data (re. STASH group membership, and number of messages sent); and general project monitoring data (log included record of: any untoward incidents (see Harms document in annex 2); recruitment and retention information (eg. who completes/drops out); field notes from school visits and other significant meetings; contemporaneous events, media coverage, and any other factors forming broader context of the intervention.

Pilot process evaluation work aimed to contribute to refining the intervention by assessing the pilot in terms of implementation, mechanisms of impact, and context. This included assessing: intervention acceptability; reach; exposure; fidelity (ie. extent to which intervention is delivered as intended); contextual factors including barriers to and facilitators of implementation; recruitment and retention; relevance to target group; and perceived impact of the intervention. Findings were reviewed by the trial management group/steering group and a decision was made about whether to continue based on the progression criteria (see table three).

Progression to exploratory trial

In month 16, the independent Trial steering committee (TSC) reviewed progress on the intervention development and assessed the results of the pilot intervention using clear progression criteria (see table 3 below). They recommended progression to Stage 2.

	Criteria	Indicator	Method of assessment
1	Funding secured	Funding shortfall for exploratory study met by matched funding	Confirmation of funding letters
1	Was it feasible to implement the STASH pilot?	40% of nominated students are recruited to peer leader role Full training delivered by training organisation	Project monitoring data Training reports
2	Was the STASH intervention acceptable to peer supporters?	50% of peer supporters report at least three interactions (online and face-to-face) 50% report that they 'liked' the role	Process questionnaire to peer supporters
3	Was the intervention acceptable to stakeholders and target group?	50% of students in follow-up survey rate the intervention as 'acceptable' Around half of stakeholders interviewed rate the intervention as 'acceptable'.	Follow up questionnaire Focus groups with school management, parents and staff.
4	Were the evaluation methods acceptable and feasible?	Acceptable student response rates at baseline (>70%) and follow up (>60%) surveys	Baseline/follow-up questionnaire data

Table 3. Criteria for progression from pilot to main trial

12.2 Stage 2 (Months 18-36): Exploratory study.

The exploratory study will include a non-randomised feasibility trial and process and economic evaluation. It will aim to assess the feasibility and value of progression to a full scale trial, covering study objectives 2-8, including assessment of the acceptability of the intervention and collecting information on key parameters for the optimal design of such a trial. The subsequent trial (post this proposal) will be a cluster randomised trial.

The exploratory trial will involve the recruitment of six schools, and the intervention will be delivered to the S4 student cohort in all 6 schools between month 20 (August 2017) and month 30 (Jun 2018), when baseline and follow-up measurements respectively will be collected (see flow diagram). In addition, the same measures will be collected in month 15-18 (March to June 2017) from the previous S4 cohort in each of the six schools who are unexposed to the intervention (since they will have progressed to S5 by the time the intervention is delivered). Collecting data from this previous cohort doubles the information we have to estimate student consent and response rates and evaluate outcome measures, questionnaire content and data collection procedures. It also provides repeated cross-sectional data to assist in estimation of potential intervention effects. Since both control and intervention students will complete measures in March or June (final month before exams start or first month after exams end), though one year apart, their data can be considered comparable.

The baseline/follow-up questionnaire was cognitively tested via 6 interviews with students attending the development panels to test comprehension and acceptability of items. Data from the pilot was analysed to check for possible misunderstanding, spread of responses, item total correlations. The baseline and follow up questionnaires will be administered as a web-based survey by trained fieldworkers under 'exam conditions'. 'Mop up' visits will be scheduled to collect data from absentees.

Comparison arm: The intervention will be offered to all S4 students in the pilot school and in all 6 exploratory trial schools. As an exploratory study the main purpose is not to demonstrate effect but to establish the feasibility and acceptability of the intervention and the parameters required for a subsequent full scale trial. Students in the previous cohort of S4 in all 6 schools will be the controls; data will be collected from them prior to implementation of the intervention. They will receive their usual sex education which in most Lothian schools is a version of the SHARE education package [3].

Feasibility study process evaluation

We follow recent MRC guidance [51] in our examination of intervention ingredients, focusing on whether and how norm change and social support for healthy sexual behaviour is spread through a closed social system (the S4 year group in each school). Building on learning from the pilot process evaluation, the feasibility study process evaluation will assess the intervention in terms of implementation, mechanisms of impact, and context. This includes assessing: intervention acceptability; reach; exposure; fidelity (ie. extent to which intervention delivered as intended); contextual factors including barriers and facilitators to implementation; recruitment and retention; relevance to the target group; and perceived impact of the intervention. In doing so, the process evaluation will contribute to understanding of the overall feasibility of the intervention; identifying which components are most important to its success; explore components that did not work (and reasons why). It will thus also test and contribute to evaluating the logic model, and contribute to understanding of whether and how intermediate outcomes have or have not been achieved.

Overall, it will provide key data regarding criteria for progression to a phase III RCT (see section 10).

Feasibility study process evaluation work will involve basic evaluation activities in all six schools, and in-depth evaluation activities in two to four 'case study' schools. Case study schools will be selected on the basis of school location / population served, school size, and proportion of free school meals (see STASH Process Evaluation Protocol).

Basic data collection will comprise: **(1)** quantitative student evaluation of two-day peer supporter training (acceptability, fidelity, context, relevance); **(2)** interviews with trainers (3 in total). Since they moderate/monitor social media activity, trainers will log any harms encountered and how these were addressed (see section 10.2) (fidelity, acceptability, context); **(3)** online questionnaire to be completed by all trained 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, relevance, perceived impact); **(4)** social network analysis (data from baseline and follow-up questionnaire and Facebook group membership) (reach, context); **(5)** project monitoring data (eg. % and characteristics of those completing training/ agreeing to role/formally dropping out etc.; field notes on school visits and relevant meetings; log of relevant contemporaneous events) (context, acceptability, fidelity, recruitment/retention); **(6)** Facebook monitoring data (on group membership, posting activity) (acceptability, reach, exposure, fidelity, context, relevance) ; **(7)** analysis of relevant items from the follow-up questionnaire on exposure and effect modifiers (exposure); **(8)** fieldwork/trainer observation pro formas for individual survey/intervention session.

In-depth evaluation will include the above with the addition of: **(9)** structured observation of peer supporter training to assess engagement by peer supporters and document reactions to

intervention, including concerns about role (acceptability, context, relevance); **(10)** paired/group interviews with trained peer supporters (2-4 pairs/groups) (acceptability, fidelity, context, relevance, perceived impact); **(11)** paired/group interviews with non-peer supporter S4s (2-4 pairs/groups, including high/low engagers) (reach, relevance, acceptability, exposure, context, perceived impact); **(12)** and individual interviews with teachers (2-3 per school) (acceptability, context, perceived impact).

Social network analysis.

Social networks exert important influences on health behaviour, including among adolescents [52] and we wish to contribute to understanding of how these networks operate. As part of the follow up questionnaire, we will ask each student to complete a short friendship questionnaire, modelled on that used in ASSIST [52]. In ASSIST, all target group students were asked to provide details of up to six friends and the data were analysed using Kliquefinder© to identify naturally occurring and non-overlapping subgroups (clusters) and examine the position of peer leaders in relation to these groups. Similarly, we will ask each student to name up to 6 friends, and for each friend to ask whether or not they are in year S4 in their school. Additionally we will ask about the degree of comfort re sharing of private matters, and about time spent with the friend. These data will enable the identification of the extent of friendships outwith the school, and therefore estimate potential contamination in a full-scale cluster randomised trial, and will assess the reach of the peer supporters across the S4 year group. Social network analysis will also provide a further source of data regarding the conversations and online contacts generated by the peer supporters. In particular they will enable identification of: clusters, of individuals considered particularly trustworthy, of 'information hubs' (measures of centrality, [53]), as well as isolated individuals (no nominations). The analysis will help to highlight whether perceived trustworthiness overlaps with the peer supporter role (are the most trusted individuals also the most active peer leaders?). It will also allow us to investigate whether information links are reciprocal or unilateral, which will provide insight into modes of communication about STIs. We plan to investigate homophily, i.e. whether subgroups of the network are formed around gender (e.g. do girls only talk to girls?), sexual behaviour (do high-risk individuals mainly talk to other high-risk individuals?), norms (are those who voice specific opinions largely connected to others with similar opinions?) and other node characteristics. SNAS data can also be mapped onto Facebook secret groups formed as part of the STASH intervention.

Economic evaluation

The aim of the economic evaluation is to assess the feasibility and acceptability of collecting sexual health related health care resource and QoL data to inform the design of a cost-effectiveness analysis to be undertaken alongside a full RCT. STI resource use will be collected from a self-completed questionnaire and costed using published sources. The EQ-5DY has been found to be a suitable measure of quality of life (QoL) in previous STI trials (unpublished results

from MENSS trial) and will be used to calculate quality adjusted life years (QALYs). We will conduct an initial cost-consequences analysis reporting descriptive statistics for the exposed and unexposed groups separately. Statistics will include data completeness and percentage that each resource contributes to total costs. This will inform areas where additional information may be needed in a full trial for more accurate costings.

Stopping rules/discontinuation criteria.

The feasibility trial will recruit all schools and students and deliver all intervention activity before outcome data are collected, so no obvious stopping rules are apparent within this stage.

12.3 Socioeconomic position and inequalities

Lothian includes areas of significant deprivation (free school meal (FSM) eligibility in West Lothian, 16%; national average, 13%).

There are strong sexual health inequalities in Lothian schools, with affluent boys more than twice as likely to have used a condom at most instances of sex than less affluent boys [54]. Current implementation of DECIPHER-ASSIST is, in most areas, targeted towards more deprived schools; we will investigate fidelity and acceptability by FSM status to see whether STASH should take a similar approach. The ASSIST peer-nomination approach results in students who are representative of their year group, and therefore should include individuals who have credibility among less affluent and less engaged students [19].

12.4 Study logic model/programme theory:

The study logic model was refined following the pilot (overleaf)

Figure 2 Proposed Logic Model

Problem, Inputs and Outcomes

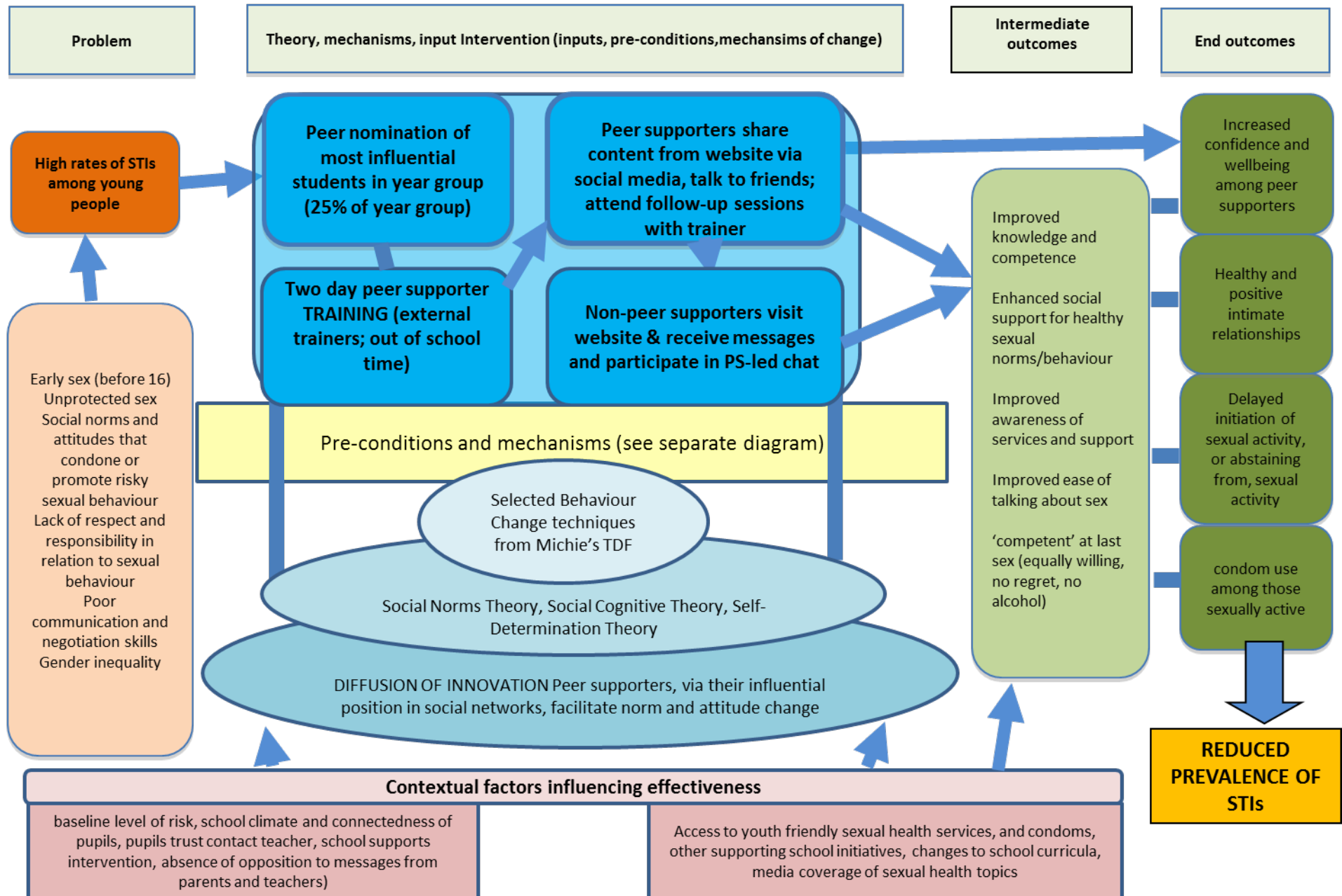
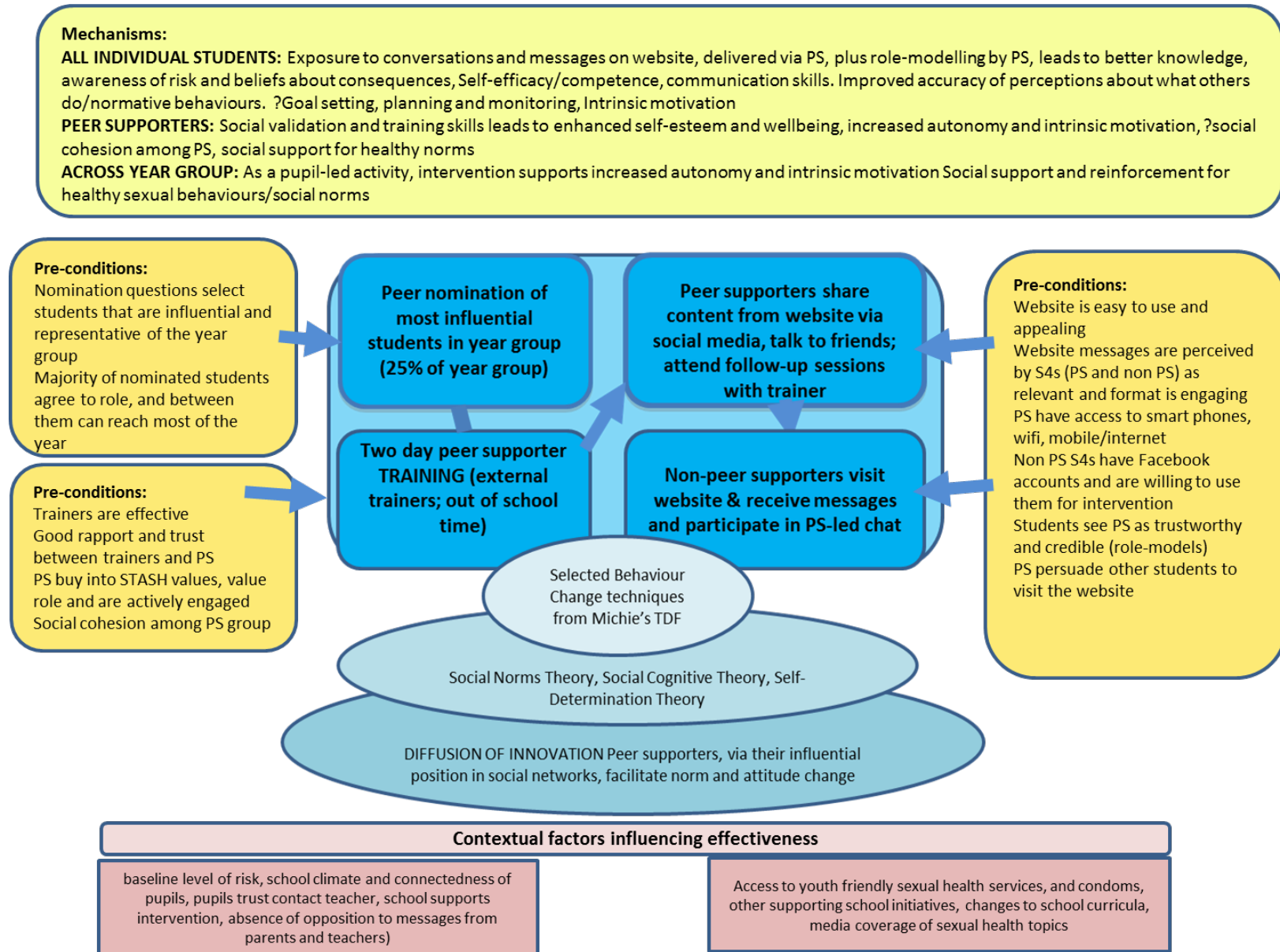


Figure 2 Proposed Logic Model



12.5 Methods to protect against sources of bias

Contamination: Contamination between schools through social media and social networks may be a concern for a subsequent cluster randomised trial. This will be assessed through the social network analysis and peer supporter questionnaire (see section 10.1), both of which will measure extent to which students from other schools have been exposed to the intervention.

Confounding: As a feasibility trial, the study is not randomised and may therefore be subject to confounding, in particular between the effect of the intervention and differences between the year groups. Baseline covariates will be adjusted for to mitigate this. In a subsequent full trial schools will be cluster randomised to the intervention or control groups, in order to minimise risk of confounding.

Attrition bias: Fieldworkers will conduct mop up visits to schools, as necessary, to obtain data from students absent at the main data collection.

13. Procedures for reporting harms

Safety reporting definitions

Untoward incidents and Harms in STASH

An 'untoward incident' is a negative event which is unintended or unplanned and may occur as a direct result of, or unrelated to, the STASH trial. Such events may include: social exclusion/isolation of participants by peers; inappropriate/inaccurate online posts by Peer Supporters; disrespectful behaviour towards others; breaches of private/personal information by peers; online bullying or sending of sexual/compromising images without consent or for the purposes of humiliation. An untoward incident may or may not cause harm.

'Harm' relates to emotional, physical and psychological harm including sexual assault

Sensitive disclosures and potential child protection issues

Relevant child protection issues which may be disclosed in the course of the STASH trial include: non-consensual sexual activity; child sexual exploitation; suicidal ideation; self-harm/injury; neglect or abuse. A separate document, 'STASH Procedures: Reporting of child protection concerns in SCHOOLS' provides details of relevant procedures relating to disclosure of sensitive information to a peer supporter or member of the STASH team.

Expectations within the STASH trial

Untoward incidents (as defined above) occur in day-to-day school life, and may occur during the trial period, irrespective of the STASH trial. In specific relation to STASH, it is important to note that some flippancy is to be expected in young people's online interactions. Untoward incidents which do not result in harm will be captured as part of the process evaluation. Procedures for reporting sensitive disclosures and potential child protection (safeguarding) issues are outlined in a separate document, 'STASH Procedures: Reporting of child protection concerns in SCHOOLS'.

Harms occurring as a *direct result* of STASH are unlikely. Harm unrelated to STASH is also unlikely during the short trial period.

Procedures in place to minimise potential for 'untoward' incidents and harms

The STASH Research Team will employ strategies to minimise the likelihood of harms occurring. Peer Supporters will be required at training to sign up to a code of conduct (the STASH Charter). Procedures for dealing with disrespectful/aggressive online behaviour will follow the ICT code of conduct and discipline code of participating schools. Social media use will be confined to private ('secret' ie. non-visible, invite-only) Facebook groups, of which STASH Trainers will be a member. Trainers will conduct monitoring 'spot checks', and Peer Supporters will also be encouraged to report any untoward incidents promptly to the Trainer and/or STASH Contact Teacher. Students will also have the option to privately message the Trainer as required. The Trainer should pass on any concerns to the Contact Teacher without delay.

All members of the Research Team and the trainers working in schools have PVG clearance/Enhanced Disclosure Scotland certification, which allows them to work with young people under 16.

Procedures for reporting and documenting harms

While there are no likely harms in relation to the trial, the following mechanisms will be put in place through which any unexpected harms will be identified and reported, regardless of whether they result from the STASH trial, or are concurrent. Schools have policies in place to deal with behaviours that constitute minor untoward incidents, and so these are not addressed here.

Identification of possible harm in relation to participants (all S4s including Peer Supporters)

In the course of stage one, we sought to identify and articulate potential untoward incidents during our consultations. We also held discussions with West Lothian Education and Child Protection Officers, and a range of experts in schools-based interventions and child protection.

Within the school setting, reporting of potential harms will follow school procedures for reporting of sensitive disclosures and child protection concerns.

The STASH Contact Teacher/DMS and those delivering the intervention (STASH Trainers and Peer Supporters) will be asked to notify the Research Team within five working days if any harm occurs to a member of staff or student, as a direct result of taking part in the STASH trial.

Members of the Research Team at the University of Glasgow will be required to document any harms reported to them during trial data collection. All documented harms will be discussed with the Principal Investigators (LM/KM) to assess severity and causality. Causality will be determined according to the criteria in Table four. In the case of discrepant views on causality the event will be handled at the highest event categorisation.

Table 4. Causal relationship between untoward incident resulting in harm and STASH trial

Relationship	Description
Unrelated	There is no evidence of any causal relationship with the trial
Unlikely	There is little evidence to suggest there is a casual relationship (e.g. the event did not occur within a reasonable time after intervention) with the trial. There is another reasonable explanation for the event (e.g. known behavioral issues).
Possible	There is some evidence to suggest a causal relationship with the trial (e.g. because the event occurs within a reasonable time after intervention). However, the influence of other factors may have contributed to the event (e.g. known behavioral issues).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not assessable	There is insufficient or incomplete evidence to make a judgement of the causal relationship.

All reported harms, for which causality is deemed 'possible' and above, will be reported in writing to the STASH TSC and the NIHR within 15 days of the Research Team receiving the initial report. The threshold for informing the TSC is set at low. The chair will circulate with rest of group if necessary. If the chair is away, the PI should inform the designated representative (DG).

A harm which is deemed ‘unrelated’ or ‘unlikely to be related’ to the trial will be reported to the TSC at the next scheduled meeting. Regardless of attribution, harms will be reported immediately to the STASH Contact Teacher and handled via school procedures (see Annex 2 and ‘STASH Procedures: Reporting of child protection concerns in SCHOOLS’).

Reporting of sensitive disclosures and potential child protection (safeguarding) issues to Peer Supporters during STASH trial

Appropriate responses to sensitive disclosures and procedures for reporting potential child protection issues are explained – and their importance emphasised – during the two-day Peer Supporter training. In particular, Peer Supporters will be advised on how to respond to sensitive information shared by peers (including respecting privacy), and when to share these with the STASH Contact Teacher/DMS. The expectation is made clear to young people acting as Peer Supporters that any disclosures about which they feel worried or uncomfortable should be reported without delay to the Contact Teacher/DMS. Schools have in place procedures for handling disclosures relating to child protection (see Annex 2), which should then be followed as normal. Peer Supporters are advised that they may also contact the STASH trainer via Facebook, if they wish (see below).

It is possible that students might make other disclosures to Peer Supporters in the trial period which do not constitute a child protection issue, but which are nonetheless experienced as concerning by either party. During training, Peer Supporters are advised to act only within their comfort level, and are not to provide support beyond what they would normally offer to a friend. We recognise that the capacity of minors to make appropriate decisions around their own safety is a contested issue. STASH Peer Supporters will be strongly encouraged to refer other students to appropriate sources of adult help, and are provided in their training with detailed guidance on when to refer and to whom (usually the Contact Teacher/DMS). These will be established at the initial Peer Supporter training and maintained throughout the trial, via the regular follow-up sessions led by STASH Trainers.

Disclosures of harm to Research Team and/or STASH trainers

The role of the Research Team and STASH trainers includes: having awareness of relevant child protection/safeguarding procedures; recognising indicators of abuse; recording and passing on relevant information without delay; consultation with an appropriate person. Procedures for referral follow school procedures and relevant national guidance.

In the course of the process evaluation, all S4 participants will also be asked whether they perceived any negative untoward incidents resulting from the trial. The Research Team and STASH Trainers will only break confidentiality where a disclosure during Peer Supporter training or evaluation fieldwork (group discussions, paired interviews) suggests that a young person might be at risk or pose a risk to others (see Annex 2). We will work closely with the school (via the Contact Teacher) to ensure that any relevant information is shared.

Referral for sexual health advice

The Research Team will also work with local young people's sexual health services, school nurses/sexual health drop-in services, and youth organisations to ensure appropriate referral for young people requesting help with personal issues related to their sexual health. Every member of the Research Team will be provided with relevant contact details for local services, which they can provide to students as appropriate. Local sexual health services will be invited to attend Peer Supporter training and/or follow-up sessions, in order to consolidate pathways to support.

14. Statistical considerations

Feasibility outcomes

Baseline characteristics (including deprivation) will be summarised overall, and for those who were and were not followed up (or dropped out of intervention).. Exploratory investigations of the associations between baseline characteristics and successful follow-up may be carried out using appropriate statistical tests and mixed effects logistic regression models (to reflect the clustered nature of the data by school), to identify potential sources of bias in future studies.

Outcome data

Outcome data will be summarised overall and by study group. Mixed effects regression models, with a random effect for school, will be used to estimate the magnitude of intervention effects with 95% confidence intervals. The effects of individual-level factors (effect modifiers) potentially associated with outcomes will be explored by extending these regression models, to identify factors to be adjusted for in future studies and indicate their impact. Interaction models may be considered to explore whether the intervention might be more or less effective (or inferior) for particular subgroups of pupils. The within-school intra-class correlation coefficients will be reported for each outcome and used to inform sample size calculations for the future RCT. Note that the study is powered for exploratory analysis only and so we do not anticipate reaching statistical significance for the outcome comparisons.

Analysis for economic evaluation

We will assess the feasibility and acceptability of collecting sexual health related health care resource use from a self-completed questionnaire and a measure of QoL and associated utility scores for calculating quality adjusted life years (QALYs). The aim is to inform the design of a cost-effectiveness analysis alongside a full RCT of a peer led sexual health intervention compared to control. Costs will include the cost of intervention development and implementation for the intervention group and sexual health resource use (STI testing, treatment and contraception) multiplied by published unit costs for both groups and will be reported by funder/commissioner/out of pocket costs. A particular focus will be the impact on costs for schools of the intervention. QALYs will be calculated as the area under the curve for the duration of the trial. Although a measure of sexual quality of life (SQoL) that can be used in

economic evaluations does exist (SQoL reference) our experience in other trials is that it is not sensitive to changes in sexual health outcomes. Instead we will use the CHU-9 to calculate QALYs. Given its limited use in this population group and STIs we will test how well it functions alongside our primary outcome of frequency of unprotected sex. Descriptive statistics will be reported for questionnaire completion alongside means, standard deviations and bootstrapped 95% confidence intervals by exposed/unexposed group for each variable. This will form the basis of a cost consequences analysis, reporting costs alongside consequences such as QALYs and measures of behavioural change for intervention and control groups. Missing data in the economic evaluation will be handled in the same way as for the statistical analysis.

Qualitative Analysis

The qualitative analysis will primarily be conducted in the course of intervention development and process evaluation components of the trial, and will be integrated with key segments of the quantitative analysis (see separate STASH Process Evaluation Framework). Qualitative analysis has informed the design of the intervention, refinement of the logic model, and design of the subsequent trial. At the development and pilot stage, qualitative analysis has sought to address key design issues for the intervention, including those relating to recruitment and retention of peer supporters; and feasibility and acceptability of the intervention among peer supporters, participants and key stakeholders. At the exploratory trial stage, the analysis will seek to assess the acceptability, fidelity and reach of the intervention. It will also be used to examine hypothesised causal pathways of the logic model, focusing on how messages are diffused and on the added value (or otherwise) of using social media.

The qualitative analysis method used takes a thematic analytic approach informed by the Framework method (Spencer et al. 2014). A coding framework is developed and applied to transcripts, based on the initial themes identified in open coding, and on the key aims of the development work and process analysis. From this descriptive stage the data are interpreted further in order to establish links between themes, develop potential explanations around such links, and to better understand the functioning of the intervention. Following this thematic analysis stage in the process evaluation, integrative analysis will be conducted to bring together key components of the qualitative and quantitative data. Integrative analysis involves placing all relevant data in one integrative matrix and assessing for synergy, and will focus on assessing the overall acceptability of the intervention.

15. Data storage & retention

Storage of data and access restriction:

A unique identifier will be given as soon as possible to data transcripts and questionnaires. Personal details will be removed and stored separately. A de-code key to the ID will be kept secure and separate from the electronic data. Digital recording of interviews will be stored on an encrypted and password protected computer (unit drive), separately from identifying

information. Transcripts printed for the purpose of analysis will be stored in a locked cabinet. At the end of each day they will be returned to the locked cabinet.

All data will be kept for at least 10 years in line with University of Glasgow Research Governance Framework Regulations for clinical research. This data will be stored confidentially on password protected servers maintained on the University of Glasgow network. Data integrity will be checked every 2/3 years. We will make anonymised annotated qualitative extracts plus raw quantitative data available to other researchers on request and will deposit the data in an appropriate database, such as the UK Data Archive. Further details on data management are described in our separate data management plan.

The principal investigators (LM and KM) have custodianship of the data and will take responsibility for ensuring that the management of research data at all stages complies with legal and ethical requirements. All researchers who may have contact with the data will be obliged to read the MRC guidance on 'Good Research Practice' and "Personal Information in Medical Research' as well as University of Glasgow data policies, and will sign a confidentiality form to that effect.

16. Study closure

The end of the exploratory trial will be considered to be the date on which the last participant has completed their follow-up questionnaire (students) or web based evaluation questionnaire (peer supporters). The end of the study will be the 31st December 2018; this is the end of the grant period. The final report is due to NIHR on 15th January 2019.

17. Regulatory issues

17.1 Ethical approval

The study will be submitted to University of Glasgow, MVLS College Ethics Committee for approval. We will submit two separate ethical review applications. At the beginning of the study we will seek ethical approval for the development work only (recruitment of two S4 student panels, expert panel and interviews with parents and teachers). In month 10 (having finalised the intervention content and evaluation tools) we will seek ethical approval to conduct the pilot and exploratory trial.

17.2 Consent

Written informed opt-in consent will be sought for participation in interviews, questionnaires, development panels, focus groups and in order to take on the peer supporter role. Opt-out consent will be sought from parents of young people participating in the development panels, and from parents and young people regarding the young person's participation in the

intervention (as a recipient) and the before-after questionnaire. All participants will receive an information sheet on the study before being asked to decide. The study is low risk for participants and for those in the intervention group, taking part in the study may actually benefit their health. Students will be reassured that withdrawal from the study will have no detrimental effect on their current or future schooling. We will ensure, as far as possible, that participants are given sufficient time to consider their decision to participate (or otherwise).

17.3 Confidentiality

The Principal Investigator and the project executive team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998. All S4 student participants will be allocated a unique identifier and all personal data collected will be held in linked anonymised form. This is done by replacing student names with pseudonyms and by removing geographical identifiers such as names of towns and schools. Identifiable information, including consent forms, will be stored separately from research data.

Access to data will be restricted to the research team and transcription service, Smallbiz, with whom the unit has an ongoing contractual arrangement, confidentiality agreement and relationship of trust. 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. Digital recordings of interviews/focus groups will be stored securely, and will be held separately from transcripts and information on participant identities. In reporting the results of the interviews and focus groups, care will be taken to use quotations which do not reveal the identity of respondents or schools. All data collected as part of the project will be treated as confidential and will only be viewed by members of the research team; anonymised data will be used wherever possible. A formal privacy risk assessment will be undertaken to manage any potential risks of conducting the study. All procedures for data storage, processing and management will comply with the Data Protection Act 1998.

Information on STASH will be made available on the SPHSU website. Information on the availability of the data will be included in any publications. The Principle Investigators (Professor Laurence Moore and Dr Kirstin Mitchell) will control permission to access the study data.

17.4 Indemnity

University of Glasgow will provide indemnity and compensation in the event of a claim by, or on behalf of participants for negligent harm as a result of the study design and/or in respect of the protocol authors/research team. University of Glasgow will provide indemnity with regards to the conduct of the research. The University has in force a Professional Indemnity and/or Clinical Trials Policy which provides cover for negligent harm and the activities here are within that coverage

17.5 Study sponsorship

The University of Glasgow will act as sponsor for trial.

17.6 Funding

The study is funded by NIHR Public Health Research Board (PHRB). The intervention is funded by the Scottish Government and Edinburgh and Lothian Health Foundation.

17.7 Audits and inspections

The study is subject to inspection by the NIHR PHRB as the funding organisation.

18. Study management

This is a single-centre study and the Principal Investigator (LM) will have overall responsibility for the conduct of the study.

STASH Project Executive Group: Professor Laurence Moore and Dr Kirstin Mitchell are Principal Investigators. Professor Laurence Moore will take overall responsibility for the conduct of the study and provide mentorship and support to Kirstin Mitchell. Kirstin will oversee all aspects of the project with support from the Project Executive Group and Trial Management Group. Mr Ross Forsyth is Project Manager and will support Kirstin in the day-to-day coordination of the study. Dr Carrie Purcell is Research Associate and responsible for intervention development, as well as contributing to qualitative design, data collection and analysis. Collectively they form the Project Executive Group, responsible for day-to-day delivery of the trial.

Intervention Development Group: In the first year an intervention development group (IDG) will meet regularly to oversee the design of the intervention. It will comprise KM and CP, plus SS who has expertise in behavioural analysis and intervention design. Members of the TMG with expertise in this area (JB, SS, LMCD and LE) plus the project collaborators (Fast Forward and Healthy Respect Lothian) and the Project Manager will be invited to attend a portion of these meetings as appropriate.

Trial Management Group: The Trial Management Group (TMG) includes the Project Executive Team plus all the co-investigators. They will guide all aspects of the trial and are the key decision making group. They are responsible collectively for delivery of the study and will meet every 6 weeks to undertake this task.

Trial Steering Committee: The Trial Steering Committee (TSC) consists of independent members responsible for oversight of the trial on behalf of the sponsor and funder and ensuring the safety of participants.

Young people's steering committee (YPSC): The YPSC will comprise young people between 16 and 20 years old. They will meet separately with the Project Executive Group to contribute ideas and comment on project design and implementation from their perspective as members of the target age group.

The TMG and TSC charters outline in more detail the roles and responsibilities of each group.

19. Data monitoring & quality assurance

19.1 Trial Steering Committee (TSC)

An independent steering committee (TSC) will be established and will meet at least four times during the course of the study, consisting of an independent chair, and three other independent members. The TSC will be chaired by Dr James Hargreaves who is an expert in public health evaluation. Other members include Dr. Simon Forrest, expert in young people's sexual health, Dr. David Gillespie who has expertise in statistical methods for randomised controlled trials, and Ms Alice Hoyle (lay member), an SRE teacher with expertise in sexual health and sex education. The TSC will meet in month two to review the protocol; in month 17 to decide whether to proceed from pilot to exploratory trial, and in month 35, to decide whether to proceed to full trial. Additionally the TSC will be asked, on occasion, to review final drafts of intervention materials and evaluation tools, either at a meeting or via email. Professor Laurence Moore and Dr Kirstin Mitchell are non-independent members of the TSC. The research associate (CP) will attend TSC meetings, and the trial statistician (SB) will attend the final meeting, both as observers. The TSC will provide overall supervision for the trial and provide advice through its independent chair. The ultimate decision for the continuation of the trial lies with the funder and the sponsor but the TSC will advise them. The project will use standardised research protocols and adherence will be monitored by the PT, TMG and TSC.

19.2 Data Monitoring and Ethics Committee (DMEC)

The nature of this study means that a Data Monitoring and Ethics Committee will not be required for this exploratory trial, since the study is low risk, non-randomised, and we will not be conducting interim analyses. The TSC will be asked to cover the functions of the DMEC in this instance, in particular in relation to ethical issues, and monitoring of any unintended outcomes, and the continuation of the trial.

20. Publication policy

The publication policy will be drafted and approved by the Trial Management Group. It will state principles for publication, describe a process for developing output, contain a map of intended outputs and specify a timeline for delivery. The publication policy will respect the rights of all contributors to be adequately represented in outputs (e.g. authorship and acknowledgments) and the study to be appropriately acknowledged. Authorship of parallel studies initiated outside of the Trial Management Group will be according to the individuals involved in the project but must acknowledge the contribution of the Trial Management Group and SPHSU.

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ANNEX 1: BEHAVIOUR CHANGE TECHNIQUES RELEVANT TO STASH

BC Target	BCT	THEORY
Facilitate and encourage social support through the peer group.	Facilitate and build on social support within the peer group.	SCT; IMB
Promote autonomy	Facilitate choices Consider individual viewpoints and include individuals in decision making Encourage individuals to think about how to change (what makes sense to them) Help them develop new skills to take forward in their lives.	SDT
Boost (intrinsic) motivation	Identify needs of individuals Encourage active participation Encourage individuals to take more responsibility Give constructive feedback Give emotional support Give choices Help them develop new skills to take forward in their lives.	SDT; TPB
Support self-efficacy	Give encouragement/feedback and support Use role models Tailor intervention Practice behaviour Set achievable goals	SCT
Provide general encouragement/reinforcement	Peer supporters encourage participants and reinforce behaviours	SCT
Provide information on consequences of behaviour/risks	Provides information about the benefits and costs of different actions or inaction to the individual based on their characteristics. This can include any costs/benefits and not necessarily those related to health, e.g. feelings.	TPB; IMB
Provide information on affective consequences	Provide information concerning how the individual may/will feel if (s)he performs or does not perform the behaviour, including enjoyment and anticipation of regret.	TPB; IMB

Provide information on sexual health topics	Provide information on sexual health topics via peer supporters	IMB
Goal setting	The individual is encouraged to make a behavioural resolution (e.g. use condoms). This is directed towards encouraging individual to decide to change or maintain a change.	SCT
Planning	Involves planning of what the individual will do e.g. how to break up with someone. Should include; when, in which situation, and/or where to act. "When" may describe frequency (such as how many times a day/week or duration).	SCT
Barrier identification/ problem solving	The individual is prompted to think about potential barriers and identify ways of overcoming them e.g. to use of a condom. Barriers may include competing goals in specified situations. This may be described as "problem solving" in relation to particular behaviours.	SCT
Provide instruction/guidance on how to perform the behaviour	Involves telling the individual how to perform a behaviour or preparatory behaviours, either verbally or in written form.	SCT/IMB
Model/demonstrate the behaviour	Involves showing the individual how to perform a behaviour eg through physical or visual demonstrations of behavioural performance, in person or remotely.	SCT
Provide instruction/guidance and opportunities to practice	Through discussion with peers	SCT
Prompt identification as role model	Involves focusing on how the individual may be an example to others and affect others behaviour. Also includes providing opportunities for individuals to persuade others of the importance of adopting/changing the behaviour.	SCT
General communication skills training	This includes any technique directed at general communication skills but not direct towards a particular behaviour change. Often this may	

	include role play and work focusing on listening, assertive and/or negotiation skills, and resisting social pressures.	
Enhance self esteem	Provide reinforcement, information, encouragement, skills development, reward achievements	SDT (<i>SCT as overlaps with self efficacy</i>)
Enhance competence	By providing information, guidance, opportunities for practice, role models etc	IMB/SCT
Accuracy of perceptions about what others do/normative behaviours	Provide information about norms as well as potentially inaccurate perceptions of what others do	TPB/SNT
Challenge social norms	Provide information and suggest ways to challenge social norms, encourage reflection on social norms and attitudes (including critique attitudes/norms)	TPB/SNT

- TPB – Theory of Planned Behaviour
- SCT – Social Cognitive Theory
- SDT – Self Determination Theory
- SNT - Social Norms Theory
- IMB – Information, Motivation, Behaviour Theory

Underpinned by ‘Diffusion of Innovation’ Theory which offers an explanation of how change will percolate through the target population and suggests the need to focus on behaviours and ideas that are easy to adopt, are compatible with existing values, easy to try out and visible to others.

Normalisation Process Theory is used to identify potential barriers and facilitators to implementation in schools.

ANNEX 2: GUIDANCE ON REPORTING HARMS

Procedures for reporting harms associated with STASH (Sexually Transmitted infections And Sexual Health): an NIHR-funded trial of a schools-based peer supporter intervention

The following document outlines the procedures for reporting to the Trial Steering Committee any occurrences of harm to participants in the course of the STASH trial. It defines the terms used, outlines the extent to which such occurrences are expected within the trial period, and details procedures for documenting and reporting these. The document has been developed in line with West Lothian Schools Child Protection Procedures – in collaboration with West Lothian Council Child Protection – and in line with National Institute for Health Research (NIHR) reporting procedures. This document should be read alongside ‘STASH Procedures: Reporting of child protection concerns in SCHOOLS’, which details procedures for reporting and recording sensitive disclosures and potential child protection issues which occur in participating schools in the course of the trial.

Acronyms and terminology

‘Designated member of staff for Child Protection (DMS)’: Member(s) of school staff with specific responsibility for Child Protection

‘ICT’: information and communications technology

‘NIHR’: National Institute for Health Research (study funder)

‘Peer Supporters’: S4 students who have completed two-day training in STASH and have agreed to take on a role of passing on positive sexual health messages to S4 peers (see STASH Protocol)

‘STASH contact teacher’: teacher agreed as contact point between school and STASH Research Team, and as contact for Peer Supporters for the duration of STASH trial

‘STASH Research Team’: Prof Laurence Moore (Principal Investigator), Dr Kirstin Mitchell (Co-Principal Investigator), Dr Carrie Purcell (Researcher), Mr Ross Forsyth (Project Manager)

‘Trial participants’: Any members of S4 in the trial school

‘TSC’: STASH Trial Steering Committee

1. Safety reporting definitions

1.1 Untoward incidents and Harms in STASH

An ‘untoward incident’ is a negative event which is unintended or unplanned and may occur as a direct result of, or unrelated to, the STASH trial. Such events may include: social exclusion/isolation of participants by peers; inappropriate/inaccurate online posts by Peer Supporters; disrespectful behaviour towards others; breaches of private/personal information by peers; online bullying or sending of sexual/compromising images without consent or for the purposes of humiliation. An untoward incident may or may not cause harm.

‘Harm’ relates to emotional, physical and psychological harm including sexual assault

1.2 Sensitive disclosures and potential child protection issues

Relevant child protection issues which may be disclosed in the course of the STASH trial include: non-consensual sexual activity; child sexual exploitation; suicidal ideation; self-harm/injury; neglect or abuse. See ‘STASH Procedures: Reporting of child protection concerns in SCHOOLS’ for full details of relevant procedures relating to disclosure of sensitive information to a peer supporter or member of the STASH team.

2. Expectations within the STASH trial

Untoward incidents (as defined above) occur in day-to-day school life, and may occur during the trial period, irrespective of the STASH trial. In specific relation to STASH, it is important to note that some flippancy is to be expected in young people’s online interactions. Untoward incidents which do not result in harm will be captured in the process evaluation of STASH (see STASH Protocol). Procedures for reporting sensitive disclosures and potential child protection (safeguarding) issues are detailed in ‘STASH Procedures: Reporting of child protection concerns in SCHOOLS’.

This guidance is concerned only with the recording and reporting of untoward incidents in the trial period which result in harm. Harms occurring as a *direct result* of STASH are unlikely. Harm unrelated to STASH is also unlikely during the short trial period.

3. Procedures in place to minimise potential for ‘untoward’ incidents and harms

The STASH Research Team will employ strategies to minimise the likelihood of harms occurring. Peer Supporters will be required at training to sign up to a code of conduct (the STASH Charter). Procedures for dealing with disrespectful/aggressive online behaviour will follow the ICT code of conduct and discipline code of participating schools. Social media use will be confined to private (‘secret’ ie. non-visible, invite-only) Facebook groups, of which STASH Trainers will be a member. Trainers will conduct monitoring ‘spot checks’, and Peer Supporters will also be encouraged to report any untoward incidents promptly to the Trainer and/or STASH Contact Teacher. Students will also have the option to privately message the Trainer as required. The Trainer should pass on any concerns to the Contact Teacher without delay.

All members of the Research Team and the trainers working in schools have PVG clearance/Enhanced Disclosure Scotland certification, which allows them to work with young people under 16.

4. Procedures for reporting and documenting harms

The following sets out reporting procedures at each point of interaction in the STASH trial. These relate to the involvement of the STASH Research Team, STASH Trainers, STASH Contact Teacher/DMS, Peer Supporters, and the whole S4 year group.

While there are no likely harms in relation to the trial, the following mechanisms are in place through which any unexpected harms will be identified and reported, regardless of whether they result from the STASH trial, or are concurrent. Schools have policies in place to deal with behaviours that constitute minor untoward incidents, and so these are not addressed here.

4.1 Identification of possible harm in relation to participants (all S4s including Peer Supporters)

In the course of STASH Year 1 (2016) preparatory work, we sought to identify and articulate potential untoward incidents via a number of avenues. These have included: consultation sessions with young people; a young peoples' advisory group; interviews and friendship group discussions with participants from the pilot school; interviews with key school staff (including the STASH Contact Teacher school and DMS for Child Protection); and preparatory discussions with West Lothian Education and Child Protection Officers, and a range of experts in schools-based interventions and child protection.

Within the school setting, reporting of potential harms will follow school procedures, which require immediate reporting of sensitive disclosures and child protection concerns (see Annex 1 for example from one school). These procedures are in turn steered by national guidance and local (West Lothian Local Authority) protocols on child protection and underage sexual activity (eg. 2010 National Guidance on Underage Sexual Activity – see Annex 2).

The STASH Contact Teacher/DMS and those delivering the intervention (STASH Trainers and Peer Supporters) will be asked to notify the Research Team within five working days if any harm occurs to a member of staff or student, as a direct result of taking part in the STASH trial. In such a case, a trial-specific harm report form will be used to record information on the event (see Annex 3).

Members of the Research Team at the University of Glasgow will be required to document any harms reported to them during trial data collection. All documented harms will be discussed with the Principal Investigators (LM/KM) to assess severity and causality. Causality will be determined according to the criteria in Table 1. In the case of discrepant views on causality the event will be handled at the highest event categorisation.

Table 1. Causal relationship between untoward incident resulting in harm and STASH trial

Relationship	Description
Unrelated	There is no evidence of any causal relationship with the trial
Unlikely	There is little evidence to suggest there is a casual relationship (e.g. the event did not occur within a reasonable time after intervention) with the trial. There is another reasonable explanation for the event (e.g. known behavioral issues).
Possible	There is some evidence to suggest a causal relationship with the trial (e.g. because the event occurs within a reasonable time after intervention). However, the influence of other factors may have contributed to the event (e.g. known behavioral issues).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not assessable	There is insufficient or incomplete evidence to make a judgement of the causal relationship.

All reported harms, for which causality is deemed 'possible' and above, will be reported in writing to the STASH TSC and the NIHR within 15 days of the Research Team receiving the initial report.

Reporting should be made via the form in Annex 3 The threshold for informing the TSC is set at low. The chair will circulate with rest of group if necessary. If the chair is away, the PI should inform the designated representative (DG).

A harm which is deemed ‘unrelated’ or ‘unlikely to be related’ to the trial will be reported to the TSC at the next scheduled meeting. Regardless of attribution, harms will be reported immediately to the STASH Contact Teacher and handled via school procedures (see Annex 1 and ‘STASH Procedures: Reporting of child protection concerns in SCHOOLS’).

4.2 Reporting of sensitive disclosures and potential child protection (safeguarding) issues to Peer Supporters during STASH trial

Appropriate responses to sensitive disclosures and procedures for reporting potential child protection issues are explained – and their importance emphasised – during the two-day Peer Supporter training. In particular, Peer Supporters will be advised on how to respond to sensitive information shared by peers (including respecting privacy), and when to share these with the STASH Contact Teacher/DMS.

Peer Supporters are given guidance on how to identify sensitive disclosures and potential CP issues, and when and how to report these incidents to the Trainer or Contact Teacher/DMS. The expectation is made clear to young people acting as Peer Supporters that any disclosures about which they feel worried or uncomfortable should be reported without delay to the Contact Teacher/DMS. Schools have in place procedures for handling disclosures relating to child protection (see Annex 1), which should then be followed as normal. Peer Supporters are advised that they may also contact the STASH trainer via Facebook, if they wish (see below).

It is possible that students might make other disclosures to Peer Supporters in the trial period which do not constitute a child protection issue, but which are nonetheless experienced as concerning by either party. During training, Peer Supporters are advised to act only within their comfort level, and are not to provide support beyond what they would normally offer to a friend. We recognise that the capacity of minors to make appropriate decisions around their own safety is a contested issue. STASH Peer Supporters will be strongly encouraged to refer other students to appropriate sources of adult help, and are provided in their training with detailed guidance on when to refer and to whom (usually the Contact Teacher/DMS). These will be established at the initial Peer Supporter training and maintained throughout the trial, via the regular follow-up sessions led by STASH Trainers.

4.3 Disclosures of harm to Research Team and/or STASH trainers

The role of the Research Team and STASH trainers includes: having awareness of relevant child protection/safeguarding procedures; recognising indicators of abuse; recording and passing on relevant information without delay; consultation with an appropriate person. Procedures for referral follow school procedures (see Annex 1) and relevant national guidance.

In the course of the process evaluation, all S4 participants will also be asked whether they perceived any negative untoward incidents resulting from the trial. The Research Team and STASH Trainers will only break confidentiality where a disclosure during Peer Supporter training or evaluation fieldwork (group discussions, paired interviews) suggests that a young person might

be at risk or pose a risk to others (see Annex 1). We will work closely with the school (via the Contact Teacher) to ensure that any relevant information is shared.

4.4 Referral for sexual health advice

The Research Team will also work with local young people's sexual health services, school nurses/sexual health drop-in services, and youth organisations to ensure appropriate referral for young people requesting help with personal issues related to their sexual health. Every member of the Research Team will be provided with relevant contact details for local services, which they can provide to students as appropriate. Local sexual health services will be invited to attend Peer Supporter training and/or follow-up sessions, in order to consolidate pathways to support.

Annex 1.

AA (PILOT SCHOOL) CHILD PROTECTION PROCEDURES

All members of staff have the responsibility to follow Edinburgh and Lothians Inter-Agency Child Protection Procedures. Copies of the procedures are held in the school office.

The designated members of staff for Child Protection are:

LIST OF TEACHERS WITH RESPONSIBILITY FOR CHILD PROTECTION

Action procedures for managing a disclosure are in the Child Protection Policy and E&L Inter-Agency Procedures.

Remember:

When faced with a disclosure or concern –

Do not guarantee confidentiality

Be receptive and reassuring

A signed, hand-written record of concerns noting the date and time when the matter was passed to DMS

Share your concern with the DMS on the same day

Where DMS is unavailable, you must not delay, but make a referral immediately to one of the Core Agencies:

List core agencies and contact details

Annex 2.

The two most relevant documents relating to schools-based policy on the above issues are:

1. GIRFEC <http://www.gov.scot/Topics/People/Young-People/gettingitright/wellbeing> (sets out roles and responsibilities, information sharing, risk assessment and responding to child protection concerns) and
2. NATIONAL GUIDANCE: Under-age Sexual Activity: Meeting the Needs of Children and Young People and Identifying Child Protection Concerns (2010)
<http://www.gov.scot/resource/doc/333495/0108880.pdf> (to be read alongside GIRFEC)

While specific protocols are developed locally, the latter document outlines examples of potential indicators of harm / circumstances in which information should be shared amongst agencies with responsibility for child protection (see below). All adults involved in STASH will operate with these guidelines in mind.

'Automatic sharing of concerns'

There are certain circumstances in which practitioners should automatically share child protection concerns:

- if the young person is currently 13 or over but sexual activity took place when they were 12 or under;
- if there is evidence or indication that the young person is involved in pornography or prostitution;
- if the 'other person' is in a position of trust in relation to the young person;
- if the young person is perceived to be at immediate risk.

In these circumstances, the practitioner should:

- where appropriate, speak with the child and young person prior to passing on the child protection concern – every reasonable effort should be made to seek their agreement;
- share the child protection concern in line with their local child protection procedures, detailing those who are involved, the nature of the concerns etc; and
- if agreement is not reached, the professional should share the child protection concern and inform the child and young person that this will be the course of action.

If the young person is not at risk of harm:

If the practitioner has assessed that the sexual behaviour is consensual teenage sexual activity where there are no concerns of abuse or exploitation, the practitioner should:

- uphold the confidentiality rights of the young person; and
- provide practical assistance and advice as required. Practitioners not qualified to provide this should signpost young people to the appropriate local services (e.g. sexual health services).

If the practitioner has assessed that the sexual behaviour is not abusive or exploitative, but that there remain concerns about the young person's behaviour e.g. their ability to assess risk, their use of drugs/alcohol, the environment in which they seek sexual contacts etc, then the practitioner should:

- uphold the confidentiality rights of the young person; and
- provide practical assistance and advice as required within their own agency or, with their permission, refer them to the appropriate clinical or support services, including forensic or sexual health services.

In both these scenarios, a single-agency decision-making process is normally appropriate.

If there are concerns that the young person might be at risk of harm:

If the practitioner is concerned that the young person's behaviour, or the nature of the sexual behaviour and/or relationship, could indicate that the young person is at risk of harm, the practitioner should:

- seek guidance from a line-manager in accordance with their agency's guidelines and decide if further action is required;
- inform the young person about the need speak to other practitioners, where required, and seek their consent if possible;
- share appropriate information with other practitioners about the young person;
- if required, seek advice from other services and agencies to assist in this decision-making; and
- share information with the police if there are concerns about the young person's sexual partner.'

Annex 3

Annex 3

STASH TRIAL

REPORT TO RESEARCH TEAM OF SERIOUS NEGATIVE EVENTS RESULTING IN SIGNIFICANT EMOTIONAL AND/OR PSYCHOLOGICAL HARM TO ONE OR MORE INDIVIDUALS

STASH Contact Teachers and Trainers are asked to contact the Research Team within five working days if they become aware of any sensitive disclosure and/or potential child protection issue occurs, as a direct result of the STASH study. Young people acting as peer supporters are asked to pass on any sensitive disclosure and/or potential child protection issue to DMS or Trainers for reporting as soon as possible.

1. Details of person making report

Name:	
Role relating to STASH:	
Telephone:	
Email:	

2. Circumstances of event

Date on which untoward incident/ harm occurred:	
Location:	
Type of incident (eg. cyberbullying, unlawful activity):	
Please describe the circumstances of the event and actions taken:	

3. Declaration

Signature of reporting person:	
Print name:	
Date of submission to Research Team:	

FOR STASH Research Team Use Only

4. Acknowledgement of receipt by main Research Team

The Research Team acknowledges receipt of the above report.

Signed:	
Print name:	
Position on Research Team:	
Date:	
Causality judgment: Unrelated; unlikely; possible; probable; definite; not assessable	
To be forwarded to TSC? (Yes/No) If YES, date forwarded.	

If causality is deemed possible between serious negative event and STASH trial, the TSC chair should be informed within 15 days. The threshold for informing the TSC is set at low. The chair will circulate with rest of group if necessary. If the chair is away, the PI should inform the designated representative (DG).

Signed original to be retained by STASH Research Team.

5. Acknowledgement of receipt by STASH Trial Steering Committee

The TSC acknowledges receipt of the above report

Signed:	
Print name:	
Position on Research Team:	
Date:	