



equally safe at school

a whole school approach to
preventing gender based violence

MRC/CSO Social and Public Health Sciences Unit



FUNDED BY

 National Institute
for Health Research

Project: **Whole-school approach to addressing Gender-Based violence in secondary school (Equally Safe at School): A type I hybrid effectiveness-implementation trial**

STUDY PROTOCOL V5

Start date: 01/07/2023

End date: 30/09/2026

Duration: 39 months

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

This protocol has been authorised by:



Name	Role	Signature	Date
Prof Laurence Moore	SPHSU Director		16/10/23
Name	Role:	Signature	Date
Professor Kirstin Mitchell	Principal Investigator		16/10/23

Table of Contents

1.	Summary	6
2.	Introduction	8
2.1	Background to GBV	8
2.2	Background to ESAS intervention	9
2.3	Rationale	10
2.4	Aims/Research Questions	11
3.	Study Design/Methods	12
3.1	Study Design	12
3.2	Settings/context	13
3.3	Sampling	13
3.4	Study Procedures	14
3.4.1	Recruitment	20
3.5	Data Analysis	23
4.	Research Governance and Regulatory Issues	26
4.1	Ethical issues	26
4.2	Data Monitoring/Quality Assurance	27
4.3	Data Management	28
4.4	Data Storage and Retention	29
5	Project Management	30
5.1	Project Manager	30
5.2	Project Management Group	30
5.3	Advisory Group / Steering Committee	31
5.4	Project Filing Structure	31
6.	Dissemination	31
6.1	Communication method	31
6.2	Publication Policy	32
6.3	Public Engagement and Knowledge Exchange	32
7.	Project Milestones / Timelines	33
8.	Project Risk Assessment	35
9.	References	35

Contact details - Principal Investigator & Co-Investigator

PRINCIPAL INVESTIGATOR:

Kirstin Mitchell
Prof, Social Science & Public Health
School of Health & Wellbeing
University of Glasgow
kirstin.mitchell@glasgow.ac.uk

CO-INVESTIGATORS, UNIVERSITY OF GLASGOW

Ms Carolyn Blake, Research Co-ordinator. Carolyn.blake@glasgow.ac.uk

Dr Ruth Lewis, Process Evaluation Lead ruth.lewis@glasgow.ac.uk

Prof Laurence Moore, Complex Trial Design Laurence.moore@glasgow.ac.uk

Prof Rod Taylor, Trial Statistician rod.taylor@glasgow.ac.uk

Prof Emma McIntosh, Health Economist emma.mcintosh@glasgow.ac.uk

CO-INVESTIGATOR, RAPE CRISIS SCOTLAND

Ms Kathryn Dawson, Lead for RCS kathryn.dawson@rapecrisisScotland.org.uk

Ms Lisa Waiting, ESAS Co-ordinator lisa.waiting@rapecrisisScotland.org.uk

Ms Niamh Kerr, Prevention Manager, RCS niamh.kerr@rapecrisisScotland.org.uk

FUNDER: NIHR 154376

SPONSOR: University of Glasgow

TRIAL REGISTRATION: ISRCTN29792495



Amendment History

Amend No.	Protocol Version	Date	Author(s)	Details
1	4	17/01/24	Kirstin Mitchell	Changed inclusion criteria to allow independent schools to participate in evaluation.
2	4.1	03/06/24	Kirstin Mitchell	<p>Added a secondary outcome (student report of forced sexual activity) which had been omitted from the protocol in error.</p> <p>Delayed the timing of the parent survey in case study schools (from 9-12 months after baseline survey to 12-18 months after baseline) to allow schools to make more progress in intervention before parents are surveyed.</p>
3	5	08/07/25	Kirstin Mitchell	<p>Table 2, Activity 6: removed reference to health resource care use in parent survey. At outset of trial, it was agreed that this information should be collected from pupils, since response rate to parent survey is anticipated to be low. This information should have been removed earlier but was picked up during a review of the protocol.</p>
			Claire Hamilton	<p>Research questions: RQ1, RQ2, RQ3 updated to differentiate between effects after 1 year and 2 years.</p> <p>Updated study design to type I hybrid effectiveness-implementation trial.</p> <p>Data collection updated to clarify the student survey will be completed via Qualtrics on student devices.</p> <p>Table 2: Process evaluation methods updated to reflect the following: analysis of multiple years of data from all-staff survey removed as schools are only implementing this survey once. School policy audit moved from end of Year 1 to end of Year 2. Number of workshops removed.</p>

				<p>Outcome measures (baseline, 12 and 24 months) reidentified as primary, secondary and intermediate outcomes. Process evaluation reidentified as process measures, with addition of usual practice and contamination and mechanisms of action (which combines mechanisms of change embeddedness).</p> <p>Addition of recruitment criteria for case study schools.</p> <p>Data analysis: Study 1; addition of handling missing data. Study 2A; separating this analysis from study 1. Study 3; provide more detail on economic evaluation.</p> <p>Addition of protocol signature page.</p>
--	--	--	--	--

Protocol Signature

I confirm I have read v5 of this protocol:

Name	Signature	Date
Claire Hamilton		14/07/2025
Kirstin Mitchell		14/07/2025

1. Summary

BACKGROUND: Gender-Based Violence (GBV), including sexual harassment, is common in secondary schools and has significant detrimental impact on physical and mental health in adolescence and later life. Schools are key sites to address GBV because norms are established and experience of GBV often begins in adolescence. Intervening to improve gender equal attitudes and prevent GBV at school can interrupt pathways to adult male aggression towards women in later life. Whole-school approaches to addressing GBV have political support, but the evidence base is sparse. Equally Safe at School (ESAS) is a whole-school approach designed by Rape Crisis Scotland/University of Glasgow, co-produced and piloted in 8 schools, and recently launched in Scotland. Schools access resources via a web-based Hub and undertake self-assessment, establish an action group, and complete staff training, curriculum enhancement, and policy review. Theorised mechanisms of sustainable change include perceived coherence of the approach; active and collective staff/student involvement in efforts to change school culture; development of skills to recognise and address GBV; and social reward for positive attitudes and behaviour.

AIM: To evaluate the effectiveness, cost-effectiveness, implementation and mechanisms of change of the ESAS intervention.

OBJECTIVES: Establish the effect of ESAS on student experiences of sexual harassment and a priori secondary outcomes regarding school prevention of, and response to, GBV. (2) Assess implementation processes and intervention mechanisms, how these vary within and between schools, and if/how ESAS embeds in school systems over time; (3) Establish what ESAS costs (and what activities it displaces) compared with the outcomes, and the long-term societal cost effectiveness.

METHODS: Overall design is Type I hybrid effectiveness-implementation trial. Study 1: Pragmatic cluster randomised trial with repeated cross sections in 36 schools in Scotland, randomised (1:1) to immediate start or 12-month delayed start. Primary outcome (student experience of sexual harassment) will be measured at 12 months post-randomisation. Analysis of primary and secondary outcomes (student and school level) will be conducted on an intention to treat basis comparing schools according to their original allocation. Study 2: Mixed-methods evaluation. Study 2A: longitudinal follow-up will assess primary, secondary and intermediate outcomes at baseline, 12 and 24 months. Study 2B: systems and realist-informed process evaluation – will assess intervention and control school context, fidelity, dose and reach, acceptability and actor response, and how this varies by school and students. We will also assess implementation processes and mechanisms of action, including if and how change is embedded over time, and if and how ESAS helps schools leverage other assets and resources. Study 3: Economic evaluation to evaluate the within trial and longer-term cost effectiveness of ESAS.

TIMELINE: Year1: Schools recruited and randomised after baseline survey; immediate start schools begin ESAS; process evaluation measures collected in all schools and in-depth in case study schools. Year2: Follow up survey at 12 months (primary outcome); delayed start schools begin ESAS activities; immediate start schools continue to embed ESAS; process evaluation activities in both arms. Year3: 24-month follow-up in all schools; analysis; dissemination to participants, stakeholders & scientific community.

IMPACT: Potential impacts on Students - less exposed to sexual harassment; more confident to intervene and report incidents of GBV. School staff - acquire advanced skills to

prevent and intervene to address GBV. Wider society – reduced GBV-related harms (and associated burdens on healthcare, policing, education sector, and wider economy).

2. Introduction

2.1 Background to GBV

This study purposefully targets early roots of male violence against women: inequitable gender norms, harmful attitudes, discrimination, gendered bullying, sexual harassment and sexual assault in secondary schools [1]. These behaviours are included in Gender-Based Violence (GBV), defined as 'any form of violence used to establish, enforce or perpetuate gender inequalities and keep in place gendered orders' [2]. Data on sexual harassment (a manifest form of GBV) is scarce for UK schools. An online Girlguiding survey of 1900 young women in 2017, found two-thirds of 13–21-year-olds had experienced sexual harassment at school/college in the last year (increased from 2014) [3]. A 2021 UK Government review found that sexist-name calling was ubiquitous among 13–18-year-olds, and 64% of girls had experienced unwanted touching [4]. In our pilot survey, two-thirds of secondary students reported experiencing at least one type of sexual harassment behaviours at school in the past three months, with half of those reporting physical sexual harassment [5]. Our study and others demonstrate an elevated risk for students with minoritized gender and sexual identities [5], [6], [7]. In PPI meetings with Education leads, concerns were raised about recent rises in far-right antiwomen attitudes among young men through exposure to extremist social media posts.

School-based GBV primarily stems from inequality between boys/men and girls/women [1], [8] but may also implicate sexual orientation or gender identity [1]. Patriarchal and unequal attitudes in society shape norms in schools that excuse and enable GBV [9], [10]. Patterning of sexual harassment shows a continuum in which exposure to 'milder' forms, such as 'sexual jokes, gestures or looks' increases risk of exposure to more invasive behaviours like sexual coercion [5]. There is an association between experiencing and perpetrating sexual harassment; while boys perpetrate more than girls. Gendered 'teasing' normalised as 'banter' pressures boys to conform to hegemonic norms of masculinity supporting violence [9], [11]. In terms of sexual harassment victimization, most studies find higher victimization rates among girls; and in both boys and girls there is a link between perpetration and victimisation [12], [13]. Studies also suggest that gender minority students are more likely to experience sexual harassment victimization than girls or boys [6], [14].

Existing research demonstrates causal associations between any type of sexual harassment victimization at school and adolescent well-being and later-life health, and economic and social outcomes [15], [16]. School-based sexual harassment has a stronger adverse impact on health than bullying and these effects are more notable in girls [17]. Sexual harassment in school is also serious because it normalises sexual violence [9], [18]. In Britain, 10% of women (1.4% of men) report sex against their will, most commonly in late adolescence [19]. The European Institute for Gender Equality (EIGE) recently estimated the cost of GBV across the EU at €366bn per year [20], and a 2019 report estimated the cost of domestic abuse for victims in 2017 to be approximately £66 billion in England & Wales [21]. The costs include lost economic output, use of the health system and criminal justice system, and physical and emotional impacts on victims [22]. Prevention of GBV therefore, has significant public health and societal benefits.

The evidence on the effectiveness of school-based interventions to reduce sexual harassment is fragmented. Much more is known about interventions to address related problems (Dating and Relationship Violence (DRV) and bullying) than is known about interventions focusing on sexual harassment and GBV in general. Reviews of DRV find a focus on curriculum sessions and individual behaviour, with few interventions tackling structural influences [23]. Overall, interventions have demonstrated impacts on attitudes and knowledge but there is weak evidence for effects on behaviour [23]. In one of the few

effective interventions, *Shifting Boundaries*, the building-based component (e.g. increasing teacher/security presence in unsafe areas) was key [23]. Disappointing results from curriculum-based health interventions have led to interest in whole-school approaches which seek to change the school environment as well as addressing broader upstream social, physical, and cultural contexts for health and wellbeing [24]. Reviews have established effectiveness of whole-school interventions focused on bullying [25]. In the UK, the INCLUSIVE trial had small but significant effects on bullying [26], but there are few studies outside North America and little reliable evidence on programmes that have sustained effects, why, and for whom [25]. The evidence for whole-school approaches to GBV is nascent and focuses on goals of gender equality in low- and middle-income country settings [27]. Researchers and policy makers have called for robust evaluations of whole-school approaches to GBV [27].

2.2 Background to ESAS intervention

ESAS is a whole-school approach to prevent gender-based violence and promote gender equality in secondary schools. All individuals within the school environment are actors and beneficiaries. Wider beneficiaries include individuals who avoid exposure to GBV due to changes in attitudes and behaviours of students in ESAS, and wider society benefits from reduced GBV-related harms (and associated healthcare, legal/sentencing costs, and loss to workforce productivity/educational attainment). Schools meet the costs of delivering ESAS in terms of dedicated teacher time. Full information is at <https://www.equallysafeatschool.org.uk/>

ESAS was developed via a 6-year collaboration between University of Glasgow and Rape Crisis Scotland (RCS). The intervention development phase (2016-2018; CSO Catalytic Research grant CGA/16/9) involved student/staff group interviews and stakeholder consultation. The resulting 'theory of change' and draft intervention design were refined via consultations with voluntary and statutory stakeholders. MRC programme funding [MC_UU_00022/3] supported small-scale formative evaluation research alongside a 3-school pilot implemented by RCS.

The intervention is summarised as follows:

What ESAS involves: Web-based Intervention Hub with log-in and dashboard for registered schools. Schools use tools and guides on the dashboard to undertake 5 activities (procedures):

[A] Whole-school self-assessment: Schools undertake a self-assessment (via online surveys and focus groups) with management, staff, and students to identify how gender inequality, adherence to stereotypes, and gendered bullying, harassment, and abuse manifest in their schools. The results of the online surveys are presented via an auto-generated report on the school's online ESAS hub and provide a basis for plans by the Action Group (B) to address priority areas.

[B] Action group: Schools then establish a student-led Action group, with several supporting staff. The terms of reference state the group should include students from a range of year groups and should be diverse, inclusive, and reasonably representative of the wider student body. The group meets regularly, first reviewing the self-assessment findings and developing ideas to address the key issues outlined in the report. These form the group's action plan. Schools can access a range of materials to support them to recruit, run and sustain an Action Group on their ESAS hub.

[C] Two-tier staff training: School staff undertake training to develop capacity and capability to deal with issues relating to gender-based violence. All school staff complete an e-module hosted on the ESAS hub. The e-module provides foundational information about

GBV and supports staff to identify ways in which they can embed principles into everyday practice. Staff in student support roles within the school additionally attend a two hour 'enhanced' in-person training session delivered by their local rape crisis centre to further equip them to respond to safeguarding issues in relation to gender-based violence.

[D] Curriculum enhancement: Staff can access a range of resources and lesson plans to support them to embed teaching about gender equality into the school curriculum to develop students' understanding of issues relating to gender-based violence and gender equality.

[E] Policy review: Schools review key policies and behavioural codes (such as Promoting Positive Behaviour, Equality and Diversity, Safeguarding) to ensure explicit, consistent, and appropriate handling of issues relating to gender equality and GBV. Via the online ESAS hub, schools can access policy review templates and tools, including prompt questions to ensure inclusion of gender and GBV, example paragraphs and suggestions for ongoing student co-production.

Who provides ESAS: Schools implement these activities at their own pace and take ownership of their activities. They are encouraged to undertake [A] and [B] early and to complete activities in year 1 and embed them in year 2. A member of school leadership is designated to co-ordinate intervention activities (ESAS Lead teacher). Ad-hoc guidance and support is available from the national Rape Crisis ESAS Coordinator. Local Rape Crisis Centres provide the enhanced staff training and can also provide locally tailored support (including referral pathways for students experiencing sexual violence). Schools are encouraged to access other resources and initiatives as part of the ESAS activities, including initiatives such as Mentors in Violence Prevention (MVP).

How: Schools access intervention materials via an online platform (via their 'My ESAS' account featuring resources such as a project dashboard for senior leadership, self-assessment materials, and an e-learning training module for staff). They implement these materials in a face-to-face mode of delivery. Modes of delivery include assemblies, group trainings for staff, classroom teaching to students, staff-student Action Groups, and activities.

Where: ESAS takes place in secondary schools only. Infrastructure and equipment used for this intervention belong to the schools and Rape Crisis Scotland (website, training materials).

Tailoring: The general intervention framework and five procedures are the same across all schools. However, schools (teachers and students) will be actively engaged in tailoring ESAS based on needs and gaps identified in the whole school assessments [A]. Variation between schools will primarily concern the type and scale of actions identified and undertaken by the Action Group [B].

Intervention Theory of change: ESAS is underpinned by Markham and Aveyard's theory of health promoting schools [28] which states that student health can be achieved through capacity for practical reasoning and capacity for affiliation with others, and thus can occur via changes to school organisation, staff-student relationships, and curriculum. Initial theorised mechanisms of sustainable change from the pilot study are: that staff and students view ESAS (and the link between gender inequality and GBV) as coherent; that they are actively and collectively involved in efforts to change school culture; that they develop skills to recognise and address GBV; and that they are rewarded for positive behaviours (e.g. via positive feedback or positive experiences of reporting sexual harassment). These hypothesised mechanisms derive from the Social Development model [29], Theories of Social Capital [30], and the General Theory of Implementation [31].

2.3 Rationale

We address a crucial gap in evidence for effective and cost-effective ways to address gender inequality and school-based GBV in secondary school. Our primary outcome of school-based sexual harassment represents the most visible manifestation of

GBV in school, with a measurable link to health. Sexual harassment can affect all students, regardless of sexual or relationship experience. Intervening to tackle adolescent sexual harassment and GBV within school settings is essential [32], [33]. Adolescence is characterised by identity formation and initiation of intimate relationships and is a common period for onset of GBV; schools are key sites in which norms are established (including those normalising sexual violence), and in which sexual harassment is enacted [31]. Perpetration of sexually coercive behaviours in adolescence is a key risk factor for perpetrating sexual violence in later life [32]. A universal primary approach that addresses systemic drivers of inequalities, transforms gender norms, and includes young men (and male teachers) as part of the solution is recommended [9]. A specific focus on sexual harassment is important; previous conflation of sexual harassment with bullying in education policy and research has held back attempts to address root causes of gender inequality and gendered power differences [17].

Political recognition of necessary urgent action on school-based sexual harassment and GBV is relatively recent [4], [34]. Political action was provoked by a campaign that compiled over 50,000 testimonies of sexual harassment and assault in UK schools (everyonesinvited.uk). In direct response to this, the UK Government (Ofsted) then undertook a rapid review, confirming the significant scale of the problem and advocating for a whole-school approach [4].

Spurred by social movements (e.g. 'Everyone's Invited,' #MeToo), the issue is increasingly gaining public attention (coverage of our pilot study: bit.ly/3A0Zrgm), demonstrating policy momentum and sustained interest. The specific focus on sexual harassment is important as previous conflation of sexual harassment with bullying in education policy and research has held back attempts to address root causes of gender inequality and gendered power differences [17].

The ESAS trial provides long overdue and urgently needed evaluation evidence on a UK intervention using a whole-school approach to address this problem directly at being implemented at scale. The trial will add to empirical knowledge by using baseline data to address critical gaps in understanding of the scale and nature of sexual harassment in school; intersecting inequalities in experience of sexual harassment; how victimisation/perpetration of sexual harassment links with harmful gender norms [35], and school-level factors. The trial will meet a crucial gap in evidence for effectiveness of whole-school approaches to tackling GBV. This will be the first school-based trial in UK to test impact on school sexual harassment. The trial will contribute to theory by using evaluation data to interrogate the programme theory and thus advancing theory on mechanisms of sustainable change in whole-school approaches to tackling GBV. With respect to policy, trial findings will contribute to evidence of the effectiveness/cost-effectiveness of a whole-school approach to GBV in high-income countries. It will also enhance understanding of how systemic factors in schools can deter or facilitate tackling of GBV in schools (building on participatory mapping work in pilot phase). Finally, the trial will seek to advance methods of systems-informed evaluation of complex interventions. Process evaluation and longitudinal outcomes study are designed to explore how ESAS combines with the context; alters relationships between actors; facilitates cultural change; leads to shifts in the distribution of resources and replaces other activities during and beyond the intervention period [36].

2.4 Aims/Research Questions

Research aim. The study aims to evaluate the effectiveness, cost-effectiveness, implementation and mechanisms of change of the ESAS intervention. We will address 9 research questions:

RQ1: What is the effect of ESAS on student experiences of sexual harassment (primary outcome) and a priori secondary and intermediate outcomes? (RQ1A – after one year?; RQ1B – after two years?)

RQ2: What is the effect of ESAS on school prevention of, and response to, GBV? (RQ2A – after one year?; RQ2B – after two years?)

RQ3: Does ESAS have a differential impact depending on student age, gender, socio-economic status, ethnicity, sexual orientation or by school-level academic attainment or area deprivation or by other factors identified as important? (RQ3A – after one year?; RQ3B – after two years?)

RQ4: Is ESAS delivered with good fidelity, reach/dose, acceptability and actor response, and how does this vary between schools, and between students/staff within schools?

RQ5: What GBV-relevant activities and initiatives take place in delayed start (control) schools?

RQ6: To what extent does ESAS enable schools to leverage other assets and resources in short and medium term?

RQ7: What does ESAS cost (and what activities does it displace) compared with the outcomes, and what might be the long-term societal cost effectiveness of this intervention?

RQ8: After two years, what is the prevalence of sexual harassment and how well do schools prevent and respond to it?

RQ9: What do study findings overall suggest about intervention theory of change and potential for ESAS to be delivered and be effective/cost-effective elsewhere (particularly other parts of UK)?

3. Study Design/Methods

3.1 Study Design

The study is a type I hybrid effectiveness-implementation trial [37]. This study type involves testing an intervention while also collecting information on its delivery in a real-world situation [37].

The evaluation comprises three studies:

Study 1: Pragmatic Cluster randomised trial in 36 schools in Scotland, randomised (1:1) after collecting baseline data to either immediately start the ESAS intervention (intervention arm) or 12-month delayed start (control arm). Treatment as usual includes usual school initiatives on GBV and continues in both arms. Our primary outcome - student experience of sexual harassment - will be measured at 12 months. Analysis of primary, secondary and intermediate outcomes will be conducted on an intention to treat (ITT) basis comparing schools according to randomised allocation [RQ1A; RQ2A].

Study 2. Mixed-method evaluation based on realist and systems thinking. **Study 2A (longitudinal follow-up)** will assess primary, secondary and intermediate outcomes at baseline, 12-month and 24-month follow-up (school-level). **Study 2B (process evaluation):** Guided by realist and systems-informed frameworks for evaluating complex interventions [38], [39], [40], [41], [42], we will assess fidelity of intervention implementation, reach/dose, acceptability and actor response [RQ4]; risks of contamination and any relevant “usual practice” activities in control schools [RQ5]; and implementation processes and mechanisms of action (beneficial or harmful), including if and how ESAS enables schools to leverage other assets and resources [RQ6], and if and how change is embedded over time [RQ9]. We will collect some data from all schools and in-depth data in six case study schools. We will also collect data from wider education stakeholders and regionally based RC staff involved in delivering ESAS training [RQ1B; RQ2B; RQ3-9].

Study 3: Economic evaluation will compare the intervention outcomes (consequences) with costs of delivering the intervention and health and social care resource use, and,

pending findings from study 1 and 2, evaluate the likely long-term societal cost effectiveness [RQ7].

3.2 Settings/context

Most schools in Scotland have policies and procedures in place to address bullying and harassment, but the extent to which these effectively address school culture and ethos with respect to GBV is highly variable or unknown. All schools are expected to work towards health and wellbeing indicators as part of the Scottish Curriculum for Excellence and many schools have undertaken self-assessment of the school environment under the 'How Good is Our School' quality framework. In the last 12 months, 70 schools have registered for an ESAS account; 12 schools have begun to implement ESAS activities and new schools regularly contact RCS for support to start activities. There is growing awareness of, and interest in ESAS across schools and 6 Education Authorities have met with RCS to discuss area-wide approaches. The Mentors in Violence Prevention (MVP) programme (<https://education.gov.scot/improvement/practice-exemplars/mentors-for-violence-prevention-mvp-an-overview/>) is also being rolled out in Scotland. Nationally, the implementers of MVP and ESAS are taking a collaborative approach, recognising that MVP and ESAS are highly complementary; MVP focuses on peer mentoring and ESAS addresses wider culture. In a PPI interview with a school leadership team, teachers said they envisaged ESAS as a 'gel' bringing together various initiatives. MVP is referenced frequently on the ESAS website and incorporated into ESAS teaching (curricular development) section. Schools are encouraged to engage with both. Some schools interested in ESAS will have already engaged with MVP. For this reason, we will stratify by 'MVP status' in the outcome evaluation and explore synergies between ESAS and MVP in the process evaluation.

3.3 Sampling

Study population: Scottish secondary schools comprise 6 academic years (1-6) for students aged 11-18. All Students and teaching/non-teaching staff in school are eligible to participate in ESAS. Students in Year 2 (Y2, age 13), Year 4 (Y4, age 15) and Year 6 (Y6, age 17) at each follow up are eligible participants for the baseline and follow-up surveys and qualitative data collection (Year 5 omitted as this is a major public exam year). For the process evaluation we will analyse data from school staff self-assessment surveys (study year 1 for immediate start schools and study year 2 for delayed start schools); all teaching staff are eligible for these surveys, and staff in case study schools are eligible for qualitative data collection. All parents/carers in study schools are eligible for the parent survey. Exclusion criteria: students and teachers who refuse their consent; students who are opted out of data collection by their parent/carer.

Sampling unit: Mixed-gender secondary schools in Scotland.

Exclusion criteria are: (1) Schools with fewer than 300 students. This is because they are atypical, and additionally because of the high-unit cost of data collection. (2) Single-gender schools (3) Schools who have already undertaken one or more ESAS intervention activity.

State schools will be recruited first; up to four independent schools will be recruited if there are places remaining after December 2023.

Proposed sample size

We have estimated a self-reported prevalence of primary outcome of 35% (see primary outcome below). Based on a relative risk reduction of 23% (which in consultation with RCS, we judged a meaningful difference), we determined that recruiting 36 schools (with a mean

of 327 pupils/school & coefficient of variation of school size of 0.23, across 3 year groups assuming 75% response) provides 84% power to detect a difference in the primary outcome of 35% [5] in delayed start schools versus 27% (odds ratio 0.77) [43] in immediate start schools at 12-months follow up assuming a moderate level of clustering (intracluster correlation coefficient (ICC) of 0.025, see note below) and an alpha of 0.05.

We remain adequately powered (i.e. $\geq 80\%$) when we apply a number of potential scenarios to key sample parameters: (1) attrition bias (10% loss schools at 12-months follow up); (2) decreased prevalence of primary outcome (32%) (3) increased ICC of 0.05 if relative risk increased to 30% (odds ratio 0.70). Conservatively our sample size calculation assumes no correlation in school primary prevalence between baseline and follow up; a modest correlation (≥ 0.4) increases power to $\geq 90\%$ in the base case (see Table 1) and would compensate for any reductions in power due to these reasons.

Table 1. Statistical power under base case assumptions and alternative scenarios for key sample size parameters.

Scenario	Power	Effect size	Odds ratio	ICC	N schools	N pupils
Base case*	84%	35% vs 27%	0.77	0.025	36	11,772
Baseline-follow up primary outcome correlation (0.40)	90%	35% vs 27%	0.77	0.025	36	11,772
Loss of 10% schools (2 per arm)	80%	35% vs 27%	0.77	0.025	32	10,464
Decreased prevalence of primary outcome (32%)	80%	32% vs 24.6%	0.77	0.025	36	11,772
Increased ICC (0.05)	82%	35% to 24.5%	0.70	0.05	36	11,772

Note on calculation of ICC: In our pilot (618 students from 3 schools), the ICC for our 5-item primary outcome measure of sexual harassment victimisation was 0.007, similar to those reported in other trials of adolescent GBV (0.006 [44] and 0.005 [45]). Baseline data from a school-based cluster RCT of *Dating Matters*, a teen dating violence intervention, indicated that ICCs for their six teen dating violence outcomes ranged from $\sim .000$ to $.073$ [46], so to prevent this trial being underpowered, we based our sample size on an ICC of 0.025 with power of 84-90%.

3.4 Study Procedures

Methods for data collection:

Study 1/2A: Assessment and follow-up Student baseline and follow-up questionnaires (12 and 24 months) will be administered to whole year groups (S2, S4, S6) by the study fieldwork team. We omitted S1 based on acceptability to schools (pilot study finding) and S5 because it is the key year for public examinations. Students will complete the web-based survey (programmed using Qualtrics [47]) on their mobile phones in class time, following a briefing video and after ticking a box to indicate their consent to participation. The ESAS pilot demonstrated that this is feasible with minimal need for back-up phones/tablets, however the fieldwork team will supply tablets and bring Wi-Fi routers as required. Prior to data collection days we will discuss fieldwork logistics with each school and tailor to their need. Ahead of data collection, parents will be informed of the survey and given opportunity to opt out their child. Our PPI with students suggested a preference for survey completion in class (ideally Personal Social Education) but use of assembly halls may be necessary in some schools. Students will be supervised either by teachers or fieldworkers and requested to complete the survey under exam conditions. Survey length will be limited to 25 minutes for ease of

administration within a classroom period. Students complete the questionnaire anonymously (informed by pilot work) to enhance response rates, validity, and questionnaire completion. However, we will ask students in Year 2 and 4 to generate their own unique ID. This involves a set of instructions to students to create an ID using static and unique information that another person could not answer. The same set of instructions is given at 24-month follow-up, allowing the surveys to be linked. This allows for nested cohort analysis (study 2A), while maintaining real and perceived anonymity of questionnaire responses. We will maximise efficiency, reliability of data, response rates and student safeguarding in the following ways: (1) brief instructional video and instruction sheet for teachers (including how to create a conducive and safe environment, FAQ to deal with student queries and offer support if needed, devised with support from our Young People's Advisory Group (YPAG)); (2) Mobile fieldworkers who move between classes/assembly rooms and are available via mobile phone to address issues that arise for teachers supervising administration; (3) Arranging for additional time and support for younger students and those with additional needs; (4) use of class lists to identify students not completing survey and arranging of up to 2 'mop up' sessions for these students. A summary report of the student survey is shared with school ESAS leads once they begin the intervention and serves as the self-assessment data for the school (outside of the evaluation study, schools collect this information themselves via the dashboard).

Study 2B: Process Evaluation. We will use a combination of methods (online questionnaires, interviews, observations, document analysis, workshops) to generate detailed quantitative and qualitative data to contextualise the results of the RCT. Data will be generated in all 36 schools, with more in-depth evaluation activities conducted within six case study schools (all case study schools will be immediate start schools to enable evaluation over a two-year period). In-depth evaluation in case study schools will aim to capture the wider impacts and adaptive nature of systems change efforts. Schools will be eligible to be case study schools if they have completed at least one of the five components of ESAS. Among schools willing to be case studies, we will purposively select for variation in size of pupil body, %FSM/socio-economic catchment area, rural/urban setting, MVP status. An evaluation monitoring log will be kept and analysed to capture any adverse events; recruitment and retention figures; notes from significant communications among the research team, Coordinator, and schools; contemporaneous events, media coverage and other relevant information. Table 2 summarises the data generation methods, key topics covered, and evaluation issues addressed.

Table 2: Summary of process evaluation methods and topics

Data source, method, and timescale	Key questions/topics	Issues addressed	ref# for recruit section
Study 2B			
Evaluation monitoring log	To document: adverse events; recruitment and retention figures; communications with schools; contemporaneous events, media coverage and other information	Fidelity, Unanticipated outcomes	
Study 2B: Assessing year 1 of ESAS implementation within schools (<i>study year 1 for immediate start schools, study year 2 for delayed start schools</i>)			

1. All schools: Online survey (closed & open questions) of key leadership/ management staff e.g. member of school SMT, ESAS lead, Action Group lead (~1 per school; n=36). Survey administered by research team ~12m after baseline survey (18 immediate start schools), ~12m after follow-up survey (18 delayed start schools).	Early perceptions and experiences of implementing ESAS, including prioritisation of ESAS, facilitators, and barriers to implementation (school-level and wider context), and unintended consequences	Acceptability, mechanisms of action	RA2
2. All schools: Analysis of data from online staff survey self-administered by schools in first year of implementation via ESAS Intervention Hub as part of their self-assessment. Estimated response n=1350.	Staff perceptions of school culture, leadership, and policies relevant to gender equality and sexual harassment; awareness of GBV and gender inequality as issues requiring action; confidence to report and intervene in instances of sexual harassment/ assault.	Mechanisms of action	RA12
3. All schools: Analysis of school's self-completed dashboard information at end of Year 1 of implementation (all schools)	Number, type, and pace of activities completed as reported on dashboard; staff feedback on enhanced training.	Fidelity, Acceptability, Reach	RA14
4. Case study schools: In-person paired/group discussions with school staff involved in implementing ESAS and/or experience handling GBV reporting. Discussions conducted ~12-15m after baseline survey. Approx. 2 groups per school; 2-4 staff per group (total: 24-48 staff).	Staff involvement in and response to ESAS components/activities (e.g. staff training); local adaptations to ESAS delivery; perceptions of conditions for mechanisms of change and any effects of ESAS in year 1.	Reach, Fidelity, Acceptability, Mechanisms of action	RA5
5. Case study schools: In-person paired/group discussions approx. 12-15m after baseline survey. 4 groups per school, ~4 students per group (approx. ~96 students total); students identified from spread of year groups and including existing student-led groups in schools.	Awareness of ESAS activities within the school setting; perceptions of the relevance, acceptability, and effect of ESAS activities; any unintended outcomes	Reach, Fidelity, Acceptability, Mechanisms of action	RA4
6. Case study schools: Brief online survey of parents/carers ~12-18m after baseline survey. Survey link sent by school to all parents/carers; prize draw to increase response.	Perceptions of school culture and policies regarding gender equality and GBV; awareness and acceptability of ESAS activities within school;	Reach, Acceptability, Mechanisms of action	RA6

	awareness of effects of ESAS activities;		
7. Case study schools: Structured observations of ESAS activities (e.g. enhanced staff training session; Action Group meetings) and school culture regarding GBV and gender inequality (e.g. assemblies). ~2 observations per school at different time points in Year 1.	Staff and student participation in, and response, to ESAS activities; visibility of ESAS-relevant material in open school spaces	Fidelity, Reach, Acceptability, Mechanisms of action	RA11
8. Delayed start schools: Brief online survey of school lead (1 per school, n=18) at end of waitlist year.	Any GBV-relevant school events/activities/policies that occur during waitlist.	Usual practice	RA3
Study 2b: Assessing embedding of ESAS within school system over time (immediate start schools only; study year 2)			
9. Immediate start schools: Online survey of key leadership/management staff e.g. member of school SMT, ESAS lead (1 per school; n=36). Survey administered by research team at end of year 2.	Perceptions on facilitators/barriers to ESAS embedding in school system; unintended consequences.	Sustainability/ Embeddedness, Mechanisms of sustainable action	RA2
10. Immediate start schools: Updated dashboard analysis from second year of ESAS implementation.	Number, type, and pace of activities completed as reported on dashboard.	Fidelity	RA14
11. Case study schools: Audit of school policies updated as part of ESAS towards end of Year 2.	ESAS-relevant prevention policies and procedures	Mechanisms of change, Fidelity	RA13
12. Case study schools: Workshops to understand the wider impacts of ESAS in school system over time, from staff/student perspectives.	Perceived impacts, including unanticipated outcomes; resources/ conditions for sustainable change; interaction between ESAS and wider context (school, local authority, national).	Sustainability/ Embeddedness, Mechanisms of sustainable change	RA7
13. Interviews with ESAS lead staff within less engaged/non-active immediate start schools (1 ESAS lead staff member per school; n=3-5 total)	Perceived barriers to implementing and embedding ESAS, including absence of hypothesised mechanisms of change (e.g. lack of support by senior management)	Sustainability/ Embeddedness, Mechanisms of sustainable change, Acceptability	RA8
14. Interviews (online or in-person) with local Rape Crisis Scotland coordinators supporting schools' implementation of ESAS, across	Perceived facilitators/ barriers to implementing and embedding ESAS (reflection on variation between different	Sustainability/ Embeddedness, Mechanisms of sustainable change	RA9

different Local Authorities (n=4-5)	schools); unintended outcomes		
15. Interviews (online or in-person) with Local Authority education stakeholders from different LAs (n=6)	How ESAS fits with ongoing priorities/remit, sector challenges to implementation	Sustainability/ embeddedness	RA10

Study 3: Economic evaluation. The data for the economic evaluation will be collected via the student baseline and follow-up surveys. Measures include the Child Health Utility instrument (CHU-9D) and a bespoke health economics questionnaire capturing a broad set of resource use (use of health and social services such as GP, school nurse, school counsellor). The cost of the ESAS intervention (actual cost; opportunity cost) and the comparator (i.e. standard GBV activities part of school curriculum) will be collected through several sources, including school interviews, ESAS hub, qualitative interviews, and Rape Crisis Scotland.

Measures

Outcome measures (baseline, 12 and 24 months)

Primary outcome: Our primary outcome measure is a binary measure of whether a student reports at least one episode of sexual harassment victimisation in the previous two months. This will be ascertained using a five-item measure of sexual harassment victimisation in school settings that was adapted from the AAUW Sexual Harassment Survey (items 1-5) [49] and De Gue et al 2021 (items 1-4) (for their school-based cluster RCT of the “Effects of *Dating Matters*® on Sexual Violence and Sexual Harassment Outcomes among Middle School Youth” [43]. Refinements to wording were made during our within-trial pilot in one school. The five items are: (1) receiving unwelcome sexual comments, jokes, or gestures, (2) being called gay, lesbian or trans in a negative way, (3) being touched, grabbed or pinched in an unwelcome sexual way, (4) being shown sexual pictures that they did not want to see, and (5) being blocked or cornered in a sexual way. De Gue et al [43] included a sixth item from a separate measure to capture online sexual harassment (i.e. being asked to do something sexual online when they did not want to). We will not include this item in our primary outcome because our intervention focuses specifically on sexual harassment in school or on the way to school, but we will retain in questionnaire as a potential measure of displacement effects. De Gue et al [43] found that the internal consistency of those six items when using a four-month reporting timeframe was between .64 and .74, and 47% of students reported at least one instance of sexual harassment victimisation. In our 2019 pilot (618 students across three schools) in which we asked about these five experiences of sexual harassment victimisation using a three-month reporting timeframe, we found similar evidence regarding their reliability (Cronbach’s $\alpha = .72$) and that 44% of students reported at least one instance of sexual harassment victimisation in school during the previous three months. Evidencing the validity of this five-item measure, we found that it was significantly associated in the expected directions with gender stereotypes, school attitudes, and self-efficacy to make school safer.

Because we are interested specifically in sexual harassment that takes place in school or on the way to school, we will reduce the reporting timeframe to two months to maximise the chance that the reporting period will only cover term time (i.e. if students were asked in October about school-based sexual harassment in the past three months, their responses would be biased given that part of the reporting period would have taken place during summer holidays). To account for this reduction in the reporting timeframe, we reduced our expected baseline prevalence of sexual harassment from 44% to 35% (which is reflected in our sample size calculation). In our 2023 pilot (98 students in one school), 37% of students reported at least one instance of sexual harassment victimisation in school or on the way to or from school during the previous two months.

Secondary outcomes:

Students' sexual harassment perpetration will be measured using three items that assess engagement in unwelcome behaviours at or on the way to or from school in the last two months. The four-month prevalence of perpetrating sexual harassment reported in DeGue et al [43] was 29% (Cronbach's $\alpha = .73-.83$ across waves); the three-month estimate from our pilot data was 27% (Cronbach's $\alpha = .62$) (adapted from DeGue et al [43]).

Student's experience of forced sexual activity will be measured via single item: Forced you to do something sexual (at school or the way to/from school in the last 2 months) [43].

Students' attitudes toward teen dating violence will be measured using two items (adapted from Meikskin et al [50]).

Students' quality of life will be measured using the CHU-9 [51].

Students' mental wellbeing will be measured using the 7-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) [52].

Students' use of health and social services. Questions on external health appointments and in-school health professional support (number of appointments of each service type in last 3 months).

Intermediate outcomes

Students' perceptions of feeling safe at school will be measured using two items that assess fear of sexual harassment or feeling unsafe at or on the way to or from school (adapted from Fisher et al [53]).

Confidence to report problematic behaviours in school will be measured using three items that assess students' confidence in reporting three types of sexual harassment. Original items that were piloted.

Students' endorsement of gender stereotypes will be measured using three items (adapted from Meiksin et al, Rebecca et al, Flood and Kendrick [50], [54], [55]).

Students' endorsement of gender equal attitudes will be measured using three items (adapted from Meiksin et al, Flood and Kendrick, Boxley et al [50], [55], [56]).

Student's self-efficacy to make the school safer will be measured using three items that assess students' perceived ability to help make their school a safer place. Original items that were piloted.

Student's perceptions of staff and student response to sexual harassment at school will be measured using five items; three of these items are based on a vignette describing a hypothetical incident of sexual harassment involved fictional students at their school. Original items that were piloted.

Student's attitudes toward sexual harassment and GBV will be measured using 3 items. Two original items that were piloted and an item adapted from another study [57].

Student's perceived ease of talking about GBV in school will be measured using 2 items. Original items that were piloted.

Student's perceived scope of sexual harassment as a problem at school will be measured using 3 items that assess whether students think three types of sexual harassment are an everyday part of life in their school. Original items that were piloted.

Students' perceptions of general school climate will be measured using 6 items that assess students' thoughts on belongingness, participation, and commitment in their school. These are adapted from Sawyer et al [57].

Students' perceived quality of teacher-student relationships will be measured using 5 items; 3 of which adapted from Sawyer et al [57]. The other two are original items that were piloted.

Process Measures

Process measures will be collected in all schools, with greater detail in immediate start schools, and most detail coming from case-study schools.

Context: Context of schools in both arms of the trial, such as culture of student participation in decision-making, school-level student belonging, school leadership and organisational capacity, and other initiatives and priorities within schools.

Fidelity: Whether and how what is delivered in practice adheres to the ESAS guidance for schools (*adherence*), including quality of delivery of the five intervention components (*quality*), and variations between and within schools, and if/how any local adaptations are either consistent with or undermine the programme theory.

Dose and reach: The quantity of intervention implemented in schools (*dose*), and extent to which members of the school community (management and staff, students, parents/carers) demonstrate awareness of, and engagement with, ESAS (*reach*), including variations within and between groups.

Acceptability and actor response: How systems actors within schools (students, senior leadership, school staff, parents/carers) respond to ESAS, perceive its acceptability; and how well it meets their needs; and variations between and within schools.

Usual practice and contamination: Any GBV-relevant school events, activities or policies that occur in delayed start schools before implementing ESAS. Any relevant contact between schools in different trial arms in year 1 (e.g. “good practice” sharing between immediate start and delayed start schools).

Mechanisms of action: How intervention mechanisms interact dynamically with context (e.g. school culture). Evaluative focus will be placed on assessing mechanisms hypothesised in the programme theory (e.g. collective involvement by staff/students), alongside attention to identifying any unanticipated mechanisms. Informed by a complex systems perspective [36] we will examine whether and how ESAS becomes embedded within school systems, including conditions of *sustainable* change. We will explore how ESAS and school systems adapt and co-evolve over time, including if/how ESAS enables schools to leverage other assets and resources (e.g. schools’ participation in other GBV-relevant initiatives, such as MVP).

3.4.1 Recruitment and randomisation

Summary of participants recruited to study: All students in S2 (age 13), S4 (age 15) and S6 (age 17) are eligible participants for online surveys (baseline and follow up) in all schools, and for qualitative data collection (only in 6 case study schools). All teaching staff are eligible for self-assessment surveys (part of the intervention package), and leadership and teaching staff in the 6 case study schools are eligible for qualitative data collection. Parents/carers from 6 case study schools are eligible for the parent survey.

Recruitment of schools: Informal expressions of interest currently being taken from schools via (1) Email to ~60 schools who have registered for an ESAS account but not yet logged any ESAS activities (i.e. expressed a previous interest in ESAS); (2) Advert for the ESAS study via the SHINE Network and presentations at their annual conference (Schools Health Research Network in Scotland run by colleagues at MRC/CSO SPHSU; <https://shine.sphsu.gla.ac.uk/about/>); (3) Working via Education Authority Leads (~9) who are introducing ESAS to schools in their area by emailing all schools leads, inviting particular schools with known interest, or facilitating the research team to speak about the project at one of their regular meetings with school heads. Information on the study is shared via the school’s brief. Schools email the study (sphsu-esas@glasgow.ac.uk) to express interest and the PI follows up with a phone call to run through the ESAS intervention and what taking part in the evaluation involves (including implications of randomisation for timing of starting ESAS activities). Schools are advised that they can choose to: (a) take part in the evaluation and undertake ESAS as a trial school; (b) undertake ESAS but not join the trial, or (c) do neither. If they express interest in the trial, they are advised that formal recruitment into the trial will take place from July 2023, once ethical approval has been secured. Formal recruitment is indicated by completion of baseline survey.

After recruitment to trial and completion of baseline student survey (Oct 23-Dec 24), schools will be randomised (1:1) using minimisation to ensure balance between arms in: (i) proportion of students receiving free school meals (FSM), (ii) school size and (iii) whether they are currently undertaking the Mentors in Violence Prevention (MVP) peer mentoring programme. Schools will be randomised either to start the ESAS intervention immediately in addition to usual practice (n=18), or to continue usual practice and start ESAS after 12 months (n=18; delayed start; control condition). The randomisation will be performed using centralised computer-generated randomisation sequence (Sealed Envelope™) by trial statistician (AP).

All immediate start schools will be informed of the opportunity to be one of the six case study schools. Schools will be eligible to be case study schools if they have completed at least one of the five components of ESAS. Among schools willing to be case studies, we will purposively select for variation in size of pupil body, %FSM/socio-economic catchment area, rural/urban setting, MVP status.

Consent to participate: Schools. The school leadership team consents to participation in trial on behalf of school. Leads of immediate start schools consent to being a case-study school on behalf of their school. Consent is implied via signing of the Collaboration Agreement between School and Trial. Schools will be given £500 to compensate for disruption of fieldwork (plus additional £1k for case study schools). Parents and key staff taking part in surveys will have option to be entered into a prize draw for a £50 voucher (2 vouchers available at each school for the parents' survey; 8 for key staff survey across all participating schools). In interviews, participants will be provided with refreshments but not monetary incentives since interviews will take place during school time and/or as part of official/professional role.

Recruitment and consent to participate: Individuals.
(Numbers (RA1 etc.) refer to ref# in table 2).

Surveys

Student surveys (Research Activity RA1): Within all trial schools, all students in S2 (age 13), S4 (age 15) and S6 (age 17), invited to participate in a web-based questionnaire during class time. At least one 'mop up' survey administration for students absent on day of initial survey. Survey introduced to students via usual school communication channels; information letter and opt-out consent form sent home for parents/carers. *Obtaining consent:* Students and their parents/carer will be sent an information letter/privacy notice prior to the in-person survey administration. Parents/carers will be given the opportunity to opt-out their child by return of slip. If a student states that either their parents are unwilling but have not returned the opt-out form, or that they themselves do not wish to be involved, then they will be free to withdraw. Prior to completion of online survey, students read information about the survey (purpose, content, use of data), and are reminded of option to skip questions/withdraw (survey consent screen). Students indicate consent via tick box on the online survey platform.

Key/leadership staff surveys (RA2,3): For RA2, participants are school staff recruited according to role in school (e.g. responsibility for guidance, child protection) or role in relation to ESAS intervention (e.g. supporting Action group). The ESAS lead teacher identifies participants in conjunction with research team. First email invite sent by the ESAS lead teacher, then follow-up email invite sent by research team from study account (sphsu-esas@glasgow.ac.uk). For RA3, survey completed by school leadership as part of their role. *Informed consent to participate:* Information about online survey first sent via recruitment email. On consent screen prior to survey, staff participants are given information about the survey (purpose, content, use of data), reminded that participation is optional, reminded of

option to skip questions/withdraw. Participants indicate consent via tick box prior to completing survey.

Parent survey in Case Study schools (RA6). All parents in CASE STUDY schools eligible to take part. Survey link sent by school leadership to parents by email or other usual communication channels. Up to 2 reminder emails and/or mention of survey in regular school newsletter/communications. *Informed consent to participate:* Information about online survey first sent via recruitment email. On consent screen prior to survey, participants are given information about the survey (purpose, content, use of data), reminded that participation is optional, reminded of option to skip questions/withdraw. Participants indicate consent via tick box prior to completing survey.

Semi-structured interviews (single, paired, group)

Student paired/group interviews in case study schools (RA4; RA7): One group will be recruited from the ESAS Action Group, or another existing student-led group interested in gender-related topics (e.g. LGBT+ pupil council). Three further groups of students will be recruited from a spread of year groups (e.g. S2, S4 and S6) and will be single gender friendship groups (with any trans or non-binary students who wish to take part being able to choose which group they feel most comfortable participating in). Teachers will be asked to nominate friendship groups of students, with the research team explicitly requesting that teachers consider inclusion of students from a diverse range of backgrounds and circumstances, and that students should not be nominated on the basis of high academic performance or conformity to school rules. *Informed consent to participate:* Students and their parents/carers sent information letter/privacy notice prior to group discussion taking place, and with sufficient time to make informed decision. Parents/carers will be required to sign opt-in consent. Prior to the start of the interview, researchers will explain the purpose of the study (and how data stored/used), the voluntary nature of participation, and the option to withdraw at any time with no negative consequence. Researchers will seek permission to digitally record the interviews. Indication of informed consent via signed consent form prior to start of interview (by hand as in-person interview). The research team will emphasise to students that they are under no obligation to take part in the research interviews, and there are no negative consequences of withdrawal from interview. Participants will have up to 2 weeks to contact the research team if they wish to redact any of their data or remove altogether.

Staff paired/group interviews (RA5; RA7; RA8): Potential participants will be identified in discussion with the ESAS lead teacher and selected according to their involvement in implementing ESAS and/or experience handling GBV reporting (e.g. senior teacher, staff responsible for delivering ESAS, child protection officer/pastoral care teacher, campus cop, counsellor). Research team will send email invite to ESAS lead teacher who will then forward email on to identified staff; ESAS lead teacher will also introduce interviews informally in meetings, based on wording in email invite. Interested staff can contact project email or the ESAS lead teacher to register interest in taking part.

Rape Crisis Scotland local co-ordinators/Local Authority staff (RA9; RA10): Potential participants invited based on role (RCS local staff involved in providing training, supporting schools; LA staff involved in recruiting schools). Invitation will be sent via email from study email address.

Informed consent to participate (Staff paired/group interviews (RA5; RA7; RA8) AND Rape Crisis Scotland local co-ordinators/Local Authority staff (RA9; RA10)): Information sheet/privacy notice sent to participants prior to group interviews taking place and with sufficient time to make informed decision. Prior to the start of the interview, researchers will explain the purpose of the study (and how data stored/used), the voluntary nature of

participation, and the option to withdraw from the interview with no negative consequence. Researchers will seek permission to digitally record the interviews. Indication of informed consent via signed consent form prior to start of interview (by hand for in-person interview or electronic signature and return via email for online interviews). Participants will have up to 2 weeks to contact the research team if they wish to redact any of their data or remove altogether.

Observations

Structured observations of ESAS activities (RA11): Potential participants are students and staff taking part in ESAS activities (e.g. Action group meetings; assemblies; enhanced staff training). *Informed consent to participate:* It is not practical to obtain individual consent for observations. Where possible, those attending the activity will be informed in advance that a researcher will be present and making fieldnotes. These notes will focus on context and group dynamics and will not contain any comments that could identify any individuals.

3.5 Data Analysis

Study 1: Cluster randomised trial:

Primary analysis: Analysis of primary and secondary outcomes at 12-months follow up will be conducted on an intention to treat (ITT) basis comparing schools according to randomised allocation, without imputation for missing data. The primary analysis for all outcomes will be a model adjusted for school-level baseline prevalence and minimisation variables (school size, percentage receiving free school meals, MVP status). Sensitivity analysis for all outcomes will compare cluster-level models with individual-level models with school included as a random effect. The cluster level models may be more robust for dichotomous outcomes. Further sub-group and exploratory analysis may be conducted based on emergent data/findings from the process evaluation.

Subgroup analysis: Exploratory analyses will be undertaken to assess if ESAS has differential effects on 12-month primary and secondary outcomes by adding interaction terms for pre-specified (i) school-level variables (including school size, percentage free school meals, undertaken MVP) and (ii) student-level (e.g., age/gender/SES) variables. We will explore effects by measures of intervention dose/implementation. Data analysis will be conducted and reported in accord with SPIRIT and CONSORT extensions for cluster RCTs. ICCs for all outcomes will be reported by trial arm. Analyses will be performed by a statistician blinded to group allocation and performed using STATA. A detailed statistical analysis plan will be prepared prior to analysis and agreed with independent Trial Steering/Data Monitoring committee.

Key sources of missing data within the trial include: (1) School level data due to a school withdrawing participation from the study, (2) Missingness of specific pupil responses to questions in each survey round and (3) Missingness of self-generated pupil IDs for the longitudinal follow-up at 24-months. Suitable approach methods for handling each of these sources of missingness will be developed and finalised prior to data analysis. Sensitivity analyses will be conducted to assess the potential effect of these sources of missing data on our primary analysis at 12-months follow up using an appropriate imputation method.

Study 2A: Longitudinal follow-up

Further analyses will be conducted including the 24-month follow-up data. Three proposed analytical approaches are described below. These will support mediation analyses relevant for study 2B.

1. Additional analysis of effectiveness: The primary analysis of intervention effectiveness will be based on the initial 12-month cluster randomised trial. The inclusion of 24-month

follow-up data and the Year 2 implementation of ESAS in delayed start schools, enables an additional set of analyses based on treating the study design as a two-step stepped wedge. These analyses will have marginally more power than the primary trial analyses but have increased risk of bias and are hence useful as sensitivity analyses. Under varying assumptions relating to secular trends and duration of intervention effects, models applied to data from all three time points will be used to estimate intervention effectiveness, using before and after data from both immediate and delayed start schools in a stepped wedge analysis [58].

2. Analysis of embedded cohort: The repeat cross-sections at baseline and 24 months will be among the same cohorts (S2 and S4 at baseline; S4 and S6 at 24-month follow-up). To enable within-student longitudinal analysis, students will be asked to self-generate an ID code based on stable personal characteristics; this will generate an embedded cohort with linked individual-level data, while allowing students to remain anonymous [59]. These analyses will assess whether 24-month outcomes are related to dose/duration of intervention exposure and to identify whether 24-month outcomes vary across subgroups defined by baseline characteristics (e.g. exposure to harassment).
3. Within immediate start schools, change in primary and secondary outcomes over the 12-24 month period will be calculated for each of the 18 schools to assess whether 12-month outcomes have attenuated, sustained, or amplified and whether this varies significantly across schools. Exploratory analyses guided by emerging findings from the process evaluation will assess how this variation may relate to implementation (e.g. fidelity, reach, acceptability), as well as identified barriers and facilitators.

Study 2B: Process evaluation

Informed by frameworks for process evaluation grounded in a complex systems perspective [38], [39], [41], [42], the evaluation itself will be dynamic, with analytic insights generated through earlier evaluation activities used to inform and define evaluation questions for focus at later stages. Analysis will seek to generate insights into mechanisms of action-including what works, for whom and in what circumstances [60], [61] - in order to interrogate and refine the theoretical basis for ESAS. Qualitative data will be managed using NVivo software and analysed thematically, combining inductive (i.e. open, in vivo) and deductive coding (i.e. pre-specified codes based on research questions and intervention theory). A priori codes will reflect the intervention components (e.g. school self-assessment, staff training, action group), aspects of implementation (context, fidelity, dose/reach, acceptability/actor response), anticipated mechanisms (beneficial and harmful). Codes will be developed iteratively as analysis progresses.

Drawing on a complex systems perspective, an overarching analytic goal for the process evaluation will be to synthesise evidence to build a “system change narrative” [39], explaining if and how the ESAS intervention disrupts school systems over time [36]. Qualitative data from observations, discussions and workshops with staff and students will be used to describe and visualise (e.g. using mapping software such as Kumu) indications of change within school systems (e.g. to norms, relationships, processes) to refine hypotheses regarding longer-term systems change and contextualise results from Study 2A. Analysis will seek to describe how school systems and the ESAS intervention adapt and co-evolve over time; identify factors that either amplify or dampen change, and unanticipated consequences. We will look for a range of different examples within the data of meaningful progress and actions, including local adaptations which indicate that schools have taken ownership of GBV prevention and response and are applying the principles of ESAS in context-specific ways, while remaining consistent with the programme theory. Ultimately analytic insights from the process evaluation will be used to refine and visualise the programme theory.

Study 3: Economic evaluation

Given the known societal costs, health harms and quality of life impacts associated with GBV, an economic evaluation is integral to this research. However, currently there are no economic evaluations of GBV interventions conducted in schools.

The economic evaluation conducted alongside the ESAS trial investigates whether the ESAS intervention is cost-effective compared to the control. It will follow standard guidance for complex population health economic evaluation [62], [63], [64], taking the complexity of the ESAS intervention into account in the design and conduct stage, using multiple economic evaluation framework and multiple perspectives (NHS and Personal Social Services (PSS), educational and societal perspective).

The economic evaluation alongside the ESAS RCT (study 1) will include a within-trial analysis, exploring the cost-effectiveness of the ESAS intervention vs the comparator using a 12-month time horizon, and, pending findings from studies 1 and 2, a long-term model projecting likely changes in GBV episodes into long term intersectoral costs and outcomes. An additional analysis will also use the data collected at 24 months, in line with the planned statistical analysis.

The within-trial analysis will assess cost-effectiveness of ESAS vs control using multiple evaluation frameworks:

- 1) a cost-utility analysis (CUA) evaluating the cost-effectiveness of ESAS compared to the control in terms of additional cost per QALY (quality-adjusted life years), estimated using CHU9D [51]; validated age-appropriate measure validated for use with adolescents.
- 2) a cost-effectiveness analysis (CEA) calculating the incremental cost per reduction in sexual harassment (primary outcome [43]).
- 3) a cost-consequence analysis (CCA), collating costs and outcomes (within trial QALYs, sexual harassment, coercion and violence; mental wellbeing etc.) in a summary table, as recommended by the NICE public health economic evaluation guidance [62] and recent methods publications [38], [64].

The baseline and all follow up surveys will include the preference-based quality of life instrument, the CHU-9D. They will also include a bespoke resource use questionnaire designed to measure cross-sectoral health and social care use (e.g. GP and educational psychologist), community services (e.g. judicial contacts) and personal health-related activities and costs (e.g. Private counsellors). Resources required to deliver ESAS (including displaced school activities and their associated opportunity cost) will be measured via resource use logs completed by researchers and informed by school leads. All resources measured will be valued using readily available unit costs [65].

In line with the statistical analysis plan (SAP), we will follow the approach described by Hooper, et al. [66], adapted to account for non-normality of health economics outcomes and costs.

We will estimate the incremental difference in total cost and outcomes, using a mixed effect generalised linear (MGLM) model, adjusted for school-level baseline characteristics such as school size, percentage free school meals, MVP status (i.e. school partaking in MVP activities). Total cost and outcomes will be also adjusted by baseline costs and outcomes to adjust for any imbalance between treatment arms [67]. Time and treatment arm will be included as fixed effect, while schools will be included as random effect to account for clustering. Mean cost and outcomes by treatment arm, as well as incremental cost and outcomes and incremental cost-effectiveness ratio (ICER) will be predicted from the chosen econometric model and reported alongside bootstrapped standard errors. The uncertainty surrounding the estimate of incremental costs, QALYs, and ICERs will be investigated by use of a nonparametric bootstrap of the cost and effect pairs for 1,000 iterations. This uncertainty will then be presented on the cost-effectiveness plane with a 95% confidence interval of the bootstrapped ICER estimated. Results will be summarised using a cost-effectiveness acceptability curve (CEAC) to reflect the probability of ESAS being cost-effective at various willingness-to-pay thresholds. The £20,000 to £30,000/QALY threshold that NICE typically considers cost-effective will be incorporated.

Within the CEA framework, there is no accepted threshold value for changes in the primary outcome. Therefore, sensitivity analysis using different willingness to pay (WTP) values will

be performed. In addition to probabilistic sensitivity analysis, several scenarios will be explored in the deterministic sensitivity analysis.

In line with the statistical analysis plan, we will explore three approaches for the analysis of the 24 months follow-up data:

1. Stepped-wedge analysis: we will follow best practices and recommendations described by Lung, et al. [68] (e.g. accounting for clustering, correlation between costs and outcomes, time adjustment) to conduct an analysis of costs and outcomes alongside the ESAS two-stepped wedge design.
2. Analysis of embedded cohort: within the longitudinal study, we will conduct a secondary analysis to explore determinants of QALYs, outcomes and costs, calculated over 24 months.
3. Within intervention (immediate start) school analysis: we will assess whether outcomes and costs have sustained over time.

To support interpretation of the health economic data and acknowledging that key economic impacts are likely to be long term, we will also build an economic conceptual model [69] with the aim of depicting the complex causal linkage between the intervention and its associated intersectoral societal costs and outcomes over the short and long term.

Depending on the trial results, this conceptual model may inform a long-term economic model, extrapolating the 12 months effectiveness of the ESAS intervention over the long term and considering the wide spectrum of cross-sectoral impacts and costs to society of the ESAS intervention over the lifetime [20] (e.g. risk behaviours such as substance use; long-term emotional, behavioural and mental health; academic performance, employability, and teenage delinquency and crime).

The long-term model will use 24 months outcome data to predict the likely long-term cost-effectiveness of the intervention effect beyond 12 months and will be further supported by evidence from a systematic literature review.

4. Research Governance and Regulatory Issues

4.1 Ethical issues

Research Ethics Committee: *MVLS (Medical, Veterinary & Life Sciences) Ethics Committee*

Research Ethics Committee Reference: **200220268**

With regard to individual participation, this study conceptualises consent as an ongoing, freely given, informed and active agreement to take part [70]. Participants will be reassured that non-participation or withdrawal will have no detrimental effect on their current or future experience at the school. This will be particularly emphasised to students recruited via school staff. The voluntary nature of participation, and right to withdraw will be emphasised throughout the study. Informed consent for observation of intervention activities is not practical, but the presence of the observer will be explained where possible, and reassurance given regarding the anonymity of data generated by observations.

The research team will preserve the confidentiality of participants in accordance with the 1998 Data Protection Act and 2018 General Data Protection Regulation. We will adopt rigorous procedures to protect data confidentiality (see below).

Child Protection/Safeguarding in the ESAS Intervention and Evaluation.

GBV is a sensitive topic and may trigger difficult feelings for participants. To safeguard participant wellbeing, we will adhere to the following:

- In qualitative research, discussion topics made clear to participants so they can make informed decisions about participation.
- List of support services will be provided along with the participant information sheet and signposted at end of interview.
- If participants become upset during the discussion, the researchers will ask them if they would like to take a break or stop.
- Research team will draw on extensive experience of quantitative and qualitative research on sexuality with young people and adults, in expressing empathy and communicating in non-judgmental ways.

Reporting procedures in case of disclosures: Serious Adverse Events (SAE) in this study could include incidents of sexual harassment and violence; and mental/physical ill health resulting from such incidents. These occur in schools regardless of ESAS and are highly unlikely to result from it. However, disclosures of already-occurring GBV may increase due to greater awareness and confidence to report (an aim of ESAS). Any disclosure made to the survey (open comment box at end) cannot be followed up because the survey is anonymous. Upon completion of the survey respondents are encouraged to approach a trusted adult if they need support and directed to services. We will also give participants the option to write their name (via a separate link) if they wish us to connect them to a member of staff. In this instance, safeguarding procedures apply, regardless of where the harm took place. In group interviews, we will discourage recounting of real-life incidents, but these may surface inadvertently. We will have information on sources of support to signpost to students as appropriate and we will advise young people that they can talk to a member of the research team privately about any concerns. If disclosures are made which give reasonable grounds to suspect risk of harm from physical, emotional, or sexual abuse or exploitation, the researcher will tell the student that they (researcher) need to notify the child protection lead for the school (via the study Principal Investigators). The researcher will be empathic and will seek agreement to notification from the student as far as possible. Any disclosures to the research team will be reported to the school safeguarding officer and will be handled via usual school safeguarding procedures. These are confidential within schools and the study will not usually be made aware of the outcome.

Although harassment/bullying between staff or by students to staff may be an issue, it is not a focus of this intervention. However, if disclosure is made, the ESAS Coordinator will discuss options, help the individual decide on the best option and link them into emotional support. Violence occurring within student and staff homes and families is also outside the scope of this intervention. However, if students or staff disclose any information in this regard, safeguarding and reporting measures will apply.

Where SAEs become known to the study team (either directly or indirectly), these will be reported internally and to the TSC chair (and sponsor, University of Glasgow, as appropriate) within 24 hours of the study team becoming aware of an event. Population Health Research Facility (PHRF) is part of UoG Clinical Trials Unit (CTU) and has standard operating procedures for managing and reporting any serious adverse events, following guidelines for Good Clinical Practice.

4.2 Data Monitoring/Quality Assurance

The principal investigator (KM) has overall responsibility for the study and its data management.

Quality Assurance for qualitative research:

- make field notes about the conduct and contents of the interview.
- confirm that participants satisfy the study's inclusion criteria and are therefore eligible to take part in the study.
- follow the ethically approved procedure for confirming and recording informed consent.
- allocate pseudonyms and study identification numbers.
- access and use suitable audio recording equipment.
- check the quality of audio files after interviews conducted prior to sending these to transcribers.
- ensure that transcribing is done by an approved professional transcribing service.
- check the accuracy of a random 5-minute excerpt of each recording's transcription; and
- work with colleagues to set up secure password protected data storage.

Quality assurance for monitoring and analysing quantitative data:

- Cognitive Interviewing for new survey measures.
- Create codebook for analysis.
- Consistency checks and data cleaning.
- Pre-specified analytical plan.

4.3 Data Management

The Project Data Management Plan is stored under the name Whole-school approach to addressing Gender-Based violence in secondary school (Equally Safe at School): A pragmatic cluster-randomised trial and mixed-methods evaluation at <https://dmponline.dcc.ac.uk/>

University of Glasgow is the data controller. The transcription service is a data processor.

Format and type of data:

SPSS/CSV/Excel –de-identified survey data

Excel –contact information from schools, LAs, Rape Crisis Scotland coordinators (name, role, phone number and email address; Data of key leadership/ management staff and parents/carers who opt-in to taking part in a prize draw (name, email address); interview participants information (name, school).

MP3 files – audio recordings

Word – transcripts; observation log; school policy analysis framework; fieldnotes from qualitative interviews; field notes from student survey data collection; signed consent forms.

Access to data

During the lifetime of the project only named members of the research team will have access to the data. The only exception is the interview audio recordings which will be transferred to a professional transcription company via their own secure online website, and in accordance with SPHSU's written agreement with the agency about procedures for secure and confidential data transfer. This company follows the Data Protection Act, registered number Z2116676 and have also signed the Code of Practice on Data Handling.

Data transfer

Transfer of school-administered staff survey data (RA12) and school dashboard information (RA14) from RCS will be via SPHSU secure cloud with encryption using 7 zip and password protection. Use of this data is governed by a separate data sharing agreement.

Data protection and confidentiality

All procedures for data storage, processing and management will comply with the 2018 GDPR and will follow UK data service recommendations for recording and management of data (<http://ukdataservice.ac.uk>). Data will be stored on secure systems (password protected computers) and data access will be restricted to the named research team. SPHSU (UoG) has Cyber Essentials Plus certification and works to ISO 27001, 27002 for information technology security, though it does not have formal certification. The Unit does an annual internal audit of IT security processes. In particular: access to the building is restricted by electronic keys, all network servers are protected with strong passwords and a firewall, screens are locked after 5 minutes of inactivity, workstations and portable devices are encrypted, we have our own cloud computing for secure transfer of data. All members of the Unit have signed a confidentiality agreement and have undergone training in data protection. Staff involved in research have done Good Clinical Practice Training. We will adhere to specific policies applying to the data as described in the GUI-DM-001_Guidance on the Management of Research Data and associated standard operating procedures and we will abide by the University of Glasgow data protection policy.

Qualitative data: Qualitative interviews will be recorded using a portable digital recorder and the sound file saved in mp3 format. Sound files will be deleted from the recorder after uploading. Each sound file will be named with an anonymised identifier and transcribed into a Word document with corresponding name. Both sound files and word documents will be stored in a restricted access folder on password protected computers. Transcripts will be pseudonymised – names and specific address references removed – and imported as sources into NVivo. We will establish a metadata file for easy retrieval of qualitative data.

Identification of individual study members is the main security risk, but we will take steps to reduce this risk including removal of any identifying information; particular care will be taken to avoid deductive disclosure in qualitative interviews. Where data requires transfer to collaborators will use the SPHSU own cloud with encryption using 7 zip and password protection. This includes transfer of audio files and transcripts between us and a transcribing company with which we have an agreement and whose staff have signed a confidentiality agreement.

4.4 Data Storage and Retention

All data on the SPHSU project drives (Q and T) are backed up daily in line with Unit back up procedures.

- *Electronic files containing de-identified research data*, will be stored in project folders (T: drive) with access restricted to members of the Trial team (monitored via an access log).
- *Electronic files containing non-anonymised transcripts and audio-recordings* will be stored separately in the Confidential Data folder within the T: drive. Access to folders containing non-anonymised research data will be strictly restricted to designated members of the project management group (Mitchell, Lewis, Blake, and Vaczy). Access to this folder is restricted using a Data Privacy Access Log.
- *Electronic signed consent forms, adult email addresses, and the key linking school ID with school name* will be stored in separate drive (Q: drive). No research data is stored in the Q: drive. Access to folders containing personal data will be strictly restricted to designated members of the project management group (Mitchell, Lewis, Blake, Purvis,

Hamilton, Farquhar and Vaczy). Access to the Q: drive is restricted using a Data Privacy Access Log.

- *Paper documents containing personal data* will be stored within the Population Health Research Facility (study CTU) in locked filing cabinets in an area with restricted access and separate to any research data.

Electronic research data files will be stored in secure folders on the SPSHU servers protected against unauthorised access by user authentication and a firewall until the archiving or destruction of the data. *All hardcopy materials* (e.g. paper consent forms) will be scanned and stored in digitised format on the restricted access Q: drive for a minimum of ten years after completion of the study or for as long as research data are available. Hardcopy research data will be destroyed after being digitised. *Personal contact data* will be kept until the completion of the study, and then it will be securely deleted using Fileshredder (<https://www.fileshredder.org/>) to DOD7 standards or above.

Metadata for interviews: participant codes or pseudonyms, date of interview, time/duration of interview, code of location, filename of interview schedule used, filename(s) of interview recordings obtained (audio record, field notes), confirmation that consent form has been obtained (log of consents rather than original consent forms), filename of original interview transcript, filename of anonymised interview transcript.

Metadata for surveys: codebook of survey items and final word version including routing instructions.

Archiving and sharing

Research data and consent forms will be kept for a minimum of 10 years or for as long the research data are archived, in line with University of Glasgow policy. Personal contact data will be kept until the completion of the study.

We are requesting participant consent to archive anonymised data so it can be shared with other researchers or organisations that carry out high quality work in the area of GBV. The data will be offered to the UK data archive Re-Share for archiving (all safeguarded access). If that is unsuccessful, they will be archived in the University of Glasgow Enlighten: Research Data repository. Regardless of where the data are archived, there will be an entry for the study in the University of Glasgow Enlighten: Research Data repository.

The data will be archived and available for sharing but will be embargoed until two years after the study is completed or the publication of the main study papers (whichever happens later). Until then, the study team will have exclusive use of the data. The principal investigator will endeavour to make the data available as soon as possible.

5 Project Management

5.1 Project Manager

The Principal Investigator is accountable to NIHR and provides strategic leadership of the study. The team members with responsibility for the day-to-day management of the project are: Claire Hamilton (Trial Manager) and Carolyn Blake (Research Co-ordinator).

5.2 Project Management Group

Project Executive Group (PEG): will meet weekly or fortnightly (depending on project phase), chaired by KM and attended by the trial manager, study co-ordinator, process

evaluation lead and research assistants. Other individuals will be invited to these meetings as appropriate.

The **Project Management Group** will meet monthly and consist of the **PEG**, plus Rape Crisis collaborators and all co-investigators.

Minutes of PMG meetings will be taken on the SPHSU template, and a Decision Log will be created and maintained by the Project Manager.

5.3 Advisory Group / Steering Committee

An independent TSC will meet at least annually to advise on progress, study conduct and broader policy context. The DMEC will meet annually to monitor data quality and completeness; recruitment and loss to follow up; advise on protocol modifications and data analysis plans. Membership will include experts in schools-based interventions and trials, GBV, as well as a teaching professional.

5.4 Project Filing Structure

The electronic project files will be kept on: T:\projects\Equally safe T00014. Identifiable participant data and digital consent forms will be stored on a separate drive with access restricted to the research team. Non-sensitive/confidential and 'live' documents will be stored on the ESAS Teams site. A filing guide will be stored on TEAMS for reference of all team members. The paper project files will be kept in a locked cupboard in PHRF, UofG offices.

6. Dissemination

6.1 Communication method

Academic audiences

- Analysis plans in Open Science Forum.
- Published protocol.
- >2 publications in high impact journals.
- Survey dataset deposited in UK data archive.

Policy/practitioners

- Presentation at relevant conferences.
- Email newsletter to multi-sectoral stakeholders (3x per year)
- Dissemination workshops for policy makers/practitioners.
- Summary of findings and recommendations for policy makers.

General public

- Blog pieces/writing for the Conversation.
- Updated content on research page of the ESAS website.
- Press releases for published papers.
- Twitter updates.
- Proactive engagement with existing media contacts to raise awareness.

Study participants

- Regular email updates and annual newsletter.

- Study page on ESAS website.
- Plain language summary of trial findings.
- Lesson plans to facilitate discussion of the study within Personal and Social Education classes.

6.2 Publication Policy

All publications and presentations relating to the project will be authorised by the Project Management Group. The project will aim for two open-access academic papers. Final authorship and authorship order will be decided by the PIs. A lead author and writing group will be identified, and all other PMG members will be offered opportunity to contribute. PMG members not meeting authorship criteria will be recognised where appropriate. Authorship criteria will follow [ICMJE guidelines](#). Non-academic staff will have opportunity to contribute to papers and will be acknowledged if they do not meet ICMJE authorship criteria.

6.3 Public Engagement and Knowledge Exchange

We will engage and share knowledge as follows:

Academic: Analysis plans in Open Science Forum; published protocol; >2 publications in high impact journals; published case-study of mixed-methods evaluation for teaching/training and future methods guidance; Survey dataset deposited in UK data archive; presentation at relevant conferences.

Policy/Practitioners. We will build on an environment already supportive of whole school approaches (e.g. <https://www.gov.scot/publications/developing-positive-whole-school-ethos-culture-relationships-learning-behaviour/>). Rape Crisis will lead on dissemination to local authority educational leads, Quality Improvement Officers, Education Scotland and the Scottish Government as well as GBV and other equalities agencies. Rape Crisis are strongly networked to third sector partners and schools (mainly via Rape Crisis-delivered sexual violence prevention workshops in over 100 schools annually). Opportunities to contribute to policy discussions are likely to be significant, given Scottish Government financial investment in the intervention. Policy contributions will be both proactive and responsive, primarily via focused events/meetings, working groups (e.g. government-led Harmful sexual behaviours education sub-group on which KD sits) and published summary findings. We will liaise with other GBV agencies in England and Wales to discuss adaption and transferability to other educational settings. Activities to include: email newsletter to multi-sectoral stakeholders (3x per year); dissemination workshops; summary of findings and recommendations for policy makers.

Lay Public. Dissemination to the lay public aims to raise awareness of upstream drivers of GBV and the role of schools/communities in tackling these issues. We will work with the SPHSU communications team and University of Glasgow press office. We will aim to produce blog pieces; updated content on research page of the ESAS website; press releases for published papers; social media updates; proactive engagement with existing media contacts to raise awareness.

Public, third sector: We will inform non-ESAS schools via an information event to discuss end of study findings; we will hold a wider stakeholder event to discuss findings and respond to requests to contribute to third sector meetings on whole-school approaches/policy meetings on GBV. The public-facing Equally Safe website will show the key trial results and we will signpost to this via our professional networks, UofG and RCS social media accounts.

RCS sits on a range of strategic working groups and has a strong platform for dissemination of findings.

Study participants. During the trial we will email regular study updates to school leadership teams and ESAS lead teachers. These will include a brief paragraph that they can use in their own communications with students, parents/carers, and Education Authorities. We will create and maintain a study page on the ESAS website and will direct schools and any ad hoc stakeholder enquiries here. With assistance from our youth advisory group, we will create an annual newsletter for students in schools undertaking ESAS activities (immediate start in year one; all schools in year two). At the end of the trial, we will produce a plain language summary of trial findings within one year of study completion and disseminate to all participating schools. This will be accompanied by a set of lesson plans to facilitate discussion of the study within Personal and Social Education classes.

7. Project Milestones / Timelines

Project Milestones:

Project month	Milestone
Pre-grant	Meetings with Education Leads and schools to secure expressions of interest
July-Sept 2023	Ethical approval secured; sampling frame and randomisation strategy finalised; fieldworkers recruited and trained; TSC/YPAG/advisory group established; study measures and materials ready;
Sept 2023-December 2024	Baseline surveys complete; Schools randomised; 18 immediate start schools receive survey feedback and begin ESAS activities.
June 2024-Jun 2025	Study 2B in-depth process evaluation conducted in 6 case study schools; analysis of school-collected staff survey data in intervention schools;
June 2024-Feb 2025	Key staff survey conducted; Collation of 'dashboard' intervention data collected by schools;
Oct 2024–December 2025	Follow-up survey in all schools (primary outcomes); Waitlist schools begin ESAS intervention (after follow-up survey); Intervention schools continue with ESAS activities
Aug 2025 – Jun 2026	Study 2b in-depth case-studies conducted (6 schools); collation of school-collected dashboard information; Analysis of school-collected staff survey data in waitlist schools; Analysis of follow-up survey data.
Oct 2025–Mar 2026	Longitudinal follow-up survey conducted in all schools (study 2A); Qualitative analysis of case study schools (study 2B)
March-Sept 2026	Analysis of survey data; write up of study findings and dissemination.

Stop Criteria

If the following targets are **not** met, the TMG and TSC should discuss whether to continue the trial:

- 20 schools express interest in signing up to trial by July 2023 (start of trial).
- 30 schools recruited and have undertaken baseline data collection by March 2024.

- <5 schools drop out in February 2025.
- >10 immediate start schools complete staff training and set up an Action Group by 12 months post baseline.

Timetable for school involvement in study:

IMMEDIATE START SCHOOLS:

Month	Action
Month 0:	Baseline student survey and randomisation
Month 1:	All staff survey (administered by schools; data shared with study team)
Month 12:	Online survey of key leadership/management staff
Month 9-24:	CASE STUDY SCHOOLS ONLY: structured observations, staff and student paired/group interviews, parent survey.
Month 12:	Schools give study access to intervention dashboard
Month 13:	Follow-up student survey
Month 23-32:	CASE STUDY schools: Workshops.
Month 21-24:	Interviews with ESAS lead staff in less engaged schools
Month 24:	Online survey of key leadership/management staff
Month 24:	School gives study access to intervention dashboard
Month 25:	Longitudinal follow-up survey

DELAYED START SCHOOLS:

Month	Action
Month 0:	Baseline student survey and randomisation
Month 11:	Online survey for school ESAS leads
Month 12:	Schools give study access to intervention dashboard (to check no activity)
Month 12:	Follow-up student survey
Month 13:	All staff survey (administered by schools; data shared with study team)
Month 24:	School gives study access to intervention dashboard
Month 24:	Online survey of key leadership/ management staff
Month 24:	Longitudinal follow-up survey

8. Project Risk Assessment

The risks relevant to the project are recorded in the risk assessment form and contained in the initial Project Risk/Issue log within the Trial Master file.

The Risk Log will be reviewed and updated at Project Management Group meetings.

9. References

- [1] F. Leach and S. Humphreys, 'Gender violence in schools: taking the "girls-as-victims" discourse forward', *Gend. Dev.*, vol. 15, no. 1, pp. 51–65, Mar. 2007, doi: 10.1080/13552070601179003.
- [2] J. Lang, 'Keynote address', presented at the The International Conference on Eradicating Violence Against Women and Girls – Strengthening Human Rights, Berlin, 2002.
- [3] Girlguiding, 'Research briefing: It happens all the time. Girls' and young women's experiences of sexual harassment', London, 2021. [Online]. Available: https://www.girlguiding.org.uk/globalassets/docs-and-resources/research-and-campaigns/girlguiding-research-briefing_girls-experiences-of-sexual-harassment_june2021.pdf
- [4] 'Ofsted review of sexual abuse: terms of reference', GOV.UK. Accessed: May 28, 2024. [Online]. Available: <https://www.gov.uk/government/publications/ofsted-review-of-sexual-abuse>
- [5] H. Sweeting, C. Blake, J. Riddell, S. Barrett, and K. R. Mitchell, 'Sexual harassment in secondary school: Prevalence and ambiguities. A mixed methods study in Scottish schools', *PLOS ONE*, vol. 17, no. 2, p. e0262248, Feb. 2022, doi: 10.1371/journal.pone.0262248.

- [6] A. L. Norris and L. M. Orchowski, 'Peer victimization of sexual minority and transgender youth: A cross-sectional study of high school students.', *Psychol. Violence*, vol. 10, no. 2, pp. 201–211, Mar. 2020, doi: 10.1037/vio0000260.
- [7] A. S. Mueller, W. James, S. Abrutyn, and M. L. Levin, 'Suicide Ideation and Bullying Among US Adolescents: Examining the Intersections of Sexual Orientation, Gender, and Race/Ethnicity', *Am. J. Public Health*, vol. 105, no. 5, pp. 980–985, May 2015, doi: 10.2105/AJPH.2014.302391.
- [8] Scottish Government, 'Equally safe: Scotland's strategy for preventing and eradicating violence against women and girls', 2014. [Online]. Available: <http://www.gov.scot/Publications/2014/06/7483/9>
- [9] R. Jewkes, M. Flood, and J. Lang, 'From work with men and boys to changes of social norms and reduction of inequities in gender relations: a conceptual shift in prevention of violence against women and girls', *Lancet*, vol. 385, no. 9977, pp. 1580–1589, 2014, doi: [https://doi.org/10.1016/S0140-6736\(14\)61683-4](https://doi.org/10.1016/S0140-6736(14)61683-4).
- [10] H. L. M. Reyes, V. A. Foshee, P. H. Niolon, D. E. Reidy, and J. E. Hall, 'Gender Role Attitudes and Male Adolescent Dating Violence Perpetration: Normative Beliefs as Moderators', *J. Youth Adolesc.*, vol. 45, no. 2, pp. 350–360, Feb. 2016, doi: 10.1007/s10964-015-0278-0.
- [11] D. L. Espelage, J. S. Hong, G. J. Merrin, J. P. Davis, C. A. Rose, and T. D. Little, 'A longitudinal examination of homophobic name-calling in middle school: Bullying, traditional masculinity, and sexual harassment as predictors.', *Psychol. Violence*, vol. 8, no. 1, pp. 57–66, Jan. 2018, doi: 10.1037/vio0000083.
- [12] E. R. Clear *et al.*, 'Sexual Harassment Victimization and Perpetration Among High School Students', *Violence Women*, vol. 20, no. 10, pp. 1203–1219, Oct. 2014, doi: 10.1177/1077801214551287.
- [13] S. Fineran and R. M. Bolen, 'Risk Factors for Peer Sexual Harassment in Schools', *J. Interpers. Violence*, vol. 21, no. 9, pp. 1169–1190, Sep. 2006, doi: 10.1177/0886260506290422.
- [14] K. J. Mitchell, M. L. Ybarra, and J. D. Korchmaros, 'Sexual harassment among adolescents of different sexual orientations and gender identities', *Child Abuse Negl.*, vol. 38, no. 2, pp. 280–295, Feb. 2014, doi: 10.1016/j.chiabu.2013.09.008.
- [15] S. Rinehart, D. L. Espelage, and K. Bub, 'Longitudinal effects of gendered harassment perpetration and victimization on mental health outcomes in adolescence', *J. Interpers. Violence*, vol. 35, no. 23–34, pp. 5997–6016, 2020, doi: <https://doi.org/10.1177/0886260517723746>.
- [16] S. E. Moore, R. E. Norman, S. Suetani, H. J. Thomas, P. D. Sly, and J. G. Scott, 'Consequences of bullying victimization in childhood and adolescence: A systematic review and meta-analysis', *World J. Psychiatry*, vol. 7, no. 1, p. 60, 2017, doi: 10.5498/wjp.v7.i1.60.
- [17] J. E. Gruber and S. Fineran, 'Comparing the Impact of Bullying and Sexual Harassment Victimization on the Mental and Physical Health of Adolescents', *Sex Roles J. Res.*, vol. 59, no. July 2008, pp. 1–13, doi: <https://doi.org/10.1007/s11199-008-9431-5>.
- [18] S. Y. Sneen, 'The current state of sex education and its perpetuation of rape culture', *Calif. West. Int. Law J.*, vol. 49, no. 2, pp. 463–490, 2019.
- [19] W. Macdowall *et al.*, 'Lifetime prevalence, associated factors, and circumstances of non-volitional sex in women and men in Britain: findings from the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3)', *The*

- Lancet*, vol. 382, no. 9907, pp. 1845–1855, Nov. 2013, doi: 10.1016/S0140-6736(13)62300-4.
- [20] European Institute for Gender Equality., *Estimating the costs of gender-based violence in the European Union*. LU: Publications Office, 2014. Accessed: Sep. 26, 2024. [Online]. Available: <https://data.europa.eu/doi/10.2839/79629>
- [21] R. Oliver, B. Alexander, S. Roe, and M. Wlasny, *The economic and social costs of domestic abuse*. Leeds: Corporate Document Services, 2019.
- [22] European Institute for Gender Equality. and ICF Consulting Services Ltd., *The costs of gender-based violence in the European Union*. LU: Publications Office, 2021. Accessed: Oct. 03, 2024. [Online]. Available: <https://data.europa.eu/doi/10.2839/063244>
- [23] L. De La Rue, J. R. Polanin, D. L. Espelage, and T. D. Pigott, 'A Meta-Analysis of School-Based Interventions Aimed to Prevent or Reduce Violence in Teen Dating Relationships', *Rev. Educ. Res.*, vol. 87, no. 1, pp. 7–34, Feb. 2017, doi: 10.3102/0034654316632061.
- [24] C. Bonell *et al.*, 'Systematic review of the effects of schools and school environment interventions on health: evidence mapping and synthesis', *Public Health Res.*, vol. 1, no. 1, pp. 1–320, Jun. 2013, doi: 10.3310/phr01010.
- [25] S. Lester, C. Lawrence, and C. L. Ward, 'What do we know about preventing school violence? A systematic review of systematic reviews', *Psychol. Health Med.*, vol. 22, no. sup1, pp. 187–223, Mar. 2017, doi: 10.1080/13548506.2017.1282616.
- [26] C. Bonell *et al.*, 'Effects of the Learning Together intervention on bullying and aggression in English secondary schools (INCLUSIVE): a cluster randomised controlled trial', *The Lancet*, vol. 392, no. 10163, pp. 2452–2464, Dec. 2018, doi: 10.1016/S0140-6736(18)31782-3.
- [27] E. Fulu, A. Kerr-Wilson, and J. Lang, 'What works to prevent violence against women and girls? Evidence Review of interventions to prevent violence against women and girls'. 2014. [Online]. Available: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://assets.publishing.service.gov.uk/media/57a089a8ed915d3cfd00037c/What_Works_Inception_Report_June_2014_AnnexF_WG23_paper_prevention_interventions.pdf
- [28] W. A. Markham and P. Aveyard, 'A new theory of health promoting schools based on human functioning, school organisation and pedagogic practice', *Soc. Sci. Med.*, vol. 56, no. 6, pp. 1209–1220, Mar. 2003, doi: 10.1016/S0277-9536(02)00120-X.
- [29] J. D. Hawkins and J. G. Weis, 'The social development model: An integrated approach to delinquency prevention', *J. Prim. Prev.*, vol. 6, no. 2, pp. 73–97, Dec. 1985, doi: 10.1007/BF01325432.
- [30] A. Portes, 'Social Capital: Its Origins and Applications in Modern Sociology', *Annu. Rev. Sociol.*, vol. 24, no. 1, pp. 1–24, Aug. 1998, doi: 10.1146/annurev.soc.24.1.1.
- [31] C. May, 'Towards a general theory of implementation', *Implement. Sci.*, vol. 8, no. 1, p. 18, Dec. 2013, doi: 10.1186/1748-5908-8-18.
- [32] J. W. White and P. H. Smith, 'Sexual Assault Perpetration and Reperpetration: From Adolescence to Young Adulthood', *Crim. Justice Behav.*, vol. 31, no. 2, pp. 182–202, Apr. 2004, doi: 10.1177/0093854803261342.
- [33] K. Gillander Gådin and N. Stein, 'Do schools normalise sexual harassment? An analysis of a legal case regarding sexual harassment in a Swedish high school',

- Gend. Educ.*, vol. 31, no. 7, pp. 920–937, Oct. 2019, doi: 10.1080/09540253.2017.1396292.
- [34] House of Comms Women and Equalities Committee, 'Sexual harassment and sexual violence in schools', UK Parliament, Sep. 2016. [Online]. Available: <https://publications.parliament.uk/pa/cm201617/cmselect/cmwomeq/91/9102.htm>
- [35] J. Pulerwitz *et al.*, 'Proposing a Conceptual Framework to Address Social Norms That Influence Adolescent Sexual and Reproductive Health', *J. Adolesc. Health*, vol. 64, no. 4, pp. S7–S9, Apr. 2019, doi: 10.1016/j.jadohealth.2019.01.014.
- [36] P. Hawe, A. Shiell, and T. Riley, 'Theorising Interventions as Events in Systems', *Am. J. Community Psychol.*, vol. 43, no. 3–4, pp. 267–276, Jun. 2009, doi: 10.1007/s10464-009-9229-9.
- [37] G. M. Curran, M. Bauer, B. Mittman, J. M. Pyne, and C. Stetler, 'Effectiveness-implementation Hybrid Designs: Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact', *Med. Care*, vol. 50, no. 3, pp. 217–226, Mar. 2012, doi: 10.1097/MLR.0b013e3182408812.
- [38] K. Skivington *et al.*, 'A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance', *BMJ*, p. n2061, Sep. 2021, doi: 10.1136/bmj.n2061.
- [39] E. McGill, D. Marks, V. Er, T. Penney, M. Petticrew, and M. Egan, 'Qualitative process evaluation from a complex systems perspective: A systematic review and framework for public health evaluators', *PLOS Med.*, vol. 17, no. 11, p. e1003368, Nov. 2020, doi: 10.1371/journal.pmed.1003368.
- [40] C. Bonell, G. J. Melendez-Torres, and E. Warren, *Realist Trials and Systematic Reviews: Rigorous, Useful Evidence to Inform Health Policy*. Cambridge: Cambridge University Press, 2024. doi: 10.1017/9781009456616.
- [41] A. Luna Pinzon *et al.*, 'The ENCOMPASS framework: a practical guide for the evaluation of public health programmes in complex adaptive systems', *Int. J. Behav. Nutr. Phys. Act.*, vol. 19, no. 1, p. 33, Mar. 2022, doi: 10.1186/s12966-022-01267-3.
- [42] G. F. Moore *et al.*, 'Process evaluation of complex interventions: Medical Research Council guidance', *BMJ*, vol. 350, p. h1258, Mar. 2015, doi: 10.1136/bmj.h1258.
- [43] S. DeGue *et al.*, 'Effects of Dating Matters® on Sexual Violence and Sexual Harassment Outcomes among Middle School Youth: a Cluster-Randomized Controlled Trial', *Prev. Sci.*, vol. 22, no. 2, pp. 175–185, Feb. 2021, doi: 10.1007/s11121-020-01152-0.
- [44] A. Mennicke, H. M. Bush, C. J. Brancato, and A. L. Coker, 'Bystander Intervention Efficacy to Reduce Teen Dating Violence Among High School Youth Who Did and Did Not Witness Parental Partner Violence: A Path Analysis of A Cluster RCT', *J. Fam. Violence*, vol. 36, no. 7, pp. 755–771, Oct. 2021, doi: 10.1007/s10896-021-00297-y.
- [45] A. L. Coker *et al.*, 'RCT Testing Bystander Effectiveness to Reduce Violence', *Am. J. Prev. Med.*, vol. 52, no. 5, pp. 566–578, May 2017, doi: 10.1016/j.amepre.2017.01.020.
- [46] P. H. Niolon *et al.*, 'Prevalence of Teen Dating Violence and Co-occurring Risk Factors Among Middle School Youth in High-Risk Urban Communities', *J. Adolesc. Health*, vol. 56, no. 2, pp. S5–S13, Feb. 2015, doi: 10.1016/j.jadohealth.2014.07.019.

- [47] Qualtrics. (Nov. 2024). Qualtrics, Provo, Utah, USA. [Online]. Available: <https://www.qualtrics.com>
- [48] J. Nobles *et al.*, 'Ripple effects mapping: capturing the wider impacts of systems change efforts in public health', *BMC Med. Res. Methodol.*, vol. 22, no. 1, p. 72, Dec. 2022, doi: 10.1186/s12874-022-01570-4.
- [49] J. Lipson, Ed., *Hostile Hallways Bullying, Teasing, and Sexual Harassment in School*. Place of publication not identified: Distributed by ERIC Clearinghouse, 2001.
- [50] R. Meiksin *et al.*, 'A school intervention for 13- to 15-year-olds to prevent dating and relationship violence: the Project Respect pilot cluster RCT', *Public Health Res.*, vol. 8, no. 5, pp. 1–338, Mar. 2020, doi: 10.3310/phr08050.
- [51] K. Stevens, 'Valuation of the Child Health Utility 9D Index', *PharmacoEconomics*, vol. 30, no. 8, pp. 729–747, Aug. 2012, doi: 10.2165/11599120-000000000-00000.
- [52] G. J. Melendez-Torres *et al.*, 'Measurement invariance properties and external construct validity of the short Warwick-Edinburgh mental wellbeing scale in a large national sample of secondary school students in Wales', *Health Qual. Life Outcomes*, vol. 17, no. 1, p. 139, Dec. 2019, doi: 10.1186/s12955-019-1204-z.
- [53] B. W. Fisher, S. Viano, F. Chris Curran, F. Alvin Pearman, and J. H. Gardella, 'Students' Feelings of Safety, Exposure to Violence and Victimization, and Authoritative School Climate', *Am. J. Crim. Justice*, vol. 43, no. 1, pp. 6–25, Mar. 2018, doi: 10.1007/s12103-017-9406-6.
- [54] S. D. Baird Rebecca; Hamory, Joan; Iyasu, Abreham; Jones, Nicola; Presler-Marshall, Elizabeth; Yadete, Workneh, *Transforming gender norms through life-skills programming in rural Ethiopia: short-term impacts and emerging lessons for adaptive programming (Afar case study)*. London: Gender and Adolescence: Global Evidence, 2021.
- [55] M. Flood and V. Kendrick, 'LOVEBiTES: An evaluation of the LOVEBiTES and respectful relationships programs in a Sydney school'. 2012. [Online]. Available: <https://ro.uow.edu.au/artspapers/1923>
- [56] J. Boxley, L. Lawrance, and H. Gruchow, 'A Preliminary Study of Eighth Grade Students' Attitudes Toward Rape Myths and Women's Roles', *J. Sch. Health*, vol. 65, no. 3, pp. 96–100, Mar. 1995, doi: 10.1111/j.1746-1561.1995.tb03356.x.
- [57] M. G. Sawyer *et al.*, 'School-based prevention of depression: a randomised controlled study of the *beyondblue* schools research initiative', *J. Child Psychol. Psychiatry*, vol. 51, no. 2, pp. 199–209, Feb. 2010, doi: 10.1111/j.1469-7610.2009.02136.x.
- [58] F. Li, J. P. Hughes, K. Hemming, M. Taljaard, E. R. Melnick, and P. J. Heagerty, 'Mixed-effects models for the design and analysis of stepped wedge cluster randomized trials: An overview', *Stat. Methods Med. Res.*, vol. 30, no. 2, pp. 612–639, Feb. 2021, doi: 10.1177/0962280220932962.
- [59] L. A. Yurek, J. Vasey, and D. Sullivan Havens, 'The Use of Self-Generated Identification Codes in Longitudinal Research', *Eval. Rev.*, vol. 32, no. 5, pp. 435–452, Oct. 2008, doi: 10.1177/0193841X08316676.
- [60] R. Pawson, *The Science of Evaluation: A Realist Manifesto*. 1 Oliver's Yard, 55 City Road, London EC1Y 1SP United Kingdom: SAGE Publications Ltd, 2013. doi: 10.4135/9781473913820.
- [61] R. Pawson and N. Tilley, *Realistic evaluation*, Reprinted. London: SAGE, 2010.
- [62] *Methods for the development of NICE public health guidance*, Third edition. London: National Institute for Health and Care Excellence, 2012.

- [63] NICE, *NICE health technology evaluations: the manual*. London: NICE, 2022. [Online]. Available: <https://www.nice.org.uk/process/pmg36>
- [64] R. Tudor Edwards and E. McIntosh, Eds., *Applied Health Economics for Public Health Practice and Research*, 1st ed. Oxford University Press, 2019. doi: 10.1093/med/9780198737483.001.0001.
- [65] K. C. Jones and A. Burns, *Unit Costs of Health and Social Care 2021*. Personal Social Services Research Unit, 2021. doi: 10.22024/UNIKENT/01.02.92342.
- [66] R. Hooper, A. Forbes, K. Hemming, A. Takeda, and L. Beresford, 'Analysis of cluster randomised trials with an assessment of outcome at baseline', *BMJ*, p. k1121, Mar. 2018, doi: 10.1136/bmj.k1121.
- [67] A. Manca, N. Hawkins, and M. J. Sculpher, 'Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility', *Health Econ.*, vol. 14, no. 5, pp. 487–496, May 2005, doi: 10.1002/hec.944.
- [68] T. Lung, L. Si, R. Hooper, and G. L. Di Tanna, 'Health Economic Evaluation Alongside Stepped Wedge Trials: A Methodological Systematic Review', *PharmacoEconomics*, vol. 39, no. 1, pp. 63–80, Jan. 2021, doi: 10.1007/s40273-020-00963-x.
- [69] H. Squires, J. Chilcott, R. Akehurst, J. Burr, and M. P. Kelly, 'A Framework for Developing the Structure of Public Health Economic Models', *Value Health*, vol. 19, no. 5, pp. 588–601, Jul. 2016, doi: 10.1016/j.jval.2016.02.011.
- [70] P. Alderson and V. Morrow, *The Ethics of Research with Children and Young People: A Practical Handbook*. 1 Oliver's Yard, 55 City Road London EC1Y 1SP: SAGE Publications Ltd, 2020. doi: 10.4135/9781529682694.