Social and Emotional Education and Development (SEED): a Stratified, Cluster Randomised Trial of a Multi-component Primary School Intervention that follows the Pupils' Transition into Secondary School

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1. Aims/Objectives

The overarching aim is to rigorously evaluate via a stratified, cluster randomised trial the impact of a multi-component primary school intervention (SEED) that aims to improve pupils' social and emotional wellbeing.

Pupil related research questions include:

- Does SEED improve pupils' social and emotional wellbeing?
- If so, is the impact different for different subgroups of pupils (gender, deprivation)?
- Is SEED more effective if started younger?
- What is the duration of the SEED effect?
- What are pupils' experiences of SEED?
- Does SEED improve the social and emotional experience of transition from primary to secondary?
- What is SEED's impact on health behaviours in early secondary?

Teacher related research questions include:

- Were teachers involved, and if so how, in selecting initiatives to respond to the pupils' needs assessment?
- What contextual factors facilitate or inhibit the delivery of SEED?
- What contextual factors support or hinder SEED's ability to improve pupils' social and emotional wellbeing?
- Which teachers engage best with SEED?
- What are teachers' experiences of SEED?
- Are there changes in teachers' knowledge, attitudes and behaviour relating to developing pupils' social and emotional wellbeing?

Parent related research questions include:

- Do parents notice a difference in their child(ren)'s emotional and social development?
- Where appropriate, what was parents' experience of SEED?

Economic research questions include:

- Is SEED cost-effective?

2. Background

2.1 Existing research

Evidence from existing reviews and studies - In a recent UNICEF report on child and adolescent health and wellbeing in high income countries, the UK was ranked bottom of 21 nations, highlighting the urgent need to improve children and young people's health in the UK [1]. Traditionally, school based public health interventions aimed at improving the health and wellbeing of young people have focused on the prevention or reduction of specific health conditions or behaviours, such as obesity, exercise, alcohol, tobacco and illicit drug use and sexual risk behaviour. However, systematic reviews of these interventions have revealed that these have had very mixed and often disappointing effects on outcomes, with few interventions proving to have a strong impact that can be sustained in the longer term [2-8]. Universal approaches attempt to promote wellbeing in all children, while targeted approaches are directed at vulnerable children, or those already experiencing problems. There is growing evidence that universal interventions addressing the underlying determinants common to these health conditions and behaviours might be more effective and efficient at improving health and wellbeing in adolescence and adult life [9]. Furthermore, there is evidence that programmes addressing these underlying determinants need to be introduced in the early years of primary school, and sustained over time to include key transition periods. Improved social and emotional wellbeing during primary school years has been shown to have an impact on physical health and to be a protective factor against a range of risk behaviours in later years, including tobacco, illicit drug and alcohol misuse, violence and crime, and teenage pregnancy [10]. A recent review and meta-analysis included over 200 controlled studies of school-based interventions designed to enhance social and emotional skills of children aged 5-18 [11]. The review found positive benefits on a range of outcomes including significant improvements in social and emotional skills, attitudes and positive social behaviours and academic performance. Maximum benefits were observed when the programmes were evidence-based and well implemented by school staff. In addition, there is good evidence that interventions with a longer programme duration period (i.e. multi-year interventions) are likely to have a greater effect than shorter-term programmes [12].

Evidence for a multi-component approach - Other systematic reviews of the effectiveness of universal interventions to improve the mental wellbeing (encompassing emotional, psychological and social wellbeing) of children in primary education have found that curriculum-only interventions appear to be effective only in the short-term. In contrast, there is good evidence to support the use of programmes that combine a social and emotional development curriculum with components that focus on behaviour management and improvement of child-teacher relationships [10]. The multi-component intervention approach appears to be particularly effective in improving mental health, as well as reducing bullying and violence [13]. One of the key studies in this area is the Seattle Social Development Project (now known as Raising Healthy Children), which was implemented in Year 1 of elementary school for six years, with follow up into adolescence and young adulthood. The programme sought to promote connectedness to school and family and strengthening of children's social competencies. It consisted of three components: teacher training; child social and emotional skill development; and parent training. Follow-up at age 21 revealed significant reductions in the intervention group in health risk behaviour (including alcohol, tobacco and illicit drug use, sexual risk behaviour), violence and crime,

emotional and mental health, and positive functioning in university or work [14-16]. Some of these effects remained significant when the study population was followed up at age 30.

As with multi-component interventions, "whole school" approaches that focus on the school ethos and school environment can have an effect on social competence, aggression and health risk behaviours [17, 18]. A comprehensive review of the impact of school environment interventions in both the primary and secondary school settings on health and wellbeing is currently underway [19]. However, some of the best evidence for the effectiveness of the "whole-school" approach within the secondary school setting comes from the Australian Gatehouse Project, which was designed to promote a sense of social inclusion and connection in secondary schools [20]. Importantly, the strategies to achieve this varied between schools, according to students' perceptions of need, with the conceptual framework focusing on three areas of action: 1) building a sense of security and trust; 2) enhancing communication and social connectedness; and 3) building a sense of positive regard through valued participation in aspects of school life [21, 22]. After three years of follow up there were reductions in substance use, and among new students surveyed a year later, there were significant reductions in composite measures of risk behaviour and early sexual intercourse [21, 22]. Both the Seattle Social Development Project and the Gatehouse Project included a curriculum component that focused on developing or improving emotional and social wellbeing.

There is also some evidence that targeted programmes can have an impact. A review of these targeted programmes in primary schools reported modest improvement, particularly in social problem solving and development of positive peer relations, for lengthy, multi-component programmes [23]. The evidence therefore supports an integrated approach which provides targeted support for those experiencing particular difficulties within a supportive whole-school approach to promote mental wellbeing [17]. For instance, a review on family based programmes to promote mental wellbeing [24] supports the need for generic programmes to promote mental wellbeing at a population level and more intensive programmes for more serious problems. NICE guidance on promoting children's social and emotional wellbeing in primary education strongly supports the adoption of universal approaches, which have the capacity to address emotional wellbeing in a connected way that reduces potential for stigmatisation, but which also include provision of targeted approaches and early identification of children at risk [25].

UK context - The importance of social and emotional wellbeing of primary age children has received considerable attention from the UK and Scottish Governments and is reflected in a strong body of current and recent governmental policy and initiatives (Every Child Matters; Social and Emotional Aspects of Learning (SEAL) [26,27]) and at the Scottish Level (Early Years and Early Intervention; Equally Well; Getting It Right For Every Child; Curriculum for Excellence's Health and Wellbeing Outcomes [28-31]). Over-arching this is the influence of the WHO's Health Promoting Schools Framework, which requires schools to simultaneously address the domains of school ethos, school curriculum and family/community involvement. In Scotland, social and emotional aspects of learning are embedded within the Curriculum for Excellence, with Health and Wellbeing being given equal importance with Literacy and Numeracy. There are also a number of localised curriculum programmes that have been used successfully within primary schools in Scotland, including Creating Confident Kids, a programme based on SEAL, The Motivated School and Being Cool in School. These programmes lack robust evaluation but are currently supported by the Scottish Government's Positive Behaviour Team which adopts both universal and

targeted approaches to positive behaviour through improving relationships and environments in schools [32].

Limitations of, and gaps in, current evidence - Although the evidence-base suggests a number of promising intervention approaches, there are limitations and gaps that need to be addressed. The majority of the evidence for improving emotional and social wellbeing in primary school children is non-UK- and largely US-based. The effectiveness of these approaches in the UK setting therefore needs to be determined through robust evaluation. Some approaches (particularly family or parenting approaches) target vulnerable children only, as opposed to taking a universal approach, therefore the success of universal approaches that incorporate elements such as parent support needs to be assessed. Also, the cost-effectiveness of addressing emotional and social wellbeing in the primary school years has rarely been determined. However, economic evaluation of the Seattle Social Development Project revealed substantial economic benefits of such an approach in the US setting, which were far higher than basic curriculum based programmes implemented during early adolescent years [9]. To date, evaluation studies have rarely examined the differential effects of specific programmes according to gender and socioeconomic status. It is essential to evaluate the effectiveness of programmes on these subgroups to ensure that there is no widening of health inequalities in these groups, and to show any narrowing of health inequalities. Finally, many studies have included short-term follow-up only, and importantly, have not included key transition periods within the duration of follow-up. The transition period between primary and secondary has been shown to be an important indicator for wellbeing and attainment in later life [33] therefore it is important to include this key period within the follow-up period of any primary school-based intervention.

We believe SEED will work because it will enable schools to focus their social and emotional curricular materials and whole school practices according to their pupils' needs. In addition, the focus on addressing staff needs will help support a positive classroom and school level ethos. There will be the opportunity for schools to engage the pupils' parents, which would further support a consistent approach between home and school.

2.2 Rationale for current study

The need for robustly evaluated social interventions - In Scotland, primary schools are encouraged to include programmes for promoting emotional and social development, in line with the Curriculum for Excellence. However, to date there is little rigorous evidence to support social interventions and government initiatives [34] and a lack of robust evaluation of school initiatives in the UK. Thus, there needs to be a focus on translating this policy into practice through appropriate and rigorous evaluation of promising interventions and the development of a rigorous evaluation evidence base. Furthermore, the importance of assessing school and pupil need and producing a tailored intervention approach is currently being overlooked in Scottish educational practice.

2.3 Pilot Study

A pilot study (funded by Scottish Collaboration for Public Health Research and Policy) was conducted in 2012 in four Glasgow primary schools to refine the SEED programme and the methodology for evaluating SEED. The pilot's purpose was to test whether the combination

of elements worked together as intended and whether they worked in the intended setting. This was necessary in order to confirm the programme's feasibility, ensure that the intended mechanism and outcomes are plausible, and pilot aspects of the research process and procedures, such as recruitment, the acceptability of questionnaire measures, their appropriateness for the target population, and collect data to improve estimates of likely effect size.

Qualitative data were collected from staff in participating pilot schools and other educationalists. Results indicated that SEED was seen as valuable to schools and was a good fit with existing improvement planning processes. Statistical analysis of the pilot data was used to develop and refine the questionnaires measures.

2.4 The SEED Intervention

The SEED intervention is a school-based programme to promote emotional and social wellbeing in primary school pupils and has three components:

1) Needs Assessment
A pupils' needs assessment including the Strengths and Difficulties Questionnaire (SDQ), completed by teachers for two cohorts of pupils (one initially in Primary 1, the other in Primary 5) and a self-completed questionnaire by the older cohort of pupils (initially in Primary 5) (aged 9 or 10). The needs assessment will also include a staff questionnaire and a parent questionnaire for parents of both cohorts.

2) Feedback and Reflexive Discussion
The needs assessment scores (aggregated by junior and senior primary) will be reported to school staff by members of the research team during feedback session(s) where Local Authority Educational Psychologists associated with the school will facilitate a reflexive discussion around current school policy, practice and culture, and needs identified in the feedback received. The aim of this will be to develop commitment to positive change and support staff to select and co-produce school-appropriate initiatives tailored to the needs of their individual schools.

3) Selection, Implementation and Maintenance of initiatives
Following the initial feedback session there may be further supportive sessions where staff, with the support of the Educational Psychologist, select or co-produce initiatives/approaches with a view to incorporating these into the school's improvement plan. These initiatives are likely to be of three kinds: (a) classroom packages for delivery to pupils, e.g. *Creating Confident Kids*; *Being Cool In School*; (b) training for teachers and/or parents, e.g. to promote proactive classroom management and interactional instruction, or to understand the importance of social and emotional wellbeing of children and being positive role-models (*Growing Confidence*); (c) whole school initiatives, e.g. the implementation of restorative practice approaches. The programme contributes to the central goals of the *Curriculum for Excellence*. Possible, evidence-based, activities and initiatives have been compiled into an accessible resource guide for schools called The SEED Resource Guide. It draws on two similar guides previously used in international research: CASEL's Safe and Sound [35] and Kidsmatter SEL Programs [36].

In subsequent waves of the study (in 2015, 2016 and 2017) schools will have further feedback sessions following data collection at each wave. The purpose of these sessions will remain the same as the initial session but will also incorporate feedback on any changes in the data between waves and reflection on the usefulness of initiatives selected at previous waves.

SEED works with pupils, teachers and potentially parents/carers and allows for an appropriate tailored response to school need. Schools will be supported to work at both class and school level to implement change. Although the project will be set within the context of Scottish education policy, the intervention has generic importance to the rest of the UK and beyond.

Strengths of SEED intervention programme:

- Able to respond flexibly to local need, through a focus on providing tailored support skills for children, teachers and parents via a needs analysis
- Strongly aligned with many of the key recommendations in the NICE guidelines for promoting children's social and emotional wellbeing in primary education, including: the use of a whole-school approach to create positive safe and secure learning environments; training and development of teachers; provision of support for parents and carers; identification of vulnerable children; and the need for programmes to work in partnership with children, allowing them to express their views [25]
- Draws upon the most effective/promising interventions aimed at improving emotional and social wellbeing
- Includes key elements from the Gatehouse Project, which has been rigorously evaluated. It can also incorporate Growing Confidence, which in an initial evaluation has been found to be popular in Scotland [37]
- If required it can include training for teachers in social and emotional wellbeing and classroom management
- If required it can offer an opportunity for training for parents in social and emotional wellbeing

3. Methods/Design

3.1 Setting

38 primary schools have been recruited to the study and lie within Dundee, Falkirk and South Lanarkshire Local Education Authorities (LEAs).

3.2 Participants

The study involves two cohorts of pupils:

- Younger pupils (Cohort Y) – in Primary 1 (aged 5-6) in Spring Term 2013
- Older pupils (Cohort O) – in Primary 5 (aged 9-10) in Spring Term 2013

And two further cohorts of participants:

- Staff – All staff within the Primary School setting (teaching and non-teaching)
- Parents/Carers – Parents or Carers of pupils in Cohort Y or Cohort O

Following recruitment of 38 schools, the parents/carers of 1469 Cohort Y and 1330 Cohort O pupils (2799 pupils in total) were approached for their consent to include their child in the study (by opt-out consent).
These parents/carers (2799) will be approached again during data collection for their own participation in addition to their child's participation.
1147 Staff members will be approached during data collection for their participation.

Inclusion/Exclusion – Unless opted out by their parents/carers we intend to include all primary school pupils in each cohort year group as far as possible. Since teachers or classroom support assistants will complete Strengths and Difficulties Questionnaires (SDQ) on behalf of their pupils, individual pupils will not be excluded on the basis of additional support needs or language difficulties unless it is felt in liaison with the class teacher and Head Teacher that the SDQ would not be a valid measure for a particular child, in which case that child's data will not be used in either the feedback or evaluation. Pupils completing the self-complete questionnaire will be given additional support where needed unless that it is felt, in liaison with the class teacher and Head Teacher, that the pupil's level of understanding of the questions would not allow them to complete the questionnaire accurately or where participation would be detrimental to the young person's wellbeing.

3.3 Recruitment

Local Education Authority (LEA)
The Directors of Education in each LEA were approached by email and then by phone. This was followed by meetings with nominated Educational Psychologists and Quality Improvement Officers. Following these discussions all LEAs granted permission and we were instructed to contact primary schools directly inviting them to take part.

Schools
Schools across Dundee, Falkirk and South Lanarkshire LEAs were approached by post initially and followed up by phone and email inviting them to participate. 38 primary schools were recruited within 19 Learning Communities (a Learning Community refers to primary schools and their related secondary school) with between one and three primary schools per Learning Community. In total, 92 schools were approached and no school that wanted to take part was refused inclusion in the study, some schools did not refuse but simply did not reply.

Pupils
Since the SEED intervention operates at whole school level, the parents of individual pupils could not opt their child out of the intervention (if the school was randomised to the intervention arm) but parents of Cohort Y and Cohort O were contacted by post offering them the opportunity to opt their child out of the evaluation component. Any children who have been opted out will not be part of the aggregated feedback to schools.

Staff

Schools will be given staff questionnaire packs to distribute to their staff including an invitation letter, questionnaire, information sheet and pre-paid return envelopes. Staff will return their completed questionnaires to the research team if they wish to participate.

Parents/Carers

The parents/carers of Cohort Y and Cohort O will be sent questionnaire packs by post including an invitation letter, questionnaire, information sheet and pre-paid return envelopes. Parents/carers will return their completed questionnaires to the research team if they wish to participate.

3.4 Design

- Cluster Randomised Controlled Trial

  The schools will be randomised into intervention and control arms after the collection of baseline data, and the two arms will be treated identically in terms of data collection. The randomisation will be at the level of Learning Community in order to minimise contamination, therefore all participating primary schools within a learning community will be in the same arm of the trial. The randomisation will be conducted by colleagues at the Robertson Centre for Biostatistics, University of Glasgow. There will be a baseline survey followed by three annual follow-ups. The programme will be implemented by SEED researchers, local authority educational psychologists and school staff.

  The key outcome measure for pupils is the Total Difficulties Score of the Strengths and Difficulties Questionnaire (SDQ). This scale is well established and validated [38]. We shall evaluate all five SDQ subscales (emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and Prosocial behavior) as well as additional measures of pupils' self esteem, ability to manage their feelings and behaviour; social resilience; respect and empathy for others; relationships, attitudes to school and academic performance. We shall measure changes in staff and parents' knowledge, attitudes and behaviour relating to children's social and emotional wellbeing.

  We originally estimated that 36 primary schools would be recruited (in actual fact we have recruited 38 primary schools to offer protection from any school dropping out within the life of the trial), 200 primary school staff, 1,094 parents (allowing for 60% attrition) and 1,026 P1 (aged 4/5) and 1,026 P5 (aged 8/9) pupils will participate (allowing for 25% attrition).
  Based on an average of 38 pupils per year at each school and the initial estimate of 36 schools participating we estimated that there would be a potential 2,736 pupils for recruitment at baseline. We expect few to opt out of participation, and have assumed that 75% of the target population can be followed up for 4 years, a total of 2,052 pupils, 1,026 from each age group, with an average 28.5 pupils per year per school. Assuming a cautious intraclass correlation coefficient of 0.05 (i.e. 5% of the variation in the primary outcome will be attributable to school- and class-level variability), the design effect will be 2.375. Therefore, within each age group, with 513 pupils randomised to both the intervention and control arms of the study (allowing for attrition), the effective sample size will be 216 per group (513÷2.375) within both Cohorts Y and O.

This sample size provides 95% power at a 5% significance level to detect a between-group difference of 0.35 standard deviation (SD) units, within each age band. Assuming the SD of the primary outcome (SDQ Total score) to be 6 points, this equates to an average between-group difference of 2.1 points. There is also 80% power to detect differences of 0.27 SD units (i.e. 1.6 points on the SDQ Total score).
Assuming an equal split between boys and girls, then within each gender, the study will have 95% power to detect intervention effects of 0.49 SD units (3.0 SDQ Total score points), or 80% power to detect an effect of 0.38 SD units (2.3 SDQ Total score points).

- Process Evaluation

In order to interpret the trial outcomes and to answer secondary research questions related to process, a process evaluation will be conducted. We will conduct in-depth interviews with at least two senior education officials in the participating local authorities at the start and end of the trial, to explore the education authorities' perspectives on the key research questions. In all schools data will be collected through the main teacher, pupil and parent questionnaires. Head teachers or deputy heads (as appropriate) will be interviewed by phone at the start, middle and end of the trial, and fieldworkers will complete forms on their perceptions of each school for each visit.

This will be supplemented by eight case studies, selected in Year 2. In each arm four schools will be selected representing four cells of a matrix: high vs low SDQ scores and actively engaged vs reluctantly engaged in SEED (intervention schools) or other initiatives related to social and emotional wellbeing (control schools). In each case study school head teachers will be interviewed in person rather than by phone, to maximise rapport and collect non-verbal data, and since researchers will be visiting schools anyway. Teachers of the participating pupils will be interviewed in Years 2 and 3, combining structured questions with open-ended exploratory questions on teachers' perceptions. One group discussion will be conducted with a group of pupils from each cohort near the end of the study. Teachers' classroom management skills will be assessed through observation of a randomly selected lesson with each cohort in each case study school. We have costed in capacity to conduct 8 further in-depth interviews with key informants in response to issues as they arise.

- Health Economics Evaluation

Cost utility studies have not been included as part of major evaluations of primary school based interventions to promote mental and physical health however some researchers have undertaken cost comparison analyses. For example, a recent evaluation lead by Warwick University of three programmes in the UK compared the cost per participant across the interventions but did not compare the additional costs associated with the interventions against observed changes in health [39]. We therefore plan to conduct a cost utility evaluation as part of the present study.
We will collect data on the costs associated with the provision of the interventions including staff time and consumables as well as the costs incurred by parents such as

travel and child care. The Child Health Utility 9D (CHU9D) has recently been developed and validated specifically for use in children aged 6-11 years and it can be used with other age groups [40]. This will be used to generate a measure of utility change in each arm of the study. We will use the area under the curve method to assess the within study QALYs which together with the cost data will allow us to calculate an incremental cost utility ratio [41]. Reflecting the analysis in the main study we will also conduct a subgroup analysis focusing on young people from lower socio-economic groups. Our results will be subjected to a sensitivity analysis. In line with current recommendations in the UK the costs and outcomes will be discounted at 3.5% per annum [42].

The final part of our analysis will involve utilising information from the literature and other studies to extrapolate from the observed trial outcomes to determine the potential longer term intervention impacts on health and wellbeing. These studies will include the extensive evaluations of the Seattle and Gatehouse programmes upon which our intervention is based.

Strengths of the proposed evaluation of SEED:

- Robust, cluster randomised controlled trial, with long-term follow up from primary through to secondary school, thereby incorporating the crucial transition period from primary to secondary school
- Will collect robust, measurable outcomes with the potential for long-term follow-up for a variety of outcomes including educational attainment and health-risk behaviour
- Includes a strong process evaluation
- Contains an economic evaluation, including a cost utility analysis
- Powered to look at effect of intervention on subgroups (e.g. gender and socioeconomic status)
- Can draw on the wealth of survey data on children and young adolescents in Scotland (e.g. Health Behaviour in School-aged Children survey; SALSUS; Growing Up in Scotland [43-45]) to make comparisons between the SEED cohort and others
- Strong research governance in accordance with MRC and NIHR PHR guidelines

3.5 Data Collection

<u>Baseline</u>

- Teacher-complete Strengths and Difficulties Questionnaires (SDQs)
  Teacher or classroom support assistants who work regularly with the pupils in Cohort Y and O and have known them for a minimum of 6 months will complete SDQs about the pupils.

- Pupil Self-Complete Questionnaires
  Cohort O pupils will self-complete a questionnaire that includes the SDQ among other items focused on social and emotional wellbeing.

- Staff Self-Complete Questionnaires
  Teaching and non-teaching staff will self-complete a questionnaire that includes items on reported relationships with pupils, attitudes to classroom discipline, self-efficacy to influence

pupils' social and emotional wellbeing, staff's own social and emotional wellbeing and delivery of SEED and other programmes relating to social and emotional wellbeing.

- Parent/Carer Self-Complete Questionnaires
  Parents/carers of Cohort Y and O pupils will self-complete a questionnaire that includes reports of their child(ren)'s social and emotional wellbeing, including the SDQ, quality of family relationships, experience of SEED (if any) or other programmes relating to social and emotional wellbeing, quality of contact with the school (if any), self-efficacy to influence child(ren)'s social and emotional wellbeing, and basic questions relating to relative deprivation and income (number of cars, employment status, etc.)

<u>Follow up</u>

Repeated measures will be taken using the above set of questionnaires in three waves of follow up: 1.Spring Term 2015 (Cohort Y in Primary 3, Cohort O in Primary 7), 2.Spring Term 2016 (Cohort Y in Primary 4, Cohort O in Secondary 1) and 3. Spring Term 2017 (Cohort Y in Primary 5, Cohort O in Secondary 2).

Changes to data collection in Follow Ups:

- Beyond baseline, Teacher-complete SDQs will only be completed for Cohort Y as the self-complete SDQ completed by Cohort O is validated for use with this age group.
- Cohort Y will complete the self-complete questionnaire (including SDQ) in the final Follow Up 3 when they are in Primary 5.
- The self-complete questionnaire that Cohort O will complete will be amended in Follow Ups will have some minor modifications to take account of maturation and changing lifestyles. This will include changing the wording of items that measure domains such as self-esteem and resilience as children's understanding matures.
- Modifications for the pupil self complete questionnaire are also planned for follow-ups 2 and 3 when the older cohort will have transitioned into the first two years of secondary school (S1 and S2). We know that children's social and emotional wellbeing in primary school is related to physical health as well as adolescent risk behaviours. As such, we would want to include some questions on:
  - Experience of transition
  - Adolescent risk behaviours, including smoking, illicit drug and alcohol use

<u>Additional data</u>

3.6 Data Analysis

Planned analyses - The primary analysis will compare mean SDQ Total scores at 4 years between intervention and control schools using a multilevel linear regression model. Models will include a binary indicator for being in the intervention arm of the study, as well as binary indicators for age group at baseline (P1 or P5), gender, and each variable used in the stratification at randomisation. To increase power, an adjustment will be made for baseline

SDQ Total score. Clustering will be taken into account by allowing for hierarchical random effects due to schools and classes within schools. The SDQ results will enable an assessment to be made of the intervention's impact on pupils' social and emotional wellbeing. Secondary analyses will consider SDQ subscales and additional measures of pupil wellbeing. Models will also be extended to estimate intervention effects within subgroups defined by age group, gender and deprivation level; interaction terms will be included to derive separate intervention effect estimates and to test for differences in intervention effects between subgroups. Analyses will be repeated at intervening time points (2 and 3 years post-baseline). Finally, repeated measures analyses will be carried out for each outcome at all time points simultaneously. Sensitivity analyses will be performed to test the robustness of the analyses to alternative assumptions regarding missing outcome measures.
Reflecting the main study, the cost-utility study will conduct a subgroup analysis focusing on young people from lower socio-economic groups. Our results will be subjected to a sensitivity analysis. In line with current recommendations in the UK the costs and outcomes will be discounted at 3.5% per annum [42]. In the final part of our analysis we will use information in the literature to model the potential longer term impacts of the trial outcomes on health and wellbeing.

4 Trial Management

MRC/CSO Social and Public Health Sciences Unit, the lead applicant's employer, will be the sponsor of the SEED Trial. A Steering Committee will be set up to provide independent expert advice. It is envisaged that we will invite a member from Scottish Government's Positive Behaviour Unit, an Educationalist, an Educational Psychologist, a statistician, a teacher, a parent and a member of the public.

5 Ethical Considerations

We have gained ethical approval from University of Glasgow College of Medical, Veterinary & Life Sciences Ethics Committee for Non Clinical Research Involving Human Subjects who will assess independently that we comply with ESRC Research Ethics Framework.

Informed Consent
For pupils, a letter and participant information sheet were sent out to all pupils' parents/carers informing them of the research and offering an option for their child to be withdrawn from the evaluation. Opt-out consent is critical since previous research over many years has shown that the lower participation with opt-in consent is strongly biased away from the most vulnerable children [46]. Pupils who have not been opted out will be included in Baseline and Follow-ups 1-3. On each occasion pupils completing the self-complete questionnaire will have the questionnaire and research study explained to them in age appropriate language and will be given the opportunity to choose not to complete it (although they will remain in the study if their parent/carer has consented)and will be informed that even if they start the questionnaire that they can omit questions on a question-by-question basis.

Parents and staff will be fully informed of the research process through a participant information sheet and will be given opportunities to ask about the study before consenting to take part. The participant information sheets will make clear that participation is voluntary and confidential, and participants will be informed of the study prior to consenting

to take part. Their consent to take part will be assumed by their voluntary return of a completed questionnaire. Similarly during qualitative interviews as part of the process evaluation, parents and staff will be given information sheets and sufficient time to ask questions and decide whether or not they wish to take part. Their written consent will be obtained prior to conducting the interviews.

Confidentiality and anonymity

All data collected will be stored securely in accordance with MRC Best Research Practice Guidelines in either locked filing cabinets or password-protected databases accessible only by main research and survey office staff. Identifying information will be held separately at all times from non-identifying information.

No names will be retained on any pupil, teacher or parent questionnaires. Unique ID codes (and corresponding barcodes) will be used to identify all participants in order to link them throughout the study and identifying information linking participants to ID numbers will be stored securely in a database accessible only by main research and Survey Office staff and held separately from participant questionnaire responses.

Non-identifying questionnaire data will be processed and stored by the Robertson Centre of Biostatistics (the Clinical Trials Unit based at University of Glasgow). Identifying questionnaire data which has been attached following pupil or parent completion and returned to the MRC SPHSU separately will be processed by the MRC Survey Office Team and stored securely and separately from non-identifying data.

During questionnaire completion by the older pupils, care will be taken to ensure pupils have as much privacy to complete questionnaires as possible. Pupils will be requested and encouraged to complete questionnaires quietly on their own and not to confer with neighbours.

Results will be fed back to school staff in aggregate form, broken down by year group and, potentially, gender. Neither teachers nor parents will be informed of individual pupils' SDQ scores. There is a remote possibility that parents might request to know their child's SDQ scores, we will have to remind them of our commitment to confidentiality regarding individual scores. SDQs are in the public domain and freely available, so in effect, there is nothing to stop a parent from completing it for their child if they so desire, but project scores will remain confidential.

Responses from free text fields in the staff and parent questionnaires will be fed back to schools in a way that removes any identifying information.

Care will be taken to conduct interviews ethically and sensitively. Complete confidentiality of interview content and recordings will be ensured and all best efforts will be made to ensure that quotations and comments cannot be traced back to the interviewee.Participating schools will not be identified in anypublication and pseudonyms will be used where necessary. .

Abbreviations

SEED	Social and Emotional Education and Development
LEA/LA	Local Education Authority/Local Authority
SDQ	Strengths and Difficulties Questionnaire
MRC/CSO	Medical Research Council/Chief Scientist Office
SPHSU	Social and Public Health Sciences Unit
ESRC	Economic and Social Research Council
NICE	National Institute for Health and Care Excellence

Competing interests

None of the authors have competing interests

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