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A cluster randomised controlled trial evaluation and cost-effectiveness analysis of the Roots of Empathy schools-based programme for improving social and emotional wellbeing outcomes among 8-9 years olds in Northern Ireland.

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1. Aims/Objectives:

Objectives

The proposed research seeks to:

1. Evaluate the immediate and longer term impact of the Roots of Empathy programme on social and emotional wellbeing outcomes among 8-9 year old pupils
2. Evaluate the cost-effectiveness of the programme

Purpose

The purpose of the research is to answer the following research questions:

1. What is the impact of the programme at post-test and up to three years following the end of the programme on a number of specific social and emotional wellbeing outcomes (see below for details) for participating children?
2. Does the programme have a differential impact on children depending on: their gender; the number of siblings they have; and their socio-economic status and/or the socio-economic profile of the school?
3. Does the impact of the programme differ significantly according to variations in implementation fidelity found?
4. What is the cost-effectiveness of the programme in reducing cases of aggressive behaviour and increasing prosocial behaviour among school-aged children?

2. Background:

Existing research

A substantial body of evidence now exists to suggest that well designed school based prevention programmes can be effective in improving a variety of social, health and academic outcomes for children and young people.[10,11] Several reviews have been conducted in the area of socio-emotional learning (SEL) programmes and while the types of intervention, participants and outcomes have varied between reviews, the general consensus is that universal school based programmes positively impact on child outcomes.[12,13,14,15]

The most relevant and recent of these reviews is Durlak *et al*'s meta-analysis[16], which focused exclusively on school-based universal SEL programmes and their impact on a number of student outcomes including: SEL skills, attitudes, positive social behaviour, conduct problems, emotional distress and academic performance. The analysis included 213 programmes and 270,034 students. The mean effect sizes for each outcome ranged from -0.22 (conduct problems) to +0.57 (SEL skills), which the authors note is consistent with effect sizes reported by other studies and reviews of similar programmes and outcomes. The most effective SEL programmes in this review (defined as those that significantly and positively impacted on all six outcomes) were those that did not experience implementation problems and, consistent with Payton *et al*.'s conclusions[13], also incorporated the following four recommended practices commonly referred to as 'SAFE':

- **S**equenced: applying a planned set of activities to develop skills in a step by step fashion
- **A**ctive: using active forms of learning (i.e. role plays, behavioural rehearsal with feedback)
- **F**ocused: devoting sufficient time to developing social and emotional skills
- **E**xplicit: targeting specific social and emotional skills

Durlak *et al*. concluded that SEL programmes tended to: impact significantly and positively on students' social and emotional competence; increase pro-social behaviour; reduce conduct and internalizing problems; and improve academic performance. They also reported that in those studies that followed up participants, these effects remained statistically significant for at least six months post intervention. Only a small number of studies in this review (15%) reported follow up data that met the inclusion criteria and so little is known about the long-term effects of SEL programmes. Adi *et al.*,[17] whose review informed the NICE guidelines, reinforced this view and observed that while programmes teaching social skills and emotional literacy show promise, there remains a need for good quality trials to assess their long-term effectiveness.

The Roots of Empathy programme

It is within this broader context that the Roots of Empathy programme (ROE) represents an extremely timely and relevant intervention that is only just being introduced into the UK. ROE is a universal programme delivered on a whole-class basis for one academic year (October to June) and conforms to the 'SAFE' recommended practices described above. It is a 27 lesson programme that runs over a school year and is based around a monthly classroom visit by an infant and parent, typically recruited from the local community, whom the class 'adopts' at the start of the school year.

During these monthly visits children learn about the baby's growth and development via interactions and observations with the baby. Each month a trained ROE instructor, who is not the class teacher, visits the classroom three times for: a pre-family visit; the visit of the parent and infant; and a post-family visit. Instructors undergo a total of four days intensive training that is delivered directly by a specialist ROE trainer from Canada. The specialist trainer also provides on-going mentoring support via regular telephone calls to all instructors. In addition, on-going support is also available to each instructor through each Health and Social Care Trust's lead ROE coordinator. Each ROE lesson provides opportunities to discuss and learn about the different dimensions of empathy, namely: emotion identification and explanation; perspective-taking; and emotional sensitivity. The parent-infant visit serves as a springboard for discussions about understanding feelings and infant development and effective parenting practices.

ROE seeks to develop children's social and emotional understanding, promote prosocial behaviours and decrease aggressive behaviours, and increase children's knowledge about infant development and effective parenting practices. The way in which it seeks to do this is summarised in the logic model set out in the Appendix.

As the name suggests, at the heart of the programme is the development of empathy among young children. Empathy is the capacity to recognize and to some extent share the feelings being experienced by others. Baron-Cohen[18] describes empathy as spontaneously and naturally tuning into the other person's thoughts and feelings. The existence of empathy lays the basis for helping and for other forms of prosocial behaviour because it underpins the motivation to respond to the feelings of others. Similarly the absence of empathy leaves the person to consider their own needs

without reference to the feelings of others, which results in asocial or antisocial behaviour, depending on the degree of impact on the other person.

Baron-Cohen suggests there are two major elements to empathy: cognitive (perspective taking) and affective (sharing the feeling of the other person). The cognitive element of empathy is less problematic in some respects because the capacity for perspective taking occurs as part of a wider developmental pattern of growth (as described by Piaget). The feeling element on the other hand is considered to develop mainly in response to close personal relationships, the prototype for which is the attachment bond between mother and child. The centrality of the attachment relationship was first established by Bowlby and developed later by Ainsworth[19] to include patterns of attachment between caregiver and child. For Ainsworth and many subsequent researchers, secure attachment is regarded as the basis for sound psychological development.

The means through which attachment has its beneficial effects on development is still not fully understood. Fonagy *et al*.[20] argue that securely attached individuals tend to have more robust capacities to represent the state of their own and other people's minds. This ability to perceive and interpret human behaviour in terms of intentional mental states (e.g. needs, desires, beliefs, goals, purposes and reasons) is known as mentalization. The concept of mentalization is receiving increasing empirical support as a core process in the attachment relationship. It appears however that mentalization can be acquired outside infancy and indeed there is a form of mentalization therapy used in adults for which an evidential basis has been developed.[21]

A characteristic of ROE is that it is a mentalization-based programme that has the principal aim of developing empathy in children. The labelling of feelings and the exploration of the relationship between feelings and behaviour is achieved through the mother-infant interaction as observed by the children in the classroom. Clearly, the baby cannot communicate in words and can only express his/her feelings through behaviour. For this reason, the baby in ROE provides an ideal opportunity for the children to learn mentalization skills through interpreting and labelling the baby's emotions, and by this means learning the affective and cognitive components of empathy, which will enable them to empathise with others. If and when children learn empathy, they have the basis for developing positive social partnerships with others as depicted in the Appendix.

Development of the Roots of Empathy programme

ROE was initially piloted in two classrooms in Toronto in 1996 and since then has been extensively rolled out in schools throughout Canada. It is also being delivered in New Zealand and the United States and is, currently, being piloted in the Isle of Man, Scotland, Northern Ireland, and the Republic of Ireland. In relation to Northern Ireland, the programme is being delivered this year (2010/11) in 30 primary schools in the Belfast Health and Social Care Trust and the South Eastern Health and Social Care Trust areas. It has attracted significant interest from the education sector and many more primary schools have expressed an interest in delivering the programme than there is current capacity. Both Trusts, with the support of the Public Health Agency, are committed to delivering the programme in a further 10 schools each during the 2011/12 school year and two of the remaining three Trusts (Southern and Western HCS Trusts) are also committed to begin delivering the programme in 15 schools between them.

However, while there is significant international interest in ROE –evident most recently by its coverage in *Time Magazine*[22] and on *CNN* and *Fox News* among many other

media outlets – the evidence base for the programme is currently limited. The ROE website (www.rootsofempathy.org) reports nine evaluations that have been conducted to date. These suggest that it is effective in relation to: improving children's social and emotional understanding; promoting prosocial behaviours and decreasing aggressive behaviours; and increasing children's knowledge about infant development and effective parenting practices. In addition, some evidence is claimed that improvements in behaviours continue up to three years after programme delivery.

However, of these nine evaluations, only two have been randomised controlled trials and none has been published in peer-reviewed journals to date. Results from a cluster randomised controlled trial (CRCT) reported in a poster presentation and conducted in Manitoba has reported reduced aggression (both physical and indirect) and increased prosocial behaviour and that these benefits were maintained across a three year follow-up period.[23] The primary outcomes assessed in the Manitoba CRCT, with reported effect sizes consistent in magnitude with Durlak *et al.*'s meta-analysis, have been: physical aggression (effect size = -0.25), indirect aggression (effect size = -0.51) and prosocial behaviour (effect size = 0.21).[23]

Overall, therefore, given the high level of interest in ROE internationally and the commitments already being made across many parts of the UK and Ireland to pilot the programme, a robust and independent evaluation of the effectiveness and cost-effectiveness of the programme is extremely timely. Not only would it make a significant contribution to the international evidence base regarding ROE and primary school-based social and emotional wellbeing programmes more generally, but the evaluation would also be pivotal in informing directly the future policy priorities and public health investment decisions of the government in Northern Ireland and in other regions.

Risks and benefits

No risk to health or injury is envisaged in the proposed evaluation of ROE. Other forms of risk potentially associated with a CRCT will be minimised by several methods, including: only using trained, police-checked fieldworkers for data collection; not offering incentives to take part in the trial; and storing data under strict data protection guidelines. Control group subjects are not being placed under any educational disadvantage due to the randomisation process as the study will be an add-on to the existing Personal Development and Mutual Understanding (PDMU) curriculum that all children in Northern Ireland receive. Expected benefits of participating in the research are anticipated improvements in the predicted outcomes described below.

Finally, given the strong interest that has already emerged within the UK and Ireland regarding ROE, one significant risk associated with *not* undertaking this proposed independent evaluation is that it may lead to a programme being extensively rolled out with very little robust evidence of its effectiveness in improving young children's social and emotional wellbeing. This, in turn, could represent a considerable opportunity cost associated with schools not being able to deliver alternative programmes that may have been effective.

3. Need:

Rationale for current study

There is a growing consensus in academic and policy circles regarding the importance of attending to young children's social and emotional wellbeing. There is substantial evidence that links early socio-emotional development to later academic performance[1] and a number of key health outcomes, such as stress and mental

health.[2] Deficits in basic skills, such as the ability to identify emotions, tend to have wide ranging implications, including being rejected by others and excluded from peer activities and being victimised.[3] Such deficits are also related to lower peer-rated popularity and teacher-rated social competence.[4,5] Chronic physical aggression during primary school also increases the risk of violence and delinquency through adolescence in boys.[6,7] In turn this can lead to destructive forms of emotion management, such as alcohol abuse.

In recognition of this, a comprehensive set of public health guidelines were published by NICE in 2008 aimed at encouraging the promotion of social and emotional wellbeing in primary school children.[8] According to the guidelines, child wellbeing is not only important in it's own right but can also be a determinant of success in school and physical health. The guidelines recommend that schools must create an ethos that supports positive behaviours for learning and successful relationships, provide an emotionally secure and safe environment that protects against bullying and violence and which offer teachers and practitioners the support they need in developing children's social and emotional wellbeing.

However, perhaps the most significant recent development has been the publication of the Marmot Review in England.[9] At the heart of the Review's key recommendations is the policy objective of giving every child the best start in life. Of the six policy objectives identified by the Review, this was held up as its 'highest policy recommendation' and reflected the Review's life course perspective. Alongside a call to increase the proportion of overall expenditure allocated to the early years, the Review also placed an emphasis on reducing inequalities in the early development of physical and emotional health and cognitive, linguistic and social skills and thus building resilience and well-being among young children. This should be done, according to the Marmot Review, through investment in 'high quality maternity services, parenting programmes, childcare and early years education to meet need across the social gradient.'[9(p.16)]

A second, linked policy objective identified by the Review is to enable all children, young people and adults to maximise their capabilities and have control over their lives. This, in turn, should be achieved by ensuring that schools, families and communities work in partnership to improve health, well-being and resilience. Among some of the key recommendations made in this regard is the need to prioritise developing the capacity of schools to address and improve children's 'social and emotional development, physical and mental health and well-being.'[9(p.18)]

4. Methods:

a. Setting

All primary schools located in the four participating Health and Social Care Trust areas will be eligible to volunteer to participate in the trial except for: Special Schools; schools with Year 5 (aged 8-9) classes that have less that 10 children; and schools already implementing the ROE programme. All children who are entering Year 5 (aged 8-9) at baseline in the participating schools will be included. If a school has more than one Year 5 class, then one will be selected at random. The mean number of eligible pupils per school is estimated to be 33. Children will be followed up annually for three years until the end of their first year in secondary school (aged 11-12).

b. Design

Cluster randomised controlled trial

The study will be a cluster randomised controlled trial (see flow diagram, Appendix 2). The trial will be undertaken in four of the five Health and Social Care Trust areas in Northern Ireland. A total of 70 primary schools will participate in the trial and each Trust will be responsible for recruiting a specific number (20 in the South Eastern Trust; 20 in the Belfast Trust; and 30 from the Southern and Western Trust areas combined). Where there are parallel classes in any specific school, one Year 5 class (8-9 year olds) will be randomly selected from these to take part in the trial.

Once recruited, simple random selection will be undertaken within each of the three Trust strata such that: 10 primary schools will be randomly selected to be part of the intervention group in the South Eastern Trust area from the 20 recruited; 10 schools will be similarly randomly selected to join the intervention group from the 20 schools recruited in the Belfast Trust area; and 15 schools randomly selected from the 30 schools recruited in the combined Southern and Western Trust areas. Randomisation will be carried out independently by the Clinical Research Support Centre, a Trials Unit centrally funded by the Northern Ireland HSC R&D Office.

The 35 schools randomly allocated to the intervention group will then receive the ROE programme in their selected Year 5 class for one academic year (2011/12). The remaining 35 schools in the control group will not receive the ROE programme but will continue with the regular curriculum and usual classroom activity. The control group will be placed on a waiting list to receive the programme the following year, but on the understanding that ROE is not delivered to their current Year 5 cohort as they progress through Years 6 and 7.

Initial pre-test data from the children, parents and teachers will be gathered in October 2011 across all 70 participating schools prior to the first sessions of ROE being delivered in the 35 intervention schools. The first post-test data will be collected in June 2012 and then follow-up data will be gathered from the same children in June 2013, June 2014 and June 2015 (when they will be 11-12 years of age and at the end of their first year in secondary school).

Socio-economic position and inequalities

The proposed trial will take the participating parents' and children's socio-economic position into account in two ways. In relation to data collection, fieldworkers will visit the participating schools to explain the nature of the research face-to-face with parents and to increase parental consent rates, especially for those parents from low socio-economic backgrounds. A fieldworker will also be present with each class teacher during the administration of questionnaires to children. For those children with poor literacy skills, they will be aided in completing the questionnaires both by the practice of reading each question out aloud and also, where necessary, by direct support from the fieldworker. A record will be kept of all instances where such individual assistance was required.

Alongside data collection, socio-economic position will also be taken into account during the analysis phase. While ROE is a universal programme, this proposed trial will seek explicitly to explore whether there is a differential impact of the intervention according to the socio-economic status of the children's family background. Aside from knowledge of free school meal entitlement, each child's home postcode will be collected from the school and this will be used to assign a measure of deprivation using the Northern Ireland Statistics and Research Agency's Multiple Deprivation Measure 2010 which is the official measure of spatial deprivation in Northern Ireland.[26]

Planned interventions

The main features of the planned intervention – ROE – have been described above.

The control group will not receive the ROE programme between October 2011 and June 2012. Instead they will continue with usual classroom activities and practice. In this regard, all schools in Northern Ireland, as part of the statutory requirements of the Revised Curriculum, deliver Personal Development and Mutual Understanding (PDMU). The developers of the curriculum, CCEA (Council for the Curriculum, Examinations and Assessment), describe PDMU as: 'Encouraging each child to become personally, emotionally, socially and physically effective to lead healthy, safe and fulfilled lives and to become confident, independent and responsible citizens, making informed and responsible choices and decisions throughout their lives.'PDMU is delivered using active and participatory learning methods, follows an issues-based approach and aims to explore pupils' and society's attitudes and beliefs.This evaluation will therefore examine the effect of Roots of Empathy above and beyond any effects of the PDMU part of the curriculum, which is also focused on the social and emotional development of the child.

Control schools will be offered the ROE programme the following year for their 8-9 year olds. The control schools will, however, be required not to deliver the programme to children participating in the trial, who move into Years 6 and 7, to avoid their exposure to the intervention.

As regards loss-to-follow-up, the intervention is delivered in the school setting and the data collection will also take place in the school setting. This minimizes likely loss-to-follow-up unless children move out of the area and cannot be traced. Should a child be absent on the day of data collection the researcher will arrange to return to the school at a later date to collect the data from any absentees. The research team's experience of conducting large-scale cluster randomized controlled trials in a school setting suggests typical attrition rates of less than 8% per year.

Information will be collected from all participating schools on what additional programmes and initiatives they run in their school that might impact on children's socio-emotional development.

Proposed sample size

Previous evaluations of ROE together with the wider meta-analysis of socio-emotional learning programmes, suggest effects will range in magnitude between d=.22 and .57. For the primary outcome measure (SDQ), typical ICCs have been found to range between .05 and .15. With the inclusion of the relevant pre-test scores and other covariates, it is also reasonable to assume that the multi-level models used to estimate the effect sizes of the intervention will be able to account for approximately 20% of the variation in post-test outcome scores.

With these assumptions, it is estimated that for the proposed trial to be able to detect the lower bound anticipated effect size of d=.22 with between 85% power (for ICC=.05) and 60% power (for ICC=.15), a sample size of 630 children per arm would be required (1,260 in total). For the highest estimate of ICC=.15, the trial would achieve sufficient power (80%) for effects of d=.28 or above. These estimates have been calculated using Optimal Design (Version 2.0).

The proposed sample will consist of 70 classes in 70 primary schools. With an average class size of 33 children, anticipated initial recruitment rate of 75% and an 8% attrition rate per year, for three years from baseline, this gives an estimated average class size at the end of the trial of 18 children. With 35 classes in each arm of the trial, this gives 630 children per arm or 1,260 in total.

c. Data collection

Proposed outcome measures

The primary child outcomes for ROE are increases in prosocial behaviour and decreases in aggressive behaviour. These outcomes will be measured using the Strengths and Difficulties Questionnaire (SDQ). There are three versions of the SDQ: parent, teacher and child and all three versions will be used to triangulate the data. The teacher and parent versions will be administered to teachers and parents at every data collection sweep. The child version is only suitable for administration with children aged 11 and above and so this version will be used in the final two data sweeps (Jun14 and Jun15).

The secondary outcomes are derived from the logic model (see Appendix) and largely reflect the key precursors expected to lead, in turn, to behavioural change. The exceptions to this are quality of life and educational attainment where improvements in these are likely to flow from improved behavioural change. All outcomes are detailed in Table 1 and this combination of measures has been piloted successfully with children and teachers (see below).

Alongside being asked to complete the SDQ for each child in their class, teachers will be asked to record and provide data on detention rates and misconduct referrals. Similarly, each parent will be asked to provide additional contextual information alongside completing the SDQ for their child. This information will consist of their: postcode; family composition, including the number of siblings; highest parental education qualifications achieved; and parental occupations.

Table 1. Outcomes and measures

Outcomes	*Measures*
1. Increase in understanding of infant crying	Infant Facial Expression of Emotions Scale
2. Increase in ability to recognise emotions	Emotional Recognition Questionnaire
3. Increase in empathy	Interpersonal Reactivity Index
4. Increase in ability to regulate emotions	Child Anger Management Scale
5. Increase inprosocial behaviour	SDQ
6. Decrease in aggressive behaviour	SDQ; Child Behaviour Scale; Olweus bully/victim questionnaire; class detention rates
7. Increased quality of life	CHU 9D
8. Increased educational attainment	InCAS standardised maths and English scores that all schools in Northern Ireland now collect

Assessment and follow up

Assessment of efficacy/effectiveness

All children will be tested on the outcome measures at baseline (pre-test) and at the end of the nine month programme (post-test) and subsequently followed up at 12, 24 and 36 months post-intervention using the same measures. During each data sweep, parents will be sent the SDQ to complete via the school and, on the first occasion, the questionnaire will include a small number of additional questions to gather information on the child's family background (see above). Parents will be given the option of returning the questionnaire in a sealed envelope to the school or returning it directly to the research team via a freepost envelope. Teachers will be asked to complete the teacher version of the SDQ for each participating pupil.

In addition to the main outcomes described above, data will also be collected on programme delivery and fidelity across all 35 intervention schools as well as data on activities undertaken across all 70 schools (intervention and control) regarding other specific activities and programmes they undertake that include a socio-emotional focus and that are delivered either as part of the PDMU aspect of the Northern Ireland curriculum or separately and in addition to this.

Finally, qualitative case studies will be conducted in six of the 35 intervention schools to track the experiences and perspectives of the children, parents and teachers and to study the actual implementation of the programme. The schools will be selected purposively to represent different Trust areas and to include a mix of urban/rural schools and schools of different sizes and with different catchment areas in terms of socio-economic background. The case studies will run for the whole of the intervention year (2011/12) and involve three waves of visits to each school. The first will be immediately prior to the commencement of the programme, the next will occur during the programme year and the final wave will occur following completion of the programme.

During the first and last waves, semi-structured interviews will be conducted with all of the class teachers, school principals, ROE instructors and four parents from each school. In addition, two focus group discussions from each of the case study schools will be undertaken (12 in total). In each school, one group will be all boys and the other all girls and the children will be randomly selected from their respective classes. In addition, between three to five individual semi-structured interviews will be undertaken with specific children purposively selected to represent a range of observed responses to the programme (from resistance/non-response to active engagement).

During the middle wave of visits, the same number of interviews and focus groups will be undertaken, roughly mid-way through programme delivery, and classroom observations conducted of between four and five ROE lessons per school. Observational visits will be selected to ensure that all 27 lessons are observed from a variety of different schools. All data will be transcribed verbatim (in the case of interviews) or written up in detail (in the case of observational fieldnotes and other secondary source data). These data will then be analysed systematically and thematically using the software package MAXQDA 10. It is likely that this number of focus groups will be sufficient to ensure no new themes are emerging. If, however, saturation of ideas and opinions is not reached at this stage, further groups would be conducted as necessary.

Assessment of harms
Based on the reports of previous evaluations of ROE and also on the findings of the Northern Ireland pilot study, adverse effects on children, parents or teachers are not anticipated. However, close contact will be maintained with the ROE instructors and class teachers of each of the 35 intervention schools for the duration of the intervention year. They will be asked explicitly to report any potential harm or adverse effect of the programme as soon as they become aware of it.

d. Data analysis

Outcomes analysis
The initial characteristics of the intervention and control groups will be compared at baseline (Oct 11) in relation to their core characteristics (gender, highest education qualifications of parents, parental occupations, deprivation scores) and mean scores on the main outcomes.

At the end of each year from baseline testing (Jun12, 13, 14 and 15), the effects of the intervention will be estimated using multilevel modelling to take account of the clustering of the data, with children (level 1) clustered within classrooms/schools (level 2). As only one classroom per school will participate in the trial, it is not possible to distinguish between classroom- and school-level effects. A series of models will be estimated for each outcome measure at each follow-up data sweep. For each model, the relevant outcome measure at that data sweep will form the dependent variable and a number of independent variables will be added including: a dummy variable representing whether the child was a member of the intervention or control group (coded '1' and '0' respectively); the children's baseline pre-test scores for the outcome variable in question and a series of other covariates representing the children's core characteristics and pre-test scores on the other outcome measures. The main focus for the analysis will be the estimated coefficient associated with the dummy variable that represents the difference in mean scores on the respective outcome variable between the intervention and control groups, once pre-test scores and other differences at baseline have been controlled for. This coefficient will then be used to estimate the effect size of the programme in relation to the respective outcome variable as the standardised mean difference between the two groups (Hedges' g).

In addition to this analysis of the main effects, each model will be extended through the inclusion of higher order interaction effects involving the relevant covariate in the model to test for any subgroup differences in the effects of the programme between: boys and girls; children with differing numbers of siblings; and the child's familial socio-economic background. These analyses will be exploratory in nature and any subgroup differences found will be reported cautiously given the nature of the multiple testing involved and that such tests will also be underpowered. Also, because it is not possible to conduct a blinded RCT, among the sensitivity analyses planned, it will be investigated whether the effect size varies according to whether the teacher, parent or child based SDQ scores are used and the how it is affected by imputation for missing values.

In relation to assessing the external validity of the findings arising from the trial, propensity scores will be used to compare the characteristics of trial participants with the population as a whole in Northern Ireland, using available child- and school-level data. A method proposed by Stuart *et al*. will be used to calculate the propensity score distance between trial participants and the target population and thus a quantitative indicator of how generalizable the findings of the trial are to the target population.[27] In line with Stuart *et al*., these propensity scores will also be used as the basis for a diagnostic test to ascertain whether a weighting method can be employed, using the scores, to generalise the results to the target population.

Cost-effectiveness analysis

In addition, a cost-effectiveness analysis will be undertaken to compare the costs and outcomes associated with ROE to those associated with usual education at two time-points. The initial analysis will be based on the costs and outcomes measured within the study period, while the second analysis will project the likely longer term impacts associated with ROE. Both analyses will be conducted from a public sector perspective incorporating costs on NHS, personal social services, educational services and the judicial system. In addition, a sensitivity analysis will be undertaken to explore the potential importance of any personal costs to the family.

Measurement of resource use will include resources employed to provide the programme, plus children's use of health, social, and special educational services. National costs will be applied to these services, drawn from a number of published

sources including Unit Costs of Health and Social Care and NHS reference costs. Additional out of pocket costs incurred by the child's family will also be collected for use in the sensitivity analysis.

For the initial within study analysis, the outcome measures used will be (a) changes in the average SDQ conduct problems subscale scores; and (b) a within study measure of QALYs determined from CHU 9D (a generic preference based measure of health related quality of life developed exclusively with children for use in children aged 7-11[28]). QALYs will be adjusted for any imbalances between arms at baseline using the area under the curve method.[29] Thus, the initial analysis will present an estimate of cost-effectiveness of the intervention in terms of costs associated with preventing aggressive behaviour and cost/QALY gained. The uncertainty surrounding the estimates of cost and effects for ROE and usual education will be investigated through the use of bootstrapping.[30]This approach employs re-sampling techniques to generate a distribution of estimators; in this case the distribution of mean costs and mean outcomes for each treatment. This will provide an estimate of the extent of uncertainty surrounding the costs and effects individually and will be presented graphically on the cost-effectiveness plane using cost-effectiveness acceptability curves. In a sensitivity analysis we will compare subgroups and assess the uncertainty in their ICERs by plotting the associated cost effectiveness acceptability curves.

The longer term analysis will employ a decision model, populated with reference to the literature, to link short term study outcomes to longer term impacts on health and wellbeing. The model structure will be informed by a review of other models undertaken in this area, including the modelling work undertaken for NICE in 2008[31] and in consultation with project collaborators. Data will be embodied in the model through the specification of probability distributions for each parameter, to reflect the uncertainty. Probabilistic sensitivity analysis will be undertaken, using Monte Carlo simulation techniques, to investigate the uncertainty surrounding the longer-term estimates of costs, effects and cost-effectiveness for ROE and usual education. The outputs reported from the analysis will be the same as those reported for the within study analysis. As a further sensitivity analysis, the external validity of the ICERs will be checked by comparing the profile of trial participants (e.g. SDQ and socioeconomic distributions) with the profile of children in the pilot and with children who did not consent participate in the trial. [32]

5. Contribution of existing research:

Pilot study

In the current school year (2010/11), ROE has been delivered in 30 primary schools within the Belfast and also South Eastern Health and Social Care Trust areas in Northern Ireland. This year has been used by the research team as a confirmatory pilot study with the aims of: assessing the feasibility of programme implementation in Northern Ireland; assessing the recruitment process of schools and children to a trial; and pilot testing outcome measures and data collection processes.

Firstly, in relation to the feasibility of programme implementation, ROE was found to have been successfully delivered with high fidelity, as measured by the delivery of lessons as per the ROE manual, in the 30 pilot schools. A total of 28 instructors across the two Trusts were recruited and trained to deliver the programme in classrooms. Nearly all of these instructors were female (with only two male instructors). Just over half of instructors came from within the school, either as classroom assistants or teachers, with the remaining instructors recruited from outside the school in allied occupations such as community work or health development officers.

The delivery process was studied through qualitative case studies of a sample of five of the primary schools that were selected purposively. Each case study included a series of repeat semi-structured interviews during the delivery period with the programme coordinators, class teachers and instructors as well as observations of ROE sessions and informal discussions with the children. One-to-one semi-structured interviews were conducted with a variety of pilot trial participants and these were transcribed verbatim and analysed thematically using MAXQDA. The feedback from the programme coordinators from the two Trusts has been very positive. All coordinators reported no difficulties in bringing schools, mothers and babies or instructors on board. Overall, the interviews with the coordinators disclosed a strong sense of engagement and supportiveness for the project both from schools, teachers, and the instructors; sentiments which were echoed, without exception, in interviews with the instructors and teachers themselves. Instructors had been made to feel welcome in the school and had been both helped and supported by the class teacher. However, one issue that all interviewees appeared to agree upon was the varied level of interest and awareness of the programme from the parents. This issue of parental awareness and involvement will therefore be examined in greater detail in the proposed CRCT.

Secondly, in relation to the recruitment process, parental consent was sought during the pilot study on an opt-in basis. An overall response rate of 61% was achieved (72% in the intervention group and 48% in the control group). This rate is comparable to other studies where, for example, a recent review of 500 studies that reported consent data found that active consent studies achieved a mean rate of 65%[24]. Nevertheless, such a response rate is a matter of concern. It is with this in mind that the Centre for Effective Education has been exploring differing methods for increasing parental consent. A multi-armed strategy combining reminder letters, active teacher involvement and fieldworkers visiting schools to meet parents at the morning and the end of the day has been found to be particularly effective. In a recently completed randomised trial of a volunteer mentoring scheme in 50 primary schools involving children of the same age, this strategy resulted in an overall response rate of 94%[25]. Another trial that is currently ongoing, involving an evaluation of the book-gifting programme, Booktime, among 4-5 year olds in 30 primary schools, has achieved an overall response rate of 76%. While limited resources meant that such an approach, specifically in relation to the use of fieldworkers attending schools, was not possible in the ROE pilot, it is one that will be used in the proposed trial. In this regard, an anticipated response rate of 75% represents a conservative estimate for the proposed trial.

As regards the recruitment of schools, the South Eastern Trust has already received expressions of interest from 26 additional schools to take part in the trial and the Belfast Trust has received the same from 15 schools. Both Trusts have a target of recruiting 20 schools each (see the flow diagram, Appendix 2). The Southern and Western Trusts have only recently agreed to join the proposed trial and will begin recruiting schools in time for the new academic year, working to a combined target of 30 schools. This will coincide with a regional visit by the ROE programme developer, Mary Gordon, whose previous visit and talks to schools in the Belfast and South Eastern Trust areas generated significant interest among schools. It is expected the same will occur again as a result of her talks to schools in the Southern and Western Trust areas. Given the active support that the Public Health Agency, it is thus expected that the target of recruiting 70 schools for the trial will be met by the end of this summer term (Jul 11), ready for the trial to commence in the Autumn term (Oct 11).

Thirdly, and finally, the pilot study found no problems in the collection of data from children or from teachers in relation to the outcome measures proposed for the full trial and as detailed below. For the children, data will be gathered through a self-completion questionnaire that will be administered to the whole class. For the pilot, trained fieldworkers visited each participating school and administered the questionnaire to the class as a group. Children were asked not to confer and this was ensured by the fieldworker and the class teacher. Each question was read aloud to the class and any words/phrases that were difficult were explained. Depending on the ability level of the group, testing took between 30 and 40 minutes. Similarly, teachers were asked to complete the Strengths and Difficulties Questionnaire (SDQ) for a sample of the children in their class. While teachers reported no problems using the SDQ, a number of them did raise the issue of the time required to do this for a whole class (equivalent to one full day). It is with this in mind that costs have been included to enable schools to use supply teachers to release their respective class teachers for one day during each of the data collection sweeps.

Alongside collecting outcome data directly from the children and teachers, attempts were made in the pilot to collect observational data of children's behaviour in classrooms. However, the measures used were found to be much too intrusive in the classroom and proved not to be reliable. Indeed feedback from the pilot study showed that all children exhibited prosocial or on-task behaviour during the observation visits suggesting that the measure is likely to be skewed towards positive behaviours. School principals and teachers also found this measure to be controversial, suggesting that there would be difficulties in incorporating this in the trial in a meaningful way.

6. Plan of Investigation:

Ethical arrangements
This study will conform fully to the ESRC's Framework for Research Ethics and will receive a full ethics review by the School of Education Research Ethics Committee, Queen's University Belfast.

Informed consent
Both parent and child consent will be sought. The consent process to participate in the evaluation will be undertaken by the research team and will remain separate from the consent process to participate in the Roots of Empathy programme, which will remain the responsibility of the Health and Social Care (HSC) Trusts implementing the ROE programme.

In relation to parental consent, an information sheet and consent form will be sent home to the parent(s)/guardian(s) of all Year 5 children via the school. The information Sheet will outline to parents in plain English that their child's school is taking part in an independent evaluation of the ROE programme and that the purpose of the evaluation is to determine how effective the programme is in improving children's behaviour, increasing their empathy for others and decreasing any aggressive behaviours. All of the key details of the trial design will be explained as will the precise nature of the commitments required of the parents and their children in relation to data collection and follow-up. It will also be explained that additional data will be collected from the schools (regarding postcodes and InCAS scores). The normal reassurances will be given regarding the secure storage of anonymised data, ensuring anonymity and confidentiality in all published reports from the study. The information sheet will contain the contact details of the research team should the parent have any further questions they wish to ask.

Once parental consent has been secured, the children's written consent will also be sought. The questionnaires will be administered on a group basis, within each participating school, to those children for whom parental consent has been secured. Prior to administering the questionnaire, the researcher will verbally explain the purpose of the study to the group of children before data collection and tell them that they do not have to take part if they do not want to; even if their parents have said they can. Children will be given the opportunity to ask questions and will be asked to sign a consent form included at the front of the questionnaire that summarises in a clear and simple way the key details of the study and what is required of the children that will have been explained verbally. They will be given a duplicate of the consent form which will also contain the details of the researcher should they wish to ask any further questions about the study.

Data analysis, storage, archiving and reporting of findings

A Data Monitoring and Ethics Committee will meet flexibly but at least annually, 2-3 months after each data collection sweep. In accordance with good practice[33] a DMEC Charter will be drafted before the study commences, specifying its membership and modus operandi. It will be chaired by a member of the Northern Ireland government's Department for Education, and will also be served by an independent statistician from the Clinical Research Support Centre (CRSC) in Northern Ireland and a senior non-executive member of the Public Health Agency. The Charter will detail the organization of meetings, the relationships between members and with the Trial Steering Committee, trial documentation and measures to ensure confidentiality, decision-making processes and formal reporting arrangements.

All data gathered as part of the trial will be stored in line with the requirements of the Data Protection Act. It will be stored securely and anonymously as set out in the descriptions of the information sheets provided above. An anonymised dataset will be submitted to the UK Data Archive to be made available for secondary analysis. Prior to submitting the dataset, relevant contextual data will be carefully assessed, and specific variables removed where necessary, to ensure that no individual child or school can be identified from the data provided.

Possible unintended consequences

While maximising parental consent is important, undue pressure should not be applied to parents. The proposed system described earlier of a multi-arm strategy involving follow-up letters, actions from the respective class teachers and fieldworkers visiting the schools, will be undertaken carefully and sensitively to ensure that parents do not feel pressurised or obliged to provide consent and/or to complete the questionnaires they are sent at each data sweep.

Similar care and sensitivity will be applied to the children when asking for their initial consent and then their cooperation in completing questionnaires during successive data sweeps. In addition, there is the potential risk that those children for whom parental consent has not been secured may feel marginalised or excluded from the process. As such, the organisation of data collection will be undertaken carefully to reduce this risk and separate activities for those children who are not participating in the trial will be arranged with the school.

As outlined earlier, on the basis of previous evaluations of ROE and also of the findings from the piloting of the programme in Northern Ireland, it is not anticipated that the trial will have any harmful effects on the children, parents or teachers. However, the progress of the trial will be carefully monitored through close contact with the ROE instructors and class teachers who will be asked to report any potentially harmful effects immediately to the research team.

Research governance

Sponsor

Queen's University Belfast will be the sponsor of this trial. As with all research involving human subjects, the University has clear and rigorous procedures in place for considering and granting ethical approval of research studies and for agreeing contracts, monitoring expenditure and preparing financial reports. Within these procedures, the lead applicant will assume the roles and responsibilities of Principal Investigator as described below.

Trial Steering Committee

The delivery of the ROE programme represents a key element of a wider public health strategy aimed at children and young people being led regionally by the Public Health Agency in Northern Ireland and in partnership with other key departments and agencies. This strategy is being taken forward by a central Child Development Project Board and with five Work Strands with responsibility for different elements of the strategy and reporting to the Board.

Given the importance of the ROE programme to the overall regional strategy, one of these Work Strands – the Roots of Empathy Project Group – has been tasked with promoting collaborative working and driving forward action to ensure the effective delivery of the ROE programme. The Group meets monthly and has agreed the following terms of reference:

1. Support the introduction and delivery of Roots of Empathy programme in Northern Ireland
2. Facilitate engagement with local delivery partners to secure overall regional delivery
3. Ensure that strategic and policy stakeholders are both informed and active in the development of the programme to regional level.
4. Develop a regional project plan that anticipates and supports the development of ROE to scale
5. Address the legal, research, quality standard and sustainability issues associated with the development of Roots of Empathy to a regional level
6. Develop appropriate communication pathways as part of the Roots of Empathy Project Plan

It has been agreed that this Group will also assume the role of Trial Steering Committee for this proposed study; ensuring that the trial will be closely coordinated with, and effectively feeds into, regional policy making and planning regarding ROE the wider public health strategy. The Group includes representatives from each of the five Health and Social Care Trusts with operational responsibility for the delivery of the ROE programme, together with representatives from the Department of Education, the Council for Catholic Maintained Schools (CCMS) and the Education and Library Boards. The lead applicant is also a member of the Group, as well as being on the parallel Research Work Strand and a member of the overarching Child Development Project Board.

Project timetable and milestones

Milestone	*Start Date*	*End Date*
Project set-up (milestones to be achieved prior to the commencement of funding for the proposed trial): • Recruitment of 70 schools by the four H&SC Trusts • Ethical approval granted for the trial	1 Oct 2010 9 May 2011	1 Jul 2011 29 Jul 2011
• Parental consent gained from those in 70 schools • Finalise and print questionnaires • Train fieldworkers • Selection of six schools for qualitative case studies and additional consent gained from schools, teachers, parents and children	5 Sep 2011	26 Sep 2011
Pre-testing of children, parents and teachers	26 Sep 2011	21 Oct 2011
Qualitative case studies in the six selected schools taking place in three waves: 1. Pre-test interviews 2. Lesson observations and mid-term interviews (Jan-Feb) 3. Post-test interviews	26 Sep 2011 24 Oct 2011 4 Jun 2012	21 Oct 2011 8 Jun 2012 29 Jun 2012
Immediate post-testing of children, parents and teachers	4 Jun 2012	29 Jun 2012
Data entry, cleaning and analysis of trial and qualitative case study data. Preparation of first interim report	2 Jul 2012	30 Dec 2012
12 month follow-up testing of children, parents and teachers	3 Jun 2013	28 Jun 2013
Data entry, cleaning and analysis of additional trial data. Preparation of second interim report	1 Jul 2013	27 Sep 2013
24 month follow-up testing of children, parents and teachers	2 Jun 2014	27 Jun 2014
Data entry, cleaning and analysis of additional trial data. Preparation of third interim report	30 Jun 2014	26 Sep 2014
36 month follow-up testing of children, parents and teachers	1 Jun 2015	26 Jun 2015
Data entry, cleaning and analysis of additional trial data. Preparation of final report	29 Jun 2015	31 Dec 2015

7. Project Management:

Team members and contributions

Paul Connolly is Professor of Education and Director of the Centre for Effective Education, Queen's University Belfast. He is founding editor of *Effective Education* (Routledge) and Co-Chair of the Campbell Collaboration Education Coordinating Group. He has experience directing a number of large-scale randomized trials in schools in Northern Ireland. He will assume overall responsibility for leadership of the research team and strategic direction and delivery of the project. (www.qub.ac.uk/schools/SchoolofEducation/Staff/Academic/ProfPaulConnolly)

Frank Kee is Professor of Public Health and Director of UKCRC Centre of Excellence for Public Health at Queen's University Belfast. He has doctoral level training in epidemiology, and training in mathematics, statistics and health economics. He has experience of directing several large public health community level intervention projects. He will be responsible for advising on the design, conduct and analysis of the trial and providing public health expertise. (coe.qub.ac.uk/index.php?option=com_content&view=article&catid=52:principal-investigators&id=63:kee-frank)

Martin Bland is Professor of Health Statistics at the University of York. He has expertise in health statistics and epidemiology and a particular research interest in the design and analysis of cluster randomized trials. He will be responsible for advising on the design, conduct and analysis of the trial and providing statistical expertise. (www-users.york.ac.uk/~mb55)

Harry Rafferty is Senior Lecturer in Educational Psychology at Queen's University Belfast. He is also Senior Education Psychologist for the South-Eastern Education and Library Board in Northern Ireland. He will be responsible for advising on the design, conduct and analysis of the trial and providing expertise in educational psychology and particularly pupils' emotional, behavioural and social development. (www.psych.qub.ac.uk/Staff/staff.aspx?name=rafferty)

Elisabeth Fenwick is a health economist with experience in the application of economic evaluation to public and social health interventions as well as within health technology assessment. Her research includes a systematic review and economic model of the use of PET/CT for staging Colorectal Cancer, an evaluation of a primary care-based complex intervention to support patients with multiple morbidities and an economic evaluation of practice nurse health checks for people with learning disabilities. She will lead the health economics aspects of the study and supervise the health economics research fellow. (www.gla.ac.uk/researchinstitutes/healthwellbeing/staff/elisabethfenwick)

Sarah Miller is Lecturer in Quantitative Research Methods and Deputy Director of the Centre for Effective Education, Queen's University Belfast. She is a psychologist with expertise in managing large-scale school-based randomized controlled trials and psychometric measurement and assessment. She has particular expertise in the assessment of developmental outcomes in young children. She will assume the role of Trial Manager. (www.qub.ac.uk/schools/SchoolofEducation/Staff/Academic/DrSarahMiller)

Lisa Maguire is Research Fellow at the Centre for Effective Education, Queen's University Belfast. She is a psychologist with expertise coordinating data collection

and management across several large-scale cluster randomized trials. She will be responsible for coordinating data collection and data management for the trial. (www.qub.ac.uk/schools/SchoolofEducation/Staff/Research/DrLisaMaguire)

Supervisory arrangements
The research team will meet monthly for the duration of the trial. These meetings will be chaired by Connolly and will occur two weeks prior to each monthly meeting of the Trial Steering Committee to allow the production and pre-circulation of monthly progress reports. The two team members not based at Queen's University Belfast (Bland and Fenwick) will attend three of these meetings per year in person and will participate in the rest via conference call. The expert advice and support of these two members of the team, together with that of Kee and Rafferty, will be coordinated through team meetings where clear activities and tasks will be agreed and monitored.

The day-to-day conduct of the trial will be overseen by Miller, the Trial Manager. Miller will provide detailed reports to the monthly meetings of the research team and will also report directly to and attend weekly supervision meetings with the lead applicant, Connolly. Miller will liaise with key stakeholders and will also directly line manage Maguire and the additional Research Assistant to be appointed to undertake the qualitative case studies. Fenwick will assume responsibility for the economic effectiveness aspect of the study and will directly line manage the associated Research Fellow to be appointed at Glasgow University. Fenwick will provide monthly reports to the Research Team meetings and be ultimately responsible to the lead applicant, Connolly.

8. Service users/public involvement:

A User Group will be established to ensure the active engagement of members of the public in the conduct and dissemination of the trial. The User Group will consist of six parents, three class teachers and three school principals from schools involved in the delivery of the Roots of Empathy programme over this current pilot year (2010/11) in Northern Ireland. Members of the Group will be selected to represent different types of school and socio-economic backgrounds.

The User Group will be chaired by the lead applicant, Connolly, and will also be attended by the Trial Manager, Miller. It will meet twice-yearly for the duration of the study but members will also be consulted at other points during the year when required. The purpose of the User Group will be to consider interim findings as they emerge from the study and to help identify their practical significance and implications for the further delivery of the ROE programme. The User Group will also play an important role in helping plan a wider dissemination strategy, including a national dissemination seminar in Belfast and will read and comment on draft research summaries prepared for public circulation.

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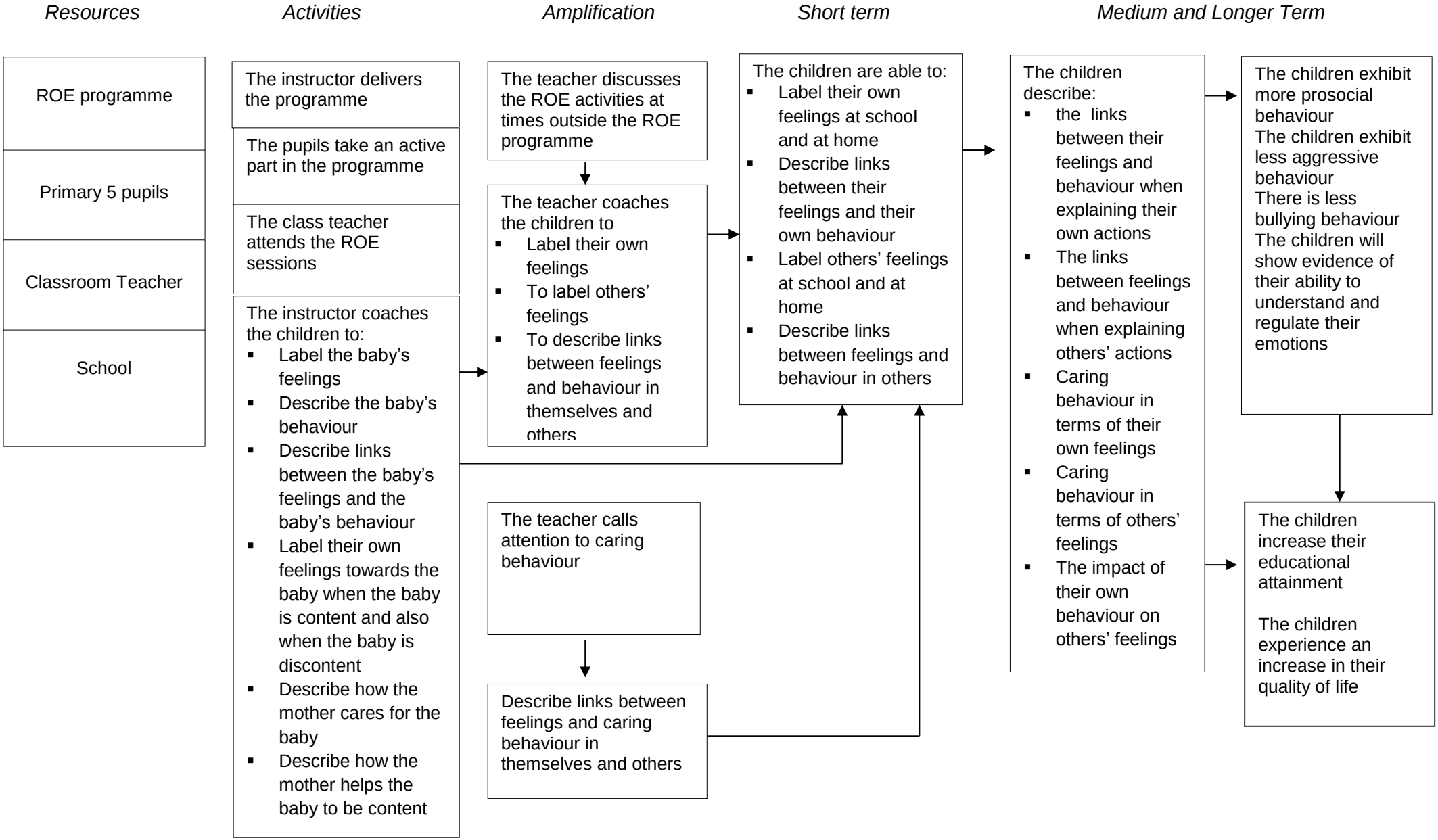
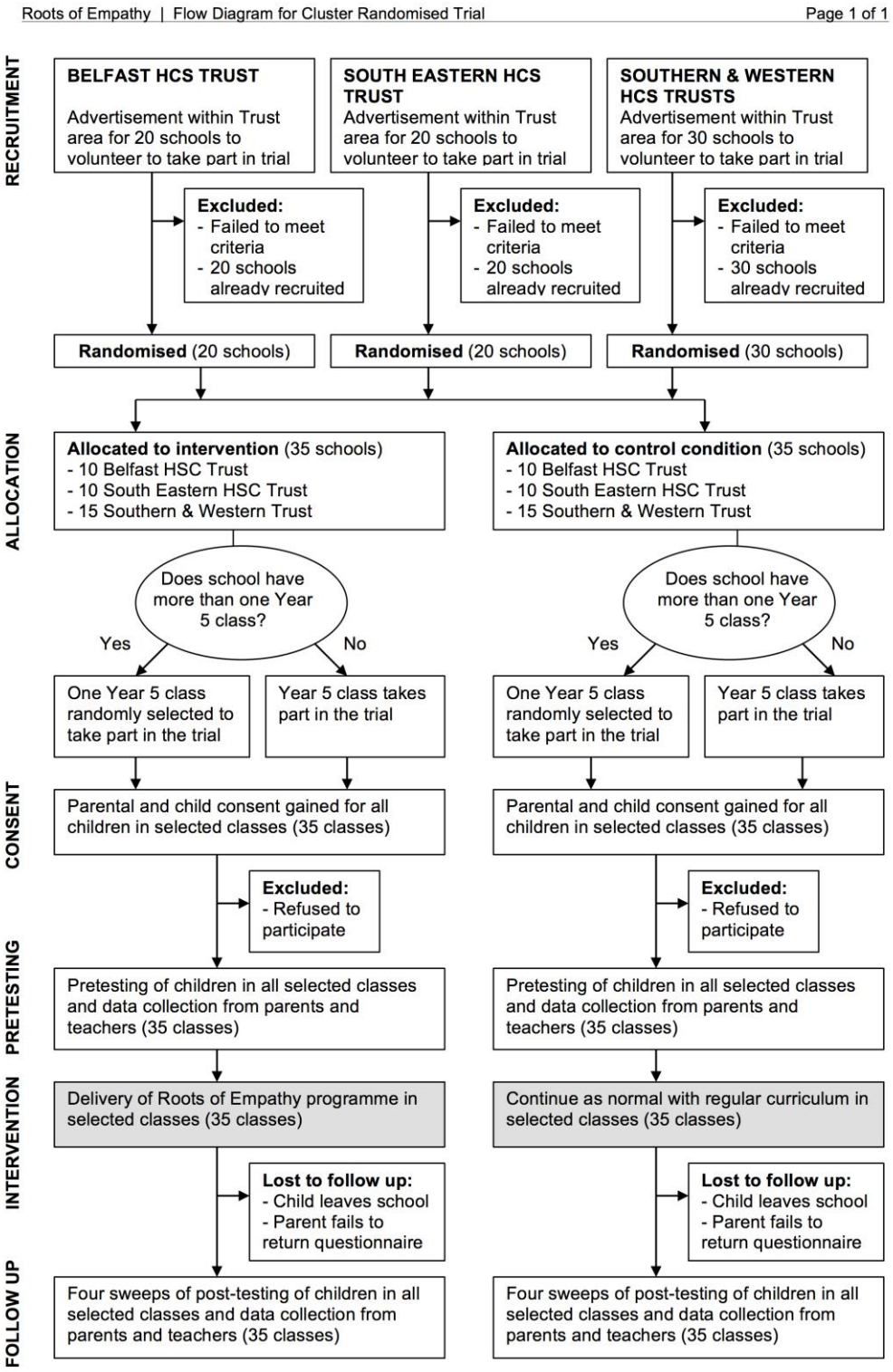
***Appendix 1* Logic Model for the Implementation of the Roots of Empathy Programme**



Appendix 2 Flow Diagram for Roots of Empathy Cluster Randomised Trial Evaluation



This protocol refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the PHR programme or the Department of Health.