

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

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Scientific summary

The Roots of Empathy schools-based programme

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Background

Children's early social and emotional development remains a significant predictor of future social, education and health outcomes, and there is substantial evidence linking early social and emotional development to later academic performance and a number of key health outcomes. The recent Marmot Review in England (Marmot M. *Fair Society, Healthy Lives: The Marmot Review. Strategic Review of Health Inequalities in England Post-2010*. Executive Summary. London: Department of Health; 2010) identified the policy objective of giving every child the best start in life as its 'highest policy recommendation' (p. 14), placing particular emphasis on reducing inequalities in the early development of physical, cognitive and non-cognitive skills. Among some of the key recommendations 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' (p. 18).

A substantial body of evidence now exists that suggests that well-designed school-based prevention programmes can be effective in improving a variety of social, health and academic outcomes. Roots of Empathy (ROE) is a universal school-based social and emotional learning (SEL) programme that has been developed and implemented in Canada, and has only recently been introduced into the UK. It is delivered on a whole-class basis for one academic year and consists of 27 lessons, which are based around a monthly classroom visit from an infant and volunteer parent (typically the mother) who are usually recruited from the local community. Children learn about the baby's growth and development through interactions and observations with the baby during these monthly visits. ROE is a mentalisation-based programme that aims to develop 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.

Several evaluations of ROE have been conducted to date and this report synthesises the findings from these. Of seven eligible studies, only one was a (cluster) randomised controlled trial. The pooled data from these studies suggest that ROE is effective in leading to small improvements in prosocial behaviour [standardised mean difference (SMD) 0.13] and reductions in aggressive behaviour (SMD –0.18). There is no evidence to suggest that it is effective in improving other SEL outcomes among children, in this case empathy and emotional regulation. Only one evaluation studied the longer-term impact of the programme, suggesting that after 3 years the intervention group had poorer prosocial behaviour than the control group [SMD –0.12, 95% confidence interval (CI) –0.17 to –0.07]. With respect to aggressive behaviour 3 years post intervention, the intervention group was displaying only slightly less aggressive behaviour than the control group (SMD –0.06, 95% CI –0.09 to –0.03) and, although statistically significant, this effect was greatly reduced from that observed immediately post test (SMD –0.25).

Objectives

Given the limited existing evidence base for ROE, the aims of the current evaluation are to:

- evaluate the immediate and longer-term impacts of ROE on social and emotional well-being outcomes among 8- to 9-year-old pupils
- evaluate the cost-effectiveness of the programme.

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

1. What is the impact of the programme post test, and up to 3 years following the end of the programme, on a number of specific social and emotional well-being outcomes 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 socioeconomic status and/or the socioeconomic 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?

Methods

This study consisted of a cluster randomised controlled trial, a qualitative process evaluation and a cost-effectiveness evaluation.

Sample

Seventy-four primary schools from four of the five trust areas in Northern Ireland were recruited to the trial between March and June 2011. All primary schools and their Year 5 cohort were eligible to take part in the study. Schools were randomly assigned to each of the intervention ($n = 37$) and control ($n = 37$) groups. The intervention schools received the ROE programme in their selected Year 5 class for one academic year (2011/12). The remaining schools in the waiting list control group continued with the regular curriculum and usual classroom activity.

Outcomes and measures

The primary child outcomes are increases in prosocial behaviour and decreases in difficult behaviour as measured by the teacher-rated version of the Strengths and Difficulties Questionnaire (SDQ). Additional data from alternative sources (parent- and child-rated SDQ) and alternative measures (teacher-rated Child Behaviour Scale) were collected in order to triangulate the data. Secondary outcomes included understanding of infant feelings (Infant Facial Expression of Emotions Scale), recognition of emotions (Emotion Recognition Questionnaire), empathy (Interpersonal Reactivity Index), emotional regulation (Child Anger Management Scale), bullying (Revised Olweus Bully/Victim Scale) and quality of life [Child Health Utility – 9D (CHU9D)]. The additional information was the parents' home postcode, the number/age of any siblings the child had, the parents' highest level of qualification and the parents' occupation.

Data collection

Initial pre-test data from the children, parents and teachers were collected in October 2011. The first post-test data were collected in June 2012 and data were collected again at 12, 24 and 36 months. Teachers were asked to complete a questionnaire for each participating child at each time point. Parents were contacted by post and asked to complete a questionnaire and return it to the research team in a Freepost envelope. Field workers administered questionnaires to the children on a whole-class basis.

Seven schools withdrew from the study before the start of the trial; however, retention rates were good overall, with 1182 pupils tested pre test and 902 (76.3%) remaining in the study at the final 3-year follow-up.

Cost-effectiveness analysis

The economic evaluation aimed to conduct:

1. a cost–utility analysis comparing the costs and utilities of the two groups over a 3.75-year period
2. a cost-effectiveness analysis comparing costs and effects between groups such as decreases in difficult behaviour and increases in prosocial behaviour as measured by the SDQ.

The base-case analysis compared the ROE intervention group with the usual classroom activities control group in terms of (1) costs incurred over the 3.75-year period and (2) quality-adjusted life-years (QALYs) gained over the 3.75-year period. Data were collected at five time points: pre test, post test, 12-month follow-up, 24-month follow-up and 36-month follow-up. A cost–utility analysis was undertaken, in which costs considered from a public sector perspective (2014 GBP) and health outcomes were measured by QALYs. Health utilities were measured using the CHU9D. All of the analyses were performed on individual patient-level data, taking clustering into account, and collected from the ROE trial.

Resource use was measured over the length of the trial and made up of the following data collection: (1) resource use resulting from the delivery of the intervention, (2) NHS resource use and (3) societal costs.

Process evaluation

A qualitative process evaluation was conducted alongside the trial to provide in-depth qualitative data on both the implementation and outcomes of the ROE programme. The delivery process of the programme was monitored and tracked across all schools, and a more detailed inquiry of underlying broad patterns outlined from across the schools was the focus of an in-depth case study approach conducted in six of the intervention schools. Interviews and focus groups were carried out with school personnel, local programme co-ordinators, volunteer mothers, children and parents. Observational classroom data were also collected.

Results

Immediately post test

After controlling for pre-test scores and clustering, children who participated in the ROE programme were rated by their teachers as more prosocial (effect size, $g = +0.20$; $p = 0.045$) and as exhibiting less difficult behaviour ($g = -0.16$; $p = 0.06$) than those in the control group.

With regard to the secondary outcomes, children who participated in the ROE programme were able to report a greater number of reasons why infants cry (effect size $g = +0.24$; $p = 0.01$). It is important to note, however, that part of the intervention involves explicitly teaching children about how infants communicate and why they cry, and it is conceivable, therefore, that this measure is biased in favour of the intervention group. Furthermore, the effect is small. No evidence of any differences between the groups was found in relation to the other secondary outcomes.

Prespecified subgroup analyses were undertaken to explore whether or not the programme worked better according to gender, socioeconomic background and number of siblings. No clear or consistent pattern emerged to suggest that there are underlying differential effects. The programme was found to have been uniformly delivered with high fidelity across all intervention schools. It was, therefore, not possible to assess the potential moderating effects of varying levels of fidelity on the outcomes achieved.

Effects at 12-, 24- and 36-month follow-up

The initially positive effects on prosocial behaviour were found to disappear at all subsequent time points. Moreover, there were no statistically significant differences in scores between those in the intervention group and those in the control group at any of the subsequent follow-up time points for any of the other outcome variables (at 12, 24 or 36 months post intervention). There also remained no clear or convincing pattern of any subgroup effects at any of these subsequent time points.

However, and in relation to total difficulties (as measured by the teacher-rated SDQ), the effect size immediately post test appears to have been maintained at the 12-month ($g = -0.14$), 24-month ($g = -0.13$) and 36-month ($g = -0.14$) follow-up time points. However, and because of the reduction in sample size owing to attrition, this effect is not statistically significant and so it needs to be treated with a degree of caution.

Sensitivity analysis

Multiple imputation was used to test whether or not attrition introduced any bias into the findings; however, the findings using the imputed data sets are broadly similar to those using just the observed data.

Cost-effectiveness analysis

Overall, it is estimated that the average cost of delivering ROE is £4057 per school and £175 per pupil. The incremental cost of delivering ROE was £153 (95% CI £14 to £292). The incremental QALY gain from ROE was 0.0160 (95% CI -0.0143 to 0.0462). Against generally accepted national guidelines, the findings of this present study suggest that ROE is a cost-effective intervention. In particular, the National Institute for Health and Care Excellence suggests that interventions costing the NHS < £20,000 per QALY gained are cost-effective. It also suggests that those costing between £20,000 and £30,000 per QALY gained may be cost-effective. For the present evaluation, the incremental cost-effectiveness ratio was £9571 per QALY gained (95% CI -£87,776 to £106,676). It was found that ROE had an 83.1% chance of being cost-effective at the £20,000 per QALY threshold and a 90.1% chance at the higher threshold of £30,000 per QALY.

Process evaluation

The ROE programme was delivered with high fidelity, with all lessons being delivered in all of the intervention schools. This was seen as being the result of the clearly defined structure of the programme and the strong training and ongoing support provided to ROE instructors in schools. The programme was also very well received overall and was felt to include good resources and be linked in closely with the Northern Ireland curriculum, particularly the element on personal development and mutual understanding. Five key issues emerged from the qualitative process evaluation:

1. A belief among some that it would be beneficial for ROE instructors to be teachers within the school to facilitate stronger communication and planning between the instructor and the class teacher.
2. A perception that the delivery of the programme in the first year may have been a little more challenging, especially for those schools where the ROE instructor was not a teacher within that school.
3. A concern regarding the resources required to deliver the ROE programme, especially if the ROE instructor is to be one of the teachers within the school, and whether or not it is sustainable in the longer term.
4. A concern that the ROE programme lasts for only 1 year and is not followed up in subsequent years. Additionally, and relatedly, there was a view among some that it would be worthwhile building the key knowledge and skills among children at an earlier age and before the ROE programme, with some mentioning the Seeds of Empathy programme.
5. The relative lack of involvement of or engagement with parents around the programme and how this may have been partly restricted because of the emphasis on maintaining fidelity to the existing programme.

Conclusions

First, this trial has provided strong and robust evidence that ROE did have a positive impact on children's behaviours in the directions expected immediately post test. More specifically, there is evidence that the programme enhanced children's prosocial behaviour and some evidence that it reduced difficult behaviour, above and beyond the typical effects associated with attending school.

Second, the trial has also provided clear evidence that, although ROE was originally developed in Canada, it is possible to deliver it extremely effectively and with fidelity in a different country and a different cultural context, in this case Northern Ireland.

Third, the trial found no evidence to support the hypothesised theory of change. It is not possible to conclude with certainty how ROE achieved positive behavioural effects without associated increases in social and emotional outcomes. However, it is clear from the qualitative process evaluation that the

children enjoyed the ROE lessons and that the lessons did, progressively, help to encourage the development of a collective sense of concern and caring for the baby, which may have resulted in a positive shift in the group norms (i.e. class norms) of prosocial behaviour. Peer groups play an important and influential role in the development of children's behaviour and attitudes, and they are an important social context within which individual development takes place. Further research is required to explore this possible explanation for behavioural change.

Fourth, the current ROE programme provides only limited opportunities to engage with parents. However, and as found through the process evaluation, there is significant interest among teachers and some parents for a greater degree of parental involvement in the programme. It is, therefore, recommended that consideration be given to incorporating greater parental involvement in the future.

Finally, the findings are not so positive in relation to the sustainability of initial gains in prosocial behaviour. In this respect, further work would be beneficial in terms of developing a more holistic and progressive curriculum that seeks to use evidence-based programmes such as ROE but in a way that is able to sustain and build on the short-term gains found in a developmentally appropriate way.

Trial registration

This trial is registered as ISRCTN07540423.

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