A proportionate, universal parenting programme to enhance social-emotional well-being in infants and toddlers in England: the E-SEE Steps RCT

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Scientific summary

The E-SEE Steps RCT

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Scientific summary

Background

Behavioural and mental disorders have become a public health crisis. Early prevention is key to prevent mental health issues in childhood and to mitigate the personal, familial and societal costs of related later negative outcomes. Evidence-based group parenting programmes are effective for parents of children aged ≥ 3 years; however, there is a lack of evidence for programmes for parents of children aged ≤ 2 years. A proportionate universal approach has been advocated to reduce the overall gradient of health inequality by offering support/services commensurate with individual/family level of need.

Two parenting programmes that aim to enhance child well-being and development are the Incredible Years® infant programme (IY-I) and the Incredible Years toddler programme (IY-T). These programmes were delivered and evaluated in a proportionate universal intervention model called Enhancing Social–Emotional Health and Well-being in the Early Years (E-SEE) Steps.

Objectives

- Does the E-SEE Steps model enhance child social and emotional well-being at 20 months of age when compared with services as usual (SAU)?
- Is the E-SEE Steps model cost-effective in enhancing child social and emotional well-being at 20 months when compared with SAU?
- Can the E-SEE Steps model be delivered as a proportionate universal model, and what are the organisational or systems-level barriers to and facilitators of delivering in this way, with fidelity?

Methods

Design

The design was informed by a large randomised pilot study, which involved two research sites, with over 200 families, and parent advisory committees. The trial was a pragmatic two-arm randomised controlled trial and economic appraisal, with an embedded process evaluation to examine the outcomes, implementation and cost-effectiveness of the intervention, and intervention uptake, plus three additional substudies.

Setting

The intervention was delivered in community settings by early years children's services and/or public health staff in four local authorities. Research sites had adequate birth rates to support the trial, were not offering the intervention as SAU and were willing to train staff to deliver the intervention.

Blinding

Data collectors, referrers, the chief investigator, the statistician (until final analysis), the Trial Steering Committee and the Trial Management Group were blind to participant allocation. Participants, Incredible Years leaders and some study team members, such as trial co-ordinators, were not blind.

Sample size calculation

Sample size was calculated on the child primary outcome of social and emotional well-being using the Ages and Stages Questionnaire: Social and Emotional, 2nd edition (ASQ:SE-2). We defined the clinically important difference at follow-up 3 (18 months post baseline) (FU3) to be 5 units on the ASQ:SE-2 for

the intervention arm when compared with SAU. Assuming a standard deviation of 18 units on the ASQ:SE-2 at FU3, the correlation between baseline and FU3 scores is 0.26, and between pairs of measurements after baseline is 0.40. For a design effect of 1.25 for the intervention arm, two-sided 5% significance level and 90% power, we would require the study to have retained 441 intervention participants and 92 control participants. Allowing for 12% overall attrition, the target was 606 randomised parents, with an allocation ratio of 5 : 1 to ensure that sufficient numbers of eligible parents were able to attend the group parenting programmes.

Participants

Inclusion criteria

Parents were eligible for inclusion if they consented to participate, had a child aged $\leq$ 8 weeks, were willing to be randomised and, if allocated to intervention, were able to receive the Incredible Years services offered.

Exclusion criteria

Parents whose child had obvious, or diagnosed, organic developmental difficulties or who were enrolled in another group parenting programme at sign-up were not eligible to participate.

Recruitment

Health visitors and family support workers invited families to hear more about the study. Those parents who consented were contacted by the research team. Researchers recruited parents and obtained informed consent during a home visit. Parents could also self-refer to the study and co-parents could participate in the study if the 'primary' parent invited them. Families received shopping vouchers of modest value, increasing at each data collection point.

Randomisation and allocation

Randomisation occurred following baseline data collection, using a web-based randomisation system. Parents were randomly allocated to the intervention or control arm in a 5 : 1 ratio stratified according to level of need at baseline based on the parent Patient Health Questionnaire-9 items (PHQ-9) score or child ASQ:SE-2 score, sex of child and parent, and research site.

Intervention

The E-SEE Steps model comprised a proportionate universal intervention model with three levels [one universal level (i.e. *The Incredible Years* baby book) and two targeted levels (i.e. IY-I and IY-T, which were 10 and 12 weeks long, respectively, with one 2-hour group session per week)]. Parents were offered the groups if they rated themselves as at least mildly depressed on the PHQ-9 or if they rated their child in the monitoring zone or above on the ASQ:SE-2. Within the E-SEE Steps model, four intervention 'doses' were possible for each family: (1) the book only, (2) the book plus IY-I, (3) the book plus IY-I plus IY-T and (4) the book plus IY-T.

Main outcome measures

Data were collected in the home by a researcher at four time points [baseline, follow-up 1 (2 months post baseline), follow-up 2 (9 months post baseline) and FU3].

Primary outcome

Child social and emotional well-being assessed by the ASQ:SE-2.

Secondary key outcomes

Parent depression assessed by the PHQ-9.

Child secondary outcomes

Parent–child interaction was independently observed and was assessed using the Infant CARE-Index. Cognitive development and health (quality of life) was assessed using the Pediatric Quality of Life Inventory (PedsQL™) at final follow-up only. Child behaviour was assessed by the Strengths and Difficulties Questionnaire 2–4 version at final follow-up only.

Parent secondary outcomes

Maternal/paternal–child attachment/interaction was assessed by the Maternal Postnatal Attachment Scale and Paternal Postnatal Attachment Scale at final follow-up only. Parenting skill was assessed using the Parent Sense of Competence questionnaire. Health (quality of life) was assessed using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L).

Other outcomes

Demographic information was captured via a bespoke structured interview form and included age, ethnicity, religion, income, marital status, parent/co-parent education, housing, family composition, infant feeding and prematurity. Further economic evaluation outcomes to examine resource use and costs based on access to health, social and educational services by parents and children were reported by parents using a modified Client Service Receipt Inventory. Costs of intervention delivery were gathered via implementation staff and existing data sources. The process evaluation included group attendance, leader contact rates, leader self-rated adherence checklists, a researcher-rated parenting programme implementation checklist and (modified) Incredible Years parent satisfaction questionnaires.

Analysis

Primary analysis applied intention to treat.

The marginal model for overall effectiveness was fitted using general estimating equations with a Gaussian family, identity link and autoregressive covariance structure of order 1 AR(1). AR(1) means that each observation in the time series is directly related to the observation that preceded it. Model estimates with standard errors that are robust to the non-normality and non-independence of observations were computed. Statistical analyses used Stata®/MP 16.0 (StataCorp LP, College Station, TX, USA). Item non-response was imputed using questionnaire developer rules. Robustness to outcome and baseline non-response was explored using multiple imputation (MI) methods. Covariates included in the model were baseline PHQ-9 and ASQ:SE-2 scores, whether or not the parent had a degree, whether or not the parent was in a relationship, ethnicity, child's sex, follow-up time and delivery site. We explored the extent to which intervention effectiveness differed between subpopulations by testing the significance of the interaction between randomised treatment group and subgroup. The impact of individual E-SEE Step components was investigated using non-randomised observational analysis where participants in the control arm with outcome scores above the eligibility threshold were used as a pseudo-control group. To assess the robustness of the outcome analysis, the primary analysis was repeated with alternative specifications of the primary outcome measure using MI. Per-protocol and complier-average causal effect analyses were not conducted, as there is no satisfactory way of defining compliers without biasing the estimated impact of IY-I and IY-T on compliers because of the conditional design. Descriptive analysis of the characteristics associated with compliance was undertaken.

Process evaluation/treatment processes: method and analysis

A multimethod approach assessed fidelity of delivery and explored parents', leaders' and service managers' experiences of the E-SEE Steps model, as well as the organisational, team and individual factors that facilitate or hinder its implementation. Quantitative monitoring data were collected for all parent groups. Pre- and post-training questionnaires assessed leaders' qualifications, existing experience of parenting groups and working with families, perceived competence to deliver the programme, perceived organisational support, and experiences of delivering Incredible Years. All quantitative data were reported descriptively. Qualitative data were gathered during focus groups and semistructured interviews with key stakeholders. Thematic analysis was applied to the qualitative data.

Economic evaluation: method and analysis

Cost-effectiveness and cost–consequence analyses were conducted. Costs in both trial arms were estimated from alternative perspectives, including a NHS and Personal Social Services perspective, a wider public sector perspective and a societal perspective, which includes costs to participants. A micro-costing of Incredible Years group delivery established delivery costs.

Initial analysis presents incremental results for the primary/key outcome measures for children (i.e. ASQ:SE-2) and adults (i.e. PHQ-9) separately. These results were compared with the incremental costs measured from the alternative perspectives. Secondary outcomes in terms of quality-adjusted life-years (QALYs) (using the PedsQL for children and EQ-5D-5L for adults) were also considered.

Alternative methods for combining primary and secondary outcomes across children and adults and across outcomes were explored for a full assessment of the benefits, and compared with costs. Links between trial outcome measures and longer-term outcomes were explored. Probabilistic sensitivity analyses were conducted to reflect the uncertainty around the adoption decision. Sensitivity analyses determined the robustness of the results to altering certain assumptions.

Results

The target sample size was not reached. A total of 341 parents were randomised, with a retention rate of 94%. There were no baseline differences between arms. The E-SEE Steps model was not effective in enhancing child social and emotional well-being compared with SAU. No significant differences were found between the E-SEE Steps and control arms. All secondary outcomes, including the key parent outcome (i.e. depression) also did not show any difference between arms. Sensitivity analyses confirmed the findings.

Overall, parent take-up of the targeted parenting programmes was low, which could have had an impact on results. Sites, although enthusiastic, identified barriers to delivering the intervention, such as lack of capacity, resource and time. Adaptations to the intervention were also suggested (e.g. to ensure compatibility with UK guidance and context-specific video content).

The E-SEE Steps model had higher costs and more QALYs [0.031 QALY gain, 95% confidence interval (CI) –0.008 to 0.071 QALY gain] than SAU, resulting in an incremental cost-effectiveness ratio of approximately £20,062 per QALY compared with SAU. The mean incremental public sector cost of the E-SEE Steps model was £621 per family compared with SAU (95% CI –£103 to £1288). There was a small gain in mean QALYs, with positive increments in adults exceeding minor decrements reported in child outcomes over the trial period. Findings were sensitive to changes in the key assumptions used in the analysis. All scenarios found the E-SEE Steps model cost-effective at the maximum recommended threshold of £30,000 per QALY.

The trial also found that child emergency department (ED) attendance was predicted by younger gestational age, older age at recruitment to trial, mothers' poorer mental health and younger age, mother attending ED and study site. For mothers, ED attendance was predicted by mixed ethnic origin, having a boy, having poorer quality of life at baseline and having been hospitalised during the trial. Mothers' admission to hospital was predicted by ED attendance for themselves and being anxious or depressed.

Limitations

The study was not powered to establish the effectiveness of each of the intervention's three individual levels, only the effectiveness of the overall E-SEE Steps model. Planned secondary analysis to explore each level of intervention could not be conducted because of low attendance rates in the group programme (and the very small number of parents in the control arm). *The Incredible Years* baby book will be explored further by combining pilot and main trial data; however, it will not be possible to combine data for the group levels because of design changes made within the pilot.

Owing to low co-parent numbers ($n = 68$), we could not provide insights into the role of co-parents in shaping children's social and emotional development, but our co-parent substudy explored further co-parent perceptions of parenting programmes and engagement into such programmes.

We had to resort to using parent-reported attendance at EDs and hospital admissions, as Hospital Episode Statistics data were unobtainable within the study time frame because of various barriers to, and during, the NHS Digital application process.

We are unsure how representative our sample is of the population in each site, or nationally. We have documented the challenges of exploring trial sample 'representativeness'; however, our main trial sample is predominantly well educated, with only a small proportion (11%) of parents identifying themselves as single and not in a live-in relationship. Therefore, it is unlikely that our sample is representative of families that are experiencing the greatest threats to their social and emotional well-being.

Conclusions

- The E-SEE Steps proportionate universal delivery model did not enhance child social and emotional well-being.
- The E-SEE Steps model can be implemented in community settings and delivered by health and/or family and children services; however, system changes need to occur, and resources and capacity increased, to embed any such model successfully. Intervention adaptations are also required.
- Although the E-SEE Steps model demonstrates higher costs over the trial duration, this may not be the case longer term. Programme delivery costs will reduce over time (e.g. training costs may no longer be needed in the future).
- More work is needed to ensure better engagement of parents. We suggest that a pre-intervention component or a set of implementation strategies devoted to identification and engagement (and retention) of parents and also co-parents be developed and adhered to consistently, while being fully resourced.
- Maternal mental health predicted child ED attendance and mothers' own hospital admissions. This finding highlights the importance of tackling/preventing maternal depression or anxiety during pregnancy and within the perinatal period through enhanced evidence-based service provision.

Trial registration

This trial is registered as ISRCTN11079129.

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