A video-feedback parenting intervention to prevent enduring behaviour problems in at-risk children aged 12–36 months: the Healthy Start, Happy Start RCT

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Scientific summary

Healthy Start, Happy Start RCT

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Scientific summary

Background

As many as 1 in 10 children experience behaviour problems, and enduring problems can undermine children's health, social and educational outcomes across their life course. As well as the distress that these issues can cause for children and families, there are considerable costs to society. An important factor that influences the development of behaviour problems is the quality and style of early parental care that children experience. Parenting strategies can lead to improvements in child behaviour; systematic reviews have shown that parenting programmes are effective in reducing behaviour problems in preschool- and school-aged children. However, there are very few effective early psychological interventions available. Intervening earlier in childhood before problems become established could increase the impact that parenting programmes have on children and families.

An evidence-based programme that is suitable for use with children aged $\geq$ 12 months is the Video-feedback Intervention to promote Positive Parenting and Sensitive Discipline (VIPP-SD) programme. VIPP-SD has been developed in a systematic way, has been tested in 12 randomised controlled trials and has been shown to be effective in improving parenting practices and child behaviour outcomes. However, the intervention is yet to be tested in a routine health service context in the UK.

The Healthy Start, Happy Start study was a pragmatic, assessor-blinded, multisite, two-arm, parallel-group randomised controlled trial to test the clinical effectiveness and cost-effectiveness of VIPP-SD for parents of young children (aged 12–36 months) who were at risk of developing enduring behaviour problems.

Objectives

The objectives were to:

- undertake a randomised controlled trial to evaluate whether or not a brief parenting intervention (VIPP-SD) leads to lower levels of behaviour problems in young children who are at a high risk of developing these problems, compared with usual care in the NHS
- undertake an economic evaluation to assess the cost-effectiveness of the intervention compared with usual care.

Methods

Design

The study was a pragmatic, assessor-blinded, multisite, two-arm, parallel-group randomised controlled trial.

Setting

The participants were recruited from health visiting and community services in six UK NHS trusts.

Participants

The participants were 300 children aged 12–36 months who demonstrated elevated behaviour difficulties (as measured by a parent-reported screening questionnaire) and their caregiver(s).

Target population

Target participants were children aged 12–36 months who scored in the top 20% for behaviour problems on the parent-reported Strengths and Difficulties Questionnaire. We excluded children or parents with a severe sensory impairment, learning disability or language limitation that was sufficient to preclude participation in the trial. We also excluded children with a participating sibling, those whose parents were actively involved in family court proceedings and those participating in a closely related research study and/or receiving an individual video-feedback-based intervention.

Randomisation

We randomly allocated participants in a 1 : 1 ratio to either VIPP-SD or usual care, stratified by recruitment site and the number of participating caregivers (one vs. two).

Intervention

All families continued to access usual care, which comprised mainly general practitioner and health visiting services. Families allocated to the VIPP-SD group were offered six home-based, fortnightly sessions of 1–2 hours' duration. Each visit was composed of two parts. In the first part, therapists recorded videos of parents during everyday interactions with their children. In the second part of the visit, therapists provided structured feedback based on the intervention manual and the contents of the interaction. This feedback aimed to promote parents' sensitivity; and their capacity to identify their child's attachment cues and exploratory behaviour, and to respond to their child appropriately, as well as providing sensitive discipline, which involves a consistent but non-harsh response to challenging behaviour. The manualised intervention was delivered predominantly by health professionals, including health visitors, community nursery nurses and psychologists, following 5 days of training and a supervised practice case. Therapists received ongoing clinical supervision throughout intervention delivery.

Outcome measurements

Baseline information

We collected demographic data at baseline on parents' sex, age, ethnicity, educational attainment, employment status and relationship status. We also collected data on childrens' sex, age and ethnicity. Baseline measures of all outcome data were also collected.

Primary clinical outcome

The primary outcome was severity of behaviour problems (as measured by the Preschool Parental Account of Children's Symptoms interview) at the 5-month follow-up.

Secondary clinical outcomes

Key secondary outcomes included severity of behaviour problems, measured using the Preschool Parental Account of Children's Symptoms interview at the 24-month follow-up, as well as parent-reported child behaviour, measured at the 5- and 24-month follow-ups using the Child Behaviour Checklist and the Strengths and Difficulties Questionnaire. Additional secondary outcomes included parent-reported measures of parenting practices (Parenting Scale), parent mood (Patient Health Questionnaire-9) and anxiety (Generalised Anxiety Disorder-7) and couple functioning (Revised Dyadic Adjustment Scale) at the 5- and 24-month follow-ups.

Economic measures

Health and social care service use was recorded using the Child and Adolescent Service Use Schedule. In the short term ('within-trial'), the cost-effectiveness of the VIPP-SD was explored in terms of the primary outcome measure (Preschool Parental Account of Children's Symptoms) at the 24-month follow-up and a cost–consequences analysis was carried out. The cost–consequences analysis outlined costs alongside the key secondary outcome measures (Child Behaviour Checklist and Strengths and Difficulties Questionnaire) to explore potential economic impacts of the intervention on outcomes more broadly.

Sample size

A sample size of 300 participants was selected to provide between 80% and 90% power to detect standardised effect sizes of 0.36 and 0.42, respectively, at a 5% level of statistical significance and assuming a 20% attrition rate.

Statistical methods and analyses.

Clinical outcome analyses

We conducted the primary analysis using intention to treat for primary and secondary outcomes. We also undertook secondary analysis to estimate the effect of receiving the intervention using complier-average causal effects analysis on the primary outcome and key secondary outcomes. In the primary analysis, we estimated the effects of the VIPP-SD programme by comparing the VIPP-SD and usual-care groups using linear regression, which adjusted for baseline levels of the same outcome, treatment centre, length of follow-up, age of the child and number of participating caregivers. We undertook a sensitivity analysis to assess the impact of missing data and adjusted for the length of follow-up. For the primary outcome (measured using the Preschool Parental Account of Children's Symptoms), we used multiple imputation to fill in missing items in the Preschool Parental Account of Children's Symptoms scales (as some items were unrateable for some children) and we used multiple imputation for the families where follow-up data were not available (5% at the 5-month follow-up, 6% at the 24-month follow-up).

Economic analyses

Cost-effectiveness was assessed at the 24-month follow-up through the calculation of incremental cost-effectiveness ratios (the additional cost of one intervention compared with another divided by the additional effect) and using the net monetary benefit approach. Uncertainty around the mean estimates of cost and outcome was explored using bootstrapping and plotting the bootstrap iterations onto a cost-effectiveness plane for interpretation. Cost-effectiveness acceptability curves were constructed to examine the probability of VIPP-SD being cost-effective compared with usual care for a range of possible values of willingness to pay per unit improvement in outcome. All economic analyses were adjusted in line with the clinical analyses and based on multiply imputed data sets of total costs and outcomes using chained equations and predictive mean matching. Sensitivity analyses explored the impact of missing data, influential outliers and the selected end point, repeating the analysis for the 5-month follow-up.

Results

Between July 2015 and July 2017, we assessed 2248 families for eligibility. In total, 1430 families were ineligible, 518 families did not progress to the trial (declined/could not be contacted) and 300 families were randomised. Of the randomised families, 151 (50%) were randomly allocated to the intervention (VIPP-SD) group and 149 (50%) were randomly allocated to the usual-care group. Participant-level characteristics at baseline were well balanced between groups. Of the 151 families randomised to receive the intervention, 129 (85%) completed at least four VIPP-SD sessions (the compliance cut-off point for treatment adherence). Retention was high, with primary outcome data available for 286 (95%) participants at the 5-month follow-up and 282 (94%) participants at the 24-month follow-up.

On the primary outcome (Preschool Parental Account of Children's Symptoms at 5 months by intention-to-treat analysis), we found that VIPP-SD was superior to usual care [mean 28.80 (standard deviation 9.2) vs. 30.31 (standard deviation 9.9); adjusted mean difference 2.03 (95% confidence interval 0.06 to 4.01); $p = 0.04$], indicating a positive treatment effect (Cohen's $d = 0.20$, 95% confidence interval 0.01 to 0.40). VIPP-SD was found to be superior to usual care on the conduct problems subscale of the primary outcome (difference 1.61, 95% confidence interval 0.44 to 2.78; $p = 0.007$, $d = 0.30$, 95% confidence interval 0.08 to 0.51), but not the hyperactivity subscale (difference 0.29, 95% confidence interval −1.06 to 1.65; $p = 0.67$, $d = 0.05$, 95% confidence interval −0.17 to 0.27). The positive effect of VIPP-SD

on the Preschool Parental Account of Children's Symptoms total score at 5-month follow-up was robust to sensitivity analyses. The complier-average causal effects analysis on the primary outcome of child behaviour showed higher estimated treatment effects in those with acceptable treatment adherence, that is those who received at least four core VIPP-SD sessions (Preschool Parental Account of Children's Symptoms difference increased from 2.03 to 2.59, 95% confidence interval 0.24 to 4.94; $p = 0.03$, $d = 0.26$, 95% confidence interval 0.02 to 0.50). At the 24-month follow-up, there was evidence of a sustained intention-to-treat treatment effect favouring the VIPP-SD group (difference 1.73, 95% confidence interval −0.24 to 3.71; $p = 0.08$, $d = 0.17$, 95% confidence interval −0.02 to 0.37). Again, the difference was higher for the conduct subscale (difference 1.07, 95% confidence interval −0.06 to 2.2; $p = 0.06$, $d = 0.20$, 95% confidence interval −0.01 to 0.42) than for the hyperactivity scale (difference 0.62, 95% confidence interval −0.60 to 1.84; $p = 0.32$, $d = 0.10$, 95% confidence interval −0.10 to 0.30). Those who received at least four VIPP-SD sessions continued to show a greater improvement in behaviour (complier-average casual effects Preschool Parental Account of Children's Symptoms difference increased from 1.73 to 1.96, 95% confidence interval −0.30 to 4.23; $p = 0.09$, $d = 0.20$, 95% confidence interval −0.03 to 0.43).

On the main secondary outcomes (total scores of the Child Behaviour Checklist and Strengths and Difficulties Questionnaire), the results indicated a positive direction of effect favouring the VIPP-SD group at the 5-month follow-up, but less evidence of a sustained effect at 24-month follow-up. We found no appreciable evidence of differences between groups on other included secondary outcomes at the 5- or 24-month follow-up.

No treatment- or trial-related adverse events were reported. There were no group differences in the reporting of unrelated adverse events.

Mean total costs were significantly higher in the VIPP-SD group than in the usual-care group at the 24-month follow-up (adjusted mean difference £1450, 95% confidence interval £619 to £2281; $p = 0.001$) and were driven by the cost of the intervention (mean cost £1466 per family). However, VIPP-SD was also associated with Preschool Parental Account of Children's Symptoms scores that favoured the intervention, thus generating a trade-off, with VIPP-SD being more costly but also more effective than usual care. The probability of VIPP-SD being cost-effective compared with usual care increased as willingness to pay for improvements in Preschool Parental Account of Children's Symptoms score increased, with VIPP-SD having higher probability of being cost-effective at willingness-to-pay values of approximately £800 per 1-point improvement in Preschool Parental Account of Children's Symptoms score (equivalent to 0.10 standard deviation) and above. In theory, this would be equivalent to approximately £7920 for one standard deviation improvement. Because the Preschool Parental Account of Children's Symptoms is not associated with a willingness-to-pay threshold to support decision-making, it is not possible to come to any firm conclusions about the relative cost-effectiveness of VIPP-SD in the short term. These results were robust to changes in assumptions in sensitivity analyses (complete case, excluding outliers and analysis at the 5-month follow-up).

Conclusions

We found evidence that a brief, home-based intervention, VIPP-SD, was more effective than usual care in reducing behaviour problems in this group of children aged 1 or 2 years. Evidence of superiority was found for the primary outcome (the interview-based Preschool Parental Account of Children's Symptoms assessment) at the 5-month post-treatment assessment. The findings were strongest on the conduct problems scale of the Preschool Parental Account of Children's Symptoms assessment, rather than the attention deficit hyperactivity disorder/hyperkinesis scale, which is in keeping with the sensitive discipline focus of the VIPP-SD intervention, which targets conduct problems. Our results are consistent with a meta-analysis of the VIPP-SD intervention, which demonstrated similar effect sizes for child behaviour problems [Juffer F, Bakermans-Kranenburg MJ, van Ijzerdoorn MH. Video-feedback Intervention to Promote Positive Parenting and Sensitive Discipline (VIPP-SD): Development and

Meta-Analytical Evidence of Its Effectiveness. In Steele H, Steele M, editors. *Handbook of Attachment-based Interventions*. 1st edn. New York, NY: Guildford; 2017. pp. 1–26]. Thus, it is noteworthy that the present study demonstrates that this effect is robust in a routine health service context. Our best estimate is that most of the effect of VIPP-SD is retained over 24 months. However, we are less certain about its value for money.

Implications for health care and future research

The results of this research show that the VIPP-SD intervention can be delivered successfully in routine NHS care to specified groups of children with behaviour problems, and that those with particularly high levels of behaviour problems may benefit most. Furthermore, these problems can be identified using a simple, brief screening questionnaire. There is significant scope for this intervention to be incorporated in routine practice.

Key implications for future research include the following. First, further study is needed to assess the potential longer-term outcomes of early interventions such as VIPP-SD. Second, further study is needed to investigate whether or not the benefits of this early intervention can be enhanced with the addition of booster sessions or other later intervention. Third, future research is needed to elucidate the mechanisms underlying effective early interventions such as VIPP-SD and for whom the intervention may work best.

Early intervention represents a substantial opportunity for the future positive development of young children and a lack of effective interventions is a key challenge. The results of this study provide a significant step forward and represent a new opportunity for effective early childhood intervention to prevent enduring mental health problems.

Trial registration

This trial is registered as ISRCTN58327365.

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This report

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