A support package for parents of excessively crying infants: development and feasibility study

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

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Background

During the first 4 months after birth, approximately 20% of infants cry for long periods without an apparent reason. Early studies attributed this crying to gastrointestinal disturbance and pain, leading to the word ‘colic’ to describe it; however, evidence has accumulated that suggests that most of these infants are healthy and grow and develop normally. About 5% of infants cry a lot because of organic disturbances; in most cases, the crying is attributable to normal developmental processes. Although most infants who cry a lot are well, the crying can distress parents and disrupt their care. This has encouraged a focus not just on the crying but on parents’ responses and subsequent outcomes. One reason for that focus is that parental concerns are responsible for health service contacts and costs, which are considerable: the professional time spent advising parents about infant crying and unsettled behaviour in the first 3 months after birth is estimated to cost the NHS > £65M per year. Parents’ judgement of excessive infant crying can also trigger premature termination of breastfeeding, overfeeding, parental distress and depression, poor parent–child relationships and, in rare cases, infant abuse.

The distinction underlying this research is between infant crying and its evaluation by, and impact on, parents. The aversive sound of crying and crying bouts that resist soothing techniques – a feature particular to the first 4 months – trigger frustration in many parents. However, the impact of excessive crying on parental emotions and actions depends on how parents cope with it, which is affected by parental vulnerabilities, circumstances and resources. Vulnerabilities such as depression, anxiety and high arousal influence how parents evaluate and respond to infant crying and affect its outcomes. Social isolation may also increase its impact.

Against this background, it is striking that there are no evidence-based NHS practices for supporting parents in managing infant crying. Instead, parents turn to books, magazines or websites, which give conflicting advice, or take babies to clinicians or hospital emergency departments, adding to the NHS cost of infant crying. By developing evidence-based services that support parents, the Surviving Crying study, described in this report, was designed to take the first steps towards NHS provisions that improve the coping and well-being of parents whose babies cry excessively, their infants’ outcomes and how NHS money is spent.

The phrase ‘excessive infant crying’ is used throughout this report to refer to a parent’s judgement that an infant is crying too much, often accompanied by concern that the crying is a sign of infant ill health. The phrase ‘prolonged infant crying’ refers to a measure of crying duration.

Objectives

This was a preliminary study to develop a novel package of materials to support parents of excessively crying babies and examine the feasibility of delivering and evaluating it in the NHS. The aims included preparing for a possible large-scale controlled trial and advising on the form it might take. The study comprised two stages:

1. the development of an intervention package for this purpose
2. a feasibility study of package implementation in the NHS.

Each stage is described in the following sections, followed by a summary of the overall conclusions.
**Stage 1: development of an intervention package**

**Aims**

- Update a 2011 systematic review to identify example support packages.
- Obtain parents’ guidance on the supports needed by parents whose babies are excessively crying.

Parents were also asked to rate four example support packages identified by the literature review.

**Method**

**Literature review**

A literature review was conducted to update an existing systematic review of interventions to support parents whose infants are excessively crying. The review also searched for evidence of interventions that were effective in supporting parental coping and mental health in the postpartum period.

**Leicestershire Partnership NHS Trust involvement**

Health visitors (HVs) or specialist community public health nurses (SCPHNs) provide universal primary care for UK parents with infants and are the obvious choice for delivering the intended service within the NHS. However, this topic is not included in current HV/SCPHN training. With the assistance of Leicestershire Partnership NHS Trust (LPT), HVs/SCPHNs in five areas were invited to briefings and to take part in the research. A total of 55 HVs/SCPHNs gave written informed consent to collaborate by referring parents who had previously been distressed by their baby’s excessive crying to the research team.

**Recruiting stage 1 parents**

To supplement HV/SCPHN contacts with parents, flyers about the study were distributed via local National Childbirth Trust networks and children’s centres. Once contacted, researchers explained the study and sought parents’ written informed consent to take part. The eligibility criteria for parents were:

- living in the LPT area
- previously having a healthy baby whose excessive crying in the first 6 months had concerned either parent
- English speaking or supported by an English speaker.

**Focus groups and interviews with the parents**

The recruited parents were asked to take part in a focus group. Twenty parents (18 mothers and 2 fathers) took part. Sessions were audio-recorded for later analysis.

Parents described their experience of having a baby who cried excessively, what supports they would have liked and what routine services should include. They were asked about the most suitable delivery method (e.g. website, leaflet, direct or telephone contact with a professional) and what devices they would use to access online information (i.e. computer, tablet computer and mobile phone). Parents then completed rating scales to evaluate materials from the four example support packages identified by the literature review. Each package included a website with additional materials. Parents were asked to revisit the websites after the focus groups. Follow-up telephone calls were used to confirm if they had done so and whether or not this had changed their opinions and ratings. Consent was sought to include quotations from the focus group transcripts, and written or video presentations of their story, in the study materials.

**Results**

**Literature review**

Four example packages that met the study criteria were identified and contracts were arranged to include them in the study focus groups. The packages were called Period of PURPLE Crying®, What Were We Thinking! and Coping with Crying and Cry Baby. Cognitive–behavioural therapy (CBT)-based interventions
were found to be effective in helping parents in the postpartum period to cope with stressful conditions and moderate psychological distress.

Focus group quantitative data
Eighteen mothers (mean age 30.4 years) and two fathers took part. Most were white British, had a degree and were married or living with a partner when their baby cried excessively. Nearly half of the babies were second- or third-born, with 8 of the 18 families having other children who had not excessively cried. The babies comprised equal numbers of boys and girls and were divided almost equally between breastfeeding, formula feeding and mixed feeding when the crying started. None had a fever and only two seemed unwell. Typically, the babies’ excessive crying started at around 2–4 weeks and stopped by 4–6 months of age; the crying lasted from 4 to 100 weeks.

During the excessive crying period, 89% of parents visited a HV/SCPHN, doctor or other health professional, 50% spoke by telephone with a health professional and 89% considered these to be effective resources. Websites were valued by all 20 parents and considered effective by 89%. Most parents preferred to access online information through their mobile phone, and some preferred to access it via tablet computers. Most of the parents considered leaflets to be helpful, but just 45% had used them. All parents considered that groups to meet other parents with excessively crying babies would provide valuable support.

Most parents rated all four websites as attractive, clear and helpful. All 20 parents reported that materials like these should be included as part of routine NHS care.

Twelve of the 20 parents were recontacted after the focus groups. Eight had revisited one or more of the example websites. None wished to amend their focus group responses.

Focus group qualitative data
The transcripts underwent thematic analysis supported by NVivo 10 software (QSR International, Warrington, UK). Four themes emerged:

1. disrupted experience of parenthood
2. feeling different and social isolation
3. reluctance to seek support
4. validation of experience and seeking help.

Production of a set of parental support materials
Following the literature review and focus group findings, three package elements were developed: a Surviving Crying website, a printed version of the website and a programme of CBT-based support sessions delivered to parents by a qualified practitioner.

A commercial agency was appointed to assist in developing the website materials. Care was taken to ensure that all advice was evidence based. The text was adjusted to a reading age of 9–12 years. With permission, three videos of parents describing their experiences and five written stories were uploaded onto the website with names changed to maintain anonymity, together with three videos of professionals providing guidance. The draft website materials were sent to the focus group parents for review (16 provided feedback), circulated to HVs/SCPHNs for approval, checked by the study paediatrician and revised as necessary.

Following the website design and content as much as possible, a printed booklet version of the website was prepared.
Based on CBT evidence and the developmental course of infant crying, a programme of practitioner CBT support was designed to include up to five sessions, each lasting 60–90 minutes, delivered to parents in person or by telephone within a 4- to 6-week period. A practitioner manual for delivering the CBT programme was prepared with a CBT-qualified psychologist experienced in supporting adult mental health in the NHS (please contact the corresponding author to request access to the practitioners’ manual).

Safeguarding procedures
Together with the LPT safeguarding officers, clinical staff and the study paediatrician, the study team developed safeguarding protocols for parents and babies involved in the study.

Methods for evaluating the package materials
These methods are described together with the stage 2 findings in the following sections.

Stage 2: evaluation of the intervention package

Main aims

* Assess parents’ and NHS professionals’ willingness to enter and complete a study of the support package.
* Measure parental use and evaluation of the package components.
* Estimate package component costs.
* Assess the feasibility and methods for a future large-scale trial of the intervention package, including parents’ willingness to participate in this trial.

Methods

Health visitor and community public health nurse involvement
Workshops were held with six centres to recruit HVs/SCPHNs into stage 2 of the study. Forty-eight HVs/SCPHNs agreed to participate by introducing the study to parents and, with their consent, passing contact details to the research team. Additional HVs/SCPHNs were recruited as the study progressed; in total, 124 from 12 centres took part.

Recruiting parents
The first group (the ‘referred crying group’) comprised parents who sought HV/SCPHN help because of their baby’s current excessive crying. Following HV/SCPHN referral, the research team explained the study fully, offered the support package and obtained parents’ written informed consent to take part. Based on LPT birth numbers and a 20% incidence, one or two parents were expected to be recruited to this group each week; the target was 30 cases in 5 months.

The 20% excessive crying incidence in the literature stems from surveys with unknown recruitment bias, so fewer cases might seek HV/SCPHN help. This approach would also miss cases in which parents with excessively crying babies did not approach HVs/SCPHNs. To address these concerns, a ‘new birth visit group’ was recruited by asking HVs/SCPHNs to invite families to enter the study at the statutory home visit in postnatal days 10–14. It was expected that 10 families per week would give informed consent, be followed up and screened for excessive infant crying by researchers, giving 150 recruited families and 30 excessive crying cases in 4 months. This approach would indicate differences between new birth visit group cases and referred crying group cases, provide an incidence estimate and might allow earlier detection and intervention.
Procedures and measurements
Recruited parents were asked to complete a demographic questionnaire. Parents whose babies were excessively crying were asked to complete validated baseline questionnaire measures: the Edinburgh Postnatal Depression Scale, the Generalised Anxiety Disorder-7 scale, the EuroQol-5 Dimensions questionnaire, the Maternal Confidence Questionnaire, the Crying Patterns Questionnaire and parental sleep adequacy and social support items from previous studies. They were offered the support package and their use of each component was measured.

Outcome measures 4–6 weeks later repeated the baseline assessments, supplemented with measures of length of breastfeeding and crying knowledge. Parents and HVs/SCPHNs rated each package component and their suitability for NHS use. Parents’ willingness to participate in a randomised controlled trial (RCT) to evaluate the Surviving Crying materials was assessed. Measures of costs of each package component, together with costs of crying-related NHS contact time for new and existing services, were collected.

Results
All 52 parents and 85% of HVs/SCPHNs providing data would support the inclusion of the package materials in the NHS. Package use was associated with substantial reductions in parental frustration, anxiety and depression, together with reductions in reported infant crying, the extent to which parents considered it a problem and contact with professionals for help with the crying. Parents’ knowledge of infant crying patterns, how crying develops and how to cope with frustration because of the crying improved. Most parents (69%) said that they would be willing to take part in a RCT of the package, rising to 85% if a waiting list control group were to be offered. The costs of NHS services for excessive infant crying depend on its incidence, which is uncertain. Based on this study’s figures, providing these services during the first 15 weeks of infancy costs the UK NHS £48.6M per year. The Surviving Crying website was estimated to have an annual maintenance cost of £1482.75, together with an additional cost per new registration of £32.33. The cost per family for each printed booklet was £6.46. The mean cost per family participating in the CBT programme was £437.

Overall conclusions
It proved feasible to work together with parents and HVs/SCPHNs to develop an evidence-based package of support materials for parents with excessively crying babies. All 52 parents and 85% of HVs/SCPHNs who provided data would support the inclusion of the package in the NHS. Use of the package was associated with improvements in parental well-being and knowledge of infant crying, together with reductions in the extent to which the crying was considered a problem and parents’ contacts with health professionals because of it. Methods were developed for a future RCT to fully evaluate the clinical effectiveness and cost-effectiveness of the support package. Such a trial is feasible and desirable.

Trial registration
This trial is registered as ISRCTN84975637.

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This report

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