

Mental health and wellbeing in parents of excessively crying infants: prospective evaluation of a support package

Abstract

Background

During the first four months of age, approximately 20% of infants cry a lot without an apparent reason. Most research has targeted the crying, but the impact of the crying on parents, and subsequent outcomes, need to receive equal attention. This study reports the findings from a prospective evaluation of a package of materials designed to support the wellbeing and mental health of parents who judge their infant to be crying excessively. The resulting 'Surviving Crying' package comprised a website, printed materials, and a programme of Cognitive Behaviour Therapy - based support sessions delivered to parents by a qualified practitioner. It was designed to be suitable for United Kingdom (UK) National Health Service (NHS) use.

Methods

Parents were referred to the study by 12 NHS Health Visitor/ Community Public Health Nurse teams in one UK East Midlands NHS Trust. Fifty seven parents of excessively crying babies received the support package and completed the Edinburgh Postnatal Depression Scale and GAD-7 anxiety questionnaire, as well as other measures, both before receiving the support package and afterwards.

Results

Significant reductions in depression and anxiety were found, with numbers of parents meeting clinical criteria for depression or anxiety halving between baseline and outcome. These improvements were not explained by changes in infant crying. Reductions also occurred in the number of parents reporting the crying to be a large or severe problem (from 28 to 3 parents) or

feeling very or extremely frustrated by the crying (from 31 to 1 parent). Other findings included increases in parents' confidence, knowledge of infant crying and improvements in parents' sleep.

Conclusions

The findings suggest that the Surviving Crying package may be effective in supporting the wellbeing and mental health of parents of excessively crying babies. Further, large-scale controlled trials of the package in NHS settings are warranted.

[total 300 words]

Introduction

Approximately 20% of infants cry for long periods without an apparent reason during the first four months of age (Alvarez, 2004; Douglas & Hill, 2011; St James-Roberts & Halil, 1991). Traditionally, this crying was called 'infant colic' and attributed to gastro-intestinal disturbance (Illingworth 1954; Wessel, Cobb, Jackson, Harris & Detwiler, 1954). However, this and other explanations of the crying remain controversial (St James-Roberts, Alvarez & Hovish 2013; Sung et al., 2014).

Evidence is growing that this focus on the infant crying needs to be matched by equal attention to its impact on parents and subsequent outcomes. For instance, crying parents judge to be excessive can trigger premature termination of breastfeeding (Howard, Lanphear, Lanphear, Eberly & Lawrence, 2006), over-feeding (Stifter, Anzman-Frasca, Birch & Voegtline, 2011), parental distress and depression (Kurth, Kennedy, Spichiger, Hoesli & Stutz, 2011; Murray & Cooper, 2001), poor parent-child relationships (Papoušek, Wurmser & von Hofacker, 2001) and infant abuse in a small number of cases (Barr, Trent & Cross, 2006). Parental concerns are responsible, too, for health service contacts and costs, which are substantial (Morris, St James-Roberts, Sleep & Gillham, 2001).

As well as crying's loud and aversive sound, a feature particular to the first four months – bouts which resist soothing manoeuvres - trigger frustration in many parents (Fujiwara, Barr, Brant & Barr, 2011). However, the impact on parental emotions and actions depends partly on how parents cope with the crying and hence on parental resources, vulnerabilities and circumstances. Factors such as depression, anxiety and high arousal influence how parents interpret and respond to infant crying (Frodi & Lamb, 1980; Laurent & Ablow, 2012; Pearson, Cooper, Penton-Voak, Lightman & Evans 2010). Social isolation may increase its impact. Parental vulnerabilities can increase the likelihood of long-term child disturbances (Smarius et al., 2016).

Given this background, it is striking that there are no evidence-based UK provisions for supporting parents in managing infant crying. Instead, parents turn to popular books, magazines or websites,

which give conflicting advice (Catherine, Ko & Barr, 2008), or take infants to clinicians or hospital emergency departments, adding to the burden and cost of infant crying for services (Barr, Rajabali, Aragon, Colbourne & Brant, 2015; Freedman, Al-Harthy & Thull-Freedman, 2009). UK legislation and healthcare services have prioritized the need to support adult mental health, including parental mental health in the postpartum period. For the most part, the resulting support programmes target parental cognitions, emotions and behaviours, but overlook environmental factors. Programmes which support coping with infant crying may be particularly effective in improving some parents' wellbeing and mental health and enhancing services.

The 'Surviving Crying' study was designed to take a first step in meeting this need by developing a package of materials which support the coping and wellbeing of UK parents who judge their infant to be crying excessively. The development process involved collaboration between academic, voluntary sector and NHS staff. Since Health Visitors or Community Public Health Nurses (HV/CPHNs) provide universal support for UK parents and infants and are likely to be key professionals in delivering the package, they were closely involved. The resulting package, comprising a website, printed materials, and Cognitive Behaviour Therapy - based support sessions delivered to parents by a qualified practitioner, has been described (Garratt et al., 2017; Long et al., 2017). The study reported here aimed to provide an initial longitudinal evaluation of whether the package might improve the wellbeing and mental health of parents of excessively crying infants. We hypothesized that the package would be associated with reductions in parental anxiety and depression, the number reporting crying to be a problem, and in frustration because of the crying. In addition, it would be associated with increases in parents' confidence, knowledge of infant crying, and improvements in parents' sleep.

To avoid terminological confusion, the phrase 'excessive infant crying' is used to refer to a parent's judgment that an infant is crying too much, often accompanied by concern that the crying is a sign

that the infant is unwell. The phrase ‘prolonged infant crying’ refers to a measure of crying duration, such as the widely used Wessel et al., (1954) ‘Rule of Threes’ (e.g. Wolke, Bilgin & Samara, 2017).

Methods

Governance

Study public registration no. ISRCTN84975637; ethical approval provided by De Montfort University (13450) and the National Research Ethics Committee East Midlands (Nottingham): ID 152836; NRES: 14/EM/1202. A safeguarding protocol was used to ensure participants’ safety and exclude illness.

Recruitment

Recruitment involved collaboration with 12 HV/CPHN teams in city, suburban and rural areas of one UK East Midlands region. HV/CPHNs provided eligible participants with written details about the study. Where parents gave provisional written informed consent, researchers explained the study, assessed eligibility and invited them to participate by signing a consent form. Participants were (1) parents of a healthy infant age six months or less who they judged was crying excessively; (2) English speaking or supported by an English speaker; (3) living within the study area. Parents who did not meet these criteria were excluded.

Participants were recruited to one of two groups:

- Group 1 ‘Referred Crying’ (RC) group were parents who sought HV/CPHN help because of their infant’s current excessive crying, or self-referred after seeing the call for eligible parents on local websites or printed announcements.
- Group 2 ‘New Birth Visit’ (NBV) group included parents invited to enter the study by their HV/CPHN at the statutory ‘universal’ home visit 10-14 days after childbirth. These parents were told about the availability of the Surviving Crying materials and followed up by researchers until 6-8 weeks after their baby’s birth. If parents reported excessive infant crying

at any point, the support package was offered. If not, they were thanked and not followed up further. We anticipated that this group would provide figures for the incidence of excessive infant crying and allow earlier detection.

We aimed to recruit 30 parents to each group. As this was an exploratory study there was no control group.

Assessments

Following recruitment, baseline assessments were conducted in participants' homes. Parental measures included four validated rating scales: EQ-5D Quality of Life Questionnaire (EuroQol Group, 1990); Edinburgh Postnatal Depression Scale (Cox, Holden & Sagovsky, 1987); GAD-7 General Anxiety Scale (Spitzer, Kroenke, Williams & Löwe, 2006); Maternal Confidence Questionnaire (Badr, 2005).

Due to the lack of validated paternal confidence questionnaires, fathers also completed the MCQ with minor adjustments to wording. In addition, parents rated their infant's crying problem severity and the degree to which they were frustrated by the crying, and provided information on their own sleep and social supports, using items from previous studies (Cook, Bayer, Le, Mensah, Cann & Hiscock, 2012; Fujiwara et al. 2011; Hiscock, Cook, Bayer, Le, Mensah, Cann, Simon & St James-Roberts 2014; St James-Roberts & Halil 1991). To understand the basis for parents concerns, measures of their babies' perceived crying, health and feeding problems were obtained using items from previous studies (Cook et al. 2012; Hiscock et al. 2014; St James-Roberts & Halil).

Following baseline assessments, parents in both groups were offered the support package. Parents could choose which support package elements they received and how often they accessed them.

Outcome assessments were designed to occur approximately 4-6 weeks later, allowing access to the package. Baseline measures were repeated and parents were asked five questions about crying knowledge addressed in the package, adapted from Barr et al., (2009). All recruited parents received a £20 shopping voucher at outcome to acknowledge their contribution.

Data Analysis

Questionnaire summary scores were treated as continuous variables. Confidence intervals for the summary scores were calculated from linear regression models, adjusting for the baseline score. Confidence intervals calculated were for the outcome score and the change from baseline, both overall and by group. Since few differences were found between the two groups their data are combined except where indicated.

Results

Figure 1 provides a flow diagram for parents' progress through the study. Table 1 summarises participants' demographic characteristics. Thirty RC group participants received the support materials. Of 124 NBV parents who consented to participate, 27 reported their baby to be crying excessively and received the support package (Figure 1); this corresponds to an incidence of 21.7%. This group fell just short of the target 30 cases. Overall, 55 parents requested access to the website, 27 the printed booklet and 32 the CBT sessions. Five participants could not be contacted at outcome. The average interval from baseline to outcome was 5 weeks 5 days (range: 1 week 6 days – 13 weeks 6 days). The interval was longer where parents received the CBT sessions.

The majority of participants (80-100%) were mothers and married or co-habiting (81-95%). They were predominately white, but small numbers of Asian, Black, Mixed and Other-ethnicity parents took part. Around 40% had university degrees. Many (50-76%) were on maternity or paternity leave when their baby cried excessively. Because of some missing data, participant numbers are given for each analysis.

Parental Wellbeing and Mental Health

Table 2 presents the outcome scores and changes from baseline in measures of parents' wellbeing and mental health. Total EQ-5D scores can vary from 0 to 1 and a score near 1 indicates an excellent quality of life. Low scores were not expected, since the scale is used across physical and mental

health areas including severe disabilities. The mean parental EQ5-D baseline score of 0.87 (SD 0.2) indicated a good quality of life. The mean outcome score of 0.90 (SD 0.16; 95% CI: 0.88, 0.92) showed a modest improvement.

The EPDS provides screening for postnatal depression. A score of ≥ 13 is often used for clinical purposes, but a score of ≥ 10 is recommended for screening (Wisner, Parry & Pointek, 2002). As Table 2 shows, the average parental EPDS score at baseline exceeded this cut off (mean score 10.08; SD 4.9). Using a head count and a cut off of 10, 30 (53%) of the 57 parents with excessively crying infants were classified as depressed at baseline. A cut off of ≥ 13 identified 17 (30%) parents as depressed at baseline. EPDS scores at outcome were substantially reduced (mean 7.10; SD 4.5), a reduction of 2.98 points (95% CI: -4.05, -1.92). The number of parents with an EPDS criterion score for depression ≥ 10 halved (from 30 to 15 parents) between baseline and outcome (from 17 to 8 parents using a cut off ≥ 13).

The GAD- 7 measures generalised anxiety. Total scores range from 0 to 21 with cut points of 5, 10 and 15 representing mild, moderate and severe anxiety (Spitzer et al., 2006). At baseline, parents' mean (SD) score was 6.47 (SD 4.9) with 16 parents (28.1%) mildly anxious, 11 (19.5%) moderately anxious and 4 (7.0%) severely anxious. By outcome, the adjusted mean had reduced to 3.9 (SD 3.8), a significant reduction of -2.55 points (95% CI: -3.48, - 1.61). The number mildly anxious had decreased from 16 to 12, moderately anxious from 11 to two, and severely anxious from four to two.

The Maternal Confidence Questionnaire (MCQ) is a unidimensional measure with scores ranging from 1 to 5, a higher score indicating higher confidence. The combined parents' MCQ scores showed a modest increase between baseline and outcome, with an adjusted mean increase of 0.13 (95% CI: 0.089, 0.17) from 2.02 (SD 0.21) to 2.15 (SD 0.19).

Parental Sleep and Social Supports

Table 3 summarises parents' reports of the amount and quality of their own sleep. Both groups reported increased sleep from baseline to outcome, amounting to an average increase of one hour and six minutes per 24 hours. The number reporting fairly bad or bad sleep quality halved at outcome.

Table 3 also shows parents' reports on the support received from partners, and family and friends. At baseline, most parents (about 70%) judged these supports to be enough; about 10% reported insufficient support. At outcome 73-76% of parents reported receiving enough support.

Parents' Knowledge about Infant Crying

Some parents knew some evidence about infant crying before taking part in the study, and some learned information from their HVs (Table 4). However, 32-64% (depending on the information) acquired knowledge from the support package. Up to 14% of parents indicated the information remained new to them, suggesting that they did not access or remember it.

Parents' ratings of how much their baby's crying was a problem, and was frustrating, for them

At baseline most (78%) parents judged their baby's crying to be a moderate or large problem, 16% a severe problem (Figure 2). Most (71%) parents were moderately or very frustrated by the crying, and 16% extremely frustrated (Figure 3). By outcome, the number reporting crying to be a severe or large problem reduced from 28 (50%) to three parents (6%); the number feeling extremely or very frustrated by the crying reduced from 31 (55%) at baseline to one (2.0%) at outcome.

Parental reports of Infant Crying, Feeding and Health

These measures were obtained to provide evidence about the bases for parents' concerns rather than to provide objective measures of infants. Since five couples participated in the study, baseline assessments were available for 52 infants. Fewer than half (44%) were first-borns, 44% second-born, 12% later-born. The average age for NBV infants (6.6 weeks) was significantly less than for RC

infants (12.8 weeks), indicating that the NBV recruitment method identified excessive crying cases at a younger age (mean difference: 6.13, 95% CI: 3.50, 8.77).

Excessive crying began at a mean age of 3.1 weeks (SD 2.8 weeks). At baseline, infants were reported to cry for 6.9 hours per 24 hours on average (SD 3.7 hours, Table 5). Of the 52 infants, 45 (86%) were judged by parents to meet the Wessel et al. (1954) Rule of Threes criteria for prolonged crying by fussing and crying for more than three hours per 24 hours most days of the week.

Fourteen infants were still crying excessively at outcome, at an average age of 15 weeks 6 days, implying the need for a longer follow up in future studies. For the 33 infants who had stopped excessive crying, the crying lasted an average of 8 weeks and 1 day (SD 4.3 weeks). The total time per 24 hours infants spent fussing and crying halved between baseline and outcome, from 6.9 hours to 2.6 hours (mean difference:-4.3 hours, 95% CI: -5.2, -3.3).

Linear regression was used to examine whether the reductions in infant crying from baseline to outcome could account for the changes in parental wellbeing and mental health (Table 6). None of these associations was statistically significant, implying that factors other than the crying were involved.

When excessive crying began, most infants (71%) were breast-fed; 40% were fed formula (some received both). At baseline and outcome, respectively, 52% and 53% were breast fed (Table 5), suggesting that where breastfeeding was discontinued this happened at a young age, before joining the study. Of 21 infants whose parents stopped breast-feeding by outcome, the average infant age at stopping was 3.6 weeks (SD 4.1 weeks).

Parents reported that 40-50% of infants had feeding problems or repeatedly brought up feeds at baseline (Table 5). However, all but one infant (98%) had been weighed by a health professional and 58% had received a feeding check, without a definitive diagnosis. Parents judged around a quarter of infants to be unwell and half had been seen by their GP in the last fortnight for reasons other than

crying (Table 5). At outcome, these parent-reported measures of infant ill-health reduced in frequency, but 25% of parents reported infant feeding problems and 40% that infants repeatedly brought up feeds. The proportion of parents reporting signs of illness other than crying in the last two weeks remained similar at outcome, but fewer infants had been seen by their GP in the last fortnight.

Discussion

This study aimed to provide an initial, prospective evaluation of whether the Surviving Crying support package might improve the wellbeing and mental health of parents of excessively crying infants. Both validated rating scales and **descriptive items** from previous studies showed significant changes from baseline (before receiving the package) to outcome, approximately six weeks later. Numbers of parents who met clinical criteria for depression halved and numbers who met clinical criteria for anxiety reduced from 31 to 16 parents. The number reporting crying to be a large or severe problem reduced from 28 (50.0%) at baseline to three parents (6%) at outcome; the number feeling very or extremely frustrated by the crying from 31 (55%) at baseline to one (2.0%) at outcome. If frustration is the trigger for infant abuse, as studies indicate (Fujiwara et al., 2011), this reduction is a particularly encouraging finding.

The findings support the notion that the impact of infant crying on parents (and vice versa) involves parental mental health and wellbeing. However, the direction of causation remains uncertain.

Petzoldt et al., (2014) concluded that maternal anxiety during pregnancy predicted excessive infant crying, while her recent systematic review (Petzoldt, 2018) found that maternal depression was more often a correlate or a consequence of excessive infant crying. This study's finding that substantial numbers of parents reduce their depression during the postnatal period is consistent with that view of depression, but an equal number of parents also reduced in anxiety. The implication is that postnatal experience makes an important contribution to both depression and

anxiety. Although the findings do not tell us whether the Surviving Crying package is responsible for those improvements, they allow that possibility.

Other findings include increases in amount and quality of parental sleep and in parental confidence. Although modest, these increases are encouraging so far as the aim is to improve parents' confidence and coping skills. Notably, most parents reported receiving adequate social support from partner, family and friends and there was little change in these measures. The intervention was not associated with changes in numbers breast-feeding. Although approximately a third of parents discontinued breast-feeding, infant age averaged 3-4 weeks when this happened. This finding adds to evidence that excessive crying is associated with stopping breast-feeding (Howard et al., 2006) and indicates that breastfeeding support **for parents of excessively crying infants** needs to be delivered at an early age.

The study's limitations include failure to recruit sufficient numbers of fathers and, by design, the lack of a control group and randomisation, preventing any conclusions about causation. Since infant crying development follows an inverted U-shaped curve, the increases found in parental wellbeing and mental health might be due to reductions in the crying. Using regression analyses, that proved not to be the case. A previous study, too, found that reductions in infant crying were not matched by parent-reported crying problems (Hill et al., 2005). A possible explanation is that parental concerns about excessive infant crying involve more than the amount their baby cries. For instance, the 'unsoothability' of some cry bouts during early infancy is the primary source of parental frustration (Fujiwara et al. 2011). Other factors indicated here include concerns about infant feeding and health. The findings point to a cluster of infant and parental factors, rather than duration of crying alone, as the basis for parental concern. The implication is that intervention studies need to broaden their outcome measures beyond cry duration.

In conclusion, these findings are promising. Towards the goal of evidence-based health services, this evaluation indicates that large-scale controlled trials of the Surviving Crying package to substantiate and clarify the improvements in parental mental health found here are warranted.

References

- Alvarez, M. (2004). Caregiving and early infant crying in a Danish community. *Journal of Developmental & Behavioral Pediatrics, 25*(2), 91-98.
- Badr, L. K. (2005). Further psychometric testing and use of the maternal confidence questionnaire. *Issues in Comprehensive Pediatric Nursing, 28*(3), 163-174.
- Barr, R. G., Rajabali, F., Aragon, M., Colbourne, M., & Brant, R. (2015). Education about crying in normal infants is associated with a reduction in pediatric emergency room visits for crying complaints. *Journal of Developmental and Behavioral Pediatrics, 36*, 252-257.
doi:10.1097/DBP.0000000000000156
- Barr, R., Barr, M., Fujiwara, T., Conway, J., Catherine, N., & Brant, R. (2009). Do educational materials change knowledge and behavior about crying and shaken baby syndrome? A randomized controlled trial. *Cmaj, 180*(7), 727-737.
- Barr, R. G., Trent, R. B., & Cross, J. (2006). Age-related incidence curve of hospitalized shaken baby syndrome cases: Convergent evidence for crying as a trigger to shaking. *Child Abuse & Neglect, 30*(1), 7-16.
- Catherine, N. L., Ko, J. J., & Barr, R. G. (2008). Getting the word out: Advice on crying and colic in popular parenting magazines. *Journal of Developmental and Behavioral Pediatrics, 29*(6), 508-511.
doi:10.1097/DBP.0b013e31818d0c0c.

Cook, F., Bayer, J., Le, H. N. D., Mensah, F., Cann, W., & Hiscock, H. (2012). Baby business: A randomised controlled trial of a universal parenting program that aims to prevent early infant sleep and cry problems and associated parental depression. *BMC Pediatrics*, 12, 13-13. doi:10.1186/1471-2431-12-13

Cox, J. L., Holden, J. M., & Sagovsky, R. (1987). Detection of postnatal depression. development of the 10-item Edinburgh Postnatal Depression Scale. *The British Journal of Psychiatry*, 150, 782-786.

Douglas, P., & Hill, P. (2011). Managing infants who cry excessively in the first few months of life. *BMJ (Clinical Research Ed.)*, 343, d7772-d7772. doi:10.1136/bmj.d7772

EuroQol Group. (1990). *EuroQol-a new facility for the measurement of health-related quality of life*. Elsevier.

Freedman, S. B., Al-Harthi, N., & Thull-Freedman, J. (2009). The crying infant: Diagnostic testing and frequency of serious underlying disease. *Pediatrics*, 123(3), 841-848. doi:10.1542/peds.2008-0113.

Frodi, A. M., & Lamb, M. E. (1980). Infants at risk for child abuse. *Infant Mental Health Journal*, 1(4), 240-247.

Fujiwara, T., Barr, R. G., Brant, R., & Barr, M. (2011). Infant distress at five weeks of age and caregiver frustration. *The Journal of Pediatrics*, 159(3), 425-430. e2.

Garratt, R., Bamber, D., Powell, C., Long, J., Brown, J., Turney, N., Chessman, J., Dyson, S. & St James-Roberts, I. (2017). Parents' experiences of having an excessively crying infant and implications for health services: the Surviving Crying Study. In submission.

Hadjistavropoulos, H. D., Craig, K. D., Grunau, R. V., & Johnston, C. C. (1994). Judging pain in newborns: Facial and cry determinants. *Journal of Pediatric Psychology*, 19(4), 485-491.

Hill, D. J., Roy, N., Heine, R. G., Hosking, C. S., Francis, D. E., Brown, J., Speirs, B., Sadowsky, J., Carlin, J. B. (2005). Effect of a low-allergen maternal diet on colic among breastfed infants: A randomized, controlled trial. *Pediatrics*, 116(5), e709-e715. doi:10.1542/peds.2005-014

Hiscock, H., Cook, F., Bayer, J., Le, H. N., Mensah, F., Cann, W., Simon, B., St James-Roberts, I. (2014). Preventing early infant sleep and crying problems and postnatal depression: A randomized trial. *Pediatrics*, 133(2), e346-54. doi:10.1542/peds.2013-1886

Howard, C. R., Lanphear, N., Lanphear, B. P., Eberly, S., & Lawrence, R. A. (2006). Parental responses to infant crying and colic: The effect on breastfeeding duration. *Breastfeeding Medicine*, 1(3), 146-155.

Illingworth, R. S. (1954). Three-months' colic. *Archives of Disease in Childhood*, 29(145), 165-174.

Kurth, E., Kennedy, H. P., Spichiger, E., Hoesli, I., & Stutz, E. Z. (2011). Crying babies, tired mothers: What do we know? A systematic review. *Midwifery*, 27(2), 187-194. doi:10.1016/j.midw.2009.05.012

Laurent, H. K., & Ablow, J. C. (2012). A cry in the dark: Depressed mothers show reduced neural activation to their own infant's cry. *Social Cognitive and Affective Neuroscience*, 7(2), 125-134. doi:10.1093/scan/nsq091.

Long, J., Powell, C., Garratt, R., Bamber, D., Brown, J., Dyson, S. & St James-Roberts, I. (2017). Development of materials to support parents whose babies cry excessively: findings and health service implications. In submission.

Morris, S., James-Roberts, I. S., Sleep, J., & Gillham, P. (2001). Economic evaluation of strategies for managing crying and sleeping problems. *Archives of Disease in Childhood*, 84(1), 15-19.

Murray, L., & Cooper, P. (2001). The impact of irritable infant behavior on maternal mental state: A longitudinal study and a treatment trial. In R. G. Barr, I. St James-Roberts & M. Keefe (Eds.) *New*

Evidence on Unexplained Early Infant Crying: Its Origins, Nature and Management (pp.149-164).

Skillman, NJ: Johnson & Johnson Pediatric Institute.

Papousek, M., Wurmser, H., & von Hofacker, N. (2001). Clinical perspectives on unexplained early crying: Challenges and risks for infant mental health and parent-infant relationships. In R. G. Barr, I. St James-Roberts & M. Keefe (Eds.), *New Evidence on Unexplained Early Infant Crying: Its Origins, Nature, and Management*. (pp. 289-316). Skillman NJ: Johnson & Johnson Pediatric Institute.

Pearson, R., Cooper, R. M., Penton-Voak, I. S., Lightman, S., & Evans, J. (2010). Depressive symptoms in early pregnancy disrupt attentional processing of infant emotion. *Psychological Medicine*, 40(04), 621-631.

Petzoldt, J., Wittchen, H., Wittich, J., Einsle, F., Hofler, M., & Martini, J. (2014). Maternal anxiety disorders predict excessive infant crying: A prospective longitudinal study. *Archives of Disease in Childhood*, 99(9), 800-806.

Petzoldt, J. (2018). Systematic review on maternal depression versus anxiety in relation to excessive infant crying: it is all about the timing. *Archives of Women's Mental Health*, 21, 15-30.

Smarius, L. J. C. A., Strieder, T. G., Loomans, E. M., Doreleijers, T. A., Vrijkotte, T. G., Gemke, R. J., & van Eijsden, M. (2016). Excessive infant crying doubles the risk of mood and behavioral problems at age 5: Evidence for mediation by maternal characteristics. *European Child & Adolescent Psychiatry*, doi: 10.1007/s00787-016-0888-4

Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine*, 166(10), 1092-1097.

St James-Roberts, I., Alvarez, M., & Hovish, K. (2013). Emergence of a developmental explanation for prolonged crying in 1-to 4-month-old infants: Review of the evidence. *Journal of Pediatric Gastroenterology and Nutrition*, 57, S30-S36.

St James-Roberts, I., & Halil, T. (1991). Infant crying patterns in the first year: Normal community and clinical findings. *Journal of Child Psychology and Psychiatry*, 32(6), 951-968.

Stifter, C. A., Anzman-Frasca, S., Birch, L. L., & Voegtline, K. (2011). Parent use of food to soothe infant/toddler distress and child weight status. an exploratory study. *Appetite*, 57(3), 693-699.

Sung, V., Hiscock, H., Tang, M.L.K., Mensah F.K., Heine, R.G., Stock, A., Barr, R.G., & Wake, M. (2014). Treating infant colic with the probiotic *Lactobacillus reuteri*: double blind, placebo controlled randomised trial. *BMJ* 348,g2107 doi: 10.1136/bmj.g2107

Wessel, M. A., Cobb, J. C., Jackson, E. B., Harris, G. S., Jr, & Detwiler, A. C. (1954). Paroxysmal fussing in infancy, sometimes called colic. *Pediatrics*, 14(5), 421-435.

Wisner, K. L., Parry, B. L., & Piontek, C. M. (2002). Postpartum depression. *New England Journal of Medicine*, 347(3), 194-199.

Wolke, D., Bilgin, A. & Samara, M. (2017) Systematic review and Meta-analysis: fussing and crying durations and prevalence of colic in infants. *Journal of Pediatrics*, 185, 55-61.

Key Messages

- During the first four months of age, approximately 20% of infants cry repeatedly for long periods without an apparent reason.
- Most research has targeted the crying and its causes, but there is a need for equal attention to the impact of the crying on parents and subsequent outcomes. This encompasses parental resources, vulnerabilities and circumstances.
- This study provides an initial, prospective evaluation of the Surviving Crying support package for parents who judge that their infant is crying excessively. The package, which includes a website,

printed materials and Cognitive Behaviour Therapy - based programme, is designed to be suitable for National Health Service use.

- The package was associated with substantial reductions in parents' frustration because of their infant's crying and numbers meeting clinical criteria for anxiety or depression halved. Parents' knowledge of infant crying increased, perceived crying amounts and the extent to which parents considered them a problem reduced, and parents' confidence and sleep improved. The improvements in parental mental health were not explained by reductions in infant crying.
- Towards the goal of evidence-based health services, this evaluation indicates that large-scale controlled trials of the Surviving Crying package to substantiate and clarify the improvements in parental wellbeing and mental health found here are warranted.

Table 1: Socio-demographic characteristics of participating parents

| Socio-demographic characteristics | Referred Crying Group | New Birth Visit Group | | All parents with an excessively crying baby | All parents |
|--|-----------------------|-----------------------|----------------|---|-------------|
| | | Crying Baby | No Crying Baby | | |
| <i>Parental Sex: n (%)</i> | | | | | |
| Female | 24 (80) | 27 (100) | 94 (97) | 51 (89) | 145 (94) |
| Male | 6 (20) | 0 (0) | 3 (3) | 6 (11) | 9 (6) |
| <i>Parental Age</i> | | | | | |
| Mean age (years) | 31.5 | 29.6 | 30.7 | 30.6 | 30.7 |
| SD | 5.7 | 4.7 | 5.2 | 5.3 | 5.2 |
| (min – max) | (20-43) | (21-38) | (16-42) | (20-43) | (16-43) |
| <i>Parental Ethnicity: n (%)</i> | | | | | |
| White | 24 (80) | 23 (85) | 86 (89) | 47 (82) | 133 (86) |
| Mixed | 0 (0) | 1 (4) | 2 (2) | 1 (2) | 3 (2) |
| Asian | 5 (17) | 2 (7) | 5 (5) | 7 (12) | 12 (8) |
| Black | 0 (0) | 1 (4) | 3 (3) | 1 (2) | 4 (3) |
| Other | 1 (3) | 0 (0) | 1 (1) | 1 (2) | 2 (1) |
| <i>Highest Education Level: n (%)</i> | | | | | |
| Postgraduate degree | 5 (17) | 6 (22) | 22 (23) | 11 (19) | 33 (21) |
| Undergraduate degree | 6 (20) | 7 (26) | 21 (22) | 13 (23) | 34 (22) |
| Higher post A-level vocational qualification | 4 (13) | 3 (11) | 8 (8) | 7 (12) | 15 (10) |
| A level/NVQ level 3 | 8 (27) | 6 (22) | 19 (20) | 14 (25) | 33 (21) |
| GCSE/NVQ level 2 | 3 (10) | 2 (7) | 10 (10) | 5 (9) | 15 (10) |
| Secondary school education | 0 (0) | 0 (0) | 3 (3) | 0 (0) | 3 (2) |
| Primary school education | 2 (7) | 1 (4) | 1 (1) | 3 (5) | 4 (3) |
| Other | 2 (7) | 2 (7) | 13 (13) | 4 (7) | 17 (11) |
| <i>Employment Status: n (%)</i> | | | | | |
| Full time | 6 (20) | 0 (0) | 2 (2) | 6 (11) | 8 (5) |
| Part time | 2 (7) | 0 (0) | 0 (0) | 2 (3) | 2 (1) |
| Maternity/Paternity leave | 15 (50) | 18 (67) | 74 (76) | 33 (58) | 107 (69) |
| Self-employed | 0 (0) | 2 (7) | 3 (3) | 2 (3) | 5 (3) |
| Unemployed looking for work | 2 (7) | 2 (7) | 1 (1) | 4 (7) | 5 (3) |
| Not in paid employment | 4 (13) | 5 (19) | 14 (14) | 9 (16) | 23 (15) |
| Student | 0 (0) | 0 (0) | 3 (3) | 0 (0) | 3 (2) |
| Full time carer | 1 (3) | 0 (0) | 0 (0) | 1 (2) | 1 (1) |
| <i>Marital/Living Status: n (%)</i> | | | | | |
| Married/cohabiting | 28 (93) | 22 (81) | 92 (95) | 50 (91) | 142 (92) |
| Living alone but supported by partner | 2 (7) | 2 (7) | 1 (1) | 2 (3) | 3 (2) |
| Living with parents/friends | 0 (0) | 0 (0) | 2 (2) | 0 (0) | 2 (1) |
| Single parent living alone | 0 (0) | 3 (11) | 2 (2) | 3 (5) | 7 (5) |

Table 2: Outcome scores and changes from baseline in psychometric measures of wellbeing and mental health for parents with excessively crying infants

| Measure | | Parents overall |
|--|---|----------------------|
| | N ^a | 51 |
| EQ-5D total score | Baseline, mean (SD) | 0.87 (0.20) |
| | Outcome, mean (SD) | 0.90 (0.16) |
| | Adjusted mean at outcome (95% CI) ^b | 0.90 (0.88, 0.92) |
| | Change from baseline, adjusted mean (95% CI) ^c | 0.033 (0.011, 0.055) |
| Edinburgh postnatal depression scale | Baseline, mean (SD) | 10.08 (4.93) |
| | Outcome, mean (SD) | 7.10 (4.50) |
| | Adjusted mean at outcome (95% CI) ^b | 7.10 (6.03, 8.16) |
| | Change from baseline, adjusted mean (95% CI) ^c | -2.98 (-4.05, -1.92) |
| GAD-7 anxiety questionnaire | Baseline, mean (SD) | 6.47 (4.87) |
| | Outcome, mean (SD) | 3.92 (3.87) |
| | Adjusted mean at outcome (95% CI) ^b | 3.92 (2.99, 4.86) |
| | Change from baseline, adjusted mean (95% CI) ^c | -2.55 (-3.48, -1.61) |
| Maternal/ Paternal confidence questionnaire | Baseline, mean (SD) | 2.02 (0.21) |
| | Outcome, mean (SD) | 2.15 (0.19) |
| | Adjusted mean at outcome (95% CI) ^b | 2.15 (2.11, 2.19) |
| | Change from baseline, adjusted mean (95% CI) ^c | 0.13 (0.089, 0.17) |
| ^a Statistics were calculated using individuals with complete data for baseline, outcome, group and change in crying. ^b Linear regression models for means at outcome, both overall and by group, for each questionnaire were adjusted for their baseline score, with group also added as a covariate. ^c Linear regression models for mean change from baseline, both overall and by group, for each questionnaire were adjusted for their baseline score, with group also added as a covariate. | | |

Table 3: Parents' reports of their own sleep and social supports

| | | Baseline | Outcome |
|--|----------------------|------------|------------|
| Average hours of sleep per night | N | 57 | 52 |
| | Mean (SD) | 5.3 (1.3) | 6.5 (1.3) |
| | Range | 2 - 8 | 3 - 9 |
| | Median | 5 | 6 |
| Average hours of sleep per 24 hours | N | 57 | 52 |
| | Mean (SD) | 5.9 (1.3) | 6.8 (1.3) |
| | Range | 3 - 10 | 4 - 10 |
| | Median | 6 | 7 |
| | Missing | 0 | 1 |
| Parental sleep quality rating | N | 57 | 52 |
| | Very Good | 2 (3.6%) | 7 (13.5%) |
| | Fairly Good | 26 (46.4%) | 35 (67.3%) |
| | Fairly Bad | 22 (39.3%) | 8 (15.4%) |
| | Very Bad | 7 (12.5%) | 2 (3.9%) |
| Support from partner | N | 56 | 51 |
| | Enough | 39 (69.6%) | 39 (76.5%) |
| | Not Enough | 14 (7.1%) | 8 (15.7%) |
| | None | 2 (3.6%) | 1 (2.0%) |
| | Don't need | 0 (0.0%) | 3 (5.9%) |
| | Prefer not to answer | 1 (1.8%) | 0 (0.0%) |
| Support from family & friends | N | 57 | 52 |
| | Enough | 40 (70.2%) | 38 (73.1%) |
| | Not Enough | 14 (24.6%) | 9 (17.3%) |
| | None | 2 (3.5%) | 3 (5.8%) |
| | Don't need | 0 (0.0%) | 1 (1.9%) |
| | Prefer not to answer | 1 (3.7%) | 1 (1.9%) |
| How often need support but cannot get it | N | 57 | 52 |
| | Very often | 3 (5.3%) | 1 (1.9%) |
| | Often | 6 (10.5%) | 5 (9.6%) |
| | Sometimes | 33 (57.9%) | 23 (44.2%) |
| | Never | 14 (24.6%) | 19 (36.5%) |
| | Don't need | 1 (1.7%) | 4 (7.7%) |
| | Prefer not to answer | 0 | 0 |

Table 4: Measures of parents' knowledge of infant crying at outcome (n=50)

| | This is new to me | Learned in study | Learned from HV | Already knew* |
|--|-------------------|------------------|-----------------|---------------|
| Infant crying reaches a peak in the first 2 or 3 months before getting less | 7 (14.0%) | 32 (64.0%) | 6 (12.0%) | 5 (10.0%) |
| Infants of this age cry more often in the late afternoon and evening | 2 (4.0%) | 24 (48.0%) | 6 (12.0%) | 18 (36.0%) |
| Even healthy infants sometimes cry unexpectedly or without a clear reason | 1 (2.0%) | 16 (32.0%) | 5 (10.0%) | 28 (56.0%) |
| Even good parents are sometimes unable to soothe their crying infant | 0 (0.0%) | 21 (42.0%) | 3 (6.0%) | 26 (52.0%) |
| It is ok to walk away from a crying infant when his or her crying becomes very frustrating, providing the baby is in a safe place. | 4 (8.0%) | 21 (42.0%) | 7 (14.0%) | 18 (36.0%) |

*Already knew, learned from somewhere else, or can't remember where this was learned.

Table 5: Parents' reports of infant feeding, crying and health

| | Baseline (n=52) | Outcome (n=47) |
|--|-----------------|----------------|
| Infant Age (weeks): | | |
| Mean (SD) | 9.6 (5.6) | 15.3 (5.6) |
| Median | 7 | 13 |
| Range | 3 – 24 | 9 – 30 |
| Infant feeding method: | | |
| Breast milk N (%) | 27 (51.9%) | 25 (53.2%) |
| Formula milk | 28 (53.9%) | 25 (53.2%) |
| Infant solid foods | 2 (3.9%) | 3 (6.4%) |
| Family foods | 1 (1.9%) | 0 (0%) |
| Infant's feeding checked by a professional? N (%) | 30 (57.7%) | – |
| Infant's weight checked by a professional? N (%) | 51 (98.1%) | – |
| Total hours of fuss/crying in a typical day: | | |
| Mean (SD) | 6.9 (3.7) | 2.6 (2.3) |
| Median | 5.7 | 2.1 |
| Range | 1.3 – 17.0 | 0.3 – 13.0 |
| Crying Pattern: hours (%) of fuss/crying in each period of a typical day | | |
| Morning | 1.6 (20.1%) | 0.7 (25.5%) |
| Afternoon | 2.0 (29.5%) | 0.8 (33.5%) |
| Evening | 2.3 (35.9%) | 0.9 (43.8%) |
| Night | 1.1 (15.3%) | 0.2 (6.9%) |
| When crying excessively: | | |
| Infant seemed unwell | 12 (23.1%) | 6 (12.8%) |
| There were concerns about their weight gain | 7 (13.5%) | 8 (17.0%) |
| Infant had feeding problems | 21 (40.4%) | 12 (25.5%) |
| Infant repeatedly brought up feeds | 26 (50.0%) | 19 (40.4%) |
| Admitted to hospital specialist care unit in 1 st week after being born | 4 (7.7%) | – |
| Any other signs of illness in last fortnight? | 18 (34.6%) | 18 (38.3%) |
| Seen GP or other doctor in last fortnight for anything other than crying? | 26 (50.0%) | 17 (36.2%) |

Table 6: Linear Regression using measures of change in crying amount from baseline to outcome to predict changes in parental wellbeing and mental health

| Outcome | Coefficient (95% CI) |
|---|------------------------------|
| Change in EQ-5D | -0.0000135 (-0.007 to 0.007) |
| Change in EPDS | -0.069 (-0.409 to 0.270) |
| Change in GAD-7 | 0.110 (-0.187 to 0.408) |
| Change in Total Confidence | 0.068 (-0.279 to 0.415) |
| Change in Mean Confidence | 0.00242 (-0.009 to 0.015) |
| * Model for change from baseline included the following variables: score at baseline, group and change in crying. | |