

TROUBLESOME CRYING IN INFANTS

The effect of advice to reduce stimulation

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## ABSTRACT

The observation that babies with troublesome crying improve quickly during hospital admission suggested that, if true, a common, quickly reversible, factor may operate. Histories from the parents of such babies suggest that much work goes into trying to console them. It is hypothesised that this may lead to excessive/inappropriate stimulation and the improvement seen in hospital reflects a reduction/change in stimulation.

Two studies were undertaken: 1) To validate the first observation subjects would have to be randomised to home or hospital management. Study 1 was a pilot study which indicated that too few carers were willing to be randomised but there was strong indication of improvement in mothers' distress and in crying in hospital. In a group advised to reduce stimulation at home similar improvement justified the second study. The subjects enrolled for Study 1 were paired with age-matched controls. Biographical data and a measure of carers' distress in the two groups was compared. In this way, a description of the cohort was obtained. 2) Study 2 was a randomised controlled study of the effect of advice to reduce stimulation in addition to an empathic interview. Non-parametric statistical methods, which described qualitative change, were used to measure change in crying and in carers' distress. The results indicated that the advice was helpful.



Whether this advice is any better than any other advice and whether stimulation is reduced is not known. In any event these studies suggest that most infants with troublesome crying are unlikely to have an underlying organic disorder.

Previous research into the effect of interventions in infant colic have examined the effect of the intervention on crying and fussing times. The subject is difficult to study because of difficulties with the definition of 'colic' and crying and fussing. This is the first undertaking of a systematic study of the effect of an intervention to treat troublesome crying in infants and the first time non-parametric statistical methods have been used.

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## ADDITIONAL MATERIAL

A video tape of an example of the techniques used in this study has also been presented and has been used as a teaching tool. It demonstrates an interview with carers and the method used to soothe infant crying, to show carers how to develop alternative communication methods and reduce arousal and how to encourage the development of a normal sleep pattern.

## CHAPTER 1 - INTRODUCTION

There are two broad views of the problem of troublesome crying in infants. One proposes an **organic** cause for a syndrome of excessive crying in infants of less than three months - colic. This is presumed to be caused by pain and associated with excessive flatus. A second proposes a **non-organic, constitutional or behavioural** cause which is responsible for troublesome crying throughout infancy. It is possible that the two are associated and, indeed, there may be many reasons. The difficulty of defining either colic or excessive crying, which may also be troublesome, has confounded research into cause and treatment. Recent workers have used the terms 'colic' and excessive or troublesome crying interchangeably (Carey,1984; Illingworth, 1985; Forsyth,1989). Discovering satisfactory methods of measuring colic or crying and the difficulty of designing clinical trials of treatment have hampered progress (Sampson,1989; St James-Roberts,1992).

Until the middle of this century there was little written about either crying or colic. Illingworth (1954) reviewed the literature. He found only 38 references to the subject in the *Indicus Medicus* and no reference in three contemporary paediatric textbooks. Bax (1975) also drew attention to the dearth of systematic study of the subject and to the relationship between crying and child abuse (Ounsted et al 1974). Since then there has been a growing body of literature on the topic of both colic and crying but even so a recent major textbook on infant development (Osofsky, 1987) included only 2 references to crying. In recent years an international

multidisciplinary group of workers interested in infant crying - including psychologists, psychiatrists, paediatricians and even experts in acoustics - has convened a conference and workshop at three-yearly intervals to discuss developments in research in infant crying. The subject of excessive infant crying has been included at these meetings.

Excessive crying and/or colic are common complaints in Western countries. How much of a problem these are in other cultures is known for only a few groups (Winn et al, 1984). Forsyth (1985) identified the problem as the commonest complaint in a North American population of mothers of infants under 4 months. It is a frequently cited reason for giving up breast-feeding (Bernal, 1972; Forsyth, 1985). Because there are no satisfactory explanations or treatment and because the symptoms cause great family distress, there has been much written for the lay public (Douglas and Richman 1984; Weissbluth 1985). Some books offer a bewildering range of approaches, from cranial osteopathy to baby gymnastics (Gray, 1987). One of the most recent suggests a single set of procedures (Taubman, 1992). Help groups, such as the London-based 'Crysis', offer telephone counselling for carers who are worried or exasperated by their infant's crying. Excessive crying in an infant as a cause of assault is regularly reported in the media (The Times, 1989; Daily Star, 1990). Several writers have highlighted the importance of such crying as a source of family disruption and an element in child abuse (Berger, 1977; Frodi, 1985). Weston (1968) found that excessive crying was

given as the reason for battering by 80% of the parents whose infants were less than a year old. Serious study of this common and distressing complaint seems justified.

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## 'NORMAL' CRYING

Since all babies cry it is appropriate to consider how developmental psychologists and allied workers view this behaviour and to review what is known about how infant caretakers respond to crying. This will provide a background for the understanding of 'troublesome crying'.

### Attachment

Attachment behaviours of infants (Ainsworth, 1969; Bowlby, 1958,1969) which promote proximity to and contact with the mother include signalling behaviours which stimulate the mother to come into closer proximity or contact with the infant. Crying is the most conspicuous of early attachment behaviours. Bowlby (1969) has argued that the biological function of infant-mother attachment is protection from danger from the environment. Observations of many closely-related mammals support this hypothesis. Indulgence of early infant signals, carrying and immediate suckling in response to crying are characteristic of several monkey species (Hinde and Spencer-Booth, 1967; Jensen, 1968; Kaplan, 1972). It has been demonstrated using skin thermography that human infant crying results in a rapid rise in skin temperature over the mother's breasts and so appears to prepare the mother for feeding (Vuorenkoski et al, 1969).

Wolff (1969) addressed the hypothesis that the discomfort from being wet or soiled causes crying. This is biologically an adverse condition for an infant. Whether carers replaced wet nappies with others which were also

wet and at the same temperature or whether they replaced them with dry nappies the infants stopped crying. However, those given a cold, wet nappy did not. He drew the conclusion that the infant is crying to make contact with the caregiver.

It seems then that infant crying signals both hunger and cold and is biologically designed to effect parent proximity.

Thus this phenomenon can be likened to an "acoustic umbilical cord" (Ostwald, 1972). Crying in the first three months for whatever reason is of such intensity and persistence that all within earshot are alerted. Tavolga (1970) calls these signals "biosocial". They elicit general protective nurturant responses from adults and remain available for the organism's life if needed under emergency conditions. He believes that the persistence of the capacity to vocalise emotions in this way guarantees a response which under normal conditions is immediate and universal.

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### Settings for the study of crying

Crying has been the subject of laboratory studies where the acoustic quality of the cry has been analysed and where the response of listeners has been examined. This is the study of infant crying at what Barr (1990) calls the 'microlevel' where the morphology of crying revealed by spectrographic techniques is applied to single cry *cycles*. (Wasz-Hockert 1968; Lester and Boukydis, 1985) and where listener response to such cycles is examined. These studies are therefore quite different in context from 'macrolevel' studies which examine crying and responses to it in the home and in the clinical context and refer to duration and frequency of crying over hours, days, weeks and months. Studies using direct observation by the investigator of infant and carer examine cry *events* - consecutive series of cry cycles - (Bell and Ainsworth, 1972; Hubbard and van Ijzendoorn, 1987; Barr and Elias, 1988;) and those using diaries, questionnaires, recordings of crying on cassettes and so on examine crying *bouts* - clusters of cry events, often including pauses between events - (Brazelton, 1962; Hunziker and Barr 1986; St James-Roberts, 1989).

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## Spectrographic and listener perception studies

### i) Acoustic quality of the cry:

Wasz-Hockert et al, (1964) believed parents were able to identify four types of cries: birth, pleasure, pain and hunger. They also found concordance between spectrophotographic identification and the ability of adults to identify the cry types by auditory perception. This varied according to the adults' experience with infants. However, Muller et al (1974) believe that acoustic features of the cry carry little unique meaning for the care-giver. In a controlled experimental protocol, three types of cry were elicited - pain, hunger and startle - from 4 male and 4 female infants aged 3-5 months. Extracts of 2 stages of each recording were presented to groups of the infants' mothers and mothers of infants of a comparable age. Both groups incorrectly perceived an excessive number of samples as hunger cries. Murry et al (1975) observed that mothers could recognise their own children simply on the basis of a 15 second cry, although they could not recognise the cry type. Correct responses ranged from 86% to 98%, much higher than chance. Thus, there was more information common to all three cry types than for any one cry type which influenced a mother's recognition.

There are some areas however where it is claimed that the acoustic quality of the cry might be useful clinically. Babies who have suffered birth asphyxia (Michelson, 1971) or who are hyperbilirubinaemic (Wasz-Hockert, 1964) can have distinctive cries in the neonatal period. This however may have little bearing on the prognosis, although it appears that asphyxiated

babies who have normal cries do not sustain permanent brain damage (Michelson et al, 1977). Babies with unusual syndromes such as cri du chat have very abnormal acoustic cry quality (Wasz-Hockert, 1968).

More recently, it has been claimed that neonatal cry patterns in preterm infants relate to mental performance in the second year (Lester, 1984). It has been suggested that infant cry analysis might be important in identifying high-risk infants who appear normal and that, this being so, cry analysis could be as important as other screening tests in the newborn period (Golub and Corwin, 1985). A group that might benefit are those at risk for sudden infant death (SIDS). There is anecdotal evidence that some infants who have died of SIDS have had abnormal sounding crying or an unexplained bout of crying just before death (Naeye et al, 1976). Golub (1992) has recently undertaken a prospective analysis of a large group of approximately 1000 infants, 12 of whom suffered SIDS. He has identified by acoustic cry analysis a group who have an increased risk of SIDS with an odds ratio of 35.

ii) Adult cry perception:

The attempt to understand adult perception of the meaning of infants' crying has included the examination of the quality of the cry, presumed to affect the disposition or motivation of the listener to respond, by feeding the infant or at least trying to stop the crying (Murray, 1979). What determines response is, however, far more complex: infant state - ranging

from deep sleep to awake, alert and active - patterns of cry features, time since last feed, cultural influences and the history of the relationship between the carer and the infant all affect response.

Zeskind et al (1978) examined the relationship between neonatal cry features and obstetric histories. On the basis of the acoustic quality of cry elicited from a pain stimulus healthy 2-day infants of complicated pregnancies could be distinguished from a similar group of infants from pregnancies of low complications. Naive adults could distinguish between the 2 groups, the first group being perceived to have more aversive features - features which evoked a negative, non-empathic response - and to have more distressing cries.

This difference in crying and the carer's response to the aversiveness may contribute to the notion of the 'difficult' infant (Thomas and Chess, 1977). The concept of a difficult infant focuses on the lack of a good fit between the infant's rhythms i.e. sleep and feeding patterns and behavioural style and the caregiver's goals and expectations. Zeskind et al (1985) suggested that adult perceptions of infant crying are based on the nature of the sound rather than the cause of the sound. Thus, even though two infants may be crying for the same reason, infants may receive differential treatment depending on the quality of the cry sound. Differences in the nature of the caregiving environments will determine the response offered. In anecdotal references to child abuse excessive patterns of high-pitched cry sounds are often reported (Gil, 1970; Parke and Collmer, 1975).

The terms egocentric or altruistic have been used to describe whether responses are to the listener's or to the distressed subject's advantage (Hoffman, 1975). 'The listener who cannot escape usually reduces the noise by soothing whatever baby-needs occasion it' (Ostwald, 1963). This describes an egocentric response. The altruistic response to distress operates when the listener who is also distressed is motivated to relieve the other. There may be an optimal range of distress cues; they must be sufficient to activate distress in the observer so that help can be offered but not be so disturbing as to elicit avoidance or aggression towards him (Murray, 1985). The notion of a graded response is a *liet motif* throughout the literature on infant cry research.

Frodi et al (1978) conducted several studies examining listener perception to infants' crying. In a study of a 5-month old infant 96 parents - 48 mother-father pairs - viewed and heard a video-tape with the baby smiling or crying. Some parents were told the infant was 'normal', some that it was 'difficult' and some that it was premature. Measurements of autonomic arousal were made and parents reported how they felt (Frodi et al, 1978a). The cry elicited a response of increased skin conductance and diastolic blood pressure, a pattern previously identified as a response to aversive and aggression-provoking stimuli, in other words a response which indicates that the listener is upset. The parents also reported negative feelings. The 'difficult' and 'premature' infant elicited less sympathy than the 'normal' infant. The infant's smile was associated with normal physiological responses and positive feelings. Mothers and fathers

did not differ in their responses. Thus the response of the members of a large group of adults to the same cry depended on perceptions of the baby's temperament or physical condition.

A second study by the same group examined responses in the same way to premature and normal infants' cries at a time when both were ready for discharge (Frodi et al 1978b). Once again the premature infants' cries provoked the more negative responses. Taking the findings of these two studies together the perceptions of listeners about the infant - 'difficult' or premature i.e. frail and vulnerable - contribute to the response to crying. Furthermore, mothers who had had premature babies responded to the cries of premature babies with greater aversive responses than mothers of term infants. Mothers who perceived their own babies as difficult were also more likely to demonstrate the physiological arousal associated with an aversive response and less likely to interact with the stimulus babies than mothers with 'easy' babies. Similar studies with parents who had abused their infants (abusers) and non-abusers demonstrated that the abusers had more pronounced physiological responses and more negative feelings to infants' cries than the non-abusers (Frodi and Lamb, 1980).

Lounsbury and Bates (1982) recorded crying just before a feed in infants perceived by their mothers to be either 'easy' or 'difficult'. Hunger was the presumed cause of the crying. These cries were played to mothers who had infants of their own. The listeners were not told to which group the recorded cries belonged. The cries of infants with the 'easy' temperaments were believed to be due to physical discomfort or hunger by the listening



mothers, whilst the cries of those classified as 'difficult' were believed to be crying for psycho/emotional reasons. The cries of the 'difficult' temperament group produced most negative responses from the listeners and also demonstrated as a group acoustic features which identified them.

Boukydis and Burgess (1982) examined autonomic arousal in three groups of listeners by measuring changes in skin conductance in response to the cries of babies rated difficult, average or easy by their mothers. The groups of listeners were primiparous, multiparous and non-parents. Overall, primiparous women showed the highest arousal. Multiparous parents with previous exposure to infant crying showed lowest overall arousal but most arousal to 'difficult' cries. Subjects also recorded their perceptions of cry. Men felt more anger and described the cries more 'spoiled' and the highest scores were for the difficult group. 'Difficult' cries were perceived as being caused by more psychologically complex reasons thus confirming Lounsbury and Bates' work and suggesting that there is a component to the cries of difficult babies that can be identified by listeners. Are the cries of these 'difficult' infants constitutionally different or do they reflect an environmental effect, the most obvious effect being care-giver responsiveness?

By manipulating cry acoustics with audiotape recordings and having adults rate cry tapes, one could determine the acoustic features that adults use to discriminate among cries. Adults do not however respond uniformly to the cries of infants and so the acoustic features have very limited clinical value. What does seem to be of clear importance is the variability of care-giver perception and this must relate in some measure to care-giver

responsiveness to crying. Zeskind (1980) in a follow-up to a study of adult perceptions to low and high-risk infants examined the responses to such infants. Parents but not non-parents responded to the cries of high-risk infants with more 'tender and caring' intentions and intentions that would be 'more effective immediately at terminating the crying'. Their responses to these high-risk infants were more consistent. It was postulated that these responses reflected a functional perspective of the cries of the high-risk infant.

iii) Methodological difficulties of spectrographic and listener perception studies

Boukydis (1985) has drawn attention to the methodological difficulties around the study of the cry as a communication and interpersonal event (Lester and Zeskind, 1978; Ostwald and Murray, 1985). How is one to define the conditions which cause a cry? Stimuli producing pain are poor imitations of what causes babies pain in reality. Heel pricks within the context of necessary investigations may be excessive stimuli and cause an exaggerated response. Flicks with a rubber band may not be acceptable ethically. Future laboratory investigations of these aspects of crying will need to address more carefully the conditions of crying and will require a more rigid definition of cry types. The intertwining aspects of the 'event' must be teased out: adult perceptions of the measurable characteristics of the cry, assumptions about the infant's underlying physical or psychological state, report of the response to the cry. Each may influence the other. Physiological measures can correlate with the experience of the

event but can only indirectly reflect what the cry means for the individual. The stress arousal response to the cry may be initially adaptive, moving the hearer to a positive care-taking response, but as the cry and context changes the arousal may increase so that the response is eventually aversive and maladaptive.

Without successful resolution of the cry, the listener becomes helpless. Failure to master this conflict may promote a breakdown of the carer-infant caregiving relationship and, at worst, lead to abuse. von Eckartsberg (1978) has drawn attention to methodological difficulties in studies of interpersonal perception and has emphasised the difficulty of unravelling the many variables which confound such studies. Social psychology demands that observations, descriptions, countings and comparisons of whatever is the subject of study must be undertaken within the domain of everyday living. However '.....merely focusing on (the) observable behaviour, and thus condemning oneself to an outsider-observer position, still leaves the reality that is experienced by the actor in the event untouched....."Why don't we just ask the person what's going on?".....'

There is no firm evidence that listeners can consistently distinguish between the cries of hunger, pain and other discomforts in a way that would be clinically helpful. In summary, the individual carer may be unable to determine the cause of their infant's crying simply by listening to it and must use other information - such as time from the last feed - to adduce cause.

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### Care-giver responsiveness

Bell and Ainsworth (1972) considered maternal responsiveness to infant crying with reference to the belief popular in the United States earlier in the century that to respond to an infant's cries was to 'spoil' him. These workers reviewed the U.S. Children's Bureau *Infant Care* pamphlets which showed that in the period between 1920 and 1940 mothers were admonished not to pick up a baby between feedings. From the 1924 edition they quote 'crying will get him what he wants, sufficient to make him a spoiled fussy baby and a household tyrant whose continual demands make a slave of his mother'. They believed that this advice may have been based on extrapolations from learning theory which assume that to respond to a cry would enforce crying behaviour. Experimental studies on both infants (Etzel and Gewirtz, 1967) and a very small number of preschool children (Williams, 1959; Hart et al, 1964) suggested that crying and temper tantrums could be reduced by extinction procedures. In other words letting the infant or child continue with the behaviour - crying or having a tantrum - would discourage further episodes of the same behaviour. In the infant study smiling and eye-to-eye contact was reinforced at the same time.

Bell and Ainsworth studied 26 mother-infant pairs. Maternal responsiveness to crying, interventions and their effectiveness were all observed regularly over about one year. The data suggest that in the first 3 months

crying was a signal that promoted proximity and contact with the mother by activating her behaviour. The most frequent intervention was picking up the infant - 80% - and this stopped the crying. Over the year crying decreased as other communication signals developed. The infant was less ready to use crying as a signal by 3-6 months. The more responsive the mother was the less likely the baby was to cry and the more likely he was to develop more varied modes of communication.

Bell and Ainsworth believed that their data showed that those infants whose mothers had responded promptly in the early weeks of life were surprisingly content with less physical contact at the end of the first year whereas those held for relatively brief periods during the early days tended to be ambivalent about contact at the end of the first year. The authors believed that infants from the latter group do not respond positively when held but yet protest when put down and do not turn readily to independent activity.

Thus, Bell and Ainsworth suggest that low early maternal responsiveness produced high subsequent infant crying.

The contradiction of advice about what to do when an infant cries requires further examination. It is possible that this has arisen because of confusion about the paradox of the positive function of crying in the promotion of care-giving and the negative aspects of crying which can lead to rejection. Barr (1990) has discussed this paradox. He argues that it is not simply crying but prolonged bouts of crying which promote negative responses. This would fit in very well with the hypothesis of an optimum

range of distress cues that elicit an altruistic response from the listener. Anything in excess of this range elicits an egocentric response and aversion or even aggression. Once again an argument is presented for a graded response.

If a crying baby is perceived as uncontrollable i.e. the parent is unsuccessful in terminating the cry, he/she may develop a sense of helplessness. If a caretaker is unable to develop effective soothing techniques, the crying infant may trigger the expression of abusive behaviour.

Crockenberg and Smith (1982) studied the characteristics of infants and mothers which influence the nature of their interaction during the early months of life. They considered the potential effects of an irritable infant temperament on the evolving mother-infant relationship, - the reverse of Bell and Ainsworth's' hypothesis - and alternately, the effects of mother-interaction patterns on subsequent infant irritability. Neonatal irritability was measured independently of the mother and was defined as 'time to calm'. The intervention used to calm and who was calming was not described. Newborn irritability did not predict the amount of subsequent crying or fussing. However, unresponsive maternal attitudes and behaviour did predict the amount of fussing and crying at three months. The authors believed that, like Bell and Ainsworth, the amount of crying and fussing at three months is most likely a function of mother behaviour and not related to infant irritability. Gewirtz and Boyd (1977) took issue with Bell and



Ainsworth's findings on the grounds that the analysis and interpretation of their data was flawed. They in turn believed that infants were conditioned to cry less with less maternal responsiveness.

Landau (1982) has outlined the controversy. In contrast to Bell and Ainsworth's findings, Moss (1967) found that prompt reaction to infants' fussing during the first three weeks of life resulted in a higher rate of fussing at 3 months. It has also been demonstrated by Brackbill (1958) and Etzel and Gewirtz (1967) that rates of fussing and crying could be reduced through procedures of extinction in which crying and fussing are ignored and smiling, a competing response to crying, is reinforced. In Landau's own study he examined the responses of Bedoin tribespeople whose culture does not allow for any fussing. This culture responds by picking the infant up and feeding. More responding however led to more fussing. Landau has reconciled his findings with Bell and Ainsworth's by indicating that even in their study the Western mothers did not respond to a 'little cry' such as one when the baby was going to sleep or being turned over. And so Landau too has argued for a graded response.

To try to address the debate, Hubbard and van Ijendoorn (1987) replicated the Bell and Ainsworth study and described an inverse relationship between maternal unresponsiveness early in the first year and crying later in the year. In their report is presented the debate which followed publication of the Bell and Ainsworth study. The main criticisms of the study concerned the documentation of the observations and the statistical handling of data which they claim allowed 'spurious correlations'

to be made. Hubbard and van Ijendoorn have discussed the possibility that lack of responsiveness results in a reduction in crying and represents an extinction process. In other words, the infant is conditioned to stop crying. However, their main proposal is that the response depends on the cry. Mild forms of distress vocalisations do not require responses, while severe cries demand them.

The hypothesis of differential responsiveness implies that maternal unresponsiveness has an increasing effect on severe distress vocalisations and a declining effect on mild forms of distress vocalisations.

This is in accordance with Bowlby's hypothesis, that crying is a graded signal. It is his view that, as a rule, crying leads a mother to arrest it; this she does either instantly, as when she hears a sudden pain cry, or in her own time, as when rhythmic crying builds up gradually (Bowlby, 1971).

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### Infant crying and development

Emde et al (1976) indicated that the coincidental decline in crying and fussiness and the onset of smiling between 2 and 3 months after birth is associated with parental delight and a sense that the infant is 'truly human'. An alert infant is available for reciprocal interaction and for smiling and eye contact and thereby provides a mother with tangible reward for the extraordinary effort she expends in caring for her baby (Robson, 1967). The infant has developed signals other than crying for communication.

At three months the infant is free of the primitive reflexes which dominate motor activity in the early weeks of life. He is able to open and close his hands at will and follows people and objects with his eyes. His ability to sustain prolonged periods of sleep and wakefulness must be dependent on an increasingly higher level of organisation of the central nervous system. The electroencephalogram shows evidence of a maturing cortex and this is consistent with the anatomical evidence of remarkable growth in cortical connections in the first three months of life (Conel, 1947). The development of the diurnal cycle is explained by a combination of central nervous system development, learning in relation to the family's behaviour and the effects of metabolic diurnal rhythms most of which in turn depend on central control (Parmalee, 1964). Thus, nature and nurture work together to allow the infant to develop methods of communication more appropriate to independence. The infant no longer needs such long periods of close proximity to the caregiver and so crying is less essential.

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## Quantifying crying and responses

### i) Crying times

Brazelton (1962), Barr et al (1988) and St James-Roberts and Halil (1991) have all examined 'normal' crying times and related them to the time of day. Although the methods used were different their conclusions were similar. Barr has highlighted the difficulties of defining crying and has outlined the problems of recording by diary and by questionnaire.

Brazelton's 80 subjects were asked to complete daily diaries for 12 weeks from birth. He acknowledges that the demanding effort involved in this and the contact with a paediatrician during the study must have been major confounding factors in the accuracy of his data. His results showed median crying times of 2 - 2.5 hours each day over the first 2 months with a wide range (1.5-3.5 lower - upper quartile) between subjects and then falling to 1 hour each day with much less variability (0.5-1.2 lower - upper quartile) at 12 weeks.

The 10 patients reported by Barr et al (1988) kept diaries over a 24 hour period and the records were compared to tape-recordings of vocalisations made by the babies at the same time. There was a correlation between the amount of crying recorded in the diaries and that on the tape-recordings but none between fussing and 'negative vocalisations' on the tape. There was however no agreement between the amount of crying and fussing in the diaries and tapes, mean 125 minutes/24 hours (standard deviation

(SD) = 45 minutes) in contrast to 29 minutes/24 hours (SD = 15 minutes) respectively. This study makes a most important point: tapes record only the vocal component of crying and not the distress perceived by parents who see their babies being distressed on the basis of motor and other behaviours when they are not demonstrating the vocal component of crying. As part of the same study, a group of parents were asked to complete diaries when their infants were 6 weeks old for seven days. 91% did so and so it was concluded that diaries were generally acceptable. The authors acknowledged that diaries are exacting to complete and may result in selective data loss for particular sub-groups in the community, such as low educational and socio-economic status groups. Barr (1990) has also admitted that day-to-day fluctuations may be considerable so that measurements over a 24 hour period may be unreliable and thus an unsuitable tool for measurement.

St James-Roberts and Halil (1991) examined infant crying patterns in the first year in groups of normal community subjects and clinical subjects i.e. those whose carers had complained that crying was a problem or that the baby had colic. A 7-point questionnaire was used to gather information about crying times and also associated parental variables. Parents were asked to record from memory how much and when their babies cried over the previous 7-day period in each quarter of the first year. 100 subjects were enrolled in each quarter. In the first 3 months the mean crying time was 121 minutes (SD = 105 minutes), a figure not dissimilar to Barr's. This fell to between 60 and 70 during the remainder of the year. Smaller numbers of clinical cases were studied in the same way.

37 subjects in the first quarter cried for a mean of 320 minutes in the first quarter and 10 in each subsequent quarter for a mean of about 200 minutes each day. In the first 3 months the predominant time of day was the evening, comprising 40% of the time. For the rest of the year where a peak was perceived it was in the evening.

St James-Roberts et al (1990) recorded 24 hour voice-activated tape-recordings of infant vocalisations which confirmed that infants referred for persistent crying cry, on average, twice as much as community infants. This study also indicated afternoon and evening clustering of crying at 6-8 weeks in community and referred infants. These convergences confirm that, in these respects, maternal perceptions of infant crying are direct reflections of infant crying itself. In other words, when mothers report that their babies have excessive crying they should be believed.

## ii) Caretaking style and its relationship to crying

Studies quantifying infant crying have related the time spent crying with or without fussing each day to caretaking variables such as the time mothers take to respond (Bell and Ainsworth, 1972), carrying (Hunziker and Barr, 1986), 'responsive' nursing (Sander et al, 1970) home versus institutional caregiving (Roe, 1988) and cultural caregiving styles (Caudill and Weinstein 1969; Landau, 1982; Thoman, 1983; Hubbard and van Ijzendoorn, 1987). One of the things that differs between groups offering different caregiving styles is the amount of crying.



Roe et al (1988) showed that institutionalised infants cried and fussed less than home infants. Biological mothers rocked and touched their infants and vocalised in a face-to-face fashion significantly more than caregivers who provided more vocalisation without establishing eye contact. A recent report from Prague describing the day of institutionalised infants between 0700h and 2100h indicated that only 30-40 minutes were spent crying at 4 weeks, increasing to about 60 minutes at 8 weeks and falling to low levels thereafter (Dittrichova, 1992). These low levels of crying and the absence of prolonged bouts of crying were ascribed to the institutionalised routine for these infants together with the responsiveness of the nurses.

These observations on institutionalised children are very difficult to interpret as observation of caregiving style is over a short timespan. It is important not to draw conclusions about cause and effect.

All these studies documented an early peak pattern at about 8 weeks.

Most studies have been undertaken in modern or Westernised societies. Anecdotal reports of infant behaviour in primitive societies suggest that infants are on the whole quieter. Brazelton (1969) observed that Zinacanteco Indian infants remained in quiet alert states for long periods with none of the deep sleep, intense crying or sucking behaviour seen in infants of industrialised societies. Kenell (1980) reported that crying in African tribal infants was rarely heard.

Konner (1976) set out to examine the behaviour of infants and their caretakers in the hunter-gatherer society of !Kung San infants. This group was chosen as it was believed to represent a contemporary group with a culture similar to our predecessors. Five dimensions of infant caretaking were considered of interest: the "dense social context" in which the infants are raised, the constant caretaker contact, the carrying in a sling, the continuous feeding pattern, and the universal and immediate response to infant signals. These dimensions differ from Western norms. !Kung San infants are carried for 80% of the time in contrast to 25% in western infants. !Kung infants feed three or four times an hour from the breast for 2 minutes per feed. They may nurse many times a night without waking their mothers. It seems quite possible that some of this 'feeding' may represent non-nutritive suckling, and fulfils the same function as that of a pacifier. Bell and Ainsworth (1972) reported no response to crying in 46% of crying episodes in their group of American infants and Hubbard and van Ijdoorn (1987) 44% in a group of Western Europeans. The rapid response rate is not only a feature of the !Kung San infants but of many other hunter-gatherer societies and of related mammalian species (Barr 1990). Barr et al (1987) showed that in the !Kung San infants, as in Western infants, the amount of crying peaked in the early months.

Hunziker and Barr (1986) tested the hypothesis that increased holding and carrying might reduce crying in Western infants. Infants were studied between week 3 and 12 in a randomised controlled study. The subjects were asked to increase carrying to a minimum of 3 hours per day and not just in response to crying. The results showed that both the amount of crying was reduced and the pattern of crying changed from a peak at 6

weeks to a fall during the period of the study to reach levels similar to !Kung infants (Barr,1990). There was however no difference in the frequency of the crying.

Barr and Elias (1987) further compared the effect of decreased feeding intervals in a group of American mothers - the La Leche League - which promotes the practice of increased proximity and frequent nursing, with a control group of mothers. Mothers who had decreased feed intervals and quick response times had infants at 2 months who cried less than those who were slow responders and who had long interfeed times. This difference was not true at 4 months i.e. after the early crying peak was over.

Thus three of the elements of the !Kung caretaking style - quick response to crying, constant carrying, and frequent feeding - may influence crying in Western infants and all tend to reduce crying.

Barr (1990) resolves the early crying paradox - the adaptive function of bringing carer and infant into proximity and the maladaptive function of alienating care-givers and other listeners - by suggesting that the caregiving practices in Western societies potentiate bout length. Frequent short bouts are sufficient for the positive adaptive function of nutrition, protection and mother-infant interaction. Prolonged bouts of crying rather than frequent crying episodes are not seen in those non-Western groups which have been studied. Possibly this was also the case in our evolutionary past. Thus an argument can be made that it is not the

frequency but the length of the crying episodes that is maladaptive and predisposes to complaints of excessive crying, discontinuing breast-feeding and, in extreme cases, to abuse.

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## Infant temperament and crying

There has been much debate about whether it is care-taking style or infant temperament which is responsible for infant 'difficultness' (page 17). Included in this concept is the amount of crying and fussing. Bates et al (1979) using a questionnaire documented that mothers regarded fussy, hard-to-soothe, labile infants as difficult. Barr et al (1989), by asking mothers about how easy or difficult their infant was, examined temperament as a determinant of early infant crying and concluded that although it appeared to predispose to crying it did not predict crying.

Are infants because of innate temperamental differences more likely to be troublesome or difficult and thus cry more? Wolke (1990) has reviewed this topic. Are difficult infants born like this or is their difficultness a perception ascribed to them? If this is so then the environment in which they develop may be coloured and the infant managed and related to in the context in which he/she is perceived.

Wolke asserts that traditional behaviour researchers have assumed that parent reports of infant behaviour are accurate accounts of infant behaviour (Thomas et al, 1982; Carey, 1982). This has become the focal point of infant temperament research in the last decade. He argues that there is little correlation between maternal measures of infant temperament and laboratory - based assessment of behaviour in the first 9 months and that maternal reports are partly or mainly maternal subjective perceptions rather than reports of objective infant difficult temperament. Most of the

work had been undertaken in infants 3 months or older. St James-Roberts and Wolke (1988) compared mother's and professionals' assessments of newborn behaviour. 40 primiparous, breast-feeding, middle-class mothers and their healthy newborns were studied. There was low-moderate agreement between the different 'objective' measures of newborn difficult behaviour and moderate agreement between the different mothers' measures of newborn unsettled behaviour. In contrast, there was poor agreement between objective and maternal measures on who is a difficult or easy newborn. In other words, there is only agreement on what behaviour features characterise a difficult newborn, but only poor agreement who these newborns are. Maternal ratings were not influenced by obstetric factors. Maternal confidence as reported by the mother herself or by the nurses was found to predict maternal specific and global ratings of newborn unsettled behaviour. More confident and secure mothers rate their babies as easy.

Vaughn (1987) has shown that maternal anxiety in the prenatal period when it cannot have been influenced by neonatal behaviour is a powerful predictor of maternal perceptions of difficult infant temperament.

Zuckerman et al (1990) showed that maternal depression during pregnancy was positively associated with infant inconsolability and excessive crying. They suggested that maternal depressive symptoms may be part of a sequence which starts before parturition.

As Wolke has asserted, these findings do not lend much support to the idea that temperament traits are expressed in the newborn period or that they exist at all.

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## COLIC, EXCESSIVE AND TROUBLESOME CRYING

### Definitions

Charles Darwin in 'The Expression of Emotion in Man and Animals' (1886) described an infant behaviour complex very similar to what is now called colic as follows: 'Infants when suffering even slight pain scream. Whilst thus screaming their eyes are firmly closed so that the skin round them is wrinkled and the forehead contracted into a frown. The mouth is widely opened...so as to assume a squarish form. The breath is inhaled spasmodically.'

Wessel et al (1954) gave a more precise definition of a fussy infant. This is one who, otherwise healthy and well-fed, has paroxysms of irritability, fussing or crying lasting for a total of more than three hours a day and occurring on more than three days in any one week.

Illingworth (1985) again addressed the problem of definition. The classic symptom complex described by Brennemann (1943) and Spock (1944) was of a thriving infant who in the evening, for no apparent reason, develops paroxysms, beginning with flushing of the face, a frown, drawing up of the legs, followed in a few seconds by high-pitched screaming, suddenly ending in a few minutes and followed at intervals for up to two or three hours. During the attack the baby is inconsolable, there are loud

borborygmi, and the pain is relieved by the passage of flatus from the rectum, by the passage of stool, or by an enema. Milder attacks were those of intermittent evening fussiness.

In the minds of many the term 'infantile colic' is used for the complaint of troublesome crying for no apparent reason, as all needs such as hunger or other discomforts have been met (Brazelton, 1962; Forsyth, 1989). Carey (1984) stressed that the amount of parental complaining about crying, whether normal or excessive, is not necessarily proportional to the extent of crying. He used the term primary excessive crying to describe crying substantially in excess of the mean. Infants who cried excessively thus represented the extremes of the normal distribution in intensity, frequency and duration. Colic seems to have been reserved both in professional and lay texts for symptoms in the first three months of life (Illingworth, 1954; Brazelton, 1985).

Most recently Barr et al (1992) have tried to further define 'colic'. They asked groups of carers who complained that their infant had colic to keep diaries of the complaint for 7 days. The group was divided into 2: those who had 'Wessel-type colic' of more than 3 hours/day for more than 3 days each week and those who did not. This latter group was not shown to differ from controls in total amount of crying or in number of bouts/day or in length of bout. The only difference was in the sound of the crying which was considered more 'sick-sounding'. What differed between the colic groups was bout length. The Wessel's colic babies cried for a mean 4 hours/day (SD 1.3) and the non-Wessel's infants for a mean 1.8 hours/day (SD 0.8). Thus there appears to be a complaint of colic when

babies cry for the same time as controls and a complaint of colic when they cry for longer in total each day with each bout being longer and had more days in the week when the crying is over three hours in the day.

Because the definition of colic is imprecise it is difficult to know how to evaluate and compare studies of the subject. What appears to be common to all infants with 'colic' is inconsolable crying. For the purposes of this report the terms will be used interchangeably unless otherwise stated.

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## Prevalence

Wessel et al (1954) in a study of 98 infants and using the definition described above identified 25% as having colic.

Paradise (1966) in a prospective study of 146 normal newborns reported 'significant' colic in 23% and could not relate the symptom to economic class, maternal age, type of feeding, birth order or family history of allergy or gastrointestinal disturbance. Nor could he relate it to maternal emotional factors.

Moore et al (1988) in a prospective study reported that 68% of 122 infants developed colic and in about two-thirds this was considered either moderate or severe.

Hide and Guyer (1982) did not define colic but in a survey of infant feeding in the Isle of Wight it was reported in 16% of infants and rarely (20%) only in the evening. Only 47% improved by three months and 12% continued to the end of the first year. No differences were found in breast or formula fed infants. The reporting was significantly more frequent by professional groups (23%) than in unskilled groups (7%).

Hyams et al (1989) in their study of 110 subjects and using a definition of crying for over 3 hours a day identified 28% of infants with colic. However using subjective parental dissatisfaction as an additional criterion just over half of these infants were considered to have significant colic.

Interestingly, there is no documentation of excessive crying or a colic-like syndrome in the !Kung infants although there is mention of 'difficult' infants in Masai tribes (DeVries, 1984). In a recent examination of institutionalised Middle-European infants there is reported to be neither colic nor excessive crying (Dittrichova, 1992)

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## Historical background and overview

Illingworth (1954) reviewed the literature on colic and considered that it was an evening phenomenon and it probably reflected local obstruction to the passage of gas in the colon by local spasm or kinking of uncertain cause. In other words the cause was **organic**. Wessel et al (1954) also reviewed the literature and concluded that colic was probably one of the earliest somatic responses to the presence of tension in the environment. In other words the cause was **non-organic**.

The description of the colic 'attacks' is similar in many early papers and differs only from Darwin's by the mention of wind.

In 1928 Lippman in a study of 'Restlessness in Infancy' described 63 subjects with colic, vomiting and restlessness. Hypertonicity was observed in all. After a number of strategies, including leaving the baby in a quiet room, these infants were given atropine. In nearly all there seemed to be a definite improvement and in half this was apparently immediate. The author admitted that improvement may have occurred had no treatment been given. The hypothesis of autonomic imbalance and excessive air swallowing was believed to account for a few cases. Also mentioned was the effect the crying had on the emotional state of the mother. In the discussion of this paper is the first reference to the speedy recovery from all symptoms when babies with colic are removed to hospital. Lippmann felt that many of these infants were suffering from overattention and too much handling. In the author's conclusion was included advice to sedate the baby if

air-swallowing was a problem and dose with atropine but first of all he believed that every attempt should be made to ensure the mother rest and relaxation in a peaceful environment and that the presence of the child in the home should not preclude other emotional outlets for the parents.

Thus, here is an early discussion of both organic and behavioural theories. Lippman believed on the one hand that autonomic imbalance caused a tense hypertonic baby and on the other hand postnatal influences of feeding and emotional attitudes of parents could both cause colic.

Branneman (1943) believed there was a similarity between the behaviour of the baby with colic and the symptoms of 'gas pains' after abdominal operations and in peritonitis. He pointed out that colic due to renal stones and gallstones and the pains of labour and intestinal obstruction had all one thing in common: ' a hollow viscous attempting to overcome an acute obstruction'. Nevertheless, he also observed that babies with pyloric stenosis do not exhibit this kind of behaviour, although they have good reason to cry since they are extremely hungry. He distinguished the fussy, irritable, uncomfortable, crying baby as one who did not have colic, and did not accept that these babies could have an 'imbalanced' nervous system which was only troublesome in the evening. He discounted the benefits of atropine. He also acknowledged that the excitement, the tiredness and the nervous strain on both mother and baby at the end of a modern day could have been important factors. His treatment included walking, cuddling, rocking and jiggling, in addition to an enema. Overfeeding, underfeeding, too infrequent feeds, too frequent feeds and an inappropriate constitution of the feeds were all blamed. Allergy to

substances in milk and to allergens in the mother's diet were all cited. Both diarrhoea and constipation were described in association with colic and a condition called 'hypertonicity' which describes a tense and jittery infant suggested a neurological disorder.

One of the most popular explanations then, as now, is excessive wind in the bowel due to the swallowing of air. Jorup (1952) in careful radiological studies found that there was no excess wind in the intestine but that there was excessive propulsive activity of the colon. His belief was that 3 months' colic is attributable to this. In a study of 111 infants with symptoms of crying, feeding difficulties and diarrhoea and 38 normal infants he addressed both environmental and physical issues. Both symptomatic and radiographic improvement followed treatment with an anticholinergic drug. He concluded that both the neurolabile and gastrointestinal symptoms were in a high degree dependent on constitutional factors.

This suggestion that both irritability and gastrointestinal symptoms were secondary to a primary factor was not one which attracted much critical attention in the '50s and '60s. The apparent success of treatment with anticholenergetic drugs encouraged the view that the problem of colic was due to a primary gastrointestinal dysfunction, namely colonic spasm, and this view has persisted to modern times (Illingworth, 1985). Treatments with anti-spasmodics have been assessed. Illingworth (1959) and later Grunseit (1977) examined the efficacy of dicyclomine hydrochloride (Merbentyl) but claims for its value are not supported by the data presented in these two studies as they were not double-blind.





Weissbluth et al (1984) tested the hypothesis that if dicyclomine proved to be effective then subsequent parental reports of infants given dicyclomine would describe easier temperaments and fewer sleep disturbances compared with infants given placebo. Thriving infants were enrolled who had >3 hours crying each day on 3 or more days each week. It was not considered practical to request a pre-treatment parental record because the parents were so distressed. Treatment eliminated the colic, based on the definition used for enrolment, in more babies than did placebo. Parents were not told to which group their infant had belonged. At 4 months there was no difference between the group that did improve (whether on treatment or not) and those who did not improve in temperament ratings, sleep patterns or parental perceptions. There was however wide variation in scores for each of the characteristics and any differences which could have existed may have been obscured by a Type 2 statistical error. There is also the argument that change from baseline for two groups would have been a more appropriate way of testing the hypothesis. The authors believe that progression from colic to difficult behaviour with brief sleep durations proceeds even when the colic is eliminated.

Hwang and Danielsson (1985) criticised these three studies on the grounds that the placebo did not taste like dicyclomine. These workers undertook a double-blind cross-over study with preparations which tasted the same. They confirmed the previous findings that dicyclomine was more effective than placebo in reducing crying, but crying was still more than in babies whose parents do not complain they have colic.

The mode of action of dicyclomine in infant colic is unclear. One suggestion is that its anti-cholinergic effect reduces gut spasm. Another is that the effect is mediated by the central nervous system, as one of its side-effects is sedation (Williams and Watkin-Jones, 1984).

In one of the first studies clearly addressing colic as a problem of excessive infant crying due to inappropriate maternal responses Taubman (1984) showed that advising parents to modify their interaction with their infants was helpful. 30 subjects and 30 controls were enrolled. The first 6 subjects were advised to leave the infants alone for half an hour but although the parents reported improvement there was no improvement in the times recorded in diaries. The advice was modified to a structured programme of response which did not include excessive stimulation, although it is not explained what this is. These babies' crying improved. Taubman (1988) went on to compare this approach with the elimination of cows' or soya milk protein and demonstrated that the counselling was better. Both Taubman studies can be criticised because he was both 'treater' and 'recorder' of results, an obvious source of bias which is acknowledged.

Present day views of the 'complaint' of colic agree with the views of older physicians such as Wessel et al (1954) and Paradise (1966). Barr et al (1992) using well-tested diary recordings has demonstrated that there is a group of carers who complain that their infants suffer from colic but who do not cry any more than controls. This group differed from controls in that they thought the cry sounded more 'sick'. Paradise (1966) also

described babies with 'mild' colic which was trivial and in his view no different from the crying of normal babies. This group nevertheless made up 47% of a prospective study of 146 infants. 23% had moderate or severe crying which was inconsolable. Wessel et al (1954) describe colic as crying for >3h/day for more than 3 days each week and in both Barr's study and that of Paradise there are groups which fit this pattern.

Thus it would appear that the complaint of colic does not always imply excessive crying but troublesome crying which may or may not be excessive. Paradise has remarked, and this has been repeated by countless others, that anxious mothers are most likely to bring their babies to the physician's attention. It would seem, then, that the complaint is related to how carers perceive crying.

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## Feeding

Overfeeding was first described by Budin (1907) as a cause of colic, among other problems, and has more recently been examined by Woolridge and Fisher (1988) in breast-fed infants. Sucking for a short time from both breasts gives the infant a diet low in fat and thus calories and high in lactose. The lactose overwhelms the infant's bowel capacity to digest it and colic, wind and loose bowel movements result. These authors suggest that infants should be encouraged to empty the first breast first in order to benefit from fat-rich hind-milk.

Some workers have felt that breast-fed infants are more likely to suffer from colic (Illingworth, 1961; Rubin and Prendergast, 1984) while others have blamed cow's milk allergy for 'colic' (Lothe, 1982). Hide and Guyer (1982) in a survey of 843 infants showed that the prevalence of colic in initially breast-fed infants was 15.4% and in initially bottle-fed infants was 13.8%. Forsyth et al (1985) studied prospectively 180 breast-fed and 184 formula-fed infants. 35% of mothers in each group reported that their infants had moderate or severe problems of feeding or crying.

Bernal (1972) reported that colic was a frequent cause of giving up breast-feeding.

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## Cow's milk allergy

Classical cow's milk allergy results in diarrhoea, sometimes bloody, and failure to thrive with a therapeutic response to a diet free of cow's milk. Infants and young children with eczema may also respond to such a diet. Because crying is often part of the syndrome it has been postulated that cow's milk allergy may be the cause of colic in babies who do not have diarrhoea and who are thriving. Jakobsson and Lindberg (1978) studied 18 breast-fed infants with colic. Their mothers were given a cow's-milk free diet which appeared to result in improvement in their infants' colic. This was an open and uncontrolled study. A further study from the same group (Lothe et al, 1982) examined the effect of either cow's milk or soy milk on 60 symptomatic infants. Again this study was not free of bias - both mothers and investigators knew which milk the infants were fed - and, although claims for the benefit of a cow's milk free diet were made, no conclusion could be reached. Le Blanc (1983) pointed out the design faults of the Scandinavian study and claimed from his own work that a soy based i.e. cow's milk free diet was not helpful. Evans et al (1981) repeated the study of excluding cows' milk from the mother's diet of breast-fed babies with colic and found that this was not helpful either. A further double-blind study by the Scandinavians examined colic in breast-fed infants (Jakobssen and Lindberg, 1983) of a small number of mothers whose infants' colic had improved after they had started a milk-free diet. These were a minority of a group of 66 breast-feeding mothers who had

tried a cow's milk-free diet. The mothers in the trial received either cow's milk protein or placebo. The results indicated that those challenged with the milk protein were more likely to have colicky infants.

Forsyth (1989) in a double-blind multiple cross-over study of the effect of changing milk formulas in colicky infants showed that in only 2 of the 17 studied was there clinically meaningful changes in crying with each formula change. Once again the study design was challenged (Sampson, 1989). Mothers had kept diaries to record crying. It is possible that as a study progresses these might be filled in less carefully. The cross-over periods from one formula to the other were considered too short as inflammation in the gut can last for several days. As Forsyth himself observed there is a marked day-to-day variability in colic independent of the formula used and so studies of short duration and small numbers are not appropriate.

It would seem therefore that there is no good evidence to support cow's-milk allergy as a cause of colic in the large majority of healthy babies with colic.

Despite his reservations about Forsyth's results Sampson still felt able to recommend the occasional use of hypoallergenic feeds (Sampson, 1989) but did not indicate when and for which infants he would recommend this course of management.

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## Lactose intolerance

Like cow's milk allergy lactose intolerance in infants causes diarrhoea and failure to thrive. Lactose appears in the stool and the stools become increasingly acidic. However in a comprehensive review of the subject (Harrison et al, 1976) neither colic nor excessive crying were mentioned as symptoms of the disorder. The most common cause of lactose intolerance is gastroenteritis, which causes intestinal lactase deficiency, and the treatment is with a lactose-free diet. Because of the symptom of wind in colic, lactose intolerance was considered as a possible cause. Liebman (1981) using stool analysis for pH and reducing substances, could find no relationship between lactose intolerance, as judged by these measurements, and colic in infants aged 2-20 weeks.



Anaerobic fermentation of unabsorbed carbohydrate is a source of gas in the colon. Hydrogen production in the colon is derived exclusively from bacterial fermentation of carbohydrate; this is the basis of the noninvasive breath hydrogen test (BHT). Moore et al (1988) recruited 150 newborns prospectively and kept in contact by telephone after their birth. A history of colic was taken at every contact. The definition of colic was related only to crying and was graded into mild, moderate or severe according to how easily unexplained crying could be consoled. 122 babies were available for testing and of these 83 had colic, 20 severely. Those with moderate or severe colic had significantly higher breath hydrogen concentrations than those who did not but there was a substantial overlap between the groups. The mean concentrations increased with the severity of the colic. The authors concluded that babies with colic represented increased lactose malabsorption, differences in colonic bacterial fermentation or differences in the handling of colonic gas produced. A similar study (Miller et al, 1989) showed that babies with colic had increased breath hydrogen concentrations and the authors concluded that incomplete lactose absorption may be a cause or effect of colic. In this study too there was overlap of the breath hydrogen concentrations in both colicky and non-colicky groups.

In neither study was diarrhoea reported as a symptom. It would be interesting to know how many babies with secondary lactose intolerance had inconsolable crying and to compare the stools and breath hydrogen tests with a group of colicky babies. If elevated breath hydrogen is secondary to colic then it can be proposed that there is an increased

delivery of lactose into the colon because of rapid transit of the small bowel. The very high work of crying and the adrenergic response to it may be in keeping with this theory. Hyams (1989) examined colonic gas production and mouth-to-caecum transit time in colicky and non-colicky infants using BHT. Only 11 and 13 infants were enrolled into each group, not enough to demonstrate a difference if there was one (Type 2 error), but there was enormous overlap between the rise in BHT concentrations and a very wide variation in the rise in concentrations, about ten-fold. Similarly there was a large variation in mouth-to-caecum transit times - 20-180 minutes - in each group. Many of the infants in the study showed no irritability at the time of maximum breath hydrogen excretion. These observations may be analogous to those made in the case of older children and adults with carbohydrate malabsorption, who show no clear association between symptoms of carbohydrate malabsorption and the absolute elevation of breath hydrogen (Hyams et al, 1989).

Although the numbers were small the authors concluded that colicky infants do not produce more hydrogen from malabsorbed carbohydrate than non-colicky infants. The publication of this study was defended against criticism of a Type 2 error because the overlap between subjects and controls was so large that huge numbers would have to be enrolled for any difference to be shown was there one, in which case the difference between subjects and controls would be clinically irrelevant (Mauro, 1990; Hyams, 1990).

Barr et al (1987) changed the carbohydrate in the milk of a group of normal infants from 100% lactose to a mixture of low-lactose, glucose and polycose in a randomised cross-over study. There was no change in the amount of crying between the two periods and neither was there excessive crying at times of high breath hydrogen concentration. There was no difference in the amount of breath hydrogen between the two periods.

Physiologic lactase-deficiency occurs in a proportion of normal neonates (Barr et al, 1984) and these babies do not necessarily suffer from colic. Breath hydrogen concentrations increase throughout the day and are higher in the first three months of life than later in infancy. Since babies cry more in the first three months of life and in the evening (St James-Roberts, 1991) this observation would not be inconsistent with lactose intolerance being secondary to the physiological effects of crying.

In a double blind crossover study 10 children with infantile colic were fed breast milk untreated and treated with lactose (Stahlberg and Savilahti, 1986). Colic was present on 71% of treated and 89% of untreated days, not a clinically important difference.

Thus with the overlap of breath hydrogen concentrations in normal and colicky infants it would seem that there is little to support lactase-deficiency as a major primary cause of colic. There is theoretical support at least that it may be secondary to inconsolable crying as indeed may the explosive stools and borborygmi but there is no evidence that there is increased colonic transit time to support this. In none of these studies however was colicky behaviour reported to be associated with the

time of the elevated BHT concentrations. It would be interesting to consider if BHT concentrations are elevated in colicky babies in relationship to periods of crying.

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## Smoking

Said et al (1984) reported more post-prandial colic in smokers but no increase in evening crying. Post-prandial colic was defined as crying after meals. They hypothesised that gastrointestinal contractions are triggered by olfactory or gustatory stimulation through a vagal reflex mechanism.

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### Disturbed mother-infant relationship

Stewart et al (1953) looked at colic from a psychodynamic point of view. They defined colic as excessive infant crying and considered that the crying was a response to distress. The papers they reviewed in preface to their study were mainly those which considered management and psychological issues concerning mother and child. They advised that 'the child's physiologic reactions and his environment should be investigated for causes of this distress'. This group studied a small number of student families to assess the interaction between parents and infants as an aetiologic factor in the crying. They concluded that crying was a response to tension which rose internally from unsatisfied needs or from inappropriate external stimulation. They considered that the parents of babies who cried excessively responded inappropriately and inconsistently to their infants' needs either with overstimulation or with relative neglect. Thus, in contrast to caretakers' responses to 'normal' crying, these parents had responded inappropriately. Maternal anxiety, tension, insecurity and conflicts about accepting the feminine or maternal role were cited as possible responsible factors. These were subjective impressions.

The belief that excessive crying is a reflection of a disturbed relationship between carer and infant is the basis for psychotherapeutic interventions which address the mother-infant relationship. These are described by Daws (1989) and Stern-Buschweiler and Stern (1989). Mothers are interviewed about their baby's timetable and about their memories of pregnancy and birth, the

parents' relationship and their relationship with their own parents. The therapist indicates possible links between infant difficulties and family events and encourage parents themselves to consider the nature of such links. In this approach the source of clinical information is almost exclusively the mother's discourse as she perceives, describes and interprets her infant's behaviour and her response to it. Stern-Buschweiler and Stern (1989) describe their work as largely a consideration of the mother's past and present experiences to discover the origin of the mental constructions of her infant. Using this approach, Acquarone (1992) has described the management of 45 mother-infant pairs who presented with crying in the child as a problem. She has divided the children - some were as old as three years - into five groups: those with exclusively night crying, physically handicapped children, healthy children with special sensitivity, healthy children who do not smile and children who are receptors of family tension. The method of working with these mother-infant pairs through the mother is described but the outcome of the group is not reported.

The difficulty of evaluating psychotherapeutic interventions and counselling in general is well-appreciated. Milton (1992) has outlined the problems of proving the value of therapy. As with treatment for any complaint, without controlled trials it is impossible to decide how much improvement is due to treatment and how much is due to other factors, such as the passage of time, other events which occur during treatment and so on (McKenzie, 1989). Thus, for proper evaluation of these treatments the rules for any clinical trial must operate and the same difficulties can be expected (Pocock, 1987). Enrolling subjects willing to have their treatment selected randomly is one such difficulty. When this is possible and treatments are compared it is then difficult to know which aspect

of the treatment has most influenced outcome. Was it the treatment or the personality of the therapist? In many ways, medical trials of treatments and interventions are just as difficult to interpret. For example, similar questions could be asked of a new apparently successful surgical technique. Was it the operation or the skill of the surgeon? To have the same 'operator' undertake two treatments would encourage bias. The design for the studies described in this thesis try to address some of these difficulties.

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### Inappropriate management and maternal anxiety

There were many suggestions in the '30s and '40s that inappropriate management by parents was to blame. Picking the baby up too much and bouncing him up and down after a feed to get the wind up (Brenneman, 1943) and communicating anxiety were all mentioned. Illingworth (1954; 1985) was sceptical of this. He concluded that a baby with colic was healthy and grew up to be a normal child in no way different from other children. The assumption appeared to be that since this was so mishandling and parental anxiety could not have played a role. He did however wonder why colic seemed to occur mainly in the evening, an observation difficult to explain on proposed organic causes. Brazelton (1962) suggested that this was a time when parents were tired, siblings most demanding and fathers after work tried to have some contact with their baby. In other words evening colic was related to family tension or lack of attention. No other explanation of evening colic has been offered.

Case reports have clearly described the work which goes into trying to soothe the infant with excessive crying. Brazelton describes the onset of colic at the time the baby came home from hospital. He goes on to say that the mother did everything she knew to do. Wessel et al (1954) describe a nurse's experience and once again it is apparent that whatever else had operated the carers had done everything possible to soothe and calm the infant. This is undoubtedly far from the low maternal responsiveness discussed by Bell and Ainsworth (1972). When comparing these and other reports, however, it is important to be clear about whether responses to crying or to excessive crying are being

compared. Carey (1985) describes a similar routine of picking up, burping, offering more feed, carrying around, bouncing and rocking. The infant quiets momentarily and then starts again as soon as put back in the crib. Taubman (1984; 1986) believes that in their efforts to placate and satisfy their infant who cries too much carers may try so many manoeuvres that they may end up overstimulating the infant and provoking further crying. In his view, carers misinterpret cries. Hunziker and Barr (1986) showed that increased carrying reduced crying in 99 pairs of infants but when crying had become excessive and troublesome, extra carrying as an intervention did not help (Barr et al 1991).

Wessel et al (1954) in an uncontrolled prospective study of a selected group of babies also considered that family tension was associated with colic in 50% of cases but wondered why the colic stopped at two months when the family tension continued. He made the observation that its cessation may be related to the achievement of a certain level of motor and social development (see page 31). He believed that when the infant began to be able to use his eyes and hands to amuse himself, he apparently no longer needed to call on adults to comfort him. This explanation is close to later developmental psychologists' explanation of changing forms of communication at about three months of age - eye-to-eye contact, following, laughing and increasing face-to-face interaction with carers - which replace the cry as a prominent signal (Robson, 1967).

In Brazelton's 1962 study of 'normal' crying he chose 80 mothers seen in private practice in Cambridge, Massachusetts. The families were chosen because they were perceived to be normal and without 'tension'. Contact was maintained by telephone. During the crying periods mothers were advised to

address obvious reasons for crying i.e. to feed their baby, to wind him, to offer lactose periodically (at least hourly) to facilitate the mobilisation of stomach gas, to change them when wet or dirty, to offer them more sucking, to play with them, to change them periodically, to place them on their stomachs, to prop them up, to rock them and even to swaddle them. During a bad period a more restrained routine was advised. Mothers were not to pick their babies up more often than 20-30 minute intervals and not to feed more than 2.5-3 hourly during these upset intervals. The results showed that babies cried up to three hours each day and the majority of the fussing was during the evening. This, Brazelton considered, was the peak period of tension in the family as a whole. Parents were tired and siblings at their most demanding.

Paradise (1966) in turn reviewed the literature when he described his cohort of 146 infants and drew attention to the flaws in previous studies. His study differed from the others in that 1) the evaluation of maternal factors was prospective and 2) maternal factors were assessed by a standardised, objective psychological test, the Minnesota Multiphasic Inventory (MMPI). His mothers were 'stable, cheerful, and feminine'. His evidence 'and other evidence when critically reviewed' did not support the view that colic results from an unfavourable emotional climate created by an inexperienced, anxious, hostile, or unmotherly mother.

Carey (1968) also contended that colic was associated with maternal anxiety although he admitted that not all anxious mothers had colicky babies. He criticised Paradise's study because the MMPI was designed to find only

abnormal personality traits and did not measure situational stresses such as difficult pregnancy or friction with relatives. Carey did not believe Paradise had drawn the correct conclusion from his own data. His analysis of Paradise's data showed that mothers who reported being tense, depressed or both during pregnancy had significantly more moderately or severely colicky babies. This has more recently been confirmed by Zuckerman (1990). Carey's view was that the anxiety was relayed to the baby by inappropriate handling. He reported that in 10 of 13 babies the colic improved dramatically within days of treatment. This included advice about handling and feeding. He recommended a quiet environment, a minimum of unnecessary handling and always gave an optimistic prognosis. An evaluation of management along the lines of Carey's plan (Carey, 1984) formed the basis for the present project and thesis.

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## SUMMARY

Infant crying is a signal which communicates infant needs to carers. Some listeners can tolerate crying better than others. 'Normal' crying times are derived from reports of carers who have no complaints of excessive or troublesome infant crying. Infants whose carers complain they have colic cry on average longer each day but there is an overlap between the two groups. Thus, where some carers complain that their infants suffer from colic when they cry no longer than those who do not, there are others who do not complain when their infants cry excessively.

Physical causes which have been proposed for excessive infant crying or colic include intolerance to cow's milk protein and lactose, and colonic spasm. Dietary treatments have no proven lasting value. Drug treatment with dicyclomine has been helpful in reducing crying times, although whether this is due to a gastrointestinal or a central sedative effect is not known. Difficult mother-infant relationships and the background for these difficulties are the basis of psychotherapeutic management. Inappropriate responsiveness of carers to infant signals has been cited as a cause of excessive and troublesome crying and parental counselling consisting of advice about how to respond to infants' cries has been reported successful. Infant overstimulation from endeavours to quieten infants' crying has been proposed by a number of workers as contributing to the problem. It is this aspect of inappropriate responsiveness which this thesis addresses. The intervention is with the carer(s) to change their responses to their infant's crying. The outcome is judged by the carer's reports of the change in their infant's crying and their own distress.

## CHAPTER 2 - BACKGROUND, OBSERVATIONS AND PURPOSES OF THE PROJECT

In 1986 a Crying Baby referral system was organised in the Department of Paediatrics, Rush Green Hospital in Romford. This was in response to the numbers of infants referred from the community to paediatric clinics for investigation and management of 'colic possibly due to food allergy'. These infants had no clinical features of any organic disorder which could have been the cause of the principle symptom, inconsolable crying, which was causing considerable distress to carers. Some infants were admitted to hospital because it was felt that a carer who might harm their child was in need of respite. Others were admitted to ensure there was no underlying disorder, such as urinary tract infection or intussusception.

**Observation 1:** Most of the hospitalised infants' crying improved in hospital within a day or two with no change of diet, medication or other prescribed change in management. Parents were always surprised by this and often felt that the infant had let them down. The doctor had had no chance to see what they 'had to put up with'.

This observation has been made before in a pilot study by Barbero et al (1957). These workers studied 30 infants under 7 months who had a symptom complex which included irritability, sleep disturbance, vomiting, feeding difficulties and changes in stool frequency. Many had had difficulties from the

second neonatal week. The infants were admitted to hospital and separated from their mothers for 48 hours. During the admission 'intensive psychiatric interviews' were held with the mothers. 29 infants showed complete symptomatic remission or considerable improvement during hospital admission and mothers reported that the infants had improved considerably following discharge. This was a pilot study reported as a society abstract and was never followed up with a rigorous study to validate the observation. If true, the observation that the infants stopped crying quickly in hospital would suggest that there might be a common factor operating in hospital that was not operating at home. If that was identified then it might be possible to treat infants at home; it might also be possible to gain some insight into the cause of troublesome crying.

Observation 2: Also noticeable, both on history and on observation at the time of presentation, was how hard the carers worked to try to stop the crying. All reported many interventions which included lifting and laying, rocking, walking up and down with the baby, passing the baby around, playing the radio, driving around in the car, running the vacuum-cleaner, using white noise tapes, and medication. When an infant began to cry during an interview almost always a carer present would immediately intervene. What was most noticeable was that, instead of rocking their baby by using a swaying or swinging motion, most used a rapid jiggling motion and employed this to jig the infant on their knees or in the pram or cot. The infant's back was patted at a similar frequency. The result of both manoeuvres was to jig the infant's head on the trunk and this often seemed to have a frenetic quality to it. Other interventions included the rattling of toys in the infant's face and other



distracting manoeuvres such as encouraging the infant to look at him/herself in the office mirror. None of these interventions resulted in more than temporary improvement.

**HYPOTHESIS:** The improvement in troublesome crying observed after infants were admitted to hospital was because the nurses were not responding to the crying in the same way as the carers were at home. Stimulation in hospital was reduced or changed. This was the reason for an improvement in crying.

Similar changes in carers' response to the crying could effect improvement in infants managed at home.

## PURPOSES OF THE PROJECT

- 1) To discover whether it would be feasible to undertake a study to validate the observation that infants with troublesome crying improve after admission to hospital.
- 2) To describe the distress in the carers of infants with troublesome crying at the time of presentation.
- 3) To develop ways of measuring changes in perceived crying and distress before and after an intervention.

These three purposes were addressed in the first study which also served as a pilot for the second.

- 4) To discover whether advice to reduce stimulation is effective in reducing troublesome crying managed at home.

The second study addressed this question.

## REFERENCE

Barbero GJ, Rigler D, Rose JA (1957) Infantile gastrointestinal disturbances: a pilot study and a design for research. *Am Med Ass J Dis Child*94, 332-3

## CHAPTER 3 – METHODS FOR BOTH STUDIES

### DEFINITIONS AND TERMS

*Troublesome crying* - crying with which parents felt they could no longer cope and for which they sought help. This term is used for the complaint with which the carers presented.

*Crying* - for the purposes of this report the term crying is used for any reported crying whether troublesome or not. Included in this is the crying perceived by nurses and carers and recorded in diaries and the changes in such crying reported to observers on the telephone.

*Carer(s)* - this term is used for mother, father, grandparent, partner or friend, foster-parent and any other person involved in the day-to-day management of the subjects of the study. There could be several combinations of such persons attending an interview or living in the same household.

*Subjects* - Carer-infant pairs where the infant was under the age of 12 months.

## REFERRAL SYSTEM

Through the Health Visitor Liaison scheme the community was made aware that a service was in operation for infants <1 year old by arrangement at Rush Green Hospital. Referrals were from Health Visitors, General Practitioners, Community Medical Officers and Casualty Officers. Consecutive infants were enrolled for each study. Families were interviewed within 72 hours of referral in an office separate from out-patients.

## INTERVIEW

Only the interviewer - a consultant paediatrician - the carer(s) and infant were present. All carers who attended the appointment were included in the interview. For single parent families a friend if they attended was also included. The setting was designed to facilitate trust between the carers and paediatrician. General Practitioners or Community Doctors had already assessed the infant to exclude physical illness. A decision was made not to re-examine the infant again unless requested. This was to try to disabuse carer(s) of the idea that their infant may be suffering from a physical illness. Each interview lasted for 30-45 minutes.

## BIOGRAPHICAL DATA

It was not the purpose of either study to establish an association between troublesome crying and any of the factors detailed in the biographical history. It was recognised that it was likely that the numbers of patients in either study would be too small to be able to draw conclusions about the relevance of any of the factors unless there was an exceptionally strong representation of any of them. The data were collected on a pro-forma (Table 1), were coded (Table 2) and analysed with this in mind.

There were two main purposes of the gathering of this information: firstly, to describe the patient base so that, if necessary, future comparison could be made between the subjects of this study and any other study and, secondly, to facilitate an empathic relationship between interviewer and carer(s). Carers may well have considered associations between many of the factors and their infant's crying and the interview would give them a chance to discuss them.

Items included those which had been highlighted by previous workers as important in infants with troublesome crying or with colic. Questions were open-ended and carers were given the chance to elaborate when indicated.

TABLE 1

Number:

Group:

Date first seen:

Name.....

Date of birth.....

Telephone number.....

Age at referral.....

Length of time crying.....

Crying pattern in last 48 hours.....

Evolution of pattern.....

Carers views of cause.....

.....

Previous interventions.....

.....

Pregnancy/labour.....

Family and Support.....

Breast/bottle.....

Smoking.....

Other symptoms.....

.....

Comments.....

TABLE 2

BIOGRAPHICAL DETAILS

Age - in weeks

Crying - length in weeks of troublesome crying

Time of day (T.o.d.) -

- 1-daytime
- 2-night-time
- 3-evening
- 4-anytime

Hours (hrs.) - total estimate of number of hours in the day crying or fussing ('whingeing') was troublesome

Cause\*:

- 0-don't know
- 1-'colic'
- 2-pain
- 3-hunger
- 4-other

\* - the first documented i.e. given cause

Medication and/or change to milk other than cow's (Med.)

- 0 - no
- 1 - yes

Pregnancy (Preg.) -

- 0-uncomplicated
- 1-complicated i.e. premature labour, hospitalised during pregnancy, fetal distress, previous infertility, previous post-natal depression.

Order -

- 1-first live baby
- 2-subsequent baby

Feed -

- 1-breast
- 2-bottle
- 3-both

Support (Supp.) -

- 1-supported by partner or family
- 2-single parent outside parental home or separated from partner

Questions were open-ended and carers were given the chance to elaborate when indicated. Items included those which had been highlighted by previous workers as important in infants with troublesome crying or with colic.

Age It was important to know the age-spread above and below three months of the infants with troublesome crying in these studies and to know how many carers associated this with 'colic' (see page 45).

Length of time crying It was interesting to know whether crying had always been a problem, if in older babies it had begun within the first three months and how long carers had perceived the crying as troublesome.

Crying pattern in the last 48 hours. This would give some idea whether the crying was related to a particular time of day or whether it was troublesome all round the clock. The irritability associated with what is described as 'colic' has often been described as an evening phenomenon (page 62).

Evolution of pattern. This question would give the interviewer a chance to explore how exasperated the carer(s) had become and allow them to express just how upsetting they found it.



Carers views of the cause It was important to know if the parents believed there was a physical disorder causing the crying, if the baby was in pain or if they held other views about cause, bearing in mind the large number of causes proposed by professionals.

Previous interventions The question 'what do you do when the baby starts crying/won't stop crying' gave the carers a chance to describe the manoeuvres. They were asked about use of medication.

Medication There are many propriety drugs on the market for 'colic'. The use of such drugs may reflect carers concern that the crying is due to a physical condition but more likely reflects their wish to try anything.

Pregnancy and labour A difficult pregnancy and labour may result in more anxiety about a baby's well-being and this may have some bearing on the response to crying. The effect of maternal anxiety on the development of colic has been debated (page 65).

Birth order It seems reasonable to consider whether inexperience contributes to difficulties such as troublesome crying in early infancy. This question was included to give carers a chance to discuss comparisons in behaviour between their children and, more importantly, to allow carers of first-born children to air their anxieties about their new experience.

Family and support It was important to identify conflicting views among family members about what to do about the crying so that guidance about dealing with these could be given. An unsupported carer might be more likely to find crying troublesome than carers supporting each other.

Feeding It has been suggested that the incidence of colic in bottle and breast-fed babies is different (page 55). Since the role of milk in the development of colic appears to be widely debated among health professionals, it was important to take a feeding history and highlight any difficulties with it. It was also important to discover how much advice had been given about feeding and whether milks had been changed.

Smoking This has also been implicated in the aetiology of colic (Page 69).

## DISTRESS QUESTIONNAIRE

This questionnaire was modelled on the Malaise Inventory described by Rutter and colleagues (1970) which in turn was modelled on the Cornell Medical Index Health Questionnaire (Brodman et al, 1949) which has been shown to be a useful indicator of emotional disturbance and which agrees fairly well with independent psychiatric assessments (Gibson,1967). The 10-item questionnaire (Table 3) highlighted both emotional and physical components to mothers' distress. Five sub-groups of items highlighted poor self-esteem (items 1-3), feelings about the baby's manipulation (items 4 and 5), anger (items 6 and 7), effect on health (items 8 and 9) and other

relationships (item 10). The questionnaire simply documented only how the mothers felt. Since it was quite possible that this would change with change in the baby and because the interview itself was structured to reduce distress, it was considered inappropriate to use two of the standard validation tests for questionnaires, retest reliability and independent assessment. The questions had been understood by previous families who had attended the Crying Baby Clinic before the study began. Previous mothers had indicated that simply filling in the questionnaire had made them feel better.

Only mothers were asked to fill in the questionnaire as fathers did not always attend. Following history-taking, each mother was given a questionnaire and was asked to circle either 'Yes' or 'No' to each question. Mothers were not prompted.

The purpose of the questionnaire was, as with the collecting of biographical details, to describe the patient base and to compare questionnaires answered by mothers of subjects with those of a control group.

TABLE 3

DISTRESS QUESTIONNAIRE

Since the birth of your baby have you ever felt:

- |  |        |
|--|--------|
| 1) Not a good mother   | Yes/No |
| 2) Helpless  | Yes/No |
| 3) Cannot satisfy baby   | Yes/No |
| 4) Baby crafty/sly   | Yes/No |
| 5) Baby deliberately preventing you from<br>having anything for yourself | Yes/No |
| 6) Feel like hitting or getting rid of the baby                          | Yes/No |
| 7) Other feelings of anger   | Yes/No |
| 8) Exhausted/frustrated  | Yes/No |
| 9) Sleeping/eating badly   | Yes/No |
| 10) Quarrelsome  | Yes/No |

## ADVICE TO REDUCE STIMULATION

The carers were asked to not to pat or wind their babies excessively. It was explained that there was no evidence that winding manoeuvres were at all helpful. Review of Leiderman et al (1973), Nugent et al (1984) and Osofsky (1987) did not reveal any mention of winding procedures in child-rearing practices in primitive or modern cultures and nor was winding mentioned in two modern paediatric textbooks (Nelson, 1990; Forfar and Arneil, 1992). Carers were advised that the prone position was an anatomically appropriate position to facilitate the removal of gas from the stomach as in this position the gastro-oesophageal junction was above the fluid level in the stomach (Orenstein, 1983).

They were advised to cuddle or rock their baby gently and to distinguish between rocking - a relaxed 60 beat per minute swaying movement of baby in arms, on chest or in pram - and excessive jiggling - a >140 beat per minute jerking movement of the baby on their knees or in their arms - and to avoid the latter. The interviewer demonstrated the difference and demonstrated how vigorous jiggling shook the baby's head on the trunk.

They were advised to reduce stimulation from loud music, rattling toys, snapping fingers in the face, asking the baby to look at himself in the mirror and so on. Quiet singing in a peaceful environment was encouraged. It was pointed out that although the running of a vacuum cleaner or other machine might seem to stop the baby crying this was usually only temporary and did not solve the problem in the long-term.

Carers were asked not to intervene during the early part of sleep when the baby may vocalise and appear restless. An explanation of active and quiet sleep was given (Prechtl, 1974). Young infants enter active - rapid-eye-movement sleep early in the sleep cycle - and may be more easy to arouse during this time. For younger babies and those with prolonged night-time crying it was suggested that the rhythmical progression in and out of these phases of sleep appeared either never to have been established or to have become for some reason disordered. An analogy was drawn with the irritability adults often feel when their sleep cycles are disturbed, for example with jet-lag or following work-shift changes. It was explained that one of the tasks was to try to establish an acceptable sleep-wake cycle appropriate for the infant's age.

An assurance was given that a certain amount of crying is normal and may occur at the beginning of sleep (Brazelton, 1962).

Finally, the carers were given permission to leave their infants if they felt that because of the crying they could no longer tolerate their being close. This was recommended in case carers felt like abusing their infants. It was suggested that they might like to leave the baby within earshot so that they would feel they had not abandoned their baby and so that the baby could hear them talking. If babies slept in the same room as carers, carers were advised to move them to an adjacent room if possible and to leave the door ajar for the same reasons.

## CRYING DIARIES

These diaries (Table 4) were used to document crying periods. No distinction was drawn between crying and fussing, or whingeing, as this is called locally. Room was provided to document four periods of crying and if there was more crying than this informants - nurses or carers - could record further episodes on the reverse. The purpose of these diaries is described under each study.

INFANT CRYING DIARY

Name	Address	Telephone	Date first seen		Comments
			1st Episode Started	1st Episode Finished	
Monday	.....	.....	.....	.....	.....
Tuesday	.....	.....	.....	.....	.....
Wednesday	.....	.....	.....	.....	.....
Thursday	.....	.....	.....	.....	.....
Friday	.....	.....	.....	.....	.....
Saturday	.....	.....	.....	.....	.....
Sunday	.....	.....	.....	.....	.....
Monday	.....	.....	.....	.....	.....
Tuesday	.....	.....	.....	.....	.....
Wednesday	.....	.....	.....	.....	.....
Thursday	.....	.....	.....	.....	.....
Friday	.....	.....	.....	.....	.....
Saturday	.....	.....	.....	.....	.....
Sunday	.....	.....	.....	.....	.....

TABLE 4



FIGURE 1



CHANGE RATING CHART

A change rating chart was constructed as suggested by MacKenzie (1986) to record the change in both the crying and in the mothers' distress on day 3 and day 7 (Figure 1). This chart was a symmetrical ordinal scale and was simply a line divided into equal intervals from +5 (better) through 0 (no change) to -5 (worse). Carers were asked to indicate on the chart a score which best reflected change in both crying and distress from the time of the first interview. A score of +2 or better or -2 or worse was considered a clinically important change.

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## CHAPTER 4 - STUDY 1

This study addresses the first three objectives of this project.

1. It examines whether carers of infants with troublesome crying would be willing to have their infants randomised to a group for management at home or in hospital.

To validate the observation that when such infants are admitted to hospital there is a clinically important reduction in crying, a randomised controlled study would have to be undertaken. Neither group would have any specific treatment or change in diet or basic care. Measurement of the change in crying and in mothers' distress would be made for mother-infant subjects of both groups and compared. It was recognised at the start that it would be likely that the proportion of carers who would agree to randomisation would be too low for a rigorous study ever to take place as too many would not want their child hospitalised. Nevertheless it was important to discover if this was the case.

2. The study records biographical data of mother-infant subjects and age-matched controls and compares the distress of mothers.

It was not the purpose of the study to try to correlate any of these details with the crying or the outcome of any intervention. The purpose of collecting these data was to provide a description of the cohort to compare with previous or subsequent studies whose subjects may be drawn from a different culture, social class or background.

3. Methods which could be used in studies of troublesome crying were examined. In this respect this study serves as a pilot study.

Methods piloted were:

- a) The measurement of crying by the use of diaries.
- b) The use of scales for measuring improvement or deterioration in crying and in mothers' distress.
- c) Interview techniques for families with this problem.

It was also important to discover whether carers were receptive to the idea that a reduction in stimulation may be helpful. The management of subjects with troublesome crying at home whose carers were advised to reduce stimulation would be examined to see whether a rigorous study of such management would be worthwhile.

## METHODS FOR STUDY 1

Subjects were enrolled, carers interviewed, biographical data were collected and distress questionnaires filled as described in Chapter 2.

### Hospital and home management

For subjects, after the collection of biographical data and completion of questionnaires, the purpose of the study was explained to the carer(s). They were asked to agree to randomisation or to elect for their babies to be managed either in hospital or at home as part of a research study. Randomisation was by random numbers.

Hospital subjects were admitted immediately for a period of three days. Carers could elect to stay or to go home. The carers of subjects managed at home were asked to reduce stimulation of their babies as described in Chapter 2.

Those admitted to hospital were cared for in cubicles where carers could sleep if they wished. Nurses kept note of crying times using a crying diary (Table 4). Babies' diets were not changed and the nurses were advised that babies had been admitted for observation and for respite for carers. Mothers who elected not to stay overnight initially with their babies were asked to stay during the third 24 hour period. They were all encouraged to come for as long and as often as they could during the day. Before discharge mothers recorded on a change rating chart how

much they felt their baby's crying had changed and how much their own distress had changed. At discharge on Day 3 parents were given the same advice as those at home. Those at home were reviewed on Day 3 either on the telephone or in their homes and both groups were reviewed in the same way on Day 7, recording change in the same way on all occasions at home by the carers.

Diaries were kept to examine for concordance between rating scores and recorded crying times and to see if carers would keep diaries.

### Controls

Controls were enrolled to see if there was any exceptional difference in biographical profiles from subjects but in particular to compare distress questionnaires.

For each child within the study, an age-matched control from a local well-baby clinic was selected and the mother interviewed in the same way. The interviewer attended local clinics on a morning or afternoon when convenient. Selection was carried out by identifying the first family who attended with a baby of an age within 2 weeks of the subject for infants under 3 months, within 1 month for those 3-6 months and within 6 weeks for infants older. The family members were asked if they would be willing to answer a few questions and fill in a questionnaire for a Crying Baby

research study. The same proformas were used for the controls as had been used for the subjects. The interview ended at the point of completion of the questionnaires.

#### Analysis of data:

Chi-square tests were used to compare biographical details and responses to items on the distress scores. A 'Nanostat' statistical package was used for this (AlphaBridge Ltd).

95% confidence intervals of percentages reflected how well or poorly the study was able to identify biographical differences between subjects and controls.

For the distress questionnaires, total scores for each patient (out of a possible total of 10) were calculated and scores for subjects and controls were compared by the Wilcoxon Rank sum test for paired values. The sub-groups of items contained different numbers of items and these were likely to be correlated. To guard against distortion, therefore, a second score was calculated in which one or more than one positive responses in a subgroup scored only 1, giving a maximum score of 5.



Ethical approval:

An account of the background, observations and purpose of the study together with a description of the methods was made in application to the local Ethical Committee who approved the project.

RESULTS FOR STUDY 1

The study was stopped after a total of 31 subjects was admitted since only 12 carers agreed to randomisation (39%; 95% confidence interval 21% - 57%). (Table 5).

TABLE 5

RANDOMISATION TO HOME OR HOSPITAL

Subject	Randomisation	Home/Hospital
1	Yes	Home
2	Yes	Hospital
3	No	Home
4	Yes	Home and then Hospital
5	No	Home - LOST TO FOLLOW-UP
6	No	Home
7	Yes	Hospital - SELF-DISCHARGE & LOST TO FOLLOW-UP
8	Yes	Home
9	No	Home
10	No	Home
11	No	Hospital
12	Yes	Hospital
13	No	Home
14	Yes	Hospital
15	No	Home
16	No	Hospital
17	No	Home
18	Yes	Home
19	No	Home
20	No	Home
21	No	Home
22	No	Home
23	Yes	Hospital
24	No	Home and then Hospital
25	Yes	Hospital
26	No	Home and then Hospital
27	No	Home
28	Yes	Hospital
29	No	Home and then Hospital
30	Yes	Home
31	No	Hospital

Randomised = 12

Home = 21 - 1 lost to follow-up.

Hospital = 14 - 1 discharged and lost to follow-up.

Biographical details of subjects and controls are outlined in Tables 6 and 7 using the codes in Table 2. The results are summarised in Table 8.

TABLE 6

BIOGRAPHICAL DETAILS OF SUBJECTS

Subject	Age	Crying	T.o.d.	Hrs.	Cause	Med.	Preg.	Order	Feed.	Supp.
1	5	4	3	7	0	1	0	2	1	0
2	12	6	4	12	0	1	0	2	2	1
3	5	1	4	18	2	0	0	1	2	0
4	12	6	2	6	1	1	1	1	1	0
5	6	6	4	12	3	1	0	1	2	0
6	11	8	1	12	0	0	0	2	3	1
7	14	14	4	18	0	1	0	2	2	0
8	12	8	2	15	0	0	0	2	2	0
9	48	34	4	12	1	1	0	1	3	1
10	43	32	2	5	0	0	1	1	2	0
11	7	7	3	10	1	1	0	1	3	0
12	8	8	1	12	0	1	0	1	2	0
13	6	3	4	12	1	1	0	2	3	0
14	12	5	2	5	0	0	1	1	3	0
15	22	22	1	12	1	1	0	2	1	0
16	18	2	4	7	3	0	0	2	2	0
17	24	8	1	4	0	0	1	2	2	1
18	8	5	4	12	1	0	1	2	3	0
19	26	26	1	8	0	0	1	1	2	0
20	18	17	1	10	1	0	0	2	1	1
21	10	5	1	5	3	0	0	1	2	1
22	8	5	1	5	3	0	0	1	2	1
23	4	2	4	12	0	0	0	2	2	0
24	26	12	4	12	0	1	0	1	2	0
25	12	12	4	18	0	0	0	2	2	0
26	20	3	4	20	0	0	1	1	2	0
27	6	6	2	18	1	0	0	1	3	1
28	12	8	4	6	0	1	0	2	2	1
29	8	8	2	16	0	0	0	1	1	0
30	6	6	1	10	1	1	0	1	2	0
31	3	1	4	18	0	0	0	1	2	0

TABLE 7

## BIOGRAPHICAL DETAILS OF CONTROLS

Subject	Age	Crying	T.o.d.	Hrs.	Cause	Med.	Preg.	Order	Feed	Supp.
1	6	0	3	<3	3	0	0	1	3	0
2	10	0	3	<3	3	0	1	1	3	0
3	7	0	4	<3	3	0	0	2	1	0
4	10	0	4	<3	3	0	1	1	3	0
5	6	0	3	<3	3	0	0	2	1	0
6	10	0	1	<3	3	0	1	2	2	1
7	12	0	4	<3	4	0	0	2	1	0
8	10	0	3	4-5	1	0	0	2	3	0
9	42	36	3	4-6	3	1	0	1	3	0
10	36	0	3	<3	4	0	1	1	3	0
11	8	0	4	<3	3	0	1	2	2	0
12	7	0	3	<3	1	0	0	2	1	0
13	6	0	4	<3	3	0	1	2	2	0
14	10	0	1	<3	3	0	0	2	2	0
15	25	0	1	<3	3	0	0	2	2	0
16	20	0	1	<3	1	0	1	2	2	0
17	26	0	3	<3	1	0	0	2	3	0
18	8	6	1	12	2	0	0	2	2	0
19	26	0	1	<3	3	0	0	1	2	1
20	20	0	1	<3	3	0	0	2	2	0
21	9	0	1	<3	4	0	0	2	1	0
22	8	0	1	<3	3	0	1	1	3	0
23	6	0	1	<3	1	0	1	1	3	1
24	28	0	1	<3	3	0	1	2	2	0
25	10	0	3	4-5	4	0	0	1	1	0
26	24	0	4	<3	3	0	0	2	3	0
27	8	0	4	<3	4	0	0	2	2	0
28	8	0	1	3	3	0	0	2	2	0
29	8	0	3	<3	3	0	0	2	2	0
30	5	0	4	3	1	0	1	1	1	0
31	5	0	4	<3	3	0	0	2	2	1

TABLE 8

SUMMARY OF BIOGRAPHICAL DETAILS

<u>Age</u>	SUBJECT	Median 12 weeks Range 3-48 weeks	CONTROLS	Median 10 weeks Range 5-42 weeks
------------	---------	-------------------------------------	----------	-------------------------------------

Time crying was troublesome before first appointment

SUBJECTS ONLY - median 5 weeks - Range 1 - 34 weeks  
- 10 'from birth'

SUBJECTS    CONTROLS

Time of day

- Daytime only	9	12	
- Night-time only	6	0	chi <sup>2</sup> =12.84
- Evening only	2	10	with 3 degs freedom
- Anytime	14	9	0.01>p>0.001

Time of crying

SUBJECTS

Hours each day crying, fussing and whingeing was troublesome -  
Median 12 hours  
Range 4 - 20 hours

CONTROLS

All but 3 controls described crying as occurring rarely and were given times of less than 3 hours unless stated otherwise. Two families described crying as troublesome, Pt9 and Pt18.

Median <3hrs  
Range 0 - 12 hours

SUBJECTS    CONTROLS

Cause

Don't know	17	0	
Colic*	14	6	Chi <sup>2</sup> =32.2
Pain	1	1	with 4 degs freedom
Hunger	4	19	p<0.001
Other	0	5	

Items 1 & 4 significantly different.

'Colic': 10 of 21 carers with subjects under 3 months offered a diagnosis of colic compared with 4 of 10 carers with babies over 3 months. 6 controls offered 'colic', 4 under 3 months and 2 over 3 months.

Table 8 continued

SUMMARY OF BIOGRAPHICAL DETAILS (CONTINUED)

		SUBJECTS	CONTROLS	
<u>Medications</u>				
	Yes	18	1	Chi <sup>2</sup> =19.4 p<0.001
	No	13	30	

<u>Pregnancy</u>				
	Uncomplicated	24	20	Chi <sup>2</sup> =0.7 0.5>p>0.1
	Complicated	7	11	

Difference in percentage with complicated pregnancies = 13% more in controls (95% CI=36% - -10%)

<u>Birth order</u>				
	First	17	10	Chi <sup>2</sup> =2.36 0.5>p>0.1
	Subsequent	14	21	

Difference in percentage with first pregnancies = 23% more in subjects (95% CI=48% - -2%)

<u>Feeding</u>				
	Breast	5	7	Chi <sup>2</sup> =0.8 with 2 degs freedom p>0.5
	Bottle	19	14	
	Both	7	10	

Difference in percentage who had ever breast fed = 16% more in controls (95% CI=41% - -9%)

<u>Support</u>				
	Supported	22	27	Chi <sup>2</sup> =2.0 0.5>p>0.1
	Unsupported	9	4	

Difference in percentage who were unsupported = 16% more in subjects (95% CI=37% - -5%)

## DISTRESS SCORES

The results of the distress scores are shown in Tables 9 and 10 illustrated in Figure 2 and 3. The median score for subjects was 7 (range 3-10) and for controls 3 (range 0-7) ( $p < .0001$ ). The median difference within subject-control pairs was +3 (range +7 to -3) ( $p < 0.0001$ ). Table 11 shows the comparison of scores for individual items of the questionnaire. The results of the sub-groups are shown in Table 12 and illustrated in Figures 4 and 5. For the sub-groups the median score for subjects was 4 (range 2 - 5) and for controls 2 (range 0 - 5) ( $p < 0.001$ ). The median difference within patient-control pairs was 2 (range +4 to -2) ( $p < .0001$ ).

TABLE 9

DISTRESS SCORES OF SUBJECTS (STUDY 1)

Subject	ITEM 1	2	3	4	5	6	7	8	9	10	TOTAL
1	+	+	+	+	+	+	+	+	+	+	10
2	-	+	+	+	-	-	-	+	-	-	4
3	-	+	+	-	+	-	+	-	+	-	5
4	-	+	+	-	-	-	-	+	+	-	4
5	+	+	+	+	-	+	-	+	+	+	8
6	-	+	+	+	+	-	+	+	+	+	8
7	+	+	+	+	+	-	+	+	+	+	9
8	-	+	+	+	+	+	+	+	+	-	8
9	-	+	+	+	+	+	+	+	+	+	9
10	-	+	+	-	-	-	+	+	+	+	6
11	-	+	+	-	-	+	+	+	+	+	7
12	+	+	+	-	-	+	+	+	-	-	6
13	-	+	-	-	-	-	+	+	-	+	4
14	-	+	-	-	-	-	+	+	+	-	4
15	-	+	-	+	+	+	+	+	+	+	8
16	-	+	+	-	-	-	+	+	-	-	4
17	+	+	-	-	-	-	+	-	-	-	3
18	-	+	+	-	-	-	-	+	+	-	4
19	+	+	+	-	-	-	+	+	-	+	6
20	-	+	-	+	-	+	-	+	-	-	4
21	-	+	+	+	+	-	+	+	+	-	7
22	-	+	+	+	+	-	+	+	+	-	7
23	-	+	+	+	-	-	+	+	+	+	7
24	+	+	+	+	-	-	+	+	-	+	7
25	+	+	+	-	-	+	-	+	+	+	7
26	-	+	-	+	+	-	+	+	+	+	7
27	+	+	+	+	-	-	+	+	+	+	8
28	+	+	+	+	-	-	+	+	+	-	7
29	+	+	+	+	-	-	+	+	+	-	7
30	+	+	+	+	-	+	+	+	+	-	8
31	-	-	+	+	-	-	-	+	+	+	5
TOTAL	12	30	25	19	10	10	24	29	23	16	

MEDIAN (RANGE)

7(3-10)



TABLE 10

DISTRESS SCORES OF CONTROLS (STUDY 1)

ITEM	1	2	3	4	5	6	7	8	9	10	TOTAL	DIFF*
Subject												
1	+	+	-	-	-	-	-	+	-	-	3	7
2	-	-	+	-	-	-	+	-	+	+	4	0
3	-	-	-	-	-	-	-	+	-	+	2	3
4	-	-	-	+	-	-	-	+	+	-	3	1
5	+	-	+	+	-	+	-	-	+	-	5	3
6	-	-	-	+	-	-	-	-	-	-	1	7
7	-	-	-	+	-	-	-	-	-	-	1	8
8	-	-	+	+	-	-	-	-	-	+	3	5
9	+	+	-	+	-	-	+	-	-	-	4	5
10	-	-	-	+	-	+	-	-	+	+	4	2
11	-	-	-	-	-	-	-	-	-	-	0	7
12	-	-	+	-	-	-	-	+	-	-	2	4
13	-	-	-	-	-	-	-	+	-	-	1	3
14	-	+	-	+	-	-	-	+	-	-	3	1
15	-	+	-	+	-	-	-	+	-	-	3	5
16	-	-	-	+	+	-	-	+	+	+	5	-1
17	-	-	+	+	-	-	-	+	-	-	3	0
18	+	+	+	-	-	+	-	+	+	+	7	-3
19	-	+	+	-	-	+	+	+	+	-	6	0
20	-	-	-	+	-	-	-	-	-	-	1	3
21	-	-	-	+	+	-	-	-	-	-	2	5
22	-	-	-	+	-	-	-	-	-	-	1	6
23	+	-	+	+	-	-	+	+	-	-	5	2
24	-	-	-	+	-	-	+	-	-	-	2	5
25	-	-	-	+	-	-	-	+	-	-	2	5
26	+	+	+	-	-	+	+	+	+	-	7	0
27	-	-	+	+	+	-	-	+	+	-	5	3
28	-	-	-	-	-	-	+	+	-	-	2	5
29	-	-	-	-	-	-	-	+	-	-	1	6
30	+	-	+	+	-	+	-	+	-	+	6	2
31	-	-	-	+	-	+	-	+	-	-	3	2
TOTAL	7	7	11	20	3	7	7	19	9	7	97	

MEDIAN (RANGE)

3(0-7) 3(-3 - +8)

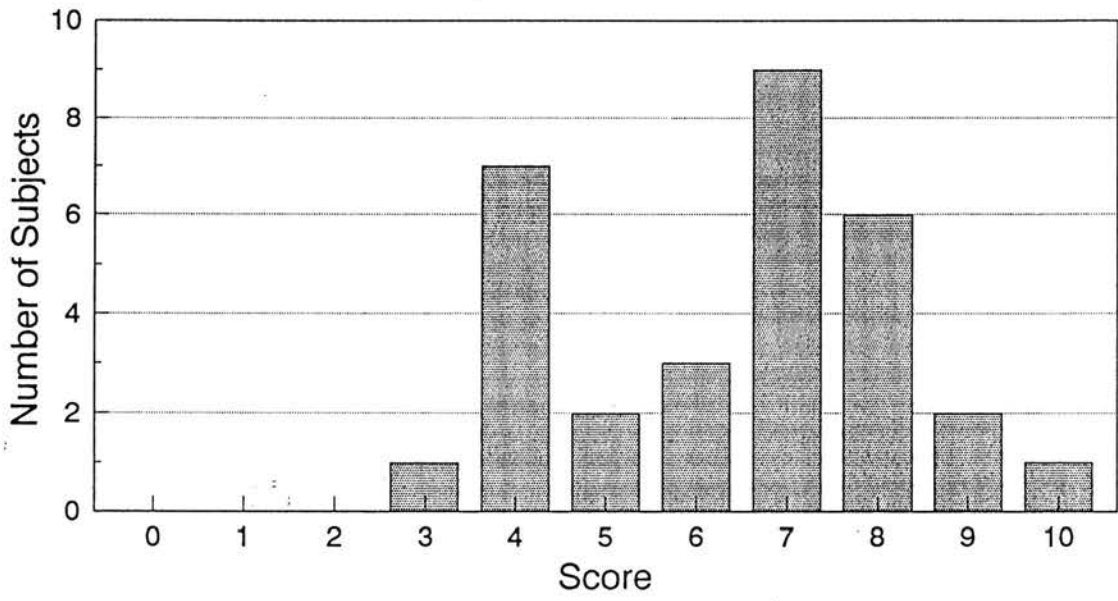
Wilcoxon Rank Sum Test for Pairs  $p < 0.0001$

\*DIFF - Difference between subject and control

FIGURE 2

DISTRESS SCORES (STUDY 1)

Subjects n = 31



Controls n = 31

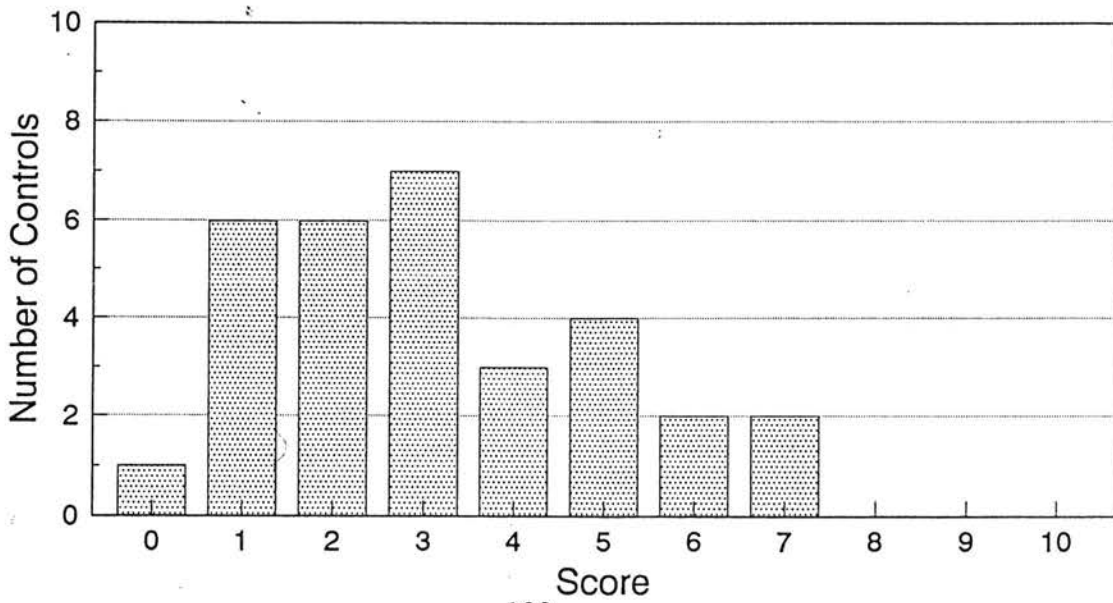


FIGURE 3

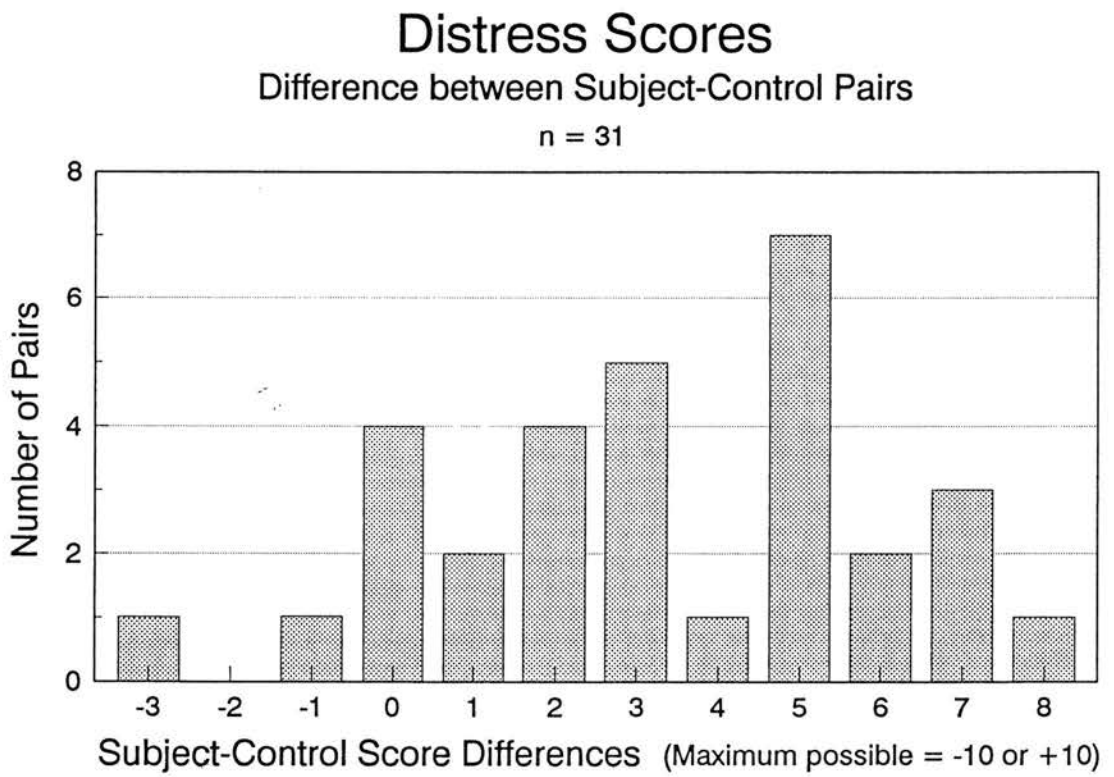


TABLE 11

## COMPARISON OF DISTRESS SCORE ITEMS

	Subject	Control	chi <sup>2</sup>	p
Item				
1	12	7	1.21	0.27
2	30	7	32.44	<0.0001
3	25	11	11.19	0.0008
4	19	20	0.00	1.0
5	10	3	3.5	0.06
6	10	7	0.32	0.57
7	24	7	16.52	<0.0001
8	29	19	5.94	0.015
9	23	9	10.9	0.001
10	16	7	4.42	0.035

TABLE 12

DISTRESS SCORES OF SUBJECTS AND CONTROLS  
USING SUBGROUPS

Pair no.	Subject	Control	Difference
1	5	2	3
2	3	4	-1
3	4	2	2
4	2	2	0
5	5	4	1
6	5	1	4
7	5	1	4
8	4	3	1
9	5	3	2
10	5	4	1
11	4	0	4
12	3	2	1
13	4	1	3
14	3	3	0
15	5	3	2
16	3	3	0
17	2	3	-1
18	2	4	-2
19	4	3	1
20	4	1	3
21	4	1	3
22	4	1	3
23	5	4	1
24	5	2	3
25	4	2	2
26	5	3	2
27	5	3	2
28	4	2	2
29	4	1	3
30	4	5	-1
31	4	3	1
MEDIAN (RANGE)	4 (2-5)	2 (0-5)	2 (-2-4)

Wilcoxon Ranked Sum Test for Pairs =  $p < 0.0001$

FIGURE 4

DISTRESS SCORES USING SUBGROUPS (STUDY 1)

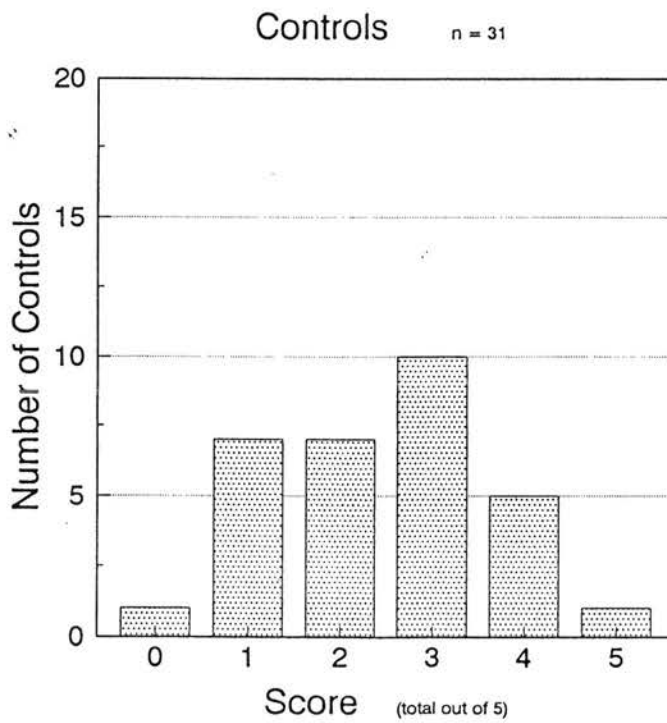
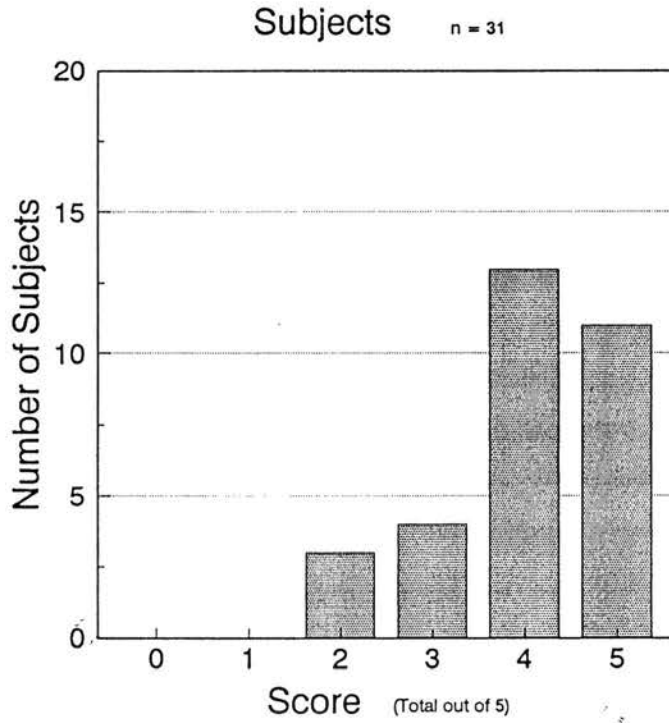
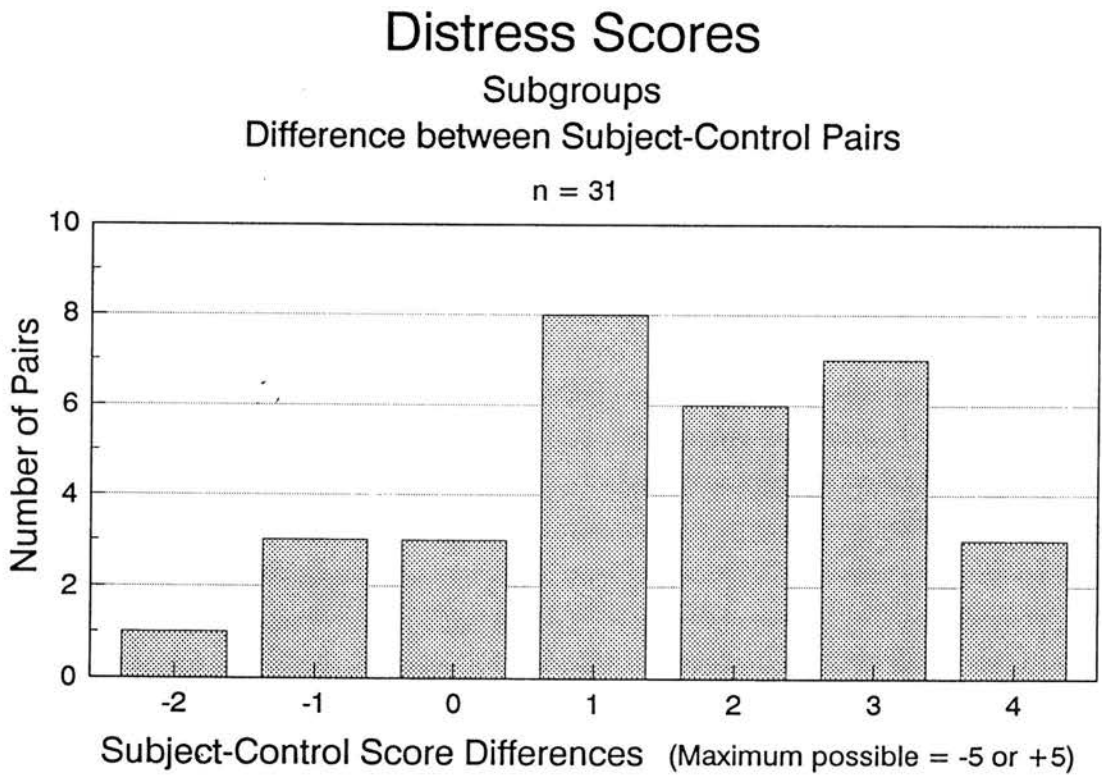


FIGURE 5



### Hospital and home management

10 and 21 babies entered hospital and home groups respectively (Table 5). One from each group dropped out. 4 babies from the home group were admitted to hospital after 7 days as there had been no change in crying. All but one mother chose to sleep at home.

Thus 13 babies were admitted to hospital and 20 were managed at home. Of the hospital group only one mother elected to come in overnight. Eight diaries which the nurses had kept were available for analysis. Diaries had either not been kept for the remaining infants or had not been filled in properly. The median number of hours cried during the third 24 hour period after admission was 2.5 (range 1 - 4). Thus the crying times documented by the nurses represented an improvement on that reported by the carers and was concordant with the improvement on the change rating chart. 10 of those managed at home did not return diaries or returned diaries which they admitted were incomplete. Expressions such as 'good day' or 'OK' or 'terrible' had been used instead of documentation of crying times. Eight of the 10 diaries completed showed improvement which was consistent with the improvement on the change rating chart but two who scored 'no change' on the change rating chart - Pt21 and Pt22 - documented 2 hours and half an hour respectively in their diaries. The results of the change rating charts are shown in Table 13 and summarised in Table 14. Figure 6 demonstrates these graphically.



TABLE 13

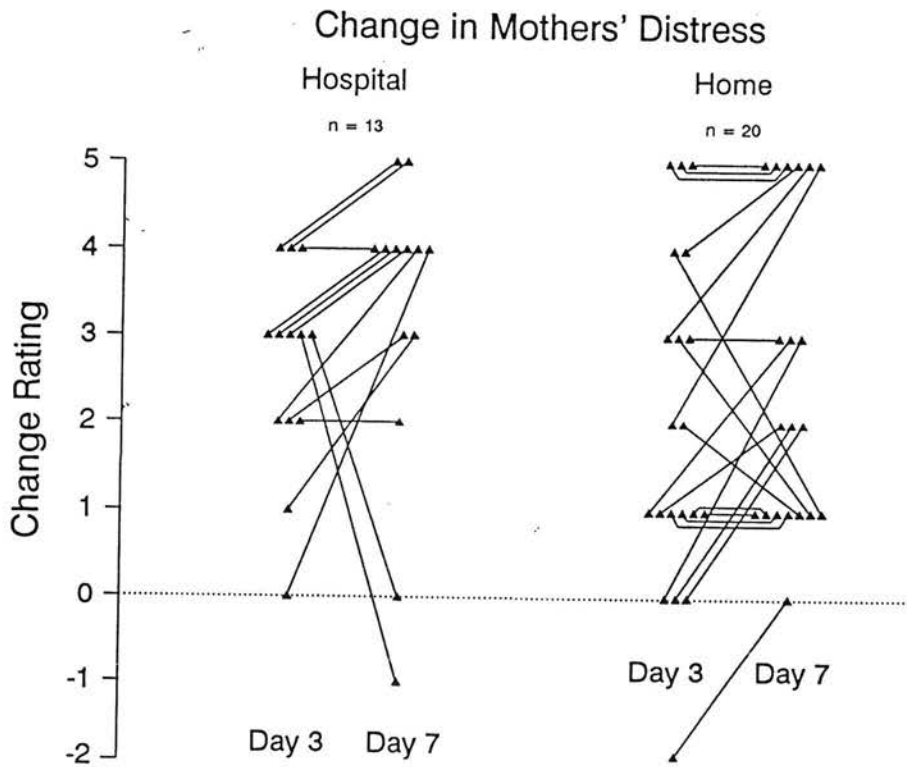
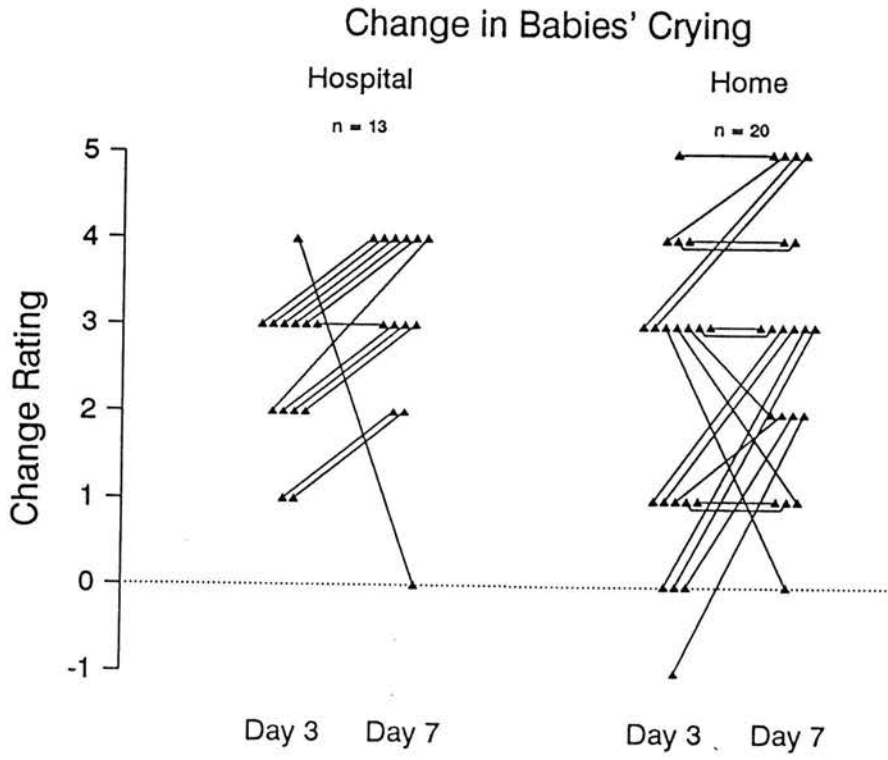
CHANGE RATINGS

SUBJECT	HOME				HOSPITAL			
	Mother		Baby		Mother		Baby	
	3	7	3	7	3	7	3	7
1	-2	0	0	3				
2					3	0	4	0
3	5	5	4	4				
4	1	1	1	2	4	4	1	2
5	DNA							
6	1	1	3	3				
7								
8	5	5	3	3				
9	1	1	1	3				
10	3	3	4	4				
11					2	3	2	3
12					4	5	2	4
13	2	5	4	5				
14					3	-1	2	3
15	3	5	3	5				
16					3	4	3	4
17	5	5	5	5				
18	4	5	3	5				
19	1	2	1	3				
20	1	3	3	2				
21	0	2	0	2				
22	0	2	0	3				
23					1	3	1	2
24	1	1	1	1	3	4	3	4
25					3	4	3	4
26	2	1	3	1	2	2	2	3
27	0	3	-1	2				
28					4	5	3	4
29	4	1	3	0	2	4	3	4
30	3	1	1	1				
31					0	4	3	3

TABLE 14 Hospital and home management. Percentage (95% confidence interval) of babies and mothers who scored >+2 on the change rating scales

		Baby's crying	Mother's distress
Hospital	Day 3	85% (65-100)	85% (63-100)
	Day 7	92% (76-100)	85% (63-100)
Home	Day 3	55% (32-78)	50% (26-74)
	Day 7	80% (61-99)	60% (36-84)

FIGURE 6



## SUMMARY OF RESULTS OF STUDY 1

Because too few subjects agreed to randomisation a rigorous study to compare home and hospital management could not be planned. No more than about half, at the very most, of a group selected from a similar background would be likely to volunteer for randomisation. Thus the first objective of this project could not be fulfilled.

Nevertheless examination of the change in crying and in mothers' distress suggested that there was definite improvement following hospital admission which is sustained after discharge.

A biographical profile and a measure of mothers' distress in age-matched subjects and controls was successfully undertaken, thus fulfilling the second objective of the project.

Crying diaries were not kept successfully by carers of subjects. There was however concordance between improvement on the change rating scores and the time crying on the ward as recorded by the nurses thus satisfying one of the criteria for a suitable ordinal scale (see Discussion). The use of change rating charts was rehearsed and the initial interview was practised. The third objective of the project was therefore fulfilled. Because it was established that a combination of interview and advice to reduce stimulation suggested a substantial improvement in babies managed at home, a second study to examine the role played by the giving of advice was justified.

Had there been indication that carers were willing to have their infants randomised to hospital or home care then the lessons learnt from this pilot study would have been put to use. There would have been more rigorous supervision of diary-keeping by both nurses and carers and the diaries would have been redesigned to encourage better recording. Recording of change ratings would have been undertaken by observers uninvolved in the study to avoid bias.

## CHAPTER 5 - STUDY 2

This study addresses the fourth objective of this project, to discover whether advice to reduce/change stimulation of babies with troublesome crying managed at home was more effective than an empathic interview only.

### METHODS FOR STUDY 2

In the first study, 80% of babies with troublesome crying managed at home achieved change scores of +2 or more at Day 7. It was considered that a difference of 40% in this proportion between a group which received advice and one which received only an interview would be of practical importance. To demonstrate this with a type 1 error of 0.01 and a type 2 error of 0.2, 30 babies in each arm of a randomised trial would have to be enrolled. It was planned to make a single interim analysis when approximately 20 babies had been enrolled in each arm. It had taken almost one year to enrol subjects and controls for Study 1. Study 2 was undertaken on the assumption that it would take a further two years to complete. This seemed a reasonable time-scale for the project.

Carers were interviewed as described in Chapter 3. All were given an optimistic outlook. All agreed that information about their babies' crying and its management could be used in a research project. It was considered

ethically acceptable that families should not be asked to agree to randomisation as knowledge of this may have prejudiced the quality of the information gathered; all eventually received the same treatment. Patients were randomised into two groups using random numbers. Each subject of the 'empathy' group was asked to fill in a diary of crying times and interventions for a week. This diary record was not for formal analysis; it was explained to the families that it would provide a background for advice in 7 days' time. The other group was advised to reduce stimulation as described in Chapter 3. All were given a change rating chart and knew they would be contacted by telephone by someone who was not involved in the study and who would therefore not be able to advise and whose role was solely to record change rating scores.

All were contacted by telephone on Days 3,7,10,14 and at 1 month by an observer, usually a house-officer, who did not know to which group infants had been assigned. The observer was given written instructions about how to conduct the telephone conversation with examples of questions and responses; he was asked to introduce him/herself by first name only and to request the results of the change scores on that day. Observers were to avoid conversation about anything else. All carers were contacted on the same days by the interviewer who did not know the results of the change scores. 'Empathy' group subjects returned on the afternoon of Day 7 and were given the same advice about reducing stimulation as the other group.

## Analysis

Biographic details were compared by chi-square testing for subjects in Study 1 and Study 2 to discover whether the groups were similar. Items in the distress scores were compared with subjects in Study 2 by comparison of percentages if there were no differences discernible by chi-square testing. This was done to calculate a 95% confidence interval for differences to give some idea of how consistent the scorings were.

As in Study 1, a change score of +2 or better was counted as a positive response, and the proportions of such responses were compared using Chi<sup>2</sup> testing with Yates correction for continuity.

## RESULTS

When 45 infants were enrolled an interim analysis was made. 3 babies were not included; one requested hospital admission, two were not available on the telephone. Biographical details are recorded in Tables 15 and 16 and comparison with subjects of Study 1 is made in Table 17. Distress scores are recorded in Tables 18 and analyses of distress score items and comparison with subjects in Study 1 are recorded in Tables 19 and 20. Grouping following randomisation is recorded in Table 21.



TABLE 15

## BIOGRAPHICAL DETAILS OF SUBJECTS (STUDY 2)

See Table 2 for Codes

Subject	Age	Crying	T.o.d.	Cause	Int.	Preg.	Order	Feed.	Supp.	Smok.
1	44	38	2	4	2	0	1	1	1	0
2	18	9	4	1	1	1	1	2	1	0
3	12	12	2	1	1	0	2	2	1	1
4	3	1	1	1	2	0	1	2	1	0
5	7	7	1	0	2	0	2	3	1	0
6	47	20	4	2	2	0	2	3	0	0
7	48	48	4	4	1	0	2	2	0	1
8	10	2	4	1	2	1	1	3	1	0
9	8	8	4	1	2	0	2	1	0	1
10	12	12	4	1	1	1	2	3	1	1
11	26	26	4	0	2	0	2	3	1	1
12	7	4	1	2	1	1	2	1	1	0
13	36	32	4	0	2	0	2	2	1	0
14	14	14	1	4	2	1	1	3	1	1
15	8	8	4	0	2	0	1	1	0	1
16	14	14	1	1	2	0	1	1	1	1
17	5	5	4	1	1	0	2	1	1	1
18	4	4	4	1	2	0	1	3	1	0
19	10	6	1	1	1	0	2	1	1	0
20	5	3	4	1	1	0	1	3	1	0
21	6	6	1	3	2	0	1	1	1	0
22	10	9	1	1	1	1	2	2	1	1
23	11	7	4	3	1	0	1	1	1	1
24	8	6	4	0	1	0	1	3	1	1
25	12	12	1	0	2	0	2	3	1	0
26	6	4	3	3	1	0	2	1	1	0
27	8	7	1	1	1	1	2	3	1	0
28	9	5	2	0	1	1	1	1	1	1
29	10	9	4	2	1	0	1	3	1	0
30	18	16	4	1	1	0	1	3	1	1
31	3	3	4	2	2	1	1	3	1	1
32	8	8	4	1	2	0	1	2	0	1
33	44	32	4	0	2	1	2	1	1	1
34	7	7	3	1	1	0	1	3	1	0
35	6	6	1	4	2	0	2	1	1	1
36	46	46	2	0	2	0	2	1	1	1
37	6	6	4	0	2	0	2	1	1	0
38	20	18	1	1	2	0	2	2	1	0
39	46	26	2	0	1	0	2	3	1	1
40	24	22	2	1	1	1	1	1	1	0
41	40	37	4	4	1	0	1	3	1	1
42	26	6	4	0	1	1	2	1	1	1
43	9	9	1	0	2	0	1	1	1	1
44	7	5	4	1	2	0	2	1	1	1
45	50	26	2	0	1	0	1	1	1	1

TABLE 16

SUMMARY OF BIOGRAPHICAL DETAILS - STUDY 2

Median age = 10 weeks (range 3-50).

Under 12 weeks = 28 (one excluded)

Length of time crying troublesome - 19 since birth  
- 36 since neonatal period

Time of day - 13 daytime  
7 night-time  
2 evening  
23 anytime

Cause - 14 don't know  
19 colic  
4 pain  
3 hunger  
5 other

Of 28 babies <3 months, 23 listed colic among the causes.  
Of 17 babies >3 months, 9 listed colic among the causes.

Medication - Yes - 22  
No - 23

Pregnancy - Uncomplicated - 33  
Complicated - 12

Birth order - First - 22  
- Subsequent - 23

Feed - Bottle 20  
Breast 8  
Both 17

Unsupported - 5

Smoking - 25

TABLE 17  
COMPARISON OF BIOGRAPHICAL DETAILS (STUDIES 1 & 2)

	STUDY 1	STUDY2	
Age	10weeks	12weeks	
Crying	5weeks	9weeks	
From birth	10/31	19/45	chi <sup>2</sup> 2.41 p = 0.12
Time of day			
Day	9	13	
Night	6	7	chi <sup>2</sup> 0.43
Evening	2	2	p = 0.934 3df
Anytime	14	23	
Duration each day	12 (4-20)		
Cause			
Don't know	17	14	
Colic	14	19	
Pain	1	4	chi <sup>2</sup> 7.1
Hunger	4	3	p = .13 4df
Other	0	5	
Medication	18	22	chi <sup>2</sup> = .31 p = .58
Pregnancy			
Complicated	7	12	chi <sup>2</sup> = 0.02 p = 0.89
Birth order			
First	17	22	chi <sup>2</sup> = 0.01 p = 0.93
Feeding			
Breast	5	8	
Bottle	19	20	chi <sup>2</sup> = 2.39
Both	7	17	p = 0.30
Support			
Supported	22	40	chi <sup>2</sup> = 2.82 p = 0.093

TABLE 18

DISTRESS SCORES (STUDY 2)

ITEM	1	2	3	4	5	6	7	8	9	10	TOTAL
SUBJECT 1	+	-	+	+	-	+	+	+	+	-	7
2	+	+	+	-	+	+	+	+	+	+	9
3	-	-	+	+	-	-	+	+	+	-	5
4	+	-	+	+	+	-	+	+	-	+	7
5	-	+	+	-	-	-	-	+	+	-	4
6	-	-	+	-	-	-	+	+	+	-	4
7	+	+	-	+	+	+	-	+	+	+	8
8	-	+	+	+	-	-	+	+	-	-	5
9	-	+	+	+	+	+	+	+	+	+	9
10	-	+	+	+	+	-	-	+	+	+	7
11	+	+	+	-	-	+	+	+	+	+	8
12	-	+	+	+	+	+	+	+	+	+	9
13	-	+	+	-	-	-	+	+	+	+	6
14	-	+	+	+	-	-	+	+	-	-	5
15	+	+	+	+	+	+	+	+	+	+	10
16	-	+	+	-	-	-	+	+	+	-	5
17	-	+	+	+	-	-	+	+	+	-	6
18	+	+	+	+	-	-	+	+	+	+	8
19	-	+	+	-	+	-	+	+	+	-	6
20	-	+	+	+	-	+	+	+	+	-	7
21	+	+	+	+	+	-	-	+	-	-	6
22	+	+	-	-	-	-	+	+	+	-	5
23	-	+	+	+	+	-	+	+	+	+	8
24	+	+	+	-	-	-	-	+	+	+	6
25	+	+	+	-	+	-	+	+	+	+	8
26	+	+	+	+	+	+	+	+	+	+	10
27	-	+	+	-	-	-	+	+	+	+	6
28	+	+	+	-	-	-	+	+	-	+	6
29	-	+	+	+	+	+	+	+	+	+	9
30	-	+	+	+	-	-	+	+	+	-	6
31	+	+	+	-	+	+	+	+	+	-	8
32	+	+	+	-	-	-	-	+	+	-	5
33	-	+	+	+	-	-	-	+	+	+	6
34	-	+	+	-	-	+	+	+	+	+	7
35	-	+	+	+	+	+	-	+	+	-	7
36	+	+	+	+	-	+	+	+	+	+	9
37	-	+	+	+	-	+	+	+	-	+	7
38	+	+	+	-	-	+	-	+	-	+	6
39	-	+	+	+	-	-	+	+	+	-	6
40	+	+	-	+	-	-	+	+	+	+	7
41	+	+	+	-	-	+	+	+	+	+	8
42	-	+	+	+	-	+	+	+	+	+	8
43	+	+	+	+	+	+	+	+	+	+	10
44	-	+	+	-	-	-	+	+	+	+	6
45	+	+	-	+	-	+	+	+	+	+	8
	21	41	41	27	16	20	36	45	38	28	

TABLE 19

COMPARISON OF DISTRESS SCORES (STUDIES 1 & 2)

Median scores:

7 (range 3-10) - STUDY 1  
 7 (range 4-10) - STUDY 2

Scores for separate items:

ITEM	1	2	3	4	5	6	7	8	9	10
STUDY 1 N=31	12	30	25	19	10	10	24	29	23	16
STUDY 2 N=45	21	41	41	27	16	20	36	45	38	28

TABLE 20

POSITIVE REPLIES FOR ITEMS IN STUDY 1 AND STUDY 2 SUBJECTS

ITEM	1	2	3	4	5	6	7	8	9	10
STUDY 1 N=31	32%	97%	81%	61%	32%	32%	77%	94%	74%	52%
STUDY 2 N=45	47%	91%	91%	60%	36%	44%	80%	100%	84%	62%
DIFFERENCE	15%	6%	10%	1%	4%	12%	3%	7%	10%	10%
STANDARD ERROR	11%	5%	7%	11%	11%	11%	10%	4%	7%	12%

TABLE 21

RANDOMISATION TO GROUP 1 - INTERVIEW ONLY  
 GROUP 2 - INTERVIEW AND ADVICE

Patient number	Group	Patient number	Group
1	1	23	2
2	2	24	1
3	1	25	1
4	2	26	2
5	2	27	2
6	1	28	2
7	1	29	1
8	2	30	1
9	1 EXCLUDED*	31	1
10	1	32	2
11	2	33	1 EXCLUDED*
12	2 EXCLUDED***	34	2
13	1 DAY 10	35	1
14	1	36	1
15	2 EXCLUDED***DAY7	37	2
16	2 EXCLUDED**	38	2
17	1	39	1
18	2	40	1
19	2	41	2
20	1	42	2
21	1	43	2
22	2	44	2
		45	1
			EXCLUDED
			DAY 10***

\* NO TELEPHONE

\*\* ADMITTED TO HOSPITAL \*\*\* LOST TO FOLLOW-UP

Group 1 - 22 ----2 excluded as no telephone; 1 lost after 10 days

Group 2 - 23 ----1 excluded as wanted hospital admission

----1 lost after 7 days

The results of the change scores for crying on days 3, 7, 10, 14 and 1 month are shown in Table 22 and results on days 3 and 10 are illustrated in Figure 7 and summarised in Table 23. The proportion of positive responses, both for babies' crying and for mothers' distress, was significantly higher in the 'advice' group on days 3 and 7. At this point the 'empathy' group also received advice, and the proportion of positive responses rose to a level similar to that in the 'advice' group (Figure 7). The results appeared sufficiently clear cut that no further subjects were enrolled. 39 families were available for follow-up 1 month after receiving advice and their change scores showed 37/39 mothers scored +2 or better (21=+5) and 33/39 babies scored +2 or better (17=+5).

TABLE 22

Day	CHANGE RATINGS									
	Baby			Mother						
	3	7	10	14	1month	3	7	10	14	1month
1	0	0	1	2	1	0	-1	2	2	2
2	2	2	4	4	4	4	4	4	5	5
3	2	3	3	3	3	2	3	3	3	3
4	3	3	3	3	4	5	5	5	5	5
5	3	-3	1	2	4	3	-1	3	5	5
6	-3	-2	3	3	5	-1	-2	3	2	5
7	0	0	2	2	0	0	0	2	3	-2
8	2	2	3	4	2	2	2	3	4	4
9	EXCLUDED									
10	1	0	2	5	5	0	-1	4	5	5
11	4	4	4	5	5	3	3	5	5	5
12	0	-3	-2	EXCLUDED		0	2	0	EXCLUDED	
13	2	2	-1	3	3	2	2	-1	3	3
14	1	1	2	4	4	3	3	4	4	4
15	2	4	EXCLUDED			2	4	EXCLUDED		
16	EXCLUDED									
17	1	3	4	4	5	3	5	4	4	5
18	1	3	4	4	5	1	5	5	5	5
19	3	4	5	5	5	1	3	3	4	5
20	0	3	2	3	5	0	3	3	4	5
21	4	-1	1	3	5	5	-1	1	3	5
22	4	3	1	4	5	1	3	2	5	5
23	1	2	1	2	2	3	3	3	2	2
24	0	3	3	3	5	1	3	5	5	5
25	0	0	2	2	5	0	0	2	1	5
26	3	3	3	-3	5	3	3	3	2	5
27	2	3	5	5	5	1	2	3	3	5
28	0	3	-1	2	2	1	5	3	3	2
29	0	-1	3	5	5	0	-1	2	4	5
30	0	1	-1	1	1	0	0	-1	1	2
31	0	1	1	2	4	0	0	4	4	4
32	5	4	4	4	-2	5	5	5	5	4
33	EXCLUDED									
34	2	3	3	3	4	2	3	3	3	4
35	1	3	4	0	0	2	3	4	4	4
36	0	0	2	5	5	0	0	2	5	5
37	1	2	2	1	3	4	4	4	1	3
38	0	0	0	0	0	0	0	0	0	0
39	1	0	0	5	5	1	0	-1	5	5
40	0	0	1	4	5	0	0	1	4	5
41	5	5	5	5	5	3	5	5	5	5
42	3	5	4	4	4	3	5	4	4	4
43	1	-1	3	3	3	1	1	-2	3	3
44	5	5	5	5	5	5	5	5	5	5
45	-2	3	0	EXCLUDED		0	0	0	EXCLUDED	



FIGURE 7 Changes in infants' crying and mothers' distress on days 3 and 10 in subjects and controls illustrated on Change Rating Charts.

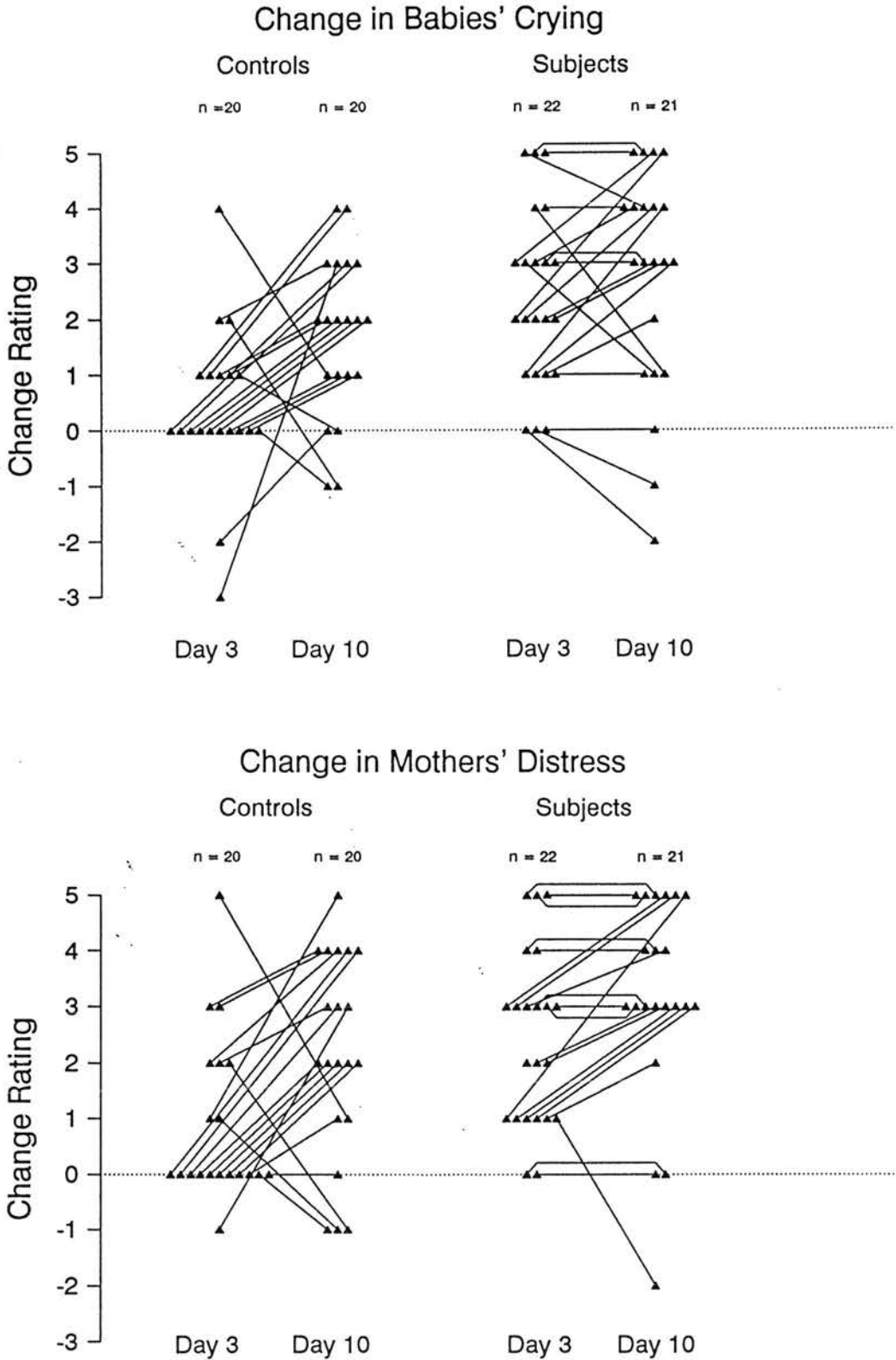


TABLE 23

'Empathy' and advice management.

Numbers of babies and mothers who scored +2 or better on the change rating charts for baby's crying and mother's distress. The 'empathy' group received advice on Day 7.

		Empathy	Advice	chi <sup>2</sup>	p
Crying	Day 3	3/20	15/22	8.1	<0.01
	Day 7	7/20	18/22	9.5	<0.01
	Day 10	12/20	15/21	0.2	>0.5
	Day 14	17/19	17/20	0.1	>0.5
Mother's distress	Day 3	4/20	15/22	6.1	<0.01
	Day 7	6/20	19/22	13.8	<0.001
	Day 10	14/20	17/21	0.7	>0.2
	Day 14	16/19	16/20	0.12	>0.5

## COLIC AND WILFULNESS

Although it was not the original intention to enrol enough babies for an analysis of the outcome of separate sub-groups, the opportunity was taken to examine the complaint of colic and the perception of wilfulness for those aged below and above 12 weeks. This is the age many believe is the upper limit for colic and is also the age past which an infant developmentally is believed to begin to have control over his/her environment.

17 of 28 carers with babies 12 weeks old or less first gave the cause of the crying as colic or pain (codes 1 and 2 in Table 2) and 6 of 17 with older babies ( $\chi^2=0.21$ ;  $p=0.65$ ).

Items 4 and 5 of the questionnaire - perception of baby's wilfulness - were examined in babies older and younger than 12 weeks. The younger babies scored 31 out of a possible total score of 56 compared with a score of 17 out of a possible 34 for older babies ( $\chi^2=0.57$ ;  $p=0.45$ ).

## SUMMARY OF RESULTS OF STUDY 2

This study has shown that the group who received advice at the first interview demonstrated a clear benefit over the 'empathic' group during the first week. Within 3 days there was a marked difference (Figure 7 and Table 23). Whether this advice was any better than any other enthusiastic advice is not known and of course there is no way of knowing from this study whether the advice was followed or not.

Ideally a group studied over 14 days with no advice to reduce stimulation should have been included. It was not considered ethical to do this as the results from Study 1, whilst only suggestive that this advice might be helpful, seemed enough to warrant that all subjects enrolling for the project were promised that they would be treated in the same way within a reasonable period of time. The improvement in both infants' crying and mothers' distress in the 'empathic' group between days 7 and 14 after they were given advice would have to be compared to a group who did not receive advice over this period to know whether or not the improvement was a result of the advice or whether it reflected seeing and talking to an empathic physician over a 14 day period.

39 of 45 subjects were available for interview at one month after entry. 21 scored the maximum on the change rating chart for distress and 17 for infants' crying. All except 2 mothers scored 2 or more on the

distress change rating and all except 6 scored 2 or more for their infants' crying. It was not part of this study to enrol a group who had never had contact with the crying baby clinic. Neither was there a group who had not had advice but only supportive care throughout and so it is impossible to say whether this improvement at one month was related to the intervention in any way. What can be said is that in this group of subjects who reported that their infants at the time of presentation had troublesome crying for a long time each day, the majority of these subjects improved. There was no worsening of the condition, only improvement either because of or in spite of the intervention. In other words the intervention with respect to the changes over a month was not harmful in the majority of subjects.

The complaint of colic seems not to be exclusive to subjects with infants under the age of 3 months and some mothers with infants under the age of 3 months perceived them as wilful.

## CHAPTER 6 - DISCUSSION

In this chapter definitions, methods, the results of the questionnaires and the outcomes of both studies will be discussed. These discussions will integrate information from the literature and will be supported by speculation about the implications of the results.

### Definition

This is the first time that the term **troublesome crying**, in preference to either **colic** or **excessive crying**, has been used for a formal study. This was to address the problem of studying a complaint rather than a phenomenon which can be measured. An analogy can be made with the study of pain, joint stiffness or headache, all complaints which cannot be measured using parametric methods. The term 'troublesome' addresses only what the crying means for the carer(s). With reference to the perception of another event which causes distress - pain - Bakan (1968) has argued that the understanding of pain in another starts with each individual's isolated internal reference to his or her own experience. Different individuals have different levels of tolerance. Attempts to 'measure' pain have been difficult precisely because measurement must fall back on some form of introspective report by those experiencing pain.

The term 'troublesome' describes a negative effect on the listener, much in the same way as 'aversive' has been used in laboratory studies (Chapter 1). Listeners enrolled to listen to tape-recorded crying in a laboratory setting can find such crying aversive. It is easy to understand how carers who have to live with crying which they are helpless to stop and who become overwrought due to sleeplessness and frustration become angry to the point of abusing their infant. Crying is commonplace and it may seem an unusual topic for examination. Nevertheless, excessive and troublesome crying can be fatal if abuse leads to death which it has been regularly reported to do. It can of course be argued that crying is merely a trigger for abuse and not the primary reason. Nevertheless, as this study has indicated, it can cause a great deal of distress in carers and puts stress on relationships.

The difficulty of defining colic has already been discussed. Measuring crying by using audiotapes in a naturalistic setting invites the question about how to define crying. When does crying start and stop as a clear and undisputed vocal phenomenon? When do the vocalisations become what is termed fussing or whingeing? Golub (1985) has defined a cry as 'The total sound response to a specific stimulus'. While this may be a satisfactory definition for acoustic analysis it hardly suffices in the clinical setting as it is often unclear what the stimulus is.

Barr et al (1988) in the diaries given to carers who were to record crying and fussing defined 'fussing' as 'not quite crying but not awake and content either'. Tape-recorded vocalisations were described

as negative or non-negative and here there was intraobserver reliability. Carers however did not document 20% of negative vocalisations in their diary recordings. Perhaps they did not consider them negative or simply did not notice them.

What an individual perceives as crying in an adult is made up not only of what he/she hears but also of what is seen - tears, facial configurations implying distress, gestures - and what is assumed about the emotional state of the individual. Crying is not only an expression of distress but also relief and ecstasy. In the case of infant crying, signals in addition to vocalisations must mean for carers that their infant is 'crying' and explain some of the difference between the audiotape records and parents recordings in a diary. There appears to be no information available which measures how well recordings of crying times, as opposed to fussing and other vocalisations, agree within or between listeners. This would have to be a laboratory study using videos. It is possible that there will be a certain amount of disagreement between observers about the recording of crying and distinguishing it from fussing and it may be that observers themselves may record differently from day to day according to how they feel themselves.

Barr et al (1992) have demonstrated using diaries that there is a group of infants whose carers complain of colic who cry as little and for the same time as controls. There are also some carers - controls in Barr's study - whose infants do cry for over three days a week, thus fulfilling one definition of colic (Wessel et al, 1954), but who do not complain that their infants suffer from it. These results are very similar to those of



St James-Roberts' (1991) who also showed there was a big overlap between normals and 'clinical' infants' crying. Of Hyams group (1989) who cried for over three hours a day, only half complained that the crying was troublesome. As with pain, where there may be pain without tissue injury and tissue injury without pain, there may be complaining with very little crying and also a great deal of crying without complaint.

There has been controversy surrounding the use of parental reports of their children's behaviour. Several studies have indicated that objective measures are not generally superior to maternal measures (Achenbach and McConaughy, 1987; St James-Roberts and Wolke, 1988). St James-Roberts has defended their use very effectively (St James-Roberts and Halil, 1991). When a mother complains that her baby is crying too much objective measures indicate that this is the case. Mothers' reports correlate with infants' crying. Whilst this may be true for the majority it is not true for all, as Barr et al (1992) have indicated.

And so, when carers complain their infant has colic it seems that a number of such infants do not cry for any longer than infants of carers who do not complain of colic. The crying is troublesome, is complained about and may be perceived to be more 'sick-sounding' but it is not necessarily any longer in total duration through the day although plainly in most babies it is. The term **troublesome** seems to be reasonable.

## Subjects

For both studies consecutive infants presenting with troublesome crying were enrolled. Some were later excluded if they had no telephone, or if they were unavailable for follow-up for example. This gave some idea of what proportion of a population of subjects who filled the entry criteria would be amenable to treatment. The dropout rate was low enough not to confound the results, only 2 in Study 1 and 6 in Study 2.

Subjects were all seen within 72 hours of referral to ensure consistency. After the appointment was made the hope of a specialist seeing their troublesome infant may have changed care-giving routines. It was therefore important to ensure each subject was seen as soon as possible. In addition there was the anxiety that some carers may have been at the point of abusing their infants.

In contrast to conventional medical advice about the importance of examining infants who present with crying, those in this study were not examined. This was because they were not being seen in a primary care setting and had already been examined. A recent review of the emergency room management of excessive crying documented the number of physical conditions which were discovered (Poole, 1991) and quite plainly examination at the time of presentation is crucial. Very few carers, a total of 5 of the 76 subjects enrolled for both studies, felt that pain for physical reasons other than 'colic' was the cause.

## Controls

The first study group were matched with controls from the community. These were matched only for age as this seemed to be the only unequivocal variable which is related to crying (Chapter 1).

## Biographical data

### Age

The median age of presentation was 10 weeks and 12 weeks in subjects of Study 1 and 2. As most crying normally occurs in the first three months (Barr, 1990) it is not surprising that most subjects drawn from the first year of life present in the first half.

### Time crying troublesome

What is interesting is that of a total of 76 subjects - 31 in Study 1 and 45 in Study 2 - 29 complained that the crying had been troublesome from birth or from very early in the neonatal period. This has been reported in other studies (Brazelton 1962; Paradise 1966; Carey 1968). The length of time the crying had been troublesome was 5 weeks in

Study 1 and 8 weeks in Study 2 but for some carers the crying had been troublesome for several months. Stahlberg (1984) in a review of Finnish infants reported that of those whose carers complained that their infants had colic in the first 2 weeks - 40% - more had symptoms which lasted more than 3 months and more had symptoms for more than 3 hours in a day. Rubin and Prendergast (1984) in a study of Norfolk infants also documented the persistence of colic for longer than 3 months in many cases.

In this study, families had had advice from a number of agencies and although the precise reason for their referral so late was not documented it was clear that for some of them the crying was causing disruption within the family. Quarrelling and exhaustion were documented but disruption of sleeping arrangements was also reported. It is also true that the Crying Baby Clinic had become known in the community and that families who had previously hoped that the problem would go away were eventually referred, albeit late in the first year. In this context it is surprising that more younger infants were not represented in the second group.

#### Duration of crying each day

For Study 1 the duration of crying each day was calculated on what families remembered for the previous 48 hours. The range of times reported was wide, 4-20 hours, median 12 hours. Because it was felt that the length of crying in hours per day was not what mattered, it was not recorded for Study 2. In retrospect it would have been interesting

to have known how the groups compared in this respect as it might be expected that, as the Crying Baby Clinic became known infants would be referred either earlier or with less excessive crying.

The controls, except for two, reported crying less than 3 hours/day, a figure in keeping with St James-Roberts' for community patients (1991).

### Time of Day

Subjects differed from controls in Study 1 in the time of day the crying was troublesome. Since the total time reported crying was long for subjects it is hardly surprising that subjects were more likely to report that crying occurred at any time while controls reported it mainly in the evening. St James-Roberts (1991) observations indicated that 'community' subjects, equivalent to the controls in this study, cried mainly in the evening but so also did the 'clinical' subjects. Hide and Guyer (1982) however found that patients complaining that their infants had colic claimed that this was a problem throughout the day. In both studies health visitors enrolled the subjects. In these studies it is difficult to know whether the complaint was offered by the parents or if they were asked if their infants suffered from colic i.e. was the symptom a complaint, suggesting that it was troublesome, or was it a phenomenon which was identified but not complained about. This illustrates once again the difficulty of defining crying and colic, and distinguishing between a complaint and a phenomenon.

There has been no satisfactory explanation for evening colic (page 61). Earlier writers (Brennemann, 1943; Jorup, 1952; Wessel et al, 1954; Brazelton, 1962) have suggested that this is the time when household fatigue may be at its greatest. It may be that this is reflected in a difference in infant handling than during the rest of the day. Stern (1985) describes how fathers on their return home interact with their infant 'at a higher level of stimulus intensity than what has been going on all day with mother'. This may exceed the infant's capacity to cope and process stimulation and he/she will 'panic'. It may even reflect reporting bias; if colic is *expected* in the evening then this is when it will be mentioned. Continuous studies over days would have to be made to address these contentions and, as with all naturalistic studies, the problem of intrusion of the researcher and their attention, no matter how subtle, would always be a factor which could not be controlled.

Barr et al (1984) demonstrated that colonic hydrogen production, reflecting lactose malabsorption, was highest at the time of day when colic was most often reported i.e. the evening. However, whether this is the cause or result of the crying has been widely debated (Miller et al 1989; McKenzie, 1990) and in any event the very great overlap in breath hydrogen production between subjects and controls lends very little support to lactose malabsorption and a build up of wind late in the day being a cause of evening colic/crying.

### Carers' views on cause

By the time subjects arrived at the Crying Baby Clinic nearly all in both studies were certain that there was nothing wrong with their infants that needed surgical treatment or treatment with drugs. They either did not know why their infant was crying or ascribed it to colic. Nearly all the controls ascribed the crying to hunger. As mentioned in Chapter 1 when infants cry this is the first reason considered and feeding any early response. A few worried that their infant may be in pain.

The only studies of pain have been laboratory based studies, pain being produced by artificial means such as heel pricks and rubber band snaps on the foot. These stimuli seem to be quite unlike, one imagines, the pain associated with abdominal wind. In fact there has been very little written at all about wind, the function of burping and so on and yet 'wind' is regularly cited as a cause of colic. The almost universal practice, at least in Western societies, of winding or burping infants by patting and jiggling has received no serious evaluation. Stokes et al (1988) have studied 'colic' in adults by inducing mild phasic pain with balloon distention and saline bolus injections. They suggest that the pain described as colic is phasic, slowly rising to a zenith and subsiding within a minute, in other words a very short time.

It is worth mentioning the recent debate about the relationship of pacifiers and pain. Pacifiers are widely used for the management of crying (Levine and Bell, 1950). Their use with and without sucrose has been studied in relation to the management of pain (Lancet,1992). The experiments of Blass and Hoffmeyer (1991) show that infants who are being circumcised cry less if they are given a pacifier dipped in water and even less if the pacifier is dipped in sucrose. The conclusion that management along these lines is suitable for analgesia is based on the assumption that crying indicates pain and that no crying indicates analgesia. This is contentious.

In both studies colic was given as a reason for the crying in infants both under and over 3-months. Colic is a rather poorly defined symptom complex and perhaps it would be clinically more helpful to identify which symptoms are those which are causing problems. Troublesome crying, feeding difficulties, regurgitation and so on are symptoms which may be better addressed individually. The term colic, derived from 'colon', suggests that these symptoms are caused by a pathology in the gut, something which is not proven. Very likely the notion of colic is modelled on the symptoms caused by 'wind' and flatus in adults. The so-called 'irritable bowel syndrome' embodies another symptom complex related to stress and is diagnosed in the absence of organic disease. Jorup (1952) is the only investigator to have looked for excessive gas in the bowel. He did not find this. As already discussed, wind in infants is a subject which has received very little attention.



## Medications

More subjects than controls had given medications for colic. These included a wide range of proprietary compounds marketed for the purpose. Two over-the-counter preparations are available in the United Kingdom, 'Infacol' and 'Dentinox' colic drops. Both contain activated dimethicone and neither has proven value (Drug and Ther Bull, 1991).

Dicyclomine - Merbentyl - is an antispasmodic formerly prescribed for colic. It has now been removed from the market because of side-effects. There is little to support the use of medication (page 52) although it is possible that it may have a placebo effect on the perception of crying by parents.

## Feeding

In keeping with the findings of many other workers (page 53) there was no difference between breast and bottle feeding in Study 1 subjects and controls. Despite there being no documented difference one of the commonest interventions for colicky infants is changing the feeds. Taubman (1988) has shown that the elimination of cow's milk and the substitution of soy makes no difference. Unfortunately, in spite of all the evidence to the contrary, milks are still regularly changed not just from breast to cow's milk and from cow's to soy milk but also from one cow's milk formula to another. Another concern which is frequently

reported is the adequacy of the size of the hole in the teat. This is reflected in the marketing of a range of teats of different sizes and shapes and with different sizes of holes.

Since it is true that infants cry when they are hungry as a signal to be fed, it is hardly surprising that when they cry too much one of the first items to be addressed is the adequacy of the feeding. As the answers to the distress questionnaire indicate, mothers of subjects more than mothers of controls feel they cannot satisfy their infants.

#### Pregnancy, position in family and support

There was no difference in subjects and controls in these biographical respects. Because the numbers are small the confidence intervals for differences in percentages are wide but since the detection of differences was not the primary purpose of the project it is reasonable to conclude that if there were differences between the groups then they were small. Wessel et al (1954) indicated that the mothers of first-born infants were more likely to complain that their infants had colic. His subjects were 98 of 180 mothers who responded to a questionnaire circulated in the mail and so was quite a different study from this one. Neither Paradise (1966) or Carey (1968) demonstrated any difference between first born and subsequent children. Crockenberg and Smith (1982) showed that although later-born infants experience less contact with their mothers than do first-born infants, they do not experience

less responsiveness. If responsiveness is related to infant crying as Bell and Ainsworth (1972) suggest then there should be no difference in crying between first and subsequent-born infants.

The notion of support is important. The word support in the modern context implies that a child's parents whether married or single live under the same roof. It gives no idea of how much help parents give each other in child care. This study did not document how often parents were sleeping in separate rooms because of the crying of their infant or how often fathers attended to the crying when they were at home. Quarreling was more common in families of subjects than of controls and this seemed to reflect disagreements about how to contend with the crying, whose responsibility it was to 'do something' and, simply, exhaustion. Frodi (1981) has indicated that physiological measures suggesting aversiveness in some subjects are as great in non-abusing adults as they are in abusing adults when they listen to infant crying. Her studies were undertaken in laboratory settings. It is not difficult to imagine how difficult it must be for unsupported carers to contend with infants who cry too much.

### Smoking

The question about smoking was asked only in Study 2. In about 40% of households there was one carer who smoked. Said's study (1984) of 253 subjects was unconvincing. Post-prandial crying was related to class, method of feeding and smoking but most strongly to smoking. The authors hypothesise that gastrointestinal contractions are triggered by

olfactory or gustatory stimulation through vagal reflex mechanism. It is also possible that crying is associated with stress which in turn is related to cigarette smoking.

### **Distress questionnaires**

As explained in Chapter 3 the purpose of these was to describe the patient base. Many patients indicated that they felt great relief just from filling in the questionnaires as they understood that the reason each question appeared on the questionnaire was because other carers had made the complaint. This seemed to give many the feeling that others had experienced the same problems and somehow reinforced the fact that they were not alone. Other people had infants like this and shared the same feelings.

The origin, design and validation of the model for the distress questionnaire have been discussed in Chapter 3.

Analysis scoring for all ten items or by using subgroups of items gave the same result: subjects differed from controls in their distress and this is hardly surprising. What is of interest is the difference in items. The most significant differences between the subject and control groups were in feelings of 'helplessness', which were present in nearly all carers in both studies, inability 'to satisfy the baby' and in 'other feelings of anger'. It was interesting that 7 of 31 controls had felt at some time 'like hitting or getting rid of their baby' and this compared

with 10 of 31 subjects. It is possible that subjects did not wish to acknowledge their feelings of wanting to harm or reject their infants and that the positive responses for 'other feelings of anger' included such feelings.

Subjects and controls compared favourably with feelings of not being 'a good mother'. Only 12 of 31 (32%) subjects and 7 of 31 (23%) controls felt they were not good mothers. More mothers felt this in the second study (47%). These figures could suggest that even although mothers felt helpless and unable to satisfy their infants they were no less likely than controls to feel that this was due to a lack of mothering skills. When Items 4 and 5 were examined, which concerned mothers perceptions of infants' wilfulness, more subjects than controls felt that their infant was deliberately preventing them from having anything for themselves. Taking these results together it would seem that mothers tended to feel that by and large the problem was with the baby and not with them although this was clearly not the case for everybody.

Subjects differed from controls in Items 8 and 9, effects on their own health and Item 10, effects on relationships. These results are hardly surprising in a household where an infant seems to be constantly crying and miserable.

In all but one of the ten distress questionnaire items subjects in Study 2 were more distressed than Study 1. The reasons for this are unclear. There are no apparent biographical differences. One would think that when a new service is established less severe cases are referred simply

because a specialist service is available. This does not seem to be the case here. It may be that referral agencies who had become aware of the service were referring more cases which they had given up on. This is an important point and could be used to justify the establishing of a service similar to this one.

### **Randomisation**

It was no surprise that too few subjects were willing to be randomised for home or hospital treatment in the first study. The observation of Barbero (1957) and the anecdotal evidence of many others that hospitalisation of infants with troublesome crying is helpful is unlikely to ever be properly examined. It would be interesting to know how many more parents would be willing to have their infants admitted to hospital if they knew that some investigation was to be carried out, or some treatment would be given. It is an impression that parents are less reluctant for hospital admission if they feel that the physician considers a treatable physical disorder to be the problem. This is understandable. It could be argued that in this case very few parents would be willing to be randomised for fear they would be allocated to home care.

## Methods

### 1) Diaries

Brazelton (1962), Taubman (1984) and Barr et al (1992) have used diaries to measure times of crying in infants with 'colic' as well as 'normal' crying times (pages 33 and 53). St James-Roberts (1991) used recall over the previous 7 days. All document much shorter crying times than reported here. Brazelton's 6 'heavy fussers' cried for a median of 4 hours each day at the height of their colic and Taubman's for a mean of 2.6 hours each day. The maximum of number of hours crying in Barr's study of 36 infants was 7 for one baby; 26 cried for less than 3 hours a day. In St James-Roberts study where subjects were divided into groups according to age, those 37 clinical cases in the 1-3 month age group cried for a median of 4 hours each day but the range as judged on the results of the same group by a mean of about 5 hours with a standard deviation of 4.5 indicates that some patients cried much in excess of this.

The large median in the present group probably reflected selection of infants referred via a number of other health-caring agencies to a consultant paediatrician. The other studies mentioned considered subjects in private practice in North America (Taubman, 1984) or health visitor referrals (St James-Roberts,1991). Subjects here had already been seen by a General Practitioner and by a health visitor and because the complaint had persisted were then referred.

All studies except St James-Roberts' were prospective. The difficulty with prospective studies is that a complaint of this nature may well be perceived differently as soon as any health care worker or research worker takes an interest. In defence of parental reports using recall St James-Roberts has argued that, so far as comparison is possible, his measures closely match the others particularly for the 'normal' crying times and for the time of day recorded, namely mostly in the evening for both 'normal' and clinical subjects. In the present study, recall was used but because of the problems of definition of crying and the reliability of documentation, the time given is only for the purposes of describing the cohort and not for a quantitative comparison with times following intervention.

As mentioned before Barr et al (1988) noticed that carers did not document as many negative vocalisations in diaries as recorded on audiotape or because they did not hear them due to inattention, or because they recorded inaccurately. Thus although diaries and tapes correlate crying and negative vocalisation times there is little agreement between the two. Also noticeable in Barr's study were the large differences among parents when using cry and fuss symbols for filling in their diaries. The authors claim that these diaries for all their limitations may be the only reasonable way of studying crying patterns. The authors also acknowledge that where there is a researcher in the home the diaries may be better filled in. It is also possible that carers who do *not* have babies with *troublesome* crying are probably more likely to keep a diary especially when they have volunteered for a study.



It would be important for any intervention study that used diaries that day-to-day recordings are reliable. Because of the reservations just described and because of the poor diary keeping of subjects (and nurses) in Study 1 it was decided not to employ diaries but to use methods appropriate for measuring qualitative change in 'troublesome crying'. It may be that carers who are especially distressed are less likely to keep a diary accurately.

## 2) Use of change rating scales

The structure of this scale was in accordance with the guidelines for transition measures using ordinal scales set out by Mackenzie and Charleston (1986) and Forrest and Anderson (1986). Ordinal scales are used in clinical trials to quantify outcomes which are non-dimensional. Transition measures using ordinal methods examine change from baseline state. Ratings represent magnitude of change and are arranged in a hierarchical manner. They must also be symmetrical to detect equally improvement and deterioration. These scales assess directly within-patient measures. Concordance reflects whether the scales yield results that are consistent with other measured outcomes.

Non-parametric methods are obligatory for the statistical analysis of data collected using ordinal scales as the magnitude of each 'interval' on the scale cannot be measured and cannot be assumed to be equal. Such scales are used widely in psychological statistics.

What constitutes a clinically important improvement is in most trials determined empirically. In Study 1 patients seemed to indicate that anything equal to +2 on the change rating chart was more than a little better but not as good as much better. Figures recorded of +2 or more therefore seemed to represent a clinically important change.

Calculation of the numbers to be enrolled for Study 2 and the timing of the interim analysis were in accordance with the guidelines of Pocock (1983). To undertake a trial which cannot be completed because of lack of numbers or to continue a trial when a clear outcome has been established is unethical. Advice of a statistician was therefore crucial.

Non-parametric analyses have been used throughout as described in Chapter 3. There was concordance between diary crying times and change rating charts in Study 1 i.e. when the crying improved in the diary the rating offered by the carer also indicated improvement.

The enrolment of subjects for both these studies took place over nearly three years. Analysing the data from Study 1, setting out the protocol, seeking statistical advice and obtaining ethical approval for Study 2 took several weeks. Patients were enrolled at a rate of 1 or 2 every 2 weeks except for holiday times. The time for subject accrual for any clinical trial needs to be assessed before embarking on the trial to ensure that the time for completion of the study is not unrealistic.

### 3) Interview technique

The purposes of a pilot study are to iron out methodological difficulties before the principle study is undertaken. Whether enough patients are likely to be enrolled and remain until completion needs to be clarified, whether subjects would be available by telephone, whether they understood the questionnaires and rating charts had all to be established. Difficulties with the interview are difficult to describe and are not amenable to scientific analysis, at least not in this study. Only an impression, which is necessarily anecdotal and personal, can be formed. It seemed clear that to be an experienced and senior interviewer was an advantage. Conviction about the value of the advice seemed important (see below). A generation gap between interviewer and carer may have played an important role, especially with young and inexperienced mothers who may have lacked confidence. It certainly seems true that the consistency of advice throughout the time of each study was important. The lack of examination and investigations was designed to reinforce the message that the doctor was not worried about the health of the infant. Taking part in a research study must give subjects the feeling that the researcher really cared about the outcome. Because of the wish to please an empathic and apparently knowledgeable interviewer, it was of enormous importance that an observer whom subjects did not even know could be a doctor was enrolled to collect the change ratings in Study 2. Using the same interviewer would address some of the problems of controlling for the personality of the interviewer (page 67).

## Hospital and home management

Because of the failure of randomisation and the intervention in the home group the results in Study 1 cannot be compared. Study 1 was a pilot study and all that can be said about the results is that there was a strong suggestion that infants managed in hospital improved and this was sustained following discharge.

These results suggest that an organic disorder causing crying is not likely. There are many anecdotal reports that infants stop crying almost as soon as they are admitted to hospital. If there is no marked improvement it may be worth discovering how involved the nursing staff have become with the infant and to discover whether they are employing the same stimulatory techniques as the carers to try to soothe the infant.

At the end of Study 1, what was surprising was that those managed at home with the advice to reduce stimulation seemed also to improve.

## Reduction in stimulation

The subjects in Study 2 who received advice to reduce stimulation at the first interview improved more quickly over the first week and especially over the first 3 days than those who did not. As discussed on page 135 a group who had not received any advice would have had to have been studied to know whether the group who were not given advice at the first interview benefited from the advice over the second week. Whether subjects took the advice to reduce stimulation is not known and whether the giving of other enthusiastic advice would have produced the same the same results is not known either.

Stimulation such as rocking and suckling is used cross-culturally to counter infant crying and this has been shown to be effective (Bowlby,1969; Moss and Robson 1968; Pederson and Ter Vrught, 1973). The terms 'level of arousal' and 'state' when used in relation to infants describe the position of the infant's state of alertness on a continuum ranging from deep sleep to awake, alert and active. Events that propel the infant towards the 'low' end of this continuum have been referred to as quieting or pacifying techniques. The pacifying effect of rocking seems to be augmented with increasing frequency or rate (Ambrose, 1969; De Lucia,1969; Ter Vrught and Pederson 1973; Van Den Dale, 1970, 1971) and this effect is maximised when frequency and amplitude of rocking are both increased. In a study of 2-month old infants, Pederson (1975) showed that rocking at a frequency of 60/minute was more effective than at 45/minute. These investigators have studied the effects

of rocking with infants in the supine position in a mechanical cradle and have not included the effect of bodily contact. These laboratory experiments may seem somewhat artificial but they may mimic the effect of rocking an infant in an old-fashioned rocking cradle.

Byrne and Horowitz (1981) examined some of the situations which might be expected to better characterise the natural soothing strategies of caregivers. Their subjects were 1-3 day-old infants. The stimulation was a foot-flick, an unpleasant and probably painful stimulus. They examined the influence of direction i.e. horizontal and vertical, and type of rocking i.e. continuous and intermittent, compared these interventions with each other and with picking up and placing at the shoulder only. A no-intervention situation was also included to examine the self-quieting capabilities of initially distressed infants. The results showed that the four conditions which included a rocking component were more effective than just picking up or leaving alone. Rocking at a 2 second cycle i.e. 30 rocks/minute was likely to induce more soothing and sleepiness than intermittent rocking which was a 1 second rock followed by a 1 second rest. The authors postulate that this is because there may have been more acceleration in the intermittent rock which was less soothing for the infant. Picking up and rocking the infant was more soothing than just picking up the infant.

This cumulative stimulation supports the conclusions of Brackbill (1971) who demonstrated that the more stimulation the more pacifying to the baby. The stimulatory inputs in her experiments were auditory, a tape-recorded heart-beat, visual, illumination above the infant's crib and

proprioceptive-tactile stimulation, swaddling. Temperature stimulation was raising the temperature from 25.5C to 31C. The results showed that continuous stimulation shifts the extremes of state i.e. there was more quiet sleep and less awake crying but no change on the intermediate state levels. The effect of swaddling was most marked on crying. Similar effects can be demonstrated with the use of white noise (Spencer et al 1990). The use of audiotapes of placental blood flow to soothe infants presumably are based on the same principle.

These laboratory studies would seem at first sight to have provided results opposite to those in this study. In the present study it is only the advice to reduce stimulation that effected improvement. Whether the subjects took the advice is not known. Assuming that they did take the advice and that a reduction in jiggling, distracting with toys, loud music and generally providing a quieter, more restful and less arousing environment was what brought about change, these stimulatory inputs are quite different from the stimulation of swaddling, lying in a lighted area and heart-beat sounds. It could be argued that the former techniques employed by carers of infants with troublesome crying could overstimulate the infants. This has been proposed by others (Brazelton,1962; Taubman, 1984; Schmitt, 1985). Constant jiggling may override crying, temporarily bringing carers relief. The extremes of these stimulatory methods employed by carers are the using of vacuum cleaner and washing-machine noise. These may also stop the infant crying temporarily by over-riding but as soon as they stop the infant cries again. Many carers report that taking the infant out for a ride in the car or in the pram helps. Whether this is the effect of rocking at

an appropriate frequency or simply a reflection of a reduction in anxious parental handling is unclear. Rocking an infant at a 60 cycle frequency is difficult to do sitting down in an armchair. Perhaps this is a reason carers use other 'oscillatory' methods, such as rattling toys and jiggling which may be less suitable.

Suckling is a biological oscillatory activity and the use of the pacifier allows the infant to self-stimulate. This auto-regulation of arousal may allow the infant to set for himself just how much stimulation is enough for the purposes of soothing. Lester (1985) has discussed oscillatory mechanisms in relation to crying. Rhythmic stimulation such as rocking and sucking compete with another rhythmic system, crying. He warns against the overuse of consoling techniques which do not allow the infant to develop his own ability to regulate his behaviour.

It is possible then that there is an optimal amount of stimulation an infant needs for consolation. Rocking, sucking and swaddling are undoubtedly helpful. Exceeding the optimum may overstimulate the infant and increase instead of decreasing the state of arousal.

Noticable is the difficulty carers have in stopping the jiggling. Partners were encouraged to draw each other's attention to the habit. The urge to 'work' to soothe a crying infant is a very powerful one and in the context of the normal infant is also appropriate. Hunziker and Barr (1985) have shown that infants cry less when carried but this did not work for infants with excessive crying (Barr et al (1991).



The practice of winding has had no scientific evaluation. This is an intervention widely taught and practised. Some carers go to great lengths to try to facilitate eructation in their infants and do not let up until a 'burp' is heard. This procedure is usually carried out with the infant sitting on the carer's lap. In this position the gastro-oesophageal junction may lie beneath the milk in the stomach. Wind will not come up until milk leaves the stomach and gas can make contact with the gastro-oesophageal junction. This may explain why some carers complain that their infant is hard to wind. Orenstein (1983) has published radiographs which illustrate this important point. A question arises: is it possible that following a feed an infant who is ready to sleep is patted and rubbed so much that instead of being allowed to fall asleep he is prevented from falling asleep and kept in an inappropriately high state of arousal?

50% of infants' crying had been troublesome from the neonatal period, many from before hospital discharge. St James-Roberts (1988) has shown that there is no consistency between carers' and nurses' opinions of difficultness and so the idea that the infant's crying is a reflection of a difficult temperament is not easy to support. It is possible that a combination of inappropriate responses to crying, not necessarily just by the mother, has set up a cycle of overstimulation and crying.

## Interference with sleep - a cause of excessive crying in infants?

Newborn infants enter active sleep - or rapid-eye-movement (REM) sleep - much earlier than adults (Precht1, 1974). REM periods appear soon after sleep begins and are of random duration at any time of the night. REM sleep assumes a high proportion of total sleep during the first few days of life (as it does in related species), and lessens in amount and proportion during the first year (Fagioli and Salzarulo, 1982). The onset of REM sleep in adults is 50-70 minutes following falling asleep. In children of 4 - 7 years who do not nap, REM is later in onset than in adults or the early REM phase is missed and replaced by non-REM sleep. This pattern is also seen in adults who are sleep-deprived. Roffwarg et al (1966) speculate that under circumstances of prolonged arousal (and possibly intensive activity) the normal balance between REM and non-REM is disturbed, and the need for deep non-REM sleep is augmented. Perhaps, say these authors, the immature CNS is more vulnerable to this 'fatigue'.

The passage from the awake state to REM sleep in neonates is accompanied by transient eye-lid openings, frequent twitches, body and eye movements, irregular respiration, and vocalisations (Precht1, 1974). Actual commencement of sleep can be easily identified with the assistance of electromyography (which records very low or no resting muscle activity, quite unlike the awake state) and it can be understood how the sleep state can clinically be mistaken for the awake state. Is it

possible that this state and the vocalisations that accompany it are mistaken for the onset of crying? If a carer heard vocalisations at this point and intervened by picking up the baby - in order to abort the onset of crying - it is possible that instead of the baby falling into quiet sleep he/she is prevented from doing so. The infant remains in a state of arousal.

The more immature the infant the more sleep is REM sleep. It may be postulated that these large proportions are passively determined by a lack of restriction on the pontine centre - which controls REM sleep - because of insufficient cortical superimposition in the very young infant. However decorticate animal and human studies show that REM sleep does not take over the Non-REM sleep but the awake state. Following a period of REM-deprivation there is more REM sleep which could suggest a neurohumeral control, the extra REM representing a backup of a substance. It is also suggested that pontine REM activity stimulates cortical growth in the first few years and is therefore less necessary in the mature adult. That it remains however suggests that it may serve a physiological function in the adult. It is known that REM sleep deprivation induces behavioural and psychological disturbances and thus it is assumed that it serves an important function.

If infants sleep more and have a larger proportion of REM sleep, if they are then sleep-deprived, is it possible that they suffer effects similar to adults who are sleep deprived? If a carer misinterprets vocalisation at the start of REM sleep and stimulates the infant so that he/she awakens then the infant may become sleep deprived of specifically REM sleep.

Anecdote suggests that many infants with troublesome crying 'never really rest, even when they are sleeping, they are constantly wriggling'. This study has not attempted to address this hypothesis, but it may be helpful to point out to parents that infants when they fall asleep may vocalise and that excessive intervention at this point may succeed in awakening the infant rather than encouraging the move into non-REM sleep.

The practice of 'winding' and the inappropriate position often used for this has already been mentioned (page 164). The procedure of patting and back-rubbing taught by nurses and midwives can go on for many minutes until a 'burp' is heard. This is a time when a normal newborn infant would normally fall asleep. Is it possible that this manoeuvre is preventing the onset of sleep and setting the scene for sleep-deprivation?

## **Development**

Lester (1985) has summarised the psychologists ideas about infant crying and infant 'regulation'. The 'balancing of internal and external demands' is tied in with crying. As the baby grows periods of increasing alertness and attention increase, putting 'increasing demands on regulatory functions'. Crying can occur in response to too much stimulation, when the system becomes overloaded due to external stimulation. The need for tension reduction is especially acute at times

of major developmental upheavals and shifts. Periods of so-called unexplained fussiness and sudden increases in crying that occur in the first few months are probably related to maturational changes in brain structure and shifts in the organisation of brain structure that occur between 3 and 12 weeks of age. It is proposed that at times of major developmental changes there is a decreased threshold for arousal. It is interesting that colic develops in preterm infants within 2 weeks of the expected date of delivery, undoubtedly a time of great maturational change (Pierce, 1948; Meyer et al 1971).

Without evidence, these hypotheses are difficult to prove. It is easier to accept the hypotheses of Bowlby who extrapolates from higher mammals and believes that crying is firstly a signal useful for gaining proximity to a caregiver at a time when the infant is most vulnerable. As the infant matures this signal gives way to others such as smiling and eye-to eye contact which serve the infant well in the progress of attachment. Brazelton's view (1962) that crying is a normal mechanism for the discharge of energy and tension certainly holds credibility for older children and adults but is more difficult to explain in infants.

Brazelton (1969) describes how in the United States 3-month infants are viewed as having a will of their own and suggests that at this time parents had better modify their caretaking practices if they are to win this battle of wills. The increasing perception of caretakers of an infant's awareness at this age also occurs in other cultures (Winn et al, 1989). Thus the development of awareness and forms of communication in addition to crying, together with changes in caretakers' responses, may

explain the improvement in colic and indeed the reduction in 'normal' crying at about three months of age. By this time, the mother is assured that the infant is thriving and healthy and that the cries do not necessarily signal distress or unmet needs. In the present study positive responses to the items selected to reflect carers' perception of wilfulness were given for many infants less than three months. Carers may have ascribed these attributes - craftiness and slyness - out of feelings of frustration and in an effort to provide some sort of explanation for the distressing behaviour.

#### **Troublesome crying or sleep disturbance?**

Care-givers play the major role in allowing an infant to organise sleep-wake cycles over the first year. By 4 months many infants sleep from 8 to 10 hours each night (Parmalee et al 1964), twice as much as they do during the day. Breast-feeding infants are more likely to waken at night at the end of the first year than bottle-fed infants (Elias et al, 1986). Eaton-Evans and Dugdale (1988) in a study of 132 infants showed that the only factor consistently associated with night-waking is breast-feeding. The findings in their study did not support the hypothesis that mothers of wakeful infants prolong breast-feeding to soothe those infants back to sleep. Zuckerman (1987) described sleep problems in early childhood and indicated that 18% of 328 8 month infants either woke over 3 times each night or took an hour to settle. What is interesting about this report is that the problem is described as a sleep problem rather than wakefulness with crying at night which

probably more accurately describes the complaint. The study does not document how long these infants had had the sleep problem. In the present study the carers of many of the infants who at the time of presentation were over three months old complained that crying had been a problem from the neonatal period. It would be interesting to know how these infants differ from infants who are referred for 'sleep difficulties'. It may be that the latter only have problems i.e. crying, at night.

#### Care-giver responsiveness

Bowlby (1969) has referred to a graded responsiveness to infant crying which would seem to be wholly in accordance with the development of infant regulation. Carers respond to signals of severe distress while they respond in their own time to signals of less severe distress, allowing the infant to develop independence. Stern (1985) has referred to the attunement of carers to infants' needs. Although Stern acknowledges the difficulty researchers have had in documenting continuity in infant temperament, he considers it worth speculating on how a temperamental difference in tolerance for stimulation might be viewed clinically. Different infants will have different levels at which they can cope with stimulus input and some will fail to cope and 'experience something like panic'.

Paediatricians too have advised on empirical grounds about responding in a less stimulatory way to infant crying (Schmitt, 1985; Taubman, 1984).

This is the first systematic study which has shown that such advice is useful. It is the first study to use non-parametric methods to examine the effect of an intervention on the complaint of troublesome crying. The results suggest that by advising carers to respond to crying by using more consistent and less stimulating interventions, their infants will become calmer and less distressed. The carers reported that after receiving the advice they too became less distressed. Whether any other enthusiastic advice would produce the same result is not known. From a clinical viewpoint what matters is the resolution of the complaint. The intervention described here was useful.

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