

**A STUDY TO DETERMINE THE
EFFICACY OF CHIROPRACTIC SPINAL
ADJUSTMENTS AS A TREATMENT
PROTOCOL IN THE MANAGEMENT
OF INFANTILE COLIC**

by

CATHERINE ANNE MERCER

Dissertation submitted in partial compliance with the requirements
for the Master's Degree in Technology : Chiropractic in the
Faculty of Health at Technikon Natal.

I, CATHERINE ANNE MERCER,

do declare that this dissertation is representative of my own work.

CATHERINE MERCER

5 MARCH 1999

DATE

APPROVED FOR FINAL SUBMISSION

DR ANDREW JONES
M.Dip.Chiropractic (SA)

5-3-99.

DATE

Dedication

*To my parents, with thanks and gratitude for all their love,
support and encouragement through the long haul.*

To my sisters, my friends through life.

To Lally, for her reassuring prayers and unwavering faith in my ability.

Acknowledgements

Dr Evelyn Funk –

The assistance offered by Dr Funk by acting as the consulting paediatrician for this study is greatly appreciated, as a strict diagnosis of infantile colic was paramount to the validity of this study.

Dr Andrew Jones –

In appreciation for the time, effort and input entailed in supervising this study.

Dr Brian Nook –

In deep gratitude for his inspiring love, dedication and enthusiasm for the chiropractic profession.

The babies –

If it were not for these little ones, this study would not have been possible. My thanks goes out to the parents of the participating infants for their trust and belief in the study.

Mr Zeleke Worku –

The statistician's assistance in computing the statistical data is greatly appreciated.

And to Him, through whom all things are possible – thank you.

Abstract

Infantile colic is a common condition in paediatric practice (Larson & Ayllon 1990) with very little consensus in medical circles as to its aetiology, diagnosis, treatment and prognosis (Pinyerd & Zipf 1989). The purpose of this study is to ascertain the therapeutic efficacy of chiropractic spinal adjustments in relieving the symptomatology of infantile colic.

Thirty infants comprised the sample group. All participating babies were diagnosed as suffering from infantile colic by a paediatrician before inclusion into the study. The infants, aged 0-8 weeks at the commencement of the study, were allocated into the placebo or the experimental group according to the Random Sampling Technique. The fifteen infants in the placebo group were "treated" with a de-tuned ultrasound machine whereas the fifteen infants in the experimental group were treated with chiropractic spinal manipulation. All infants were screened at each consultation for the presence of spinal fixations. Each infant underwent a maximum of six treatments over a period of two weeks with a follow-up consultation one month after the cessation of treatment.

The subjective information regarding the parents' perception of their infants' response to treatment was collected from questionnaires which the parents were required to complete before commencement of treatment and at each subsequent consultation.

Non-parametric tests were used to statistically analyse the data. The Mann-Whitney unpaired two-tailed tests (at the $\alpha = 0,05$ level of significance) compared with the results obtained from the two groups' response to treatment to determine which group responded better to its respective treatment method. The Wilcoxon's sign ranked tests (at the 5% level of significance) analysed results obtained from comparing the response to

treatment at three stages in the study within each group. The data was analysed using the Statgraphics version 6+ statistical package and displayed with the aid of tables.

The results obtained from the study demonstrated a statistically significant difference in the response to treatment by the experimental group as opposed to the placebo group in terms of the parents' subjective perception, with a complete resolution of symptoms by 93% of the infants in the experimental group within the two week period, which comprised a maximum of 6 treatments. In addition, no recurrence of the infantile colic was observed in any experimental infant in the intervening month between cessation of treatment and the follow-up telephonic interview.

It can thus be concluded that chiropractic care has proven to be therapeutically beneficial as a treatment protocol in the management of infantile colic.

Table of contents

	<i>Page</i>
Dedication	(i)
Acknowledgements	(ii)
Abstract	(iii)
Table of contents	(v)
List of tables	(ix)
List of charts	(x)
List of appendices	(xi)
Definition of terms	(xii)

CHAPTER ONE

1. INTRODUCTION	1
1.1 The problem and its setting	1
1.2. The statement of the problem	3
1.3 The objectives of the study	3
1.4 The significance of the study	3

CHAPTER TWO

2. REVIEW OF RELATED LITERATURE	5
2.1 Introduction	5
2.2 Definition and prevalence	5

	<i>Page</i>
2.3 Clinical features	6
2.4 Aetiology of infantile colic	8
2.4.1 Intrinsic theories	8
2.4.2 Extrinsic theories	9
2.5 Consequences of infantile colic	10
2.6 Protocols for the treatment of infantile colic	11
2.7 Summary	12

CHAPTER THREE

3. MATERIAL AND METHODS	14
3.1 Introduction	14
3.2 Objectives of the study	14
3.3 The study design	15
3.3.1 The sample group	15
3.3.2 Allocation of subjects	16
3.3.3 Ethics	17
3.3.4 The methodology	18
3.4 Interventions	19
3.4.1 Cervical spine adjustments	19
3.4.2 Thoracic spine adjustments	20

	<i>Page</i>
3.5 The data	21
3.6 Statistical methods of data analysis	22
3.6.1 Procedure 1	22
3.6.2 Procedure 2	22
3.6.3 Procedure 3	23
3.6.4 Procedure 4	23
3.6.5 Procedure 5	23
3.6.6 Procedure 6	23
3.6.7 Statistical packages	23
 CHAPTER FOUR	
4. THE RESULTS	25
4.1 Introduction	25
4.2 Demographical data	25
4.3 Collation of data	27
4.4 Wilcoxon's signed-rank tests within group 1 and 2	27
4.5 Mann-Whitney unpaired two-sample tests between groups 1 and 2	29
4.6 The power of Mann-Whitney unpaired two-sided tests in this study	30
4.7 Levels of spinal fixation	31

	<i>Page</i>
CHAPTER FIVE	
5. DISCUSSION OF THE STUDY	33
5.1 Introduction	33
5.2 General discussion	33
5.3 Interpretation of the demographical data	34
5.4 Interpretation of the Wilcoxon's signed-rank tests	36
5.5 Interpretation of the Mann-Whitney unpaired two-sided tests	37
5.6 Interpretation of the power analysis of the Mann-Whitney unpaired two-sided tests	39
5.7 Levels of spinal fixation	40
5.8 Limitations of the study	40
5.9 Summary	41
CHAPTER SIX	
6. CONCLUSIONS AND RECOMMENDATIONS	42
6.1 Conclusions	42
6.2 Recommendations	42
REFERENCES	44

List of tables

		<i>Page</i>
4.2.1	Table 1	
	Demographical data : patient data	26
4.2.2	Table 2	
	Demographical data : patient history	26
4.4.1	Table 3	
	Comparison of the response to treatment after the first, fourth and sixth consultation by infants in the placebo group	26
4.4.2	Table 4	
	Comparison of the response to treatment after the first, fourth and sixth consultation by infants in the experimental group	28
4.5.1	Table 5	
	Comparison of the response of the placebo and experimental groups to treatment after each consultation	29
4.6.1	Table 6	
	Results of the power analysis of the Mann-Whitney statistical tests	30

List of charts

Page

PIE-CHARTS

4.7.1 Pie-chart 1

Pie-chart depicting the percentage distribution of spinal fixation 31

BARCHARTS

4.8 Barchart 1

Barchart depicting a comparison between groups 1

and 2 with respect to response to treatment 32

List of appendices

	<i>Page</i>
APPENDIX A Consent form	47
APPENDIX B Treatment record	48
APPENDIX C Pre-treatment questionnaire	49
APPENDIX D Post-treatment questionnaire	50
APPENDIX E Follow-up questionnaire	51

Definition of terms

Infant –

a child from birth to 12 months (Whittles & Whittles 1995 : 117).

Infantile colic –

benign paroxysmal abdominal pain during the first 3 months of life (Saunders 1989 : 135).

Chiropractic intervention –

refers to the manipulation (also termed adjustment) of spinal vertebrae to remove fixations in the facet joints and restore normal movements to these joints (Penter 1994 : 7).

Motion palpation –

a palpatory diagnostic procedure utilised to assess the character of the motion of a motion unit to determine if motion dysfunction exists (Nook 1998 : 28).

Joint play –

Discrete, short-range movements of a joint, independent of the action of voluntary muscles, determined by springing each vertebra in the neutral position (Gatterman 1990 : 409).

Fixation –

lack of movement of a joint (Gatterman 1990 : 408).

Adjustment –

the movement of a specific motion unit with a high velocity, low amplitude specific dynamic thrust given at the end of the passive range of motion (Nook 1998 : 28).

Diversified manipulative technique –

uses the normal biomechanics of the spine and extremities to create motion at a vertebral joint (Nook 1998 : 29).

Placebo –

a procedure with no intrinsic therapeutic value, performed in controlled studies to determine the efficacy of the experimental treatment (Saunders 1989 : 471).

Note: for the purpose of this study, the placebo treatment comprised the application of detuned ultrasound paraspinally at the levels of spinal fixations.

Subjective perception –

for the purpose of this study, the individual discernments by the parents of how they rated their infants' response to treatment.

Paediatrics –

the branch of medicine dealing with the child and its development and care and with the diseases of children and their treatment (Saunders 1989 : 455).

Chapter one

1. INTRODUCTION

1.1 The problem and its setting

Infantile colic is an enigma in medical circles with continuing debate as to the definition, aetiology, treatment and prognosis of the condition (Pinyerd & Zipf 1989).

Infantile colic is defined by Wessel *et al.* (1954) as crying that occurs during the first three months of life and that lasts for three or more hours per day for at least three days in any one week. This pattern should persist for at least three weeks. Typically, the paroxysms of crying occur for no obvious reason in an otherwise healthy and thriving infant (Berkow & Fletcher 1992 : 1955).

The above definition, although widely accepted, is vague and allows for differing interpretations. It is for this reason that the prevalence of infantile colic is only an estimated figure at 10-40% of all paediatric conditions (Larson & Ayllon 1990).

Onset of colic is within a couple of days of birth, but often begins some weeks later; frequently persisting until three or four months of age. Thereafter, it may spontaneously cease (Berkow & Fletcher 1992 : 1955). Common features of an attack are persistent crying, often scream-like in pitch; baby's face becomes red; non-response to normal means of placation; thrashing about; drawing up of legs to the abdomen or arching backwards; tenseness of the abdomen; and expelling of flatus (Pinyerd & Zipf 1989).

The aetiology of infantile colic is unknown. Postulated causes may be classified as either intrinsic or extrinsic (Pinyerd & Zipf 1989). The intrinsic or organic pain theory

suggests an underlying gastrointestinal problem causes visceral pain. For example, motilin (a hormone controlling gut motility) levels have been found in increased concentrations in colicky infants (Lothe *et al.* 1990). The extrinsic theory postulates that the causes of colic are maternal anxiety, inappropriate handling, and poor maternal-child interaction (Pinyerd & Zipf 1989). However, supporting medical evidence for the respective theories is inconclusive (Gurry 1994; Larson & Ayllon 1990; Stoppard 1993 : 184).

Regardless of the specific causative mechanism, colic is a distressing and frustrating condition with disruption of the normal home environment (Berkow & Fletcher 1992 : 1955). The degrees of parental anxiety, tolerance and coping skills are variable. Infants sense their care-giver's insecurity and often respond with excessive irritability (Kibel & Wagstaff 1991 : 253). Extreme sleep deprivation (Shore *et al.* 1978 : 331) leads to impaired mental function with the propensity for child abuse a possibility (Gurry 1994).

An effective management protocol for the treatment of infantile colic has not been established (Gurry 1994; Pinyerd & Zipf 1989; Stoppard 1993 : 184). Common interventions include counselling and support for the parents; parental and infant dietary changes; and handling modification (Pinyerd & Zipf 1989). Pharmaceuticals [e.g. non-scheduled drugs: Gripe water, Telament drops and "Behoedmiddel", and scheduled drugs: Buscopan syrup (schedule 2) and Domatal Elixir (schedule 5)] provide temporary relief through their sedative effects. Other treatment modalities include acoustic therapy (Larson & Ayllon 1990) and alternative medicine [e.g. herbal teas (Weizman *et al.* 1993), acupuncture (Matheson 1995) and chiropractic treatment comprising spinal manipulative therapy (Klougart *et al.* (1989))].

The role alternative medicine can play in the treatment of infantile colic has not been fully investigated (Matheson 1995). There is some evidence to suggest that chiropractic treatment may relieve, if not cure, the symptomatology of colic. Klougart *et al.* (1989) conducted a study which produced results demonstrating a reduction in the duration

and frequency of colic attacks. 94% of all infants included in the study showed positive responses after an average of three treatments and within 14 days. A weakness in the Klougart *et al* (1989) study was the lack of a control group which excluded the impact of a placebo effect influencing the results.

1.2 The statement of the problem

The purpose of this investigation was to evaluate the effect of chiropractic treatment in relieving the symptomatology of infantile colic in terms of the parents' perception, in order to determine the efficacy of chiropractic spinal adjustments as a treatment protocol for infantile colic.

1.3 The objectives of the study

The primary objective was to assess the two treatment groups (i.e. infants who received spinal adjustments versus those who received placebo treatment in the form of detuned ultrasound) for intra-group improvement. Intergroup statistical analysis was then performed on the collected data to determine which of the two treatments, if any, was more effective.

The second objective was based on the hypothesis that chiropractic spinal adjustments would prove to be more effective (than placebo treatment) as a treatment protocol for infantile colic. And as such, the aim of the study was to determine how many treatments were required before a positive response was noted and for how long the positive response was maintained.

1.4 The significance of the study

Infantile colic is a distressing condition for infant and parents alike. Although it tends to be self-limiting, the impact it has on family life for its duration is profound. This study demonstrated the significant benefits on the mental and physical well-being of the parents of infants participating in the experimental group. It was a common observation by parents that their infants appeared to be more relaxed, more comfortable, and slept better after treatment commencement. As a result, the infants were less demanding, allowing the parents time for other recreational or occupational activities.

This study allowed for greater interaction between the medical and chiropractic health care professions. The wider implications of this study is continuing education of the medical field of the role chiropractic can make in health care.

However, the primary purpose of this randomised, controlled study – comprising the standard control and experimental sample groups – is to more accurately assess the validity of chiropractic as a treatment modality for infantile colic.

Chapter Two

2. REVIEW OF RELATED LITERATURE

2.1 Introduction

Ronald Illingworth stated that “the outstanding impression given by the colicky baby ... is that he is a well, happy, thriving, well-fed, well-managed baby with nothing wrong with him” (Stoppard 1993 : 382). Typically, the infant feeds and gains weight well (Berkow & Fletcher 1992 : 1955). Yet despite the infant’s obvious thriving, the parents are often not reassured that their baby is healthy and it is a source of great anxiety.

Infantile colic is an enigma in medical circles with continuing debate as to the definition, aetiology, treatment and prognosis of the condition (Pinyerd & Zipf 1989).

2.2 Definition and prevalence

The definition of colic is not a universally accepted one (Bolton 1991). Most authorities accept the definition provided by Wessel *et al.* (1954) namely, crying that occurs during the first 3 months of life and that lasts for 3 or more hours per day for at least 3 days in any one week. This pattern should persist for at least 3 weeks. However, this definition is essentially vague. Lothe *et al.* (1990) provides a more comprehensive description of the condition as intermittent unexplained excessive crying (at full force) many times a day, at least 4 days a week and continuing for one week or more in a thriving well-nourished infant. Each episode lasts from 30 min to 2 hours, and the infant cries for at least 3 hours per day at approximately the same time each day. There is a trend towards lowering the crying duration criterion of recent studies to 2 hours and as little as 1.5 hours

per day (Sloman *et al.* 1990). In support of this approach, it is suggested that parenting styles have changed in the 35 years since Wessel *et al.* (1954) formulated the criteria traditionally used in colic research (Sloman *et al.* 1990).

The vagueness and indecisiveness of definition prevents a definitive calculation as to the prevalence of infantile colic (Pinyerd & Zipf 1989). However, colic is a common problem in paediatric practice with an estimated 10-40% (with equal gender distribution) of all infants experiencing infantile colic (Larson & Ayllon 1990).

2.3 Clinical features

Commencement of colic may occur within days of birth, but often begins some weeks later, and typically persists until three or four months of age (Berkow & Fletcher 1992 : 1954) although it may persist for up to 6 months of age (Pinyerd & Zipf 1989). If commencement occurs during the first 2 weeks of life, there appears to be a longer overall duration of symptoms than infants exhibiting symptoms for the first time when older (Pinyerd & Zipf 1989). Colic may spontaneously cease at 3 months of age and it is for this reason that it is given the appellation "3 month colic" (Gurry 1994).

An early presentation in the baby who is most likely to develop colic may be observed in the first week of life. Such a baby is restless after feeds, is alert and does not sleep for long periods (Shore *et al.* 1978 : 331). The full characteristic picture of colic may develop by the end of the second week (Shore *et al.* 1978 : 331). The colic attacks are characterised by paroxysmal bouts of vigorous loud crying, occurring with regularity and most commonly in the late afternoon or early evening, most frequently between 6 and 10 pm (Kibel & Wagstaff 1991 : 252). Infants suffering from infantile colic cry for at least 3 hours per day which is a duration two-and-half times that of non-colicky infants (Pinyerd & Zipf 1989). Although a colicky baby eats well with consistent weight gains,

he may appear to be excessively hungry and often will suck vigorously on almost anything available (Berkow & Fletcher 1992 : 1955). Common features of an attack are persistent crying described by Stoppard (1993) as a scream; baby's face becomes red; non-response to normal means of placation such as being held, rocked, or patted gently; thrashing about; arching backwards as if in pain; drawing up of both legs to the abdomen (Kibbel & Wagstaff 1991 : 253); abdominal tenseness and distension; expulsion of excessive flatus; clenched fists and struggling and angry when held (Pinyerd & Zipf 1989). A distinctive feature of colic is its erratic nature with the pattern changing from day to day (Pinyerd & Zipf 1989).

Severity may range from mild to severe. The former is often seen in the evening with the restlessness or crying occurring after the feed and lasting up to an hour (Shore *et al.* 1978 : 331). Relief may be obtained by the passing of flatus (Shore *et al.* 1978 : 331). Severe cases are more typically characterised by the above features such as drawing up of the legs and arching of the back. Feeds are interrupted by bouts of high-pitched crying and crying may extend from one feed to the next (Shore *et al.* 1978 : 331). Temporary placation may be derived by holding and patting the infant with resumption of the crying as soon as the baby is put down again (Shore *et al.* 1978 : 331). When colic is severe and prolonged, it may persist until the latter part of the first year, commonly occurring in infants who are overactive and tense from birth (Kempe *et al.* 1978 : 656). It has been suggested that this may be an early manifestation of a more insistent, impatient personality type (Berkow & Fletcher 1992 : 1955). However, studies to link intrinsic temperament with infantile colic have been inconclusive (Pinyerd & Zipf 1989). It is more feasible that colicky infants just have a low threshold for frustration and discomfort and, as such, represent the extreme of a continuum of what is really normal behaviour (Kibel & Wagstaff 1991).

2.4 Aetiology of Infantile Colic

The aetiology of infantile colic with its specific mechanisms is poorly understood (Berkow & Fletcher 1992 : 1954). The lack of clarity is due primarily to conflicting medical opinions (Pinyerd & Zipf 1989). Studies on infantile colic have not discovered whether or not infantile colic is a dysfunction related to physical pain or behaviour (Matheson 1995). Postulated causes may be classified as either intrinsic or extrinsic (Pinyerd & Zipf 1989). The intrinsic or organic pain theory suggests an underlying gastrointestinal problem which causes visceral pain (Bolton 1991); whereas the extrinsic theory suggests no underlying pathophysiological process and leans towards a behavioural dysfunction (Larson & Ayllon 1990).

2.4.1 *Intrinsic theories*

- (a) The establishment of a vicious cycle where the prolonged crying causes aerophagia (air swallowing) which fills the stomach and intestines with air, causing distention, crampy pain and gas expulsion per rectum. The baby cries in response to its abdominal distress which further exacerbates the cycle of crying and aerophagia (Merenstein *et al.* 1994 : 587).
- (b) Gastrointestinal allergy to cow's milk protein may be associated with colic (Merenstein *et al.* 1994 : 587). This may occur directly in formula-fed babies or indirectly in the breast-fed baby through the mother absorbing cow's milk protein and excreting it into the breast milk, although studies have not substantiated this theory (Kibel & Wagstaff 1991 : 253).
- (c) Gut hormones are involved in the regulation of gut motility (Lothe *et al.* 1990). The gut hormones develop early in foetal life and at 25 weeks of gestation, all the

peptide-containing cells of the intestinal mucosa have developed. Serum levels of a particular hormone, motilin, are high in the neonatal period and decrease with increasing age. It is speculated that the increased levels are an expression of an immature gut. Motilin has been found to accelerate gastric emptying and to reduce intestinal transit time by increasing the motor activity of the gut. S-motilin appears to be increased in infants with infantile colic and this increased concentration may contribute to the hyperperistalsis observed in colicky infants (Lothe *et al.* 1990).

- (d) It is postulated that an immature gastrointestinal tract and an immature autonomic nervous system (characteristic of the first 2-3 months) may be an underlying physiological cause, the exact mechanisms of which are unknown (Pinyerd & Zipf 1989).

2.4.2 Extrinsic theories

The extrinsic theories relate to behavioural or interactional problems external to the infant as opposed to organically-based pain (Pinyerd & Zipf 1989).

Problems such as maternal anxiety, inappropriate handling, maternal-child interaction, parental tobacco smoke, breast milk and overfeeding / underfeeding (Pinyerd & Zipf 1989) are postulated to be the major precipitating factors. However, it is the tension theory that is generally believed to be the most likely cause, although this has not been clinically proven (Stoppard 1993 : 184). The hyperactive, tense infant is likely to develop colic (Merenstein *et al.* 1994 : 587). More commonly, the colic sufferer is the first-born who is keenly sensitive to the new mother's lack of confidence and tension (Kibel & Wagstaff 1991 : 253). However, the belief that the babies of first-time mothers have a propensity for colic is discredited by a familial history of colic (Pinyerd & Zipf 1989). Generally, any family tension or parental anxiety may aggravate the colic (Stoppard 1993 : 184).

2.5 Consequences of infantile colic

■ On family life ...

No matter what the cause is, the fact remains that persistent crying is very distressing and unnerving for the parents and a peaceful home can be transformed into a state of chaos with family tempers being severely strained (Berkow & Fletcher 1992 : 1954). This is due to the parents' exhaustion and the inconsolability of the infant leading to frustration, anxiety, and loss of parental self-esteem (Kibel & Wagstaff 1991 : 253). The degrees of parental anxiety, tolerance and coping skills are variable. Infants are keenly sensitive to their mother's reaction, and her lack of confidence and tension may lead to excessive irritability in her infant (Kibel & Wagstaff 1991 : 253). Thus, a vicious circle ensues between mother and infant with sleep deprivation the victor (Shore *et al.* 1987 : 331) and physical abuse often a real threat (Gurry 1994).

■ On infant development ...

Infantile colic appears to result in a transient developmental lag in the first year of life. A study performed by Larson and Ayllon (1990) on the impact of infantile colic on subsequent development discovered that the colicky infants scored significantly lower on the Bayley Scales of Infant Development for mental and psychomotor assessment than did the control group of non-colicky infants. The difference in test performance was marked at 6 months of age with the developmental lag narrowed by 1 year of age with both the control and experimental groups having comparable development (Larson & Ayllon 1990). The lag in development in the first few months of the colicky infant's life was attributed to less favourable patterns of caregiver – infant interaction. The method adopted by most caregivers to sooth the colicky infant was vestibular stimulation. This intervention also involved attention and visual

scanning which is a necessary component of an infant's early development (Larson & Ayllon 1990). It was postulated by Larson & Ayllon (1990) that the episodes of colic reduced the "learning time" available to the infant during his first two to three months of life, and that together with poor parent-infant interaction, contributed to the developmental lag.

2.6 Protocols for the treatment of Infantile Colic

Because it is not yet known whether colic is a dysfunction related to physical pain or to behaviour, an effective management protocol has not been established (Gurry 1994; Pinyerd & Zipf 1989; Stoppard 1993 : 184).

Common interventions include:

- (a) Counselling and support for the parents (Pinyerd & Zipf 1989);
- (b) Dietary changes (for both mother and infant) (Pinyerd & Zipf 1989);
- (c) Handling modification (Pinyerd & Zipf 1989);
- (d) Behaviour modification with acoustic therapy (Larson & Ayllon 1990);
- (e) Vestibular stimulation via a moving car (Pinyerd & Zipf 1989);
- (f) Pharmaceuticals – which offer temporary relief – include:

- *Non-scheduled drugs*

- “Gripe water” (an over-the-counter medication containing dill and bicarbonate of soda), “Telament drops” (an agent which lowers gastrointestinal surface tension), and “Behoedmiddel” (an antacid) (Sommer & Van der Horst 1997).

- *Scheduled drugs*

“Buscopan syrup” (Schedule 2) and “Domatal Elixir” (Schedule 5) which are both cholinolytic and antispasmodic (Snyman & Pope 1997).

(g) Alternative medicine e.g.:

- herbal teas (Weizman *et al.* 1993);
- acupuncture (Matheson 1995);
- chiropractic treatment spinal manipulative therapy (Klougart *et al.* 1989).

Matheson (1995) points out that the efficacy of alternative medicine has not yet been proven. However, there is some anecdotal evidence by practitioners in the field to suggest that chiropractic treatment may relieve, if not cure, the symptomatology of infantile colic (Nook, B. 1997). No formal clinical studies have been undertaken in this country to test such claims. A Danish study reported that 94% of all infants included in the study showed a reduction in duration and frequency of colic attacks within 14 days of treatment commencement and after an average of 3 treatments (Klougart *et al.* 1989). A weakness in the Danish study was a lack of a control group which introduced bias into the study and influenced the interpretation of the results and hence the placebo effect was not accurately estimated (Klougart *et al.* 1989).

2.7 SUMMARY

Infantile colic is a very distressing condition, perhaps more so for the parents than for the infant. It is often in desperation that the distraught parents seek medical assistance. Medical intervention includes medication and the very important aspect of counselling.

There is, however, strong anecdotal evidence, as well as the results obtained from the Danish study, to suggest that chiropractic treatment is effective in ameliorating, if not totally relieving, the symptomatology of infantile colic.

Chapter three

3. MATERIALS AND METHODS

3.1 Introduction

The purpose of the “Materials and Methods” chapter is to describe in detail how the study was executed. The chapter gives a detailed account of the objectives of the study, the subjects comprising the sample groups, the treatment interventions undertaken to derive the required data, the measurements and observations made on said data, as well as the statistical procedures used to assess the data.

3.2 Objectives of the study

This controlled placebo study proposed to investigate the efficacy of chiropractic spinal manipulation in relieving the symptomatology of infantile colic.

- The primary objective was to assess the two treatment groups (i.e. infants who received spinal adjustments versus those who received placebo treatment) for intra-group improvement. Once this had been achieved, intergroup statistical analysis was used to determine which of the two treatments, if any, was more effective.
- The second objective was based on the assumption that chiropractic spinal adjustments would prove to be more effective (than placebo treatment) as a treatment protocol for infantile colic, and as such, the aim of the study was to determine how many treatments were required before a positive response was noted and for how long the positive response was maintained.

3.3 The study design

3.3.1 The sample group

A minimum of thirty babies (neonates and young infants) were required to participate in the study. The sample group was obtained through referral from the consulting paediatrician, referral from the parents of other participating babies, advertisements placed in the media (radio, the main local newspaper : *Daily News*, and community newspapers : *The Highway Mail* and *The Berea Mail*), and from pamphlets distributed to the maternity wards of hospitals in Durban, Westville and Pinetown as well as post-natal clinics and pharmacies in the greater Durban and Highway areas. (The fact that the parents of the participating infants resided in the greater Durban and Highway area helped eliminate the possibility of poor compliance due to travelling or transport problems.)

All infants participating in the study were required to comply with certain criteria of admissibility, namely:

- Before admittance into the study, the infant underwent a thorough examination by the consulting paediatrician to determine the health of the infant and to exclude any underlying organic problem, thereby ensuring a strict diagnosis of infantile colic.
- Apart from the colic, the infant was to suffer from no other condition / disease.
- The infant was to be no older than eight weeks at the commencement of treatment to exclude the possibility of spontaneous cessation of the colic at three months.
- If any medication had been administered to the infant to relieve the symptomatology of colic prior to the commencement of treatment, whether prescribed or over-the-counter drugs, the infant was required to remain on the same medication for the duration of the study, if it was required.

3.3.2 Allocation of subjects

The thirty participants of the study were divided equally into two sample groups i.e. 15 infants into the control (placebo) group and 15 infants into the experimental group. Division into the respective sample groups was conducted according to the Random Sampling Technique (Cilliers : 1996):

1. The patients satisfying the delimitations of the study were considered.
2. BLocks of size 4 were chosen.
3. The patients were divided into blocks of 4 comprising 2T (treated) and 2C (control).
4. For blocks of size 4, there were $(4+2) = 6$ blocks, namely:

1 = TTCC

2 = TCTC

3 = TCCT

4 = CCTT

5 = CTTC

6 = CTCT

5. A sequence of random numbers between 1 and 6 were selected with the use of a dice.

The results produced were:

1 = TTCC

5 = CTTC

2 = TCTC

1 = TTCC

2 = TCTC

5 = CTTC

3 = TCCT

5 = CTTC

6. Thus, each infant was placed into the control (placebo) or the treatment (experimental) group as follows:

1 = T; 2 = T; 3 = C; 4 = C; 5 = C; 6 = T; 7 = T; 8 = C; 9 = T; 10 = C; 11 = T; 12 = C;
13 = T; 14 = T; 15 = C; 16 = C; 17 = T; 18 = C; 19 = T; 20 = C; 21 = C; 22 = T;
23 = T; 24 = C; 25 = T; 26 = C; 27 = C; 28 = T; 29 = C; 30 = T.

3.3.3 Ethics

The procedures followed in this study were in accordance with the ethical standards of the Responsible Committee on Human Experimentation. All parents were informed that their infants would be participating in a research study and thus had the opportunity to withdraw from the study prior to commencement of treatment. Each parent of a participating infant signed a consent form prior to commencement of the trial stating that they understood that their infant would be treated for research purposes and under research conditions.

3.3.4 The methodology

All participating infants were examined for the presence of spinal fixations.

The screening technique employed is as follows:

- The infant is held in a seated position on the examiner's lap with its chest supported in the palm of the left hand.
- With the posterior aspect of the proximal phalanges of the right hand, the entire length of the spine is palpated commencing with the sacroiliac joints bilaterally and ending at the occiput, whilst noting the springiness (joint play) of the joints at each segmental level.

***Note:** Loss of the normal springiness / joint play of a particular joint would indicate the presence of a spinal fixation at that vertebral level (motion unit) or sacroiliac joint.*

The parents of the participating infants were required to complete a pre-treatment questionnaire (Appendix C) before the commencement of the initial consultation and a post-treatment questionnaire (Appendix D) before each subsequent consultation. In addition, a follow-up interview (Appendix E) was conducted telephonically with the infant's parent one month after the cessation of treatment.

Infants which developed mild conditions [e.g. rhinitis, constipation or mild diarrhoea etc. (Merenstein *et al.* 1994 : 163, 584, 575)] during the course of the study were permitted to continue with treatment.

3.4 Interventions

All participating infants were treated every 2-3 days (with a maximum 6 treatments) over a two week period (provided the infant was symptomatic) with a follow-up consultation one month after the last treatment to assess the frequency and duration of colic attacks during the intervening month.

The interventions utilised were a de-tuned ultrasound machine for the control / placebo group and chiropractic spinal adjustments for the treatment / experimental group.

The infant placed in the control group was “treated” with a de-tuned ultrasound machine with the ultrasound head applied paraspinally at the spinal level of involvement for each infant. The use of the de-tuned ultrasound offered no therapeutic benefit. (For ethical reasons, the parents of the infants allocated to the control group were not informed that their babies were undergoing placebo treatment.)

The infant placed in the experimental group was treated chiropractically by means of gentle spinal manipulative techniques at the involved spinal level/s. The approach employed was the Diversified Technique. Common levels of involvement were the upper cervical and mid-thoracic regions (Stierwalt : 2) Adjustment techniques most applied and which were most effective are described as follows:

3.4.1 Cervical spine adjustments

The infant is placed supine on the examination table. The parent assists in immobilising the infant (to prevent excess rotation of the spine as the infant wriggles) by gently holding the infant's chest down onto the table.

Loss of PA Rotation (Nook 1998 : 60;70)

The doctor stands at the head of the table facing caudad. The index finger contacts the:

- posterior arch and posterolateral mass of the transverse process of C1-C2 on the same side as the fixation; or the
- posterior aspect of the articular pillar of C2-C7 on the same side of the fixation.
- The infant's head is rotated away until resistance is felt and an impulse thrust is delivered into the fixation.

Loss of Lateral Flexion (Nook 1998 : 64;74)

The doctor stands at the head of the table facing caudad.

The index finger contacts the:

- posterior arch and posterolateral mass of the transverse process of C1-C2 on the side of the fixation; or the
- posterolateral aspect of the transverse process of C2-C7 on the same side of the fixation.

The infant's head is laterally flexed over the contact until resistance is felt and an impulse thrust is delivered into the fixation, with very little rotation usually necessary to obtain the elastic barrier.

3.4.2 Thoracic spine adjustments (Stierwalt : 42;44)

The adjustment technique described by Stierwalt has been modified as follows:

Double transverse contact

The infant is cradled in the doctor's lap with its chest supported on the doctor's forearm with the doctor's hand resting in the infant's axillary fossa. Contact is made on either side of the spinous process of the involved vertebra (T1-12) on the transverse processes.

As the impulse thrust is about to be delivered, the doctor gently raises his forearm to elevate the chest of the infant while simultaneously opening his legs allowing the infant's chest to slump into concavity, thereby creating the fulcrum for the adjustment at the point of contact. At the maximum point of stress, the impulse thrust is delivered, applying a P-A pressure.

Alternatively, the infant is placed on the doctor's lap, facing the doctor. Contact is made with the tips of the middle fingers of each of the doctor's hand on the involved transverse processes ipsilateral to the spinous process. The doctor's thumbs are placed over the sternal area of the infant for additional support and counter-pressure. As the thrust is about to be delivered, the infant is suspended while simultaneously applying P-A pressure with the contact points. Thus, the adjustment is executed with minimal pressure or force.

3.5 The data

Primary data was collected through information obtained via:

- *Communication:* The parents' perception of their infant's response to treatment was obtained via completion of pre- and post-treatment questionnaires and follow-up questionnaires.
- *Observation:* Fixations of the involved vertebral levels were located through palpation of the spine.

Secondary data was obtained from journal articles, published reports, and medical and pharmaceutical books and publications containing information relevant to the research being conducted.

3.6 Statistical methods of data analysis

The use of non-parametric tests for statistical data analyses

The sample size per group is small ($n_1 = 15$, $n_2 = 15$). Hence, non-parametric methods were used for statistical data analyses (Van den Honert 1997 : 213-237). There were 6 consultations per group for spinal adjustments and ultrasound.

3.6.1 Procedure 1

The first procedure is a comparison between related samples within group 1 (placebo) to obtain intra-group analysis of the improvement made by the infants treated with a detuned ultrasound machine.

Wilcoxon's sign ranked tests were used to compare results from 3 related samples (beginning = consultation 1, middle = consultation 4, and end = consultation 6) within group 1. In each test, the null hypothesis states that there is no significant improvement between the 2 related samples being compared, at the α level of significance. The alternative hypothesis states that there is a significant improvement.

The decision rule states that the null hypothesis is rejected at the α level of significance if $p \leq \alpha$ where p is the observed significance level or p -value. Otherwise, the null hypothesis is accepted at the same level.

3.6.2 Procedure 2

The second procedure is a comparison between related samples within group 2 (experimental) to obtain intra-group analysis using the *Wilcoxon's sign ranked tests*.

Procedure 1 is repeated within group 2 with the same decision rule.

3.6.3 Procedure 3

The third procedure is a comparison between groups 1 (placebo) and 2 (experimental) to obtain inter-group statistical analysis in order to determine which of the two treatment modalities was more effective.

Mann-Whitney unpaired two-tailed tests were used to compare groups 1 and 2 with respect to spinal adjustments. In each test, the null hypothesis states that there is no significant difference between groups 1 and 2 with respect to spinal adjustment, at the α level of significance if $p \leq \frac{\alpha}{2}$ where p is the observed significance level of p -value. Otherwise, the null hypothesis is accepted at the same level.

3.6.4 Procedure 4

The fourth procedure is an analysis on the *power of the Mann-Whitney unpaired two-sided tests* in this study to determine the sensitivity of the tests.

3.6.5 Procedure 5

A pie-chart is constructed to demonstrate the distribution of the levels of spinal fixations.

3.6.6 Procedure 6

A barchart is constructed to compare groups 1 and 2 with respect to response to treatments.

3.6.7 Statistical packages

The data collected from the pre-, post- and follow-up questionnaires were collated on spreadsheets. The information obtained from the data entry were statistically analysed using the *Statgraphics* version 6+ statistical package supplied by Manugistics incorporated. The statistical analysis was performed at the research development department of Technikon Natal under the supervision of Dr G Worku.

Chapter Four

4. THE RESULTS

4.1 Introduction

The purpose of the “Results” chapter is to present the findings obtained through the statistical analysis of the primary data. Said data was obtained from questionnaires completed by the parents of participating infants and was based on their subjective perceptions. Non-parametric tests, comprising the Wilcoxon’s sign ranked tests and the Mann-Whitney unpaired two-tailed tests, were used for the statistical data analysis. The null and alternate hypotheses were either rejected or accepted based on the statistical criteria for each measurent parameter. In addition, the power of the Mann-Whitney unpaired two-sided tests in the study was used to determine the sensitivity of the tests.

4.2 Demographical data

The demographical data was collected from the pre-treatment questionnaires of the placebo and experimental sample groups.

4.2.1 Table 1 : Demographical data : patient data

Age of onset of treatment:	average : 6 weeks youngest : 5 days oldest : 9 weeks	
Gender distribution:	Placebo	Experimental
female	8	5
male	7	10
Racial distribution:		
White	26	
Indian	2	
Coloured	1	
Black	1	

4.2.2 Table 2 : Demographical data : patient history

Age of onset of colic:	average : 13 days youngest : birth oldest : 4,5 weeks
Duration of crying with each attack: less than an hour 1-2 hours 2-3 hours 3-4 hours 4-5 hours over 5 hours	26,0% 26,0% 16,0% 7,5% 7,5% 7,0%
Frequency in 24 hours: 1 x 2 x 3 x 4 x 5 x more than 5 x	25,0% 25,0% 14,0% 18,0% 7,0% 11,0%
Occurrence: morning afternoon evening night all day	19,0% 10,0% 19,0% 45,0% 7,0%

Continued

<i>Continued</i>		
Factors precipitating an attack: feeds other	37,5% No history of other precipitating factors	
Medication: administered prior to treatment commencement administered at the end of the study	placebo	experimental
	92,0%	78,0%
	75,0%	7,0%

4.3 Collation of data

At each of the six consultations, the parents were asked to complete a questionnaire by which their perception of their infants' response to treatment was recorded. The response was rated as either (1) completely recovered, (2) somewhat better, (3) the same, (4) somewhat worse, or (5) much worse. The recordings were then collated onto a spreadsheet from which the data was statistically analysed.

4.4 Wilcoxon's signed-rank tests within group 1 and 2

This statistical method was used to compare results from 3 related samples (the first treatment, the fourth treatment and the follow-up consultation) within each group.

The hypotheses

In each test, the null hypothesis states that there is no significant improvement between the 2 related samples being compared, at the α level of significance.

The alternative hypothesis states that there is a significant improvement.

4.4.1 Table 3 : *Comparison of the response to treatment after the first, fourth and sixth consultation by infants in the placebo group.*

CONSULTATON	P-VALUE	RESULTS
Between 1 & 4	1	$p \geq \frac{\alpha}{2}$
Between 1 & 6	0,408248	$p \geq \frac{\alpha}{2}$
Between 4 & 6	0,479498	$p \geq \frac{\alpha}{2}$

The null hypothesis is accepted at the $\alpha = 5\%$ level, and it is therefore accepted that there is no significant improvement by the infants in the placebo group between the first and fourth consultation, the first and sixth consultation, and the fourth and sixth consultation.

4.4.2 Table 4 : *Comparison of the response to treatment after the first, fourth and sixth consultation by infants in the experimental group.*

CONSULTATON	P-VALUE	RESULTS
Between 1 & 4	0,000874198	$p < \frac{\alpha}{2}$
Between 1 & 6	0,000300669	$p < \frac{\alpha}{2}$
Between 4 & 6	0,0412266	$p \geq \frac{\alpha}{2}$

The null hypothesis is rejected at the $\alpha = 5\%$ level of significance for the test comparing the response to treatment between the first and fourth consultation and between the first and sixth consultation, as there is a significant improvement in the infants treated with spinal adjustments.

The null hypothesis is accepted at the $\alpha = 5\%$ level of significance for the test comparing the response to treatment between the fourth and sixth consultations as there was no significant improvement.

4.5 Mann-Whitney unpaired two-sample tests between groups 1 and 2

This statistical method was used to compare how the two sample groups were responding to treatment at each of the 6 consultations to determine which treatment was more effective.

The hypotheses

The null hypothesis (H0) states that there is no significant difference between groups 1 (placebo) and 2 (experimental) with regards to consultation 1-6. The alternative hypothesis (H1) states that there is a significant difference between the two sample groups.

The data was analysed at a $\alpha = 5\% = 0,05$ level of significance.

4.5.1 Table 5 : Comparison of the response of the placebo and experimental groups to treatment after each consultation.

CONSULTATON	P-VALUE	RESULTS
1	0,685413	$p \geq \frac{\alpha}{2}$
2	0,000155311	$p < \frac{\alpha}{2}$
3	0,000173778	$p < \frac{\alpha}{2}$
4	0,0000524589	$p < \frac{\alpha}{2}$
5	0,0000132705	$p < \frac{\alpha}{2}$
6	0,00000529278	$p < \frac{\alpha}{2}$

The null hypothesis is accepted at the $\alpha = 5\%$ level, and therefore conclude that there is no significant difference in response to treatment between the placebo and experimental groups after the first consultation

Thereafter, for consultations 2-6 there is a significant difference in response to treatment between the two groups and the null hypothesis is rejected.

4.6 The power of Mann-Whitney unpaired two-sided tests in this study

The power of the tests was computed to determine the measure of the sensitivity of the tests.

The power of a statistical test (Portney & Watkins 1993 : 656-663) depends on the size of the sample, the accuracy of measurements involved in the study and the level of significance of the study, α . The smaller the power of a test, the larger becomes the likelihood of a Type 2 error (i.e. accepting a false null hypothesis).

4.6.1 Table 6 : Results of the power analysis of the Mann-Whitney statistical tests

TEST AVERAGE (Sample 1)	AVERAGE (Sample 2)	POOLED ERROR STD DEVIATION	POWER
1 2,73	2,93	0,70	11,22%
2 2,66	2,0	0,34	99,86%
3 2,0	2,733	0,42	99,46%
4 2,733	1,4	0,61	99,98%
5 2,5333	1,066	0,53	100,00%
6 2,533	1,0	0,53	100,00%

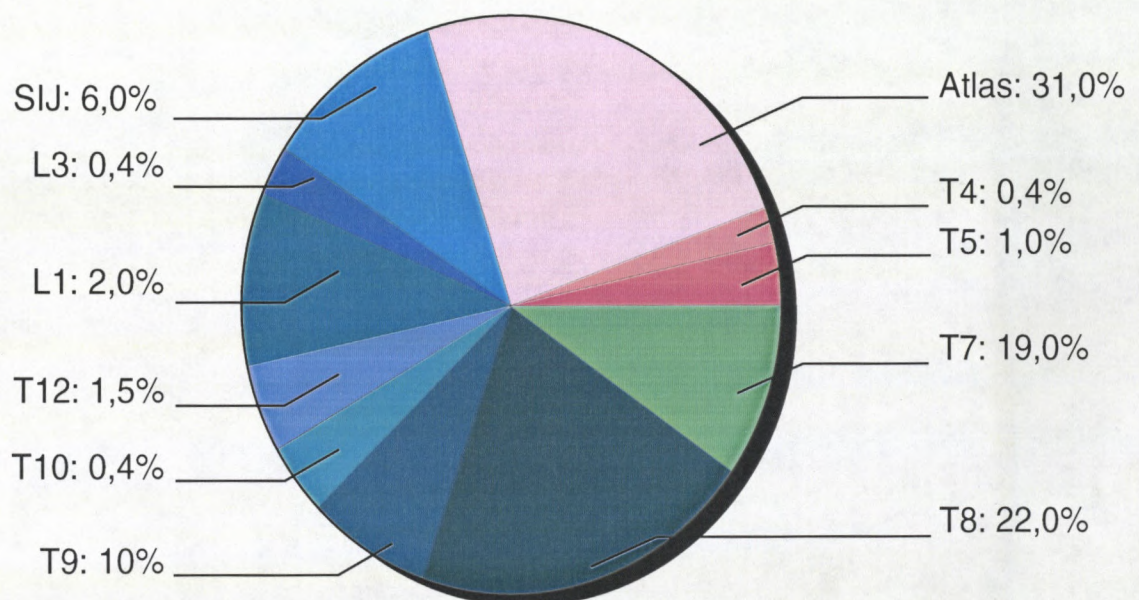
The power of the first Mann-Whitney test (for consultation 1) is very low, indicating that there is a high likelihood that a type 2 error was incurred whereby a false null hypothesis was accepted.

The results for the remaining tests are extremely high suggesting the tests for consultation 2-6 are very powerful with a true rejection of the null hypothesis.

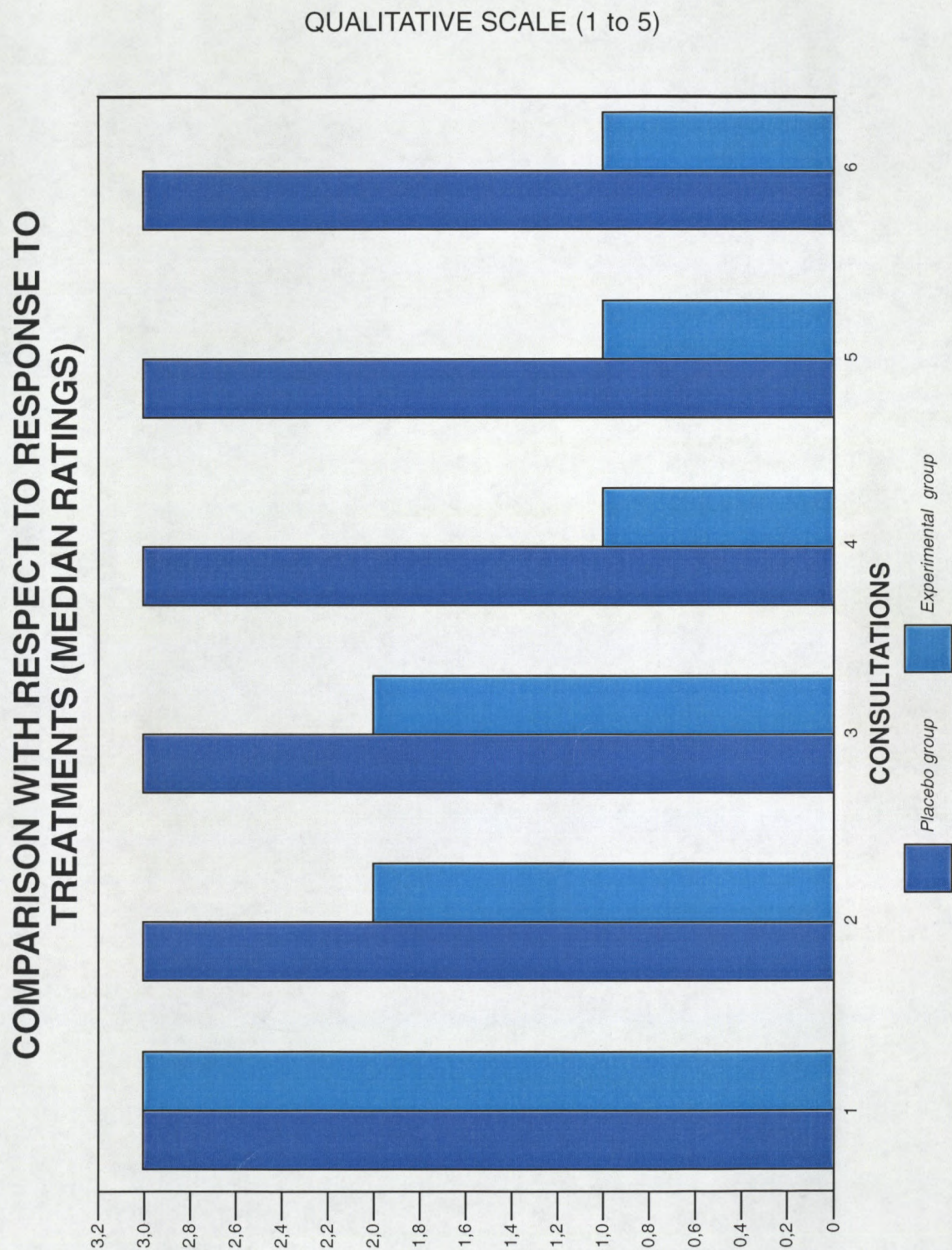
4.7 Levels of spinal fixation

The distribution of spinal fixations palpated is depicted as follows:

4.7.1. Pie-chart 1: *Pie-chart depicting the percentage distribution of spinal fixations.*



4.8 Barchart 1: *Barchart depicting a comparison between groups 1 and 2 with respect to response to treatment.*



Chapter Five

5. DISCUSSION OF THE STUDY

5.1 Introduction

The purpose of chapter five is to discuss the interpretations of the results derived from the statistically analysed data collected from the questionnaires which were used to observe the progress made by each infant in response to treatment.

An interpretation of the results is necessary to determine whether or not the premise that chiropractic spinal adjustments are effective in the treatment of infantile colic is substantiated.

5.2 General discussion

It is important to recognise that the sample size of 30 infants in this study is too small from which to draw statistically significant conclusions. However, parallels can be drawn between the findings and results of this study and those of Klougart *et al.* (1989).

Patient compliance for the duration of the study was extremely good. In total, 32 infants were admitted into the study, with 30 infants (15 in the experimental group and 15 in the control group) completing the course of treatments. The data of the two infants who withdrew from the study were excluded from statistical evaluation. The reasons for the “drop-outs” were due to an infant’s private doctor’s discouragement of participation in the study as well as parental transport and work constraints.

5.3 Interpretation of the demographical data

At the onset of treatment, the average age of the infants participating in the study was 6 weeks. This is comparable to the Klougart *et al.* (1989) study with a median age of 5,7 weeks at the beginning of treatment.

The gender distribution in the study was 17 males to 13 females, showing that in such a small population there is no significant difference in the preponderance to colic of a particular sex. This finding is supported by the Larson & Ayllon (1990) study which reported an equal gender distribution.

The current study showed that 86% of the participating infants were White, 6,66% Indian, and the Coloured and Black populations each had a 3,33% representation. However, this is an unrealistic sample of the distribution of colic sufferers amongst the various racial populations of South Africa. This is possibly due, in part, to the fact that some of the advertising undertaken to acquire patients for the study was in the form of leaflets distributed to hospitals and baby clinics in the greater Durban and Highway areas which are more commonly frequented by Whites. Thus, these statistics are probably deceiving.

This study showed that the average age of onset of infantile colic was 13 days which is in accordance with the findings of Klougart *et al.* (1989) who reported the median age to be 14 days. This is further substantiated by Pinyerd & Zipf (1989) and Shore *et al.* (1978 : 331).

This study discovered that the majority of the bouts of crying were up to 2 hours in duration, with 26% of the infants crying for less than an hour with each colic attack and a further 26% crying for 1-2 hours. Sixteen percent cried for up to 3 hours with each

attack, with the remaining sample population crying for 3 or more hours. These results are similar to those of Lothe *et al.* (1990) who reported that each episode lasts from 30 minutes to 2 hours.

Fifty percent of all the participating infants experienced one to two episodes of colic attacks per day before treatment initiation. Fourteen percent experienced three episodes daily and the remainder had four or more. This is similar to the results of Klougart *et al.* (1989) who reported an average of 2,5 periods per day before treatment initiation.

The colic attacks were most prevalent at night (45%), followed by evenings and mornings (19%), and afternoons (10%). This is in agreement with Kibel & Wagstaff (1991 : 252) and Shore *et al.* (1978 : 331) who point out colic attacks most frequently occur between 6 and 10 pm.

Approximately thirty-eight percent of parents reported feeds seemed to precipitate an attack. This is in accordance with the clinical picture as described by Shore *et al.* (1978 : 331) but differs slightly from the Klougart *et al.* (1989) study which reported 24% of their sample population obtained comfort from a feed. This possibly suggests hunger needs, and not colic, were being met by frequent feeds or supplementary bottles.

The administration of medication prior to treatment commencement was high in both the placebo and experimental groups, with 92% and 78% respectively of the infants receiving pharmaceuticals. Seventy-five percent of the placebo infants still required medication at the end of the study. The figure for the experimental infants was vastly reduced to 7% indicating that the need for medication to relieve the symptomatology of colic by infants receiving spinal adjustments is reduced if not totally unnecessary.

5.4 Interpretation of the Wilcoxon's signed-rank tests

The Wilcoxon's signed-rank tests were used to determine the improvement observed in the infants throughout the study by comparing the results obtained from the beginning, the middle, and the end of the study within each sample group.

To determine the improvement made by the infants or their response to treatment, a comparison was made between consultation 1 and 4 (i.e. between the beginning and the middle of the study), consultation 1 and 6 (i.e. a comparison between commencement and cessation of treatment), and between consultation 4 and 6 (i.e. between the middle and the end of the study).

The null hypothesis was accepted for the tests performed on the placebo group as it was noted that there was no significant improvement by the infants in the placebo group at any stage during the study or the follow-up period. (This is clearly demonstrated on the barchart.) This was the expected result as it was assumed that the infants would not respond to treatment with a detuned ultrasound machine.

In contrast, there was a marked improvement in the symptomatology observed in the infants of the experimental group between the first and fourth consultation with a rejection of the null hypothesis. The positive response to spinal adjustments is demonstrated by the complete recovery of all the participating infants of the sample group indicating a complete resolution of all symptomatology between commencement and cessation of treatment, and the maintenance of such during the intervening month between cessation of treatment and the follow-up consultation.

There was no statistically significant result obtained from the comparison between the fourth and sixth consultation with an acceptance of the null hypothesis due to the fact

that the marked improvement in symptomatology was observed in the beginning stages of the study, with the improvement being maintained throughout the middle and end stages.

It can be concluded from the results that the experimental group far out-performed the placebo group during the period from the first treatment to the follow-up consultation (refer to chapter 4 : tables 3 and 4). This substantiates the hypothesis that spinal adjustments would prove to be more effective in relieving the symptomatology of infantile colic.

The fact that the study was a randomized, controlled trial gives further credence to the results obtained, as the inclusion of the placebo treatment reduced the possibility of bias affecting the interpretation of the results, which was a weakness of the Klougart *et al.* (1989) study.

5.5 Interpretation of the Mann-Whitney unpaired two-sample tests

The Mann-Whitney tests were used to determine how the infants in the placebo group responded to treatment with a detuned ultrasound machine as compared to the response observed in the infants who were treated with spinal adjustments (refer to chapter 4 : table 5).

It was found that there was no significant statistical difference in response to treatment between the two groups after the first consultation as is shown on the barchart (chapter 4 : barchart 1). In the placebo group, the mothers of 11 of the infants reported no change in their infants condition. Four of the mothers felt that their infants were somewhat better. Seven of the 15 infants treated chiropractically were non-responsive after

the first consultation. One infant was reported as being much worse after spinal adjustments, 2 infants as somewhat worse and 5 mothers felt that their infants had responded to treatment and were somewhat better.

Thereafter, there was a statistically significant difference in the response to treatment between the two groups. The barchart clearly illustrates the steady decline in the median readings of the experimental group, as opposed to the placebo group, over the 6 consultations.

The mothers of 9 of the infants in the placebo group reported no changes in the infants' symptomatology throughout the subsequent consultations. Five infants were reported as somewhat better after the second and third consultation, with this figure decreasing to three infants for consultation 5 and 6. One mother reported her infant as being somewhat worse after consultation 3 and 4 but resuming the "no change" status in the infant's condition, as compared to the commencement of treatment, after consultation 5 and 6. Two infants were reported as being completely recovered by the fifth consultation and this was maintained during the intervening month between cessation of treatment and the follow-up consultation.

All infants in the experimental group were rated as somewhat better for consultation 2 and 3. Thereafter, the infants progressed at a steady rate with nine infants completely recovered after the fourth consultation; fourteen of the fifteen completely recovered by the cessation of the study (the fifteenth infant being somewhat better) within a two week period; and all infants reported to be completely recovered at the sixth consultation meaning the infants had shown no signs of suffering from infantile colic during the month since cessation of treatment.

It can be deduced from the study that a positive response to spinal adjustments was noted within 2-3 treatments by all the infants in the experimental group, indicating a

reduction in the symptomatology of colic by 100% of the infants. Thereafter, a complete recovery was noted by the fourth treatment by 60% of the infants, and 93% of the infants by the end of the study which was conducted over a two week period. This complete amelioration of symptomatology was maintained throughout the intervening month between the last treatment and the follow-up consultation. The question arises, should a progressive study be conducted on the experimental sample group, would a finding that no infant experienced any further bouts of colic be attributed to the chiropractic treatment or to the natural progression of the condition? (It should be stressed that the response to treatment was based on the parents' subjective perception of their infants' condition and not according to an objective measure.)

These findings are in keeping with those of Klougart *et al.* (1989) who reported that 94% of infants participating in the Danish study showed a satisfactory response to treatment after an average of 3 treatments within 14 days.

5.6 Interpretation of the power analysis of the Mann-Whitney unpaired two-sided tests

It is possible that the small sample size of the non-parametric tests introduces a Type 2 error into the study (Haldeman 1992 : 419) weakening the statistical power and allowing for the false acceptance of the null hypothesis. According to Portney *et al.* (1993), the power of non-parametric tests is usually low, thereby indicating that the results obtained from non-parametric tests are not necessarily reliable as a decision-making tool.

Only the first Mann-Whitney test performed on the first consultation of the two sample tests produced a low power suggesting the false acceptance of the null hypothesis. The remaining 5 tests all produced very high powers. However, achieving a 100% power

would suggest a perfect test. Such results are misleading. It is a potential limitation of the non-parametric tests that the samples are too small thereby producing identical observations and unreliable results.

5.7 Levels of spinal fixation

As discussed previously, the entire vertebral column of the infant (in both the placebo and experimental groups) was assessed for the presence of vertebral fixations.

It was observed that the most frequent levels of involvement were the upper cervical levels and the mid-thoracic levels, which is in compliance with the findings by Klougart *et al.* (1989).

5.8 Limitations of the study

Any infant suffering from a serious condition [e.g. pyrexia or gastroenteritis etc. (Merenstein *et al.* 1994 : 55, 578)] or a contagious disease [e.g. chicken pox or measles etc. (Merenstein *et al.* 1994 : 297, 304)], during the course of the study would have been excused from continuing with the study. (Such a situation did not arise).

The objective findings, i.e. the determination of the levels of spinal fixations, and the execution of the spinal adjustments might not have been absolutely precise and accurate due to examiner inexperience. At the beginning of the study, not all adjustments performed obtained joint motion and cavitation. This raises the question whether or not joint mobilisation is sufficient to obtain positive results in relieving the symptomatology of colic or if the response obtained from spinal adjustments would have been facilitated by greater examiner expertise.

The subjective measurements, in the form of the questionnaires, have certain limitations. The choice of phrasing in the question "How would you rate the baby's response to the treatment?" is open to wide interpretation by the parents in the sense that the rating selection (i.e. completely recovered, somewhat better, the same, somewhat worse, and much worse) is a little vague. It is possible that the use of a percentage-improvement system may be a more accurate means by which the infant's response to treatment may be rated. In addition, one's perceptions are very personal and, as such, it was extremely difficult to quantify or measure the parents' subjective perception which may have been clouded to a certain degree by the desire to please the researcher as well as the desire to detect an improvement in their child's condition which may or may not have existed.

As discussed previously, it is possible that the small sample size introduced a Type 2 error into the study (Haldeman 1992 : 419) weakening the statistical power of the test.

5.9 Summary

This study has reinforced the findings of Klougart *et al.* (1989) substantiating the claim that chiropractic spinal manipulation may influence the course of infantile colic. The results may go a little way in counteracting Matheson's (1995) claim that alternative medicine's role in the treatment of infantile colic has not been proven. Indeed, chiropractic spinal adjustments appear to be more effective than other interventions, for example behaviour modification with acoustic therapy (Larson & Ayllon 1990), which have little value as long-term solutions.

Chapter 6

6. CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

When the results of both the placebo and experimental groups were compared, it was found that the group receiving the spinal adjustments improved significantly more than the placebo group according to the parents' subjective perceptions, and in so doing, supported the stated hypothesis and proved it to be correct. In addition, only 2-3 treatments were required before a satisfactory reduction in the symptomatology of colic was noted, with complete amelioration of all symptoms in 4-6 treatments over a two-week period. All the infants participating in the experimental study maintained good health with no recurrence of the colic in the intervening month between the last treatment and the follow-up consultation. This indicates that the positive response obtained from chiropractic spinal adjustments in relieving the symptomatology of colic is long-lasting, if not permanent.

To conclude, it can be stated categorically that chiropractic spinal adjustments are a very effective and beneficial means, both therapeutically and economically, by which infantile colic may be successfully treated.

6.2 Recommendations

It is essential that further research studies be performed to validate the findings of this

study. The outcome of the study was very favourable towards chiropractic spinal adjustments as an alternative to allopathic pharmaceuticals (the most common method by which colic is treated). However, it is recommended that larger sample groups be utilised to obtain more statistically sensitive data.

This study should be regarded as a pilot study. Should this study be duplicated, it is recommended that the questionnaires be re-designed to allow for a more comprehensive collection of data to prevent the introduction of ambiguity and subjectivity into the study. In addition, it is suggested that the questionnaires include a history of how early the infant is put on solids; and whether or not the infant is bottle-fed, breast-fed, and / or fed solids in the same feed, to investigate the impact these factors have on reducing the severity and duration of the infantile colic.

A question not addressed by this study is the biomechanical and neurophysiological changes that occur with spinal adjustments. Research should be conducted into this area to investigate more fully the role chiropractic care can make in the treatment of infantile colic.

References

- BERKOW, R & FLETCHER, A.J. eds 1992. *The Merck Manual of Diagnosis and Therapy*. 15th ed. USA : Merck Sharp & Dohme Research Laboratories. 1954-1955 pp. ISBN 0911910-06-09.
- BOLTON, K. 1996. *Infantile Colic*. Paper read at conference for paediatric practitioners, Johannesburg, 1991.
- CILLIERS, K.I. 1996 *The Relative Effectiveness of Two Different Approaches to Adjust a Fixated Segment in the Treatment of Facet Syndrome in the Cervical Spine*. M.Tech.Chiropractic (SA) dissertation, Technikon Natal, Durban.
- GATTERMAN, M.I. 1990. *Chiropractic Management of Spine Related Disorders*. USA : Williams & Wilkins. 408-409 pp. ISBN 0-683-03438-3.
- GURRY, D. 1994. Infantile Colic. *Australian Family Physician*, 23(3) : 337-40.
- HALDEMAN, S. 1992. *Principles and Practice of Chiropractic*. 2nd ed. Connecticut, USA : Appleton & Lange. 419 p. ISBN 0-8385-6360-0.
- KEMP, C.H., SILVER, H.K. & O'BRIEN, D. 1978. *Current Pediatric Diagnosis & Treatment*. 5th ed. Los Altos, California, USA : Lange Medical Publications. 656 p. ISBN 0-87041-187-X.
- KIBEL, M.A. & WAGSTAFF, L.A. eds. 1991. *Child Health For All : A Manual for Southern Africa*. Cape Town, RSA : Oxford University Press Southern Africa. 252, 253, 419 pp. ISBN 0 19 5706145.
- KLOUGART, N., NILSSON, N. & JACOBSEN, J. 1989. Infantile Colic Treated by Chiropractors: A Prospective Study of 316 Cases. *Journal of Manipulative and Physiological Therapeutics*, 12(4) : 281-288.
- LARSON, K. & AYLLON, T. 1990. The Effects of Contingent Music and Differential Reinforcement on Infantile Colic. *Behaviour Research and Therapy*, 28(2) : 119-125.
- LOTHE, L., IVARSSON, S.A., EKMAN, R. & LINDBERG, T. 1990. Motilin and Infantile Colic. A Prospective Study. *Acta Paediatrica Scandinavica*, 79(4) : 410-416.

- MATHESON, I. 1995. Infantile Colic – What Will Help? *Tidsskr - Nor - Laegeforen*, Aug. 20(115) : 2386-9.
- MERENSTEIN, G.B., KAPLAN, D.W. & ROSENBERG, A.A. 1994. *Handbook of Pediatrics*. 17th ed. Connecticut, USA; Appleton & Lange, 55, 163, 297, 304, 575, 578, 584, 587 pp. ISBN 0-8385-3657-3.
- NOOK, B.C. 1998. *Chiropractic Manipulation, Mobilisation and Soft Tissue Techniques for the Spinal Joints*. Photocopied handout. 60, 64, 70, 74 pp. Technikon Natal, Durban, Chiropractic Department.
- PENTER, C.S. 1994. *Determining the Role Chiropractic Plays in the Management of Tension-Type Headache*. M.Dip. Chiropractic (SA) dissertation, Technikon Natal, Durban.
- PINYERD, B.J. & Zipf, W.B. 1989. Colic: Idiopathic, Excessive, Infant Crying. *Journal of Pediatric Nursing*, June 4 (3) : 147-61.
- PORTNEY, L.G. & Watkins, M.P. 1993. *Foundation of Clinical Research : Application to Practice*. 656-663 pp. Norwalk, Connecticut, USA : Appleton and Lange. ISBN 0-8385-1065-5.
- SAUNDERS, W.B. 1989. *Dorland's Pocket Medical Dictionary*. 24th ed. 135, 455, 471 pp. Philadelphia, USA : W.B. Saunders Company. ISBN 0-7216-3127-4.
- SHORE, S.C.L., KEET, M.P. & HARRISON, V.C. 1978. *The Newborn Baby*, RSA : The Rustica Press (Pty) Ltd. 331 p. ISBN 0 7021 0896 0.
- SLOMAN, J., BELLINGER, D.C. & KRENTZEL, C.P. 1990. Infantile Colic and Transient Developmental Lag in the First Year of Life. *Child Psychiatry and Human Development*, 21 (2) : 25-35.
- SNYMAN, J.R. & POPE A. 1997. Antispasmodics. *MIMS Medical Specialities*, June 37(6) : 139.
- SOMMER, D.K. & VAN DER HORST, E.J.J. 1997. Colic. *MIMS Guide to OTC Products.*, 3: 34-35.
- STIERWALT, D.D. *Adjusting the Child*. Distributed by: The Copy Shop, 628 Harrison Street, Davenport, Iowa 52803. 2, 42, 44 pp.
- STOPPARD, M. 1993. *Baby Care Book : A practical guide to the first three years*. Cape Town, RSA : Struik Publishers (Pty) Ltd. 184, 382 pp. ISBN 1-86825-335-X.
- VAN DEN HONERT, R. 1997. *Intermediate Statistical Methods for Business and Economics*. Cape

- Town, RSA : University of Cape Town Press. 213-237 pp. ISBN 1-919713-09-3.
- WESSEL, M.A., COBB, J.C., JACKSON, E.B, HARRIS, G.S. & DETWILER, A.C. 1954. Paroxysmal Fussing in Infancy and Something Called Colic. *Pediatrics*, 14 : 421-434.
- WEIZMAN, Z., ALKRINAWI, S., GOLDFARB, D. & BITRAN, C. 1993. Efficacy of Herbal Tea Preparation in Infantile Colic. *Journal of Pediatrics*, 122(4) : 650-2.
- WHITTLES, K.H. & WHITTLES, C.A. 1995. *Medical Dictionary*. UK : Claremont Books. 117 p. ISBN 1 85471 696 4.

Appendix A

CONSENT FORM

I hereby give consent for
to be examined and treated at the Technikon Natal Chiropractic Day Clinic.

I understand that my child shall be participating in a research study and that I shall comply with all requirements.

I understand that the paediatrician's initial consultation fee and the chiropractic treatment costs are covered by research funding for the duration of the study. If my child is placed in the control group, I understand that should I require my child to be treated chiropractically at the cessation of my child's participation in the study, I will be responsible for all treatment costs.

Name of child:

Name of parent:

Signature of parent:

Date:

Appendix B

TREATMENT RECORD

File No:

Date:

Patient's name:

Sample group: (Experimental / Control):

Level of spinal involvement
(mark with an x)

Type of adjustment

Left / Right

* atlas _____

_____ / _____

* T6 _____

☆ T7

_____ / _____

* T8 _____

_____ / _____

* other _____

_____ / _____

_____ / _____

100% 90% 80% 70% 60% 50% 40% 30% 20% 10% 0%

_____ / _____

_____ / _____

8

_____ / _____

0.0001 0.0001 0.0001 0.0001

© 2012 Blackwell Publishing Ltd *Journal of Internal Medicine* 272: 103–111

_____ / _____

_____ / _____

Appendix C

PRE- TREATMENT QUESTIONNAIRE

File No:

Date:

Patient's surname:

first name/s:

Date of birth:

Age:..... Sex:.....

Name/s of parent/s:

Paediatrician:

How old was the baby when the colic started?

.....

For how long does the baby cry with each colic attack?

.....

How often does colic occur in 24 hours?

.....

Does the colic occur at any particular time of the day or night?

.....

Does anything seem to precipitate an attack? If so, what?

.....

For how long does the baby sleep between colic attacks?

.....

Is the baby on any medication to relieve the colic?

Yes / no:

Name of the medication:

Dosage:

How often?

Does it help?

Appendix D

POST-TREATMENT QUESTIONNAIRE

File No:

Date:

Patient's name:

For how long does the baby cry with each colic attack?

.....

How often does the colic occur in 24 hours?

.....

Does the colic occur at any particular time of the day or night?

.....

Does anything seem to precipitate an attack? If so, what?

.....

For how long does the baby sleep between colic attacks?

.....

Does the baby still require medicine to relieve the colic?

Yes / no:

Name of the medication:

Dosage:

How often?

Does it help?

How would you rate the baby's response to the treatment? – *(Please mark with an "x")*

(1) completely recovered (2) somewhat better (3) the same (4) somewhat worse

(5) much worse.

Has the baby developed any other illness in the interim? If so, what?

.....

Appendix E

FOLLOW-UP QUESTIONNAIRE

File No:

Date:

Patient's name:

Does the baby still suffer from colic attacks since cessation of treatment?

If yes –

For how long does the baby cry with each colic attack?

.....

How often does the colic occur in 24 hours?

.....

Does the colic occur at any particular time of the day or night?

.....

Does anything seem to precipitate an attack? If so, what?

.....

For how long does the baby sleep between colic attacks?

.....

Does the baby still require medicine to relieve the colic?

Yes / no:

Name of the medication:

Dosage:

How often?

Does it help?

How would you rate the baby's response to the treatment? – *(Please mark with an "x")*

- (1) completely recovered (2) somewhat better (3) the same (4) somewhat worse
(5) much worse.

Has the baby developed any other illness in the interim? If so, what?

.....