Osteopathic treatment for unsettled, fussy and irritable infants in their first year of life: Mothers’ experiences and effect on infant temperament

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A thesis submitted in partial fulfilment for the degree of Master of Osteopathy, Unitec Institute of Technology, New Zealand, 2015
Declaration

Name of candidate: **Olivia Amber Covich**

This Thesis entitled “**Osteopathic treatment for unsettled, fussy and irritable infants in their first year of life: Mothers’ experiences and effect on infant temperament**” is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy.

**CANDIDATE’S DECLARATION**

I confirm that:

- This Thesis/Dissertation/Research Project represents my own work.
- The contribution of supervisors and others to this work was consistent with the Unitec Regulations and Policies.
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.

Research Ethics Committee Approval Number: **2014-1062**

Candidate Signature: ..........................................................Date: ..................

Student number: 1382791
Preface

This research project investigated mothers’ experiences and perceptions of the effectiveness of osteopathic treatment for unsettled, fussy or irritable (UFI) infants within their first year of life.

This thesis is divided into 3 sections.

Section 1 introduces the topic of interest and reviews the current relevant literature with a focus on maternal wellbeing related to caring for UFI infants. The methodology and methods used in this study are also presented in this section.

Section 2 contains the manuscript prepared in accordance with the International Journal of Osteopathic Medicine (IJOM) author information (see appendix H). It is important to note that within this manuscript where quotes are provided in support of theme identification, the concepts were commonly identified with all participants yet quotes tended to come from a few participants as some experience descriptions were richer in detail and imagery.

Section 3 presents the appendices for referral throughout this thesis. The appendices contain the recruitment poster, evidence of ethical approval, participant information and consent forms, and data collection tools including interview guides, the treatment summary template provided to osteopaths, the questionnaire and relevant questionnaire documents. It also contains aspects of data analysis and the IJOM author information guidelines.
Acknowledgements

Many people have contributed to the development and completion of this thesis. Without their help this project would not have been possible.

Firstly, I would like to thank my supervisors Dr Elizabeth Niven and Sue Gasquoine. Thank you both for your support, encouragement and guidance throughout this unfamiliar process. I appreciate the time and effort you have dedicated to this project. Thank you also to Arun Deo for your assistance in analysing the quantitative component of this study.

A special thank you to all of the mothers, Shannen, Kim, Emma, Anna, Sarah, Lisa, and Alice¹, who willingly opened their doors to me during a stressful time. I am so grateful that I had the opportunity to meet each of you and hear your stories. Thank you also to the osteopaths involved for your efforts in providing participants for this study and your contribution to the data.

Finally thank you to my family. Thank you Mum, Dad and Ben for your endless support, encouragement and understanding. I can’t imagine how I would have completed this final hurdle without you.

¹ Participant pseudonyms
Abstract

Background: Unsettled, fussy and irritable infant behaviour is a common complaint causing significant stress for parents. A lack of support during this time has been linked to negative effects on both infant and maternal health. Despite reports of anecdotal success, limited academic literature explores mothers’ first hand experiences with osteopathy during this time.

Objective: The aim of this study was to determine mothers’ perspectives on the effectiveness of osteopathic treatment in the management of unsettled, fussy and irritable infants during their first year of life to enhance clinical understanding and inform future practice.

Methods: Both qualitative and quantitative data were collected from each of 7 mother-infant dyads (2 primiparous women and 5 multiparous women) over a 3 month period, between February 2015 and July 2015. Interpretive description formed the theoretical framework used to analyse the main interview data. Supplementary mother notebooks and osteopathic treatment summaries were reviewed and summarised. The Infant Behaviour Questionnaire – Revised was also used as an objective tool to accompany subjective findings.

Results: Key findings revealed 3 central themes with 9 subthemes to express the mothers’ journeys over time. Firstly ‘this can’t go on’ (retrospective, prior to osteopathic intervention), secondly ‘realising it will be okay’ (reflecting both infant and maternal maturation evident between interviews) and lastly ‘a happy baby is a happy mother’ (improvements promoting a happier relationship between mother and infant).

Conclusions: Professional understanding and support is crucial in the management of unsettled, fussy and irritable infants to minimise the negative effects on both infant and maternal health. Osteopathy appears beneficial in
enhancing quality of life for both infant and mother during a difficult, yet self-limiting period of time.

**Keywords:** Unsettled/fussy/irritable, infant colic/crying, infant sleep, infant behaviour/development/temperament, maternal health, maternal fatigue, postpartum depression, osteopathy, interpretive description, Infant-Behaviour Questionnaire –Revised.
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Participant quotes in the manuscript have been *italicised* and presented with the appropriate mother pseudonym and interview number from which the quote was extracted.

… Omission of dialogue

…//… A large break in the quoted dialogue

*[Text]* Text added or altered for reader clarification and to maintain privacy, for example [osteopath] or [baby] to provide anonymity
Section 1: Literature Review, Methodology and Methods
REVIEW OF THE LITERATURE

Introduction

Crying is recognised as a normal behaviour in developing infants as their primary form of communication and attachment in the early stages of life (Kurth et al., 2010; Talvik, Alexander, & Talvik, 2008). That being said, if crying becomes excessive and inconsolable parents often choose to seek medical advice for their concerns commonly fearing that something is wrong and that their infant is in pain (Kurth et al., 2014). UFI is an acronym adopted throughout this research project, previously created and used by Gibbons (2008) to represent the 3 most commonly used descriptors of infant distress within the literature “unsettled, fussy and irritable” as initially reported by Viedma-Dodd (2006). Her initial exploration of these 3 terms revealed that common interpretation and use referred to crying, colic, hypersensitivity, gastroesophageal reflux disease, restlessness and infants who are temperamentally difficult (Viedma-Dodd, 2006). Furthermore, unsettled behaviour may involve prolonged and inconsolable crying, resistance to soothing and settling, poor sleep with frequent waking after short sleeps and feeding issues such as breastfeeding difficulties, colic and reflux (Christl et al., 2013; Fisher et al., 2012). Thus the acronym UFI will be used to encapsulate the above terms throughout.

The exact aetiology of UFI infant behaviour remains unclear yet the associated parental concern and distress appears significant. Within the literature the impact on maternal health is an existing and ongoing topic of interest yet only limited literature has been published on the topic, much of it over 10 years old. Furthermore, little information exists on the osteopathic approach in the management of UFI infants. This search therefore builds on 2 existing qualitative investigations, conducted by previous Unitec osteopathy students, seeking insight into mothers experiences caring for UFI infants (Gibbons, 2008; Viedma-Dodd, 2006). This review will outline UFI infant behaviour and the current theories on its aetiology, with a particular focus on
the impact on both infant and maternal health. An outline of the current treatment and management options available will also be provided with a particular interest in the osteopathic approach.

**Search strategy**
The information gathered for this review was retrieved from a variety of academic databases including Ebsco, Science Direct, PubMed, Medline, and Google Scholar. Due to the large volume of historical literature, article searches for this review were limited to the last 10 years, excluding literature prior to 2006. Literature was also limited to full text availability and articles published in the English language.

**Unsettled, Fussy and Irritable (UFI) behaviour**

**Excessive crying**
Infant crying is considered a normal infant behaviour, particularly during the first few months of life. The tendency during this period is to follow a typical pattern where crying and fussing begins in the first 2 weeks postpartum, peaks at 6 weeks and resolves by 3 months of age, reflecting normal maturation and neuro-developmental processes (Kurth, Kennedy, Spichiger, Hösli, & Zemp Stutz, 2011; Wurmser et al., 2006). However if crying becomes excessive, inconsolable or unexplained this can cause inevitable distress for parents, particularly first time parents. Excessive crying and irritability is common and often perceived as ‘medically trivial’ by healthcare professionals (Bruning & McMahon, 2009; Smart & Hiscock, 2007; Talvik et al., 2008) yet remains one of the most common reasons that a parent will consult a healthcare professional seeking assistance during early infancy (Douglas & Hiscock, 2010; Kotzampaltiris, Chou, Wall, & Crain, 2009; Kurth et al., 2011).

McCallum et al. (2011) report that more than 45% of mothers experience issues with infant crying, sleeping and feeding though few mothers identify general practitioners (GPs) as helpful sources in the management of their infants during this time (Bailey, D'Auria, & Haushalter, 2013; Keefe, Karlsen,
Lobo, Kotzer, & Dudley, 2006). Persistent crying has been linked to infant sleep problems encompassing difficulties initiating sleep, resistance to soothing and frequent waking at night thus maintaining infant distress and parental exhaustion resulting in difficulty establishing a routine (Crncec, Matthey, & Nemeth, 2010).

**Infantile ‘colic’**

Infantile colic is the term commonly used to describe a behavioural condition characterised by excessive and inconsolable crying in a young and otherwise healthy infant (Cowie, 2013). The nature of this behaviour involves paroxysms of crying, irritability and fussing affecting up to 40 percent of infants, usually between the ages of 2 weeks to 4 months old, with no specific known cause identified (Dobson et al., 2012; Johnson, Cocker, & Chang, 2015). It appears to be a self-limiting, benign, condition common to early infancy as a diagnosis of exclusion (Dobson et al., 2012). This behaviour and the uncertainty surrounding its source can cause significant distress for parents as well as the infant and other family members involved. As a result reassurance for distressed parents is often required once underlying pathology is excluded (Kheir, 2012).

Typical ‘colic’ crying is often defined in the literature using the longstanding Wessel’s ‘rule of three’, originally published in 1954. Wessel’s rule depicts colic as crying for more than 3 hours per day, for more than 3 days per week and for more than 3 consecutive weeks (Dobson et al., 2012). Interestingly, despite dating back more than 60 years, this definition continues to be cited frequently in the academic literature notwithstanding medical advances. The continued use of this definition may be deemed inappropriate with modern medical knowledge identifying flaws in the idea of ‘colic’ as a condition itself, due to its similarity to the typical pattern of normal infant crying. Defaulting to a 60 year old definition may therefore be reflective of the ongoing uncertainty and controversy surrounding this condition.

Infantile colic is reportedly associated with outbursts of high pitch crying (often in the evening), flushing of the face, passing gas, abdominal distension,
drawing up of the legs, and arching of the back (Dobson et al., 2012). The argument surrounding colic as a diagnosis recognises that symptoms tend to develop in the second week postpartum, peak in the sixth week and resolve by 3 months of age (Vik et al., 2009) similar to the ‘normal’ crying patterns reported in infant development. Furthermore, the daily pattern of greater distress in the evenings also reflects this natural pattern seen in young infants however severe inconsolable episodes can understandably lead parents, and more specifically mothers, to believe that something is wrong influencing their decision to seek medical advice.

**Aetiology for UFI behaviour**

A clinical discussion paper on unsettled infants prepared by Australian researchers, Fisher et al. (2012), suggests that at least a quarter of families are affected by UFI infant behaviour and up to a third experience issues with infant sleep. Although UFI behaviour tends to reduce within the first year of life, parents experience significant distress during this time. It is therefore intriguing that the mechanism underpinning this behaviour remains poorly understood. Despite research efforts, the exact aetiology remains unclear (Akhnikh, Engelberts, van Sleuwen, & Benninga, 2014; Miller, Newell, & Bolton, 2012). Jean Cowie, a lecturer in the School of Nursing and Midwifery at Robert Gordon University in Scotland, presents an overview of the recent theories attributed to the development of infant colic describing a number of theories that may be categorised as physiological or non-physiological (Cowie, 2013). Current theories include dietary related factors, immaturity of the gastrointestinal system, imbalances in gut flora/microbiota, immaturity of the central nervous system, stress factors (pregnancy or birth-related), or psychological factors such an inadequate interaction between the infant and mother (Cowie, 2013; Lim, 2006).

Dietary intolerances, such as intolerance to cow’s milk via breast milk, are a commonly proposed theory behind the development of UFI symptoms. Yet symptoms of dietary intolerance typically involve vomiting, red and itchy skin,
blood in stools and failure to thrive in conjunction with crying, thus crying alone is not an adequate justification for diagnosis (Fisher et al., 2012). Furthermore, St James-Roberts (2007) states that cow’s milk intolerance is not common, reportedly occurring in only 1 in 100 cases of crying infants. Gastroesophageal reflux (GER) is another condition often linked to the development of UFI symptoms (Neu, Corwin, Lareau, & Marcheggiani-Howard, 2012). GER occurs when the stomach’s acidic contents back up into the esophagus, with or without any spilling or vomiting, causing discomfort (Baird, Harker, & Karmes, 2015). GER is commonly seen in infants due to the immaturity of the esophagus and stomach thus influencing the integrity of the lower esophageal sphincter (Neu et al., 2012). It is important to note that gastroesophageal disease (GERD) on the other hand, involves reflux that causes problematic symptoms and ongoing complications for infants (Baird et al., 2015). Constipation may also contribute to gastrointestinal discomfort. The term constipation is commonly misused in infancy. The absence of a bowel motion can be considered ‘normal’ for up to 10 days in an infant, often relating to dietary intake (Plunket, 2016). Yet in the literature constipation is considered where intervals between stools are greater than 48 hours (Bergmann et al., 2014; Jain, Gunasekaran, Venkatesh, & Soundararajan, 2015). The key additional features of constipation, in conjunction with extended periods between defecation, appear to be passing a hard stool with associated distress and crying (Jain et al., 2015). Issues with feeding such as tongue-tie or problematic latching are beyond this review however it is important to mention that they can further exacerbate gastrointestinal discomfort with excess air intake during feeding.

The term ‘colic’ itself implies the traditional belief of a gastrointestinal mechanism underlying symptoms. However, recent contrary ideas expressed by an American child neurologist Amy Gelfand, suggest a potential link between maternal migraine and the development of infantile colic symptoms (Gelfand, 2015; Gelfand, Thomas, & Goadsby, 2012). From this research, a history of maternal migraine has been linked to an increased prevalence of colic symptoms in their offspring. Infantile colic symptoms are also suggested to be an early sign of future migrainous tendencies for the child due to genetic
predisposition (Gelfand et al., 2012). Sillanpää and Saarinen (2015) also support the notion of infantile colic being associated with the development of future migraines. It remains unknown whether UFI symptoms in an infant are due to a current migrainous episode in the infant or whether symptoms are indicative of a higher risk for future migraines. Nonetheless, in light of the current literature, ongoing research is required to determine the exact aetiological mechanisms behind UFI infant behaviour to inform treatment and management.

**Impact on Infant health**

For the majority of infants displaying UFI symptoms in early infancy there are no long-term effects. However, for the minority, excessive crying and UFI behaviour persisting beyond 3 months of age has been associated with the development of childhood behavioural and emotional problems in later life (Britton, 2011; Fisher et al., 2012; Hemmi, Wolke, & Schneider, 2011; Smart & Hiscock, 2007). Infant maltreatment, neglect and abuse are rare but serious consequences of excessive inconsolable crying (Barr et al., 2014; St James-Roberts, 2007). Actions such as smothering, slapping and shaking the baby are reported within the literature as having detrimental effects on infant development and the potential to be fatal (Kaley, 2011; St James-Roberts, 2007). It is therefore essential to highlight the importance of listening to and supporting parents of UFI infants to improve their support network and coping mechanisms in an attempt to minimise the likelihood of catastrophic events.

**Shaken Baby Syndrome**

Shaken baby syndrome (SBS), also known as abusive head trauma (Barr, 2014), involves intentional injury to an infant as a result of violent shaking, with or without contact with a hard surface (Barr, Trent, & Cross, 2006). SBS often provides no external evidence of trauma as damage is usually in the form of head trauma or fractures (Barr et al., 2006). Significantly, 25-30% of infants diagnosed with SBS do not survive due to the severity of their injuries (Russell, 2010). In the literature crying has been linked to the development of
SBS yet evidence is currently limited (Barr et al., 2006; Russell, 2010; Talvik et al., 2008). After failed attempts to soothe their baby, parents who have admitted to shaking their infant often reported having ‘lost control’ or ‘snapped’ (Russell, 2010). Barr et al. (2006) analysed American hospital records over a 4 year period of time identifying 273 hospitalisations for infants with SBS under 18 months of age. The aim of this study was to establish whether an age-related pattern of SBS hospitalisations exists to identify any potential link to infant crying. The authors of this study identified that hospitalisations for SBS typically peaked at approximately 10 to 13 weeks of age. In comparison, the typical peak in crying occurs at approximately 6 weeks old thus if crying persists beyond this point desperate and frustrated parents may resort to shaking in the forthcoming period with an opportunity for recurrent trauma. Debate continues on whether the presence of crying is leading to infant abuse or whether infant abuse is causing secondary crying (Barr et al., 2006). Nonetheless, the findings of Barr et al. (2006) suggest the need for imperative attention and intervention to assist those seeking healthcare advice for UFI infants in early infancy to minimise potential harm.

Talvik et al. (2008) also conducted a study examining hospital records to investigate the relationship between excessive crying and the development of SBS. This study highlighted that nearly 90% of parents with crying and irritable infants had consulted healthcare professionals yet describe a lack of support and advice. This was deemed most likely due to healthcare practitioner underestimation of both the severity of infant behaviour and the effects on those involved (Talvik et al., 2008). The lag period between normal crying peak and a peak in SBS prevalence (see Figure 1) offers healthcare professionals an opportunity to listen and intervene to minimise potential risks. It therefore appears crucial to raise awareness both publicly and within the healthcare setting to provide preventative intervention and save lives.
Figure 1. Typical infant crying and prevalence of Shaken Baby Syndrome (SBS) in the first 16 weeks of life (Talvik et al., 2008).

**Early cessation of breastfeeding**

Breastfeeding is widely accepted as ideal for its nutritional and immunity benefits for growth and development (Cornall, 2011). Mothers are therefore encouraged to breastfeed exclusively for approximately 6 months and continue until at least 12 months postpartum (Howard, Lanphear, Lanphear, Eberly, & Lawrence, 2006). The release of ‘love’ hormones, oxytocin and prolactin, during breastfeeding also stimulates maternal relaxation enhancing the mother-infant bonding experience (Cornall, 2011; Howard et al., 2006). Early termination of breastfeeding has been linked to a variety of factors such as maternal age and education, support network, perceived self-efficacy and a return to work or school (Howard et al., 2006). A group of American medical researchers conducted a large-scale study (700 mother-infant dyads) investigating the relationship between breastfeeding and infant colic concluding that there was a link between infants with colic and a shorter duration of breastfeeding (Howard et al., 2006). Mothers commonly use breastfeeding as a tool to soothe their infants however Howard et al. (2006) report that an inability to soothe UFI infants resulted in negative breastfeeding experiences thus triggering early cessation. Furthermore maternal exhaustion has also been linked to early breastfeeding cessation (Taylor & Johnson, 2010). Future research may therefore choose to focus on investigating the
potential effects of an UFI infant on maternal milk production to identify whether stress, anxiety or reduced self care further contribute to early breastfeeding cessation.

**Impact on Maternal health**

Lack of infant sleep and excessive infant crying are commonly associated with increased levels of parental stress, fatigue, depression, and anxiety consequently negatively impacting on parental general health (Giallo, Rose, & Vittorino, 2011; Keefe et al., 2006; Smart & Hiscock, 2007). Similarly excessive crying is also linked to higher rates of negative maternal mood, stress on relationships, household disruption, negative perceptions of the infant and an increased risk of infant neglect or abuse consequently impacting on parenting responsiveness and sensitivity toward their infant (Bruning & McMahon, 2009). Interestingly Bruning and McMahon (2009) conducted a study on 80 nulliparous women investigating the immediate effects of infant crying. This research used programmed baby dolls to simulate ‘real’ infant crying exposing each participant to the crying doll for only 9 minutes. The findings of this study revealed immediate negative effects with regard to mood, perceived caretaking abilities, increased anxiety levels, and feelings of helplessness, emphasising the need for a sensitive practitioner approach to affected mothers within a healthcare setting (Bruning & McMahon, 2009). Although interesting, it would seem more beneficial to conduct ‘real life’ research on primiparous and multiparous women caring for crying infants to gauge more realistic experiences to guide future clinical intervention.

Landgren and Hallström (2011) conducted a phenomenological hermeneutic study into the experiences of 23 parents caring for infants displaying colic symptoms. Interestingly, infants up to the age of 20 weeks were recruited for this study suggesting that UFI behaviour may in fact persist beyond 3 months of age despite recent debate. When unable to soothe their infant, mothers in this study reported feeling lonely, helpless, inadequate, powerless, frustrated, angry, sad and unable to perform basic tasks such as eating or using the
bathroom due to the constant demands of their infant (Landgren & Hallström, 2011). The researchers identified a main theme within the parental narratives of ‘colic overshadows everything’, demonstrating the significant impact and disruption to daily life for those involved. Another smaller scale qualitative study (12 mothers) investigated maternal experiences with an irritable infant (Megel, Wilson, Bravo, McMahon, & Towne, 2011). Mothers in this study were associated with perceived judgment by others, unhelpful external advice, exhaustion, frustration, isolation and depersonalisation from their infants (Megel et al., 2011). Interestingly the infants described as ‘colicky’ in this study ranged from 3.5 months to 4.5 years of age with a mean age of 13.5 months upon interviewing. The researchers of this study do not appear to clearly indicate that this is a retrospective investigation therefore creating confusion surrounding the trustworthiness of this study if colic is supposedly a condition limited to early infancy.

**Tiredness vs. fatigue**

The terms ‘tiredness’ and ‘fatigue’ are often used interchangeably within the literature, encompassing an imbalance between activity and rest, yet can be differentiated (Kurth et al., 2011). Tiredness has been described as a temporary, transient, physiological state relieved by a period of rest. On the other hand, fatigue is viewed as a persistent, pathological state disrupting circadian rhythm and therefore not relieved by a single period of rest and impacting on daily life, general health and wellbeing (Giallo et al., 2011; Kurth et al., 2011). Notably, fatigue is recognised as one of the most common maternal complaints following childbirth (Taylor & Johnson, 2010). Elisabeth Kurth, a midwife and researcher at the University of Basel in Switzerland, has published a variety of recent and frequently cited academic articles investigating infant crying and maternal health. She conducted a large case control study on more than 7000 infants concluding that infant crying problems have a significant effect on maternal health and mood acknowledging physical, psychological and social implications (Kurth et al., 2010). A mother’s health and wellbeing understandably influences the behaviour of her infant and vice versa. Kurth et al. (2011) describes this concept as a vicious cycle (see Figure 2) where excessive crying prevents the
mother from getting sufficient rest to care for her child optimally. Subsequent sleep deprivation, fatigue and sensitivity then create a negative impact on parenting efforts thus maintaining infant UFI behaviour and increasing the risk for maternal depression and the potential for infant abuse (Kurth et al., 2011).

![Figure 2. Influence of infant crying on maternal health (Kurth et al., 2011).](image)

**Postpartum depression and anxiety**

Excessive postpartum infant crying has been linked to a variety of physical and psychological issues for mothers (Kurth et al., 2010). Mothers caring for unsettled infants, with a diagnosis of colic, have been associated with a higher risk of developing postpartum depression and anxiety (Akman et al., 2006; Britton, 2011; Christl et al., 2013). Postpartum or postnatal depression refers to an irritable, debilitating and severely depressive mood generally occurring during the first 4 weeks after childbirth but may present up to 30 weeks later (Buultjens & Liamputtong, 2007). It is commonly associated with excessive infant crying however cause and relationship, if any, have not yet been established (Akman et al., 2006; Kurth et al., 2010). Depressive symptoms may develop in response to UFI infants or mothers with depression may be more sensitive and therefore perceive their infant to be more unsettled and difficult to manage (McGrath, Records, & Rice, 2008).

It is important to note that postpartum depression is more serious than the ‘transitory baby blues’ or ‘maternity blues’ which are relatively common and temporary, only lasting days after birth commonly resulting from maternal hormonal changes (Brunton, 2008; Buultjens & Liamputtong, 2007). ‘Baby
blues’ in the early postpartum period should not require treatment, as they should not persist whereas postnatal depression is more severe in terms of effect on mother-infant interaction and potential long-term consequences (Brunton, 2008; Buultjens & Liamputtong, 2007). Depressive symptoms that are not identified or appropriately addressed may contribute to the development of maternal psychological disorders and childhood developmental, behavioural and emotional difficulties in future (Akman et al., 2006). Interestingly, although an increased prevalence exists within this demographic, Christl et al. (2013) investigated 250 mothers of unsettled infants up to the age of 12 months old revealing that the incidence of maternal depression in their study was lower than expected and thus depression is not inevitable for all mothers. Contributing risk factors include stressful or negative life events, family history or personal history of mental health issues during pregnancy or prior, a history of abuse, a poor support network/poor relationships including marital, and infant health issues (Akman et al., 2006; Christl et al., 2013). Christl et al. (2013) emphasise the importance of early identification of maternal psychosocial risks in the development of postpartum depression and anxiety to prevent negative health outcomes for both mothers and infants.

**Treatment and Management options**

The uncertainty currently surrounding the aetiological mechanism behind infantile colic and UFI behaviour has influenced a variety of proposed treatment and management options each with their own suggested merits, limitations and reliability (Hayden & Mullinger, 2006). Professor Ian St James-Roberts, from the University of London, acknowledges that this uncertainty has also led to variation in professional opinions causing inconsistency in the advice given to parents (Kaley, 2011; St James-Roberts, 2007). This fact highlights the ongoing and urgent need for future, rigorous research to provide an evidence-based approach to the treatment and management of UFI infants. Nonetheless, common and current interventions consist of dietary modifications, pharmacological intervention, behavioural modifications, and
manual therapy (Cowie, 2013). Of note, behavioural modifications aim to target psychological theories surrounding UFI behaviour, such as improving infant-parent interaction. The osteopathic approach will be discussed in the next segment to represent manual therapy relevant to this review.

Dietary modifications involve the belief that colic is linked to maternal diet in breastfed infants. The standard recommendation for suspected intolerance to cow’s milk is removal of cow’s milk protein from maternal diet however evidence remains inconclusive for this option (Cowie, 2013). Probiotics are suggested in the management of UFI infants to reduce symptoms with no known adverse effects yet current evidence for this method is also inconclusive (Johnson et al., 2015; Kheir, 2012; Sung et al., 2013). Despite the lack of evidence surrounding the use of gripe water, its use is continued. Interestingly gripe water has been suggested as a potential risk factor in the development of gastrointestinal issues such as colic, vomiting and constipation in infants (Jain et al., 2015; Jain & Gunasekaran, 2013). This finding again highlights the crucial need for further research investigating the aetiology and treatment of colic to minimise potential harm to infant health.

Pharmacological methods target the gastrointestinal tract to either expel wind or reduce stomach acidity, in turn reducing discomfort (Cowie, 2013). Anticholinergic medication works to relax the muscular intestinal wall yet has been associated with significant side effects and is therefore considered contraindicated in the first 6 months of life (Cohen-Silver & Ratnapalan, 2009; Cowie, 2013; Kaley, 2011; Landgren & Hallström, 2011). Simethicone is the widely used active ingredient found in over the counter products targeted at reducing air bubbles in the intestines. Anecdotal support exists for Simethicone yet studies have found effects similar to that of placebo thus concluding that there is inconclusive evidence on the effectiveness of this medication (Cohen-Silver & Ratnapalan, 2009; Cowie, 2013; Hall, Chesters, & Robinson, 2012; Johnson et al., 2015; Landgren & Hallström, 2011; Lucassen, 2010). Kheir (2012) suggest that medication does not have a key role in the management of UFI infants, unless GER has been identified, and therefore suggest that management should be based on acknowledging the
issue, considering parental health and providing information and reassurance on its benign and self-limiting nature. In infants with GER proton pump inhibitors, such as Omeprazole, are typically prescribed to reduce stomach acidity with a typical course lasting up to 8 weeks (Neu et al., 2012; Omari, Haslam, Lundborg, & Davidson, 2007). Omari et al. (2007) investigated the effectiveness of Omeprazole on preterm infants with reflux symptoms concluding that medication such as Omeprazole is effective in reducing stomach acidity yet highlight issues regarding its safety and efficacy. Douglas and Hill (2011) further report that the use of proton pump inhibitors in infants may increase their risk for infection and food allergies. Inconclusive evidence remains surrounding the effectiveness of proton pump inhibitors for reflux thus leading to and maintaining confusion (Johnson et al., 2015).

It is concerning that the limited evidence currently available in support of pharmacological methods has been associated with poor methodological procedures (Hall et al., 2012). This fact in conjunction with the reported side effects is alarming given the lack of agreement surrounding aetiology and the ongoing frequent use of medication, raising concerns regarding infant health. The current recommended approach appears to be support, empathy and reassurance to enhance maternal self-efficacy to empower parents during this time (Bruning & McMahon, 2009; Landgren & Hallström, 2011).

**Osteopathy for infants**

Within the literature, manual therapy such as osteopathy has been suggested to alleviate UFI infant symptoms (Dobson et al., 2012; Hayden & Mullinger, 2006; Lim, 2006). Despite reports of anecdotal success, scientific evidence in support of this approach is currently lacking therefore making it difficult to determine its effectiveness (Clar et al., 2014; Dobson et al., 2012). A recent Cochrane review on manipulative therapy for infantile colic evaluated the existing data for this treatment approach (Dobson et al., 2012). Interestingly, according to this review, the first person to suggest a manual therapy approach to colic was Andrew Taylor Still (founder of Osteopathic medicine).
Yet there appears to be a lack of studies investigating the osteopathic approach to colic in the current literature. Dobson et al. (2012) state that, to date, there are no known adverse effects for utilising osteopathy for this condition and affirm anecdotal success for manipulative therapy in this field, highlighting variation in the quality of evidence arising from current clinical trials and therefore a definitive recommendation cannot yet be made. Nonetheless, anecdotal success for the osteopathic approach is encouraging in supporting the osteopathic belief of a mechanical involvement in the seemingly multifactorial aetiology of UFI behaviour. Nevertheless further future clinical trials are warranted to identify evidence-based effects.

**Osteopathic theory**

Osteopathy is largely based on palpatory identification of somatic dysfunction. Childbirth is a natural process yet the forces applied to the baby during the process are immense and often overlooked (Lim, 2006). From an osteopathic viewpoint, an understanding of the birth process is crucial. Osteopaths often link the birth process to the development of certain dysfunctions throughout the body, particularly within the cranium, thus giving rise to physical symptoms such as excessive crying in early infancy (Kotzampaltiris et al., 2009). The cranial base is considered most vulnerable to dysfunction following pregnancy and birth (Kotzampaltiris et al., 2009). Some osteopathic authors argue that colic may arise from irritation or compression of the vagus nerve as it exits the cranial base, potentially as a result of the birth process (Cowie, 2013; Lim, 2006). This irritation is then believed to cause parasympathetic overactivity, resulting in irritable and unsettled infant behaviour (Lim, 2006). To that end, when birth is considered particularly traumatic –perhaps a very rapid or prolonged labour, issues with establishing infant first breath, or birth processes requiring forceps, ventouse extraction or emergency caesarean section –it is understandable for physical signs and symptoms to emerge in early infancy. Common osteopathic findings of dysfunction in young infants appear to include the cranium, sacrum, pelvis, abdomen, thoracic spine, ribs, diaphragm and sternum (Philippi et al., 2006; Pizzolorusso et al., 2013). Philippi et al. (2006) conducted a blinded, randomised clinical trial investigating the therapeutic effect of osteopathy for
infants aged 6 to 12 weeks with idiopathic postural asymmetry. Infants in the treatment group were treated weekly over 4 weeks. The authors concluded a significant difference between the treatment and sham group suggesting osteopathy to be of benefit in early infancy (Philippi et al., 2006).

**The cranial approach**

Within the current literature, cranial osteopathy or osteopathy in the cranial field (OCF) appears to be a common osteopathic approach to UFI infants. OCF involves applying gentle manual techniques, commonly to the head and other regions of the body displaying an increase in ligamentous or muscular tone or a restriction in joint movement (Hayden & Mullinger, 2006). The cranial approach involves osteopathic assessment of a palpable cranial rhythmic impulse (CRI), used as a marker for dysfunction within the cranium and central nervous system (Kotzampaltiris et al., 2009). The primary respiratory mechanism is another important component of the cranial approach referring to subtle movement of the cranial bones, sacrum, dural membranes, central nervous system and cerebrospinal fluid synchronous with the CRI forming a ‘rhythmic cycle’ (Jäkel & von Hauenschild, 2011). The cranial approach aims to ease strain patterns to reduce the load on the central nervous system and enhance bodily function (Hayden & Mullinger, 2006).

Kotzampaltiris et al. (2009) investigated the relationship between CRI and excessive infant crying on 139 full term infants ranging from 37 to 42 weeks gestation. The findings of this study revealed no relationship between CRI at birth and excessive crying (p=0.23) yet showed a significant association between abnormal CRI at 2 weeks of age and excessive infant crying at 6 weeks (p<0.001). Cranial dysfunction such as molding and compression is believed to resolve as infants begin breathing, crying, yawning, suckling and moving in the first few weeks of life however the findings of this study suggest that unresolved dysfunction may contribute to excessive crying in early infancy (Kotzampaltiris et al., 2009).

Hayden and Mullinger (2006) investigated the effect of cranial osteopathy on 28 infants with infantile colic, ranging from 1 to 12 weeks of age, administering
1 treatment per week over 4 weeks. Fortunately this exploration utilised a control group to gauge change. While a reduction in both crying and an improvement in sleep were identified in both treatment and control groups a significant change was identified in the treatment group with a reduction in crying observed in 63% of infants (P<0.001) and an improvement in sleep observed in 11% of infants (P<0.002). On the other hand, in the control group, 23% of infants also experienced a reduction in crying and 2% of infants displayed an improvement in sleep. These findings suggest inevitable natural improvement as the infants developed with age, nonetheless a significant and greater change was observed in the treatment group, highlighting preliminary support for this approach. Unfortunately parents were not blinded and a sham treatment was not performed to those infants in the control group thus the potential influence of a placebo effect cannot be excluded in this study.

Interestingly, the majority of the current yet limited literature regarding the osteopathic approach arises from either osteopathic or medical perspectives thus the potential influence of bias cannot be excluded.

**Conclusion**

In light of this review, it appears that UFI infant behaviour is a significant issue for mothers and families worldwide. The severity of potential effects and risks for both mother and infant health highlight a crucial need for professional understanding and intervention. A general lack of consensus remains surrounding the aetiology underpinning these symptoms. Consequently this has resulted in a variety of proposed treatment and management options however evidence remains inconclusive. It is clear that more research is needed in this field to inform clinical care. A lack of maternal narrative is also apparent in the current literature, as the majority of the current research stems from the perspective of medical professionals thus bias cannot be excluded. To this end, despite the need for further clinical studies, determining the mother’s first-hand perspective on osteopathy for UFI infants may result in a step in the right direction to informing clinical practice and future clinical trials.
CONDUCTING THE RESEARCH: METHODOLOGY AND METHODS

This subsection will firstly outline the main qualitative methodology underpinning this research project, and the value of employing both qualitative and quantitative approaches for this investigation. The methods component will then outline the processes the researcher took to perform this study. Lastly an overview of establishing and maintaining rigour in research is provided.

Methodology

To date, there appears to be limited literature exploring the effectiveness of osteopathy in the management of UFI infants during their first year of life. Furthermore a lack of maternal narratives on the topic has been identified in the current literature. Qualitative investigation allows subjective insight into ‘real life’ experiences and perceptions to enable a more in-depth clinical understanding (Schneider, Elliot, LoBiondo-Wood, & Haber, 2004). A mother’s perspective was viewed as valuable and realistic to provide insight to enhance the clinical understanding of this phenomenon. Quantitative data were also collected in this study utilising the Infant Behaviour Questionnaire –Revised (IBQ-R) to gauge objective information on any changes in infant temperament over time to identify the effectiveness of osteopathy for UFI infants. The integration of both qualitative and quantitative methods in this study aimed to expand the current knowledge and enhance the credibility of the findings produced.

Interpretive description

Both Viedma-Dodd (2006) and Gibbons (2008) conducted research into mothers’ experiences caring for UFI infants utilising a phenomenological approach to qualitative research. Although the current study was inspired by hermeneutic phenomenology it followed a theoretical framework of interpretive description in analysis. Interpretive description is a contemporary, inductive, qualitative research method, based on the ideas of Sally Thorne,
reflecting the recent evolution in qualitative methodology (Thorne, 2008; Thorne, Kirkham, & MacDonald-Emes, 1997; Thorne, Kirkham, & O'Flynn-Magee, 2004). This method draws on, yet differs from, ‘classical’ methodology such as grounded theory, ethnography and phenomenology. It employs a small sample to gain practical insight into human experience, from those living the phenomena, to inform clinical practice and understanding (Thorne, 2008; Thorne et al., 1997; Thorne et al., 2004). This particular interpretive description presents insights from 7 mothers experiencing life with an UFI infant and their views on the use of osteopathy during this time to inform osteopathic practice and contribute to the understanding of this challenging yet time-limited phenomenon. It employed a variety of supplementary data to enrich the data collected, and the resulting analysis and interpretation. Hunt (2009) identifies that interpretive description commonly utilises a variety of data with the primary data collected from individual participant interviews, as was demonstrated in this study. The variety of data collected in this study (interview transcripts, mothers notebooks, osteopath treatment summaries, and questionnaires) allowed triangulation, encouraging a deeper understanding of the phenomenon and increasing credibility and validity of the research to generate clinically applicable findings (Hunt, 2009; Olsen, 2004).

**Rigour in research**

Rigour, or trustworthiness, refers to the steps taken to ensure that the research is performed in an appropriate manner to enhance its quality and the value of its findings (Tracy, 2012). Due to the emerging ideas surrounding interpretive description as a qualitative method, a lack of established guidelines have been developed thus consideration of rigour was essential in this project (Thorne et al., 1997; Thorne et al., 2004). Assessing the usefulness of research is based on 4 core principles: truth value, applicability, consistency and neutrality (Krefting, 1991; Ryan-Nicholls & Will, 2009). Despite ongoing debate surrounding the best method in achieving and determining rigour, general criteria for establishing and maintaining rigour in qualitative research include credibility, dependability (auditability), transferability (fittingness) and confirmability (Koch, 2006; Koch & Harrington,
The use of triangulation within this study occurred with the variety of data collected. Triangulation is aimed at deepening and widening the understanding of a phenomenon to increase credibility, dependability and validate claims in research for clinical application (Hunt 2009; Olsen, 2004). In response to the recent developments in research, Olsen (2004) encourages interaction between qualitative and quantitative methods in research utilising a triangulation approach, as was employed in this research.

Reflexivity is another important component to consider in achieving rigour within research. This concept refers to the continuous process of self reflection by the researcher to improve transparency and credibility of the study (Darawsheh, 2014) and was employed via the use of a reflective journal in this study (see appendix G). Regular discussion with research supervisors also contributed to the rigour of this project gaining differing opinions and ideas. The 3 month time period and the repetitive nature of the interviews and questionnaires allowed consistency within this study. Koch (2006) suggests that once credibility, dependability and transferability are achieved confirmability is established. Qualitative research should strive to give an account of the methods used in conducting the research to ensure that another researcher could perform this study again in the future contributing to the dependability of the study (Mays & Pope, 1995). On that note, an outline of the methods follows to provide an audit trail of insight into research and the establishment and maintenance of rigour throughout (Koch, 2006).
Methods

Research questions

- From a mother’s perspective, is osteopathy an effective approach in addressing UFI behaviour within the first year of life?
- To what extent does osteopathic treatment influence infant temperament, measured by the IBQ-R?

Sample size and recruitment

Osteopaths from 4 osteopathic clinics in the Auckland region, with experience treating infants, were approached via personal contact or email. The osteopaths were informed of the study and invited to help the researcher recruit independent participants fitting the following inclusion criteria:

- The mother would describe her infant as being unsettled, fussy or irritable
- Infant is younger than 8 months old at enrolment
- Mother is fluent in the English language
- Infant is having, or has had, osteopathic treatment for this complaint

Upon agreement to help, the clinics were provided with posters and information pamphlets to aid recruitment (see appendix A). An initial sample size of 8 mothers from 3 different osteopaths, and 3 different clinics, was achieved. Infants ranged between 10 days and 9 weeks old at enrolment. At the completion of this study, 7 mother-infant dyads remained as 1 was withdrawn after multiple failed attempts to get in contact with the mother. Most mothers in this study had no previous experience with osteopathic treatment for infants, with all admitting discovering osteopathic treatment for infants via word of mouth recommendations from either midwives or other parents, particularly mothers, of infants with similar behaviour. Each mother in this study had independently approached their osteopath seeking treatment for
their infant and was invited to participate if the osteopath confirmed potential eligibility. If the mother was interested and gave permission, the osteopath then passed the mothers details onto the researcher. From there the researcher made contact with the mother to reconfirm eligibility, provide more information, and gain initial verbal consent to participate as well as arranging a time for the first interview.

**Ethical considerations**

Prior to commencing, this study was granted ethical approval by the Unitec Research Ethics Committee (UREC) for the period between 11.12.14 until 02.08.15 (application number 2014-1062, see appendix B). In the process of applying for this approval, the researcher considered the 8 UREC guiding principles stating how they would be addressed within this study to ensure the minimisation of harm. The researcher did not assume that all participants would be willing to participate. Mothers, independently seeking osteopathy for their infant, were extended a friendly invitation to partake via a telephone call at initial contact with the researcher. It was acknowledged that being a parent of an infant is time-consuming and tiring, and therefore interview times were made sensitively and managed to allow for breaks if needed. Privacy and confidentiality were maintained with the use of participant codes and anonymous pseudonyms allocated to each mother. Pseudonyms were used in all reports to maintain participant confidentiality. The audio recordings, data and written documents were kept in a locked cupboard, and were only accessible for research purposes.

**Data Collection**

Data were collected over 3 months for each mother-infant dyad between February 2015 and July 2015. A variety of data were collected including 2 sets of semi-structured interviews, mother notebooks, osteopathic treatment summaries, and 3 sets of questionnaires –the IBQ-R. The researcher visited mothers at their homes for interviewing and collected all notebooks and questionnaires from participant homes to make participant tasks as
straightforward as possible. Similarly, the researcher visited osteopathic clinics to provide recruitment materials (such as posters and pamphlets) and to collect osteopath treatment summary forms at the conclusion of data collection.

QUALITATIVE DATA

*Interviews*

A semi-structured interview was conducted with each mother at enrolment and then again 3 months later giving rise to 14 transcripts in total. Interviews ranged between 20 to 50 minutes of recorded discussion, depending on the participant and the amount of information provided. On both occasions, interviews were flexible and arranged to suit each mother. At the first meeting the researcher further explained the study, distributed information and consent forms (see appendix C), answered any questions, and reconfirmed that the mother was willing to participate gaining both verbal and written consent. Each dyad was issued a participant code, later converted into an anonymous pseudonym for written reports. Interview guides were used (see appendix D) to collect similar data from all participants, however encouraging personal narrative and providing the opportunity for additional probing and clarification, based on the participant response. Each interview was based on what each mother felt comfortable and willing to share. The first, introductory, interview hoped to gain insight into the mother’s lives with their infant leading up to meeting the researcher. Each mother spoke about their infant’s behaviour, motherhood, their pregnancy, labour, birth and osteopathic intervention thus far. The researcher made regular contact with each mother over the 3 month period leading up to the final interview. At the second and final meeting, 3 months on from the first interview, mothers were asked about their infant’s behaviour and the progression since first meeting. They were encouraged to reflect on the past 3 months and describe their experience and perspective on osteopathic treatment for their UFI infant during this time. At the conclusion of the interview each mother was thanked and given a card and small gift of appreciation from the researcher. Due to the total volume of data collected and the number of transcripts provided, the researcher continually sent recordings for electronic transcription where possible.
throughout the data collection process. This transcription was done via a confidential, online service that broke the text up into small segments to be transcribed by separate transcribers and then electronically re-assembled and returned to the researcher.

**Mother notebooks**
Mothers were given a small notebook and asked to use it as a diary to record any thoughts, feelings, phrases or descriptive words over the 3 months between interviews to give the researcher a closer insight into their lives caring for an UFI infant and any potential change over time. Notebooks were then to be returned to the researcher at the final interview.

**Osteopath treatment summaries**
The participating osteopaths were asked to complete a brief osteopathic treatment summary form for each of the infants involved from their clinics. The purpose of this summary was to provide the researcher with a brief insight into the osteopaths’ general impressions, diagnosis and treatment, the style of treatment implemented, areas treated and the osteopaths view on the infant’s condition and progress with treatment. Osteopathic treatment summaries were collected at the conclusion of the data collection phase. The researcher provided a simple template for the osteopaths to follow (see appendix E), however the summary was left open and the osteopaths were encouraged to include any information they felt was relevant.

**QUANTITATIVE DATA**

**Questionnaires**
Gartstein and Rothbart (2003) report that the IBQ-R\(^2\) is one of the most widely used parent-reported measures of infant temperament, designed to assess infants between the ages of 3 to 12 months of age (see appendix F). Parade and Leerkes (2008) report that the reliability and validity of the IBQ-R has been tested and established. The IBQ-R was used in this study to collect data

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\(^2\) The IBQ-R is made up of 191 items covering 14 scales of infant temperament. These scales include activity level, distress to limitations, fear, duration of orienting, smile and laughter, high intensity pleasure, low intensity pleasure, soothability, falling reactivity, cuddliness, perceptual sensitivity, sadness, approach, and vocal reactivity (Parade & Leerkes, 2008). See appendix F for definitions.
on 7 infants, as reported by the mother, at 3 different stages over 3 months\(^3\). The first 2 sets were distributed at the initial meeting. The first IBQ-R was intended to capture a retrospective view of the infant’s behaviour prior to osteopathic intervention and prior to the first meeting with the researcher. The second was left with the mother at the first meeting to be completed and collected following the next upcoming osteopathic treatment to express the infant’s current behaviour. Lastly the final questionnaire was posted out to the mothers to be collected at the final interview, 3 months on from the first interview, to show changes over time providing an objective measure of infant temperament to accompany subjective findings.

**Data analysis**

Qualitative analysis involved interview transcripts, mother notebooks and osteopath treatment summaries. Quantitative analysis involved IBQ-R data.

**QUALITATIVE DATA**

*Interviews*

With participant consent, interviews were audio-recorded and transcribed for analysis, to allow the researcher to identify and extract common themes that were present among the mothers seeking osteopathic treatment for their UFI infants. After withdrawal of 1 mother-infant dyad, the researcher had 14 extensive transcripts for analysis. Initial analysis took place throughout the data collection process, following each first interview, where the researcher would review the transcript in parallel with each audio recording to check for accuracy and summarise key ideas to allow for early engagement with the data and inform final interviews and the analysis process. In addition the researcher kept a reflective journal (see appendix G). After each interview the researcher recorded a brief reflection on the interviewing process, thoughts about the data collected and any observations and key findings to recall. Following final interviews a similar process was performed in checking the transcripts and adding any key data from the reflective journal. Transcripts were read multiple times and recordings were regularly reviewed to identify

\(^3\) Permission to use this questionnaire was granted on 29th May 2014 (see appendix F).
tone in participant voices. The initial summaries were converted into smaller summaries to further highlight key ideas and phrases. From this process the researcher was able to identify and extract key themes within the data to express the mothers’ journeys following the theoretical framework of interpretive description. It is important to note that the final themes were the product of ongoing review and editing: theme one ‘this can’t go on’, theme two ‘realising it will be okay’, and theme three ‘a happy baby is a happy mother’ (see appendix G). From these 3 central themes, 9 subthemes emerged to provide insight into the mothers’ journeys with their UFI infants over the 3 month study period.

Mother notebooks
Of the 7 participants only 3 notebooks were returned to the researcher. This highlights that this form of data collection proved to be slightly unrealistic for this sample, reflective of their busy lifestyles observed throughout this process. The notebook was good in theory but realistically not very practical for the lifestyle of a mother caring for an UFI infant and their constant demands. Nevertheless, the 3 notebooks returned were reviewed and screened for key words to gain further insight into the mothers’ lives during this time.

Osteopath treatment summaries
As the mothers’ perspectives were the main focus in this study, it was outside the scope of this study to investigate the osteopathic management of these infants in depth. Furthermore, Mills (2014) recently investigated osteopathic management plans. Nonetheless the osteopath summaries intended to provide brief insight into their general impressions, diagnosis and treatment for each of their infants involved at the conclusion of the 3 months. Of the 7 participants only 6 treatment summaries were returned to the researcher. These summaries were reviewed and compared for style of treatment, number of treatments and working diagnoses to identify common themes present within the sample of infants involved.
QUANTITATIVE DATA

Questionnaires

Prior to analysis, the questionnaire data from 21 IBQ-R's was transferred into an electronic spreadsheet using Google Forms. The data were then imported into the SPSS statistical software package. The data from 191 items within the questionnaire were recoded, by grouping multiple items together, into 17 new variables\(^4\) as outlined in the scoring procedure\(^5\) (see appendix F). The data analysis was then performed on these 17 new variables.

The quantitative data analysis for this research was done in two phases. The first phase created descriptive statistics of the data and the second phase created inferential statistics.

**Phase 1: Descriptive Statistics**

This phase consisted of presenting the data using the measures of central tendency and variation. These included mean, median, standard deviation, minimum, maximum and the quartiles.

**Phase 2: Inferential Statistics**

One–way repeated measures ANOVA was chosen as the main statistical test to determine the significance of the data for each temperament scale. This was performed because there was only 1 group of participants and 3 sets of questionnaires (repeated measures) utilising the same questionnaire each time.

The hypothesis testing was done using the generic hypothesis stated below.

**Hypothesis:**

Null Hypothesis, \(H_0: \mu_{s1} = \mu_{s2} = \mu_{s3}\) (that is, the mean score for the scales of temperament in all three sets of questionnaires are equal).

\(^4\) 14 of the 17 variables represented the scales of infant temperament whilst the remaining 3 variables represented the groupings for factor analysis in determining relationships between the scales.

\(^5\) The researcher was granted access to the IBQ-R score sheet to inform recoding to guide data entry using SPSS software (see appendix F).
Alternative Hypothesis, $H_1$: Null hypothesis is not true, that is, either one of the mean scores is not equal to the others or none of them are equal.

**Significance Level and Statistical Significance**

The above hypothesis was tested at the $\alpha$-level of 0.05, which is the probability of rejecting the null hypothesis given that it is true. The $p$-value was used to ascertain statistical significance of the data in the hypothesis testing. If the $p$-value was less than the $\alpha$-level ($p<0.05$), the null hypothesis was rejected, that is, either one of the mean scores was not equal to the others or none of them were equal. Upon confirming the statistical significance of the temperament scales across the 3 sets, post hoc analysis was used to determine exactly where the differences in mean existed between sets. A variety of different types of post hoc analyses allow us to make multiple pairwise comparisons and determine which pairs are significantly different and which are not. The more popular post hoc procedures include Tukey, Tukey-Kramer, Scheffe, Bonferroni, Dunnet and Games-Howell. In this research, Tukey’s HSD (honestly significant difference) test was used as the post hoc procedure.

The qualitative and quantitative findings of this study are presented and discussed in section 2, the manuscript.
REFERENCES


Viedma-Dodd, A. M. (2006). *Fussy, unsettled and irritable infants - the mothers’ voice: How can you support me if you don’t understand me?*, A research project submitted in partial fulfilment of the requirements for the degree of Masters of Osteopathy. Unitec New Zealand.


Section 2: Manuscript
Osteopathic treatment of unsettled, fussy and irritable infants in their first year of life: Mothers’ experiences and effect on infant temperament

Note: This manuscript has been prepared in accordance with the *International Journal of Osteopathic Medicine* author information guidelines (see appendix H). It is important to note that the referencing in this document is consistent with the APA style used throughout this thesis for consistency as the chosen journal now allows manuscript submission in alternative referencing styles, such as APA, which will be then converted to the preferred style by Elsevier upon submission. It is noted that manuscripts reporting on qualitative studies are commonly longer. Although efforts have been made to keep this manuscript concise, due to the volume of data collected within this project this manuscript has not strictly adhered to the word count given. Tables summarising questionnaire data have also been included in the text for ease of reading.
Osteopathic treatment of unsettled, fussy and irritable infants in their first year of life: Mothers’ experiences and effect on infant temperament

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ABSTRACT

Background: Unsettled, fussy and irritable infant behaviour is a common complaint causing significant stress for parents. A lack of support during this time has been linked to negative effects on both infant and maternal health. Despite reports of anecdotal success, limited academic literature explores mothers’ first hand experiences with osteopathy during this time.

Objective: The aim of this study was to determine mothers’ perspectives on the effectiveness of osteopathic treatment in the management of unsettled, fussy and irritable infants during their first year of life to enhance clinical understanding and inform future practice.

Methods: Both qualitative and quantitative data were collected from each of 7 mother-infant dyads (2 primiparous women and 5 multiparous women) over a 3 month period, between February 2015 and July 2015. Interpretive description formed the theoretical framework used to analyse the main interview data. Supplementary mother notebooks and osteopathic treatment summaries were reviewed and summarised, although not all were returned to the researcher. The Infant Behaviour Questionnaire –Revised was also used as an objective tool to accompany subjective findings.

Results: Key findings revealed 3 central themes with 9 subthemes to express the mothers’ journeys over time. Firstly ‘this can’t go on’ (retrospective, prior to osteopathic intervention), secondly ‘realising it will be okay’ (reflecting both infant and maternal maturation evident between interviews) and lastly ‘a happy baby is a happy mother’ (improvements promoting a happier relationship between mother and infant).
Conclusions: Professional understanding and support is crucial in the management of unsettled, fussy and irritable infants to minimise the negative effects on both infant and maternal health. Osteopathy appears beneficial in enhancing quality of life for both infant and mother during a difficult, yet self-limiting period of time.

Keywords: Unsettled/fussy/irritable, colic/crying, infant sleep, infant behaviour/development/temperament, Infant-Behaviour Questionnaire – Revised, interpretive description, maternal health, osteopathy.
INTRODUCTION

Unsettled, fussy and irritable (UFI) behaviour most commonly refers to excessive crying/infantile colic, problematic infant sleep or feeding and infants who are temperamentally difficult (Christl et al., 2013; Fisher et al., 2012; Viedma-Dodd, 2006). More than 45% of mothers experience problems with infant crying, feeding or sleeping (McCallum et al., 2011). Current theories behind UFI behaviour include dietary related factors, immaturity of the gastrointestinal system, imbalances in gut flora/microbiota, immaturity of the central nervous system, stress factors (pregnancy or birth-related), or psychological factors such an inadequate interaction between the infant and mother (Cowie, 2013; Lim, 2006). Infantile colic is a common diagnosis of exclusion, characterised by excessive and inconsolable crying, affecting up to 40 percent of infants, usually between the ages of 2 weeks to 4 months, with no specific cause identified (Dobson et al., 2012; Johnson, Cocker, & Chang, 2015). Debate surrounding the idea of colic as a condition appears to stem from its self-limiting nature as it is similar to that of the normal crying pattern typical of early infancy beginning in the first 2 weeks postpartum, peaking at 6 weeks and resolving by 3 months of age, reflecting normal infant maturation and development (Kurth, Kennedy, Spichiger, Hösli, & Zemp Stutz, 2011; Wurmser et al., 2006). Nonetheless, excessive crying and irritability is the leading reason parents will seek medical advice in early infancy (Douglas & Hiscock, 2010; Kurth et al., 2011; Kurth et al., 2014). Despite this fact, healthcare professionals continue to perceive UFI behaviour as ‘medically trivial’ (Bruning & McMahon, 2009; Talvik, Alexander, & Talvik, 2008).
The effects of such behaviour can have significant influences on the health of those involved. Stress on household relationships, negative mother-infant interactions, maternal stress, fatigue, depression and anxiety have been associated with caring for UFI infants (Bruning & McMahon, 2009; Giallo, Rose, & Vittorino, 2011). Furthermore UFI behaviour has been associated with the development of childhood behavioural and emotional problems in later life as well as early cessation of breastfeeding (Cornall, 2011; Fisher et al., 2012; Hemmi, Wolke, & Schneider, 2011; Howard, Lanphear, Lanphear, Eberly, & Lawrence, 2006). Rare but serious consequences can also include infant maltreatment, neglect and abuse such as shaken baby syndrome (Barr, 2014; Barr et al., 2014; Barr, Trent, & Cross, 2006; St James-Roberts, 2007; Talvik et al., 2008).

A variety of treatment and management options have been proposed targeting dietary or behavioural modifications, pharmacological intervention and manual therapy (Cowie, 2013). Nonetheless, current evidence is inconclusive for all options. Osteopathy is associated with anecdotal success for alleviating UFI infant symptoms in early infancy yet research is currently lacking to support these claims. One theory behind the osteopathic approach considers UFI symptoms to arise as a result of dysfunction in the cranial base following birth disrupting the function of the nervous system (Kotzampaltiris, Chou, Wall, & Crain, 2009; Lim, 2006). This study therefore aims to determine mothers' perspectives on the effectiveness of osteopathy for UFI behaviour, within the first year of life, and identify the osteopathic influence on infant
temperament, as measured by the IBQ-R, to enhance clinical understanding and inform future practice.

MATERIALS AND METHODS

Participants
Mothers seeking osteopathic care for their UFI infants were invited, by their osteopath, to participate in this study. Recruitment produced 7 mother-infant dyads from 3 different osteopaths (in the Auckland region) who were experienced in caring for infants. Infants were between 10 days and 9 weeks of age on enrolment and were described as unsettled, fussy or irritable by their mothers and their osteopaths.

Ethical considerations
The Unitec Research Ethics Committee (UREC) granted ethical approval for this project, application number 2014-1062, to be carried out between 11.12.14 and 02.08.15. Participant codes and pseudonyms were used to maintain privacy and confidentiality for all participants. Informed consent was applied throughout.

Data Collection
Qualitative and quantitative data were collected over 3 months for each mother-infant dyad between February 2015 and July 2015. Within this period supplementary data were collected to accompany the core interview transcripts. Mothers were provided with a small notebook to record thoughts and feelings between interviews. The osteopaths were requested to provide a
brief summary entailing their osteopathic care for the infants. The mothers were also requested to complete 3 sets of the Infant Behaviour Questionnaire-Revised (IBQ-R). Firstly upon first interview with a retrospective review on infant temperament, the second following the next scheduled osteopathic treatment to reflect current behaviour, and the last in the week leading up to the final interview to depict any change over time. Data collection generated 14 interview transcripts, 3 mother notebooks, 6 osteopath treatment summaries and 21 IBQ-R’s.

Data analysis

Interpretive description, based on the ideas of Sally Thorne, formed the theoretical framework for the analysis of qualitative data in this study. This method was chosen as it seeks to gain insight into human experience of those living the phenomenon to inform clinical understanding and practice (Thorne, 2008; Thorne, Kirkham, & MacDonald-Emes, 1997; Thorne, Kirkham, & O’Flynn-Magee, 2004). Quantitative analysis was performed in 2 phases using SPSS software revealing firstly descriptive statistics and secondly inferential statistics. One-way repeated measures ANOVA were the main statistical test used to determine significance of the questionnaire data. Post hoc analysis applied Tukey’s procedure for pairwise comparisons.

Consideration of rigour was essential in this project reflecting the emerging ideas surrounding interpretive description as a qualitative method and a lack of established guidelines (Thorne et al., 1997; Thorne et al., 2004). Triangulation and reflexivity were employed to establish and maintain rigour within this project.
RESULTS

QUALITATIVE FINDINGS

The qualitative findings for this study have been grouped into 3 parts for reader clarity. Part 1 presents the primary interview findings via theme extraction, part 2 summarises the mothers’ notebooks, and part 3 summarises the osteopathic treatment summary forms.

Introduction to the themes (part 1)

Each of the 3 themes in part 1 symbolises a timeframe throughout the 3 months between interviews to depict the mothers’ experiences and the effect of osteopathic treatment on infant temperament. Prior to osteopathic treatment, theme one ‘this can’t go on’ captures mothers’ desperation and willingness to try anything in search of an answer. Theme two ‘realising it will be okay’ represents the time between interviews where the concept of dyad maturation is evident - having a reason for the UFI behaviour and observing a reduction or resolution of symptoms creates a sense of hope and belief that it will get better and it will end. Lastly, theme three ‘a happy baby is a happy mother’, a reciprocal relationship within the mother-infant unit impacting on the whole family.
Part 1. Interviews

Theme one: This can't go on

Each mother acknowledged that the behaviour observed in their infant was ‘not normal’ either due to previous parenting experience or comparing their infant with others of a similar age. They knew something was wrong and commonly perceived their infants’ crying as pain. Theme one captures the mothers’ feelings of desperation and frustration upon first interview when unable to identify why their infants were so distressed.

Living life behind closed doors

For mothers in this study, daily life seemed to revolve around their infant’s constant needs and temperament. It was clear that mothers were somewhat housebound and limited in what they could achieve during their days and were partly fearful of outsider judgment. Mothers in this sample were generally sole caregivers throughout the day while partners were at work, and again throughout a broken nights sleep to allow partners to rest for work and also manage breastfeeding duties. Days involved endless settling attempts resulting in little infant sleep, if any. Consequently, infants reportedly became overtired further fuelling the cycle of distress. Significant stress, maternal exhaustion, frustration and desperation were commonly identified, as mothers continually searched for an answer to their infant’s behaviour. Inadequate maternal rest and a lack of control over the situation became both physically and emotionally draining understandably reducing coping capacity. It was clear that mothers were doing their best to manage their infants but they
eventually acknowledged that this situation could not go on and that they needed help.

“There were nights that I was completely desperate for someone to take her off me… I was so tired, I would be feeding her, and I would fall asleep myself… I was that exhausted… I fell asleep with her in my arms… and I thought, in my sleep, I thought I’d put her back into her bed, and I hadn’t, she was on me… and when that happens, you know that you’ve got to do something” (Anna, interview 1).

Seeking help and a gap in professional understanding

Interestingly, all of the mothers in this study identified a ‘pain cry’ characterising episodes of extreme distress causing their initial concerns. With symptoms persisting, mothers commonly chose to seek medical advice from general practitioners (GPs) fearing that something was wrong. As a result of this interaction, mothers in this study described feeling that GPs seemed to skim over their concern advising them to ‘wait it out’. This approach often resulted in mothers feeling as if they were overreacting, contributing to feelings of maternal inadequacy. Furthermore 1 mother in particular highlighted how the inconsistency between healthcare opinions further fueled her stress and confusion.

“They’re just like, “oh yeah, carry on, next question”…It’s just part of the parcel of having a baby. I guess, they see it as “oh well, it’s not that
“big a deal” but for a mum that’s not getting any sleep, it is a big deal”

(Alice, interview 1).

**Needing an answer**

The mothers in this study commonly reported trying ‘everything’ in their quest to ease infant distress and were left feeling at their ‘wits end’ about what to try next. Within this sample, mothers tried a variety of methods including sleep consultants, naturopaths, natural sleep drops, Infacol®, colic calm, gripe water, an oral pacifier, self-help books and modifications to maternal diet such as eliminating dairy products. In the absence of infant speech, mothers are forced to interpret nonverbal cues. Thus with UFI symptoms persisting for unknown reasons, mothers became desperate for an answer. Most mothers had never tried osteopathy before and admitted that a lack of knowledge about osteopathy initially made them reluctant. However with symptoms persisting, it was clear to the mothers that something was wrong with their infant and they felt that there must be another option hence their decision to try osteopathy generally as a ‘last resort’.

“I was just completely exhausted and just sick of the screaming… just wanted an answer from someone… someone to help me… stop the baby from crying” (Anna, interview 2).

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Infacol® wind drops contain the active ingredient Simethicone targeted at reducing air bubbles in the intestines (Cowie, 2013).
Theme two: Realising it will be okay

Theme two expresses the mothers’ journeys during the 3 months between interviews as they began to ‘realise that it will be okay’. Over this period of time a mutual maturation process was observed within the mother-infant dyad, as the infants grew and developed the mothers appeared to become more confident and comfortable in their parenting abilities.

Finding support and reassurance

All of the mothers in this study reported a positive experience with osteopathy. They described feeling their osteopath had listened to them, and some commented that their osteopath was the only one who did. Mothers seemed to benefit when their concerns were acknowledged. All of the infants in this study underwent at least 2 osteopathic treatments, depending on the severity of their UFI symptoms. Ongoing treatment and seeing a change in infant behaviour seemed to help the mothers, providing them with support, reassurance and a belief that they were actively helping their infant to get better.

“The best thing was when I went and saw [the osteopath] was that she was so confident and so definite… There was no umm-ing or ah-ing, and there was no “oh, well, it could be this or it could be that.” It was just “yes, I can feel this. Yes this would be affecting her.” Yeah, it was just really reassuring” (Anna, interview 1).
Gaining a deeper understanding

Once all the basic needs have been met and an infant is still in distress it is understandable for a mother to worry and wonder what is wrong. Osteopathy seemed to provide mothers with a deeper insight into how their infant was feeling in terms of their musculoskeletal function. When their osteopath was able to reproduce unsettled symptoms or distress during their physical examination, the mother felt the osteopath had finally found the source of the problem, which in turn appeared to provide mothers with a sense of relief and enhanced maternal confidence.

She [the osteopath] was fantastic. When she was touching [baby] you could see where it was hurting when she touched certain areas she [baby] would scream, so you knew that there was things happening in there… I thought that was quite incredible really.” (Alice, interview 2).

Finding their feet

Over time, infant maturation was inevitable yet interestingly maternal maturation seemed to occur in parallel, regardless of parenting experience. It was apparent that both mother and infant had become more familiar with each other, enhancing the interpretation of infant nonverbal cues. Mothers appeared to become more confident realising that they were not alone and that it was not their fault that their infant was unsettled.

“… He still can’t tell me what’s wrong but you learn... the different cries as they get older” (Kim, interview 2).
Theme three: A happy baby is a happy mother

Theme three represents the reciprocal relationship identified between each mother and her infant. Therefore infant behaviour understandably influenced mothers’ emotions throughout this study.

Having a ‘normal’ baby

Upon first interviews infant behaviour was often described compared to mothers’ expectations of what a ‘normal’ baby would be doing in contrast to their own. On the other hand, at the final interview mothers seemed to portray a sense of reaching normality, describing their infant as ‘happier’ and more comparable to their initial expectations, in turn making them happier. A resolution of the previously high pitched ‘pain cry’ was noted and when crying did occur it was less frequent, more predictable and often resulting from overtiredness. An improvement in sleep duration provided mothers with more time to rest and care for themselves as well as the ability to achieve daily tasks giving mothers more confidence and encouraging a more relaxed parenting approach.

“She's sleeping better, she's eating, and she's feeding well. She's doing all the things that you would expect a baby to be doing” (Anna, interview 2).
Restoring balance within the household

Constantly attending to an UFI infant meant that by the time partners arrived home from work, mothers were exhausted and in need of a break. Mothers with other children reported feelings of guilt at not being able to equally share their time between their children. At the final interview mothers reported that having a happier infant had resulted in happier parents and a positive influence on family life allowing more time for other children and loved ones, creating a sense of balance within the household.

“I took my [older] son to soccer on Saturday and she [baby] can just stay at home with dad… It [having a settled baby] makes a huge difference to the way the family works, and just for me to feel like I'm on top of everything (Sarah, interview 2).

Enjoying motherhood

When their infant became more settled, the associated restriction on the mothers’ lives was somewhat eased, restoring a sense of normality and balance. An improvement in infant temperament and a mutual maturation within the mother-infant dyad over time built a calmer and more content relationship for enjoyment and future bonding.

“I'm not uptight and stressed out anymore. Life is really busy at the moment for us… but I don't have that added stress of an upset baby. I'm just getting to enjoy her… and she's happy. It's just nice to be able to have a nice little bond and relationship with a baby… I was feeling
really tired before, when I wasn't sleeping, I wasn't coping with things, so yeah in that respect it's changed. Everything seems a lot easier in that part of my life” (Alice, interview 2).

Part 2. Mothers’ Notebooks

The main issue apparent in the notebooks was an inability to settle infants to sleep, thus causing them to become overtired and fuel the cycle of crying and unsettled behaviour. Mothers recorded feeling ‘tired and unable to enjoy’, ‘frustrated’, ‘exhausted and emotional when unable to settle’ their infant prior to osteopathic treatment. Mothers identified having to constantly attend to and hold their infants meaning that they were unable to get anything done and were unable to find time to care for themselves. Infants were described as ‘unsettled’, ‘never happy or content for longer than a minute or two’, ‘only peaceful when finally asleep’, and ‘waking from sleep after 20 minutes crying’. First time mothers recorded feeling like a ‘failure’, feeling ‘helpless’, ‘apprehensive’, ‘sad and angry at times’.

The infants seemed to show a general improvement in sleep quality and duration over time causing them to be ‘happier’ babies and thus reciprocated by the mothers’ emotions ‘more smiles, sleeps lots’ (2-3 hours after treatment), ‘will go to sleep within 10 minutes 90% of the time’, ‘some days only crying for 1 hour in total’, ‘I was calmer and more confident’. With treatment the infants became easier to settle to sleep meaning that both mother and baby were getting more rest, making them happier and
encouraging a more enjoyable relationship. With this improvement the mothers could find more time to get things done and care for themselves.

Part 3. Osteopath treatment summaries

Overstimulation of the sympathetic nervous system (SNS) with associated strain patterns through associated fascia and musculature was diagnosed in 2 of the 6 infant treatment summaries returned to the researcher. The remaining 4 returned summaries identified compression patterns either developing in utero or following birth, potentially related to the method of birthing. In this study osteopaths acknowledged factors such as an emergency caesarean section, ventouse extraction and labour duration –fast or prolonged –as relevant to this sample of UFI infants.

A cranial approach appeared to be favoured by all osteopaths as it was performed on all infants involved in this study. Other techniques involved gentle inhibition to reduce muscular tension, gentle articulation and balanced ligamentous tension (BLT) techniques. Cranial techniques were utilised on the gut, diaphragm, pelvis and cranium. Where pure cranial treatment was performed, UFI symptoms appeared to resolve within 2 treatments. Infants with SNS overstimulation improved within 2 to 4 treatments in this sample with treatment focusing on the central nervous system (CNS) to reduce vagus nerve activity and increase parasympathetic output; treatment also targeted the gut and the pelvis. All osteopathic treatment for the infants involved in this study had ended prior to the final interview. Notably, despite structural
improvements, 1 infant was experiencing ongoing symptoms at the end of this study and was referred to their GP for further investigation.

**QUANTITATIVE FINDINGS**

Of the 17 variables analysed using the IBQ-R data, 8 showed a significant change over time with a p-value of less than 0.05. The significant variables identified include 6 of the 14 temperament scales (distress to limitations, duration of orienting, smiling and laughter, soothability, falling reactivity/rate of recovery from distress and sadness) and 2 of the 3 factors used to identify relationships between the temperament scales (negative affectivity and orientating/regulation). The factors: negative affectivity (NEG) incorporates the mean scores for sadness, distress to limitations, fear and falling reactivity/rate of recovery from distress. Similarly, orientating/regulation (REG) involves the mean scores for low intensity pleasure, cuddliness, duration of orienting and soothing. The descriptive statistics for these 8 aspects are presented in *Table 1*. This table shows a gradual reduction in mean scores over time for infant distress to limitations, sadness and negative affectivity. On the other hand, a progressive increase over time was identified for duration of orienting, smiling and laughter, soothability, falling reactivity/rate of recovery from distress and orientation/regulation. *Table 2* shows the p-value for each significant variable and where the difference in mean was located throughout the study period. Overall these quantitative findings support a decrease in crying, fussing and distress accompanied by improvements in soothability and mood over the study period.
In summary these, quantitative findings provide encouraging support for the mothers subjective reports of an improvement in UFI behaviour over time. However within this sample, it is difficult to isolate the exact effect of osteopathic treatment and as a result positive effects may instead be due to a variety of interventions independently trialed during the study period.
Table 1. Descriptive statistics from raw data. Note: scores presented in this table are rounded to 1 decimal point

<table>
<thead>
<tr>
<th>Temperament scale</th>
<th>Questionnaire set number</th>
<th>Mean</th>
<th>Median</th>
<th>Standard Deviation</th>
<th>Minimum</th>
<th>Maximum</th>
<th>First Quartile</th>
<th>Second Quartile (Median)</th>
<th>Third Quartile</th>
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<tr>
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<td>6.0</td>
<td>1.3</td>
<td>3.0</td>
<td>6.3</td>
<td>4.1</td>
<td>6.0</td>
<td>6.1</td>
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<tr>
<td></td>
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<td>0.9</td>
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<td>4.9</td>
<td>3.3</td>
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<td>4.9</td>
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<tr>
<td></td>
<td>Set 3</td>
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<td>0.8</td>
<td>2.4</td>
<td>4.3</td>
<td>2.4</td>
<td>3.0</td>
<td>3.9</td>
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<td>Duration of orienting</td>
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<td>2.6</td>
<td>2.5</td>
<td>1.4</td>
<td>1.0</td>
<td>5.0</td>
<td>1.3</td>
<td>2.5</td>
<td>3.7</td>
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<tr>
<td></td>
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<td>1.5</td>
<td>1.6</td>
<td>5.9</td>
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<td>5.0</td>
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<tr>
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<td>1.8</td>
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<td>1.6</td>
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<td>1.5</td>
<td>2.0</td>
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<td>2.8</td>
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</tr>
<tr>
<td></td>
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<td>6.7</td>
<td>3.7</td>
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<td>3.5</td>
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<td>Falling reactivity/rate of recovery from distress</td>
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<td>4.1</td>
<td>2.8</td>
<td>3.3</td>
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<td>0.9</td>
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<tr>
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</table>
Table 2. Significant variables and the point at which the change occurred over the 3 month period of time, as measured by the 3 IBQ-R sets

<table>
<thead>
<tr>
<th>Significant variable</th>
<th>P-value</th>
<th>Between which sets of questionnaires (1, 2 or 3) was the change experienced</th>
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<td>Distress to limitations</td>
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<td>All three (1-2, 2-3, 1-3)</td>
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<td>Duration of orienting</td>
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<td>1-3 and 2-3</td>
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<tr>
<td>Smiling and laughter</td>
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<td>1-2 and 1-3</td>
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<td>Soothability</td>
<td>0.035</td>
<td>1-3</td>
</tr>
<tr>
<td>Falling reactivity/rate of recovery from</td>
<td>0</td>
<td>All three (1-2, 2-3, 1-3)</td>
</tr>
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<td>distress</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sadness</td>
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<td>1-2 and 1-3</td>
</tr>
<tr>
<td>NEG</td>
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<td>1-2 and 1-3</td>
</tr>
<tr>
<td>REG</td>
<td>0.032</td>
<td>1-3</td>
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</table>
DISCUSSION

This study provides insight into the lives of 7 mothers caring for UFI infants and their views on the effectiveness of osteopathy for their infant during this demanding time. Review of the sizeable data set led the researcher to focus on the extensive qualitative interview data, with the remaining data presented to supplement these primary findings. This investigation highlighted 3 central themes to convey the mothers’ journeys with their UFI infants and osteopathy over time with the hope of enhancing future clinical understanding and care.

This can’t go on

Reports of maternal desperation, frustration, stress, irritability, anger and fatigue in this study confirm the negative influence of UFI behaviour on maternal health, as reported in the literature (Barr et al., 2014; Keefe, Karlsen, Lobo, Kotzer, & Dudley, 2006; Kurth et al., 2010). UFI infant behaviour has also been linked to the development of maternal postnatal depression, anxiety and an increased risk for infant physical abuse (Bruning & McMahon, 2009; Giallo et al., 2011). Although the researcher chose not to enquire into such topics out of respect and sensitivity to the mothers in this study, 1 mother commented that she could understand how some women get depressed with the lack of sleep associated with caring for an UFI infant. Future research may choose to investigate the deeper emotional effects and how mothers manage and cope with their desperation. Interestingly, higher scores for infant distress to limitations, measured by the IBQ-R, were observed in the first set of questionnaires in this study. Gartstein & Rothbart, 2003 report that this finding
is generally associated with maternal feelings of incompetence, negative reinforcement from the infant and negative spousal emotional support.

The current study identified a crucial gap in professional understanding of a mother’s life behind closed doors caring for an UFI infant, their concerns and their need for an answer. Healthcare practitioners often deem UFI behaviour such as excessive crying or problematic sleeping as ‘medically trivial’ given its self-limiting tendency (Bruning & McMahon, 2009; Talvik et al., 2008). However as a consequence, a crucial opportunity to enhance the quality of life and health for those involved during this time is missed. A lack of support, understanding, reassurance and empathy toward this significant issue for mothers appears to stem from the tendency to underestimate UFI effects, most likely due to the lack of current knowledge surrounding its aetiology and management (Talvik et al., 2008). Furthermore, the current lack of knowledge regarding aetiology and appropriate management has led to inconsistency between healthcare approaches contributing to parental confusion in their search for an answer (Kaley, 2011; St James-Roberts, 2007). This idea was also highlighted by mothers in this study. This current study therefore highlights the need to increase healthcare practitioner awareness of the potential severity and significant impact of UFI behaviour on those involved to enable the best possible care and outcome.

Realising it will be okay

Osteopaths generally spend at least 30 minutes in consultation with their patients with listening forming a large component of diagnosis, treatment and
management. The role of listening, understanding, support and reassurance may often be overlooked in a healthcare setting yet within this study appeared to have benefits in the development of patient-practitioner trust and rapport to improve mothers support network and coping capacity supporting the ideas of Bruning and McMahon (2009). In light of the ongoing uncertainty surrounding the efficacy of the various currently proposed treatment options, it appears that support, empathy and reassurance to enhance maternal self-efficacy form the basis of current recommendations (Bruning & McMahon, 2009; Landgren & Hallström, 2011). Kheir (2012) further emphasise the importance of acknowledging parental concerns and consideration of parental health during this time.

The current study, although small, appears to support the use of cranial osteopathy for UFI infants as all of the infants in this study were treated cranially and experienced improvements in temperament (Hayden & Mullinger, 2006; Kotzampaltiris et al., 2009; Lim, 2006). Despite improvements, all of the mothers acknowledged that due to the nature of trial and error for this complaint, it was difficult to know exactly which method in isolation had the most effect. Nonetheless, osteopathy was considered beneficial to some extent by the mothers in all cases with the influence of age, ‘becoming bigger and stronger’, highlighted as a contributing factor by all mothers. The average age for infants presenting to osteopaths within this study, prior to enrolment, was 5 weeks with the range extending from 4 days to 8 weeks old at first treatment. This age range appears comparable to the general pattern of infant maturation and development where crying and
fussing typically peaks at 6 weeks of age (Kurth et al., 2011; Vik et al., 2009; Wurmser et al., 2006). This finding and the inability to recruit infants over 9 weeks of age provides further support that UFI behaviour is a complaint commonly resolving by 3 months of age. Yet other researchers have portrayed it to persist beyond 3 months highlighting the essential need for clarity surrounding the nature of UFI behaviour (Landgren and Hallström, 2011; Megel et al., 2011).

Adjusting to motherhood, whether first time mother or not, inevitably yields new challenges without the added stress of caring for an UFI infant. Interestingly as infants matured, a maternal maturation occurred in parallel similar to the ideas of Kurth et al. (2014) who states that as parenting experience increases, attitudes and responses to infant crying become calmer thus promoting a healthier dyad relationship. Similarly mothers in this study appeared to become more relaxed and confident in their parenting abilities over time.

The osteopathic approach is based on the use of palpation to examine the musculoskeletal system for dysfunction so not generally visible to an inexperienced eye. Osteopathic findings were commonly linked to the birth process an idea supported in the literature (Cowie, 2013; Kotzampaltiris et al., 2009; Lim, 2006). In this study 3 infants were born prior to 40 weeks gestation, 2 were overdue, and 2 were born at 40 weeks gestation. Interestingly, of the 7 infants, 2 were born via emergency caesarean section, 1 was cyanotic at birth and 1 required ventouse assistance. Other infants in
this study were delivered via either a prolonged or rapid labour. As a result, all infants involved in this study were found to have a level of musculoskeletal ‘dysfunction’ identified by their osteopath and considered to be contributing to their UFI symptoms. The positive change observed over time, affirmed by the osteopaths and mothers may provide preliminary support for the osteopathic approach toward UFI infants based on the theory of an underlying mechanical aetiology.

A happy baby is a happy mother

A reciprocal relationship is evident within the mother-infant dyad impacting on family dynamics. Improvements in infant health and behaviour appeared to enhance maternal health and quality of life further enhancing family dynamics. All except 1 of the infants in this study displayed a resolution of UFI symptoms by final interview. This finding supports the notion that UFI behaviour is a self-limiting issue within early infancy resolving by 3 months of age (Kurth et al., 2011; Vik et al., 2009; Wurmser et al., 2006). GP referral was recommended for the 1 infant who displayed ongoing symptoms however the mother of this infant reported that, although temporary, osteopathy was the ‘only’ method that provided relief during the time and therefore as a result the mother admitted becoming slightly reliant on this approach to cope.

Preconceived maternal ideas and expectations on ‘normal’ infant behaviour appeared to stem from either previous parenting experience or comparing their infant to others. It is crucial to highlight that there is variation within infant behaviour therefore ‘normal’ is a broad and ambiguous term. Nonetheless the
idea of normality was a key concept that emerged within this study. Upon first interview mothers insisted that their infants were ‘not normal’ and interestingly at the conclusion of this study infants more closely resembled mothers’ previous expectations surrounding infant temperament. The subjective improvement over time is also supported by the quantitative findings in this study showing a reduction in crying, fussing and distress, and improvements in soothability and infant mood over the study period. As a result of positive experiences, many of the mothers stated that they would not hesitate to return to their osteopath in future. Mothers also suggested a benefit in seeking osteopathy as a post birth ‘check up’ (to ensure infant comfort) even if there is no obvious issue. Furthermore 1 mother suggested that antenatal classes should introduce first time mothers to osteopathy as a postnatal option as many mothers are not yet aware of it.

Strengths and limitations
It is important to highlight that infants are a complex group to study due to the constant development and maturation processes occurring thus the lack of a control group may be viewed as a potential limitation to this project. Nevertheless, considering the associated vulnerability and sensitivity, a control group was not deemed to be appropriate as it was viewed as unrealistic within the desired sample. A strength to this study was that all participants were followed for 3 months to allow insight into infant development and long term treatment effects. Another strength was that the core themes were identified within the complete sample in this study, including both primiparous and multiparous women.
A limitation to this study emerged with the use of the IBQ-R. This questionnaire was originally designed to examine infants between the ages of 3 to 12 months and was chosen for this study to allow recruitment up to the age of 8 months old, to investigate UFI prevalence within the first year of life and allow the opportunity for retrospective investigation. Inability to recruit infants over the age of 3 months reflects the demographic of UFI infants presenting to osteopaths and, based on this sample, further supports the idea of symptom resolution by 3 months of age provided no underlying issue. In light of this finding, further studies investigating UFI infants may choose to utilise an adapted early infancy questionnaire, more applicable to early infant behaviour. Nonetheless, future research utilising the IBQ-R may benefit from more in depth analysis to inform findings. The quantitative findings in this study may raise concern regarding their reliability and validity however the primary findings of this study were centred on the qualitative component whilst a triangulation method was employed to increase the credibility of this study with the supplementary data. Although the small sample size of 7 mother-infant dyads may be viewed as a limitation, it also provided an opportunity for close examination and investigation to reveal key themes. Nonetheless, future studies are recommended to utilise a larger sample.

**CONCLUSION**

In summary it is essential to highlight that under the umbrella of UFI behaviour a clear spectrum exists extending from moderately unsettled to severely unsettled creating parental distress. Lack of current knowledge and awareness makes it common for healthcare professionals to underestimate
the potential severity of effects. Although UFI behaviour is generally benign and confined to early infancy, this study highlights a crucial need for understanding, sensitivity, support and reassurance to promote mother-infant health and enhance family dynamics during this time. This study provided insight into the lives and opinions of 7 mothers caring for UFI infants who would all recommend osteopathy in future as an effective approach in the management of UFI behaviour in the first year of life. Subjective reports of a positive change in infant behaviour were also supported by quantitative findings in this study presented as an overview of the IBQ-R data to inform future research and clinical practice. It is important to recognise that the variety of treatment and management options trialed made it difficult to isolate treatment methods thus making it difficult to determine the exact extent to which osteopathy influences UFI behaviour. Consideration of the inevitable influence of age and infant development further suggests that osteopathy is not solely responsible for the positive improvements reported in this study, instead it is likely that a combination of contributing factors are at play. Nonetheless, all mothers considered osteopathy beneficial for their UFI infants during this time improving the quality of life for those involved. Despite the need for future rigorous research to determine the exact aetiology and therefore appropriate treatment, this study acknowledges a potential beneficial role for osteopathy in the management of UFI infants from the perspective of mothers and emphasises the need for future research to further support anecdotal claims.
REFERENCES


Hemmi, M. H., Wolke, D., & Schneider, S. (2011). Associations between problems with crying, sleeping and/or feeding in infancy and long-term
behavioural outcomes in childhood: a meta-analysis. *Archives Of Disease In Childhood, 96*(7), 622-629 628p. doi:
10.1136/adc.2010.191312


Viedma-Dodd, A. M. (2006). *Fussy, unsettled and irritable infants - the mothers’ voice: How can you support me if you don’t understand me?* A research project submitted in partial fulfilment of the requirements for the degree of Masters of Osteopathy. Unitec New Zealand.


Section 3: Appendices
ATTENTION MOTHERS:

Are you currently undergoing osteopathic treatment for your infant?

- Would you describe your infant as unsettled, fussy or irritable?
- Does your infant cry uncontrollably to the point of distress?
- Is your infant younger than 8 months old?
- Would you like to share your experience of osteopathic treatment for your infant with us?

A Unitec Master of Osteopathy research study wants to explore your experience, as a mother, of caring for an unsettled, fussy or irritable infant and your perspective on the effect of osteopathy for this complaint during the first year of life. Your opinions and experience will provide us with valuable insight to guide future practice.

If you are interested in participation, please contact the researcher for more information:

Olivia Covich
Phone: 021 024 33921
Email: olivia_covich@hotmail.com

This study has been approved by the Unitec Research Ethics Committee
Appendix B: Approval of ethics application

This appendix presents the original approval letter, letter to the ethics committee due to amendments and the amended application approval letter.

Olivia Covich
11 Crystal Avenue,
Glendene
Auckland

21.8.14

Dear Olivia,

Your file number for this application: 2014-1062
Title: Osteopathic management of unsettled, fussy and irritable (UIF) infants through the eyes of the mother.

Your application for ethics approval has been reviewed by the Unitec Research Ethics Committee (UREC) and has been approved for the following period:

Start date: 2.8.14
Finish date: 2.8.15

Please note that:

1. The above dates must be referred to on the information AND consent forms given to all participants.

2. You must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.

You may now commence your research according to the protocols approved by UREC.

We wish you every success with your project.

Yours sincerely,

[Signature]

Gillian Whalley
Deputy Chair, UREC

cc: Elizabeth Niven
Cynthia Almeida
October 2014

Dear Readers

Thank you for reviewing this update to Olivia Covich’s Ethics application. You will recall that she originally planned to continue a previous study by inviting the original participants to complete one more infant questionnaire and to be interviewed. As readers you expressed some concerns that the original participants might not agree to continue, but we had a warm assurance from the first researcher that the women had enjoyed the original process and had made comments along the lines of ‘anything else we could do, we’d love to help’. You will see that our problems did not lie with the mothers.

What has happened is that the first researcher has been almost impossible to contact, delaying weeks before responding to emails, texts and phone calls, but then being promising and enthusiastic; and then the same pattern of delays and promises but no action. Olivia has decided she cannot wait for something that may or may not happen, and that she needs to have a different process to meet her original research aims. We have thus made a number of changes to the ethics application, and submit it with new information and consent forms, plus the interview outlines and the letters to osteopaths and the posters for the clinics.

In brief, Olivia plans to recruit mothers and infants with Unsettled, Fussy and Irritable (UFI) symptoms via emails to osteopaths who commonly treat these infants, by word of mouth, and by posters in osteopathy clinics. Interested mothers will be invited to contact Olivia. She will select the first 6 to 8 mothers whose infants will still be under 12 months by the end of the data collection period. She wants a sample of 6, and will begin with 8 in case there is some dropout. Olivia will contact the mothers, explain the project, and if the mothers wish to continue, will arrange a meeting time. At this meeting, Olivia will share more detailed information, invite participation, and if agreement is reached, invite the mothers to sign the consents, leaving a copy with them. A retrospective IBQ will be completed, an interview looking back will take place,
and the mother will be left with a second IBQ to be completed following the next osteopathic treatment. Interviews will focus on the mother’s experience of living with an UFI infant. This first interview may take place at the first meeting if the mothers request it, or another date will be set. The mother will also be left with a small notebook to record the words and phrases she is using over the next 3 months to describe her infant to others. An appointment will be made for a third interview at 3 months following this initial interview. At the third interview the mother’s experience will again be recorded, and a third IBQ will be completed.

Olivia will plot the mother’s experience and narrative of her own journey alongside the infant’s behaviour. The osteopath will also be asked to give a small written summary of their osteopathic care for each of the infants to briefly gauge the osteopathic view on the same situation. The osteopath will be informed of this on initial contact with the researcher but the researcher will not require this summary until after the final treatment, or after the last treatment before the researchers final meeting with the mother (3 months from initial meeting).

Although different research protocols are to be used, the central issue for the study remains the same. New material in the application is in red text.

Thank you again for considering this change in Olivia’s Ethics Application.

Regards

Elizabeth Niven
(Primary supervisor)

Olivia Covich
(Researcher)
Olive Covich
11 Crystal Avenue,
Glendene
Auckland

11.12.14

Dear Olivia,

Your file number for this application: 2014-1062
Title: Osteopathic management of unsettled, fussy and irritable (UFI) infants through the eyes of the mother.

Your application for amendments to the above ethics application has been reviewed by the Unitec Research Ethics Committee (UREC) and has been approved for the following period:

Start date: 11.12.14
Finish date: 2.8.15

Please note that:

1. The above dates must be referred to on the information AND consent forms given to all participants.

2. You must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.

You may now commence your research according to the protocols approved by UREC.

We wish you every success with your project.

Yours sincerely,

Sara Donaghey
Deputy Chair, UREC

cc: Elizabeth Niven
Cynthia Almeida
Appendix C: Participant information and consent forms

Participant Information Form

Dear Participant

You are invited to participate in a research study exploring your experience, as a mother, of both caring for an unsettled, fussy or irritable infant and of osteopathic treatment for your infant regarding this complaint. This research project identifies that a mother’s perspective will provide valuable insight to add richness to the current knowledge in this field and also guide future practice.

Research project title:

Osteopathic treatment for unsettled, fussy and irritable (UFI) infants: the mothers experience and effect on infant temperament

The aim of this study is to investigate the experience of mothers caring for, and undergoing osteopathic care for, their unsettled, fussy and irritable infant to determine the mothers perspective on the effect of this approach during the first year of life.

If you agree to participate, you will not be required to take part in a number of tasks. You will continue with your normal osteopathic treatment, allowing this study to follow you and your infant for a three-month period during the first year of your infant’s life. Participation will involve two conversational style interviews and a series of three questionnaires (the Infant Behavioural Questionnaire – Revised) that will be given to you to be completed throughout the process at three different stages:

1. On initial meeting, a first questionnaire takes a retrospective view to let us know what your infant was like prior to treatment (of what you can remember). A short introductory interview will also take place at this meeting or at another time that suits you

2. Following your next osteopathic treatment the second questionnaire gauges your infant’s current behaviour

3. A meeting at three months from the initial meeting to view changes over a longer time frame. An interview with the researcher will also be conducted at this stage, at a time that suits you, to reflect on and share
your experience, opinions and future attitudes on osteopathic treatment for your infant

Your osteopath will also be asked to write a small summary about your infant regarding their diagnosis and treatment, which you may review. The interviews will be audio recorded and transcribed for analysis. Your name and any information that may identify you in written reports will be kept confidential. Pseudonyms will be used for each participant in any reports. All information collected from you will be stored securely on a password-protected computer or in a locked cupboard, to which only the researcher and her supervisors will have access.

Between the initial meeting and final meeting for interview, you will be given a small notebook to record words or phrases that you find yourself thinking or using to describe your infant to friends or family.

**Inclusion criteria for participation:**

- You would describe your baby as unsettled, fussy or irritable
- Your infant is younger than 8 months old at enrolment
- You are fluent in the English language
- Your infant is having, or has had, osteopathic treatment for this behaviour

Written consent and, verbal agreement will be established at the initial meeting and reconfirmed at final interview. This agreement does not stop you from changing your mind if you wish to withdraw from the study. The transcribed interviews will be returned to you, following the final interview, for comment before any reports are written. If you wish to withdraw from this study I ask that this be done within 2 weeks after returning the interview transcription to you.

Please feel free to contact me if you need more information about this study, 021 024 33921. You can also contact my research supervisor Elizabeth Niven, phone 021 654 935.

Regards,

Olivia Covich

*Master of Osteopathy Student,*

*Unitec New Zealand*

**UREC REGISTRATION NUMBER: 2014-1062**

This study has been approved by the UNITEC Research Ethics Committee from 11.12.14 to 02.08.15. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 8551). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Participant Consent Form

Research project title:  
*Osteopathic treatment for unsettled, fussy and irritable (UFI) infants: the mothers’ experience and effect on infant temperament*

I have had the research project explained to me and I have read and understand the information sheet given to me.

I understand that I do not have to take part in this research study, should I choose not to participate, and may withdraw at any time up to two weeks after receiving the interview transcript from the researcher.

I understand that all the information I provide will be kept confidential and used for research purposes only.

I understand that everything I say in the interview will be audio recorded and transcribed. I understand that I may request the removal of information after the interview or when I receive the transcripts. It will be kept confidential, and none of the information published will identify me. I also understand that all the information that I give will be stored securely for a period of 5 years.

**By signing this form it is assumed that the participant has read and agrees to all of the information supplied.**

I have had time to consider the information given and provide my consent to be a part of this study.

*Participant Name:* .................................

*Participant Signature:* ..........................  *Date:* ..........................

**UREC REGISTRATION NUMBER:** 2014-1062

This study has been approved by the UNITEC Research Ethics Committee from 11.12.14 to 02.08.15. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 8551). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix D: Introductory and final interview guides

First meeting outline

1. Information given and consent gained (both written and verbal)

2. Details – check inclusion criteria, infant age etc. issue participant code

3. Distribute IBQ-R (retrospective and another for current/following next osteopathic treatment)

4. Outline of interview given – approximately 30 minutes, withdrawal conditions – within 2 weeks after returning transcription – and time for any questions at the end, pencil in a time to meeting in three months time

5. Small introductory interview – this first meeting aims to explore the mother’s story/ view on her infant’s behaviour and her experience of caring for the infant up until this point and prior to osteopathic intervention. The idea of the interview is for the researcher to listen to the mother’s story and use the following topics as a guide to direct conversation as opposed to questions and answers
Introductory interview question guide

- What does unsettled, fussy and irritable behaviour mean to the mother in her case –how does the baby show UFI symptoms
  - DP, duration of symptoms
  - Mothers experience of caring for an UFI infant
- Feeding –breastfeed or bottle? Formula, mother’s milk or solids. If breastfed –how is that for the mother, any problems or pain –how often is baby feeding (normal is approximately every 3-4 hours), spilling/reflux, difficulty burping, bowel habits –how often (1-3 x per day normal)
- Sleeping –how often and duration of sleeps (babies sleep a lot initially, normally 9-18 hours per day, baby should sleep 3-4 hours in one go)
- Infant’s general health and current wellbeing, gaining weight normally?

Pregnancy

- How was the pregnancy for the mother/her general health –how did she feel, any nausea or vomiting etc. what did she do and when did she go on maternity leave if working
- Health of infant in pregnancy, positioning during pregnancy –did infant have a favoured position in the womb
- Mothers diet –any alcohol or smoking during the pregnancy
- Any concerns or complications in the pregnancy
- Any illnesses or trauma during pregnancy
- Was this the first child

Birth

- How was your labour?
  - Gestation/how far along when waters broke/onset of labour (natural/spontaneous or induced labour –if induced how and why), duration of labour –contractions (12 hour normal average) and pushing (1 hour normal average), any pain management such as an epidural, pethidine etc.
• Delivery type —where/how (water, hospital, home etc.), position of mother, duration
• Infant presentation/positioning at birth —occiput anterior or posterior, breech, sideways —any trauma or assistance required (ventouse, forceps, caesarean) and why?
• Baby length and weight (normal is 6-10 pounds)
• Any complications with the birth
• Health at birth, APGAR scores (normal >7/10) —tests 5 aspects: appearance, pulse, grimace, activity and respiration after birth to detect overall health and rated out of ten —a score of 2 is the highest for each factor. Any illnesses in the infant —any special care after birth
• Infant milestones (more relevant in older babies) —any concerns, vaccinations —antibiotics or vaccinations can influence gut flora (both baby and mother if breastfed)

The Mother
• How are you finding motherhood, how is the infant affecting the mothers health and wellbeing —sleep, lifestyle, emotions, relationships, experience of caring for the infant. Mother’s current diet is relevant if breastfeeding (garlic, onions, tomatoes, dairy) —often breastfed for up to 6-12 months old
• Household/family dynamics, how has this infant’s behaviour impacted on this
• What made the mother choose osteopathy for her infant —was this her first time experiencing osteopathic treatment in general or for an infant
• How is the osteopathic treatment going currently, how many treatments have been given
• Did the mother try anything else prior to osteopathy

Ask the mother if there is anything else she thinks would be important to know and answer any questions she may have
Final interview question guide

The aim of this interview is to reflect on the past 3 months and gauge the mother’s perspective on both caring for her infant and the effect of osteopathic treatment for her UFI infant. (Cover any changes in infant behaviour, perspective on the effect of osteopathic treatment and any impact on the mother and the household dynamics –compare before treatment and current situation).

Infant Behaviour

- How has the infant been since our last meeting –how has daily life & infant behaviour changed (if it has) DP –if still symptoms is there a daily pattern to it e.g. worse at night/how does it compare to previously
- What does a typical day involve for you and your infant now 3 months down the track
- How is the infant feeding, sleeping
- Any significant events over the past 3 months
- Any improvement? Is the infant still displaying UFI behaviour –if so has it changed in its presentation?
- How is the infants general health, current wellbeing –are they gaining weight as to be expected
- Milestones –any concerns so far?

The Mother

- How are you finding motherhood –if first child, how did your expectations compare to reality? Was it what you expected?
- Current wellbeing of the mother –daily life, sleep, relationships, emotions
- How is life in your household currently? How might it of changed over the past three months –reflect on/compare the previous and current impact of infant behaviour on the household
- Did you decide to have any osteopathic treatment for yourself?
• Looking back, now 3 months on from seeking osteopathic help what are some words that come to mind about how you felt at that time? How does that compare to your current situation?

Osteopathic Treatment
• How many treatments did you end by having for your infant/when did they stop or are they ongoing
• What did you think of the treatment –did it make a difference?
• Are you glad you tried osteopathy? Did you use anything else in conjunction with the treatment or just osteopathic treatment –so if improved do you credit the treatment for that
• From a mother’s perspective –is osteopathy an effective approach in addressing this unsettled, fussy and irritable infant behaviour within the first year of life?
• Would you recommend osteopathy for babies to your friends?
• What is your future attitude toward this approach for infants during the first year of life?

Lastly
• Does the mother have any questions for me?
• Gain permission to do a telephone follow up during data analysis if more information required for any reason
Appendix E: Osteopath treatment summary template form

Osteopath treatment summary

Dear Osteopath

Please give a small summary of your osteopathic care for ____________________________

(Insert infant/mother code)

Include any information you feel is relevant this may include the following:

- General impression of the infant prior to treating and throughout treatment
- Diagnosis
- Treatment – any particular style (e.g. cranial, structural), target areas, how did the tissues respond/how many treatments were given
- Your impression of the changes in the unsettled, fussy and irritable behaviour in the infant/prognosis

_________________________________________________________

_________________________________________________________

_________________________________________________________

_________________________________________________________

_________________________________________________________

_________________________________________________________

_________________________________________________________

_________________________________________________________
Appendix F: Infant behaviour Questionnaire –Revised (IBQ-R)

This appendix presents the documents relevant to the use of the IBQ-R in this project. Please note that due to the length of both the questionnaire itself and the IBQ-R scoring procedure, only an excerpt of each has been provided in this appendix with the appropriate reference.

Permission to use the questionnaire

The following email was received on the 29th of May 2014

Dear Olivia,

You are approved to use the measures from our website for research purposes.

You can download the appropriate questionnaire(s) and other relevant information from the following page http://www.bowdoin.edu/faculty/s/sputnam/rothbart/pdf/ and input the following information when prompted:

Username: darkstar
Password: darkstar

Although you may download any of the measures from this page, if you decide to use an instrument other than the one(s) you originally indicated, we ask that you complete a new request form at http://www.bowdoin.edu/~sputnam/rothbart-temperament-questionnaires/request-forms/

If you have difficulty in opening or printing the documents, please refer first to our Frequently Asked Questions page (http://www.bowdoin.edu/~sputnam/rothbart-temperament-questionnaires/faq/#Answer18) and email me at sputnam@bowdoin.edu if this does not resolve your problem.

My collaborators and I wish you the best of luck in your research and hope that you will contact us at the completion of your study to share the results.

Sincerely,

Sam Putnam
Associate Professor of Psychology
Bowdoin College
Infant Behavior Questionnaire - Revised

Subject No. ____________ Date of Baby’s Birth ______ _______ month day year
Today’s Date ____________ Age of Child ______ _______
mos. weeks
Sex of Child ____________

INSTRUCTIONS:
Please read carefully before starting:

As you read each description of the baby’s behavior below, please indicate how often the baby did this during the LAST WEEK (the past seven days) by circling one of the numbers in the left column. These numbers indicate how often you observed the behavior described during the last week.

<table>
<thead>
<tr>
<th>(1) Never</th>
<th>(2) Very Rarely</th>
<th>(3) Less Than Half the Time</th>
<th>(4) About Half the Time</th>
<th>(5) More Than Half the Time</th>
<th>(6) Almost Always</th>
<th>(7) Always</th>
<th>(X) Does Not Apply</th>
</tr>
</thead>
</table>

The “Does Not Apply” (X) column is used when you did not see the baby in the situation described during the last week. For example, if the situation mentions the baby having to wait for food or liquids and there was no time during the last week when the baby had to wait, circle the (X) column. “Does Not Apply” is different from “Never” (1). “Never” is used when you saw the baby in the situation but the baby never engaged in the behavior listed during the last week. For example, if the baby did have to wait for food or liquids at least once but never cried loudly while waiting, circle the (1) column.

Please be sure to circle a number for every item.
Feeding

During feeding, how often did the baby:
1 2 3 4 5 6 7 X . . . (1) lie or sit quietly?
1 2 3 4 5 6 7 X . . . (2) squirm or kick?
1 2 3 4 5 6 7 X . . . (3) wave arms?
1 2 3 4 5 6 7 X . . . (4) notice lumpy texture in food (e.g., oatmeal)?

In the last week, while being fed in your lap, how often did the baby:
1 2 3 4 5 6 7 X . . . (5) seem to enjoy the closeness?
1 2 3 4 5 6 7 X . . . (6) snuggle even after she was done?
1 2 3 4 5 6 7 X . . . (7) seem eager to get away as soon as the feeding was over?

How often did your baby make talking sounds:
1 2 3 4 5 6 7 X . . . (8) while waiting in a high chair for food?
1 2 3 4 5 6 7 X . . . (9) when s/he was ready for more food?
1 2 3 4 5 6 7 X . . . (10) when s/he has had enough to eat?

Sleeping

Before falling asleep at night during the last week, how often did the baby:
1 2 3 4 5 6 7 X . . . (11) show no fussing or crying?

During sleep, how often did the baby:
1 2 3 4 5 6 7 X . . . (12) toss about in the crib?
1 2 3 4 5 6 7 X . . . (13) move from the middle to the end of the crib?
1 2 3 4 5 6 7 X . . . (14) sleep in one position only?

After sleeping, how often did the baby:
1 2 3 4 5 6 7 X . . . (15) fuss or cry immediately?
1 2 3 4 5 6 7 X . . . (16) play quietly in the crib?
1 2 3 4 5 6 7 X . . . (17) cry if someone doesn’t come within a few minutes?

How often did the baby:
1 2 3 4 5 6 7 X . . . (18) seem angry (crying and fussing) when you left her/him in the crib?
1 2 3 4 5 6 7 X . . . (19) seem contented when left in the crib?
1 2 3 4 5 6 7 X . . . (20) cry or fuss before going to sleep for naps?

When going to sleep at night, how often did your baby:
1 2 3 4 5 6 7 X . . . (21) fall asleep within 10 minutes?
1 2 3 4 5 6 7 X . . . (22) have a hard time settling down to sleep?
1 2 3 4 5 6 7 X . . . (23) settle down to sleep easily?

When your baby awoke at night, how often did s/he:
1 2 3 4 5 6 7 X . . . (24) have a hard time going back to sleep?
1 2 3 4 5 6 7 X . . . (25) go back to sleep immediately?

When put down for a nap, how often did your baby:
1 2 3 4 5 6 7 X . . . (26) stay awake for a long time?
1 2 3 4 5 6 7 X . . . (27) go to sleep immediately?
1 2 3 4 5 6 7 X . . . (28) settle down quickly?
**IBQ-R scoring procedure excerpt**

*(Full document retrieved from http://www.bowdoin.edu/faculty/s/sputnam/rothbart/pdf/ with permission)*

**SCORING PROCEDURE**

**INFANT BEHAVIOR QUESTIONNAIRE - REVISED**

Scale scores for the Infant Behavior Questionnaire - Revised represent the mean score of all scale items applicable to the child, as judged by the caregiver. Scales' scores are to be computed by the following method:

1. Sum all numerical item responses for a given scale. Note that:
   a) If caregiver omitted an item, that item receives no numerical score;
   b) If caregiver checked the "does not apply" response option for an item, that item receives no numerical score;
   c) Items indicated with an R are reverse items and must be scored in the following way:

<table>
<thead>
<tr>
<th>Original Score</th>
<th>Reverse Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>1</td>
<td>7</td>
</tr>
</tbody>
</table>

2. Divide the total by the number of items receiving a numerical response. Do not include items marked "does not apply (N/A)" or items receiving no response in determining the number of items.

For example, given a sum of 47 for a scale of 12 items, with one item receiving no response, two items marked "does not apply," and 9 items receiving a numerical response, the sum of 47 would be divided by 9 to yield a mean of 5.22 for the scale score.

**Note:** Most statistics programs will carry out these steps for you. Users of SPSS can copy the following commands into a syntax file to reverse items and calculate scale scores. The syntax assumes that items are titled "ibqr1", "ibqr2", "ibqr3", etc. It is also assumed that no score was entered when caregivers omitted an item or checked "Does not apply".

```plaintext
COMPUTE ibqr1r = (8 - ibqr1).
COMPUTE ibqr14r = (8 - ibqr14).
COMPUTE ibqr117r = (8 - ibqr117).
COMPUTE ibqr111r = (8 - ibqr11).
COMPUTE ibqr16r = (8 - ibqr16).
COMPUTE ibqr19r = (8 - ibqr19).
COMPUTE ibqr76r = (8 - ibqr76).
COMPUTE ibqr163r = (8 - ibqr163).
COMPUTE ibqr176r = (8 - ibqr176).
COMPUTE ibqr179r = (8 - ibqr179).
COMPUTE ibqr182r = (8 - ibqr182).
COMPUTE ibqr185r = (8 - ibqr185).
COMPUTE ibqr188r = (8 - ibqr188).
COMPUTE ibqr191r = (8 - ibqr191).
COMPUTE ibqr22r = (8 - ibqr22).
COMPUTE ibqr24r = (8 - ibqr24).
```
**Information on the IBQ-R temperament scales**


- **Activity Level:** Movement of arms and legs, squirming and locomotor activity.

- **Distress to Limitations:** Baby's fussing, crying or showing distress while a) in a confining place or position; b) involved in caretaking activities; c) unable to perform a desired action.

- **Approach:** Rapid approach, excitement, and positive anticipation of pleasurable activities.

- **Fear:** The baby's startle or distress to sudden changes in stimulation, novel physical objects or social stimuli; inhibited approach to novelty.

- **Duration of Orienting:** The baby's attention to and/or interaction with a single object for extended periods of time.

- **Smiling and Laughter:** Smiling or laughter from the child in general caretaking and play situations.

- **Vocal Reactivity:** Amount of vocalization exhibited by the baby in daily activities.

- **Sadness:** General low mood; lowered mood and activity specifically related to personal suffering, physical state, object loss, or inability to perform a desired action.

- **Perceptual Sensitivity:** Amount of detection of slight, low intensity stimuli from the external environment.

- **High Intensity Pleasure:** Amount of pleasure or enjoyment related to high stimulus intensity, rate, complexity, novelty, and incongruity.

- **Low Intensity Pleasure:** Amount of pleasure or enjoyment related to situations involving low stimulus intensity, rate, complexity, novelty, and incongruity.

- **Cuddliness:** The baby's expression of enjoyment and molding of the body to being held by a caregiver.

- **Soothability:** Baby's reduction of fussing, crying, or distress when the caretaker uses soothing techniques.

- **Falling Reactivity/Rate of Recovery from Distress:** Rate of recovery from peak distress, excitement, or general arousal; ease of falling asleep.
Appendix G: Data Analysis

This appendix contains additional interview data to show evidence in the development of ideas and themes in analysis. It also contains a photograph of an excerpt of the researchers reflective journal to show early engagement in data to construct research ideas.

### Development of theme 1: This can’t go on

<table>
<thead>
<tr>
<th>Raw data/quotes</th>
<th>Ideas within</th>
</tr>
</thead>
</table>
| "It was just constant, loud screaming, like something was wrong. You could tell that it wasn’t normal…/…You know that something’s not right… you can see that they’re sore… It would be like a pain cry… it’s a different sort of cry" (Anna, interview 1). | - Sleep deprivation  
- Trying their hardest – guilt when not spending time with other children or partner  
- Desperation  
- Full on days and broken nights  
- Frustration  
- Wits end/had enough – unfamiliar situation and unsure what to do |
| "I was really desperate. I mean… two hours sleep a day. I was like a zombie…/…and also because she just looked so upset all the time… You’re looking at this tiny little baby that is just not happy and that’s uncomfortable and in distress. Yeah, I was definitely desperate. I would’ve paid whatever to get it fixed" (Alice, interview 1). | 'This is not normal’ – something’s wrong – what’s wrong with my baby |
| "[Mother feeling] a bit lost because I can’t do anything for him’ (Kim, interview 1). | - Self doubt – what am I doing wrong and why can’t I make my baby feel better.  
- Guilt and self blame (if breastfeeding – what have I eaten to upset my baby)  
- Feeling helpless unable to control infant distress |
| "[Each night] I knew I was in for a rough night… I was dreading it. I can definitely see how women get depressed… if that goes on too long, that lack of sleep. Man, it can get you down. Then, if you don’t have the help. I’m a pretty positive person, but I had some really bad days” (Anna, interview 1). | - Searching for an answer and willing to try anything  
- Exhaustion – risks  
- Confusion – lack of clarity surrounding aetiology means trial and error and lots of different opinions – lack of consistency, mothers don’t know what to do  
- Seeking professional help – often general practitioner – and feeling dismissed as if they are overreacting – lack of understanding and support |

#### Key ideas:
- Living life behind closed doors
- Seeking help and a gap in professional understanding
- Needing an answer
### Development of theme 2: Realising it will be okay

<table>
<thead>
<tr>
<th>Raw data/quotes</th>
<th>Ideas within</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;I knew it was her tummy. I remember saying it from the third week. And I remember saying it to [the osteopath], and she was the only one that... actually listened and was like, &quot;Yeah her abdomen's all blah, blah, blah&quot; (Anna, interview 2).</td>
<td>• Finally finding someone to listen and acknowledge the problem — it’s not just the mother overreacting</td>
</tr>
<tr>
<td>&quot;I feel like he was quite bad when we started going to see [the osteopath], it’s why I went to her. I was like &quot;oh, I don’t know, I’ve tried everything else. I don’t know&quot; so I went there and then that, started getting better from there...//... The more [treatment] we had, the better he just seemed to keep getting” (Emma, interview 2).</td>
<td></td>
</tr>
<tr>
<td>&quot;That’s where I think the osteo helps, is that you don’t know why they’re upset and you can’t quite pin point it and it seems to eliminate all those things that you can’t see... They’re not tired, they’re not hungry, but they’re still crying... Yeah. You’ve got rid of all the basics, it’s like &quot;What can I do next?&quot; (Sarah, interview 2).</td>
<td></td>
</tr>
<tr>
<td>&quot;...Realisation that it’s normal...//... It doesn’t matter how much maternal instinct you have. I think anybody would find it hard...//...It’s just whatever works for you” (Lisa, interview 2).</td>
<td></td>
</tr>
<tr>
<td>&quot;With the osteo, that really helped. I noticed some... like a big difference straight away. So I was really impressed with that” (Alice, interview 2).</td>
<td></td>
</tr>
<tr>
<td>&quot;I was kind of not expecting it [osteopathy] to work, but it was a last resort” (Shannen, interview 1).</td>
<td></td>
</tr>
<tr>
<td>&quot;I guess the more relaxed I am, the more relaxed she’s going to be” (Shannen, interview 2).</td>
<td></td>
</tr>
<tr>
<td>&quot;Finally finding someone to listen and acknowledge the problem — it’s not just the mother overreacting</td>
<td></td>
</tr>
<tr>
<td>Someone to provide support and reassure the mother that their infant will be okay</td>
<td></td>
</tr>
<tr>
<td>Osteopathy allowed ongoing support with follow up appointments to care for mother-infant dyad</td>
<td></td>
</tr>
<tr>
<td>Maturation of both infant and mother as they adjust to each other</td>
<td></td>
</tr>
<tr>
<td>Closer to an answer — osteopathic physical findings linked to symptoms giving mother hope that they had found the cause — having a reason for the symptoms, previously fear of the unknown not being able to identify the issue</td>
<td></td>
</tr>
<tr>
<td>Becoming familiar with their infant</td>
<td></td>
</tr>
<tr>
<td>Symptom reproduction</td>
<td></td>
</tr>
<tr>
<td>Resolution or reduction of UFI symptoms over time — seeing a change, relief, reduction in parental stress</td>
<td></td>
</tr>
<tr>
<td>Adjusting to a new life — first time mother or addition of another baby/expanding family</td>
<td></td>
</tr>
<tr>
<td><strong>Realising</strong> it’s normal to feel the way they’re feeling, it’s common and it will be okay — they’re not alone</td>
<td></td>
</tr>
<tr>
<td><strong>Realising</strong> it’s not their fault and they are not a bad mother</td>
<td></td>
</tr>
<tr>
<td>Satisfaction in knowing you are actively doing something/trying to help your baby feel better</td>
<td></td>
</tr>
<tr>
<td>Learning to understand baby’s cues</td>
<td></td>
</tr>
<tr>
<td>Gaining freedom with infant improvements</td>
<td></td>
</tr>
</tbody>
</table>

**Key ideas:**

- Finding support and reassurance
- Gaining a deeper understanding
- Finding their feet
Development of theme 3: A happy baby is a happy mother

<table>
<thead>
<tr>
<th>Raw data/quotes</th>
<th>Ideas within</th>
</tr>
</thead>
<tbody>
<tr>
<td>“You’re [the osteopathic treatment] not just having an effect on the baby, you’re having an effect on a family because you’re helping the mum too” (Alice, interview 1).</td>
<td>• A ‘normal’ baby – doing all the things that the mothers previously expected</td>
</tr>
<tr>
<td>“When they are settled, everything changes, you can cope again… but when they are unsettled, it is really draining. It is hard work” (Sarah, interview 1).</td>
<td>• Happier babies = happier mothers and vice versa (a reciprocal relationship between mum and baby affecting each others emotions)</td>
</tr>
<tr>
<td>“I feel like I can actually go out and do stuff [now], or do stuff at home and not have to always be holding him” (Emma, interview 2).</td>
<td>• Now content and a ‘completely different baby’</td>
</tr>
<tr>
<td>“I’m happier because I don’t have a screaming baby all the time and I can get things done… //… It’s just easier going out [now], before it was just so hard… I couldn’t even drive anywhere without her just screaming” (Anna, interview 2).</td>
<td>• More time for other loved ones – children, partner, and household jobs = Positive impact on family life and creating a balance</td>
</tr>
<tr>
<td>“I’m way calmer. I’m getting a lot more sleep. You know, that helps, [and also I’m] just getting the hang of everything… //… If I’m happier, then he’s happier, so it’s like a cycle… //… He has his ups and downs, but I think he’s just a normal baby” (Lisa, interview 2).</td>
<td>• Mothers more confident in their abilities and more satisfaction</td>
</tr>
<tr>
<td>“He still has a bit of a cry time at dinner time… but that’s normal for a baby, but before it was all the time he was constantly upset” (Kim, interview 2).</td>
<td>• A combination of contributing factors – age and growth, trialing many different methods means it is difficult to isolate one as better than another</td>
</tr>
<tr>
<td>“Now she’s being the calm baby that I kind of envisioned” (Alice, interview 2).</td>
<td>• All mothers reported positive experiences with osteopathy emphasising that they would recommend it in the future and go back if needed</td>
</tr>
<tr>
<td>“She’s a lot more predictable now, and she seems a lot happier and calmer. It just makes everything easier, because a happy baby is a happy mother” (Sarah, interview 2).</td>
<td>• Gaining freedom as baby improves</td>
</tr>
<tr>
<td>“He’s happy because he’s not crying all the time, he’s getting better sleep and his awake time is happier and then it makes us happier… and when my husband gets home from work, he actually gets to enjoy spending time with him rather than me handing him a crying baby” (Emma, interview 2).</td>
<td>• Now that baby is happier the mother, and family, can enjoy the good times and build a healthier relationship enhancing quality of life</td>
</tr>
<tr>
<td>“I’d put it [the improvement] to that [osteopathic treatment]… and also just getting her a little bit stronger, a bit bigger… but I definitely do think it helped, especially to get me through that time as well” (Sarah, interview 2).</td>
<td></td>
</tr>
<tr>
<td>“Honestly, I am so amazed, if I could tell anybody, any new mother… if I’d known that first time around, even if my baby was normal” (Anna, interview 1).</td>
<td></td>
</tr>
<tr>
<td>“I’m not really into that kind of stuff [osteopathy]… but it really did seem to work… I recommend it to everybody… //… if we had issues in the future I’d definitely go back” (Shannen, interview 2).</td>
<td></td>
</tr>
<tr>
<td>“I definitely think that it’s [osteopathy] helped, but I don’t know whether that was the only thing” (Emma, interview 2).</td>
<td></td>
</tr>
<tr>
<td>“Before going to a paediatrician and paying and getting them on medication, you could totally go to an osteo and see some results … //… If I have a third baby… no hesitations… I’d go back and see her [the osteopath] and just make sure everything was okay with the baby” (Anna, interview 2).</td>
<td></td>
</tr>
<tr>
<td>“I would definitely recommend it [osteopathy] to others… //… it just helps, they’re relaxed and content afterwards” (Kim, interview 2).</td>
<td></td>
</tr>
</tbody>
</table>

Key ideas:

› Having a ‘normal’ baby
› Restoring balance within the household
› Enjoying motherhood
Self doubt, blame... my fault!

- Personal assumptions, ideas & expectations on unsettled babies → beginning to see that there is a spectrum of severity
  - Unsettled → very unsettled
- Interview Qs flowing better, allowing for more indepth insight → age.
- NBO K - some Qs reported to be irrelevant to babies too young and not yet reaching task items
- Volume of data overwhelming
- Wanted to recruit infants closer to 8 months old to include diversity in all ages but just didn't happen - possibly showing a theme/trend of issue more prevalent in younger infants - first few months - natural resolution? self-limiting? possible imitation

- Mothers' experienced vs. steps lit literature - relaxed?
  - 1st time mums/literature
- Taming very common link to UFE?
- Sleep deprivation (zombie mum, mummy brain)
  - Full on 24/7 → full time job.
- Isolating - solo "shock" in baby
  - Can't put them down to sleep (constant demands)
  - Desperation - trying everything
  - Wintering to do best for baby
  - Osteo seems to be management = quality of life as opposed to magical cure

- Mums/ us have hands full - commented they find difficult to reply to a text, let alone fill out notebook but good idea in theory dependent on frequency.
- Cost of tv - mums willing to pay → desperation.
Appendix H: International Journal of Osteopathic Medicine (IJOM) author information guidelines excerpt

Edited excerpt provided due to length, full document retrieved from http://www.journalofosteopathicmedicine.com/content/authorinfo

The Guidelines are separated into the following sections:

A Online Submission  
B Types of Contributions  
C General Guidance  
D Preparation of the Manuscript  
E Specific Guidance for Original Research Articles  
F Specific Guidance for Protocols  
G Post Acceptance

TYPES OF CONTRIBUTIONS - word limits exclude tables, figures and reference list.

For all the following types of contributions authors are requested to consider the international readership of the journal and to be aware of the need to explain local contexts or define terminology where these are likely not to be commonly understood internationally.

Reviews and Original Articles (2,000 - 5,000 words)

These should be either (i) reports of new findings related to osteopathic medicine that are supported by research evidence. These should be original, previously unpublished works; or (ii) a critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine.

Before you begin

Ethics in publishing

For information on Ethics in publishing and Ethical guidelines for journal publication see https://www.elsevier.com/publishingethics and https://www.elsevier.com/journal-authors/ethics.

Human and animal rights

If the work involves the use of human subjects, the author should ensure that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans, http://www.wma.net/en/30publications/10policies/b3/index.html; Uniform Requirements for manuscripts submitted to Biomedical journals, http://www.icmje.org. Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

All animal experiments should be carried out in accordance with the U.K. Animals (Scientific Procedures) Act, 1986 and associated guidelines, EU Directive 2010/63/EU for animal experiments, or the National Institutes of Health guide for the care and use of Laboratory animals (NIH Publications No. 8023, revised 1978) and the authors should clearly indicate in the manuscript that such guidelines have been followed. All animal studies need to ensure they comply with the ARRIVE guidelines. More information can be found at http://www.nc3rs.org.uk/page.asp?id=1357.

Patient anonymity

Studies on patients or volunteers require ethics committee approval and informed consent which should be documented in the manuscript.

Patients have a right to privacy. Therefore identifying information, including patients' images, names, initials, or hospital numbers, should not be included in videos, recordings, written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and you have obtained written informed consent for publication in print and electronic form from the patient (or parent, guardian or next of kin where applicable). If such consent is made subject to any conditions, Elsevier must be made aware of all such conditions. Evidence of written consent must be provided to Elsevier on request.

Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

Authors submitting manuscripts as Case Reports, Case Problems, and Evidence in Practice should ensure that they have received consent from patients who are the subject of such reports. A statement to this effect should be included in the manuscript.

If such consent has not been obtained, personal details of patients included in any part of the paper and in any supplementary materials (including all illustrations and videos) must be removed before submission.
Conflict of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. If there are no conflicts of interest then please state this: 'Conflicts of interest: none'. See also https://www.elsevier.com/conflictsofinterest. Further information and an example of a Conflict of Interest form can be found at: http://service.elsevier.com/app/answers/detail/a_id/286/supporthub/publishing.

SPECIFIC GUIDANCE FOR ORIGINAL RESEARCH ARTICLES

The text of original research for a quantitative or qualitative study is typically subdivided into the following sections:

INTRODUCTION

Describe the wider context of the topic and its relevance providing selected citations that evidence and underpin the context. Identify key relevant research and briefly describe the strengths and weaknesses of past work and identify the gaps in the literature and key questions that are pertinent to the topic and practice. Build on this descriptive account to establish an argument for the manuscript’s focus and end the introductory section with the aims of the research that is being reported and or the research questions.

Materials and Methods

Describe your selection of observational or experimental participants (including controls). Identify the methods, apparatus (manufacturer’s name and address in parenthesis) and procedures in sufficient detail to allow workers to reproduce the results. Give references and brief descriptions for methods that have been published but are not well known; describe new methods and evaluate limitations.

Indicate whether procedures followed were in accordance with the ethical standards of the institution or regional committee responsible for ethical standards. Do not use patient names or initials. Take care to mask the identity of any participants in illustrative material.

Results

Present results in a logical sequence in the text, tables and illustrations. Do not repeat in the text all the data in the tables or illustrations. Emphasise or summarise only important observations.

Discussion

Emphasise the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the introduction or the results section. Include implications of the findings and their limitations, and include implications for future research. Relate the observations to other relevant studies. Link the conclusion with the goals of the study, but avoid unqualified statements and conclusions not completely supported by your data. State new hypothesis when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

Conclusion

A summary of the pertinent findings and, relevance of the study and implications of the study for future research.

Appendices - In addition to containing information regarding Acknowledgements, Appendices may also be used to publish supplementary files online, to which a reference should be made in the printed article.

Preparation

• Submitted papers should be relevant to an international audience and authors should not assume knowledge of national practices, policies, law, etc. Authors should consult a recent issue of the journal for style if possible. Since the journal is distributed all over the world, and as English is a second language for many readers, authors are requested to write in plain English and use terminology which is internationally acceptable.

Abbreviations - Avoid the use of abbreviations unless they are likely to be widely recognised. In particular you should avoid abbreviating key concepts in your paper where readers might not already be familiar with the abbreviation. Any abbreviations which the authors intend to use should be written out in full and followed by the letters in brackets the first time they appear, thereafter only the letters without brackets should be used. Statistics - Standard methods of presenting statistical material should be used. Where methods used are not widely recognised explanation and full reference to widely accessible sources must be given.

Review Process

The decision to publish a paper is based on an editorial assessment and peer review. Initially all papers are assessed by an editor of the journal. The prime purpose is to decide whether to send a paper for peer review and to give a rapid decision on those that are not. Manuscripts going forward to the review process are reviewed by members of an international expert panel. All such papers will undergo a double blind peer review by two or more reviewers. All papers are subject to peer review and the Journal takes every reasonable step to ensure author identity is concealed during the review process. The Editors reserve the right to the
final decision regarding acceptance.

Double-blind peer review - This journal uses double-blind review, which means that both the reviewer and author name(s) are not allowed to be revealed to one another for a manuscript under review. The identities of the authors are concealed from the reviewers, and vice versa. To facilitate anonymity, the author's names and any reference to their addresses should only appear on the title page.

Blinded manuscript (no author details): The main body of the paper (including the references, figures, tables and any Acknowledgements) should not include any identifying information, such as the authors' names or affiliations. Authors should also ensure that the place of origin of the work or study, and/or the organization(s) that have been involved in the study/development are not revealed in the manuscript – “X” can be used in the manuscript and details can be completed if the manuscript is processed further through the publication process.

NEW SUBMISSIONS
Submission to this journal proceeds totally online and you will be guided stepwise through the creation and uploading of your files. The system automatically converts your files to a single PDF file, which is used in the peer-review process.

As part of the Your Paper Your Way service, you may choose to submit your manuscript as a single file to be used in the refereeing process. This can be a PDF file or a Word document, in any format or lay-out that can be used by referees to evaluate your manuscript. It should contain high enough quality figures for refereeing. If you prefer to do so, you may still provide all or some of the source files at the initial submission. Please note that individual figure files larger than 10 MB must be uploaded separately.

References
There are no strict requirements on reference formatting at submission. References can be in any style or format as long as the style is consistent. Where applicable, author(s) name(s), journal title/book title, chapter title/article title, year of publication, volume number/book chapter and the pagination must be present. Use of DOI is highly encouraged. The reference style used by the journal will be applied to the accepted article by Elsevier at the proof stage. Note that missing data will be highlighted at proof stage for the author to correct.

Formatting requirements
There are no strict formatting requirements but all manuscripts must contain the essential elements needed to convey your manuscript, for example Abstract, Keywords, Introduction, Materials and Methods, Results, Conclusions, Artwork and Tables with Captions and “Contribution of Paper” (where applicable).

If your article includes any Videos and/or other Supplementary material, this should be included in your initial submission for peer review purposes.

Divide the article into clearly defined sections.

Figures and tables embedded in text
Please ensure the figures and the tables included in the single file are placed next to the relevant text in the manuscript, rather than at the bottom or the top of the file. Ensure that figures and tables are referred to in the body of the text and that they are clearly labelled.

ALL SUBMISSIONS
The following documents are needed for all submissions.

Title page (with author details) – This should include the title, authors' names and affiliations, and a complete address for the corresponding author including telephone and e-mail address.

Blinded manuscript (no author details) – The main body of the paper (including the references, figures, tables and any Acknowledgements) should not include any identifying information, such as the authors' names or affiliations.

Covering letter – to the editor in which you detail authorship contributions and other matters you wish the editors to consider.

What this paper adds
At submission stage, authors of reviews and original research articles are required to provide three to four bullet points outlining what the manuscript adds to the literature. This should succinctly and accurately summarise the key new knowledge resulting from the study along with the implications for clinical, educational or research practice as appropriate for the focus of the manuscript.

Manuscript Layout
The manuscript with a font size of 12 or 10 pt double-spaced with wide margins (2.5 cm at least) and number pages consecutively beginning with the Title Page. Depending on the paper type (see above) this should include the title, abstract, key words, text, references, tables, figure legends, figures, appendix. Microsoft Word or similar programme should be used.

Please check your typescript carefully before you send it off, both for correct content and typographic errors. It is not possible to change the content of accepted typescripts during production.

To facilitate anonymity, the author’s names and any reference to their addresses should only appear on the title page. Please check your typescript carefully before you send it off, both for correct content and typographic errors. It is not possible to change the content of accepted typescripts during production.
Text
The text of observational and experimental articles is usually, but not necessarily, divided into sections with the headings; introduction, methods, results, results and discussion. In longer articles, headings should be used only to enhance the readability. Three categories of headings should be used:

- major headings should be typed in capital letter in the centre of the page and underlined (i.e. INTRODUCTION)
- secondary ones should be typed in lower case (with an initial capital letter) in the left hand margin and underlined (i.e. Participants).
- minor ones typed in lower case and italicised (i.e. questionnaire).

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