Maternal Report of Outcomes of Chiropractic Care for Infants

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Abstract

Objective: The purpose of this study was to investigate the report by mothers of their infants' condition before and after a trial of care provided by registered chiropractic clinicians in addition to ratings of satisfaction, cost of care, and reports of any adverse events or side effects. A second purpose was to report the demographic profile of infants who presented for care to 16 chiropractic clinics in the United Kingdom.

Methods: This observational study prospectively collected reports by mothers of their infants' demographic profiles and outcomes across several domains of infant behavior and their own mental state using the United Kingdom Infant Questionnaire. Participating registered chiropractors were recruited through the Royal College of Chiropractors annual meeting in January 2016, and 15 clinics and the Anglo-European College of Chiropractic University College teaching clinic volunteered to participate.

Results: In all, 2001 mothers completed intake questionnaires and 1092 completed follow-up forms. Statistically significant ($P < .05$) improvements were reported across all aspects of infant behavior studied, including feeding problems, sleep issues, excessive crying, problems with supine sleep position, infant pain, restricted cervical range of motion, and time performing prone positioning. Maternal ratings of depression, anxiety, and satisfaction with motherhood also demonstrated statistically significant improvement ($P < .05$). In total, 82% (n = 797) reported definite improvement of their infants on a global impression of change scale. As well, 95% (n = 475) reported feeling that the care was cost-effective, and 90.9% (n = 712) rated their satisfaction 8 or higher on an 11-point scale. Minor self-limiting side effects were reported (5.8%, n = 42/727) but no adverse events.

Conclusion: In this study, mothers reported that chiropractic care for their infants was effective, safe, and cost-effective. Although the observational design makes it impossible to determine efficacy, the study's findings indicate that, on average, the changes observed by mothers were positive and may be clinically relevant. (J Manipulative Physiol Ther 2019;xx:1-xxx)

Key Indexing Terms: *Infant; Chiropractic; Complementary Therapies*

Introduction

An important development in health care in the past decade has been the increasing interest in patient-centered care emphasizing the patient's own perspective on their illness and treatment. Patient-reported outcome measures are designed to assess a patient's subjective impressions of their health with respect to symptoms, function, and health-related constructs such as health-related quality of life.[1,2] The World Health Organization points out that involvement of the patient in their own health care is a social, economic, and technical necessity.[3] Although patient-reported outcome measures are important, using them for the pediatric patient is challenging whether they could be helpful to improve doctor–patient or doctor–parent communication and shared decision-making.[4]

Patient-reported outcome measures are commonly used as tools for monitoring and quantifying a patient's progress while undergoing treatment[5-7] and as outcomes in clinical trials.[8] Routine collection of patient-reported outcomes (PROs) has been suggested as a method of collecting large amounts of data to capture information about what occurs in routine clinical practice.[1] These large amounts of data may be used to measure quality of care and evaluate comparative effectiveness of treatments.[1,2] Routine collection of PROs

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in chiropractic practice has been demonstrated to be feasible for adult patients[9,10] and children,[11] allowing for collection of so-called *big data*. A similar approach involving routine collection of PROs for infants undergoing chiropractic care would seem a worthwhile endeavor in attempting to address the lack of research in this area.[12] Infants are common users of chiropractic care.[13-15] In such a vulnerable population, it seems crucial that research be conducted to determine the effect of treatment on the patient's clinical condition and to measure safety and parental satisfaction. The chiropractic profession has been criticized for a lack of high-quality evidence to support the care of this population.[16-19]

To satisfy the demand for a parent-reported outcome measure, the United Kingdom Infant Questionnaire (UKIQ) was developed, based on maternal views of what is important in an infant's health, and has been tested for reliability and validity.[20] Evidence suggests that mothers are reliable reporters of their infant's behavior and therefore in the best position to provide insight into their child's clinical situation.[21-23] The UKIQ collects both demographic information about the infant and maternal impressions across several domains of their infant's behavior, including sleep, feeding, crying, inability to maintain a supine sleep position (a risk factor for sudden infant death syndrome), range of motion of the cervical spine, and use of prone positioning.[20] Difficulty in these areas represents threats to the health of the infant and public health because they are considered risk factors for early cessation of breastfeeding[24] and impaired infant–parental bonding[25] and parental abuse[26] in the short term, and behavioral issues, developmental delay,[27-29] and continued sleep difficulties in the long term.[30] Mothers were also asked about their own mental state in relation to their child's condition and experience of motherhood because maternal mental condition has been found to be key to the child's health.[31]

The purpose of this study was to investigate the report by mothers about their infant's condition before and after a trial of care provided by registered chiropractic clinicians in addition to maternal ratings of satisfaction, cost-effectiveness, and reports of any adverse events or side effects over the treatment period. A second purpose was to report the demographic profile of infants who presented for care to 16 chiropractic clinics in the United Kingdom.

Methods

The design of this study was observational, using prospectively collected maternal reporting of her infant's profile at intake and after a trial of chiropractic care. The demographic profile of the infant was collected using the UKIQ, a validated outcomes instrument,[20] and transferred directly to an Excel worksheet using a program called Formstack. Participating registered chiropractors were recruited through the Royal College of Chiropractors annual meeting in January 2016, and 15 clinics and the Anglo-European College of Chiropractic (AECC) University College teaching clinic volunteered to participate. Patients were consecutive infants, whose mothers consented to participate, presented to chiropractors. All electronically collected data were stored on a server in encrypted form. This allowed gathering of large amounts of data as part of routine practice without any confidential information included.

Ethics

The AECC Research Ethics Sub-Committee approved this study (AECC Ethics Approval Number: E94/02/19). This study was reviewed by the AECC University College ethics board. Parents all signed a form allowing the use of the infant's data in research when entering the clinic. All data were anonymized without the ability to identify any specific case through the use of any of the data.

Processes

The study was designed to have a reception staff member present the mother with either an electronic or paper form before initiation of treatment and again at the discharge visit. Reception staff provided a layer between the treating clinician and the outcomes report in an attempt to prevent the halo effect. The electronic platform was preferred because of its direct recording into the spreadsheet. If sufficient electronic tablets were not available, staff could offer a paper version of the same form. These data were input into the spreadsheet by a trained member of the research team.

The intake version of the UKIQ asked the mother to report infant age, sex, complaints at presentation, type of birth, and who referred the infant for care, if anyone. The intake and follow-up questionnaires used a scaled response for the mother to grade the degree of ease or difficulty her infant had with feeding, sleeping, and crying behaviors in the past few days (0 = no problem; 10 = serious problem). Further questions asked her to use the same type of rating for the baby's comfort in a supine sleep position and the infant's general pain or discomfort, if any. Maternal ratings of anxiety about her infant's condition, depressive feelings, and satisfaction with the quality of life with motherhood were also queried. Any issues with cervical range of motion or prone positioning were similarly rated at intake and at follow-up.

Chiropractic treatment was provided by registered chiropractors using the appropriate clinical care for this age group, which included low-force manual therapy to the spine, extremities, and fascia of patients, as indicated. The follow-up questionnaire was provided at the fourth visit or discharge visit, whichever came first. At follow-up, mothers were asked to rate on a scale their overall satisfaction with

Table 1. *Baseline Profile of Infant Patients Presented to Chiropractic Clinics*

Characteristics	Count	%
Infant sex (total N = 2001)		
Male	1092	55
Female	909	45
Type of birth (total N = 1808)		
Birth without interventions	645	36
Birth with interventions	1163	64
Induced	415	22
Ventouse	146	8
Forceps	267	15
Elective C-section	220	12
Emergency C-section	290	16
Assisted/epidural	79	4
Referral patterns (total N = 1689)		
Health care provider	989	58
Friends and family	485	29
None or other	215	13
Reason for attendance (total N = 1991)		
Crying	618	31
Feeding	935	47
Sleeping	495	25
Uncomfortable when lying on back	536	27
Unable to turn head equally to both sides	271	14
Difficult birth	372	19
Head shape	226	11
Checkup	448	23
Reflux/wind/constipation	249	13
Others	231	12
Total	4381 [a]	
Average number of complaints	2.20	
Age (wk) (total N = 1842)		
12 wk or below	1583	86
Above 12 wk	259	14

[a] Mothers could check as many boxes as desired and could write in reason for attendance.

care (0 = not satisfied; 10 = very satisfied). The mother's perception of global impression of change (GIC) in the infant's behavior and condition after care was recorded by selecting 1 of 7 options ranging from "much worse" to "completely better, made a huge difference, like a different baby."

A subset of mothers was asked whether any adverse events or side effects had been experienced from the treatment and whether they found the treatment to be cost-effective. The question about cost-effectiveness was added later when it was discovered that this type of research had particular utility in asking such a research question. Mothers also were given the opportunity to provide any other comments. The number of treatments, including the discharge visit, was recorded by the staff member who handed the questionnaire to the parent.

Data Analysis

Baseline and follow-up data were analyzed with descriptive statistics using mean percentage change in scores (mean scores at follow-up were subtracted from the mean initial scores and multiplied × 100 to obtain percentage change, in either direction). There was no differentiation between practices in the collection of data, and all data were pooled. The Wilcoxon signed-rank test was performed to test for statistical significance of change in ratings ($P < .05$) using SPSS Statistics software, version 20 (IBM Corp, Armonk, New York). The Wilcoxon signed-rank test was chosen because it is the appropriate test to use on a single sample (before and after) to determine whether their mean ranks differ. It is the appropriate alternative to the *t* test for matched pairs when the data are not assumed to be normally distributed.

Results

A total of 2001 mothers completed the intake questionnaire and 1092 (54.5%) completed the follow-up questionnaire, although there were some questions left blank on some forms. The baseline characteristics of infants presented to clinics are summarized in Table 1.

The mean age at presentation was 7.1 weeks. The most common age at presentation was 3 weeks, with 79.1% (n = 1583) of infants less than 12 weeks of age at intake (Table 1). On average, infants underwent 4 treatments during the course of care, and the most common number of treatments was 3. Figure 1 shows the reasons for presentation of infants who entered the practices. Mothers could report as many problems as they chose, and the mean was 2.2 problems/child. Regarding type of birth, 35.7% (n = 645) mothers (n = 645/1808) reported a natural birth without interventions. In all, there were 1417 birth interventions (mothers could report as many types of intervention that

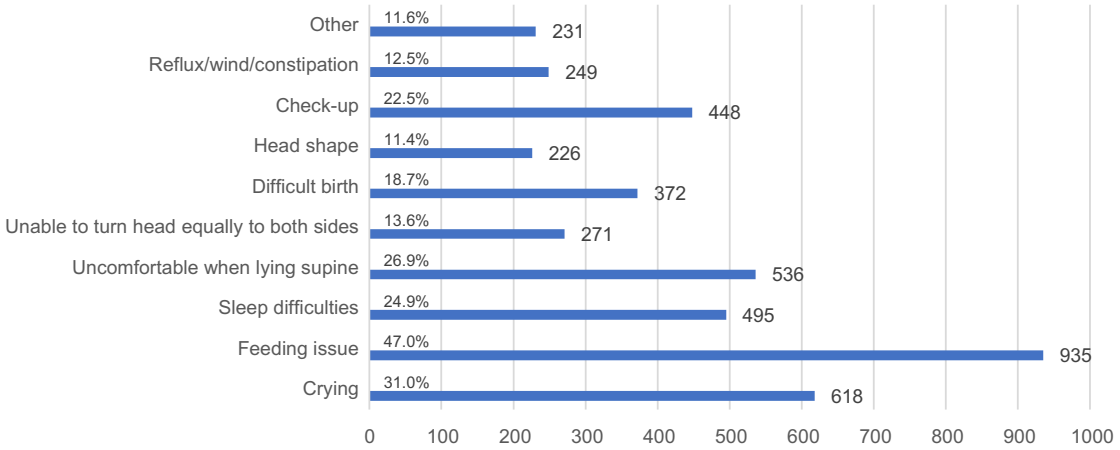

Fig 1. *Reason for infant presentations to chiropractic clinics (n = 1991).*

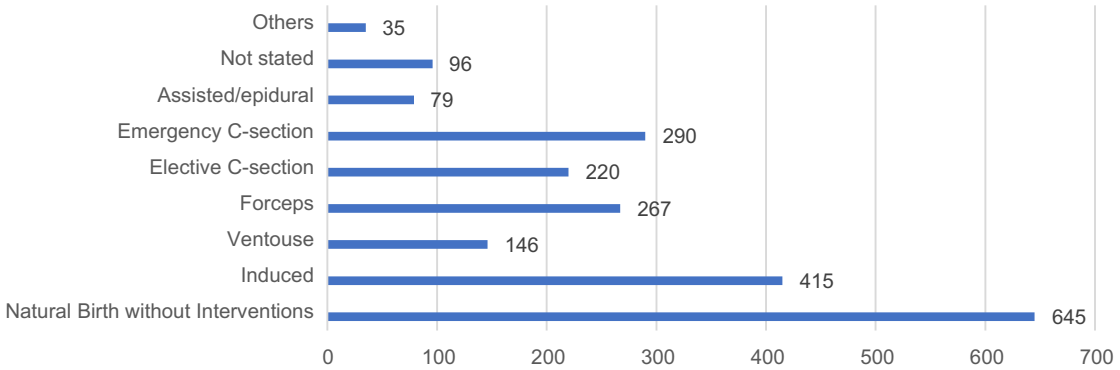

Fig 2. *Type of birth reported at intake (n = 1808).*

they had had), and 64.3% of mothers had 1 or more type of birth assistance (Table 1 and Fig 2).

Maternal ratings of infant behavior and the mother's own mental state are shown at intake and after a course of chiropractic care in Table 2 and Figure 3 along with percentage change. The observed changes were statistically significant in all categories (P = .0001). (See Table 2.)

A conservative approach was taken in analyzing the maternal GIC, with dichotomization of the ratings into the categories of "better" (using the top 2 choices) or "not better" (all other choices). The maternal rating of GIC was "better" 797 (82%) and "no better" 170 (18%) (see Table 3).

For satisfaction with their child's care, 71.7% of mothers (n = 561/783) rated their level as "very satisfied" (Table 4) and 90.9% rated their satisfaction as 8 or above on an 11-point scale. Further, 95.8% mothers reported that care was cost-effective (n = 475/496). There were no adverse events reported, but side effects of treatment were reported by 5.8% of mothers (n = 42/727). These were reported as mild in severity and duration, mainly described as unsettledness, increased crying, or better sleep after the treatment that resolved within a day (Fig 4).

Discussion

This is the first known large survey of baseline and follow-up characteristics of infant patients presented to chiropractic practices. More appropriate research designs are required to investigate actual efficacy of registered chiropractors' care of infants. This study can only illuminate maternal reports of their perceptions of effect of care. Nevertheless, studies investigating efficacy might neglect to consider whether care results in clinically significant change, and it seems likely that parents themselves are in the best position to make this assessment. A recent systematic review indeed questioned whether the small benefits observed in studies of efficacy of manual therapy for crying and distressed infants translated into meaningful changes for parents.[32] Research of this nature is

Table 2. *Mean Change in Maternal Ratings From Baseline to Follow-Up in Infants Presented to Chiropractors for Individualized Treatment*

Category Rated	Rating Before Treatment	Rating After Treatment	% Change	*P* Value
Feeding	3.93	1.26	-67.94	.0001
Sleeping	3.90	1.69	-56.67	.0001
Crying	3.67	1.48	-59.67	.0001
Supine sleep	4.21	1.61	-61.76	.0001
Infant pain	4.14	1.49	-64.01	.0001
Maternal anxiety	4.16	1.20	-71.15	.0001
Maternal depression	2.28	0.79	-63.35	.0001
Satisfaction with motherhood	2.75	1.16	-57.82	.0001
Cervical rotation	3.27	1.47	-55.05	.0001
Tummy time	3.52	4.64	31.82	.0001

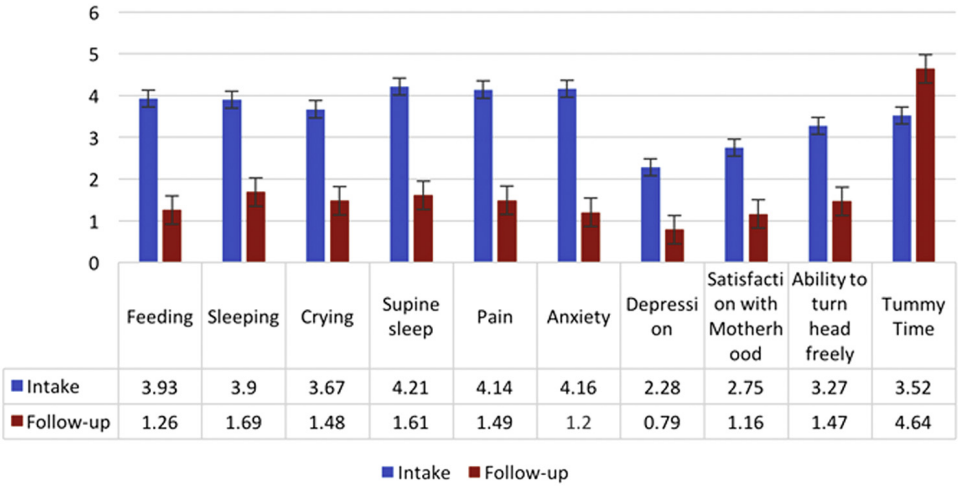

Fig 3. *Maternal ratings at intake and discharge.*

perhaps best suited to addressing this very relevant question. Mothers repeatedly have been found to be excellent reporters of their infant's state of health,[21-23] and mothers, by and large, reported good recovery from the initial complaints in this study. The greatest reductions in maternal ratings were reported in the scale of the feeding problem of the infant and in the mother's own anxiety level. It makes sense that these may go hand in hand because previous studies have found the maternal psychological experience is entwined with breastfeeding issues[33,34] and inconsolable infant crying.[35]

Anxiety and depression have been widely researched and found to be prevalent and serious problems both ante- and postnatally and often linked to the feeding, crying, and sleeping issues of the newborn.[36-38] Providers of infant care are increasingly aware of both the prevalence and effects of postpartum depression on the family unit.[39] Research has shown that screening for depression improves clinical outcomes and that postpartum depression is exceedingly common, affecting an estimated 14% to 25% of mothers.[40]

Previous studies have shown that mothers report lower scores on validated anxiety and depression indices and better quality of life after their infant has received a course of treatment at a chiropractic clinic.[41,42] It seems logical that being given an explanation for the etiology of the infant's problem and observing a reduction in symptoms could be helpful in easing maternal distress. It has been reported elsewhere that mothers want specific

Table 3. *Maternal Rating of Global Impression of Change at Follow-Up*

Rating of Change	Total	%
Completely better, made a huge difference, like a different baby	291	30.1
Better/definite improvement	506	52.3
Moderately better	96	9.9
A little better	52	5.4
No change	14	1.5
Much worse	7	0.7
Somewhat worse	1	0.1
Total	967	100

Table 4. *Maternal Rating of Satisfaction With Chiropractic Care for Their Infant (N = 783)*

Level of Satisfaction	Count	%
0 (Not Satisfied)	5	0.6
1	3	0.4
2	3	0.4
3	1	0.1
4	2	0.3
5 (Somewhat Satisfied)	12	1.5
6	10	1.3
7	35	4.5
8	64	8.2
9	87	11.1
10 (Very Satisfied)	561	71.6
Total	783	100

contextualized help for their child and not simple reassurance that their condition is not a life-threatening concern.[43]

In all categories, change was observed in a direction that can be interpreted as a clinically favorable result. The concept of clinical significance of care can be difficult to determine.[44] Other studies have found that a shift of 35% or more in ratings of improvement is most likely clinically significant.[45] It is pertinent to suggest that mothers thought the care was beneficial owing to the consistently high ratings of satisfaction, improvement, and cost-effectiveness.

This study's findings resembled those of previous research demonstrating that the effect of manual therapy for infants occurs within 2 weeks[46-50] and in 1 study after 1.1 treatments, with complete recovery after an average of 4 sessions.[46] This study was very similar, with a mode of 3 treatments and an average of 4 before release from care. A quick response to care has been suggested to be beneficial in alleviating distress and anxiety in parents.[46] The same early effect of treatment has been found in adults, although the mean number of treatments was higher (5.4) with a wider range (1-20 treatments in a 90-day span).[9] In cases where the natural history of the disorder is known, as in excessive crying that has been found to recover after 12 weeks[32] and up to 26 weeks,[51,52] there is little question that the care was an improvement over the natural history.

The results reflected statistically significant improvements in complaints of infants such as crying, sleep, pain, breastfeeding, and inability to meet the guidelines for supine sleep. The shared etiology of these problems was musculoskeletal irritability and imbalance, which is common at all ages, but in infants can result from a difficult birth.[42,47,50] Manual therapy provided by chiropractors has been found effective in treating the musculoskeletal imbalances of infants,[46,48] with modified treatments appropriate for the size and age of the child.[46,53] There is also scientific background that manual touch therapy was found effective to reduce signs of pain in premature neonates using sophisticated brain studies.[54]

Like other studies, mothers reported very high levels of satisfaction with care, even if the baby did not totally recover.[55] Satisfaction ratings are complex and therefore should be interpreted with caution because they could be explained by many other confounding factors,[56] not least because the family appreciates the time and attention given to them and their baby. A factor more meaningful than satisfaction may be the positive report of cost-effectiveness. This concept has been found to be a part of patient-centered care and defined as clinical benefit for the amount of money spent.[57] Because this care took place in the UK where National Health Service care is free of charge and chiropractic treatment is not, it is interesting that mothers will still seek additional care, even with the additional financial burden. Zuzak et al[58] found that parents throughout Europe seek complementary or integrated therapies for children, with manual therapy the most commonly chosen.[15,59]

Limitations

The information collected was from the mothers' impressions of care. No efficacy from care can be assigned from this study owing to lack of randomization or controls. However, the strength of this type of study lies in that the data came directly from the mothers and not from the caregivers, who have traditionally been the ones to

- Agitated just after treatment but much better the next day
- Slightly cranky on the night of treatment, but much better the next day
- Cried one evening post treatment for a couple of hours
- Unsettled at night more than normal
- Unsettled for one day only but back to content state
- Better sleep
- Upset that evening but difficult to tell if it's because of treatment
- Cried a little more one evening
- Unsettled after treatment for a few hours
- Lots of sleep, very nice side effect
- Slightly irritable after treatment for a few hours, then good sleep
- Tiredness after treatment
- After first jaw treatment, baby dribbled more but improved after second treatment.
- A bit of fussiness
- Cranky after treatment at the beginning but now much more comfortable
- Was cranky after treatment and quite unsettled but only after the first two appointments
- Unsettled and difficult to console after treatment, but rarely and usually calm by the next day

Fig 4. *Side effects listed by mothers after an average of 4 chiropractic treatments for their infant.*

determine whether a patient has benefited from care. The nature of these common complaints of infancy does not make them conducive to study using a double-blind, randomized design. Many infants may have experienced a combination of complaints.[60] Treatment often requires an approach customized to the individual patient, and few parents are willing to be blinded to the treatment received by their infant or whether treatment has been received. As such, this type of study presents real-world data as evidence,[61] which provides external validity not found in randomized controlled trials and thus is more applicable to heterogenous general patient populations than higher-level studies.[62]

The sample size was relatively large, and the response rate at over 50% was reasonable. A follow-up rate of 41% was reported in a successful routine PROs survey in the NHS Health and Social Care Information Centre.[7,63] In research being conducted in a routine clinical setting, it may be unrealistic to expect higher follow-up rates. Follow-up is given as part of the normal patient management process, and this means that some patients will not have received the opportunity to complete a follow-up form owing to discontinuation from care before discharge, referral to another health professional at intake, or care being deemed unnecessary at intake. Others simply will not have progressed to a point in care where follow-up is appropriate and will therefore have completed only the intake at the close of the study period. This may be a downside of accessing real-world clinical evidence.

Data were collected anonymously, making it impossible to collect follow-up data from those who dropped out from treatment or pursue any further follow-up efforts if follow-up had not been completed. It could be expected that those who did not complete the follow-up may be precisely the mothers who are unhappy with care or did not complete treatment, and this is a weakness of this study because it is impossible to know what their potential responses would be. It might be worthwhile to consider including a more extensive follow-up process for future research to capture the impressions of these mothers, but this would bring with it the disadvantage of requiring collection of more personal information at intake, which is not common practice in this type of data collection. Specifically, future research might track which infants discontinued care, were referred for other medical care, or were not treated because care was deemed unnecessary. With these data, comparisons of ratings could be made between mothers who discontinued care and those who completed care. The absence of such data is a shortcoming of this study because no such comparison is possible.

In addition, the entire study consisted of a population attending chiropractic clinics, and this group has been shown to differ from the broader population.[64,65] Although this study included 15 private chiropractic offices, data were also obtained from the AECC University College teaching clinic, and this may provide a skewed sample.[65,66] These factors may limit the generalizability of the results to the general population of mothers and infants with complaints, even though this type of study is designed for improved external validity.

A lack of validated and pragmatic outcome measures designed specifically for the infant population has been considered an impediment to conducting high-quality research in well-baby infant quality of life care, but the UKIQ may be capable of addressing this barrier. Its feasibility for use in chiropractic practice has been demonstrated for both paper and electronic versions of the tool,[42] and an electronic version has been found technically capable of large-scale data collection in chiropractic practice.[67]

Whether the patient improves or not is fundamental to clinical practice. Parent report of outcomes allows the mother to determine whether the change, if any, that occurred during a course of care should be classed as improvement or not. This facilitates patient-centered care and provides valuable information for the clinician and when the sample size is large and applicable to a wider population, to health care decision-makers, as well. Although this study's design was not capable of determining efficacy, its findings may provide insight into whether mothers perceive this care to be of value to their infant. This research reflected only the mother's point of view, and higher levels of research such as randomized controlled trials are required to determine true efficacy of this type of care for infants.

Conclusion

This was the first study of its kind to investigate prospectively collected data provided by mothers regarding presentation and outcomes from treatment from a large

cohort of infants presented for chiropractic care. The infant's care was reported by the mothers who completed follow-up as effective, safe, and cost-effective.

Funding Sources and Conflicts of Interest

No funding sources or conflicts of interest were reported for this study.

Contributorship Information

Concept development (provided idea for the research): J.E.M.
Design (planned the methods to generate the results): J.E.M.
Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): J.E.M., M.H., D.S.L.T.K., Z.M., Y.-H.T.
Data collection/processing (responsible for experiments, patient management, organization, or reporting data): J.E.M., M.H., D.S.L.T.K., Z.M., Y.-H.T.
Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): J.E.M., H.A.H., M.H., D.S.L.T.K., Z.M., Y.-H.T.
Literature search (performed the literature search): J.E.M., H.A.H., M.H., D.S.L.T.K., Z.M., Y.-H.T.
Writing (responsible for writing a substantive part of the manuscript): J.E.M., H.A.H., M.H., D.S.L.T.K., Z.M., Y.-H.T.
Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): J.E.M., H.A.H.
Retention of clinicians: D.S.L.T.K.
Background research and analysis: H.A.H.

Practical Applications

- The findings of this study indicate that, on average, mothers report improvement in common complaints of infancy (crying, problematic feeding, sleeping, and pain) after chiropractic treatment along with improvements in their own mental state.
- High maternal ratings for satisfaction and cost-effectiveness also were noted, and together these findings seem to indicate that on average, mothers note clinically important changes after chiropractic treatment of their infant.
- This is the first large prospective study reporting parental report of effectiveness of routine chiropractic care for infants.

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