

A Prospective, Longitudinal Health Outcomes Study of Pregnant Women and Children Undergoing Subluxation Based Chiropractic Care

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Abstract

Objective: To describe the development, implementation and initial data analysis for a practice based, prospective, longitudinal health outcomes study of pregnant women and pediatric patients undergoing subluxation centered chiropractic care.

Background: Chiropractic and spinal manipulation is being increasingly utilized in the care of pregnant women and the pediatric population. While there have been some initial efforts to address the safety, efficacy and health outcomes related to such care, much work remains to be done. Increasingly third party payors and regulatory agencies are scrutinizing the depth and strength of evidence relative to the chiropractic care of pregnant women, infants and children. Indeed some practice guidelines and third party payors state that the evidence for benefit is equivocal and even state in some cases that it is experimental and investigational. As health care continues to undergo changes based on accountability, outcomes and cost effectiveness the issue of chiropractic care of the pregnant female and pediatric population will continue to be a contentious one. The need exists for prospective, longitudinal outcomes studies of chiropractic care in these populations and this study is a step in that direction.

Methods: This is a practice based, longitudinal, health outcomes study assessing the safety and efficacy of chiropractic in the pregnant and pediatric populations. The setting is a private chiropractic clinic in Kennesaw Georgia that focuses on the care of women and children. All existing and new pregnant females and pediatric patients who become patients of the clinic

during the one year time period for this study will be asked to participate. It is estimated that approximately 100-150 subjects will be enrolled. Subjects will already be about to or already be undergoing chiropractic care so will be excluded only if they are not eligible to undergo chiropractic care or do not wish to participate. A co-investigator on this study will be providing the chiropractic care. This study will utilize data collected through a data repository created and maintained for the purposes of this study. Data from all existing and new pregnant and pediatric patients who become patients of the clinic during the one year time period for this study will be asked to participate. The data will be analyzed for changes in anthropometric, physiological and self reported quality of life during the study period. The remainder of this section will explore the details of the population, the sample, research design, data analysis, limitations and strengths of the study.

Results: A number of obstacles were encountered in the process of implementing this research study that included: training of staff and investigators, implementing the informed consent process, tracking subjects, scheduling follow-up evaluations and data management.

Thus far, 9 pediatric patients and 25 pregnant subjects have been enrolled in the study. Pediatric patients included three female patients and 6 male patients aged 6 months to 9 years old. Pediatric complaints included: ear infection; plagiocephaly and torticollis; reduced left neck rotation; three cases of motor vehicle accidents; sinus and asthma complaints; two cases of low back pain; and two cases of wellness care. Pregnancy patients ranged from 23 to 39 years of age and included: four complaints of sacroiliac pain; three complaints of mid back pain; ten complaints of low back pain; one complaint of a fetus being in the transverse presentation; two complaints of breech presentation; one complaint of frank breech presentation; one complaint of migraine; one complaint of knee pain; two complaints of hip pain; one complaint of asthma; one complaint of coccyx pain; one complaint of asthma; one complaint of shoulder pain; one complaint of sciatica; two complaints of neck pain; one case of a motor vehicle accident; and three cases of wellness or maintenance care.

Conclusions: Previous studies have shown chiropractic to be safe and effective in addressing various complaints of pediatric and pregnant patients. Further research in the quality of life of patients undergoing subluxation based healthcare is necessary and the need exists to train chiropractors in practice based research in order to carry this out. This study will provide valuable data on the obstacles associated with the implementation of a practice based research study as well as preliminary data on the health outcomes in these important populations.

Key words: *Pediatrics, Pregnancy, Chiropractic, Health Outcomes, Vertebral Subluxation*