

**A PROSPECTIVE, LONGITUDINAL HEALTH OUTCOMES STUDY OF PREGNANT  
WOMEN UNDERGOING SUBLUXATION BASED CHIROPRACTIC CARE**

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## **I - Introduction**

### *Background/Problem Statement*

Chiropractic and spinal manipulation is being increasingly utilized in the care of pregnant women. While there have been some initial efforts to address health outcomes in this population much of this work has focused on low back pain during pregnancy.

Increasingly third party payors and regulatory agencies are scrutinizing the depth and strength of evidence relative to the chiropractic care of pregnant women. Indeed some practice guidelines state that the evidence for benefit is equivocal. As health care continues to undergo changes based on accountability, outcomes and cost effectiveness, the issue of chiropractic care of the pregnant female will continue to be a contentious one.

The need exists for prospective, longitudinal outcomes studies of chiropractic care in pregnant females and this study is a step in that direction. This is a practice based research study assessing the health outcomes of women undergoing subluxation based chiropractic care.

### *Purpose Statement/Research Question*

The purpose of this study is to gather prospective, longitudinal outcomes data on a population of pregnant females undergoing routine chiropractic care in a clinical, private practice setting in Kennesaw, GA.

### *Null Hypothesis*

There is no significant improvement in health outcomes in pregnant females undergoing chiropractic care.

### *Significance Statement*

Increasingly women are exploring complementary and alternative (CAM) approaches in order to address the challenges associated with pregnancy as for wellness and preventive care. Chiropractic represents a significant amount of this care and a significant amount of money is spent out of pocket for these CAM services. The chiropractic profession has developed specialties focused on pediatric and maternal care, and techniques have been developed and are actively marketed for the care of pregnant females.

Chiropractors actively market themselves to women offering services contending to improve health outcomes during pregnancy and the birth process. The signature procedure associated with the chiropractic profession is the spinal adjustment (sometimes referred to as manipulation) and is by far the most common intervention performed by chiropractors. Specialized techniques such as the Webster in-utero constraint technique have been developed and are utilized by a large number of practitioners in the care of pregnant women. The culture has shifted to one of accountability in regards to health care services and the demand for demonstration of positive health outcomes. Further, since so much money, time and resources are expended either by third party payors or the patients themselves for these services then moving forward it is incumbent upon the chiropractic profession to demonstrate its efficacy in managing the pregnant female.

## **II – Methodology**

### **Introduction**

This study will utilize data collected thorough a data repository created and maintained for the purposes of this study. Data from all existing and new pregnant females 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.

### **Population and Sample**

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 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 50-75 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.

### **Research design**

The design of this study involves a prospective, longitudinal outcomes design with data collected through a data repository.

### **Procedures**

This is a prospective longitudinal study of health outcomes in a population of pregnant females undergoing chiropractic care. These women will already have agreed to chiropractic care and will be receiving the usual care ordinarily provided by the practitioner. The following data points will be collected through an online data repository and analyzed for changes in outcome:

- Subject's DOB
- Subject's Race
- Subject's Educational Level
- Subject's Occupation
- First Visit
- How Far Along
- Presentation
- Chief Complaint
- Prior Pregnancies
- Prior Births
- Type
- # Adj
- Dropped Care
- Time From Birth
- Birth Type
- Why C-Section?

- Previous Care Date
- Subluxation Levels
- Co-morbidities
- Regions/Levels Adjusted
- Webster's
- Surface EMG Data
- Thermographic Data
- Complications from Treatment
- Self Reported Quality of Life
- Other Treatment Related Outcomes

## **Data Analysis**

### *Data Repository, Protection & Access Issues*

The data utilized in this study are not publicly available. An online database and participant interface has been developed through a combination of already existing commercial services and the creation of new websites by the investigators. All data will be de-identified of all protected health information and placed in Excel format and then transferred to SPSS prior to performing any statistical analysis. The data repository was created in order to make the acquisition of data for the study easier and streamlined. It is hoped that these procedures will lessen the need for the use of paper based surveys and paper based data gathering.

The treating chiropractor, who is also a co-investigator on this study, will be trained in the data collection procedures along with the staff of the office. The data repository will be updated on a regular basis with primary responsibility resting with the lead investigator and the treating chiropractor. Two additional co-investigators will also be assigned oversight responsibility as well as responsibility for training in the areas of data collection, the web interface and the informed consent process.

Access to the database resides with each of the investigators with primary responsibility resting with the principle investigator. The database is accessed through a password protected, limited web based interface. The database can only be accessed by authorized personnel. Additional decisions about access to the database are made by the principle investigator.

All data is protected by a layered security system and network security through the commercial service known as Survey Monkey. Patients will be assigned subject identifiers and only the raw data related to the outcomes of interest will be entered into the database.

Once acquired from the web, the study investigators will store the data on a password protected desktop or laptop computer for analysis. Other than the study investigators no other individual will have access to this de-identified data.

## **Limitations of the Proposed Study**

The design of this study is a prospective, longitudinal analysis of health outcomes with no control group. Although the study involves only one practitioner and due to this the nature of the chiropractic care will be somewhat standardized, it is difficult to account for differences in the application of chiropractic care from one individual to another. The only inclusion criteria is that all existing and new pregnant females

who become patients of the clinic during the one year time period for this study will be asked to participate. Finally, it must be considered that study participants may engage in other behaviors outside the scope of this study.

### **Strengths of the Proposed Study**

Because there will only be one provider of the care, there is a greater chance for standardization of the interventions. In addition there is the potential for multiple objective assessments of physiological function and anthropometric measures which could provide robust data to work with. This provides multiple outcome measures which can be further analyzed to determine if there is a relationship between them in support of positive outcomes.

### **III - Vulnerable Subjects, Risks and Informed Consent**

Since this is a health outcomes study of pregnant women we are dealing with a vulnerable population. All participants will provide the necessary consent.

Any risks experienced by the subjects will not arise as a consequence of the study but would be inherent risks from undergoing chiropractic care. According to a recent study, chiropractic care in pregnant females was found to be safe and there were no reported adverse events.