Dynamic Chiropractic

FCER Funds Multisite Clinical Trial in Australia

WILL ASSESS HOW ASTHMATICS RESPOND TO CHIROPRACTIC

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DES MOINES, Iowa - The board of trustees of the Foundation for Chiropractic Education and Research (FCER) has approved funding for a study to be conducted in Australia over the next 18 months. The investigation, "A Multisite Trial: Chiropractic and Asthma with Physiological Markers," is directed by Ray Hayek, Bsc [Hons], MChiro, at Macquarie University in Sydney, Australia.

The aim of this undertaking is a clinical investigation at 10 sites to assess the effects of chiropractic techniques (Activator, Gonstead, diversified, and sacral occipital) on the physiological and global symptoms of patients with asthma. There will be 420 subjects, 315 of whom suffer from asthma, divided into four groups of 105 each and tracked according to a parallel study design. The asthmatics that are already under medical management will then be divided into three groups:

> [i] those receiving chiropractic treatment at the clinics;
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> [ii] those receiving no chiropractic treatment, but visiting the clinic the same number of times as the treated group for monitoring; and
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> [iii] those receiving no chiropractic treatment and being monitored at home. This group would undergo a regimen identical to Group iii above.

A fourth group will be nonasthmatics who receive no chiropractic treatment and are monitored at home.

Two weeks will be allowed for a pre-trial baseline period, followed by one of the four interventions indicated above for a six-week period, with chiropractic treatments administered three times per week. This, in turn, would be followed by six weeks of post-trial readings. The novel outcome measure in this trial is the assessment of stress by measurement of salivary cortisol and IgA against the internal standards of albumin, creatinine, and osmolality (rate of salivary production). Respiratory status will be determined by spirometry to measure lung function. Functional status outcome variables include DASS (depression and anxiety stress scale), SF-36 (general health status), VAS (visual analogue scale), and a wellness inventory.

This research plan has been propelled by previous studies that suggest:

> [i] a statistically significant pattern of spinal dysfunction is observed in young asthmatics;
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> [ii] anxiety is associated with asthma; and
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> [iii] cortisol levels may decrease in asthmatics following spinal manipulation. All biochemical markers will be measured from salivary samples that will be frozen after being taken from each subject at 8:00 a.m. and 8:00 p.m., the peak and nadir phases of the circadian rhythm in humans.

This project transcends what was observed in an earlier, more limited clinical trial that had received funding from a variety of sources within the chiropractic community. The focus of this previous trial was to attempt to differentiate high-velocity thrusting from a sham procedure that involved significant contact with the patient. Although symptom improvement was observed in both treatment and control groups, the differences between the two did not appear to be statistically significant. In this previous investigation, the "control" group received soft-tissue massage, distraction, and palpation to multiple regions of the body.[1] Massage itself has since been demonstrated to produce significant improvements in asthma symptoms and lung function, with depressed cortisol levels in children.[2]

As in any research endeavor, our sophistication grows with experience and data obtained - and the entire clinical research world now has come to the realization that so called "sham" or "mimic" procedures involving physical methods of health care intervention need to be approached with extreme caution. This is why the completion of this new Australian trial becomes an issue of highest priority.

Asthma has to be regarded as a major health concern in the United States:

- Over 17 million Americans suffer from asthmatic symptoms, the number more than doubling since 1988.[3]
- The disease is the leading cause of school absence in the United States, with the prevalence rates in children under 5 increasing 160% from 1980-1994.[3]
- Even more ominous is a recent report which suggests that in early childhood the odds ratio for asthma occurrence increases up to fourfold with antibiotic use, the risk apparently being dose-dependent and especially pronounced if antibiotics are used within the first year of life.[4]

Note from FCER: The Foundation for Chiropractic Education is seeking to help underwrite the quarter of a million dollars that it has approved for this important project. To donate by MasterCard or Visa over our secure server, or for further information, please follow this link: [url=http://www.fcer.org/html/asthmadonate.htm]http://www.fcer.org/html/asthmadonate.htm[/url]
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If you have questions, please send e-mail to fcernow@aol.com, or phone FCER at 800-622-6309. You may also send postal mail to: FCER-Asthma Study, P.O. Box 4689, Des Moines, Iowa 50306-4689.

References:

1. Balon J, Aker PD, Crowther ER, Danielson C, Cox PG, O'Shaugnessy D, Walker C, Goldsmith CH, Duku E, Sears MR. A comparison of active and simulated chiropractic manipulation as adjunctive treatment for childhood asthma. New England Journal of Medicine 1998; 339(15): 1013-1020.

2.Field T, Henteleff T, Hernandez-Reif M, Martinez E, Mavunda K, Kuhn C, Schanberg S. Children with asthma have improved pulmonary functions after massage therapy. Journal of Pediatrics 1998; 132(5): 854-858.

3.The Integrative Medicine Consult 1999; 1(1): 120, 122.

4.Wickens K, Pearce N, Crane J, Beasley R. Antibiotic use in early childhood and the development of asthma. Clinical and Experimental Allergy 1999; 29: 766-771.

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