0008-3194/92/84–90/$2.00/©JCCA 1992

# Generalizability of patient profiles from a feasibility study*

Gregory D Cramer, DC, PhD
Marion McGregor, DC, MSc
John J Triano, MA, DC
John W Emde, BS

*The potential of the physician to make clinical inference from experimental results depends upon whether the test conditions generally apply to the average practice setting. This report compares the characteristics of the patient pool of a chiropractic teaching clinic with reports from other teaching clinics and general practice. Differences between participants and non-participants of a feasibility study for randomized controlled clinical trials (RCT) which might affect the interpretation of future RCT results were also investigated. Distribution of the chief complaints was similar to data from both teaching and private practice settings. The age, gender and chronicity of symptoms for patients in the present study were much the same as general practice. In contrast, reports from other teaching clinics revealed a profile of significantly younger patients with more acute onset complaints than either private practice or this study. The number of treatments administered per case to reach clinical resolution were fewer than in previously reported studies from private practice. Generalizations to the averge practice are quite strong.*
(JCCA 1992; 36(2):84–90)

KEY WORDS: chiropractic, care, generalizability, volunteer bias, patient profile, manipulation.

*Pour qu'un médecin puisse transformer des résultats d'expériences en conclusions cliniques, il faut que les tests soient faits dans des conditions représentatives d'une pratique standard. Cet article compare les caractéristiques de trois groupes de patients, soit : d'une clinique d'enseignement chiropratique, d'autres cliniques d'enseignement, et de pratiques privées. La différence entre participants et non-participants d'une étude de faisabilité (pour des essais cliniques contrôlés effectués au hasard) fut aussi évaluée, et ce afin de minimiser les problèmes d'interprétation de futures études semblables. La distribution des patients-problèmes a été faite en respectant les données des cliniques d'enseignement et des pratiques privées. L'âge, le genre et la chronicité des symptômes des patients de cette étude représentent ce qu'on retrouve en pratique générale. En contraste, les rapports de cliniques d'enseignement démontrent un patient plus jeune avec un problème plus aigu que notre étude ou qu'en pratique privée. Pour des résultats semblables, le nombre de traitements par cas était moindre dans notre étude que dans des études faites précédemment en pratique privée. La possibilité de généraliser à l'égard de la pratique moyenne est très forte.*
(JCCA 1992; 36(2):84–90)

MOTS CLÉS : chiropratique, comparaisons, volontaires, possibilité de généraliser, biais, profil du patient, manipulation.

## Introduction

This paper focuses on the ability to apply the results of a clinical study to routine practice experience. Clinicians are expected to base their diagnostic and therapeutic decisions on sound evidence available from the literature and to change their practice procedures accordingly. Unfortunately, for most randomized controlled clinical trials, the scientific questions addressed are so narrow that they are of little value to the practicing physician. Further, even in those cases where the issues are broader, for example, the testing of the efficiency of a treatment, information is rarely available regarding how well the sample of patients in these studies represent those in general practice. Boissel[1] pointed out that the validity of negative results from an extracranial-intracranial arterial bypass surgery trial[2] were questioned on the basis of the sample population studied. The impact of applying treatment protocols to clinical practice when a non-representative subject pool is used may clearly be devastating. The identification of appropriate subjects is just as important for areas other than surgery. Efforts to identify such subjects improve the ability for the subject sample

The National College of Chiropractic, 200 East Roosevelt Road, Lombard, Illinois 60148. (708) 629-9664.
Send correspondences and reprint requests to: Gregory Cramer, DC, PhD, c/o National College of Chiropractic, (708) 268-6536.

* Supported by a restricted grant funded by the Foundation for Chiropractic Education and Research.

under study to adequately represent the typical case. These efforts are a prerequisite to the valid use of information that might be gained from any clinical trial.

## Method

Patient characteristics were gathered for 335 consecutive cases presenting to the National College of Chiropractic (NCC) main outpatient clinic over a period of 14 weeks. All patients were either new to the clinic or had not been seen in the clinic for any complaint within the previous six months. Gathering techniques consisted of self-supporting questionnaires given to patients on initial presentation, and information gained from case files. In some cases, clinicians, interns and/or the patient were asked additional questions at the time of initial presentation in order to clarify the information retrieved. After the initial presentation, however, no such contact was made.

To determine the comparability of the subjects studied with those in other chiropractic clinical settings, data was collected and evaluated with respect to both institutional teaching settings and general practice setting.[3,4,5,6,7,8,9,12,13,14,15] Characteristics chosen for comparing the patient profiles from different settings included (a) patient age, (b) patient gender, (c) total number of treatments administered to each patient, (d) description of the chief complaint site, and (e) episode chronicity.

All patients were further asked to participate in a feasibility study in order to determine the reliability and validity of a series of potential outcome measures for a clinical trial. One hundred and eighty six of the 335 patients agreed to participate in this study, and information concerning these results are available elsewhere.[16] Since it is also important to evaluate the results of clinical trials to determine if the conclusions reached are applicable to all patients or only those willing to participate in research experiments, we further analyzed the information gathered to search for differences between those who participated in the feasibility study and those who did not. Participants were sub-divided into two groups: those who completed a six week follow-up phase of study designed to assess change in the potential outcome measures ("compliers") and those who did not complete the final follow-up ("non-compliers"). Participants (compliers and non-compliers) were compared with non-participants with respect to (1) gender, (2) age, (3) Oswestry questionnaire scores, (4) Visual Analog Scale (VAS) scores, (5) location of chief complaint, (6) chronicity of complaint, and (7) clinical descriptive category.

## Results

As stated above, 335 patients were solicited for this investigation and more than 55% (186/335) agreed to participate. Six week follow-up data were obtained on 77.9% (145/186). The remaining 41 non-compliers completed the first follow-up, two hours after completing the entry series of questionnaires, but did not complete the rest of the study protocol. A total of 149 patients refused to participate and became classified as "non-participants".

Table 1 compares the age data obtained in this study with the age data obtained in other previous studies which assessed and reported patient profiles. The previous studies fall in one of two categories: (1) those performed in a private practice setting, and (2) those performed at a teaching clinic associated with a chiropractic college. The data of Table 1 indicates a trend that a larger number of patients in higher age groups are found in private practice than in chiropractic teaching clinics. This trend is highlighted in the data from six chiropractic college clinics reported by Nyiendo[14] (Table 1). The results of our study are more consistent with those previously reported from private practice settings than with those of other educational institutions. Comparison by chi square analysis between the other chiropractic educational facilities and the present study based upon the percentage of patients above and the percentage of patients below the age of 40 revealed significant differences ($X^2 = 7.293$, $p = 0.007$). (Data was unavailable from one patient; consequently the mean age and distribution findings were calculated from the other 334 subjects.)

The distribution of males and females in the current study and those recorded by others is provided in Table 2. The percent of males and females is approximately 50% for nearly all studies regardless of whether they represent an institution or a private practice.

Most studies attempted to characterize their sample by a description of the site distribution of chief complaints. Unfortunately, the terms were rarely defined from study to study and were not directly interchangeable. In addition, all of the patients' presenting complaints often were listed and the principle or "chief" complaint was not specified. The present study considered only the single, most important (chief) complaint identified by the patient. Data from Phillips[10] and Sawyer and Stewart[11] appear to have been collected by using criteria similar to those used in our study. The exact anatomical areas making up the locations described by these reports, however, is unknown. In the present report, certain anatomical regions were combined so that the neck included both the cervical and cervicothoracic regions. The thoracic area included the thoracolumbar region and the low back also incorporated the sacroiliac region. As shown in Table 3, the location of chief complaints appear comparable for all three studies.

Table 4 lists the total number of treatments administered to patients and compares them with those reported for both private office and institutional settings. The criteria for the definitions that set the end points of care are rather unclear in many of the studies in the literature, making comparison between investigations difficult. Treatment totals in Table 4 reflect the total number of treatments at the end of six weeks or to chief complaint resolution, if treatment extended past the six week time period. Resolution was defined as a return to pre-symptomatic state of the patient or when the patient returned only for maintenance care. Maintenance care was defined as treatments occurring once per week or less, for at least two weeks.

In a comparison of low back pain profiles of teaching clinic

**Table 1 Comparison of Ages**

| Type of Practice | Age Range | Practice (%) | NCCC (%) |
|---|---|---|---|
| **Private Practice** | | | |
| 1. Vear (1972) | < 21 | (10.5) | ( 5.7) |
| | 21–60 | (78.8) | (74.3) |
| | > 60 | (10.7) | (20.0) |
| | < 41 | (51.7) | (46.7) |
| | > 40 | (48.3) | (53.3) |
| 2. Connecticut (1973) | < 21 | ( 4.8) | ( 5.7) |
| | 21–64 | (81.4) | (80.5) |
| | > 64 | (13.8) | (13.8) |
| | < 40 | (32.2) | (44.9) |
| | > 39 | (67.8) | (55.1) |
| | Mean | 47.7 | 44.0 |
| 3. Shenk (1974) | < 17 | ( 7.8) | ( 2.4) |
| | 17–64 | (80.5) | (83.8) |
| | > 64 | (11.7) | (13.8) |
| 4. Sherman (1976) | < 22 | ( 8.0) | ( 7.5) |
| | 22–65 | (86.4) | (79.6) |
| | > 65 | ( 5.6) | (12.9) |
| 5. Breen (1977) | < 25 | ( 7.9) | (12.6) |
| | 25–64 | (82.8) | (73.6) |
| | > 64 | ( 9.3) | (13.8) |
| | Mean | 47.0 | 44.0 |
| 6. New Zealand (1978) | < 20 | (15.0) | ( 4.8) |
| | < 30 | (35.0) | (23.4) |
| 7. Coulter (1980) (1985) | < 18 | ( 3.4) | ( 3.3) |
| | 18–64 | (82.5) | (82.9) |
| | > 64 | (14.1) | (13.8) |
| 8. Phillips (1981) | < 21 | (11.1) | ( 5.7) |
| | 21–65 | (81.9) | (81.4) |
| | > 65 | ( 7.0) | (12.9) |
| | < 41 | (56.4) | 46.7 |
| | > 40 | (43.6) | 53.3 |
| | Mean | 39.9 | 44.0 |
| 9. Phillips (1982) | Mean | 43.4 | 44.0 |

| Type of Practice | Age Range | Practice (%) | NCCC (%) |
|---|---|---|---|
| **Chiropractic College Practice** | | | |
| 1. Sawyer & Stewart (1984) | | | |
| Northwestern | < 21 | (12.0) | ( 5.7) |
| | 21–65 | (83.9) | (81.4) |
| | > 65 | ( 4.2) | (12.9) |
| | < 41 | (79.8) | (46.7) |
| | > 40 | (20.3) | (53.3) |
| | Mean | 32.4 | 44.0 |
| 2. Nyiendo et al. (1989) | | | |
| LACC | < 40 | (64.0) | (44.9) |
| | > 39 | (36.0) | (55.1) |
| | Mean | 36.4 | 44.0 |
| Palmer-West | < 40 | (70.0) | (44.9) |
| | > 39 | (30.0) | (55.1) |
| | Mean | 36.0 | 44.0 |
| WSCC | < 40 | (69.0) | (44.9) |
| | > 39 | (31.0) | (55.1) |
| | Mean | 37.1 | 44.0 |
| Pasadena | < 40 | (47.0) | (44.9) |
| | > 39 | (53.0) | (55.1) |
| | Mean | 42.7 | 44.0 |
| Cleveland | < 40 | (65.0) | (44.9) |
| | > 39 | (35.0) | (55.1) |
| | Mean | 37.6 | 44.0 |
| Life-West | < 40 | (77.0) | (44.9) |
| | > 39 | (23.0) | (55.1) |
| | Mean | 34.5 | 44.0 |
| 3. White (1989) | | | |
| CMCC | < 21– | (10.0) | ( 5.7) |
| | 21–60 | (83.0) | (74.3) |
| | > 60 | ( 7.0) | (20.0) |
| | < 41 | (78.0) | (46.7) |
| | > 40 | (22.0) | (53.3) |

**Table 2**
**Proportion of Males and Females According to Practice Setting**

| Practice Location | % Males | % Females |
|---|---|---|
| **National College** | 51.9 | 48.1 |
| Feasibility Study (1990) 335 | | |
| **Private Practice** | | |
| 1. Vear (1972) | 56.4 | 43.6 |
| 2. Shenk (1974) | 51.2 | 48.8 |
| 3. Sherman (1976) | 56.6 | 43.4 |
| 4. Breen (1977) | 47.0 | 53.0 |
| 5. Kelner & Coulter (1980) | 46.0 | 54.0 |
| 6. Phillips (1981) | 48.6 | 51.4 |
| 7. Phillips (1982) | 49.5 | 50.5 |
| 8. Coulter (1985) | 45.0 | 55.0 |
| **Chiropractic Institutions** | | |
| 1. Sawyer & Stewart (1984) | 43.8 | 56.2 |
| 2. Nyiendo & Haldeman (1987) | 47.0 | 53.0 |
| 3. Nyiendo et al. (1989) | 42–53 | 47–58 |

**Table 3**
**Location of Chief Complaint Reported in Separate Studies**

| | Location | | | |
|---|---|---|---|---|
| | Neck | Mid-Back | Low-Back | Peripheral |
| NCCC (1990) N = 334 | 20.0 | 8.0 | 45.0 | 11.0 |
| Phillips (1982) | 34.9 | 7.1 | 45.0 | 5.9 |
| Sawyer & Stewart (1984) | 20.4 | 7.8 | 30.7 | 11.7 |

**Table 4**
**Number of Treatments**

| Location | Overall Mean Treatments | Range(%) |
|---|---|---|
| **NCCC** | N = 335 | < 6 (63) |
| Feasibility Study | 5.96 | > 8 (75) |
| Study (1990) | | < 11(14) |
| | | 6–10(22) |
| | | 8–15(19) |
| **Private Practice** | | |
| 1. Sherman (1976) | | 6 (48) |
| | | 6–10(31) |
| | | 10(21) |
| 2. Breen (1977) | 7.00 | 11–40(20) |
| 3. Kelner & Coulter (1980) | | 6 (31) |
| | | 6–10(18) |
| | | 10(35) |
| 4. Phillips (1981) | 9.02 | 8 (58) |
| | | 8–15(28) |
| 5. Phillips (1982) | 12.50 | |
| **Chiropractic Institutions** | | |
| 1. Sawyer & Stewart (1984) | 6.60[a] | |
| 2. Nyiendo & Haldeman (1987) | 4.40 | |

[a] Mean was 8.9 when third party payers were involved and 5.9 when they were not.

**Table 5**
**Category of Participant According to Gender**

| Sex | C (%) | NC (%) | NP (%) |
|---|---|---|---|
| Females | 70(48) | 24(59) | 67(45) |
| Males | 75(52) | 17(41) | 82(55) |

patients versus patients of private clinicians, Nyiendo[15] contrasted the degree of complaint chronicity in the two populations. She found a highly significant difference between her sample populations on this basis. In that study, an explicit definition of the terms related to chronicity was not given. An earlier report by the same author[14] defined a "chronic" complaint as being "greater than six weeks duration". Using that same definition for our data and, ignoring for the moment both subacute and recurrent conditions, the proportion of subjects defined as acute as opposed to chronic was 53:47, respectively. The institutional clinic data from Nyiendo's sample gave the ratio of acute to chronic as 24:76. A chi square analysis (Yates corrected (YC)) indicated a substantial difference with our data ($X^2$ (YC) = 16.56, p = 0.000). Adding the subacute and recurrent patient categories from our study to this comparison would only have strengthened the contrast, since these subjects had pain for less than six weeks and would have categorized as "acute". The data for private practice settings in Nyiendo's report indicated a ratio of acute to chronic low back patients of 45:55. No significant difference was evident between our data and that from the reports on private practices ($X^2$ (YC) = 0.98, p = 0.322).

To examine for potential volunteer bias within our study, we compared the identified sub-groups of (a) compliers, (b) non-compliers and (c) non-participants. Table 5 provides a breakdown of the number and proportion of males and females in each of the three patient categories. A chi square analysis of the proportions for these data indicated no statistically significant relationship between patient category and gender ($X^2$ = 4.347, p = 0.114), although there appeared to be a greater proportion of females in the non-complier group.

Table 6 supplies the mean age, total number of treatments to resolution, and presenting Oswestry and VAS scores for each of the three groups. One outlier with respect to total number of treatments was discovered in the complier group. This patient was under long term rehabilitative treatment for complications following a cerebrovascular accident (CVA), and the total number of treatments was 132. Analysis and post-hoc contrasts on results are presented for the treatment data, both with the outlier included and with it removed. Analysis of variance indicated a statistically significant difference in both age and total treatments across the groups (age: F = 4.417, p = 0.013; treatments: F = 4.711, p = 0.01; F = 6.676, p = 0.001, outlier removed). The age of the non-compliers was found overall to be significantly lower than the age of the compliers (F = 6.005, p = 0.015) or of the non-participants (F = 8.788, p = 0.003). We further determined that the total number of treatments for the compliers was significantly greater than the total number for either the non-compliers (F = 5.048, p = 0.025; F = 8.007, p = 0.005 outlier removed) or the non-participants (F = 7.410, p = 0.007; F = 9.783, p = 0.002 outlier removed). Neither the presenting Oswestry nor the presenting VAS scores were statistically different on analysis of variance (F = 1.359, p = 0.26; F = 0.177, p = 0.838, respectively) for the three different

**Table 6**
**Age, Number of Treatments to Resolution and Initial Severity of Complaint Measured by Oswestry and VAS for Each Group Studied**

| Category | Age | Total Treatments | Oswestry | VAS |
|---|---|---|---|---|
| | Mean (SD) | Mean (SD) | Mean (SD) | Mean (SD) |
| Compliers N = 145 | 44.2(15.7) | 7.6(11.7)<br>6.7( 5.4)[a] | 6.9(7.1) | 35.5(27.0) |
| Non-Compliers N = 41 | 37.0(15.1) | 4.2( 3.1) | 5.7(4.6) | 36.7(25.5) |
| Non-Participants N = 149 | 45.7(17.6) | 4.9( 5.0) | 8.3(8.2) | 38.2(29.6) |

[a] Data from outlier removed.

**Table 7**
**Comparison of Location of Chief Complaint**

| Location | C (%) | NC (%)[b] | NP (%) |
|---|---|---|---|
| Neck | 33(23) | 12(30) | 21(14) |
| Thorax | 13( 9) | 3( 7) | 10( 7) |
| Low Back | 72(50) | 16(40) | 61(41) |
| Peripheral | 9( 6) | 7(18) | 21(14) |
| Other | 18(12) | 2( 5) | 36(24) |

[b] Note data missing for one subject in non-complier group.

**Table 8**
**Complaint Chronicity in Each Group Studied**

| Chronicity | C (%)[a] | NC (%)[b] | NP (%)[c] |
|---|---|---|---|
| Acute | 32(23) | 15(38) | 33(26) |
| Sub-Acute | 27(20) | 4(10) | 27(22) |
| Chronic | 47(34) | 17(44) | 43(34) |
| Recurrent | 31(23) | 3( 8) | 23(18) |

[a] Compliers, missing data in 8 cases.

[b] Non-compliers, missing data in 2 cases.

[c] Non-participants, missing data in 23 cases.

**Table 9**
**Descriptive Categories in Each Group Studied**

| Descriptive Category | C (%)[a] | NC (%)[b] | NP (%)[c] |
|---|---|---|---|
| Mechanical Back Pain | 106(83) | 24(77) | 57(58) |
| Entrapment | 8( 6) | 2( 7) | 10(10) |
| Muscle | 14(11) | 5(16) | 32(32) |

[a] Missing data in 17 cases.
[b] Missing data in 10 cases.
[c] Missing data in 50 cases.

patient types.

A breakdown of patients by region of chief complaint is provided in Table 7. Data were missing from one subject in the non-complier category, reducing the total number of subjects in this case to 334. Comparison by chi square indicated that the groups were substantially different with respect to distribution of chief complaint ($X^2 = 26.905$, $p = 0.001$). However, when patients having only spinal complaints were compared, this difference disappeared ($X^2 = 4.69$, $p = 0.321$).

Data were unavailable with respect to chronicity of the chief complaint for eight patients in the complier category, for two patients in the non-compliers category, and for 23 non-participants. Table 8 was constructed from the remaining data. Analysis of the proportions indicate that categorical listing of chronicity was related to patient group ($X^2 = 18.043$, $p = 0.006$). The non-compliers appeared to have proportionately more acute and more chronic cases than did the compliers or the non-participants.

Subjects of this study were assigned to one of three forced descriptive categories (nerve root entrapment, mechanical pain, or muscular pain). The proportion of subjects listed as entrapment, mechanical, or muscular pain also was different between the patient groups ($X^2 = 18.056$, $p = 0.001$). Table 9 shows a higher proportion of non-participants having muscular pain and a smaller proportion with mechanical pain complaints.

## Conclusions

The conclusions of this study can be summarized as follows:

1 The distribution of patients according to gender in our study is approximately the same as for those in the literature describing private practices and other institutional clinics.
2 The age distribution of patients in this study matched that of the private practice descriptions, but we had a significantly larger proportion of older patients than were observed in other institutional clinics.
3 Overall, the largest proportion of subjects seeking chiropractic care in all of the studies were those presenting with the complaint of low-back pain.
4 The distribution of condition chronicity found in this study resembled that seen in private practice. The pattern of cases was, however, significantly distinct from the reports of other college clinic settings.
5 The average number of treatments administered closely resembled the pattern seen at other chiropractic colleges and showed statistically fewer treatments than provided by private practitioners.
6 The results of this study reinforce the observations of Sawyer and Stewart[11] who suggested that patients who are treated by a cash-basis practice require an average of approximately six treatments to reach case resolution.
7 Volunteer biases were identified by contrasting the results according to group participation (e.g., compliers, non-compliers, and non-participants). The characteristics showing significant differences between the groups will permit the design of future clinical studies in such a way that they will be more easily generalized to other patient populations.

## Discussion

Two of the conclusions warrant further comment. First, the observation in Table 4 on the number of treatments administered was very similar to those made by Sawyer and Stewart.[11] In that study, a trend was seen where patients using third-party payers received an average of three treatments more than patients not using third-party payers. Although not statistically significant, the average number of treatments (5.9) for their group not using third-party payment methods was remarkably close to the overall mean number of treatments in the present study (5.96). The fact that for the present study, clinic operations on a cash payment basis further emphasizes questions raised about the effects of third-party reimbursement on health-care-utilization patterns. Additional study exploring the relationship between treatment frequency and quality of health care may be warranted.

The second issue is that of differences observed between groups based upon their decisions to participate in a study. An important initial observation was the absence of difference based upon the severity of complaint as determined by the Oswestry instrument and the VAS scores. Non-compliers were, however, younger and required less treatment than either of the compliers or non-participant groups.

The several differences encountered in the non-complier group are not easily explained purely from the database of this study. Circumstantially, the younger age of the group coupled with the fact that this group dropped out of the study before completion may indicate a different personality type or a lifestyle that impacts upon their time schedules. This issue bears further consideration and study. Regardless, the total number of persons comprising this group was only an approximate 20% of the overall population that entered the study. The 80% compliance rate suggests that results can be generalized from the data

to general practice; however, the differences noted between the complier and the non-complier groups emphasize the necessity for keeping compliance with study protocols high.

A survey of the non-participants indicated a higher proportion of muscular complaints and a lower proportion of mechanical back disorders. These patients, similarly, registered the reason for consulting the clinic for treatment as "other" more frequently. We believe these patterns reflect the fact that a community service health screening was conducted at the clinic during the 14-week interval in which the study was carried out.

Overall then, it is clear that generalizability to clinical practice from the particular teaching clinic used for this study is quite reasonable. Further, while there are indeed significant differences in the profiles of subjects who completed the feasibility protocol and those who did not, compliance by a significant number of study subjects in future research should provide enough information to allow for meaningful inferences to be made. The differences found between compliant subjects and non-participants were those that would be expected given the nature of a study in a chiropractic college setting. That is, patients with complaints that were not easily considered spinal-mechanical in origin were more frequently found in non-participant groups.

In practice, clinicians make daily judgements about appropriate treatment to help patients who are ill or in pain. As they make these clinical decisions, they are expected to modify their method of practice on the basis of quality scientific data. Yet, precise results from well-controlled trials are often severely limited in their ability to be translated to private practice. Two common factors contribute to this difficulty in generalizing research results. They include the narrowness of scope of the scientific questions that are studied and the low comparability of the sample population of a study to the private practice experience where the results are to be applied. While research often is most easily completed in instructional settings, it is important to ensure that profiles of patients entering college clinics are the same as those in private practice.[15] Often, it is difficult to know whether the patients studied are similar since appropriate information is rarely provided,[17] or the terminology selected is not linked to other studies.

The project reported here has used the feasibility study method to minimize questions of generalizability by identifying the characteristics of the sample population and comparing these to published reports of private and educational facilities. In addition, the opportunity was taken to examine the effects of volunteer bias by contrasting those who completed the preliminary clinical trial with those who did not, and also with those who declined to participate.

**Acknowledgement**

Supported by a restricted grant from the Foundation for Chiropractic Education and Research made possible by Practice Consultants, Inc., Roswell, Georgia.

The authors wish to thank Deborah Emde, Drs. Maria Hondras, Eric Cerwin, and the faculty, staff and interns at the National College of Chiropractic Clinic for their help in the completion of this study.

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