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Outcome Assessment of Clinical Practice Guidelines in the Medical and Chiropractic Management of Patients with Acute Mechanical Lower Back Pain: A Randomized Control Trial

November 2007

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RS2003/04-007

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FINAL REPORT –November 21, 2007

Outcome Assessment of Clinical Practice Guidelines in the Medical and Chiropractic Management of Patients with Acute Mechanical Lower Back Pain: A Randomized Control Trial

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1. Main Research Findings and Policy / Prevention Implications

- Clinical practice guideline-based treatment that included a component of spinal manipulative therapy administered by chiropractors, had significantly better outcomes than family physician-directed guideline-discordant usual care for patients with acute lower back pain.
  - The functional improvement seen at 16 weeks post treatment in patients treated with guideline-concordant care was clinically and statistically significantly superior to family physician-managed guideline-discordant care.
  - There was a statistically greater functional improvement at 8 weeks and 24 weeks in patients receiving guideline-based care when compared with usual care and a clinically and statistically significant improvement in the quality of life measures (Bodily Pain and Physical Functioning domains of the SF-36) at 16 weeks post treatment.
- This is the first reported randomized controlled trial that compared the efficacy of full clinical practice guideline-based treatment with guideline discordant care in the treatment of patients with acute lower back pain.
- This is the first reported study that evaluated spinal manipulation administered by chiropractors in the setting of a health care treatment team.
- In summary and on a larger scale, the results of this study have validated the process of developing evidence-based treatment by critically reviewing the scientific literature, defining clinical practice guidelines lines and implementing those guidelines as a method of advancing the quality of care that patients with acute lower back pain receive.

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2. Executive Summary

Introduction:

Clinical practice guidelines for the treatment of patients with acute mechanical lower back pain have been defined on an international scale. However, several studies have demonstrated that most patients with acute lower back pain do not receive guideline-based treatment. In addition, the hypothesis that full guideline-based treatment results in improved patient outcomes has to date, not been tested in a scientifically rigorous manner. The goal of this study was to determine if full clinical practice guideline based care resulted in greater improvement in functional capacity, quality of life and time to return to work than family physician-directed guideline-discordant care in the treatment of patients with acute mechanical lower back pain.

The design of this study employed the current “gold standard” of clinical research methodology, a randomized controlled clinical trial. Patients were included in the study if they were between the ages of 19 – 59, had acute mechanical lower back pain (i.e. Quebec Task Force Categories I and II) with symptoms of greater than two and less than four weeks duration. Patients were excluded if they had symptoms of any condition consistent with any “Red Flag” sign (e.g. malignancy, infection, fracture or active inflammatory process) or any co-morbid condition (e.g. osteoporosis) contraindicating chiropractic spinal manipulation. Patients were assessed by a spine physician and were then randomized to guideline concordant care that included spinal manipulation administered by a chiropractor, or family physician-directed guideline-discordant care, the components of which were recorded. The primary outcome measure was difference in mean Roland Morris Disability (RDQ) scores between the guideline concordant and guideline discordant treatment groups at 16 weeks after the start of treatment. The secondary outcomes were difference in mean RDQ scores between the guideline-concordant and the guideline discordant treatment groups at 8 and 24 weeks,

and differences in Bodily Pain (BP), Physical Functioning (PF) SF-36 domains at 16 weeks. Determining differences in time to return to work between the guideline-concordant and guideline-discordant groups was also a goal of this study.

Hospital / University Ethics approval for this research study was obtained. The study was registered with CONSORT (Clinicaltrials.gov; Identifier is NCT00135239).

Results:

A total of 88 patients were recruited with 36 in the guideline-concordant treatment group and 35 in the guideline-discordant treatment group, completing the study. Baseline prognostic variables were evenly distributed between groups. The primary outcome showed a mean difference in RDQ scores in the guideline-concordant group (-4.1) that was statistically significantly greater than those in the guideline-discordant treatment group (-1.3) ($p<0.0001$). The secondary outcomes also showed that the guideline concordant-treatment group changes in mean RDQ scores at 8 and 24 weeks were statistically significantly better than those in the guideline-discordant group ($p< 0.05$ and $p< 0.05$ respectively). Both the SF-36 BP and PF scores were clinically significantly better ($p<0.05$) in both treatment groups when compared with baseline values. The BP and PF scores in the guideline-concordant treatment group were improved to a greater degree when compared with those in the guideline-discordant group with this difference being of borderline statistical significance ($p = 0.048$ and 0.041 respectively).

Unfortunately, time to return work could not be determined due to insufficient numbers of patients being off work at the time they entered the study.

Summary:

In summary, this is the first reported randomized controlled trial that compared the efficacy of full clinical practice guideline-based treatment that included a component of spinal manipulation administered by chiropractors, with guideline-discordant care in the treatment of patients with acute lower back pain. Clinical practice guideline-based treatment resulted in superior improvements in functional capacity outcomes and quality of life measures when compared with family physician-directed guideline-discordant care.

3. Report

- **Research Problem/Context**

Current clinical practice guidelines for the treatment of acute mechanical lower back pain have been derived from independent systematic reviews carried out on an international scale (1-12). Their recommendations have been shown to be highly consistent and based on sound scientific evidence rather than on consensus (13). The knowledge translation of these guidelines to primary health care providers has to date been unimpressive (14-16). Multiple studies have demonstrated a poor correlation between what primary health care providers think is effective treatment and what has actually been shown to be effective treatment (17-20). Without widespread implementation of guideline-recommended treatments, the degree to which the huge volume of scientific research upon which the guidelines are based can help this patient population cannot be adequately evaluated.

The purpose of this study was to compare the outcomes of treatment comprised exclusively of guideline recommended therapies, including a component of guideline concordant lumbar spinal manipulative therapy administered by chiropractors, with family physician-directed "usual care" for patients with acute low back pain. Our overall goal was to advance the process of knowledge translation and evidence-based care to this patient population. Our hypothesis was that guideline

concordant treatment strategies result in improved outcomes. The primary outcome measure was the difference in mean changes in the RDQ scores between the two treatment groups at 16 weeks following the start of treatment. The secondary outcome measures were differences in the mean changes in RDQ scores at 8 and 24 weeks after the start of treatment and in SF-36 BP and PF scores at 16 weeks post treatment.

- **Methodology**

Patient Population:

This study was designed as a two-arm, prospective, randomized, clinical trial employing blinded outcome assessment. All study patients were recruited from the patient population currently referred for assessment at the Combined Neurosurgical and Orthopaedic Spine Program (CNOSP) Outpatient Clinic at Vancouver General Hospital, a university teaching hospital located within a large Canadian metropolitan centre. The inclusion criteria for this study were; patients aged between 19 and 65 years and a chief complaint of acute lower back pain. All patients included in the study satisfied the Quebec Task Force Classification of Spinal Disorders criteria or categories I or II and had symptoms for more than two weeks and less than four weeks. Patients were excluded from the study if they had any condition related to a spinal "red flag" sign, (e.g. cauda equina syndrome, fracture, malignancy, systemic signs of infection, active inflammatory process), any spinal nerve root irritation or deficit or were pregnant. Patients were also excluded if they had persisting pain in any other areas of their spine (e.g. chronic neck pain) or had any third party involvement (e.g. Workers' Compensation or other insurance claims).

Randomization:

Patients were randomized to receive either clinical practice guideline-concordant treatment (GCT) in the CNOSP Outpatient Clinic or usual care /guideline discordant treatment (GDT) from their family physicians. Block randomization using a computer generated randomization chart was used to ensure

equal numbers of subjects between the groups throughout the recruitment period. Variable blocks of four, six and eight were used to maintain blinding of the allocation sequence to study personnel.

Treatments:

All study patients were assessed initially by a physician in the CNOSP outpatient clinic to confirm that they met the inclusion / exclusion criteria of the study. Patients randomized to received GCT then received reassurance regarding the natural history of acute mechanical lower back pain; advice to avoid certain passive treatments (e.g. bed rest, heat or the use of back supports/corsets/braces), advice to participate in mild aerobic exercise (e.g. carry out a progressive walking program comprised of two walks a day, each with an initial duration set to the patient's tolerance, starting with between five and 15 minutes, and adding two minutes a week to each walk); acetaminophen 650 mg every six to eight hours when required for pain for a period of two to four weeks, except when medically contraindicated (e.g. allergy, compromised liver function, acute porphyria); and a maximum four week course of lumbar spinal manipulative therapy using conventional side posture, high velocity, low amplitude techniques (i.e. no other areas of the spine were treated and specifically the patients did not receive any manipulation of the cervical spine). Spinal manipulation was administered two to three times per week at the discretion of the attending Chiropractor for a maximum of eight weeks. GCT group patients were also advised to avoid guideline-discordant treatments including the use of muscle relaxant and opioid-class medications, passive physiotherapy modalities, bed rest and "special" back exercise programs (e.g. "core stability" or extension exercises).

Patients randomized to the usual care / GDT treatment arm were advised of their diagnosis (i.e. acute mechanical lower back pain) and referred back to their referring family physician with a letter that explained the protocol of the current study. No specific treatment recommendations were made by

the CNOSP physician. The attending family physicians were also provided with a standardized consultation report containing information that confirmed the diagnosis of acute lower back pain and were simply advised to treat the patient at their own discretion. The family physicians were further advised that their patients would be seen for a follow-up assessment at 8 and 16 weeks after the start of their treatment and that the content of the treatment that their patients had received would be recorded.

Spinal Manipulation Treatment:

Hospital privileges were granted to four community-based Chiropractors for the duration of this study. The four Chiropractors participating in this study agreed in advance to modify their typical patterns of practice and administer spinal manipulative therapy in a standardized manner (i.e. conventional side posture, high velocity, low amplitude techniques). Specifically, the patients enrolled in this study received spinal manipulation administered to their lumbosacral spine areas only at a frequency of twice a week for a maximum of four weeks. In particular, none of the patients in the GCT group received any form of neck manipulation. In addition, none of the patients that received spinal manipulation received any other forms of chiropractic treatment (e.g. soft tissue massage, so-called physiotherapy modalities [e.g. ultrasound, interferential or muscle stimulation therapy], a home exercise program or advice to take any non-prescription medication or nutritional "supplements"). Patients in the GCT group were advised that participation in any of the treatments provided was entirely optional and that they could decline any individual component of treatment.

Outcomes Assessment:

The primary outcome of interest was the change in functional improvement at 16 weeks compared to the start of treatment, measured using the modified RDQ (21). The secondary outcomes of interest were the changes in RDQ scores at 8 and 24 weeks and the changes in both the BP and PF domain

scores of the SF-36 questionnaire, in the GCT and the usual care / GDT patient groups at 16 weeks. In addition, time to return to work data was recorded using the Occupational Role Questionnaire. (See Appendices 1 and 2).

Baseline historical, demographic, RDQ, SF-36 and Occupational Role Questionnaire questionnaires were administered by the study coordinator at the time of the initial clinical evaluation (See Appendices 1 and 2). With the exception of the initial demographic questionnaire, these same questionnaires were re-administered at the time of the patient's 8 and 16 week (after the baseline) follow-up assessments. An additional set of questionnaires was mailed to the patient at the 24-week post-treatment point. In addition, patients in the usual care / GDT group had the composition of the treatment they received recorded and scored (i.e. from 0 to 8) for guideline concordance using a standardized format previously described (14). In summary, the guideline concordance of the treatment received by each patient was scored out of a maximum of eight points: Points were given for recommending any of the four guideline concordant treatments: 1) reassurance of the favorable natural history; 2) NSAID or acetaminophen if the patient requested medication; 3) spinal manipulative therapy involving the lumbar spine for a period of up to 4-6 weeks; 4) aerobic exercise. Points were also given if not prescribed or deducted if prescribed, for four guideline-discordant treatments: 1) greater than seven day use of narcotic medication; 2) bed rest of greater than three days; 3) passive physiotherapy or massage therapy; 4) specific back exercise programs. Patients receiving GCT were also asked at the time of their 8 and 16 week follow-up assessments and in the 24 week mailed questionnaire package if they had received any other forms of treatment during their participation in the study. Subjects not returning their questionnaires within three weeks of the required dates were contacted once a week by phone, for a maximum of three times.

Statistical Analysis:

The mean change in RDQ scores and in the SF-36 BP and PF scales were compared between the GCT and usual care / GDT groups, using an unpaired t-test and analysis of covariance to adjust for differences in baseline scores between treatment groups.

Calculation of sample size:

Bombardier et al. and Roland recommended the use of two to three points as the minimal clinically important difference (MCID) on the Roland Disability Questionnaire in clinical trials of lower back pain (21, 22). Assuming a difference in mean RDQ scores between groups of three points, a standard deviation of 4.4 (as per Constant et al) (23), power of 0.80, and a significance level of 0.05 (two-sided), the estimated sample size for each arm of the study was 35. Also, assuming a potential dropout and/or loss to follow-up rate of 25%, a total required sample size of 88 (35 + 35 + 18) was estimated.

SF-36 score interpretation

The developers of the SF-36 have suggested that using a five point difference (on the 0 to 100 scale) is the smallest score change that is considered to be clinically relevant (25). In addition, Hays and Morales concluded that the MCID with respect to the SF-36 PF and BP domains is typically in the range of 3-5 points (26). We therefore chose a difference of five points to be the MCID.

Ethics approval was obtained from both the University Clinical Research Ethics Board (CREB) (CREB certificate number H04-70588). The study was registered with CONSORT (Clinicaltrials.gov; Identifier is NCT00135239).

- **Research Findings**

Spinal Manipulation:

Two patients randomized to GCT expressed mild apprehension about receiving spinal manipulation treatment from a chiropractor, but none declined the component of their treatment that involved chiropractic spinal manipulation. There were no instances of patients reporting any adverse effects or requesting that their spinal manipulation treatment be discontinued.

Patient Baseline Characteristics:

The demographics of the patients enrolled in this study are summarized in Table 1 (See Appendix 4). There were no statistically significant differences in any of the parameters studied between the GCT and usual care / GDT groups. As shown in Figure 1, a total of 96 eligible patients were needed to fulfill the required study sample of 88 patients (See Appendix 4). All of the patients that declined (8 %) to participate in the study did so due to lack of interest and were not otherwise followed. No patients crossed over from one treatment arm of the study to the other within the 16-week study period. There was an 18% and 20% loss to follow-up in the GCT and GDT groups respectively. As is shown in Table 2, the baseline characteristics of these patients did not differ significantly from those who completed the study (See Appendix 4).

Analysis of Usual Care:

As is shown if Figure 3, none of the patients in the GDT group received treatment from their family physician with a guideline-concordant score of greater than 4 / 8, with 77% having a score of less than or equal to 2 / 8. (See Appendix 4). By definition, all patients in the GCT group received treatment with a guideline concordance score of 8 / 8.

Primary and Secondary Outcomes:

The primary comparison of interest was the differences in mean changes in RDQ scores in the GCT and GDT groups at 16 weeks post baseline. The difference in mean baseline RDQ scores was not statistically significant (Figure 2) (See Appendix 4). The primary outcome of differences in mean RDQ scores at the 16-week follow-up point clearly favored the GCT group, with a mean improvement of 4.1 compared with a mean improvement of 1.3 in the GDT group. Thus, only the GCT group patients showed a clinically significant improvement in RDQ scores at the 16-week post treatment point and the difference between RDQ scores of the GCT group and GDT group was statistically significant ($P < 0 .001$).

As for the secondary outcomes, the difference in RDQ change scores between the GCT and the usual care / GDT groups at the 8-week follow-up point again showed a statistically significant difference in favor of GCT treatment (GCT 3.9 and GDT 2.0; $p < 0.005$). Interestingly, in the GCT group, the 8 week RDQ change scores were statistically significantly better than at the 16-week outcome point ($p < 0.05$) (Figure 2). The differences in 24-week mean RDQ outcome scores were also significantly better in the GCT group (SC 4.0 and UC 2.0; $p<0.005$), thus demonstrating that the therapeutic benefit seen at 8 and 16 weeks was maintained at four months following the start of treatment (Figure 2) (See Appendix 4).

The SF-36 baseline data are provided in Table 3a. There was no statistically significant difference between baseline BP score for the GCT and usual care / GDT groups, while the baseline SF-36 PF domain scores were significantly higher in the GCT group. The 16 week outcomes changes in BP and PF scores were clinically significantly improved from baseline in both the GCT and usual care / GDT groups (See Figures 4a and 4b). The GCT group BP and PF scores improved to a greater

degree than those in the usual care / GDT group with the difference just reaching statistical significance (p=0.049 and p=0.041, respectively) (Table 3b) (See Appendix 4).

The return to work data analysis revealed no significant changes in work status in either group. At baseline, 59% of patients in the GCT group were working and at 16 weeks post baseline 61% were working. In the usual care / GDT group 63% were working at baseline and 66% were working at the 16 week point.

- **Implications for future research on occupational health**

This study is believed to be the first randomized controlled clinical trial carried out to assess the efficacy of full clinical practice guideline-based treatment of patients with acute mechanical lower back pain. The results of this study show that in equivalent cohorts of patients with acute mechanical lower back pain of less than four weeks duration, carefully controlled full guideline-concordant treatment (GCT) had statistically significantly greater improvements in RDQ and SF-36 BP and PF domain scores as early as eight weeks after the start of treatment and that this effect was maintained (or improved) at 16 weeks after the start of treatment when compared with usual care / guideline-discordant treatment (GDT). These results are supportive of GCT as a whole or package of treatments and should not in any way be interpreted as an endorsement or criticism of any one particular health care profession. In particular, the chiropractic treatment that the GCT patient group received in all likelihood differed significantly from that which they would have received from chiropractors in the community.

This study follows two previous research investigations (also funded by WorkSafe B.C.) conducted by our group that studied family physician concordance with clinical practice guidelines in the management of patients with acute lower back pain. These studies have demonstrated that current

family physician-recommended treatments are highly guideline-discordant and that this non-concordance with guideline-recommended treatments was not based upon physician or patient ignorance of the guidelines (14-18). The results of these previous studies parallel those of other investigators who have demonstrated that family physicians are highly resistant to changing their patterns of practice for managing patients with lower back pain (19-20).

This study was also preceded by two other studies that addressed the principles of clinical practice guideline-based care or spinal manipulation used in combination with other therapies. The first was a non-randomized clinical trial carried out by McGuirk et al, that employed a design that bypassed the guideline implementation process by establishing “special clinics” staffed by physicians who “agreed to abide” by the guidelines to treat a cohort of patients with acute back pain. While the treatments provided under the umbrella of “evidence-based care” did not include all of the guideline-recommended treatments (e.g. spinal manipulation), evidence-based care was shown to achieve greater rates of full recovery, result in reduced need for continuing care, and was less expensive (24). Secondly, the UK BEAM study assessed the therapeutic value of adding either spinal manipulation (administered by either a chiropractor, osteopath or physiotherapist), an approximately eight week course of once a week exercise classes in a standardized fashion or both (sequentially and not concurrently) to general practice care enhanced by a booklet on back pain, in the treatment of patients with lower back pain for at least 21 of the previous 28 days (27). The primary outcome measure(s) was / were differences in mean RDQ scores at 1, 6 and 12 months post baseline. A specific single primary outcome measure was therefore not defined. The reported conclusions of the study were that manipulation (and “best care” general practice) and manipulation followed by exercise (and best care general practice) produced “small to moderate and moderate benefits” respectively, when compared to best care general practice alone. Exercise on its own added to best care general practice produced small benefits.

In comparing these two studies to our study there are some important differences. If the McGuirk et al study was considered to be an evaluation of clinical practice-guideline-based treatment, then a significant limitation of that study was that it excluded any form of manual therapy and in particular, did not include a component of spinal manipulative therapy. In addition, the validity of its conclusions was limited by its prospective design (i.e. it was not a RCT). The UK BEAM trial methodology differed most significantly from our study in that it did not exclude patients with chronic pain and thus included the potential for the confounding aspects of this patient population. In addition, three of its four treatment arms evaluated components of clinical practice guideline-based care in a "piece meal" manner. The use of "back exercise classes" as a component of treatment could also be regarded as guideline-discordant since "special back exercise program have been demonstrated to have no value when compared with a return to normal activities. However, while the methodology and study design of these two studies in our view differed significantly from the more succinct and focused methodology used in our study there were also many important similarities. It is therefore perhaps not surprising that the results of these two studies generally support the findings of our study, namely that guideline-based treatments and a component of a well-defined form of spinal manipulative therapy used in combination with other evidence-based treatments are associated with improved outcomes in the treatment of patients with lower back pain.

Furthermore, as was the case in the UK BEAM study, the framework of our study has introduced the concept of evaluating "treatment packages" that include a component of spinal manipulative therapy administered by chiropractors. Previously reported clinical studies involving spinal manipulative therapy administered by Chiropractors have largely been in the form of superiority trials involving direct comparisons with other forms of therapy. The design of this study (and the UK BEAM study) evaluated spinal manipulative therapy administered by Chiropractors as a component of therapy and in the manner recommended by current clinical practice guidelines and arguably in a manner that

resembles how many patients currently receive this treatment in the community. For this patient population, the results of this study clearly support the incorporation of this type of spinal manipulative therapy, (in this instance administered by Chiropractors), into a spine treatment team approach in the framework of evidence-based care.

Our study has several limitations beginning with the comparison of usual care / GDT, directed by a family physician with GCT provided by medical spine specialists and chiropractors in a hospital-based spine program setting. It may be argued that highly standardized evidence based care provided by spine specialists in a programmatic setting is likely to result in improved outcomes when compared to GCT provided by any group of practitioners (e.g. family physicians, chiropractors in private offices, physiotherapists, etc.). This study therefore cannot comment on the effectiveness of usual chiropractic care. As well, we acknowledge that spinal manipulative therapy may be provided by health care professionals other than chiropractors and in a guideline concordant manner.

One of the criticisms that is leveled at guidelines is that they may not be “generalizable” and that individualized treatment at the discretion of the care giver may not result in improved outcomes. The unique setting of this study creates difficulty in generalizing its conclusions. Therefore, the degree to which the outcomes of this study can be applied to a similar treatment program administered outside of a Hospital Spine Program, in the community is not known.

Although the “efficacy design” of this study makes the carte blanche application of the results to everyday practice difficult (“generalizability”), the fact that the family practitioners knew they were in a study and that their treatments and results would be reported, makes the difference between the two groups even more robust; the so called Hawthorne Effect.

- **Policy and Prevention**

This study has clearly and definitively demonstrated that a combination of evidence-based treatments that encompasses all of the clinical practice guideline-recommended elements produces superior outcomes when compared with family physician-directed care in the treatment of patients with acute mechanical lower back pain. Thus, the results of this study will help to define a new model for how acute lower back pain should be treated. Furthermore, these results may also be of assistance in determining which healthcare services or combination of healthcare services, should be deemed insured services and which should not, for the treatment of acute lower back pain.

The results and implications of this study should be of particular interest to Provincial Health Care Insurers, Provincial Worker's Compensation Boards and all other disability insurers. They may also be of interest to healthcare provider organizations such as Provincial Colleges of Family Physicians and Chiropractors and lastly to community-based family physicians and chiropractors who are currently providing patients with acute lower back pain with treatment not consistent with evidence-based practice.

Finally, the goal of advancing the process of knowledge translation and evidence-based care to this patient population should be considered to be a "work in progress". To that end, the proposed fourth research study carried out by our group in this series proposes to investigate if the demonstrated efficacy of the treatment model that has been validated in a hospital-based spine program outpatient clinic, will be as effective in a community-based setting. To that end, a multi-centre research study is now being designed and drafted.

- **Dissemination/Knowledge Transfer**

A podium presentation of the preliminary results (i.e. 16 week outcomes) of this study was made to The Canadian Spine Society (Mont Tremblanc February, 2007) (See Appendix 3). The results of this study have also been accepted by The International Society for the Study of the Lumbar Spine (Hong Kong) and The North American Spine Society (Austin, Texas). The final manuscript will be submitted to one of the highly regarded and widely read peer reviewed journals (e.g. Spine or The Spine Journal,). The results of this study will be made available to all interested parties through the web page of the CNOSP, Department of Orthopaedics, University of British Columbia.

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Appendix 1

Methods of Measurement:

Instruments (attached in full in the Appendix 2)

Roland Morris Disability Questionnaire (RDQ)

This is a self-report instrument that is designed to measure the degree to which a patient's function is limited by back pain. It has been used in a large number of back pain trials. (Time to complete: 12 minutes)

Occupational Role Questionnaire (ORQ)

This is an 8-item self-report questionnaire with demonstrated reliability and validity in capturing two aspects of occupational role functioning (productivity and satisfaction) (ref) (Time to complete: 1 – 2 minutes).

SF-36

The SF-36 Version 2.0 is 36-item self-report instrument that has been tested for both reliability and validity on varied populations including back and leg pain patients. It allows collection of standardized outcomes for two domains: Physical Health and Mental Health. These are summarized into eight variables consisting of: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, mental health. (Time to complete: 5 – 10 minutes).

Return to Work:

1. Patient reported return to work to include type / capacity (i.e. full pre-injury work or light duties) and work schedule (i.e. full time or part time or graduated return to work).
2. Job satisfaction and performance (Occupational Role Questionnaire – see above).

Appendix 2

The Roland-Morris Low Back Pain and Disability Questionnaire

When your back or leg hurts, you may find it difficult to do some things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain or sciatica. When you read them, you may find that some stand out because they describe you today. As you read the list, think of yourself today. When you read a sentence that describes you today, put a check in the yes column. If the sentence does not describe you, check the no column.

Yes No

❑ ❑ **1. I stay at home most of the time because of my back problem or leg pain (sciatica).**

❑ ❑ **2. I change position frequently to try to get my back or leg comfortable.**

❑ ❑ **3. I walk more slowly than usual because of my back problem or leg pain (sciatica).**

❑ ❑ **4. Because of my back problem, I am not doing any of the jobs that I usually do around the house.**

❑ ❑ **5. Because of my back problem, I use a handrail to get upstairs.**

❑ ❑ **6. Because of my back problem, I have to hold on to something to get out of an easy chair.**

❑ ❑ **7. I get dressed more slowly than usual because of my back problem or leg pain (sciatica).**

❑ ❑ **8. I only stand for short periods of time because of my back problem or leg pain (sciatica).**

❑ ❑ **9. Because of my back problem, I try not to bend or kneel down.**

❑ ❑ **10. I find it difficult to get out of a chair because of my back problem or leg pain (sciatica).**

❑ ❑ **11. My back or leg is painful almost all the time.**

❑ ❑ **12. I find it difficult to turn over in bed because of my back problem or leg pain (sciatica).**

❑ ❑ **13. I have trouble putting on my socks (or stockings) because of the pain in my back or leg.**

❑ ❑ **14. I only walk short distances because of my back or leg pain (sciatica).**

❑ ❑ **15. I sleep less well because of my back problem.**

❑ ❑ **16. I avoid heavy jobs around the house because of my back or leg pain (sciatica).**

❑ ❑ **17. Because of my back problem, I am more irritable and bad tempered with people than usual.**

❑ ❑ **18. Because of my back problem, I go upstairs more slowly than usual.**

❑ ❑ **19. I stay in bed most of the time because of my back or leg pain (sciatica).**

❑ ❑ **20. Because of my back problem, my sexual activity has decreased.**

❑ ❑ **21. I keep rubbing or holding areas of my body that hurt or are uncomfortable.**

❑ ❑ **22. Because of my back problem, I am doing less of the daily work around the house than I would usually do.**

❑ ❑ **23. I often express concern to other people over what might be happening to my health.**

Occupational Role Questionnaire (ORQ)

The following questions ask about the way your back pain may interfere with your job. To answer each question, please circle **one** number.

Would you say that, because of back pain,	**A lot**	***Somewhat***	***A little***	***Not at all***
1. You cut down on the amount of extra work or overtime?	3	2	1	0
2. You work more slowly?	3	2	1	0
3. You take more frequent or longer breaks?	3	2	1	0
4. You are less able to concentrate on your work?	3	2	1	0
5. You have fewer opportunities to upgrade your skills?	3	2	1	0
6. You are more likely to lose your job?	3	2	1	0
7. You have less satisfaction with your job?	3	2	1	0
8. You need more help from your co-workers?	3	2	1	0

Employment History

a) Are you currently working? ❑ Yes ❑ No

b) Have you recently returned to work? ❑ Yes ❑ No
If yes:
Date: ________________________

c) Are you working at the same capacity in which you were working prior to your injury? ❑ Yes ❑ No

Please specify: ____

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking more than a kilometre	☐ 1	☐ 2	☐ 3
h Walking several hundred metres	☐ 1	☐ 2	☐ 3
i Walking one hundred metres	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had difficulty performing the the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?.

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **During the __past 4 weeks__, how much did __pain__ interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. **These questions are about how you feel and how things have been with you __during the past 4 weeks__. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the __past 4 weeks__…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is each of the following statements for you?

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a	I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b	I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c	I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d	My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Appendix 3

Seventh Annual Meeting

CANADIAN SPINE SOCIETY

Septième réunion annuelle

SOCIÉTÉ CANADIENNE DU RACHIS

Wednesday, March 21 to Saturday, March 24, 2007

mercredi, le 21 mars au samedi, le 24 mars 2007

FINAL PROGRAM

PROGRAMME FINAL

Fairmont Tremblant
3045 Chemin de la Chapelle
Mont-Tremblant, Quebec

FACULTY OF MEDICINE | UNIVERSITY OF CALGARY

Office of Continuing Medical Education and Professional Development

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A Randomized Controlled Trial on the Effectiveness of Clinical Practice Guidelines in the Medical and Chiropractic Management of Patients with Acute Mechanical Lower Back Pain

Paul Bishop, Jeffrey Quon, David Olson, Don Nixdorf, Bradley Yee, Charles Fisher, Marcel Dvorak

Combined Neurosurgical and Orthopaedic Spine Program, Vancouver, Canada

Introduction: Evidence-based clinical practice guidelines (CPG) for the management of patients with acute mechanical lower back pain (ALBP) have been defined on an international scale. MultiCentre clinical trials have demonstrated that most ALBP patients do not receive CPG-based treatment. The purpose of this study was to determine if full CPG-based care is more effective than usual care (UC) in the treatment of ALBP. **Methods:** A two arm, parallel design, randomized control trial. Inclusion: Ages 19 –59; QTFSD I and II ALBP $\leq$ 4 weeks. Exclusion: "Red flag" conditions, co-morbidities contraindicating Chiropractic spinal manipulative therapy (CSMT). Patients were assessed by a spine physician and randomized to CPG care (re-assurance, avoidance of passive treatments; acetaminophen; four weeks of lumbar CSMT; return to work within eight weeks), or family physician-directed UC, the components of which were recorded. Primary outcome: difference in Roland Morris Disability (RDQ) scores at 16 weeks between the CPG and UC groups. Secondary outcome: differences in Bodily Pain (BP), Physical Functioning (PF) SF-36 domains. Hospital / University Ethics approval was obtained. **Results:** 88 patients were recruited with 39 in the CPG group and 38 in the UC group completing the study. The primary outcome showed a mean difference in RDQ scores in the CPG group (-2.52) that was statistically significantly greater than those in the UC group (-0.25) ($p<0.001$). The secondary outcomes showed that both the BP and PF domains of the SF-36 were statistically significantly improved ($p<0.05$) in the CPG group when compared to the UC group. **Discussion:** This is the first published randomized control trial comparing full CPG including CSMT, to family physician-directed UC in ALBP patients. It has shown that that CPG-based care is more effective.

Appendix 4

Tables and Figures

Table 1 Baseline Demographics of the Study Population

Characteristic	Usual Care	Study Care
N	35	35
Age (yr) [mean, SD, median])	38.1 (11.3); 37.6	36.5 (11.9); 36.0
Gender (% Female)	61	58
Work Status Working at Baseline (%)	63	59

Table 2 Characteristics of Patients Lost to Follow-up

Characteristic	Patients lost to follow-up
N	8
Age (yr) [mean, SD, median])	36.2 (10.2); 35.9
Gender (% Female)	60
Work Status Working at Baseline (%)	61

Table 3 SF-36 Baseline Data and ANCOVA for group difference

a) Summary of baseline data

	Group	Mean	Standard Deviation
Physical Function (PF)	**GCT**	**56.7**	**21.8**
	GDC	**50.5**	**18.1**
Bodily Pain (BP)	**GCT**	**40.6**	**19.8**
	GDC	**41.2**	**19.9**

b) ANCOVA for group difference

	Group	Adjusted Mean	Diff	p-value
PF	GCT	67.8	6.9	0.041
	GDT	60.9		
BP	GCT	53.7	5.2	0.048
	GDT	48.5		

Note: GCT (Guideline-concordant care); GDT(Guideline-Discordant care)

Figure 1

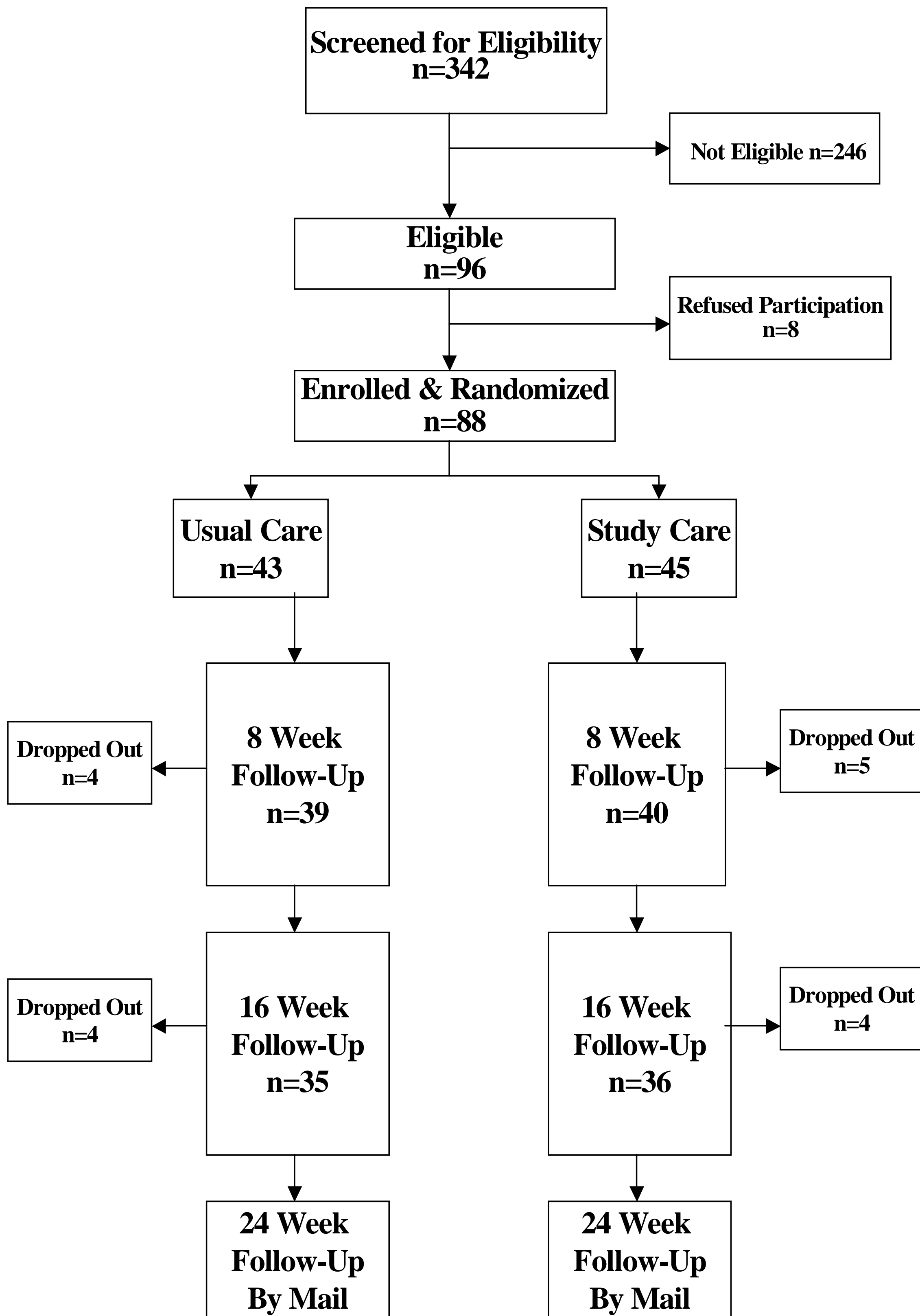

Figure 1 Legend:

Patient Flow Diagram of the Research Study:
Exclusion, Enrollment, Randomization and Follow-up

Figure 2

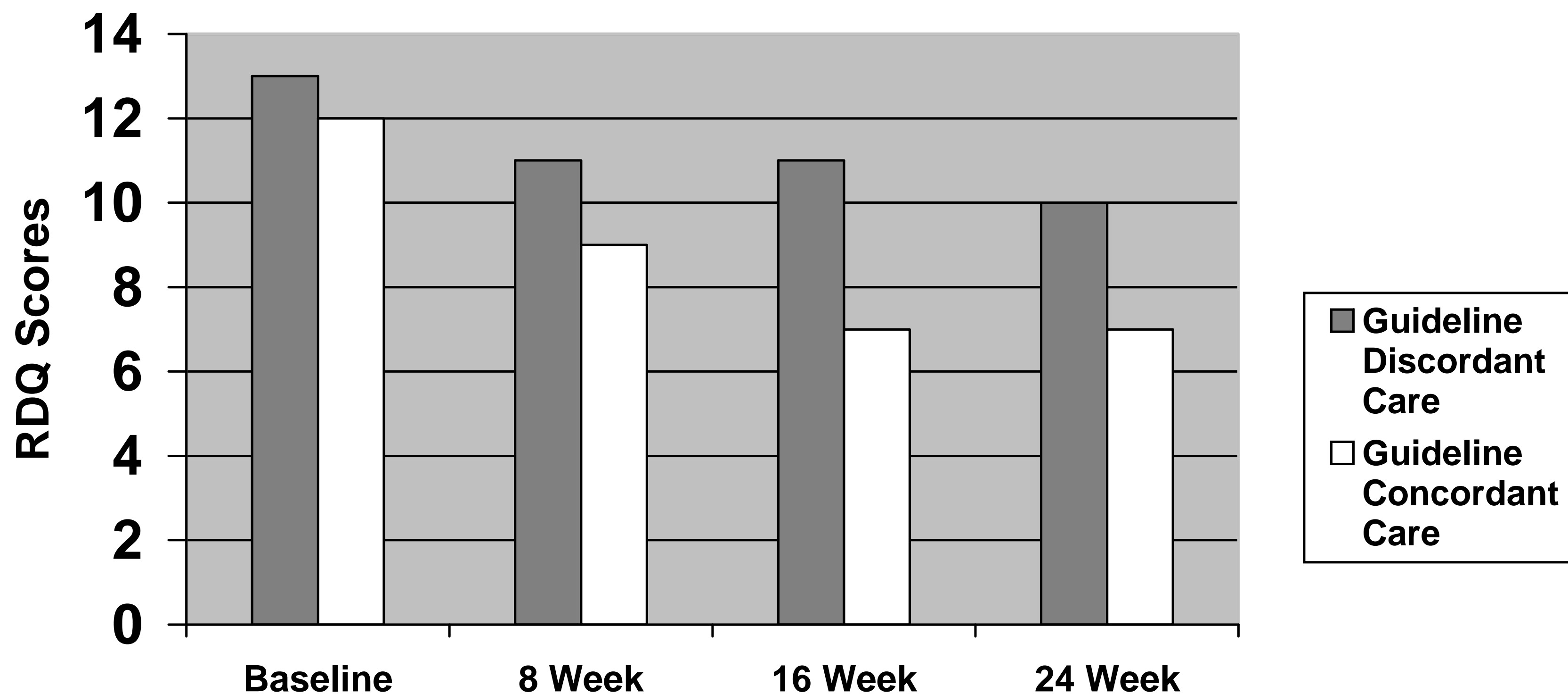

Figure 3

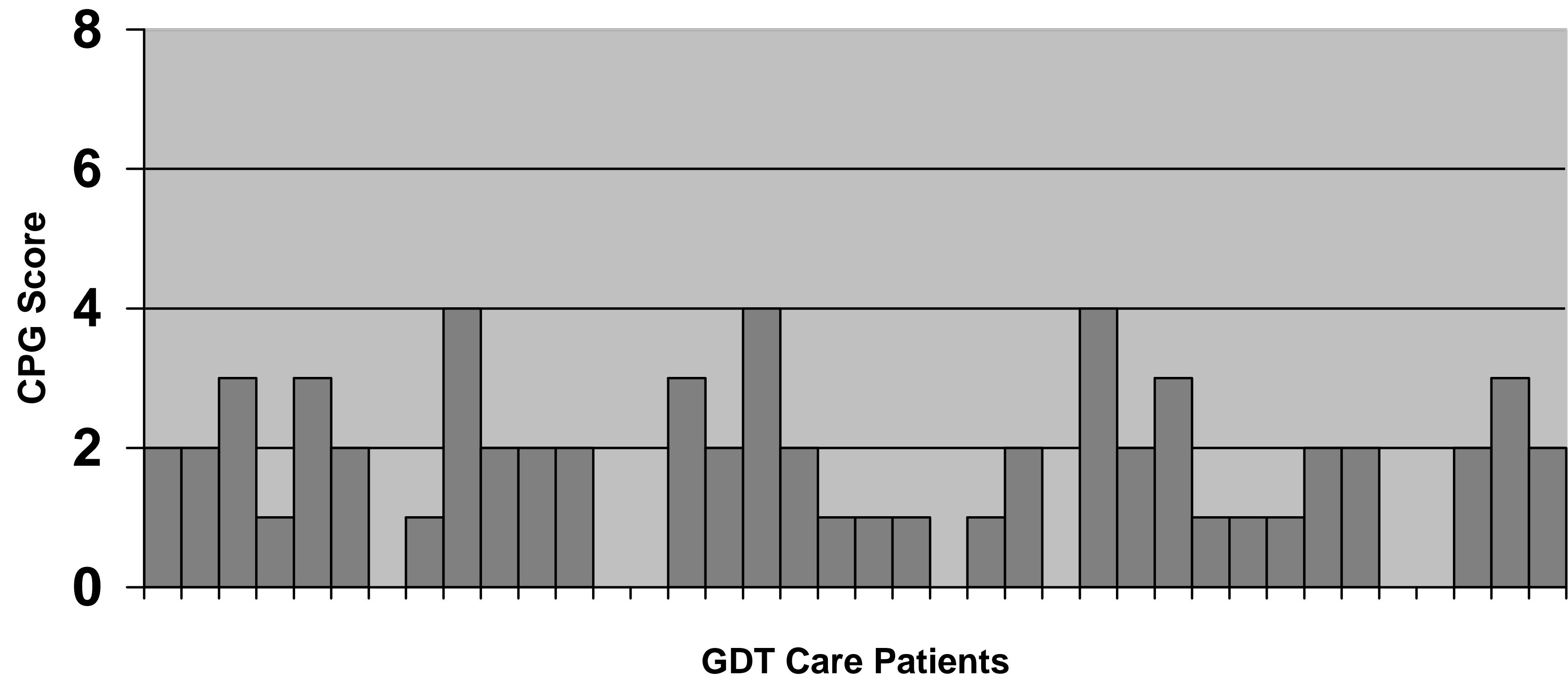

Figure 4a

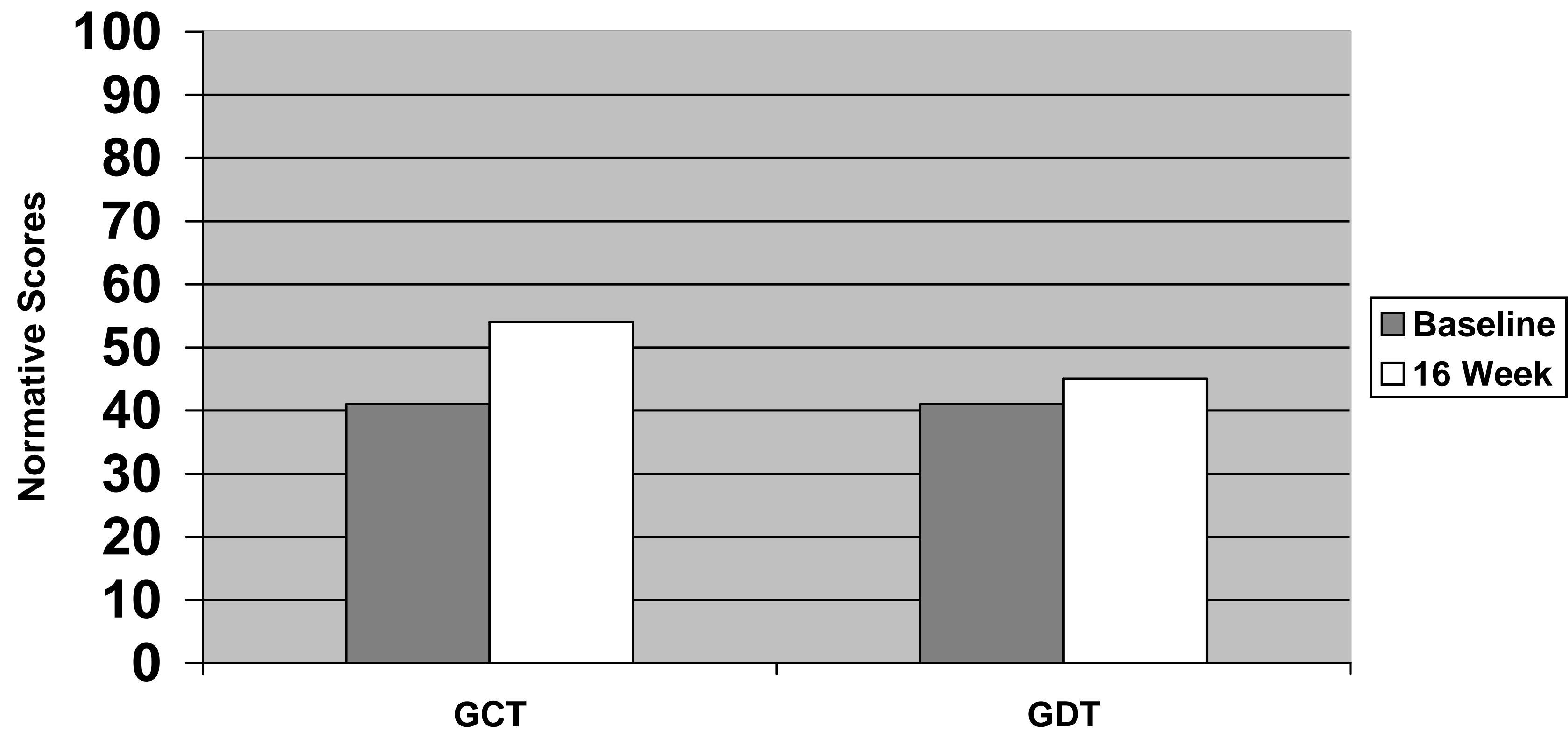

Figure 4b