

Research Paper Review

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Chiropractic Maintenance Care for Recurrent and Persistent Low Back Pain

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ABSTRACT

INTRODUCTION: For individuals with recurrent or persistent non-specific low back pain (LBP), exercise and exercise combined with education have been shown to be effective in preventing new episodes or in reducing the impact of the condition. Chiropractors have traditionally used Maintenance Care (MC), as secondary and tertiary prevention strategies. The aim of this trial was to investigate the effectiveness of MC on pain trajectories for patients with recurrent or persistent LBP.

METHODS: This pragmatic, investigator-blinded, two arm randomized controlled trial included consecutive patients (18-65 years old) with non-specific LBP, who had an early favorable response to chiropractic care. After an initial course of treatment, eligible subjects were randomized to either MC or control (symptom-guided treatment). The primary outcome was total number of days with bothersome LBP during 52 weeks collected weekly with text-messages (SMS) and estimated by a GEE model.

RESULTS: Three hundred and twenty-eight subjects were randomly allocated to one of the two treatment groups. MC resulted in a reduction in the total number of days per week with bothersome LBP compared with symptom-guided treatment. During the 12 month study period, the MC group (n = 163, 3 dropouts) reported 12.8 (95% CI = 10.1, 15.5; p = <0.001) fewer days in total with bothersome LBP compared to the control group (n = 158, 4 dropouts) and received 1.7 (95% CI = 1.8, 2.1; p = <0.001) more treatments. Numbers presented are means. No serious adverse events were recorded.

CONCLUSION: MC was more effective than symptom-guided treatment in reducing the total number of days over 52 weeks with bothersome non-specific LBP but it resulted in a higher number of treatments. For selected patients with recurrent or persistent non-specific LBP who respond well to an initial course of chiropractic care, MC should be considered an option for tertiary prevention.

ANALYSIS

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Background Information

It is well-known that lower back pain (LBP) is often recurrent and has a huge negative impact on society; thus, effective preventive strategies are needed. The prevention of chronic conditions can be described as secondary or tertiary, where secondary prevention strategies reduce the impact of existing conditions and tertiary attempts to reduce the impact of conditions that become chronic.

One of the strongest predictors of a positive outcome to manual treatments, including spinal manipulation (SMT) for back pain, is when patients report subjective improvement at the fourth visit. These "fast responders" have also been shown to report better outcomes at three and 12 months.

Many chiropractors recommend "maintenance care (MC)" to their patients for recurrent and persistent musculoskeletal pain and dysfunction, which qualifies as a form of secondary or tertiary prevention (1). Typically, such preventive care is delivered in regularly spaced visits over longer periods of time. The use of MC visits as a prevention strategy is common among Scandinavian chiropractors who participated in this study, as well as the general population of chiropractors in this region (and others, of course!) (2). Conversely, other chiropractors who do not use MC may simply discontinue a patient's care and recommend them to return if the pain recurs. In most cases, clinicians mix these two approaches (i.e. recommending MC versus symptomatic care) depending on an individual patient. It is noteworthy that in this study, chiropractors who either never or always recommended MC were not included in the trial to avoid bias.

Since it is not known which method is most beneficial to patients, the objectives of this study were to compare MC to symptom-guided care by considering:

- 1. the total number of days with bothersome LBP over 52 weeks,
- 2. the prevalence of days with pain per week over time as trajectories, and
- 3. the total number of treatments.

Pertinent Results:

After applying the inclusion/exclusion criteria and taking into consideration dropouts, 319 subjects were included in the final data analysis. The subjects were randomized into two groups (MC and symptom-guided care) that had similar descriptive baseline data, which indicates that the randomization was effective at distributing patient characteristics evenly.

Thirty-five chiropractors, who were members of the Swedish Chiropractic Association and part of a practice-based research network, participated in the study.

The total number of days that patients experienced bothersome LBP over the twelve months study period was 85.2 for the MC group and 98.0 for the control group who received symptom-guided care. The MC group also experienced a faster reduction in days with bothersome LBP and reached a lower steady state earlier.

The total number of visits over the twelve months (in the primary analysis) was 6.7 for the MC group and 4.8 for the control group. The sensitivity (secondary) analysis found the total number of visits over the twelve months to be 8.6 for the MC group and 4.8 for the control group.

There were no reports of serious harm by patients in either of the treatment groups, although there were some reports of minor side effects.

CLINICAL APPLICATION & CONCLUSIONS

This study was well-designed and executed, so its results may confidently be applied to clinical practice. Patients with recurrent and persistent LBP that respond favorably to an initial course of manual therapy may respond favorably to maintenance care! A clinician could expect these patients to experience fewer days with bothersome LBP per week, as compared to patients who receive symptom-guided treatment.

However, patients who received MC received a higher number of treatments (about 2 more), which would result in additional costs for care as compared with the use of a symptom-guided approach. For most patients, greater pain relief – even in exchange for slightly higher $\cos t$ – is preferable and this is something that can easily be discussed with each individual patient.

The concept of maintenance care has always sparked controversy both from within the chiropractic profession and from outside sources. Finally, we have a good study to discuss on this topic, with more work from these authors to come!

STUDY METHODS

This was a pragmatic, randomized controlled trial in which the investigators and assessors were blinded. Consecutive patients with persistent or recurrent LBP were recruited by participating chiropractors and screened for eligibility over a series of three visits, as follows:

- 1. Baseline 1: the initial screening visit when patients first consulted the chiropractor;
- 2. *Baseline 2:* the 4th visit at which patients showed a favorable response to treatment (or earlier if subjective improvement occurred earlier) and when patients were randomly allocated to one of the treatment arms; and
- 3. *Inclusion visit:* at which point the intervention was started.

Please note, patients had to rate themselves as being "definitely improved" in order to continue on to the inclusion visit.

Inclusion criteria at Baseline 1:

- Age 18–65 years
- LBP with or without leg pain for more than 30 days during the past year
- Previous episodes
- Access to a mobile phone
- Ability to send and receive SMS (text messages)

Inclusion criteria at Baseline 2:

• Self-rated "definitely improved" by the 4th treatment (queried via a 5-point Likert scale)

Inclusion criteria at Study Start (Inclusion visit' from above):

• Interval between treatments is one month or more.

Exclusion criteria:

- Pregnancy
- Chiropractic treatment less than 3 months ago (prior to beginning of study)
- Completely subsidized treatment from 3rd party payer
- Serious pathology (i.e. acute trauma, cancer, infection, cauda equina, osteoporosis, vertebral fractures)
- Contraindications to manual therapy

In an effort to minimize bias from the chiropractors' preconceptions and personal preferences about the use of MC, only chiropractors who recommended MC to patients at least sometimes were included in the study (that is, chiropractors who never or always

recommended MC were excluded) – in practice, most chiropractors recommend both approaches at times, depending on the individual patient! The chiropractors were instructed to tailor the type of treatment and frequency of visits to each patient's individual needs, consistent with their usual practice.

Patients in the MC group were instructed to schedule an appointment before substantial pain reoccurred (i.e. controlled by the clinician), whereas patients in the control group were instructed to schedule an appointment if and when the pain reoccurred (i.e. patient controlled).

The study's primary outcome was the number of days with bothersome LBP (3) experienced over the 52-week study period. Patients answered a text message every week that asked "On how many days during the past week were you bothered by your lower back (i.e. it affected your daily activities or routines)? Please answer with a number between 0 and 7".

Patients also completed a questionnaire that asked about pain intensity on a 0–10 Numeric Rating Scale, self-rated health (EuroQol 5 dimensions), and psychological and behavioral characteristics (MPI-S). Another questionnaire was administered on the fourth visit that asked about subjective improvement, pain intensity, and the use of pain medication.

STUDY STRENGTHS/WEAKNESSES

This was a pragmatic randomized clinical trial wherein the chiropractors used their usual clinical practices, which makes it more relevant to clinical practice. Additionally, the study was well-planned and executed, making its findings plausible and easier to justify applying its conclusions to clinical practice. The data analysis was robust because the researchers were able to collect a large high-quality data set (16,505 data points and only 1.1% missing data) over a long period of time.

One thing to keep in mind is the fact that patients were only included if they responded well to an initial course of care, so it is unknown whether similar results would be true in slower-responding LBP patients. Previous research indicates that patients who respond favorably early in care are more likely to choose MC (makes sense!). In addition, selecting such fast responders means the authors were likely targeting the right subgroup of patients for manual care – those who respond well. This factor speaks to the pragmatic approach employed in this study design, but may limit the overall generalizability of the results.

For unknown reasons, many subjects were lost during the 3-step inclusion selection process; 32% after the first visit were lost and 25% of those who were eligible at the fourth visit. The authors speculated that patients may have experienced a very fast or very poor improvement early on and decided to discontinue care (this is often what happens in clinical practice too). Fortunately, the baseline data for the lost subjects were very similar to those

for the included and the excluded subjects, which indicates a non-systematic error (so, not a major concern pertaining to the quality of the study).

Commentary from Dr. Andreas Eklund:

Maintenance Care (MC) has been around for a long time within the chiropractic profession and has become an issue of great debate and conflict. Most chiropractors have a view or an opinion of what MC is and the procedure has been used with different objectives, ranging from managing recurrent and chronic conditions to the correction of subluxations and 'Wellness Care'. Even though it has been extensively debated and criticized, up until 2008 little was really known about the procedure or its effectiveness.

In an ambitious research effort headed by Professor Charlotte Leboeuf-Yde, a serious attempt was made to study the procedure. Over the past decade a series of publications under the name the Nordic Maintenance Care Program has been published (references 4-13, listed below). The purpose of the program has been to identify indications for care, treatment content, and frequency of care and to understand the clinical reasoning process among chiropractors in the Scandinavian countries. The understanding gained from the preliminary studies were used to design a pragmatic clinical trial that mimics current clinical practice. The aim of the trial was to investigate the effect and cost-effectiveness of MC for patients with recurrent and persistent LBP. The trial was conducted between 2012 and 2016, and in September, 2018 the first in a series of papers reporting on the effectiveness of MC was published in PLoS ONE (open access). Upcoming publications will report on effect within subgroups, clinical mechanisms and cost-effectiveness, which will allow us to improve the procedure to achieve even better results for our patients.

Clinicians and researchers can now start the process of discussing how we should put this information into practice. How do we interpret the results and what are the clinical implications in terms of clinical recommendations? The efforts made over many years by the clinicians and researchers involved in the Nordic Maintenance Care Program have finally started to bear fruit and it is with a warm heart and abundance of gratitude I would like to thank them for all for their hard work.

An exciting future lies ahead given the vast amount of high-quality research coming out globally from the Chiropractic research community, those willing to reflect on old habits in the light of new information and have the ability to change, have great opportunities to learn and improve the quality of care for their patients.

Andreas Eklund, MSc (Chiro), PhD Andreas Eklund, DC, MSc (Chiro), PhD graduated from the Anglo European College of Chiropractic, England, 2002 and was in full time Chiropractic practice up until 2012 when he was enrolled in a PhD program at Karolinska Institutet. Since 2012 he has been clinically active part-time, owning and managing two publicly funded primary care multidisciplinary rehab units with two partners. The two clinics employs 40 persons in total, Chiropractors, Physiotherapists, Occupational therapists and Dietitians working as an integrated team of health professionals. He earned

his PhD degree 2016, and the title of his thesis was 'Recurrent and persistent low back pain – course and prevention". He currently works as a post Doc at Karolinska Institutet along with his clinical duties. At the moment, he also serves as the chair of the scientific committee of the Swedish Chiropractic Association and is a fellow of the Chiropractic Academy for Research Leadership (CARL). His research interests mainly concern clinical pain science with an emphasis on spinal pain and clinical trials. Specific areas have been effect and cost-effectiveness of Chiropractic Maintenance Care, psychological characteristics and clinical predictors for chiropractic patients.

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