The effectiveness of craniosacral treatment

Preliminary findings on clinical outcome research

Brian Isbell and Sue Carroll

What is outcome research?

As discussed in a previous article (Isbell *et al* 2006), there is little published research on the effectiveness of craniosacral therapy. In the recent article (Neira *et al* 2006) the challenges of carrying out a simple, single-blind, randomised, controlled trial with crossover of treatments to measure the outcome of craniosacral therapy were reported. In this article the evidence of a patient's assessment is presented to demonstrate the effectiveness, as perceived by the patient, of craniosacral treatment.

Patient outcome measures have been used increasingly in conventional and complementary therapies. (Steinsbekk *et al* 1999). By assessing the patients' perception of any changes in health during their treatment – 'Am I better or worse since the treatment?' – the focus is on the patient's assessment after treatment. Thompson and Reilly used patient outcome measures successfully in a study to evaluate the effect of complementary therapies treatment (reflexology and homeopathy) on symptom control in cancer patients (Thompson and Reilly 2002).

MYMOP (Measure Yourself Medical Outcome Profile) is a simple questionnaire designed by Dr Charlotte Paterson (1996) for measuring clinical outcomes assessed by the patients. It is a patient-generated health status questionnaire that is symptom-specific, but also considers the whole person by including the monitoring of daily activity and general well-being. Since validation in 1996, MYMOP has been used successfully for evaluating patient outcomes for both allopathic and complementary therapy treatment (Paterson and Britten 2000 & 2003, Peters *et al* 2000 and Thomas *et al* 2001). MYMOP was adopted by the University of Westminster to assess patient outcomes in the teaching clinic.

The University of Westminster clinic is the largest subsidised multi-disciplinary complementary therapies clinic in the UK offering 14 different therapies in discrete clinics. Since the craniosacral clinic opened in 2001 it has attracted a wide range of patients and is fairly representative of private practice. In addition, because of its position in the public sector offering reduced-fee treatment in central London, the craniosacral clinic receives referrals from GPs and other organisations attracting challenging cases of mental and physical pathology. It is ideally suited to participate in a continuous audit investigating the efficacy of complementary therapies using MYMOP.

The MYMOP form was modified for use within the teaching clinic to make it easier for students to use. Instead of using a visual analogue scale, ratings were recorded as numbers directly on the form and an additional space was added to record any life-affecting events, but otherwise the method remains the same. The patient selects one or two related symptoms that they consider important (would like to improve), and an activity that is affected by the symptom(s); these are then rated on a Likert scale of: 6 for the worst possible score – eg very severe neck pain, to 0 as the best possible score – eg absence of neck pain. A rating for overall well-being is also collected using the same scale. Modified MYMOP forms (mMYMOP) are completed at each consultation ensuring that any clinical changes are monitored. A reduction in scores indicates an improvement in the patient's rating of their own health, whereas any increase in scores indicates an adverse change. Each patient consistently knew their ratings for their previous consultation before rating any current symptom changes.

mMYMOP data collection started in June 2001, and is still continuing, for all craniosacral patients. Data is collected for the full course of craniosacral treatment. Clinics operate on two days each week, where an experienced craniosacral practitioner assesses and treats the patients. Students observe each consultation. A range of conditions was treated: headaches, emotional and functional problems (eg depression, lack of focus), autism and hyperactivity as well as neck, shoulder and back problems. Consultations were scheduled every 4-6 weeks for chronic conditions, but were more frequent if the practitioner considered it appropriate. The mMYMOP was completed at the beginning of each consultation. mMYMOP results were recorded by the practitioner, and entered into a computer database by a technician.

After three years, data was analysed. This has provided the basis for a pilot study. Data was used for all patients who had been treated in the craniosacral clinic who fulfilled the inclusion criteria (minimum attendance of two consultations), irrespective of length of treatment, outcome or symptom.

The results of the study

1 Analysis of the differences in scores between first consultation and latest consultation:

mMYMOP scores for the first consultation (before any treatment) and the latest consultation were collected. Initially, values for the differences in scores between the first consultation and the latest consultation were calculated by subtracting the latest score from the first consultation score for the presenting (first) symptom (see Graph 1), for each patient. This provided an indicator of any changes that may have occurred during craniosacral treatment, and the direction of change. A negative score indicated a worsening of the symptom; a positive score indicated an improvement in the symptom, as perceived by the patient.

Differences could potentially range from +6, when a patient rated their symptom to have originally measured the worst possible score (6), and on their latest consultation it had resolved (0), to –5, where a symptom had registered as being minor, and was aggravated by the treatment to 'as bad as it could possibly be'.
(NB A symptom was unlikely to start with a score of 0.)

Graph 1 Differences in mMYMOP scores between the first and latest consultation for the presenting symptom alone
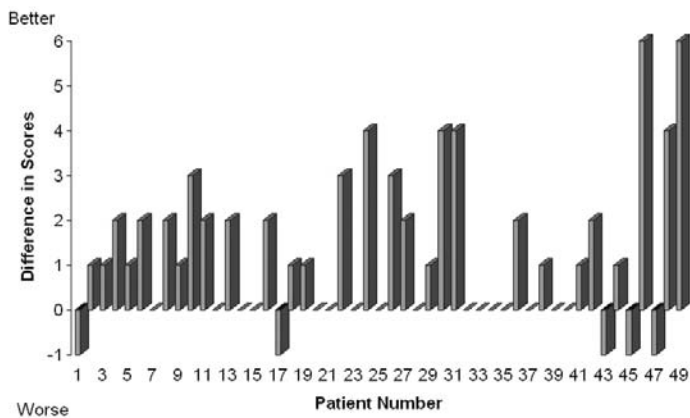

**Table 1 Table of differences between mMYMOP scores for first symptom and well-being**

	No. of patients	No. of patients with improvement in scores	Patients scoring improvement %
First (presenting) symptom	49	28	57
Overall well-being	49	17	35

Analysis over a three-year period showed that out of 49 patients, 57% (28) rated an improvement in their first symptom (see Graph 1) and 35% rated an improvement in their overall well-being.

2 Analysis of averaged scores for each patient:

A more reliable measure of overall change in patient symptoms was calculated by averaging the patients' scores for their symptoms, the activities affected by the symptoms, and overall well-being. Patients who had omitted to rate related activities were excluded from the data sample, reducing the sample size to 46. The scores were averaged for before and after treatment, and a Wilcoxon Signed Ranks Test was applied to the results.

Graph 2.1 Differences in averaged mMYMOP scores between first and latest craniosacral consultation
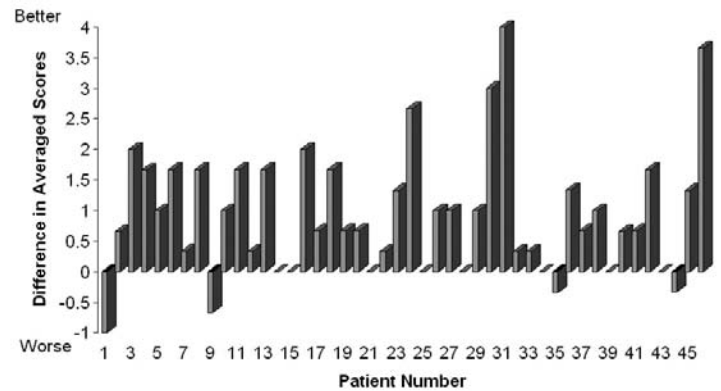
The averaged results showed that the improvement in patients' health scores was highly significant at the $p < 0.001$ level $Z = -4.603$ (n=46) *(Editor's note - this translates as: the probability of the results of this experiment happening by chance is less than one in a thousand - Z represents the average self-assessment scores of 46 patients, which reduced by 4.6 from the first to the last treatment.)*

These results were highly unlikely to have happened by chance, (see Table 2.1). Identical high levels of significance were repeated when analysing all the data by using a matched pairs T test.

Table 2.1 Analysis using Wilcoxon Signed Ranks Test for combined averaged scores

	Latest consultation score minus first consultation score
Z (average difference between first and last consultation)	–4.603
Asymp. Sig. (2-tailed) (ie probability)	.001 (ie 1 in 1,000)

Figures for averaged presenting symptoms are shown overleaf (Table 2.2):

Table 2.2 Table to show the changes in means, medians and modes for combined averaged patient data

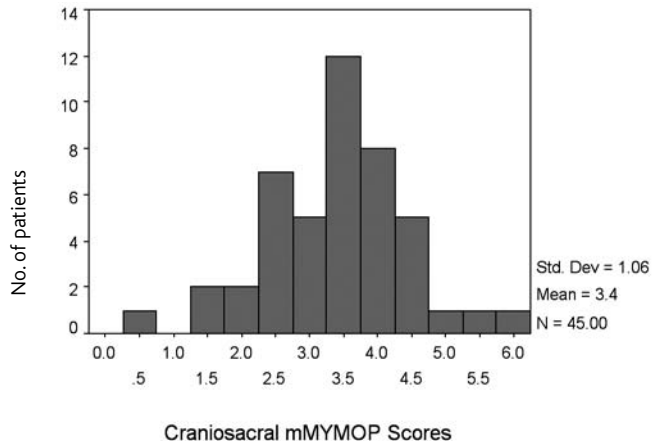|	Average	
	Before	After
Median	3.67	2.50
Mode	4.00	2.67
Mean	3.44	2.47
No. of patients	46	

Before treatment 37% of the sample (n=46) rated their symptoms as 3 or less. After treatment 78% of patients rated their symptoms as 3 or less, demonstrating a decrease in scores and therefore an improvement of the same symptoms.

The graphs below show clearly the shift in grouping of patient scores from clustering at the higher end (mean = 3.44) before treatment, to significantly lower patient scores after treatment (mean = 2.47) for the first symptom (Graph 2.2).
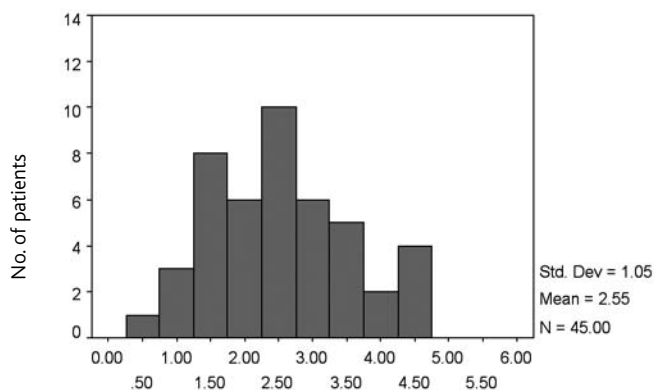
Graph set 2.2 Graphs to show the change in average mMYMOP scores before and after treatment

(0=no symptom, 6=symptom is worst it could possibly be)

Average craniosacral scores before treatment

Std. Dev = 1.06
Mean = 3.4
N = 45.00

Craniosacral mMYMOP Scores

Average craniosacral scores after treatment

Std. Dev = 1.05
Mean = 2.55
N = 45.00

The results demonstrate that patients attending the University of Westminster craniosacral clinics perceive that their health improved, and that it is very unlikely (probability of less than 1 in 1,000) that the improvement could have occurred by chance alone.

What has the study shown?

This was the first attempt to analyse mMYMOP data from the University of Westminster clinic. The study had a dual purpose: to investigate the efficacy of craniosacral treatment in the teaching clinic, and to provide an opportunity to identify potential improvements in data collection.

mMYMOP was found to be simple, quick and easy to administer. However mMYMOP needs to be evaluated as a suitable tool to measure craniosacral outcomes. A reliable measure can be obtained by averaging the severity of patients' symptoms, with their associated affected activities, and overall well-being. This provides a robust subjective measure for assessing changes in patient outcomes. (Graphs 2, table 2.2). The mMYMOP forms used have space to record changes in circumstances that are likely to affect patient outcomes eg bereavement. Larger sample sizes should limit the effect of external factors on data analysis.

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It is important not to lose sight of the longer-term beneficial effects of craniosacral treatment. mMYMOP can measure changes in the patient's health at a given time. It would also be useful to measure any changes in health after a longer period of time. A longitudinal (follow-up) survey of patients is planned for the future.

What about the other 26% patients who did not improve? This is the challenge of audit. mMYMOP scores were taken at the latest consultation, and some patients would not have completed their treatment. The consultations were held in a teaching clinic with students observing the treatment. The presence of students can affect the therapist's ability to maintain complete attention on the patient and this may affect the treatment outcome.

Scores were not available for those patients who discontinued treatment. Did their symptoms resolve, or did they opt out for different reasons? In future, patients who do not return will be asked to complete a mMYMOP form by post.

What can we conclude?

The analysis proves conclusively that patients treated in the craniosacral teaching clinics felt that their symptoms improved. The mMYMOP was quick and easy to administer, and it has demonstrated usefulness as a tool for measuring craniosacral patients' treatment outcomes.

The report on complementary and alternative medicine by the House of Lords Select Committee on Science and Technology (2000) recommends that research into complementary medicine should be undertaken to establish an evidence base. This article is submitted to encourage other craniosacral therapists in practice to consider introducing the use of patient outcome measures into their practice.

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Brian Isbell practises as a craniosacral therapist, osteopath and naturopath in the University of Westminster's teaching clinic and may be contacted at: The Department of Complementary Therapies, School of Integrated Health, University of Westminster, 115 New Cavendish Street, London W1W 6UW isbellb@westminster.ac.uk

Sue Carroll is a homeopath and was employed as a lecturer and researcher within the Department of Complementary Therapies during the period of this study. Currently Sue may be contacted at s-carroll@newbury-college.ac.uk