Can craniosacral treatment improve the general well-being of patients?

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The objective of this research was to evaluate the efficacy of craniosacral therapy in improving the general well-being of patients. The study used a single-blind, randomised, controlled trial with crossover of treatments, between simulated and actual craniosacral treatment, to measure the outcome. The variables of the research were minimised. Outcome measures of the study were collected from patients before and after each treatment and analysed to observe whether CST would improve the general well-being of patients. Although there was no overall statistically significant improvement in the well-being scores, scrutiny of the data revealed that there had been improvement in seven out of the ten subjects. It is evident from this study that further evaluation of the experimental design is required for the study of CST.

Methodology

Ten volunteer subjects were selected. The criteria for inclusion were that each subject was between 18 and 80 years of age and able to lie quietly supine on a treatment table for 30 minutes of hands-on treatment, and should not be, at the time, undergoing any manual therapy or medical treatment. Participants had to be new to craniosacral therapy and they had to present some symptoms to validate the purpose of this research. Participants were blind to which treatment they were receiving - simulated or actual CST treatment.

All the practitioners in the trial were registered professionals, including the ones carrying out the placebo treatments, although these therapists were non-related therapists (eg nutritionists or herbalists) with no training in CST. For the purpose of this research they were referred to as 'simulated therapists'.

There were twelve therapists: five simulated and seven CST practitioners. A protocol was established in order to minimise the variables of the research, eg minimal conversation to be allowed during treatments. Subjects were treated by different practitioners each time (the first two sessions with a simulated therapist and sessions three and four with a CS therapist). CS therapists addressed their subjects' needs, following their felt sense through their palpation skills. The simulated therapists were given instructions on how to act as CS therapists. A protocol was designed describing a number of craniosacral holds for them to adopt. The simulated therapists were advised to count from 1,000 backwards and also not to concentrate on trying to give any healing of any kind to the patients, to eliminate any type of intention of treatment and as a measure to control the intervention. This method has been used in previously published investigations such as Quinn 1989.

As stated, the study used a randomised, single-blind, crossover, controlled trial, together with the use of the General Well-being Schedule (GWS). Treatments were given once a week. Simulated treatments were given first to avoid any possible carry-over effect of CST treatments (Pocock 1986).

Participants completed questionnaires before and after each treatment, with a final questionnaire that was filled in on the fourth or fifth day after the last treatment of the trial, to measure the outcome from the fourth week's treatment. During the course of the trial, participants reported any changes in their health and/or physical conditions, including any relevant observations about the trial. Practitioners' comments were also recorded.

> simulated therapists were given instructions on how to act as craniosacral therapists

What was found?

The trial aimed to test the efficacy of CST in improving the general well-being of patients. The results demonstrate that CST led to an improvement in the well-being of the majority of the subjects (seven out of ten). However, from the results, it was not possible to demonstrate an overall statistically significant improvement. The proportion of patients who demonstrated an increase in their general well-being was 70%, which statistically is recognised as meaningful in clinical practice (Pocock 1986). Although these figures can represent clinically meaningful improvement in the general well-being of patients, it is worth noting that it has been reported that the placebo response rate could account for this order of magnitude of improvement, depending on the situation (Liberman 1964). The scores for three of the subjects were the only ones that showed an increase in well-being from the beginning to the end of the trial.

It could be argued that the statistically inconclusive outcome may be due to the small sample size, from which it was not possible to detect a statistically significant difference (Warber *et al* 2003). In addition, there were aspects of the experimental design that may have contributed to the apparent lack of evidence of the efficacy of CST. For example, the controlled aspect of the trial did not allow for the full assessment of needs in the normal case history taking and with this information the treatment of the individual. In addition, those subjects that did not demonstrate an improvement may have done so if more than the two treatments available in this trial had been provided.

The proportion of patients who demonstrated an increase in their general well-being was 70%

The trial used non-bodywork therapists for the simulated treatments, to avoid any type of therapeutic/healing touch that may occur from an experienced bodyworker and that consequently would invalidate the desired simulated treatment (Horrigan 1996). However, the trial could not exclude (or realistically measure) natural healing abilities of the therapists, which could have influenced the outcome. So, it is not possible for this research to identify where any improvements originated in the simulated treatments: if due to a natural improvement of the patient's condition (Kienle & Kiene 2001); due to the placebo effect (Ernst 2001); the simulated practitioner's natural healing qualities (Crawford *et al* 2003); or a combination of all of them (Hubble *et al* 2004). In fact, it is impossible to estimate how much of these effects were also part of the test treatments score (Ernst 1992). Additionally, the research did not take into consideration any changes in the participants' personal circumstances that might have occurred while they were in the trial which could have affected their well-being scores at a critical stage of the research and which might have affected the outcome. Patients' hopes, mood, expectations, and state of relaxation would also influence symptoms; it is important to collect baseline data on the subjects' psychological state and their anticipation of benefits from the treatment (Warber *et al* 2003). The subjects' reasons for participating in the trial, and their beliefs and values would have also been needed. Three subjects caught a cold or flu near the end of the trial. However, the fact that these three subjects' scores dramatically dropped in week four of the trial followed by a rapid increase of the final score of the questionnaire, showed the accuracy of the GWS in measuring changes in the patients' well-being. Also, these results could have been an indication of the subjects going through a healing crisis after the CST treatment. This could have happened due to the patients' systems being overloaded and this may have been due to the participants' compromised immune system trying to find some space for healing to occur, meaning that sometimes the patient may get worse to get better (Kern 2001).

In a future study, more precise criteria would be needed for the selection of subjects in order to ensure a well-defined group (Warber *et al* 2003). Although the subjects' presenting symptoms might have appeared good enough at first to be included in the trial, it now appears that insufficient investigation was undertaken to check whether subjects had sub-clinical conditions for which CST was not appropriate, and this would have been reflected in the questionnaire results (Kienle & Kiene 2001). In addition, some subjects may have had a state of well-being at the start of the study that was so high that it would be difficult to demonstrate an improvement. For example one subject had a score in week one of 81, showing an initial positive well-being on the GWS score (McDowell & Newell 1996) thus making her an unsuitable candidate for the research. Other points that may have affected the outcome of the trial were: simulated therapists' positive intention when treating; carry-over effects from treatments validating human caring and interaction as part of the therapeutic response; patients wanting to do well (Hawthorne effect); underestimated severity of the patients' presenting symptoms.

What can we conclude?

This study has not shown that CST produced a statistically significant improvement in general well-being. However, if incidents are taken into account, such as patients getting flu or a cold in between the third and fourth sessions of the trial, results show a dramatic improvement in these patients by the final week of the study (up to 30 points in the GWS score). These results show how the patients may have benefited from receiving CST treatment, regardless of whether they became ill for no apparent reason or due to a healing crisis triggered by the previous CST treatment. In addition, if the results of patients who showed an improvement following the CST treatments and who did not experience any illness or physical condition were added to the previous three patients, this makes six out of ten of the patients who had a remarkable increase in their general well-being. These results indicate the value of CST treatment in improving patients' general well-being. Although statistical analysis indicates that overall the outcome was inconclusive, this may be due to the inability to control variables in this research which ended up making the effects of CST statistically unmeasurable.

Further research is needed which takes into consideration the limitations and many variables mentioned in this research, such as stronger criteria for the inclusion of the subjects where thorough analysis of their presenting symptoms is carried out; bigger sample size; additional control and test treatments; more control over the way the simulated and CST therapists carry out their treatments. It is evident from the insight gained from carrying out this single-blind, randomised, controlled trial, that there are considerable opportunities to further develop this methodology to assess the efficacy of CST.

Acknowledgements

All treatment sessions took place at The Fountain Clinic, London, with permission and guidance from Ged Sumner its director.
The University of Westminster Ethics Committee gave approval for the research protocol.

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