Cerebra

Positively Different

Cranial osteopathy for children with cerebral palsy: a randomised controlled trial of the effects of cranial osteopathy on the health and wellbeing of children with cerebral palsy.

Cerebra Research Unit

Peninsula Medical School

Background

Cerebral Palsy (CP) affects approximately 1 in 400 children in the UK. Physiotherapy, occupational therapy and speech and language therapy are often provided to support children with CP. There are also many complementary therapies in existence, such as osteopathy, which claim to have beneficial effects for children with CP.

Cranial osteopathy has become a popular treatment in recent years and is used to treat a broad range of disorders. Osteopaths use various techniques during treatment, which they believe can improve movement and release stresses in the body.

Cerebra asked researchers at the Peninsula Medical School to examine the existing scientific evidence on the benefits of cranial osteopathy for children with CP. They found virtually no properly conducted scientific studies of the effects of cranial osteopathy on children with CP. One small study did suggest some improvement after receiving cranial osteopathy, but there were very few participants, making the results difficult to apply more widely. Because there was not enough existing evidence to inform parents whether cranial osteopathy was effective (and for which symptoms), Cerebra requested the researchers to carry out a large randomised controlled trial to provide families with good evidence about the effects of cranial osteopathy on children with CP.

The Osteopathy for Children with Cerebral Palsy Trial (OCP Trial) examined the effectiveness of cranial osteopathy on movement, overall quality of life, sleep patterns, pain and fits in children with CP.

Involvement of parents/carers

Before designing the trial, the researchers spoke in detail to many parents/carers of children with CP about how they would like the study to be carried out. They

explained different possible trial designs and asked parents which ones they thought would be acceptable for the families taking part. They also talked to them about the types of outcome such a trial should examine, i.e. what differences they would hope to notice in their child, that would demonstrate that a treatment had helped them. This degree of parental involvement in designing a trial is very unusual, and ensured that a trial that was acceptable to families and that had addressed the issues that they wanted to be answered had been designed.

The researchers also interviewed osteopaths from the Foundation of Paediatric Osteopathy to find out more about the treatment: what it involved for the child, who they could treat and what outcomes could be achieved from the treatment. These interviews were essential to help design the trial, and these osteopaths agreed that the OCP Trial was a fair test of the treatment.

Taking part in the OCP trial

Recruitment of children

Children with moderate to severe CP, aged between five and 12 years and who lived in either Devon (around the areas of Exeter, Plymouth and Torbay) or in Greater London (within the area of the M25) were eligible to take part in the trial. Children with mild CP, those who had received cranial osteopathy within the previous year, and those who did not have one parent who spoke English were not eligible to take part.

Many health professionals (paediatricians, physiotherapists, occupational therapists, nurses) referred children to the trial. Also numerous support groups and charities, such as Cerebra, Contact A Family, Scope, Hemihelp and many other smaller local groups, publicised the OCP trial. The research group are extremely grateful for their support.

Children were recruited between November 2006 and March 2008, and the last child had their final assessment in September 2008. In total, 142 children were recruited on to the OCP trial.

What happened to families taking part in the trial?

After the parent/carer had consented for their child to take part, children were randomly allocated to one of two groups:

- a treatment group
- a control group.

Each child's group was chosen using a computer programme, so each child had an equal chance of being in either group. A study carried out in this manner; a randomised controlled trial, is the best way of finding out whether or not a treatment is effective.

Treatment group

Children allocated to the treatment group received six sessions of cranial osteopathy. Researchers worked with osteopaths in London, Exeter, Plymouth and Paignton. Each child received a course of treatment designed around their individual needs, given by a qualified osteopath, registered to practice with the General Osteopathic Council; the professional body that regulates osteopathic practice in the United Kingdom. Uptake of treatment was good, with 49 children of the total 71 children involved receiving all six of the osteopathic sessions on offer.

Control group

Children allocated to the control group were also offered six sessions of cranial osteopathy, six months later, when they had finished the trial.

Control group parents/carers were invited to take part in two interviews where they discussed many aspects relating to their child's care, including their views of the health and social care services available and the use of complementary and alternative therapies. Of the 71 children in the control group, 59 parents took part in at least one of the interviews, meaning a wealth of very valuable information was collected. As always, any personal information was anonymised and treated in the strictest of confidence.

This trial design worked extremely well and had two main strengths:

- it enabled researchers to compare a group of children who received treatment with a group of children who did not receive treatment
- all children were offered the opportunity to have the treatment and this was paid for by the trial.

Follow-up and withdrawals

All the children were asked to take part in the trial for a total of six months. Parents completed questionnaires on three occasions; at the recruitment visit, ten weeks later, and finally, at six months. Also at six months, the movement of all children was assessed by a physiotherapist, who was unaware of which group the children had been in.

Of the 142 children who were recruited on to the trial, 133 (94%) remained in the trial for the full six months. Only nine of the families who initially signed up for the trial decided not to complete it, and withdrew. This is a great achievement and the researchers believe that it is due largely to the involvement of many parent/carers in the design of the trial, making it relevant and acceptable to the target families.

As is often the case with trials, not all participants follow the schedule of the study, for a variety of reasons; however, the information they provided was still extremely valuable. Ten of the 133 families decided that they did not want to continue having treatments/taking part in interviews, but that they were happy to complete the final follow-up measures. This is usual practice during a trial and meant that the researchers were able to use all the valuable information already collected about these children in the final results.

One hundred and twenty three (87%) children attempted to follow the plan of the trial, ensuring that full follow-up information was available on them, which is a substantial achievement. Having this large number of children take part meant that the researchers could accurately answer the question about the effectiveness of cranial osteopathy.

Results

In a trial, it is important that the groups being compared are as similar as possible. Even though all children with CP are very different, with different needs, the researchers were confident that the two study groups were very similar with respect to certain key characteristics, specifically:

- age
- sex
- severity of disability
- type of school attended
- ethnic group of main carer
- social class of mother
- whether or not the child had communication difficulties
- whether or not the main carer believed that osteopathy was likely to help their child.

The main measures examined in the OCP trial

Measures 2-5 were completed by the child's parent/carer at baseline, ten weeks, and six months. Measure 6 was completed at 10 weeks and six months only.

1. Gross Motor Function Measure - GMFM

This measure assessed the child's movement and was carried out by an experienced physiotherapist who was 'blinded' to the child's group, i.e. they did not know whether the child had received cranial osteopathy or not. This 'blinding' was essential to ensure that the assessment was completely impartial.

2. Child Health Questionnaire - CHQ

This questionnaire looked at different aspects of the child's quality of life, including the child's wellbeing and family life in general. Four summary scores were used which looked at physical health, psychological health, family activities and family cohesion.

3. Sleep diary

Parents were asked to record details of their child's sleeping patterns, including how long they took to settle and how long they slept overnight. This was recorded for one week, using a diary.

4. Paediatric Pain Profile - PPP

This questionnaire looked at the child's pain over the period of a week, and recorded the parents' views of how their child was on their 'best day' and when they had their most 'troublesome pain' during that week.

5. Adult Quality of Life – SF36

This questionnaire asked about the quality of life of the main carer of the child. In the field of research, it is the most widely used measure of adult quality of life. Two summary scores of physical and mental health were used.

6. Global assessment

Parents/carers were asked two general questions about their child's health, at 10 weeks and at 6 months:

Question 1: 'In general, do you think your child is better/the same/worse than 10 weeks/six months ago?'

Question 2: 'Do you think your child's sleeping is better/the same/worse than 10 weeks/six months ago?'

Ten-week results

These are the mid-point results of the OCP trial. There was a statistically significant difference between the two groups in five of the ten outcome measures in the children who received osteopathy:

- CHQ: physical health score
- SF36: mental health score
- Time taken to fall asleep
- Global general health: parents rated child's general health as 'better' than they had 10 weeks previously
- Global sleeping: parents rated child's sleeping as 'better' than they had 10 weeks previously.

Six-month results

The results obtained at six months were the primary (main) results of the OCP trial. In the six-months results, researchers found no statistically significant difference between the groups in terms of the child's GMFM score, their CHQ score, their sleeping pattern, their PPP score, and no difference in the quality of life score between the parents/carers in each group. A difference was found between the groups in answers to the 'Global Question 1'; i.e. parents whose children had received osteopathy rated their overall wellbeing as better than those who had not received cranial osteopathy. Finally, there was no difference between the groups in terms of parents' opinions of their child's sleeping patterns.

There were no significant differences between the two groups in terms of the other outcome measures.

Discussion

A properly conducted randomised controlled trial, such as this, is the only way to provide reliable, conclusive evidence on the effectiveness of any treatment. The researchers hope that this evidence will be used to help parents/carers make informed decisions about treatment choices for their children. It can also give health professionals the information they need to be able to advise parents about treatments.

The research team was asked to find out whether cranial osteopathy is beneficial for children with CP. This was done in a number of ways, mostly by asking parents questions about their child's health and wellbeing, but also by physiotherapists completing a detailed assessment of each child's movement; the GMFM. It was important to have this GMFM assessment as the key measure in the trial, as the physiotherapists did not know whether the child had received cranial osteopathy or not.

This trial provides little strong evidence that osteopathy leads to sustained improvement for children with CP. The main assessment point was six months after the child started the trial. When considering the GMFM assessment (the main measure) the results clearly show that cranial osteopathy is not effective, as there was no difference between the groups. Nor was there any difference in the other specific measures examined; the quality of life of the child and main carer, the child's pain, sleeping patterns and the parents' assessment of the child's sleep in general all showed no difference. At six months, only one of thirteen outcome measures showed a statistically significant improvement in the children who had cranial osteopathy, compared to those in the control group. The one exception where a difference was identified between the groups was in the question that asked parents to rate changes in their child's general health. Parents whose children had received cranial osteopathy were more likely to rate their child's general health as having 'improved', compared to the parents of the children in the control group.

Children who had received cranial osteopathy scored better than those in the control group in some, but not other, self-rated subscales of measures taken at 10 weeks, but these differences were not seen at the assessment at six months.

It is important to point out that these results only apply specifically to children who are treated with cranial osteopathy, who have CP and are aged between five and 12 years. It is worth remembering why the OCP trial was carried out in the first place: Cerebra asked the research group to carry out this trial as a direct result of their members wanting more information about cranial osteopathy as a treatment for children with CP, and this study has provided that information. Cerebra believes that is it very important to do research that answers the questions

of parents/carers. The research group was extremely fortunate in having the full co-operation and support of the osteopaths who treated the children, as this trial could not have been completed without them. It is obvious that cranial osteopathy is a treatment of interest to families, which is demonstrated by the fact that 49 families in the treatment group decided to take up the full six sessions on offer. Additionally, very few families reported any side-effects that were felt to be directly associated with the treatment.

Working with families

It is often suggested that it is extremely difficult to run clinical trials with children with CP or other significant long-term health problems. The research group have been able to deliver this trial with extraordinarily high rates of follow-up and strongly believe that the investment of substantial time at the beginning of the process in working with families to get the research question right, and to ensure that they followed the advice they gave about what designs were likely to be acceptable, was the crucial factor in the success of the OCP trial. This trial could not have been achieved without the enormous support of all the families who took part, and the network of health professionals, special schools, charities and support groups that publicised the trial.

The results have already been presented to the families who took part, during meetings held in Exeter and London in March 2009. These meetings were enjoyable, informative afternoons, and the suggestion by a number of participants that they would be interested in future studies, indicates that this will add to the success of the Cerebra Research Unit.

About the Cerebra Research Unit

The Cerebra Research Unit was founded to help establish what treatments and therapies improve the health and wellbeing of children with disabilities and their families. The Unit responds to questions from families about therapies and health services for children and young people with brain-related neurological conditions, and provides summaries of evidence to help families make decisions. Where the evidence is lacking, the Unit seeks funding to conduct clinical trials to assess the effectiveness of interventions on outcomes that families tell us are important, such as function, social inclusion and participation, and quality of life.

Staff at the Cerebra Unit will be working in partnership with parents and carers of children with additional needs to ask and answer questions about services and treatments related to their children. It is also hoped that some children might like to be involved with the Research Unit. To help achieve this, we are developing ways to involve parents, carers and children.

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More information on the osteopathy trial can be found at: http://sites.pcmd.ac.uk/ocp/.

The study has also recently been published in the journal, Archives of Disease in Childhood, which can be found at: http://adc.bmj.com/content/early/2011/02/23/adc.2010.199877.abstract.

The Cerebra In-house Research Team carries out desk-based research into a number of areas, based upon parent and professional requests, new scientific evidence and issues raised by our staff. We aim to provide information that is relevant to parents and carers of children with disabilities as well as the professionals who come into contact with them. By empowering parents and professionals with knowledge, we can help them to improve the lives of the children they care for and support.

If you require further information or would like to suggest avenues for further research, please get in touch.

These reports are made possible only by the kindness and generosity of Cerebra's supporters. Cerebra is a charity that works for a future where children living with neurological conditions enjoy lives filled with learning, opportunities and joy. We fund vital research that aims to improve children's lives and those of their families. We directly support more than 10,000 affected children and families around the UK.

With your help we can reach out to so many more. To find out how, visit www. cerebra.org.uk/fundraising or call 01267 244 221 and ask for Sadie Clark.

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The findings of this report are those of the author, not necessarily those of Cerebra.