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Consulting parents about the design of a randomized controlled trial of osteopathy for children with cerebral palsy

Vanessa Edwards RGN BA MPH,* Katrina Wyatt BSc PhD,† Stuart Logan MBChB MSc (Epidemiology) MSc (Politics) MRCP FRCPCH‡ and Nicky Britten MSc PhD FRCGP (Hon)§

*Research Fellow in Child Health, †Senior Lecturer in Child Health, ‡Cerebra Professor of Paediatric Epidemiology and §Professor of Applied Healthcare Research, Cerebra Research Unit, Peninsula Medical School, University of Exeter, Exeter, UK

Correspondence
Nicky Britten MSc PhD FRCGP (Hon)
Professor of Applied Healthcare Research
Institute of Health Service Research
Peninsula Medical School
Veysey Building
Salmon Pool Lane
Exeter EX2 4SG
UK
E-mail: nicky.britten@pms.ac.uk

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Abstract

Background Although the UK Department of Health has advocated the involvement of service users and carers in health research for several years, there is little evidence about their contribution to the design of randomized controlled trials (RCTs).

Objective To demonstrate how consulting parents about the design of a study, including which outcomes to use, led to the design and successful delivery of a RCT of osteopathy for children with cerebral palsy (CP).

Design Semi-structured interviews were carried out with 20 parents of children with CP and other neurological conditions, asking them to choose between four different trial designs, to talk about noticeable changes in their child's condition and their views about payment for trial treatment.

Setting and participants The parents interviewed were all members of Cerebra, a charity for 'brain-injured' children and young people. All interviews were carried out at the parents' homes.

Results Parents had mixed views about possible trial designs; however, a waitlist design which allowed all children eventually to receive the treatment emerged as a clear favourite. Parents did not focus on isolated outcomes, but suggested a range of factors relevant to their child's quality of life. They expressed a clear preference for the costs of treatment to be funded by the trial.

Conclusions Involvement of parents helped design a trial which was acceptable to families and addressed outcomes that mattered to them. By consulting parents about the design of the research, the subsequent trial achieved excellent recruitment and retention rates.

Introduction

The UK Department of Health strongly advocates the involvement of service users and carers in health research,[1–3] and the value of engaging patients and members of the public in research is widely acknowledged in UK policy and the research literature. Best Research for Best Health[4] emphasizes the importance of involving service users and carers in the research process, and it is a requisite of applications to funding bodies such as the Clinical Trials Advisory and Awards Committee (CTAAC) and the Department of Health (Research for Patient Benefit). Concomitantly, research organizations in the United Kingdom such as the Clinical Research Networks and the Research Design Services have begun to promote involvement in research both in their own work and in the research they support. Thus, the notion that the users of health services have a legitimate, mandated role to play in the development of health research is well embedded in policy, but the extent to which it happens in practice is less clear.

To date, there have been few published reports of extensive involvement of consumers in the design and delivery of randomized controlled trials (RCTs). A national survey of trial coordinating centres by Hanley *et al.*[5] reported that where there was involvement in the trials, it was usually in the design of patient information sheets. A more recent survey[6] found only 17% of researchers reported involving consumers, mainly as members of trial steering groups, designing research instruments and planning research methods. Whilst there are a few examples of involving service users and carers in trial design,[7,8] it remains the case that little has been published about the feasibility of involving service users and carers in the design and delivery of RCTs and the impact of this involvement.

Cerebral palsy (CP) is a relatively uncommon condition affecting approximately 1–2 of 1000 children.[9] The degree of motor impairment amongst children with this diagnosis ranges from mild impairment of function in one limb to severe impairment in all four limbs and the trunk. Many parents of children with CP will try various complementary and alternative medicine (CAM) therapies in an attempt to reduce their child's symptoms or enhance their well-being. However, the evidence base for many CAM therapies is not strong, particularly in regard to children.

The Cerebra Foundation,[10] a charity for 'brain injured' children and young people, receives many enquiries from its members about using cranial osteopathy to treat children with CP. There is little evidence about the effect of cranial osteopathy in children with CP[11,12] with most comprising case reports and anecdotal evidence. As part of the preparatory work to designing a RCT to assess the effectiveness of cranial osteopathy, we conducted a qualitative study to determine parents' views of possible study designs and outcomes.

By involving parents in the design of the study, we sought to identify their priorities and to try and produce an RCT which was feasible and acceptable, based on parents' experiences and responsive to their needs and expectations.

Methods

We conducted a qualitative interview study with parents of children with CP. Ethical approval for this study was obtained from the Southwest Multicentre Research Ethics Committee.

Cerebra wrote to their members about the study and asked permission to pass their contact details to the research team. Cerebra specified that they would only contact members who had joined within the previous 2 years as they did not want to over-burden their longer standing members who had taken part in other research projects. A convenience sample was chosen: parent members of Cerebra who lived in Southwest England were contacted and, if willing, interviewed at home between September and December 2004. A researcher (VE) visited interested parents at home to discuss the study and obtain their informed consent for this qualitative study. The parents participated in one semi-structured interview with VE, which was recorded and transcribed with the parents' permission. Parents were asked about their

child, any difficulties they had and whether these difficulties had an impact on their lives. A standard description was then given to explain the use of outcome measures in trials (Box S1), and parents were asked what changes they would want from a treatment to identify potential outcome measures for a trial.

The issue of possible trade-off between scientific rigour, to have confidence in the result from the study, and acceptability of study design was then raised. Parents were presented with a number of different study designs (Box 1) and a standard description of each (Box S2). Parents were asked which design they would regard as acceptable and which would most likely encourage families to participate in a future trial. The descriptions of the study designs and explanations were reviewed by Cerebra prior to the interviews.

Box 1 Summary of study designs

Study design 1

Group 1	Group 2
Osteopathy	No treatment (apart from the treatment they have usually having)

Study design 2

Group 1	Group 2
Osteopathy	On waiting list for 6 months before receiving osteopathy

Study design 3

Group 1	Group 2
Osteopathy	Receiving extra sessions of physiotherapy or occupational therapy

Study design 4

All children are given osteopathy, and we measure them before and after treatment

Generally, osteopathic treatment is obtained from private practitioners and paid for by parents. We asked parents to consider how this should be handled within the context of a trial, with options including payment by trial participants, copayment and treatment funded entirely as part of the trial costs.

A framework thematic analysis[13] was conducted by VE and checked by NB, with the aim of systematically describing and summarizing the data on each aspect of study design. The researchers read and re-read the transcripts and constructed an index of multiple emerging themes and subthemes. It was decided to focus the analysis for this article on the themes relating to discussion of the methodological aspects of trial design. Each transcript was coded using the index, and the data represented by each theme were extracted and collated into charts to facilitate the organization of the data. A summary of each theme was derived from the chart entries. Direct quotations were identified which represented the range of views expressed by the interviewees in relation to each theme.

Results

We interviewed 20 parent members of Cerebra who lived in Southwest England. This number was considered sufficient to cover a range of views within the available resources. The parents were from a mix of rural and urban locations and included a wide range of child and parental ages and severity of disability of the child. No parent refused to take part. Illustrative quotes are presented within the text with a participant identifier indicating the participant's gender and their child's age and diagnosis (Table S1).

Parents' views on research methodology

The need for comparison groups was considered important by many and that *treatment vs. no treatment* is the best way of assessing effectiveness.

> There's no choice, because for you to do the study correctly you need a group of people – placebos or whatever … a control group, and you can't do the study without it, so anyone who says, 'Oh, I'm not going to take part in this study and not have the treatment,' well, they're missing the point. *P4, Male, parent of 9 year old, CP*

One of the parents identified that in a trial, the only difference between groups should be the intervention under investigation.

> Both groups should be assessed and then you compare like for like with the only difference being one thing which is what science is about, isn't it? *P2, Male, parent of 21 year old, CP*

The independent assessment of outcomes was discussed as it was noted that the researchers or osteopaths might want a positive outcome. The issue of sham treatments and blind assessment of outcomes was spontaneously raised to clarify that a therapist would not 'pretend' to treat a child.

> I assume that you wouldn't keep the parents in the dark as well so that you wouldn't have to be taking your child to this place for an hour, not knowing whether they would be getting any osteopathy or not? ….It would be the people doing the study that didn't know. *P8, Female, parent of 9 year old, CP*

Views on study designs

An explanation was given on the need for research to be rigorous to have confidence in the findings and that a RCT involving two or more groups was the best way of assessing the effectiveness of a treatment. The parents were asked for their views about four different study designs (Box 1) and which would encourage participation in a trial.

Study design 1 (SD1) – osteopathy vs. no additional treatment

This design divided parents with around half considering this design an acceptable option. These parents observed that having a treatment group and a control group was required to make a comparison. It was perceived by some to be the most scientifically rigorous and logical design and the only way to measure whether a treatment works or not.

> I think study design 1 is fine because if you actually understand what the trial is about and you've got almost like a control group with the no treatment …. so study design 1 makes sense to me because you've got your control of those children who are not receiving the osteopathy and then you've got the others who are, and then you can make your comparisons there. *P10, Female, parent of 10 year old ASD*

However, other parents expressed concerns about the fairness aspect, specifically the fact that half the children would not receive treatment, feeling that parents may be disappointed if their child was allocated to the control group. There was a suggestion that some parents may try to get osteopathy privately to counter this.

> The problem I see with group1, study design1 is parents would think if they were allotted no treatment, they would have been happy to have been allotted osteopathy because they may think well this has got a reputation, it's got a good reputation my child's going to benefit from that. But they'll be disappointed by not having the treatment if you like awarded to them, and say why, why are we on the study, you know someone could come round ask us questions we don't get anything out of this and my child needs extra treatment blah blah, so they might even try and find a osteopathist, a person who gives a child osteopathy privately without informing the study organisers, so that would rather skew the results. *P2, Male, parent of 21 year old, CP*

Others felt this design would be the least appealing to families being recruited into a trial, and one parent explicitly stated that they thought the design was pointless.

> The only thing I would say is I don't understand the point of this, because – you say they're going to measure the effect of the osteopathy on the children – so if they're not having any …what's the point in that? *P5, Female, parent of 9 year old, CP*

Study design 2 (SD2) – osteopathy vs. waiting list control

This was the most popular trial design as it fulfilled the need for the control comparison group whilst allowing all children to have the treatment, which was regarded as very important in appealing to families.

> Well, I think obviously from your point of view, one group having treatment and one not is probably the best idea! But it's not very fair on group 2 not having it at all. So I think, really, the design 2 would be the best, because at least they would get it in the end. So I think definitely that. And, yes, I'd love M to take part. *P13, Female, parent of 15 year old, CP*

For many parents, it was crucial that all children should have the chance of having treatment, as this was the only fair, equitable

way of running a trial, suggesting that it would be wrong to deny treatment for children.

> I think to me design 2 would be the best way of doing it. But because you want your child to have the treatment, if you're happy for your child to actually go into the trial, it means that you would like your child to have that treatment, and I think it would be wrong to deny any child the treatment…..I would be unhappy to put a child into a group where you've got treatment or no treatment, because everybody wants their child to have an opportunity to get better. *P11, Female, parent of 15 year old, CP*

This design could act as an incentive to recruit families into the trial as all children would get the treatment eventually.

Study design 3 (SD3) – osteopathy vs. physiotherapy/occupational therapy

This design created a great deal of discussion with a few parents believing it to be a good idea as all those who were taking part would benefit from having extra treatment.

> The children who are taking part are going to get benefit from extra physio and extra occupational therapy, so they're taking part and they are going to benefit in some way. *P6, Female, parent of 12 year old, CP*

However, the majority of parents believed that this was a 'messy' and confusing option and could be answering the different question of 'does osteopathy work better than physiotherapy/occupational therapy (OT)?'

> SD3 certainly gets a bit messy - I mean, extra sessions of physio and occupational therapy - so you're not really measuring like for like, then - what I think you might be measuring is 'what are the pros and cons of with and without?' and - I mean if you had a big enough group, I guess, you could have a third group doing the extra physio or occupational therapy, and then you could compare the three groups. *P4, Male, parent of 9 year old, CP*

Moreover, the suggestion of withdrawing additional physiotherapy/OT after a trial was a cause for concern as this could have a detrimental effect on a child.

> I would be concerned about a child receiving extra sessions of physio, especially if it worked and then it's withdrawn. That would worry me. That would be my main concern, especially if the child responded well to the physiotherapy and then it was withdrawn and they, you could noticeably see that they were stiffening up. *P16, Female, parent of 9 year old, CP*

Study design 4 (SD4) – everyone receives osteopathy and measurements are made 'before and after' treatment

There was a mixed reaction to this design option. Some parents discussed the difficulty of measuring any effect of the treatment if all children received it.

> You don't know whether the child would just change in the time anyway because of growth. *P11, Female, parent of 15 year old, CP*

However, others firmly believed this was the only way to carry out the study. As all children are different and CP is such a wide-ranging condition, it would not be possible to get comparable groups to test treatment effectively; hence, no design with a comparison group was a possible option.

> I don't believe that you can use what you call a control group, because you would never get enough children with similar afflictions to be able to measure the treatment accurately, I don't think. …I'm on [a] helpline once a week, and I spoken to hundreds of parents. I've never come across two children the same. So I don't see how you can measure that, but that's just my view. I think that 4 is the only thing that would work ….well – the only thing that would work fairly. I'm not a great believer in statistics either. *P5, Female, parent of 9 year old, CP*

In the following discussion, when the researcher suggested this design did not need children to be 'identical' and that all children would receive treatment if SD2 was used, some parents altered their view, whereas others remained adamantly in favour of SD4.

> I prefer study number4, I think that would be best, measure them before and after treatment, I think that would be the one that I would, that would be the best one….. I just think that if the children needs the osteopath that they should be having it. *P14, Female, parent of 6 year old, CP*

Similar to SD2, this was perceived as a fair design as it meant that all children would have

the opportunity of having the treatment. One mother observed that as SD4 was more equitable so she would prioritize that.

> I think as a parent I think I would definitely go for design number 4 while I can appreciate that [SD1] is more scientifically rigorous. *P19, Female, parent of 2 year old, CP*

Table 1 demonstrates the spread of parents' preferences of trial designs. Twelve parents voiced a preference for a particular design with SD2 being the most popular with six parents; this design remained the most popular when the preferred and acceptable categories were combined. Other parents did not declare a single preference and judged all the designs acceptable to varying degrees. All the designs were explicitly rejected to varying degrees with SD3 proving the least popular.

Outcome measures

To understand which outcome measures should be used in a trial, parents were asked to consider what changes they would notice in their child to show that a treatment had helped them. During the course of the discussions, it became apparent that parents did not focus on isolated outcomes, with many of the suggested outcomes being linked to improved quality of life (QOL) in some way. This could be noticeable if the child was more relaxed, calmer and less anxious; however, QOL could not be separated from many other aspects of their overall health. A mother described the 'vicious circle' of her child's health.

Table 1 Spread of preferences of study design

	Preference	Acceptable	Not acceptable	No opinion expressed
Study design 1	1	9	7	3
Study design 2	6	10	3	1
Study design 3	1	6	12	1
Study design 4	4	7	6	3

> Well, I think her general health, because her epilepsy does affect her in all walks of life, but also her ability to be able to do things on her own and cope satisfactorily with that task, you know, rather than … 'Oh I can't do this,' or … to give her that sort of confidence and that feeling that she can actually do things that she's not been able to cope with before. …… Again, it's the vicious circle we're going back to - you know - one thing can affect another. *P20, Female, parent of 22 year old, epilepsy*

It was suggested that outcomes which could improve the child's sleep or how comfortable they felt were also desirable.

> I think a lot of the more subjective things like a better night's sleep, comfort, are more important to a child than reduced joint stiffness and increased mobility. That's probably about it. With a child like A, nothing is going to make her suddenly sit up and walk, so it's more the general things, whether her hands are more relaxed, then perhaps her gross motor function maybe would improve. *P8, Female, parent of 9 year old, CP*

Sleep was a key issue for many of the parents, from their own point of view as well as the child's. A father observed that a good night's sleep was essential for him as well as his daughter.

> I think again that a good night's sleep is an important thing, as it is for all of us. Being more relaxed I think, if it's got a calming effect. The feel good factor if it's something that sort of lifts you, again, it doesn't, yes OK, it doesn't cure the brain damage but it can have a positive effect. *P16, Female, parent of 6 year old, CP*

For parents, any improvement was regarded as a 'building block' which could lead to many other small but important changes in a child's life. Even when specific physical effects, such as a reduction in spasticity and an improvement in mobility were highlighted, it was felt this could lead to an improvement in self-esteem and confidence, again highlighting how that parents do not consider outcomes in isolation.

> For T it would be the mobility side - how that's improved, really, because a lot of the other stuff, like the self-esteem, will come with the improvement of everything else, and the way he sees himself and what he can do is probably the most important.....So, firstly his mobility and stuff; then self-esteem because I know then he'd be more

> confident to sort of go on the communication side, really…..it's like a building block, really. *P12, Female, parent of 20 year old, CP*

Not surprisingly, an improvement in a child's health could potentially have a positive impact on the parent as well. One mother observed that if she could do less for her son and he could do more for himself then she would know that a treatment had helped him.

> Because of T's difficulties that have an impact on me, as well, so it would be how much less I would have to do for him, I'd measure whether it was working or not, especially at the age he's at now, that's kind of the state we're at, is that I'd like to be more of his mum than his carer, and encourage him to do more for himself, so that would be another thing, to sort of say, 'Oh, I don't have to do that for him any more,' - that would be one way of measuring it, really. Does that make sense? *P12, Female, parent of 20 year old, CP*

Table 2 illustrates the outcome measures suggested by parents and those subsequently used in the OCP Trial.

Table 2 Outcome measures suggested by parents and those used in subsequent trial

Outcome measures suggested	Outcome measured used in OCP Trial
Reduction in pain	Yes
Reduction in fits	Yes
Reduction in challenging behaviour	No
Quicker recovery from illness	No
Increase in child's independence	No
Improvement in communication	No
Improved sleep	Yes
Improved motor function	Yes
Improved concentration and ability to learn	No
Better swallowing and digestion	No
Being more lively and having more energy	No
Quality of life (QOL) measures, including being more relaxed, calmer, happier, improved self-esteem and confidence	Yes[1]

[1]QOL measure for main carer also used.

Costs of treatment during trial

Parents were asked if a trial of osteopathy took place who should pay for the treatment: should the trial pay for all treatment, half the treatment or should the parents pay all? The majority of parents stated definitively that the cost of the treatment should be covered in full by the trial.

> Well I think if people are going for a study then they shouldn't have to pay anything, so I think the organisers should pay all of it for the period of the study *P1, Female, parent of 8 year old, CP*

A few parents said that they would be happy to cover half of the costs, and one parent suggested that payment could be means tested with parents contributing if they are able.

It was observed that there are many additional costs of caring for a child with disabilities, and often families do not have the money available for additional treatments so expecting parents to pay for treatment within a trial would deter people from taking part.

> I know that a lot of the families who I sort of go to meetings and meet up with, although they do receive benefits, those benefits have to cover an awful lot of areas for the youngsters and they've hardly got any money left over for things like school trips let alone fancy treatments that may or may not work, so I'm afraid you're not likely to be able to find a great number of families who could afford that. *P2, Male, parent of 21 year old, CP*

Where the benefits of a treatment are unknown, it would be hard to justify asking parents to pay for the treatment.

> I wouldn't personally feel it was appropriate to pay, myself. I'd have to be really convinced … if I'd seen someone that had had it, and I'd seen the 'before' and 'after', then, yes, I think I'd be more than happy to pay, but if I didn't know whether it was going to work or not or make any difference, then maybe not. *P18, Female, parent of 19 year old, CP/*ASD

It was also pointed out that parents would be giving their time and their child's participation

in the study so it would not be appropriate to expect them to pay.

In summary, most parents interviewed accepted the need for randomization, but virtually everyone said that a trial design in which all children were offered the intervention at some point was preferable. They were willing to delay the intervention by 6 months for half the children to provide a waiting list comparison group. The parents also highlighted numerous outcome measures, with the emphasis on a treatment that could improve a child's QOL. The consensus was also that it would be necessary for the treatment for both groups to be fully funded by the trial.

Discussion

It has been argued that consumer involvement in the early stages of planning research has many advantages including ensuring appropriate choice of outcome measures and deciding which questions are worth addressing.[14] However, a survey by Chambers *et al.*[15] reported only a small percentage of researchers actively involving the public before undertaking their research. The available evidence suggests that clinicians' and patients' agendas and priorities can be quite different as 'patients draw on kinds of knowledge and perspectives that are different from those of professional researchers'[14].

This study was set up in response to a request by Cerebra about the effectiveness of osteopathy for children with CP. Parents were consulted on differing research designs, outcome measures and treatment costs to design a realistic and acceptable trial. This study acknowledged the potential conflict between scientific rigour and conducting a trial which is regarded as ethical and acceptable by parents and children. Researchers are appropriately constrained by the concept of equipoise which dictates that it is only acceptable to withhold treatment from some participants in a trial if the researchers genuinely do not know whether the treatment is beneficial. In many situations, however, families may find it hard to accept that their child may not receive treatment when taking part in a trial, even when there is no evidence that the treatment is helpful. In seeking parental involvement, we aimed to design a trial which provided evidence about effectiveness whilst also addressing the outcomes and aspects of the design which mattered to parents.

A limitation of this study relates to Cerebra being the gatekeeper of their members' identifiable data. Cerebra contacted members who had joined their organization in the previous 2 years as they did not want to over-burden longer standing members who had previously assisted with research projects, placing a potential limitation on the sample. However, the wide range of participants reassured us that the sample was not skewed. Moreover, these parents may well be considered less 'research aware' than other members, and hence, their views could be considered to be more applicable to parents of children with a neurodisability in general.

This waiting list design, although the most popular, was not endorsed by all the parents interviewed. Some parents made the point that the outcomes they described were often inseparable and that the researchers' need to measure variables separately did not necessarily reflect how parents saw their children.

The Osteopathy for children with Cerebral Palsy Trial took place between November 2006 and September 2008[16]. We enrolled 142 children aged between 5 and 12 years with CP, who lived in either Devon or Greater London. As proposed, the trial used a waiting list design with children randomized either to an intervention group who received osteopathy straight away or a waiting list group who were offered treatment after 6 months, with treatment for both groups being paid for by the study. The trial used a range of outcome measures which reflected parents' views, although not all parents' suggestions for outcome measures were taken up (Table 2). Outcomes assessed included motor function, sleep, pain, general health and QOL of the child and the main carer. During recruitment, parents really liked a design which enabled all children to have the treatment and that parents had played an integral role in the trial design. Only eight families declined to take

part in the trial, the main reason being that they did not wish to wait to receive treatment should their child be allocated to the control group.

It is often suggested that it is extremely difficult to run clinical trials with children with CP or other significant long-term health problems with trials experiencing high number of refusals to participate and poor follow-up rates. For example, Davis *et al.*[17] in a trial of horse riding in children with CP reported that only 39% of those eligible agreed to participate and Weindling *et al.*[18] in their trial of additional support by physiotherapists or family support workers achieved 47 and 39% follow-up at 6 and 12 month follow-up, respectively. We were able to deliver this trial with high rates of recruitment and follow-up. Retention in the trial was excellent with only nine children withdrawing/lost to follow-up and outcome data on 94%.

We believe the investment of substantial time at the beginning of the process, working with families to get the research question right, and following the advice they gave us, was the crucial factor in the success of this trial. We acknowledge that the high recruitment rates may also have been a consequence of the fact that cranial osteopathy was favourably perceived by many parents. However, only 26 of 71 children in the control group took up the offer of free osteopathic treatment after the waiting list period, suggesting that participation was strongly influenced by factors other than the desire to obtain treatment for their children.

In the context of this particular study, we may conclude that parents were willing and able to make a significant contribution to three elements of trial design and that their contributions enabled the research team to write a better and more acceptable proposal than we would have done otherwise. The parents valued being consulted about the design of a future trial and the Ethics Committee commended the research team on this strategy. Parents understood the overall concepts of trial design, and different ways of conducting the study were commented on and preferences expressed. This method of Patient and Public Involvement can be used for many different study designs in diverse clinical areas.

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Conflict of interest

No conflict of interest.

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References

1 Department of Health. *Research — What*'s In It for Consumers? Report of the Standing Advisory Committee on Consumer Involvement in the NHS Research & Development Programme. London: Department of Health, 1998.
2 Department of Health. *Working Partnerships. Consumers in Research Third Annual Report*. London: Department of Health, 2000.
3 Department of Health. *Research and Development for a First Class Service*. London: Department of Health, 2000.
4 Department of Health. *Best Research for Best Health: A new National Health Research Strategy*. London: Department of Health, 2006.
5 Hanley B, Truesdale A, King A, Elbourne D, Chalmers I. Involving consumers in designing, conducting and interpreting randomised controlled trials: questionnaire survey. *British Medical Journal*, 2001; **322:** 519–523.
6 Barber R, Boote J, Cooper C. Involving consumers successfully in NHS research: a national survey. *Health Expectations*, 2007; **10:** 380–391.
7 Koops L, Lindley RI. Thrombolysis for acute ischaemic stroke: consumer involvement in design of new randomised controlled trial. *British Medical Journal*, 2002; **24:** 325.
8 Ali K, Roffe C, Crome P. What patients want: consumer involvement in the design of a randomized

controlled trial of routine oxygen supplementation after acute stroke. *Stroke*, 2006; **37:** 865–871.
9 Stanley F, Blair E, Alberman E. *Cerebral Palsies: Epidemiology & Causal Pathways*. MacKeith Press: Cambridge University Press, 2000.
10 Cerebra Foundation. http://www.cerebra.org.uk, accessed 9 December 2010
11 Duncan B, Barton L, Edmonds D, Blashill BM. Parental perceptions of the therapeutic effect from osteopathic manipulation or acupuncture in children with spastic cerebral palsy. *Clinical Pediatrics*, 2004; **43:** 349–353.
12 Duncan B, McDonough-Means S, Worden K, Schnyer R, Andrews J, Meaney F. Effectiveness of osteopathy in the cranial field and myofascial release versus acupuncture as complementary treatment for children with spastic cerebral palsy: a pilot study. *Journal of the American Osteopathic Association*, 2008; **108:** 559–570.
13 Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG (eds) *Analyzing Qualitative Data*. London: Routledge, 1994: 173–194.
14 Chalmers I. What do I want from health researchers and research when I am a patient? *British Medical Journal*, 1995; **310:** 1315–1318.
15 Chambers R, O'Brien LM, Linnell S, Sharp S. Why don't health researchers report consumer involvement? *Quality in Primary Care*, 2004; **12:** 151–157.
16 Wyatt K, Edwards V, Franck L, Britten N, Creanor S, Maddick A, Logan S. Cranial osteopathy for children with cerebral palsy: a randomised controlled trial Archives of Disease in Childhood (in press).
17 Davis E, Davies B, Wolfe R *et al*. A randomized controlled trial of the impact of therapeutic horse riding on the quality of life, health, and function of children with cerebral palsy. *Developmental Medicine and Child Neurology*, 2009; **51:** 111–119.
18 Weindling AM, Cunningham CC, Glenn SM, Edwards RT, Reeves DJ. Additional therapy for young children with spastic cerebral palsy: a randomised controlled trial. *Health Technology Assessment*, 2007; **11:** 1–90.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Box S1. Explanation of outcome measures.

Box S2. Explanation of randomised controlled trials.

Table S1. Participant and child details.

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