Additional therapy for young children with spastic cerebral palsy: a randomised controlled trial

AM Weindling,1* CC Cunningham,2 SM Glenn,2 RT Edwards3 and DJ Reeves4

1 School of Reproductive and Developmental Medicine, University of Liverpool, UK
2 Faculty of Health and Applied Social Sciences, Liverpool John Moores University, UK
3 Centre for the Economics of Health, University of Wales, Bangor, UK
4 National Primary Care Research and Development Centre, University of Manchester, UK

* Corresponding author

Executive summary

Health Technology Assessment 2007; Vol. 11: No. 16
How to obtain copies of this and other HTA Programme reports.

An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (http://www.hta.ac.uk). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public and private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:

– fax (with credit card or official purchase order)
– post (with credit card or official purchase order or cheque)
– phone during office hours (credit card only).

Additionally the HTA website allows you either to pay securely by credit card or to print out your order and then post or fax it.

Contact details are as follows:

HTA Despatch Email: orders@hta.ac.uk
c/o Direct Mail Works Ltd Tel: 02392 492 000
4 Oakwood Business Centre Fax: 02392 478 555
Downley, HAVANT PO9 2NP Fax from outside the UK: +44 2392 478 555, UK

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can only be purchased for the current or forthcoming volume.

Payment methods

Paying by cheque
If you pay by cheque, the cheque must be in pounds sterling, made payable to Direct Mail Works Ltd and drawn on a bank with a UK address.

Paying by credit card
The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order
You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of HTA on CD?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. HTA on CD is currently free of charge worldwide.

The website also provides information about the HTA Programme and lists the membership of the various committees.
Objectives
It has been suggested that children with cerebral palsy should not only have their physical needs addressed, but also that there should be support for the family.

This study separated these functions by investigating whether in the short and medium term additional support by (a) a physiotherapy assistant improved physical function in young children with spastic cerebral palsy and (b) a family support worker improved family functioning; children in all groups received standard physiotherapy in addition to the study interventions. In addition, the study examined the needs of the families and the factors affecting child and family functioning in relation to services received and outcome.

Design
This was a multi-centre randomised controlled trial (RCT) with blinded assessments and a cost-effectiveness analysis. The children studied had spastic cerebral palsy that was the consequence of perinatal adversity. All were less than 4 years old on entry to the study.

Randomisation was to: (a) a group who received extra physiotherapy from a physiotherapy assistant; (b) a group who received standard physiotherapy; and (c) a group where the child received standard physiotherapy and the family was also visited by a family support worker. Children in all groups continued to receive standard physiotherapy in addition to the study interventions.

Both quantitative and qualitative methods were used in this trial.

Participants
Seventy-six families completed the intervention period. Forty-three families were reassessed 6 months after the end of the intervention and 34 of these after a further 6-month period.

Executive summary: Additional therapy for young children with spastic cerebral palsy

Main outcome measures
The child outcome measures were:
- motor functioning (Gross Motor Function Measure)
- developmental status (Griffiths Mental Developmental Scales)
- adaptive functioning (Vineland Scales).

The family outcome measures were:
- self-reported maternal stress (Parent Stress Index)
- level of family needs
- parental satisfaction.

Results
The RCT found that:
- There was no evidence that additional physical therapy for 1 hour per week for 6 months by a physiotherapy assistant improved any child outcome measure in the short or medium term.
- Intervention by a family support worker did not have a clinically significant effect on parental stress or family needs.
- Over the 6-month period the total cost of services for each child ranged from £250 to £6750, with higher costs associated with children with more severe impairments.

The multivariate analyses found that:
- There was no significant relationship between measures of intensity of services received by the children and families and the main outcome measures.
- Low-functioning children, in terms of both motor and cognitive function, were more likely to receive more services in terms of variety and frequency.

The qualitative analysis found that:
- Parents generally reported high satisfaction ratings after all interventions and some
stated that the interventions had benefited the child and/or the family. There was therefore a discrepancy between the perceptions of these parents and the objective, quantitative measurements.

- The family support workers identified a small number of families who were experiencing considerable family problems, but who had not been referred for appropriate support by any other agency.

Conclusions

The findings of this study provide support for the current literature that there was no evidence that additional intervention (in this case by a physiotherapy assistant or family support worker) helped the motor or general development of young children with spastic cerebral palsy. Nor was there any quantitative evidence that providing extra family support helped levels of parental stress and family needs. The implication was that the provision of extra physical therapy does not necessarily improve the motor function of a young child with cerebral palsy and additional family support should not automatically be assumed to be beneficial. In addition, no significant association was found between the intensity of the local services provided and any outcome measure, other than a slight association with lowered family needs.

The provision of local services was related to the severity of the child’s impairments and not to family difficulties. A small group of families with complex family problems needed more service input.

There was a wide range in the costs of services.

Implications for health care

Physical therapy services were largely child focused. No evidence of significant provision of family support was found, other than in one area that offered wider support in facilitating contact between services and referral to other services. The qualitative methodology showed that there were some families which benefited from the family support worker intervention. These families of children with cerebral palsy had little input from other sources. They were experiencing high stress levels and had high levels of unmet needs. Support for these families was at a relatively superficial level and there was no indication of support by social or psychological support, that is, the focus appeared to be on physiotherapy services directed towards the child.

It appears that more funds are not needed. However, families who might particularly benefit from family-focused intervention were not appropriately targeted.

There was some evidence of over-provision and/or of a sub-optimal service mix for some of these children and their families. There should be specific focus on avoiding duplication and defining the criteria that are used to decide on service provision for individual children and their families.

If the physiotherapist is to be the key professional (key worker) for a child with cerebral palsy, guidance should be given on how to explain to parents that more intensive or more frequent physical therapy may not necessarily be warranted. A key worker for the child with cerebral palsy and his or her family needs to understand what family support entails, and their role in providing it and acting as gatekeepers for referral to other agencies. If this really is an important part of the paediatric physiotherapist’s role, appropriate training and resources need to be provided.

Recommendations for future research

Research is needed to examine what ‘sufficient’ levels of provision or therapy might be for which children and which families. Key issues are:

- How the allocation of resources to individual children and families is decided
- The variability among child development centres in relation to how families are assessed, the formulation of a family plan, referrals to other agencies and interagency working. One approach might be to compare the effectiveness of a service with a key worker who has clear management protocols and develops an individualised care plan with the present less structured approach.

A time series of different levels of input and outcomes would provide valuable information for practitioners.

Various methodologies were used for this study. It is recommended that future assessments of
therapies of this type adopt a similar multifaceted approach, which is likely to be more suitable than a simple RCT for the evaluation of clinical interventions where the effects are complex. The most appropriate measures of outcome should be used, including assessment of provision of information and emotional support for families.

**Publication**

The Health Technology Assessment (HTA) programme, now part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the costs, effectiveness and broader impact of health technologies for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care. The research findings from the HTA Programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’.

The HTA Programme is needs-led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, the public and consumer groups and professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA Programme then commissions the research by competitive tender.

Secondly, the HTA Programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Thirdly, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

The final reports from HTA projects are peer-reviewed by a number of independent expert referees before publication in the widely read monograph series Health Technology Assessment.

Criteria for inclusion in the HTA monograph series

Reports are published in the HTA monograph series if (1) they have resulted from work for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors. Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 94/42/06. The contractual start date was in March 1997. The draft report began editorial review in March 2004 and was accepted for publication in August 2006. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

Editor-in-Chief:  Professor Tom Walley
Series Editors:  Dr Aileen Clarke, Dr Peter Davidson, Dr Chris Hyde, Dr John Powell, Dr Rob Riemsma and Dr Ken Stein
Managing Editors:  Sally Bailey and Sarah Llewellyn Lloyd

ISSN 1366-5278
© Queen’s Printer and Controller of HMSO 2007
This monograph may be freely reproduced for the purposes of private research and study and may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising.
Applications for commercial reproduction should be addressed to: NCCHTA, Mailpoint 728, Boldrewood, University of Southampton, Southampton, SO16 7PX, UK.
Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.