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The effectiveness of a parent-held record for disabled children

Submission date 23/01/2004	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	**Overall study status** Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/02/2008	**Condition category** Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCH 14-11

Study information

Scientific Title

Study objectives
To test whether a child health record designed for pre-school children with a disability would:
1. Be used
2. Be valued by carers
3. Change the perception of the health care received by the child
4. Influence the amount of communication between the family and a professional who is seeing their child

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Mental and behavioural disorders: Behavioural disorders

Interventions
The intervention was a parent-held record for the parents of disabled children in which they could record contact details of the professionals seeing the child, the child's medical conditions and any medication and equipment used. A diary section allowed parents and professionals to record the child's progress and programme. There was also information about organisations relevant to children with disability. This was a quantitative individual controlled trial of AB design in which outcomes after six months without the intervention were compared those after a six-month intervention period. The participants were randomly allocated to three groups as follows:
Group 1: compared periods without and with the intervention
Group 2: measured any change without the intervention due to the passage of time

Group 3: estimated any effect due to the assessment after the first period without the intervention in Groups 1

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
At the end of the study, copies of the records were examined and the number of entries was taken as a measure of their value to the users. The parents also completed a questionnaire about the value of the record. The way families viewed their child's health care was tested by experimental control using a questionnaire before and after the intervention. At the same times, the amount of communication between the parents and professionals was assessed by both parties completing an identical questionnaire about the child; the similarity between their replies was taken to be a measure of communication.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1996

Completion date
31/12/1999

Eligibility

Key inclusion criteria
The participants were randomly selected pre-school children in the community who had been notified to the Education Department as likely to have special educational needs.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
99

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1996

Date of final enrolment
31/12/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greenwood Institute of Child Health
Leicester
United Kingdom
LE3 0JU

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name

NHS Mother and Child Health National Research and Development Programme (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	28/06/2008		Yes	No