

Osteopathy for children with Cerebral Palsy

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| Submission date 29/01/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 10/02/2009 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 14/07/2011 | Condition category Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.pms.ac.uk/ocp/>

Contact information

Type(s)

Scientific

Contact name

Prof Stuart Logan

Contact details

Peninsula College of Medicine and Dentistry
St Luke's Campus
Exeter
United Kingdom
EX1 2LU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

609136

Study information

Scientific Title

Osteopathy for children with Cerebral Palsy: a randomised controlled trial of the effects of osteopathy on the health and well being of children with cerebral palsy

Acronym

OCP Trial

Study objectives

In children aged 5 - 12 years of age with a diagnosis of cerebral palsy does osteopathy, compared to treatment as usual, produce improved motor function, improved quality of life, improved sleep or a reduction in fits?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southwest Research Ethics Committee approved 23rd February 2006 (ref: 06/MRE06/1)

Study design

Multicentre randomised controlled single-blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cerebral palsy

Interventions

Intervention group: six sessions of between 30 - 45 minutes duration of osteopathic treatment administered by General Osteopathic Council registered osteopaths over a six month period
Control group: waiting list control receives no treatment

Participants in both arms were in the trial for a total of six months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Gross Motor Function Measure assessed by a physiotherapist at 6 months, blinded to the child's allocation group
2. Child Health Questionnaire at baseline, 10 weeks and 6 months (please note that due to an update to this record on 03/02/2010, this outcome was upgraded from a secondary outcome to a primary outcome)

Secondary outcome measures

1. Paediatric Pain Profile at baseline, 10 weeks and 6 months
2. 36-item Short Form Health Survey (SF36) at baseline, 10 weeks and 6 months
3. Sleep and Fit Diary at baseline, 10 weeks and 6 months
4. Child Self-Report Pain Measure at baseline, 10 weeks and 6 months
5. General Global Assessment of Health at 10 weeks and 6 months

Overall study start date

01/04/2006

Completion date

30/09/2008

Eligibility**Key inclusion criteria**

1. Children with moderate to severe cerebral palsy classified as categories 2 - 5 of the Gross Motor Function Classification System
2. Aged 5 - 12 years, either sex
3. Live in study area, i.e. Devon or Greater London
4. At least one English speaking and literate parent
5. Must live at home with their parents/carers

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

150

Key exclusion criteria

1. Classified as category 1 of the Gross Motor Function Classification System
2. Those who have had osteopathy within the previous year
3. Those who live in residential school

Date of first enrolment

01/04/2006

Date of final enrolment

30/09/2008

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Peninsula College of Medicine and Dentistry

Exeter

United Kingdom

EX1 2LU

Sponsor information**Organisation**

Royal Devon and Exeter NHS Foundation Trust (UK)

Sponsor details

Royal Devon and Exeter Hospital (Wonford)

Barrack Road

Exeter

England

United Kingdom

EX2 5DW

Sponsor type

Hospital/treatment centre

Website

<http://www.rdehospital.nhs.uk/>

ROR

<https://ror.org/03085z545>

Funder(s)

Funder type

Charity

Funder Name

The Cerebra Foundation (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 | 01/06/2011 | | Yes | No |