ISRCTN58523390 https://doi.org/10.1186/ISRCTN58523390

# Generalised versus targeted physiotherapy in childhood hypermobility

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 11/08/2009 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 02/10/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 04/12/2009 | Musculoskeletal Diseases | |

**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**
04/Q1502/7

## Study information

## Scientific Title
A randomised comparative trial of generalised versus targeted physiotherapy in the management of childhood hypermobility

## Acronym
The Hypermobility Trial

## Study objectives
This study aimed to compare a generalised exercise programme with a targeted programme within a randomised trial and assess the impact of these interventions on symptom scores.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Liverpool Childrens Local Research Ethics Committee approved on the 26th April 2004 (ref: 04 /Q1502/7)

## Study design
Randomised comparative trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## 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
Symptomatic hypermobility

## Interventions
Each child received six, sequential, weekly appointments for individual half-an-hour physiotherapy treatments, in which the allocated intervention was administered. Patients were randomised to a General Exercise Program or Targeted Exercise Program.

## Intervention Type
Other

## Phase
Not Applicable

### Primary outcome measure
Improvement in the child's pain assessment score. Younger children used a faces scale ranging from 1 to 5 while older children (age greater than 11 years) used a Visual Analogue Scale (VAS). Participants were asked to indicate on the linear 100 mm scale their pain level in the past week. Change in pain-VAS was used to assess the impact of therapy on symptoms. Measured at baseline (pre-treatment), midpoint (following 6-week intervention) and follow up (3 months after midpoint).

### Secondary outcome measures
1. Parent's assessment of their child's pain: parental-VAS
2. Parent's global evaluation of the impact of their child's hypermobility in the previous week: global-VAS
3. Functional impairment measured using the Childhood Health Assessment Questionnaire (CHAQ)
4. Six-minute shuttle test (measured at baseline and midpoint only)

Measured at baseline (pre-treatment), midpoint (following 6 week intervention) and follow up (3 months after midpoint).

### Overall study start date
01/06/2004

### Completion date
31/12/2007

## Eligibility

### Key inclusion criteria
1. Children aged 7 to 16 years, either sex
2. Treated at the Department of Rheumatology, Royal Liverpool Children's NHS Trust, Liverpool, UK between June 2004 and May 2007
3. Identified as having symptomatic hypermobility*
4. Symptomatic patients had arthralgia for three preceding months or more

*Children were hypermobile if they met Revised Criteria for benign joint hypermobility syndrome (BJHS). In brief, they had to fulfil either two major criteria, one major and two minor criteria, four minor criteria, or two minor criteria and a first degree relative with hypermobility.

Major criteria were:
1. Beighton score of greater than 4
2. Arthralgia in greater than 4 joints

Minor criteria included:
1. Beighton score less than 4
2. Arthralgia in less than 4 joints
3. Mechanical back pain for greater than 3 months
4. Hypermobility in first degree relative

Beighton score assesses hypermobility of the following: placing hands flat on floor without bending knees, hyperextension of knees and elbows greater than 100, little finger metacarpalphalangeal hyperextension to greater than 900, bending thumb to forearm.

**Participant type(s)**
Patient

**Age group**
Child

**Lower age limit**
7 Years

**Upper age limit**
16 Years

**Sex**
Both

**Target number of participants**
108

**Key exclusion criteria**
Patients were excluded if they refused consent.

**Date of first enrolment**
01/06/2004

**Date of final enrolment**
31/12/2007

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Department of Rheumatology**
Liverpool
United Kingdom
L12 2AP

# Sponsor information

**Organisation**
Royal Liverpool Children's NHS Trust (UK)

### Sponsor details
c/o Ms Dot Lambert
Research and Development Manager
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Eaton Road
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### Sponsor type
Hospital/treatment centre

### Website
http://www.alderhey.com

### ROR
https://ror.org/00p18zw56

## Funder(s)

### Funder type
Government

### Funder Name
Royal Liverpool Children's NHS Trust (UK) - Research and Development Department

## 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 | 01/02/2010 | | Yes | No |