

Generalised versus targeted physiotherapy in childhood hypermobility

Submission date 11/08/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/12/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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
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
Research and Development Department
Eaton Road
Liverpool
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L12 2AP

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