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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

Protocol serial number
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)

Primary study design
Interventional

Study design
Randomised comparative trial

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s)
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).

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
16 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Royal Liverpool Children's NHS Trust (UK)

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

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