ISRCTN16760995 https://doi.org/10.1186/ISRCTN16760995

Body schema in adolescent idiopathic scoliosis

Submission date
09/05/2015

Recruitment status
No longer recruiting

Registration date
15/05/2015

Overall study status
Completed

Last Edited
26/01/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Adolescent idiopathic scoliosis (AIS) is a spinal deformity involving a bending and twisting of the spine that occurs at or near the onset of puberty. AIS most often appears around the time of a child's 'growth spurt', and tends to affect more girls than boys. It is called idiopathic because there is no identifiable cause, although various theories have been proposed. One such theory is that there is a change in body schema, a concept sometimes used to describe the way the brain interprets the size and spatial position of the body and limbs. Body schema is thought to play an important role in controlling and organising a person's physical actions. Body schema is also considered to be very important in children, because their bodies go through a lot of changes in size and proportion as they grow. If a person's body schema is altered, it is thought that the brain may no longer be able to interpret the precise location of the limbs in space, potentially leading to disorganised actions. In some as yet unknown way it may also contribute to the spinal contortion seen in people with scoliosis. A study of patients with scoliosis has been undertaken to help identify factors known to be related to altered body schema as part of a parallel study (ACTIVATES, NIHR HTA 10/38/03, ISRCTN90480705). The aim of this study is to collect similar information and perform similar tests on young people without scoliosis. It is hoped that this might provide further insight into the factors associated with scoliosis and help identify potential causes.

Who can participate?
Healthy children aged 10-16.

What does the study involve?
All participants take part in visual and non-invasive physical tests. Participants are also asked to complete questionnaires.

What are the possible benefits and risks of participating?
By looking at the differences between young people with and without scoliosis, this study aims to highlight the different factors that are linked to this condition. This may lead to the development of new treatments and has the potential for significant patient benefit.

Where is the study run from?
1. Tudor Hall School, Banbury (UK)
2. Lutterworth High School, Lutterworth (UK)

3. Marlborough Church of England School, Woodstock (UK)
4. Pattison College, Coventry (UK)
5. King Alfred's Academy, Wantage (UK)
6. The Westwood Academy, Coventry (UK)
7. Lyng Hall School, Coventry (UK)
8. Kingham Hill School, Chipping Norton (UK)

When is the study starting and how long is it expected to run for?
January 2013 to December 2015

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr P Heine

Contact information

Type(s)
Public

Contact name
Mr Peter Heine

Contact details
University of Warwick
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Body schema in adolescent idiopathic scoliosis: a case-control study

Study objectives

Data has already been collected from adolescent idiopathic scoliosis (AIS) patients within the framework of a larger NIHR HTA-funded trial (Active treatment for idiopathic adolescent scoliosis (ACTIVATES): a pilot randomised controlled trial, NIHR HTA 10/38/03, ISRCTN90480705) which received ethical approval from the East of England (Cambridge South) NRES committee (reference number: 12/EE/0331).
The aim of this research proposal is to gather similar information from non-scoliotic adolescents in order to answer the following research questions:
1. Do AIS patients differ from non-scoliotic controls in outcomes related to body schema?
2. If so, is the scale of the difference related to the magnitude of spinal deformity?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Sub-Committee University of Warwick Biomedical and Scientific Research, 05/01/2014, ref: REGO-2013-590

Study design
Multi-centre observational study using a cross sectional case control design

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
School

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Adolescent idiopathic scoliosis (AIS).

Interventions
Measurements previously collected from adolescents with AIS will be compared to age and gender matched controls to determine if there are any differences between the two groups, which may indicate alterations in body schema associated with AIS.

Intervention Type
Other

Primary outcome measure
Images of the trunk/back in different orientations will be used to test laterality discrimination ability in both control and AIS participants. Laterality discrimination is the ability to identify right

from left sides of the body and is measured by accuracy (% correct) and reaction time (seconds) to reach a correct decision. When viewing images of specific body parts in different positions, a correct response requires selection of left or right side, then a mental spatial transformation to confirm the choice. Accurate and timely response is dependent on an intact body representation.

Secondary outcome measures
1. Two point discrimination (2PD). If the two points of a compass are simultaneously applied to the skin, they will normally be perceived as separate stimuli. However, below a certain threshold distance (normally measured in millimetres), this ability is lost and instead the two points will be perceived as only one stimulus. As a test of tactile spatial acuity, 2PD depends in part on the integrity of the cortical representation of the body area being tested.
2. Tactile localisation discrimination involves determining the location of stimulation. Patients are shown a picture of the back with marked locations and are then asked to report which point was stimulated. Accuracy of response depends on an intact body schema and changes in localisation ability have been reported as being associated with cortical reorganisation and symptom reduction in chronic pain conditions.
3. Proprioception using a position matching protocol. Participants will be asked to sideflex the trunk in sitting to a point in mid-range and then, once returned to the upright position, to return to the same position where any differences will be measured.
4. Midline judgement using line bisection tests. A series of horizontal lines will be presented to the participant who will attempt to mark the centre of each one. Differences between the estimated and actual centres, along with direction, will be measured.
5. One legged standing balance. A timed test of how long subjects can maintain one leg standing without having to seek support.
6. Kinaesthetic and Proprioception Assessment Questionnaire (KPAQ). A 12 item self-report measure of proprioceptive and movement awareness (5 point likert scale).
7. Other measurement tools such as the EQ5D, a measure of self-reported function (Paediatric Outcomes Data Collection Instrument, PODCI) and demographic information will also be collected along with height, weight and puberty status.
8. Modified versions of scoliosis specific questionnaires such as the SRS-22 and the Spinal Appearance Questionnaire will be used to gain normative values and to gauge baseline characteristics compared to scoliosis cases.

Overall study start date
01/01/2013

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Adolescents (aged 10-16) with no known spinal pathology or neurological conditions

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit

10 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Between 174 - 232

Key exclusion criteria
1. Individuals that have suffered significant back pain or other musculoskeletal conditions requiring time off school or sporting activity, or requiring treatment from a health professional in the preceding 12 months
2. Individuals with significant spinal or trunk asymmetry which may indicate the presence of scoliosis

Date of first enrolment
15/10/2014

Date of final enrolment
15/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Tudor Hall School
Banbury
United Kingdom
OX16 9UR

Study participating centre
Lutterworth High School
Lutterworth
United Kingdom
LE17 4QH

Study participating centre

Marlborough Church of England School
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Study participating centre
Lyng Hall School
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CV2 3JS

Study participating centre
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Sponsor information

Organisation
University of Warwick

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Gibbet Hill Road
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CV4 7AL

Sponsor type
University/education

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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