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ACtive Treatment for Idiopathic AdolescenT Scoliosis: a feasibility study

Submission date
21/10/2011

Recruitment status
No longer recruiting

Registration date
25/10/2011

Overall study status
Completed

Last Edited
21/04/2016

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Scoliosis is a sideways curvature of the spine, in which the spinal column can also twist, sometimes resulting in an obvious deformity or hump. It affects approximately two children in every 1000 in the UK with around 10% of these children requiring treatment. By far the most common type of scoliosis in the adolescent period is one in which the cause is not known and is called idiopathic or adolescent idiopathic scoliosis (AIS). Depending on the stage of growth and the amount of spinal curvature, patients may either be offered surgery or conservative treatment along with specialist monitoring of curve progression. Conservative treatments include bracing and/or exercise. NHS standard care for patients with mild AIS (whose condition is not severe enough to need surgery) generally consists of advice and monitoring, supplemented with bracing for a limited number of patients. Exercises are not always routinely provided and there is a lack of evidence to suggest whether they are beneficial or not in the treatment of AIS. This study is a feasibility study which means that the aim of this study is to assess if it is worthwhile running a larger study (called a Randomised Controlled Trial (RCT)). The aim of this larger study would be to evaluate the benefits and costs of an exercise programme for patients with mild AIS.
During this feasibility study we will aim to find out if the exercise programme is acceptable to patients, parents and physiotherapists and what training is required to deliver the treatments in NHS hospitals. We also aim to find out whether it will be possible to recruit the numbers of patients needed for a larger study and test out how we measure spinal curvature and questionnaires to measure the impact of the exercise programme.

Who can participate?
To take part in the pilot study you must:
1. Be diagnosed with mild AIS (defined by a Cobb angle of between 10 - 50°).
2. Be between 10 and 16 years of age.
3. You cannot be on a waiting list for surgery or have had surgery in the past.

What does the study involve?
During the first 6 months we will design the exercise programme. To help us to do this we will consult experts in the field (surgeons and physiotherapists) as well as patients with AIS. We will then run a small study (pilot study) to test out the exercise programme and to find out if it

would be possible to run a larger study. We will interview patients, their parents and physiotherapists to gain their views on the exercise programme. We will also look at how easy it is to recruit patients to the study and whether we would be able to recruit enough patients to run a larger study. We hope to enrol 50 patients in the pilot study. If you participate in the pilot study then you will be randomly allocated to one of two treatments: 1) an exercise programme or 2) usual care e.g. usual appointments in the consultant clinic. You will also need to attend two appointments (at enrolment and 6 months later) where we measure spinal curvature using special equipment. At these appointments you will be asked to complete a series of questionnaires about how having scoliosis effects you and asks about pain, other symptoms and function. If you are allocated to the exercise programme then you will be given an exercise programme by a physiotherapist. The exercise programme will consist of specific exercises designed to strengthen trunk muscles and improve balance. The exercises will be done daily at home over a 6 month period. You will also need to attend between 6 and 9 physiotherapy sessions so the physiotherapist can teach you the exercises, monitor your progress and modify the exercises. You will be asked to complete an online exercise diary each day to record your exercises. You may be asked (along with your parents) to take part in an interview to tell us about your experiences of doing the exercises.

What are the possible benefits and risks of participating?
By taking part in the pilot study you will be helping to improve the treatments that are offered to patients with AIS. The risks are small. There is no evidence available to suggest that the treatments are harmful. There is some evidence that suggests that exercises may help patients with mild AIS and if you receive the exercises you may benefit from them. There is the possibility of experiencing temporary discomfort as a result of the exercises. You may require an additional X-ray to determine outcome where these do not tie in with your routine X-rays.

Where is the study run from?
This research is being run by the Warwick Clinical Trials Unit at the University of Warwick. We are working closely with experienced clinicians at the following hospitals where we will run the pilot study:
1. Nuffield Orthopaedic Hospital, Oxford
2. Frenchay Hospital, Bristol
3. Royal Orthopaedic Hospital, Birmingham

When is the study starting and how long is it expected to run for?
This study will run for 2 years. It is due to begin in March 2012 with the first patients being recruited to the pilot study in September 2012. Recruitment will continue for one year.

Who is funding the study?
The study is funded by the National Institute of Health Research Health Technology Assessment Programme (NIHR HTA), UK.

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
ACtive Treatment for Idiopathic AdolescenT Scoliosis: a feasibility study

Acronym
ACTIvATeS

Study objectives
This feasibility study aims to develop and refine a best evidence intervention of exercises for the management of adolescent idiopathic scoliosis (AIS) which can be delivered within the normal patterns of National Health Service (NHS) delivery. It also aims to assess the key parameters needed to finalise the design and project management plan for a definitive multi-centred randomised controlled trial to evaluate the clinical and cost-effectiveness of scoliosis-specific exercise treatment in AIS in comparison to standard practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot interventional qualitative randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
During the pilot RCT participants will be randomised to receive:
1. An excercise programme
2. Usual care

Those randomised to the exercise programme will carry out the exercise programme primarily as a daily home exercise programme with initial physiotherapy assessment and regular therapy review sessions (up to a maximum of 9 sessions over the 6 months) to provide support, encourage adherence, and allow monitoring and progression of the exercises. The rationale for exercise to manage AIS is that a number of underlying impairments in spinal muscular function and postural stability contribute to or accompany the development of curvature, and are potentially reversible. Exercises will aim to strengthen the affected muscle groups and improve prorioception and postural/body awareness.

Intervention Type
Behavioural

Primary outcome(s)
1. Assess the feasibility to progress to a full randomised controlled trial (RCT)
2. Calculation of the sample size for the RCT and an understanding of recruitment rates across centres
3. We anticipate that the primary outcome measures for a main RCT study will be the progression /stabilisation of curvature quantified by the Cobb angle and this will be measured in the pilot RCT

Key secondary outcome(s))
1. Progression to surgery
2. Changes to brace-wearing status
3. Respiratory function
4. Quality of life
5. Resource use associated with the provision and consequence of the different treatment options

The questionnaires to be piloted include:
1. Scoliosis Research Society-22 questionnaire
2. Paediatric Outcomes Data Collection Instrument EQ-5D-Y
3. Health Utilities Index and SF-6D

The commissioning brief requests measures of exercise tolerance and respiratory function and we will investigate the most appropriate method of capturing these outcomes (an incremental walk test is likely to be the best candidate).

Completion date
01/03/2014

Eligibility

Key inclusion criteria

Participants will be 10-16 years of age with Adolescent Idiopathic Scoliosis, defined by a Cobb angle of between 10 - 50 degrees (measured radiographically)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Individuals who have had previous surgery or are on a waiting list for spinal surgery within the next 6 months
2. Individuals with non-idiopathic scoliosis, for example congenital malformations, syringomyelia, neurofibromatosis, spina bifida, polio and cerebral palsy

Date of first enrolment
01/09/2012

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Warwick Clinical Trials Unit
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) ref 10/38/03

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	01/07/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes