

Active Treatment for Idiopathic Adolescent Scoliosis (ACTivATeS): a feasibility study

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Scientific summary

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Scientific summary

Background

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity that results in lateral deviation, rotation and flexion/extension of the vertebrae. It is of unknown cause and occurs at or near the onset of puberty. The prevalence of AIS in children aged 10–16 years is 1–3%, which suggests that there are 50,000–150,000 sufferers in the UK. The effects of AIS include pain, cosmetic concerns, functional limitations, cardiorespiratory problems and possible further curve progression in adulthood. About 10% of AIS patients require surgical or conservative management, the latter consisting of monitoring, advice and, for some, bracing. Although there is a theoretical basis for the use of specific exercise in AIS, there is little robust evidence for its clinical effectiveness. There is no information on the cost-effectiveness of the various exercise approaches and whether or not they offer a viable alternative to surgery and bracing.

Objectives

The aim of this feasibility study was to assess the feasibility of conducting a large, multicentre trial of scoliosis-specific exercise (SSE) treatment for patients with AIS, in comparison with standard care, and to refine elements of the study design. The objectives were to:

- formally update a systematic review of controlled trials evaluating the efficacy of SSEs in AIS
- undertake a survey of UK orthopaedic surgeons and physiotherapists to determine current practice, patient populations and equipoise
- randomise 50 adolescents to a feasibility trial of either usual care or SSE interventions across a range of sites
- develop, document and assess acceptability and adherence of interventions provided
- assess and describe training requirements of physiotherapists
- gain user input in all relevant stages of the treatment and protocol design.

Methods

Design

A multicomponent feasibility study including UK clinician survey, systematic literature review, a randomised feasibility trial and embedded qualitative study.

Setting

The survey of practice was conducted across all 36 NHS trusts listed by the Scoliosis Association UK as providing specialist scoliosis management. The randomised feasibility study involved four secondary care NHS trusts providing specialist care for patients with AIS and associated physiotherapy outpatient departments.

Participants

The survey of practice surveyed orthopaedic consultants and physiotherapists who worked in trusts providing specialist scoliosis management. The randomised feasibility study recruited young people aged 10–16 years with mild AIS with a Cobb angle of $< 50^\circ$. The embedded qualitative study sampled participants and their families from this group as well as the therapists delivering interventions.

Interventions

The randomised feasibility study allocated participants to standard practice of advice and education or a programme of SSE provided by a physiotherapist and supported by a home exercise plan. Our choice of intervention was informed by a systematic review of exercise interventions for AIS and expert consensus meeting.

Outcomes

The main outcome was feasibility of recruitment to the randomised feasibility study. Other elements were to inform the choice of outcomes for a definitive trial and included scoliosis curve severity, health-related quality of life, requirement for surgery/brace, adverse events, psychological symptoms, costs and health utilities. We collected data from participants at 6 months after randomisation.

Results

A UK survey of orthopaedic consultants and physiotherapists indicated a wide variation in current provision of exercise therapy through physiotherapy services. It also found that clinicians from at least 15 centres would be willing to have their patients involved in a full study.

An up-to-date systematic review of the literature found that there is still low-quality evidence for the effectiveness of SSE and that a definitive trial is still warranted for the NHS, particularly to investigate cost-effectiveness.

The randomised feasibility study recruited 58 patients from four NHS trusts over 11 months, and we exceeded the pre-specified target recruitment rate of 1.4 participants per centre per month. This report contains follow-up data from 33 of the 58 participants recruited with an acceptable response rate of 73% at time of reporting. Adherence to treatment was variable (56% of participants completed the treatment offered).

The qualitative study found the exercise programme to be highly acceptable. We learnt important lessons from patient and public involvement during the feasibility study in terms of presentation of the study and intervention, as well as practical elements such as scheduling of intervention sessions.

Conclusions

A definitive randomised controlled trial evaluating clinical effectiveness and cost-effectiveness of SSE for AIS is warranted and feasible. There is a sufficiently large patient base, combined with a willingness to be randomised within specialist centres which are responsible for the management of patients with AIS in the UK. Interventions developed during the feasibility study were acceptable to patients, families and physiotherapists and can be given within the affordability envelope of current levels of physiotherapy commissioning.

Trial registration

The feasibility trial is registered as ISRCTN90480705.

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