# Bracing AdoleScent Idiopathic Scoliosis after skeletal maturity (BASIS 2): study protocol for a randomized controlled trial within a larger trial

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## Aims

Adolescent idiopathic scoliosis affects 0.2% to 0.5% of adolescents, often requiring bracing to reduce the risk of curve progression. While bracing is typically discontinued at skeletal maturity, significant curve progression can occur afterwards, potentially necessitating surgery. The Bracing AdoleScent Idiopathic Scoliosis (BASIS) 2 study, nested within the larger BASIS trial, aims to evaluate the efficacy of prolonged full-time and night-time bracing beyond skeletal maturity in reducing curve progression. The aim is to determine if six months of additional bracing at normal prescription, after skeletal maturity, significantly reduces curve progression and is acceptable to patients with adolescent idiopathic scoliosis who were successfully treated with bracing.

## Methods

This multicentre, prospective, parallel group, pragmatic, open-label, randomized controlled superiority trial will recruit participants from the BASIS study who reach skeletal maturity with a curve < 50°. Participants will be randomized 1:1 to either continue bracing for six months or cease bracing immediately.

## Outcomes

The primary outcome is curve progression from baseline to two years post-skeletal maturity. Secondary outcomes include radiological measures, patient bracing experience and any preferences, and cost-effectiveness. The sample size is estimated at 228 participants. Results will be disseminated through peer-reviewed publications, conference presentations, and to study participants.

## Take home message

- The BASIS 2 study addresses the risk of significant spinal curve progression in adolescents with idiopathic scoliosis after they reach skeletal maturity and typically discontinue bracing.
- To address the current lack of standardized guidance regarding brace "weaning", the trial aims to build on the BASIS Study (of full-time bracing vs night-time bracing) by evaluating whether six months of additional full-time or night-time bracing reduces the likelihood of curves progressing.

## Introduction

### Background and rationale

Scoliosis is a lateral curvature of the spine, often measured using the Cobb angle. Curves of 10° or more classify as scoliosis, and this is estimated to affect approximately 2% to 3% of adolescents aged under 16 years.[1] Most patients are diagnosed with adolescent idiopathic scoliosis (AIS), which

has no known cause. AIS typically worsens during growth, sometimes necessitating surgery when the curve reaches 50°. Surgery fuses a large section of the spine, and can pose significant risks and costs, making early intervention crucial.

Bracing is a common treatment option to reduce the risk of curve progression. Full-time bracing has shown effectiveness in clinical trials.[2,3] However, compliance and psychological impacts pose challenges, leading to the exploration of alternatives like night-time bracing, which offers potential benefits for quality of life.[4] The Bracing AdoleScent Idiopathic Scoliosis (BASIS) study is currently comparing night-time bracing with full-time bracing, in terms of curve progression, quality of life, anxiety, depression, and cost-effectiveness.[5] In BASIS, as with standard care, unless surgery is required, a brace is prescribed until the child reaches skeletal maturity with a Cobb angle of less than 50°, at which point bracing is discontinued. However, it is increasingly recognized that significant curve progression may occur after brace removal, sometimes progressing beyond 50°.[6] Progression of more than 5° is considered significant. A recent scoping review found curve progression of over 5° in approximately 34% of patients, after weaning, with larger curves at greatest risk of progression (by a mean of 4°).[5] Another systematic review found a mean curve progression of 7° after brace removal.[7]

The principal method employed to reduce curve progression after skeletal maturity is prolonged bracing (often termed 'weaning') but there is no standardized guidance for how this should be implemented. A scoping review of brace cessation and weaning found 43 studies, in which 30 used weaning.[5] The weaning protocols varied between four weeks to one year, with different wear times. However, asking participants to continue to use their brace is controversial, because the affected adolescents have already worn a brace for between 1.5 and 4.5 years at the point of maturity, with inevitable impact on their quality of life.[3,8] It is therefore important to reduce the risk of curve progression after bracing is discontinued, while not prolonging brace use unnecessarily. A survey of 44 BASIS patients found that 20 (45%) were prepared to be randomized to either continue in their brace for an extra six months after skeletal maturity, or stop wearing it. Overall, 15 (35%) had preferences to continue, and nine (20%) had preferences to stop.

A recent single-centre randomized controlled trial conducted in Hong Kong found that a structured weaning protocol did not reduce Cobb angle progression when compared with immediate cessation.[9] However, in this study the weaning was defined as night-time (≥ 8 hours/day) brace wear, with compliance required for 80% of the six months. While it supplements the literature, longer periods in brace may be beneficial. Furthermore, the generalizability of these findings requires further investigation, as this is a single-centre study.

The BASIS 2 study is an additional randomized controlled trial embedded into the BASIS study, which aims to evaluate whether prolonged brace wearing of a full-time or night-time brace for six months beyond skeletal maturity reduces the risk of curve progression. Recruitment to BASIS 2 commenced in May 2024, and the study is anticipated to complete in April 2030. This document describes the BASIS 2 protocol and is an abridged version of the protocol for broad transparency. The full working protocol and iterative developments are available on the National Institute for Health and Care Research (NIHR) website.[10]

The overarching aim of this study is to determine if, among young people at skeletal maturity (Risser 4 in females, Risser 5 in males)[11] who were successfully treated with a brace for AIS (Cobb angle < 50° at skeletal maturity), six months of additional bracing at normal prescription significantly reduces curve progression and is acceptable to patients. Our specific objectives were to compare the mean change in Cobb angle between those with six months of additional bracing compared to those with immediate cessation; assess the proportion of patients in each group who reach 'clinically significant' progression (defined as > 5°) at one and two years post-skeletal maturity; determine the frequency of patients progressing to the surgical threshold (50°), and compare the incidence of actual surgical treatment for scoliosis correction between the two groups; assess whether there is a difference in anxiety, depression, and quality of life between the treatment groups, using patient questionnaires; and perform a comparative cost-effectiveness analysis between the treatment groups.

## Methods

### Trial design

A multicentre, prospective, parallel group, pragmatic, open-label, randomized controlled superiority trial. This study will run parallel with BASIS as a 'nested' study, at over 20 hospitals in the UK, with no additional clinic visits. The study will be completed concurrently with the BASIS study, with both studies completing follow-up two years after the last recruited patient reaches skeletal maturity. BASIS 2 was added to the BASIS study registration on 14 May 2024 (ISRCTN63247077).

### Study participants

To be eligible for BASIS 2, participants must be enrolled into the BASIS study. Eligibility for the BASIS study is: aged ten to 15 years; a clinical diagnosis of adolescent idiopathic scoliosis; at Risser stage 0, 1, or 2; a Cobb angle between 20° and 40° at baseline; with a curve apex at or below T7; a good level of understanding of the English language; and no previous spinal bracing or spinal surgery.

Eligibility to BASIS 2 is confirmed at the point that the primary outcome for the BASIS study is reached. To be eligible for BASIS 2, participants must reach skeletal maturity with a Cobb angle of less than 50°. Skeletal maturity must have been agreed by the Radiological Adjudication Committee (RAC): a team of clinicians who are blinded to treatment allocation and participant location, who make independent assessments based on assessment of the pattern of growth plate changes within the pelvis on a spinal radiograph (Risser 4 in females, Risser 5 in males). Alternatively, if the referring surgeon believes that a participant's Risser stage is less advanced than their true skeletal age, skeletal maturity can be agreed with the study team if the hand/wrist radiograph shows Sanders stage at least 7b,[12] with growth less than 2 cm in the previous 12 months (or < 1 cm in the last six months) and at least two years post-menarche (if female).

### Sample size

Sample size is dependent on the BASIS trial, which is expected to recruit 780 patients with an estimated 10% attrition,

resulting in 702 participants projected to reach the primary outcome. A prior multicentre study, the BrAIST study, investigated bracing in adolescent scoliosis.[3] Extrapolating the results from the BrAIST study, we would expect 72% of the 702 BASIS participants (505 patients) to achieve skeletal maturity with a curve less than 50° (i.e. eligible for BASIS 2). From a survey of 44 participants enrolled into the BASIS study, we estimate that 45% will agree to randomization, therefore BASIS 2 will aim to recruit 228 participants.

Using the largest SD from the literature of 6.6,[13] and a 5% attrition rate, 216 patients can detect a 2.9° difference at 90% power or a 2.5° difference at 80% power. The mean curve progression in the first two years after stopping bracing (control group) is estimated from the literature at 5.9°. Our BASIS participant survey indicated that patients would like a mean 50% reduction in curve progression after skeletal maturity to make the additional six months in brace worthwhile. This would be satisfied by this sample size.

We will seek to maximize recruitment beyond the estimated 45%, using carefully designed patient information aimed at re-establishing patient equipoise. The BASIS website has proven an excellent resource and further information will be provided in a similar way.[14] A recent study has shown the value of multimedia information in improving recruitment of children and young people to clinical trials.[15] An established patient group will help develop and proofread patient information.

**Study setting and recruitment**

The trial will be conducted in the NHS Paediatric Spinal Centres currently recruiting for BASIS. Patients reaching skeletal maturity with a curve less than 50° will be given information by the hospital care team about BASIS 2 and their spinal radiograph will be referred to the RAC.

If the RAC confirms skeletal maturity (or skeletal maturity is otherwise agreed with the study team based on Sanders' stage as described in the eligibility criteria) the patients will be telephoned and informed (Figure 1). The date of referral to the RAC will be assigned as the date of skeletal maturity. Patient equipoise will be explored before consent and randomization to minimize immediate or early treatment switching based on a strong preference. If happy to proceed with BASIS 2, the patient will complete a single, bespoke baseline questionnaire. This questionnaire asks how often the patient wore the brace, whether they think it helped them, whether they would recommend it, whether they are worried about their curve progressing, and whether they have a preference to continue or stop bracing (Supplementary Material Appendix A).

Patients and their parents will then be electronically consented to BASIS 2 by delegated members of the hospital care team (Supplementary Material Appendix B). If the patient is aged under 16 years, both parental consent and participant assent must be obtained for the patient to be able to take part. If the patient is aged over 16 years, they will complete a separate form for participant consent only. If participants initially provide assent but turn 16 years old during the study, they must provide additional consent to continue.

Since the BASIS study started, many clinicians treating scoliosis have moved to assessing the epiphyseal closure on hand and wrist radiograps to determine skeletal maturity in their usual clinical practice. Two studies have demonstrated that cessation of brace treatment determined using hand and wrist radiographs more accurately predicts early scoliosis curve progression.[12,16] To ensure that this study is contemporary, we will collect an image of the hand and wrist after a participant is consented to BASIS 2. This will be taken shortly before, or shortly after, randomization. Bone age will be calculated from hand and wrist radiographs with Tanner Whitehouse 3 and Greulich-Pyle taken from BoneXpert AI software (Visiana, Denmark).[17,18] This is an additional radiograph to the main BASIS study, although one already obtained as part of routine clinical care in many sites.

After the baseline questionnaire has been completed and consent (and assent if applicable) acquired, the participant will be randomly allocated to either the intervention arm (continued bracing for six months at normal prescription dependent on whether they have a full-time brace or night-time brace) or the control arm (stop bracing).

**Randomization and blinding**

Randomization will be completed through a web-based system provided by the Clinical Trials Research Unit. Participants will be randomly allocated to either the intervention arm (continued bracing for six months) or the control arm (stop bracing) on a 1:1 basis. Randomization will be completed using minimization based on site, RAC determined curve size at skeletal maturity (< 30°, 30° to 40°, 40° to 49°), and type of brace worn in the main BASIS trial (prior randomized allocation of night-time brace or full-time brace). Due to the nature of the intervention, participants and clinicians will not be blind to treatment allocation within the trial. The statistical team will remain blind at least until the finalization of the statistical analysis plan, and outcome data split by arm will not be evaluated unless pre-specified.

**Intervention and control**

Following randomization, participants randomized to stop bracing will be asked to remove their brace immediately. Participants who are randomized to continue bracing will be asked to do so at normal prescription. Patient compliance will be monitored using the temperature sensor (iButton, DS1925; Analog Devices, USA) already in the brace.

Participants will receive a brief additional questionnaire at six months post BASIS 2 randomization, which provides a second self-assessment of brace wearing compliance and asks if the participant has returned their iButton to allow for tracking of this (Supplementary Material Appendix C).

Other follow-up visits and radiographs for both groups will be the same as for BASIS: one and two years post skeletal maturity (date of radiograph referral to the RAC) (Table I). Sites will be encouraged to randomize eligible and interested participants to BASIS 2 as soon as possible after skeletal maturity is confirmed.

**Outcomes**

The primary outcome is curve progression from baseline to two years after skeletal maturity, in degrees. These will be assessed by the Central Measurement Team.

Secondary outcomes include: any patient preferences for stopping or continuing with bracing; patient bracing experience at baseline and after six months; and

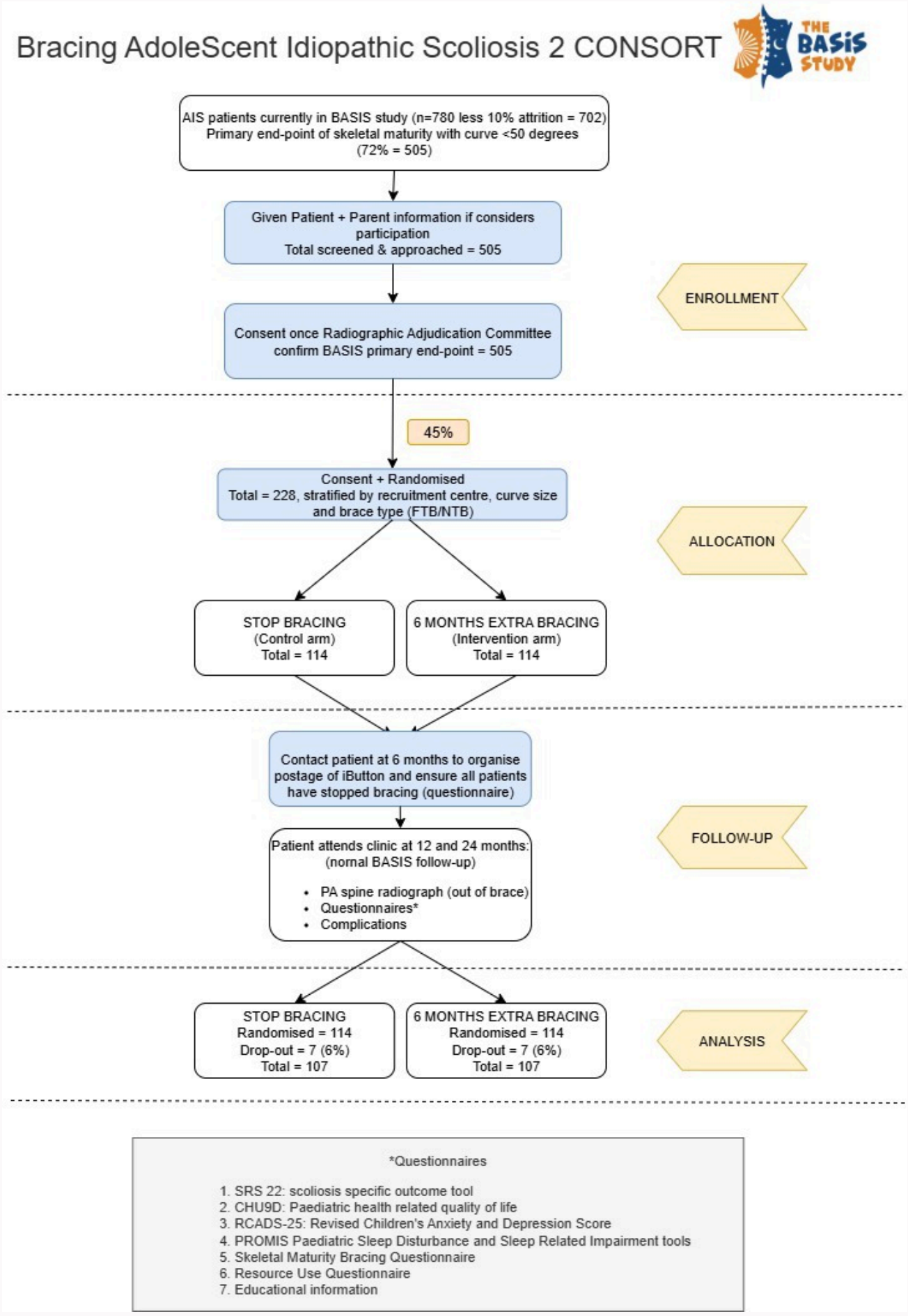


**Fig. 1**
Bracing Adolescent Idiopathic Scoliosis (BASIS) 2 study CONSORT diagram. FTB, full-time bracing; NTB, night-time bracing; PA, posteroanterior.

**Table I.** Study assessments schedule of BASIS and BASIS 2 studies.

| | Phase 1 (pre-skeletal maturity) | | | BASIS 2 (if eligible and consented) | | Phase 2 (2 yrs post skeletal maturity) | | Phase 3 (long term) |
|---|---|---|---|---|---|---|---|---|
| Variable | Screening | Baseline/ randomization | Every 6 mths, until skeletal maturity | Skeletal maturity (baseline/ randomization)* | 6 mths post skeletal maturity* | 12 mths post skeletal maturity | 24 mths post skeletal maturity | 10 yrs post skeletal maturity |
| Screening form/log (baseline visit) | MN/IP | - | - | - | - | - | - | - |
| Eligibility form | MN | - | - | E* | - | - | - | - |
| Informed consent form | E | - | - | E* | - | - | - | - |
| Demographics (age, sex, diagnosis, med history, medication) | MN | - | - | - | - | - | - | - |
| Height, weight | IP | - | IP | - | - | IP | IP | - |
| Cobb angle, Risser stage | MN (pre-randomization) | | CT/RAC | CT/RAC* | - | CT/RAC | CT/RAC | - |
| Additional radiological measures (curve type, apex, etc.) | CT | - | CT | - | - | CT | CT | - |
| Need for surgery | - | - | MN | MN* | MN* | MN | MN | E |
| In-brace correction | - | CT (0 to 6 wks after each fitting) | | - | - | - | - | - |
| Compliance | - | - | SEN | - | SEN* | - | - | - |
| Treatment switching | - | - | MN | - | MN* | - | - | - |
| Hand/wrist radiograph* | | | | IP* | - | | | |
| Skeletal Maturity Bracing Questionnaire* | - | - | - | IP/E* | - | - | - | - |
| BASIS 2 Follow-up questionnaire* | - | - | - | - | E* | - | - | - |
| SRS-22, CHU9D, RCADS 25, PROMIS sleep (disturbance and impairment) | - | IP/E | IP/E | - | - | IP/E | IP/E | E |
| BSSQ, OPUS CSD (while in brace only) | - | IP/E | IP/E | - | - | - | - | - |
| Educational information | - | - | E† | - | - | E† | E† | E† |
| Other treatments prescribed to treat scoliosis | - | IP/E | IP/E | - | - | IP/E | IP/E | - |
| Ethnicity | - | E | - | - | - | - | - | - |
| Resource use questionnaire | - | E | E | - | - | E | E | E‡ |
| Patient cost questionnaire | - | E | - | - | - | - | - | - |

(*Continued*)

(*Continued*)

| | Phase 1 (pre-skeletal maturity) | | | BASIS 2 (if eligible and consented) | | Phase 2 (2 yrs post skeletal maturity) | | Phase 3 (long term) |
|---|---|---|---|---|---|---|---|---|
| **Variable** | **Screening** | **Baseline/ randomization** | **Every 6 mths, until skeletal maturity** | **Skeletal maturity (baseline/ randomization)*** | **6 mths post skeletal maturity*** | **12 mths post skeletal maturity** | **24 mths post skeletal maturity** | **10 yrs post skeletal maturity** |
| School attendance | - | E | E | - | - | - | - | - |
| Complications and SAEs | - | - | IP/E | IP/E* | E* | E | E | E |

*Addition of BASIS 2.
†Collected summer of year 11, age 16, independent of where the patient is in the study (the final year of compulsory secondary education in England, typically consisting of students aged 15 to 16 years, equivalent to USA Grade 10).
‡Completed by the patient at 10 years.
CT, central team; E, electronic, online via an email link sent to the patient (may be chased by mail or telephone); IP, in-person; MN, medical notes or British Spine Registry form; RAC, Radiographic Adjudication Committee; SAE, serious adverse event; SEN, sensor, implanted into brace.

cost-effectiveness of retaining use of a brace for six months after skeletal maturity.

**Data collection**

All clinical data will be entered by the research site staff onto the British Spine Registry (BSR) as for the BASIS study.

**Statistical and health economic analysis**

The trial will be analyzed and reported according to CONSORT guidelines on a superiority basis.[19] The primary outcome is the progression of the curve between baseline and follow-up at two years after skeletal maturity, measured in degrees. The analysis will be completed using a linear mixed-effects model, adjusted for stratification variables, important baseline covariates, and site as a random effect.

Patient-reported repeated outcome measures will be assessed using a similar model as with the primary outcome, with the addition of the baseline variable included as a covariate.

The primary analysis will be conducted on an intention-to-treat basis with no missing data imputation, but sensitivity analysis will be used to assess the impact of these.

It is currently unknown whether retaining use of a brace for six months after reaching skeletal maturity is clinically effective or cost-effective. Retaining a brace will incur additional costs; although the brace will not be changed, other healthcare costs could be incurred such as primary care appointments, hospital admissions, or appointments, and subsequent surgery costs may be avoided. We will estimate the relative cost-effectiveness of retaining use of a brace for six months after skeletal maturity. In line with the BASIS analyses, we will present results for two key outcome measures: cost per quality-adjusted life-years (QALYs) gained, and cost per surgery avoided, and will take a NHS and personal social services perspective. The primary cost per QALY analysis will take a lifetime perspective, with proportions of patients who do and do not progress to surgery estimated based upon scoliosis degrees. A secondary analysis will present cost per QALY results restricted to the BASIS 2 trial follow-up period.

**Data monitoring**

As per the BASIS study, the research is supervised by three distinct committees. Each of these committees operates under a defined set of guidelines, either a charter or terms of reference, which thoroughly delineates their respective roles and duties. The independent Trial Steering Committee will oversee trial conduct and provide overall guidance for the study's execution; the independent Data Monitoring and Ethics Committee will focus on safeguarding the wellbeing of study participants; and the Trial Management Group handles the daily operational aspects of the research.

**Adverse events**

Serious adverse event (SAE) reporting will remain in line with that in BASIS. In this study, we consider an adverse event (AE) to be any unexpected medical issue experienced by a participant that could potentially be linked to the brace therapy or any complications from spinal surgical procedures.

The following AEs are expected and therefore do not require expedited reporting if serious: pain from the brace requiring brace adjustment or re-design; and medical device-related pressure ulcer if categorized as Stage 1: skin erythema which is non-blanching with pressure.

The following AEs/SAEs will be reported in line with standard SAE reporting procedures: Stage 2a: superficial abrasions; Stage 2b: partial-thickness skin loss; Stage 3: full-thickness skin loss (dermis and epidermis) (Serious); Stage 4: full-thickness tissue loss (Serious).

**Research ethics approval**

The study will be conducted in accordance with Good Clinical Practice,[20] and to protect the human rights and dignity of the patient as reflected in the Declaration of Helsinki.[21] The BASIS study was given a favourable ethical opinion from the North of Scotland Research Ethics Committee 1 (21/NS/0038), and approval from the Health Research Authority, on 8 April 2021. The BASIS 2 study was approved as a substantial amendment (number eight) to the BASIS Study on 10 April 2024.

### Protocol amendments

At the time of writing, the current version of the BASIS study protocol is v4.3, 16 June 2025. Any further amendments to the protocol will be agreed with the funder, sponsor, Trial Steering Committee, Data Monitoring and Ethics Committee, and Trial Management Group as required, and submitted to the Health Research Authority and Research Ethics Committee for approval. This document is an abridged version of the protocol for broad transparency.

### Patient confidentiality

Access to source data and documentation to conduct trial monitoring, audits, and regulatory inspection is sought from participants or their parents (depending on whether the participant is aged over or under 16 years) during informed consent. The research team and healthcare providers are committed to protecting participant privacy. They employ a system where each patient receives a unique study identifier for communications, maintaining confidentiality. However, as this project doubles as a clinical registry, identifiable information is retained in the study database. Access will only be granted to those who require it. Both the participating sites and the Clinical Trials Research Unit will securely archive all study-related information for 15 years after the study concludes.

## Patient and public involvement and engagement

A Patient and Public Involvement & Engagement (PPIE) group was formed at the design stage of the BASIS study. The same group contributed to the design of BASIS 2 and assisted with the production of patient-facing study materials, to ensure ease of understanding. Any significant amendments to patient-facing documents will be discussed with this group prior to implementation. PPIE representatives continue to attend Trial Management Group and Trial Steering Committee meetings regularly, with separate quarterly PPIE-only meetings.

PPIE representatives will be consulted for all patient-focused dissemination activities and on an ad hoc basis throughout the study when their input would be particularly valuable, as well as in relation to eventual implementation and knowledge mobilization work relating to both BASIS and BASIS 2.

### Dissemination

A publication and dissemination plan has been created collaboratively with study coapplicants. This outlines authorship criteria, anticipated publications, and the process for developing and submitting study-related content. The outcomes from BASIS 2 will be disseminated in peer-reviewed scientific journals, at clinical and academic conferences, to study participants, and on the study website.

## Social media

Follow D. C. Perry on X @MrDanPerry
Follow A. A. Cole on X @sheffieldchildrens

## Supplementary material

BASIS 2 Skeletal maturity bracing questionnaire, the baseline questionnaire before randomization into BASIS2; the BASIS2 Parent Consent, Participant Consent, and Participant Assent Forms; and the BASIS2 6 month follow-up questionnaire, which was sent to participants six months post BASIS2 randomization.

## References


1. **Negrini S**, **Donzelli S**, **Aulisa AG**, **et al**. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis Spinal Disord*. 2018;13:3.
2. **Costa L**, **Schlosser TPC**, **Jimale H**, **Homans JF**, **Kruyt MC**, **Castelein RM**. The effectiveness of different concepts of bracing in adolescent idiopathic scoliosis (AIS): a systematic review and meta-analysis. *J Clin Med*. 2021;10(10):2145.
3. **Weinstein SL**, **Dolan LA**, **Wright JG**, **Dobbs MB**. Effects of bracing in adolescents with idiopathic scoliosis. *N Engl J Med*. 2013;369(16):1512–1521.
4. **Karimi MT**, **Rabczuk T**, **Kavyani M**, **Macgarry A**. Evaluation of the efficacy of part-time versus full-time brace wear in subjects with adolescent idiopathic scoliosis (AIS): a review of literature. *Curr Orthop Pract*. 2019;30(1):61–68.
5. **Swaby L**, **Cui M**, **Cole A**. Discontinuation of brace treatment in adolescent idiopathic scoliosis (AIS): a scoping review. *Spine Deform*. 2024;12(5):1217–1228.
6. **Negrini S**, **Hresko TM**, **O'Brien JP**, **Price N**, **SOSORT Boards**, **SRS Non-Operative Committee**. Recommendations for research studies on treatment of idiopathic scoliosis: consensus 2014 between SOSORT and SRS non-operative management committee. *Scoliosis*. 2015;10(1):8.
7. **Luhmann S**, **Zaaroor-Regev D**, **Upasani VV**, **Shufflebarger H**. The natural history of curve behavior after brace removal in adolescent idiopathic scoliosis: a literature review. *Spine Deform*. 2023;11(3): 567–578.
8. **Wang H**, **Tetteroo D**, **Arts JJC**, **Markopoulos P**, **Ito K**. Quality of life of adolescent idiopathic scoliosis patients under brace treatment: a brief communication of literature review. *Qual Life Res*. 2021;30(3):703–711.
9. **Cheung PWH**, **Chan OKO**, **Wu H**, **et al**. Immediate vs gradual brace weaning protocols in adolescent idiopathic scoliosis: a randomized clinical trial. *JAMA Pediatr*. 2024;178(7):657–668.
10. **Cole A**, **Perry D**. Bracing Adolescent Idiopathic ScoliosIS (BASIS) Study night-time versus full-time bracing in adolescent idiopathic scoliosis. NIHR. 2025. https://fundingawards.nihr.ac.uk/award/NIHR131081 (date last accessed 16 December 2025).
11. **Hacquebord JH**, **Leopold SS**. In brief: The Risser classification: a classic tool for the clinician treating adolescent idiopathic scoliosis. *Clin Orthop Relat Res*. 2012;470(8):2335–2338.
12. **Cheung PWH**, **Cheung JPY**. Sanders stage 7b: using the appearance of the ulnar physis improves decision-making for brace weaning in patients with adolescent idiopathic scoliosis. *Bone Joint J*. 2021;103-B(1): 141–147.
13. **Kenanidis E**, **Stamatopoulos T**, **Athanasiadou KI**, **et al**. Can we predict the behavior of the scoliotic curve after bracing in adolescent idiopathic scoliosis? The prognostic value of apical vertebra rotation. *Spine Deform*. 2021;9(1):91–98.
14. **No listed authors**. The BASIS Study. www.basisstudy.org (date last accessed 16 December 2025).
15. **Knapp P**, **Moe-Byrne T**, **Martin-Kerry J**, **et al**. Providing multimedia information to children and young people increases recruitment to trials: pre-planned meta-analysis of SWATs. *BMC Med*. 2023;21(1): 244.
16. **Cheung JPY**, **Cheung PWH**, **Luk KDK**. When should we wean bracing for adolescent idiopathic scoliosis? *Clin Orthop Relat Res*. 2019;477(9): 2145–2157.
17. **Thodberg HH**, **Thodberg B**, **Ahlkvist J**, **Offiah AC**. Autonomous artificial intelligence in pediatric radiology: the use and perception of BoneXpert for bone age assessment. *Pediatr Radiol*. 2022;52(7):1338–1346.
18. **Maratova K**, **Zemkova D**, **Sedlak P**, **et al**. A comprehensive validation study of the latest version of BoneXpert on a large cohort of Caucasian children and adolescents. *Front Endocrinol*. 2023;14:1130580.
19. **Schulz KF**, **Altman DG**, **Moher D**, **CONSORT Group**. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Obstet Gynecol*. 2010;115(5):1063–1070.

20. **Vijayananthan A**, **Nawawi O**. The importance of Good Clinical Practice guidelines and its role in clinical trials. *Biomed Imaging Interv J*. 2025;4(1).

21. **World Medical Association**. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2013;310(20):2191.

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## Author contributions

K. Ridsdale: Data curation, Investigation, Methodology, Project administration, Visualization, Writing – original draft, Writing – review & editing.
L. Swaby: Data curation, Funding acquisition, Investigation, Methodology, Project administration, Visualization, Writing – original draft, Writing – review & editing.
N. Totton: Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Software, Validation, Writing – review & editing.
D. C. Perry: Conceptualization, Funding acquisition, Investigation, Methodology, Writing – review & editing.
A. J. Mills: Conceptualization, Funding acquisition, Investigation, Methodology, Writing – review & editing.
A. A. Cole: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Writing – original draft, Writing – review & editing.

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## ICMJE COI statement

A. A. Cole is a coapplicant on grants for studies unrelated to this work. A. A. Cole is also Clinical Lead for the British Spine Registry. A. J. Mills is shareholder and director of the SpineCorporation Limited, which designs and supply braces to several BASIS sites, holds a patent for TechnoSpine, and is an unpaid SOSORT Bracing Expert Advisor. D. C. Perry is funded by a National Institute for Health and Care Research Professorship Award, was a committee member on the NIHR Commissioning Board (2016-2021), and is a member of the editorial board of *The Bone & Joint Journal*.

## Data sharing

The data that will support the findings for this study will be available to other researchers from the corresponding author upon reasonable request.

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## Trial registration number

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